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Screening for Diabetes in At-Risk Populations in Primary Care: A Practice Guide

Vera Louise Pillitteri

UNIVERSITY OF NORTHERN COLORADO

Graduate School

Greeley, Colorado

SCREENING FOR DIABETES IN AT-RISK POPULATIONS IN PRIMARY CARE: A PRACTICE GUIDELINE

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Vera Louise Pillitteri

College of Natural and Health Sciences
School of Nursing
Nursing Practice

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Accepted by the Research Committee

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Kathleen Dunemn, Ph.D., APRN, CNM, Research Advisor

_____

Vicki Wilson, Ph.D., MS, RN, Co-Research Advisor

_____

Deborah Green, MD, Community Member

Accepted by the Graduate School

_____

Linda L. Black, Ed.D.
Associate Provost and Dean
Graduate School and International Admissions

EXECUTIVE SUUMMARY

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Diabetes mellitus (DM), a disease with far-reaching cardiovascular and physiological consequences, continues to grow at epidemic proportions despite efforts by the medical community to manage the disease, placing an enormous financial burden on the healthcare system. The Centers for Disease Control and Prevention released a report in 2014 reporting 29.1 million people in the United States have diabetes including 8.1 million undiagnosed cases. Colorado is one of eight states with the most significant increases in DM diagnoses, nearly doubling between 2003 and 2014. An estimated 300,000 adults have diabetes in Colorado and an estimated 110,000 more are undiagnosed (Colorado Department of Public Health and Environment, 2015).

In the last three years, the American Diabetes Association (ADA; 2017), the World Health Organization (WHO; 2011b) and the U.S. Preventative Services Task Force (USPSTF; 2017) have released new recommendations on screening and diagnosing DM--all with nearly identical criteria; yet, these recommendations are rarely referenced or utilized. Glycosylated hemoglobin A1c (A1c) and fasting glucose levels are the most widely recognized tests for screening and managing diabetes and are included in the screening recommendations for the three largest organizations. To enhance the quality and consistency of diabetes screening practices in adults in the primary care setting, the

purpose of this capstone project was to create a simple yet comprehensive clinical practice guideline utilizing fasting glucose levels and A1c as screening tests to aid providers at Park Avenue Medical Group in Ft. Lupton, Colorado.

Two rounds of Delphi surveys were completed by expert provider participants to provide the foundation for the development of a clinical practice guideline in conjunction with current literature supported by the ADA (2017), WHO (2011b), and USPSTF (2017) and a retrospective study conducted as part of this research project. Five providers responded to the first round of surveys and four responded to the second round to elicit over an 80% response rate on the utility, comprehensiveness, and practical use of a diabetes screening guideline and algorithm. The results indicated a strong need for a discrete and comprehensive practice guideline.

Data extracted from the retrospective study, literature review, and Delphi surveys were aggregated to develop the clinical practice guideline; through the use of the second Delphi survey, the guideline was refined to accommodate the provider participants' recommendations. In addition to the creation of a written guideline, an algorithm was designed that offered two clinical pathways depending on age to screen with an informal risk assessment and A1c at different intervals. Additional recommendations outside the scope of this capstone project were included to conduct a second post-implementation retrospective study after an initial pilot period. The Stetler (2001) model was used to translate the research for this project into practice utilizing a clinical practice guideline.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

A1c	Glycosylated hemoglobin A1c
ADA	American Diabetes Association
BMI	Body Mass Index
BP	Blood Pressure
CDC	Centers for Disease Control and Prevention
CINAHL	Cumulative Index to Nursing and Allied Health Literature
DKA	Diabetic Ketoacidosis
DM	Diabetes Mellitus
DNP	Doctor of Nursing Practice
DPP	Diabetes Prevention Program
ED	Emergency Department
EMR	Electronic Medical Record
FPG	Fasting Plasma Glucose
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HbA1c	Hemoglobin A1c
HDL	High Density Lipoprotein
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
IRB	Institutional Review Board

OGTT	Oral Glucose Tolerance Test
PAMG	Park Avenue Medical Group
RCT	Randomized Controlled Trial
USPSTF	United States Preventative Services Task Force
WHO	World Health Organization

CHAPTER I

STATEMENT OF THE PROBLEM

Background and Significance

Diabetes mellitus (DM) is a disease well known to the medical community. Despite continuous research efforts to manage the disease, it continues to grow at epidemic proportions, placing enormous financial burdens on the healthcare system. The National Diabetes Statistics Report released most recently in 2014 by the Centers for Disease Control and Prevention (CDC), reported 29.1 million people in the United States have diabetes. Included in that astronomical statistic was 8.1 million undiagnosed cases (CDC, 2014). An estimated 28.9 million people with diagnosed and undiagnosed DM in the United States are over the age of 20 and it affects men more than women. American Indians/Alaska Natives have the statistically highest incidence of all races and ethnicities at 15.9%, followed by non-Hispanic Blacks (13.2%), Hispanics (12.8%), and Asian Americans (9.0%); non-Hispanic Whites have the lowest rates at 7.6% (CDC, 2014). In 2012, over 1.7 million people over the age of 20 were newly diagnosed with diabetes and an estimated 37% or 86 million additional American adults are considered to have prediabetes based on fasting blood glucose or A1c levels. Two-hundred and eight thousand individuals under the age of 20 carry a Type 1 or Type 2 DM diagnosis. In the adolescent population, an estimated 23,525 individuals are diagnosed with Types 1 or 2

diabetes annually with increased incidence noted in the 10- to 19-year-old age group (CDC, 2014).

In Colorado, there was a 55% increase in the incidence of DM, identifying the state as one of eight states with the most significant increase in cases in recent years--growing from 4.7% in 2003 to 7.3% in 2014 (Colorado Department of Public Health and Environment [CDPHE], 2015). Nearly 20,000 Colorado residents were newly diagnosed with DM in 2014 alone and over half of the diagnoses occurred in the 18- to 54-year-old age group. Additionally in Colorado, an estimated 300,000 adults have a diabetes diagnosis along with an estimated 110,000 more undiagnosed (CDPHE, 2015). Hispanic and Black individuals are nearly twice as likely to have diabetes compared to White individuals. As age increases, the prevalence of DM also increases, while education and socioeconomic status are inversely related to a diabetes diagnosis. Demographically speaking, southeastern Colorado has the highest diabetes prevalence, which is nearly twice the state's average (CDPHE, 2015).

Diabetes is a disorder characterized by a marked elevation of blood glucose levels resulting from abnormal insulin production. Type 1 diabetes can be diagnosed at any age; however, it is typically diagnosed in the teens and occurs when the beta cells in the pancreas are destroyed by mediation or initiation of the body's immune response. The end result is limitation or elimination of insulin secretion, causing elevations in glucose levels. Currently, Type 1 diabetes cannot be prevented and must be treated with insulin delivery via subcutaneous injection or intrathecal pump at regular intervals (CDC, 2014). Type 2 diabetes usually develops later in life and accounts for 90-95% of all diabetes diagnoses. This type of diabetes begins with insulin resistance caused by dysfunction of

the cells within the muscles, liver, and fat tissues. The beta cells lose their ability to produce sufficient quantities of insulin, causing a gradual rise in blood glucose levels over time (CDC, 2014). Age, obesity, family history, physical inactivity, race/ethnicity, history of impaired glucose metabolism, or gestational diabetes are all risk factors for the development of Type 2 diabetes. Type 2 diabetes is treated with diet, exercise, and oral and injectable glucose lowering agents; it may be reversible depending on cause (CDC, 2014). Prediabetes is diagnosed when an individual has elevations in blood glucose or glycosylated hemoglobin levels but not yet meeting the diagnostic criteria for diabetes. Prediabetes is the precursor to Type 2 diabetes and carries the same cardiovascular risk; however, it can be avoided through lifestyle modifications including weight loss, diet, and exercise (CDC, 2014).

Diabetes is not only a disorder of blood glucose levels. It is a vascular disease with far reaching and potentially devastating consequences including end-organ failure. Most affected individuals have one or several comorbidities such as hypertension, hyperlipidemia, obesity, cardiovascular disease, and kidney disease leading to heart attack and stroke, blindness, and amputations (CDC, 2014). In addition to the comorbidities and complications mentioned, people with DM may develop neuropathies, non-alcoholic fatty liver disease, periodontal disease, hearing loss, and depression. Diabetes mellitus is the seventh leading cause of death in the United States. It is suspected to be underreported as the actual cause of death in people with several comorbidities (CDC, 2014) and is the eighth leading cause of death in Colorado (CDPHE, 2015). The risk of death among people with diabetes is almost twice as high as

individuals with similar risk factors who do not have diabetes (Deshpande, Harris-Hayes, & Schootman, 2008).

Diabetic ketoacidosis (DKA) is a diabetes-related emergency characterized by hyperglycemia, hyperketonemia, and metabolic acidosis in extremely insulin deficient individuals. Diabetic ketoacidosis is a major cause of DM related hospitalizations and can result in death (MacArthur, 2015). Recent studies indicate DKA hospitalizations are increasing in the United States. From 1996 to 2006, there was a 35% increase in the number of hospitalizations with DKA as the primary diagnosis (Palmiere, Bardy, Mangin, & Werner, 2013). Causes of DKA have been attributed to errors in insulin dosing, undiagnosed DM, alcohol use, illness or infection, trauma, surgery, or steroid use. Diabetes is often initially diagnosed during a DKA related hospitalization (MacArthur, 2015). It is estimated approximately 15% of all children and 24% of children under five years of age are not diagnosed with DM until they are in DKA and over one-third of them had been seen by a doctor at least once prior to receiving diagnosis (MacArthur, 2015). Diabetic ketoacidosis is the most common cause of death in children and adolescents with Type 1 diabetes and accounts for half of all deaths in patients under 24 years of age with DM (Palmiere et al., 2013).

Fulminant diabetes is a new subtype of Type 1 diabetes considered to be idiopathic in nature. The clinical features include abrupt onset of ketosis or ketoacidosis and nearly absent C-peptide secretion along with elevated plasma glucose levels and almost normal HbA1c levels (Imagawa & Hanafusa, 2006). This subset of DM is especially concerning because of the rapid onset of symptoms and higher potential for death. Fulminant DM does not fit the usual clinical presentation of Type 1 diabetes

including childhood onset with elevated HbA1c levels and islet-associated antibodies. Individuals with fulminant diabetes often present to the emergency department (ED) in DKA with blood glucose levels over 1000 mg/dL on the day of onset with normal levels in the days prior to their admission (Imagawa & Hanafusa, 2006). In a Korean study, the prevalence of fulminant DM in newly diagnosed patients with diabetes was reported to be 7.1% and 30.4% among patients with adult onset diabetes (Palmiere et al., 2013).

Diabetes is an expensive disease, costing the nation over $245 billion in 2012 (CDC, 2014). The average cost per patient per year in Colorado was over $13,000 (CDPHE, 2015). Medical expenditures for diabetes-related treatment is 2.3 times higher than those without a DM diagnosis (CDPHE, 2015). One in every five healthcare dollars is directly attributable to diabetes with additional indirect costs associated with absenteeism, reduced productivity at work (presenteeism), and lost capacity to work (American Diabetes Association [ADA], 2013). Forty percent of the total amount of healthcare expenditures related to DM were due to higher hospital admission rates and longer than average inpatient stays. According to the ADA (2013), this is the single largest medical cost associated with DM. Diabetic medications account for over a quarter of diabetes-related healthcare expenditures with the remainder of the costs associated with diabetes-related health resources, much of which is provided by Medicare. As the diabetic population ages, the cost per person is expected to increase due to resource utilization from inpatient, outpatient, skilled nursing facility, and medication usage (ADA, 2013).

Problem Statement

Screening for diabetes is currently performed through several methods--most commonly by fasting plasma glucose levels and glycosylated hemoglobin levels. With the emergence of recent data, current screening methods would fail to detect DM in a large population of individuals including at-risk African Americans with low triglycerides and normal high-density lipoprotein (HDL) and A1c levels, individuals with hemoglobinopathies, and individuals with unrecognized fulminant diabetes. Still troubling is the current literature suggesting DM is often unrecognized until a hospitalization following DKA, often resulting in death.

A study by Corriere, Minang, Sisson, Brancati and Kalyani (2014) addressed the use of clinical guidelines for decision-making related to diabetes. The authors concluded only 53% of queried providers used a guideline routinely, suggesting significant gaps exist in diabetes-related decision-making among providers. Surprisingly, the study revealed a low level of diabetes- related knowledge among both providers who did and did not use a clinical guideline routinely. The authors surmised this disparity as one reason guideline adherence was low. Clinical guideline use is associated with greater diabetes-related knowledge and essentially better patient outcomes (Corriere et al., 2014). The purpose of this capstone project was to develop a simplistic clinical practice guideline to screen for DM in a primary care setting in an effort to facilitate early detection and initiate treatment to minimize diabetes-related complications and mortality in those individuals at highest risk.

The following research question guided this capstone project:

Q1 In a primary care setting, how does guideline implementation to screen for diabetes mellitus compared to traditional screening techniques influence early detection in patients with previously undiagnosed diabetes?

Theoretical Framework

The high incidence of undiagnosed and underdiagnosed diabetes mellitus in the United States and locally in Colorado and the current methodology used to screen for diabetes demonstrate a lack of knowledge of significant risk factors beyond elevated glycosylated hemoglobin and plasma glucose levels in the primary care setting. Translating current research into practice is a necessary step to decreasing the morbidity and mortality related to diabetes or pre-diabetes diagnoses. The Stetler (2001) model, originally developed in 1976, uses a step-wise, practitioner-oriented approach to research utilization by converting knowledge into practice through five phases: preparation, validation, comparative evaluation/decision making, translation/application, and evaluation.

Phase I: Preparation

The preparation phase of the Stetler (2001) model addresses the purpose, context and sources of research evidence. During this phase, the purpose of the capstone project was acknowledged and internal and external factors were addressed. The perceived problems were identified and prioritized and the research design was determined. Measurable outcomes were organized and Institutional Review Board (IRB) approval was obtained through the University of Northern Colorado prior to project implementation (see Appendix A).

Phase II: Validation

The purpose of this phase was to focus on the utilization of the sources of evidence. Within this phase, a comprehensive, systematic literature review was performed that identified the strength of the evidence presented in the project. Resources were reassessed to address their applicability to improve current practices and non-credible sources were eliminated. A project without sufficient credible evidence would have been terminated during this phase of the Stetler (2001) model.

Phase III: Comparative Evaluation/ Decision Making

During Phase III of the Stetler (2001) model, the findings of the literature review were synthesized by identifying similarities and differences and an evaluation of the degree of evidence substantiation. A decision was made about which evidence would be utilized for the capstone project (Stetler, 2001).

Phase IV: Translation/Application

The translation of the synthesized findings (recommendations) into practice was the focus of Phase IV (Stetler, 2001). For the purposes of this project, a guideline was created using the data extracted from a retrospective chart review and the literature review. The plan to disseminate the guideline was formalized during this phase and entailed providing the new clinical guideline to the providers at Park Avenue Medical Group (PAMG).

Phase V: Evaluation

Evaluation is the final phase of the Stetler (2001) model. A formal appraisal of the clinical guideline implementation was evaluated for credibility, goal progress, and results. Changes and recommendations were provided as considerations for future

studies (Stetler, 2001). Phase V also appraised any unexpected or negative outcomes. A cost-benefit analysis would be performed during this phase of the Stetler model; however, post-implementation evaluations were not conducted in this capstone project due to time constraints. Figure 1 provides a visual representation of the Stetler model.

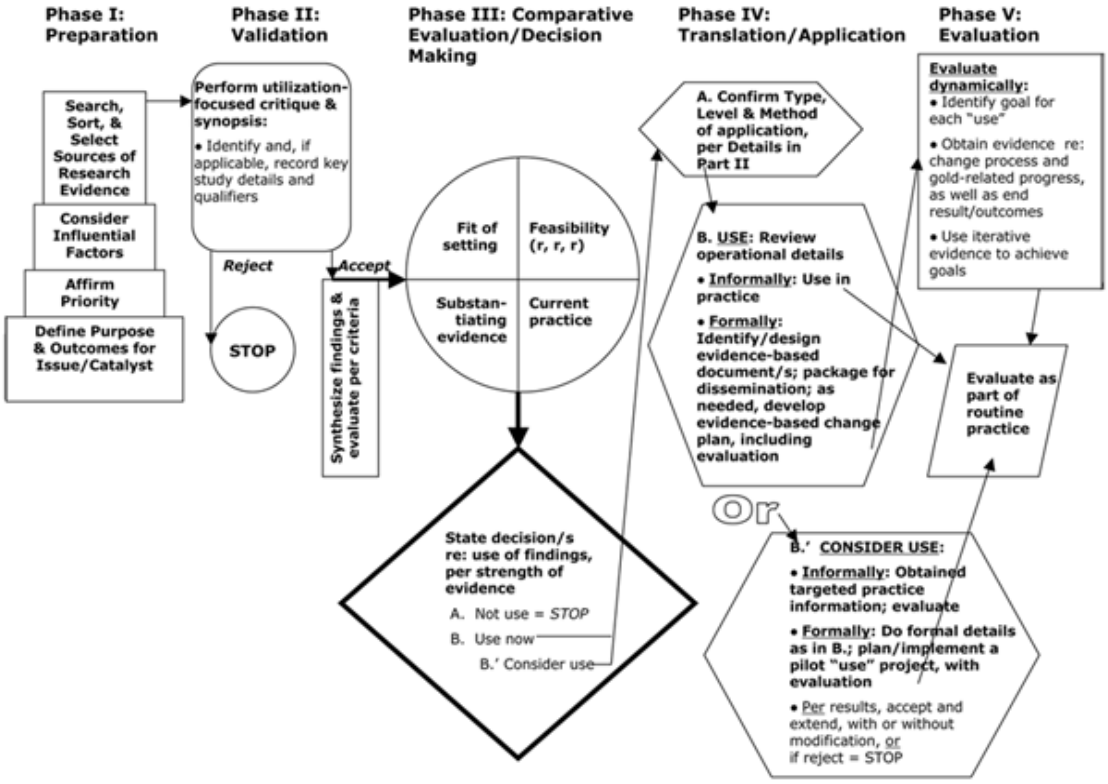

Figure 1. The Stetler model: Phases of research utilization to facilitate evidence-based practice.

Literature Review

The literature review was conducted to evaluate current diagnostic standards published by the ADA (2017), the U.S. Preventative Services Task Force (USPSTF; 2017), and the World Health Organization (WHO; 2016). The purpose of the investigation was to (a) evaluate gaps in diagnosis criteria utilized by three of the largest

research-based organizations with published diagnostic guidelines for diabetes and (b) establish congruency in diagnostic and screening techniques. The following electronic databases were utilized for the literature review: the Cochrane Database Systematic Review, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Google Scholar, and PubMed. Keywords included in the search were diabetes guidelines, diabetes in primary care, clinical guidelines, diabetes management, diabetes screening, screening criteria and diabetes diagnosis. Criteria included full text articles published between 2009 and 2017 and written in the English language. Study types were systematic reviews, meta-analysis, cohort studies, and randomized controlled studies.

American Diabetes Association Guidelines

The American Diabetes Association (Cefalu, 2017) released their 2017 *Standards of Medical Care* in January based on current literature and evidence-based practice (see Table 1). Attempting to uphold the highest standards, the majority of their recommendations were based on A- or B-level evidence. A-level evidence is derived from clear evidence from randomized controlled trials (RCT), compelling nonexperimental evidence, or supportive evidence from RCTs. B-level evidence is derived from supportive evidence from cohort studies (Cefalu, 2017).

The ADA (Cefalu, 2017) recommended several diagnostic tests for diabetes and prediabetes using fasting plasma glucose levels (FPG) or the two-hour plasma glucose value after a 75-gram oral glucose tolerance test or the glycosylated hemoglobin A1c criteria--all are equally appropriate for diagnostic testing (Cefalu, 2017, p. S12). Compared to A1c and FPG values, the two-hour plasma glucose value is predictive of more people with diabetes. A1c levels have a convenience advantage over the other two

plasma glucose values and is less influenced by stress and illness--known precursors to skewed glucose levels; however, it is less sensitive and costlier to perform (Cefalu, 2017).

Table 1

American Diabetes Association Diagnostic Criteria for Diabetes

Test	Value	Description
Fasting Plasma Glucose	≥ 126 mg/dL	Fasting is defined as no caloric intake for > 8 hours
Two-hour Plasma Glucose	≥ 200 mg/dL	Using WHO guidelines and glucose load of at least 75 g of anhydrous glucose
A1c	≥ 6.5%	Lab tested using method that is NGSP certified and standardized
Random Plasma Glucose	≥ 200 mg/dL	With classic symptoms of hyperglycemia

Note. Repeat testing recommended unless clear clinical diagnosis present.

Using the A1c level as a diagnostic tool, the ADA (Cefalu, 2017) recommends other factors also be taken into consideration. The studies used to determine the A1c recommendations were based solely on adult populations; it is unknown if the same cut-point should be used to diagnose DM in adolescents and children (Cefalu, 2017). Additionally, A1c levels may vary depending on race and ethnicity. African Americans often have higher A1c levels than Caucasians after similar fasting and post glucose load levels, suggesting a higher postprandial glycemic burden (Cefalu, 2017). Hemoglobin A1c levels might also be skewed in patients with abnormal red blood cell turnover or hemoglobinopathies such as pregnancy, sickle cell trait, hemodialysis, recent transfusion,

or erythropoietin therapy, suggesting interpretation of A1c levels in these individuals would be challenging. Plasma blood glucose criteria should be used to diagnose DM in patients with abnormal red blood cell turnover (Cefalu, 2017). The diagnosis of diabetes is made only after repeat confirmation unless there is a clear clinical diagnosis of random plasma glucose level ≥ 200 mg/dL in a symptomatic individual. The second test should be conducted as soon as possible and questionable results should be repeated in 3-6 months (Cefalu, 2017).

Screening for diabetes is recommended in overweight or obese adults with one or more risk factors including A1c level ≥ 5.7%, impaired glucose tolerance (IGT) test, impaired fasting glucose (IFG) levels, a first-degree relative with DM, high risk ethnicity, women with past history of gestational diabetes, history of cardiovascular disease or hypertension, women with polycystic ovarian syndrome or other diseases causing insulin resistance, or physical inactivity. The ADA (Cefalu, 2017) recommends routine testing for everyone beginning at age 45 and repeated every three years for individuals with normal results. More frequent testing is recommended based on risk stratification and prediabetes status (Cefalu, 2017). Children and adolescents who are overweight or obese and have at least two additional risk factors should also be tested for prediabetes using FPG, two-hour plasma glucose or A1c levels. The ADA's Expert Committee on the Diagnosis and Classification of Diabetes Mellitus defined a confirmed diabetes diagnosis if fasting or impaired plasma glucose levels were between 100 and 125 mg/dL. This differs from the World Health Organization's cutoff at 110 mg/dL (Cefalu, 2017).

The ADA (Cefalu, 2017) recommends Type 1 diabetes, also called immune-mediated diabetes, be diagnosed using blood glucose levels rather than A1c.

Additionally, antibody screening is recommended in research trials or if a first-degree relative has Type 1 diabetes. Type 1 DM is often diagnosed after a hyperglycemic crisis or life-threatening DKA. It has been suggested that measuring islet antibodies in relatives of those affected by Type 1 DM might help identify individuals at risk for developing Type 1 diabetes before a hyperglycemic crisis or DKA event. Type 2 diabetes is much more insidious and frequently goes undiagnosed for several years. The overall risk of developing cardiovascular complications is the same in undiagnosed as in diagnosed DM (Cefalu, 2017).

A diagnosis of prediabetes is instrumental in the prevention or delay of Type 2 diabetes. The ADA (Cefalu, 2017) recommends yearly monitoring for the development of DM in individuals with a prediabetes diagnosis and intensive behavioral modifications to achieve and maintain a loss of 7% of initial body weight. Additionally, the ADA recommends 150 minutes per week of moderate intensity physical activity augmented by technology assisted tools such as fitness applications, social networks, mobile diet tracking, and DVD-based content related to lifestyle modifications (Cefalu, 2017). The diabetes prevention program (DPP) is an intensive lifestyle modification program, demonstrating a reduction in the incidence of Type 2 diabetes by 58% over three years by implementing the 7% weight reduction and 150 minutes per week of moderate intensity activities. This is by far the strongest evidence presented in the prevention of Type 2 DM with numerous studies demonstrating sustained reduction in the conversion rate to DM (Cefalu, 2017).

Studies have demonstrated that reduction of caloric intake through quality of fat consumption rather than quantity has been contributory in preventing or delaying the

onset of Type 2 DM. The Mediterranean diet--whole grains, nuts, berries, coffee, tea and yogurt--includes food items known to prevent Type 2 diabetes and are effective at lowering A1c levels (Cefalu, 2017). Moderate intensity physical activity such as brisk walking improves insulin sensitivity and reduces abdominal fat in young adults and children. Resistance training and breaking up prolonged sedentary time by walking has shown to moderately lower postprandial glucose levels in addition to reducing the risk of the development of gestational diabetes (Cefalu, 2017). Pharmacologic interventions for diabetes prevention include oral glucose lowering agents such as metformin, pioglitazone, and exenatide, with metformin demonstrating the strongest evidence for long-term safety and efficacy. Lifestyle modification and DPP were more effective than metformin but were costlier over a 10-year period (Cefalu, 2017).

Medications used in the treatment of diabetes include insulin for Type 1 diabetes and various oral and injectable agents for the treatment of Type 2 DM. Initial therapy in Type 2 DM should include monotherapy with metformin unless the A1c is greater than 9% in which dual therapy in indicated. With individuals with blood glucose levels greater than 300 or A1c greater than 10%, combination injectable therapy is recommended. A1c levels are checked at regular three- to six-month intervals and a stepwise approach to pharmacologic management is utilized until target A1c levels are met (Cefalu, 2017).

World Health Organization Guidelines

The WHO (2016) released new recommendations for the screening and diagnosis of diabetes after conducting their own systematic review of international literature available on the subject (see Table 2). While the ADA's (Cefalu, 2017)

recommendations seemed to mirror the WHO guidelines, several key points were emphasized in the WHO report. Specifically, the WHO report analyzed the usefulness of the hemoglobin A1c as a diagnostic tool for the detection of Type 2 diabetes in the world population. Currently, the WHO does not endorse the use of the HbA1c for the diagnosis of diabetes due to the limited availability of the test in many countries, its influence on hemoglobinopathies, and global inconsistencies in the A1c measurement (WHO, 2011b).

Table 2

World Health Organization's Recommendations on Diagnostic Criteria for Diabetes

Test	Value
Fasting Plasma Glucose	≥ 7.0 mmol/L (126 mg/dl)
Two-hour Plasma Glucose	≥ 11.1 mmol/L (200 mg/dl)
HbA1c	≥ 6.5%

Note. Adapted from The World Health Organizations Diabetes Recommendations (2016).

The WHO (2016) guidelines, similar to the ADA's (Cefalu, 2017) guidelines, based their recommendations on the quality of evidence using the grading of recommendations, assessment, development and evaluation (GRADE) methodology; however, feasibility and resources for low and middle-income countries were also considered. The strength of the recommendations was based on a 2-point scale. Weak/conditional recommendations had a low, moderate, or high quality of evidence but were not applicable in lower resource countries. Strong recommendations were moderate or high quality of evidence and were applicable in low resource settings (WHO, 2016). The WHO concluded the A1c level could be used as a diagnostic test for diabetes only if

stringent quality assurance processes were in place based on moderate GRADE quality of evidence and conditional strength of recommendations. The A1c cut point for a diabetes diagnosis was 6.5%. Unlike the ADA's recommendations, the WHO concluded there was insufficient evidence to make any recommendations on A1c levels below 6.5% (WHO, 2011a).

The WHO's (2016) recommendations included a statement regarding the diagnosis of DM in an asymptomatic individual. The diagnosis should not be based on a single abnormal plasma glucose or A1c level. A second test with values within the diabetic range is required for diagnosis according to WHO standards, using fasting, random, or oral glucose tolerance testing in a stringently controlled testing or lab environment. Use of the same diagnostic test is recommended; however, if a different test is utilized, the results could be used to formalize a diabetes diagnosis. Periodic retesting is recommended for individuals having a singular positive diagnostic test and negative second test until DM status is clear (WHO, 2016).

U.S. Preventative Services Task Force Recommendations

The U.S. Preventative Services Task Force (Siu, 2015) released their latest recommendations on screening for Type 2 diabetes in December 2015 (see Table 3). Their recommendations pertained to the adult population ages 40-70 who are overweight or obese and asymptomatic. Like the ADA and WHO recommendations, the USPSTF's recommendations are based on the level of evidence but do not consider the cost of providing the screening services to the public (Siu, 2015). The USPSTF (2017) guidelines are based on grade B recommendations, suggesting high to moderate certainty

of beneficial health outcomes from the implementation of their guidelines (USPSTF, 2017).

Table 3

U.S. Preventative Services Task Force Diagnostic Criteria for Type 2 Diabetes

Test	Value
Hemoglobin A1c Level	≥ 6.5%
Fasting Plasma Glucose Level	≥ 7.0 mmol/L ≥ 126 mg/dl
2-hour Oral Glucose Tolerance Test	≥ 11.1 mmol/L ≥ 200 mg/dl

Note. Adapted from Siu (2015).

The USPSTF (Siu, 2015) recommendations to screen only adult patients ages 40-70 who are asymptomatic and overweight or obese were based on their research, indicating the target population is at the highest risk for cardiovascular complications related to a diabetes diagnosis and would reap the most benefit from primary prevention through intensive risk factor modification. Furthermore, the USPSTF acknowledged persons with additional risk factors such as family history of diabetes, history of gestational diabetes, polycystic ovarian syndrome, or persons of high risk ethnicities might be at risk for developing diabetes at a younger age or with a lower body mass index (BMI), and therefore recommend screening earlier for individuals with at least one of these risk factors (Siu, 2015).

Screening tests recommended by the USPSTF (Siu, 2015) included the HbA1c, fasting plasma glucose level, or the oral glucose tolerance test. Like the

recommendations of the ADA and WHO, the USPSTF recommended repeat testing with the same test on a different day to confirm a diabetes diagnosis. Screening intervals for individuals with an initial normal glucose level is recommended every three years (Siu, 2015). The USPSTF additionally recommended performing an annual risk assessment to identify risk factors for abnormal glucose metabolism such as obesity, physical inactivity, smoking, hypertension, and hyperlipidemia; however, no recommendations were offered on screening individuals with multiple risk factors (Siu, 2015).

Based on the evidence collected by the USPSTF (Siu, 2015), intensive behavioral counseling interventions for individuals at increased risk for cardiovascular disease are beneficial for lowering overall cardiovascular risk. These interventions are especially helpful in populations with hypertension, hyperlipidemia, and obesity, demonstrating a reduction in the specific risk factor values. Interventions aimed at individuals with impaired fasting glucose levels or impaired glucose tolerance could prevent diabetic conversion. Lifestyle interventions are more effective at reducing progression to diabetes than medications such as metformin (Siu, 2015).

The USPSTF (Siu, 2015) recommended sending patients with a BMI > 25 and additional cardiovascular risk factors to intensive behavioral counseling to promote cardiovascular health through healthy diet training and exercise programs. Screening for lipid disorders should begin in men over the age of 35 and women over the age of 45, who also have an increased risk for heart disease. Screening for hypertension should begin at age 18 and tobacco use assessed annually with cessation interventions offered as needed (Siu, 2015).

Comparison of the Three Organization's Modalities and Other Considerations

Clinical guidelines are intended to assist providers in the diagnosis and management of illness and disease processes. The increased prevalence of diabetes, especially Type 2 diabetes, has created an urgent need for uniformity in the diagnosis and management of the disease. Although the ADA (Cefalu, 2017), WHO (2016), and USPSTF (Siu, 2015) have minor and negligible differences in the diagnosis techniques for diabetes, all agreed early diagnosis and treatment minimize the cardiovascular complications of later stages of the disease. A meta-analysis and systematic review by Khunti et al. (2015) evaluated screening methods for the diagnosis of Type 2 diabetes by examining response rates, positive outcomes at initial and intermediate screening stages, and yield rates using 1-step, 2-step, and 3-4 step processes. Initial response rates were defined as the proportion of people who accepted the invitation to the screening study compared to the total number invited. The yield rate was the number of newly diagnosed Type 2 diabetes cases compared to the total number screened using the oral glucose tolerance test (OGTT) or blood test. Invasive versus non-invasive testing methods were evaluated for heterogeneity and sensitivity (Khunti et al., 2015).

The findings from the Khunti et al. (2015) study indicated the number needed to detect a single case of diabetes using the OGTT (1-step process) decreased as the number of steps increased. The 2-step screening strategies, where test subjects were screened for diabetes prior to the OGTT, had a higher initial response rate and yet there was no change in yield and response rates if a blood test was used as the initial screening step (Khunti et al., 2015). Conversely, considering all methods, the number of individuals at high risk for diabetes or diagnosed with diabetes decreased as the number of steps in the diagnosis

process increased, indicating less people needed to have the OGTT when screening and retesting were used. Khunti et al.'s meta-analysis was unable to compare screening strategies such as the HbA1c and random or fasting blood glucose levels utilized in the 2-step and 3-4 step processes due to a lack of available qualified studies, suggesting a study limitation or identified area for further investigation.

A similar study by Bowen, Xuan, Lingvay, and Halm (2017) evaluated the sensitivity and specificity of the ADA, WHO, and USPSTF guidelines. Over 7,100 participants met study criteria. Seventy-eight percent of participants met the screening criteria using the ADA guidelines, 24% met the USPSTF screening guidelines, and 34% met the latest USPSTF screening guidelines (Bowen et al., 2017). Bowen et al.'s study reported the ADA guideline's sensitivity to detect undiagnosed diabetes was 99.2%; however, their specificity was only 23%, causing a 78% false positive rate. The USPSTF's guideline criteria had a 76.7% specificity rate and 41.9% sensitivity rate while the WHO guideline had a 67% specificity rate and 65% sensitivity rate (Bowen et al., 2017).

The results of the Bowen et al. (2017) study suggested screening all participants with a random blood glucose level ≥ 100 mg/dL would screen an additional 23% of adults in the sample. This statistic was based on literature suggesting a single random glucose level ≥ 100mg/dL was more predictive of undiagnosed DM than traditional risk factors (Bowen et al., 2017). Identifying individuals with higher risk for the development of diabetes could be achieved by lower random glucose cut points creating higher sensitivity while higher cut points would create greater specificity. Utilizing a random glucose level ≥ 100 mg/dL would achieve balanced sensitivity and specificity in detecting

undiagnosed DM. A case-finding strategy was utilized to identify individuals with a random glucose level ≥ 100mg/dL; the authors concluded it would screen half as many people as the ADA and USPSTF guidelines to correctly identify one person with undiagnosed diabetes, thus maximizing case yield and minimizing unnecessary screening costs (Bowen et al., 2017).

Summary of a Systematic Review Using the U.S. Preventative Services Task Force Screening Guideline

Selph et al. (2015) performed a systematic review of RCT, controlled trials, observational studies, and screening methods for Type 2 diabetes using the USPSTF recommendations to determine if health outcomes were improved in individuals with impaired fasting glucose levels or impaired glucose tolerance through screening and early intervention. The meta-analysis of the selected studies discussed the results of several key factors. Benefits of screening for diabetes versus no screening were evaluated to assess long-term cardiovascular mortality and all-cause mortality over 10 years, concluding screening was not associated with better outcomes or reduced cardiovascular mortality. Similarly, screening did not reduce the risk for all-cause mortality in the studies surveyed. The harms of screening were also evaluated, demonstrating increased short-term anxiety in the initial six weeks post screening for a new diagnosis of diabetes and no negative psychological effects after one year (Selph et al., 2015).

Studies evaluating the treatment of USPSTF screen-detected IFG or IGT or early diabetes included in the systematic review suggested split support on the validity of lifestyle interventions for all-cause or cardiovascular risk reduction (Selph et al., 2015). One study out of China concluded a six-year lifestyle intervention was associated with

risk reduction in both categories after 23 years of follow-up, while other lifestyle intervention trials demonstrated no beneficial outcomes on all-cause or cardiovascular mortality (Selph et al., 2015). Pharmacological interventions were also considered for USPSTF screened individuals with new onset diabetes of IGT or IFG levels with studies demonstrating few benefits or reduction in mortality rates from trials of glucose lowering agents over placebo (Selph et al., 2015). Studies evaluating the harms associated with treating screen detected diabetes or IFG or IGT were reviewed, suggesting that compared to placebo, interventions could result in harm and included complications such as hypotension, hypoglycemia, withdrawal symptoms, and increased incidence of congestive heart failure (Selph et al., 2015).

Intensive treatment options versus standard treatment were also evaluated in the systematic review, concluding no risk reduction with intensive treatment for a first fatal or non-fatal cardiovascular event; however, all-mortality and cardiovascular event rates were lower (Selph et al., 2015). Intensive glucose lowering therapy was associated with risk reduction for non-fatal myocardial infarctions; yet management including goal HgbA1c levels between 6.0% and 7.5% resulted in no decrease for all-cause or cardiovascular mortality compared to less intensive methods of management (Selph et al., 2015). Intensive blood pressure management decreased risk for all-cause mortality according to one study but differing definitions of intensive therapy caused the trial to lose validity. More recent studies evaluated in the systematic review suggested similar results with consistent risk reduction in all-cause and cardiovascular mortality when an angiotensin-converting enzyme inhibitor and diuretic were added (Selph et al., 2015). Harms caused by intensive treatment versus standard treatment were also considered in

the review, demonstrating low and imprecise rates of reported harm with multifactorial treatment. Intensive glucose lowering treatments were associated with higher rates of hypoglycemia and other medication-related adverse events requiring hospitalization (Selph et al., 2015).

The benefits of treating impaired fasting glucose and impaired glucose tolerance levels to delay or prevent conversion to diabetes were also evaluated in the systematic review (Selph et al., 2015). The studies evaluated lifestyle and pharmacological and multifactorial interventions over six months to six years. Lifestyle interventions were associated with decreased risk of conversion to a diabetes diagnosis in six of the studies reviewed. Pharmacological interventions indicated thiazolinediones decreased progression to diabetes as well as combinations of valsartan and low dose metformin and rosiglitazone (Selph et al., 2015). Nateglinide and glimepiride were not associated with risk reduction for progression to diabetes. Multifactorial approaches to prevent progression included glucose, blood pressure (BP), and lipid control in addition to lifestyle modifications; aspirin demonstrated a statistically significant decrease in the progression to diabetes in several of the studies evaluated in the systematic review (Selph et al., 2015).

Diabetes Guidelines in Clinical Practice

Underutilization of diabetes guidelines in the primary care setting is challenging and multifactorial. According to Bouchonville, Matani, DuBroff, and DuBroff (2017), published guidelines often exclude relevant studies or are not evidence-based, causing confusion and discord in diabetes management and leading to low provider adherence. Bouchonville et al.'s study evaluated studies that target traditional cardiovascular risk

factors in diabetic patients: anti-platelet therapy, blood pressure, glycemic and lipid control, and lifestyle interventions. The results of their systematic review suggested the ADA's recommendations regarding a Mediterranean diet, blood pressure, and glycemic control were truly evidence-based but had questionable evidence to support specific pharmacological therapies. Additionally, the review suggested the ADA's evidence to support the use of aspirin or other anti-platelet therapy or statins in the management of diabetes was inconsistent and contradictory (Bouchonville et al., 2017). While Bouchonville et al.'s systematic review did not specifically pertain to the utilization of guidelines to screen and diagnose diabetes, it highlighted the confusion providers face in diabetes prevention, screening, and management. A second systematic review (De Belvis, Pelone, Biasco, Ricciardi, & Volpe, 2009) evaluating diabetes management guidelines surveyed over 1,700 abstracts and found only 13 articles suitable for their review and only one discussed guideline application and outcome/process indicators to evaluate delivery and adherence to evidence-based guidelines. To aid providers in sifting through the abundance of literature, De Belvis et al. (2009) suggested educational/ training interventions, interactive technology, audit interventions or a combination of interventions to promote uniformity in diabetes management.

CHAPTER II

PROJECT DESCRIPTION

Project Objectives

The primary care setting is ideal for preventative health care, especially screening for diabetes and other diseases of chronicity. Annual preventative or wellness visits are covered by nearly all health insurance plans and provide the opportunity to screen for diseases with far-reaching, end-organ, and cardiovascular consequences like diabetes. Recent changes in diabetes screening guidelines, lack of utilization, and absence of consensus on current screening practices provided an opportunity to intervene and create a clinical practice guideline to detect diabetes earlier in the primary care setting with the intention to screen individuals at the greatest risk or highest likelihood of reversibility through early diagnosis and treatment.

The following four objectives for this capstone project included the creation of a diabetes screening clinical practice guideline to support congruency in screening practices based on the latest evidence-based literature:

1. Gather information on current diabetes screening practices for the adult population at Park Avenue Medical Group. The information was collected through a retrospective chart review evaluating screening processes and risk stratification for adult patients over the age of 25 seen in the clinic for wellness/preventative visits.

2. Survey a panel of expert providers within and outside Park Avenue Medical Group to assess gaps in screening processes and willingness to adopt a new diabetes screening guideline.
3. Develop a diabetes screening guideline for providers to utilize during routine annual wellness visits based on the literature and consensus obtained through the survey.
4. Due to time constraints, this capstone project did not implement the clinical practice guideline.

Project Plan

Setting

The setting for this capstone project was Park Avenue Medical Group (PAMG) in Fort Lupton, Colorado. Park Avenue Medical Group is a small, privately owned practice comprised of one physician and one nurse practitioner providing services including acute and primary care; well examinations for men, women, and children; sports and Department of Transportation physicals; immunizations; minor surgeries; and laboratory/diagnostic testing. Data from a retrospective chart review were gathered from the practice's electronic medical record (EMR) from January of 2015 through June of 2017.

Sample

The sample population investigated for the retrospective portion of this project included adult males and females between the ages of 25 and 60 who visited PAMG for wellness visits from January of 2015 through June of 2017.

Resources

As part of the fulfillment of the degree of Doctor of Nursing Practice (DNP), financial resources were not considered for this capstone project. The retrospective study portion of the project was completed by this researcher utilizing PAMG's electronic medical record.

Phases

Phase one. The first phase of this evidence-based capstone project entailed the completion of a thorough literature review. The results of the literature review indicated a strong need for congruency and compliance to a clinical practice guideline to aid providers in screening for diabetes in the primary care setting. Included in phase one was the retrospective chart review, which was intended to extract data from the specified sample population. Each chart reviewed was evaluated for ADA (Cefalu, 2017), WHO (2016), and USPSTF (Siu, 2015) risk factors, if screening was performed and the results, and for glucose levels over 100 mg/dL to improve sensitivity and specificity of the screening process. In total, 709 charts were reviewed and 424 met all inclusion criteria.

Phase two. The second phase of the project was to create an evidence-based practice guideline. The Delphi method was utilized to survey a panel of clinical experts. Data extrapolated from the survey were compiled and the researcher collaborated with the expert panel to develop the practice guideline. Primary care providers for the expert panel included two physicians, two nurse practitioners, and one physician's assistant within PAMG and in other practices outside of their organization. Responses from the first Delphi survey questions in phase one helped identify methods currently utilized in primary care to screen for diabetes, risk factors identified by the providers, what

guidelines and recommendations were utilized, and specific tests performed in the screening process.

Phase three. During this phase, the clinical practice guideline was presented to the providers to review and modify. Providers were educated on how to use the guideline and the guideline was evaluated using a second round of the Delphi method for proper utilization and compliance. To promote consistency and preserve the integrity of the project, the same panel of five expert provider participants from round one of the Delphi survey was invited to participate in round two. Four of the five providers completed round two of the survey. The guideline was evaluated during this phase to ensure objectives were met.

Phase four. This phase entailed the physical implementation of the clinical guideline. The guideline was provided to PAMG for utilization. As previously stated, beyond presenting the guideline to the providers at PAMG, this phase was not completed during this capstone project.

Project Timeline

The researcher utilized the following timeline for project phases:

- Approval of phenomenon of interest--Fall 2016
- Defend proposal (Chapters I-III of project) and obtain Institutional Review Board approvals from University of Northern Colorado (see Appendix A) and PAMG (see Appendix B)—June-July 2017
- Retrospective chart review, initial Delphi survey and consent form sent (see Appendix C), and summary and responses (see Appendix D)—August-October 2017

- Development of clinical practice guideline and plan for implementation, second Delphi survey (see Appendix E), summary and responses (see Appendix F), finalize *Screening for Type 2 Diabetes in Adults Guideline and Algorithm* (see Appendix G), final defense of capstone project, and submission of completed capstone project to University of Northern Colorado—October-November 2017

CHAPTER III

EVALUATION OF PLAN

In an effort to preserve consistency and integrity of this capstone project, each phase was evaluated through the following four objectives.

Objective One

The first objective was to gather information regarding screening practices for diabetes in the primary care setting. This objective was accomplished through a retrospective chart review to evaluate current screening practices at PAMG on adult patients presenting in the clinic for wellness exams. The data were analyzed for screening methods and risk stratification in diabetic and non-diabetic patients.

Objective Two

Objective number two was completed by surveying a panel of experts using the Delphi method to gather information on the utility of a clinical practice guideline. The panel consisting of practicing physicians, nurse practitioners, and physician's assistants was queried about current methods used for screening purposes, suggestions, and general knowledge to develop a provider friendly, evidence-based practice guideline.

Objective Three

The third objective was the development of the clinical guideline. Information gathered from the review of evidence (literature review), retrospective chart reviews, and expert opinions were used to formulate the practice guideline. Since the guideline was

intended to be utilized, special attention was paid to the consensus of expert opinions to achieve 70% consensus amongst the providers. The panel of expert providers played an essential role in the development of the guideline by providing feedback on the feasibility and utility of the guideline. A second Delphi survey was provided to the panel of experts once the guideline was completed; revisions were made to accommodate the 70% consensus goal on provider practices.

Objective Four

The fourth objective was the plan for implementation. Physical implementation was not part of this capstone project; however, the staff at PAMG were trained on how to use the clinical practice guideline. If the providers decided to use the practice guideline, it was recommended that a second retrospective chart review be performed to evaluate pre- and post-implementation results and make improvements as evidence changed or was clinically necessary.

CHAPTER IV

RESULTS AND OUTCOMES

The purpose of this DNP capstone project was to evaluate current diabetes screening practices in the primary care setting and develop a clinical practice guideline to promote early detection and treatment of diabetes, thus minimizing long-term consequences and end organ damage caused by unrecognized and untreated DM. The first objective of this project was to gather information regarding screening practices for diabetes in the primary care setting through a retrospective chart review on adult patients between the ages of 25 and 60 who presented to PAMG for annual wellness exams from January 2015 through June 2017. Specifically, objective one was evaluating screening practices and risk stratification in both diabetic and non-diabetic patients. Objective two utilized the Delphi method to survey a panel of experts in family medicine about current screening practices and the practical utility of an evidence-based clinical practice guideline. Objective three included the development of a clinical guideline using information gathered from the review of evidence, retrospective chart review, and expert opinion. A second Delphi questionnaire was administered to the panel of experts to complete this objective, which sought 70% consensus on the clinical utility and practicality of the guideline. The fourth and final objective was the plan for implementation. The physical implementation of the clinical guideline was not included in this capstone project; thus, no formal evaluation was included in the final project.

Objective One

Objective one was accomplished through a retrospective chart review conducted to evaluate data on adult patients between the ages of 25 and 60 who presented at PAMG for wellness exams during the period beginning January 1, 2015 and ending on June 30, 2017. The data were examined to quantify the number of diabetes-related risk factors in the patient population as well as analyze screening methods used for a wellness visit in diabetic and non-diabetic patients. Candidates included in the chart review were either male or female from all races and ethnic backgrounds who presented to the clinic for a wellness physical where the International Classification of Disease (ICD) 10 code Z00.00 (encounter for general adult examination without abnormal findings) or Z00.01 (encounter for general adult examination with abnormal findings) was used (NuMed ICD-10 Lookup, n.d.). To be included in the chart review, the patient must also have completed routine annual blood work ordered by the provider specifically in conjunction with the wellness visit. Included blood work must have been completed within 30 days pre- or post-wellness visit and consist of at least a basic metabolic panel with an identified random or fasting glucose level.

Materials and Methods

Objective one was completed using the Aprima EMR application currently utilized by PAMG associates and providers. Historical charts were reviewed beginning on January 1, 2015 and ending on June 30, 2017 on all patients presenting to the clinic for a wellness visit. Charts on patients outside the ages of 25-60 or without routine wellness blood work consisting of a basic metabolic panel with a fasting or random

glucose level were eliminated from the study. In total, 709 charts were reviewed; 285 charts were eliminated, leaving 424 charts meeting all inclusion criteria.

Each patient chart reviewed was assigned a unique identification number and was analyzed to document ADA (2017), WHO (2011b), and USPSTF (2017) diabetes-related risk factors including age, gender, ethnicity, body mass index, fasting or random glucose levels, hemoglobin A1c if available, history of diabetes, gestational diabetes, polycystic ovarian syndrome, cardiovascular disease, hypertension, and hyperlipidemia. Initial data included all patients over the age of 25 meeting the aforementioned criteria; patients over the age of 60 were later omitted prior to the data analysis and were not included in any of the result statistics.

Results

The results analysis of the chart review reflected a total of 424 patients who visited PAMG for a physical during the selected time frame. Of the 424 patients, 169 were male (39.86%) and 255 were female (60.14%; see Figure 2). The ethnic makeup of the selected patient population was derived from demographic information documented in the patient chart and included 318 White patients (75%), 101 Hispanic patients (23.82%), two Black patients (0.005%), and three Asian or Pacific Islander patients (0.007%; see Figure 3). A total of 55 patients (12.97%) had a history of diabetes and 369 patients (87.03%) had no recorded history of diabetes in their medical records (see Figures 4, 5, and 6). Considering the risk factors identified by the ADA (2017), WHO (2011b), and USPSTF (2017), 78 patients (18.4%) had a BMI less than 25, indicating ideal or low body weight; 138 (32.55%) had a BMI between 25 and 29.9, falling in the overweight range; and 208 (49.05%) had a BMI falling in the obese range (see Figures 7

and 8). One hundred patients or 23.58% of the queried patient population had a documented history of hypertension. Two patients (0.005%) had a history of cardiovascular disease and 131 patients (30.9%) had a history of hyperlipidemia. Of gender-specific risk factors, polycystic ovarian syndrome and gestational diabetes, only one patient was documented to have polycystic ovarian syndrome in their history, accounting for 0.002% of the total surveyed patient population.

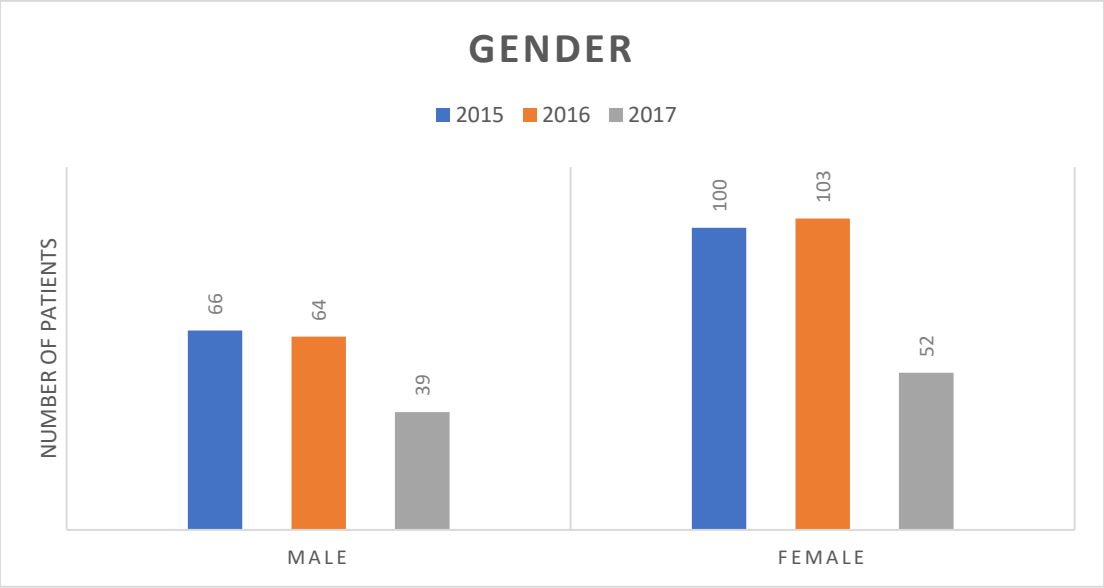

Figure 2. Gender of surveyed population at Park Avenue Medical Group designated by year.

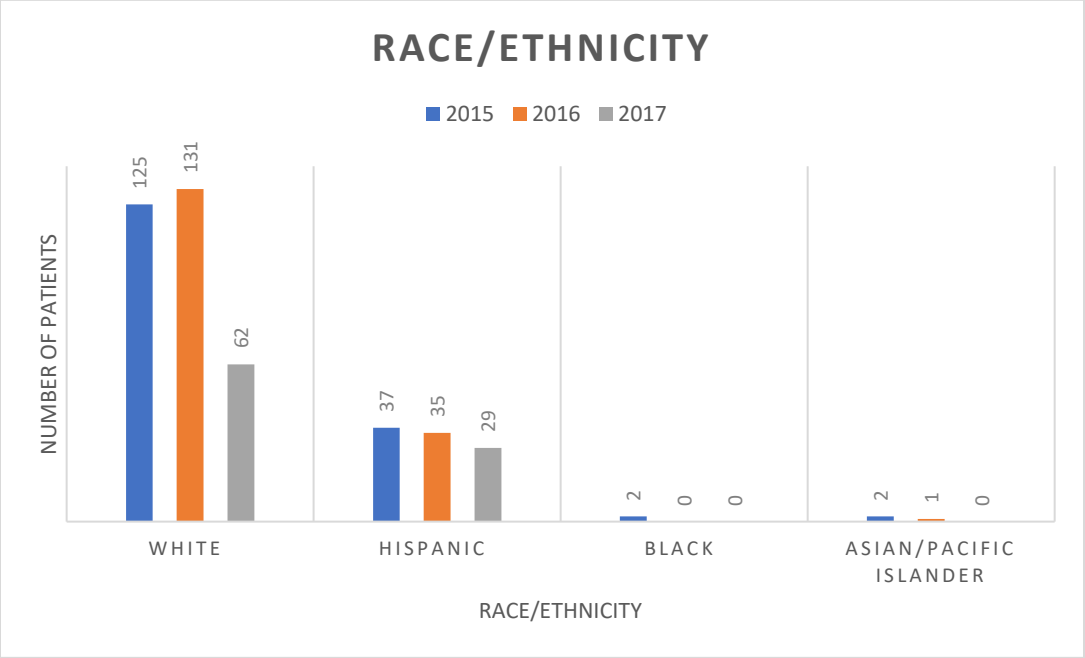

Figure 3. Racial and ethnic composition of surveyed population at Park Avenue Medical Group designated by year.

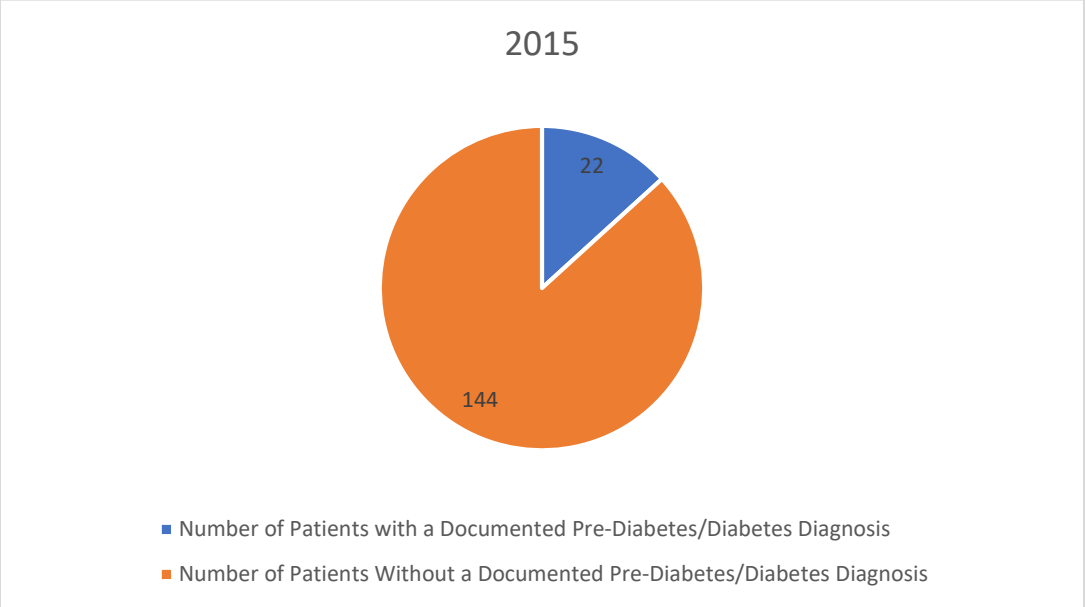

Figure 4. Surveyed patients with a documented pre-diabetes or diabetes diagnosis versus ones without for 2015.

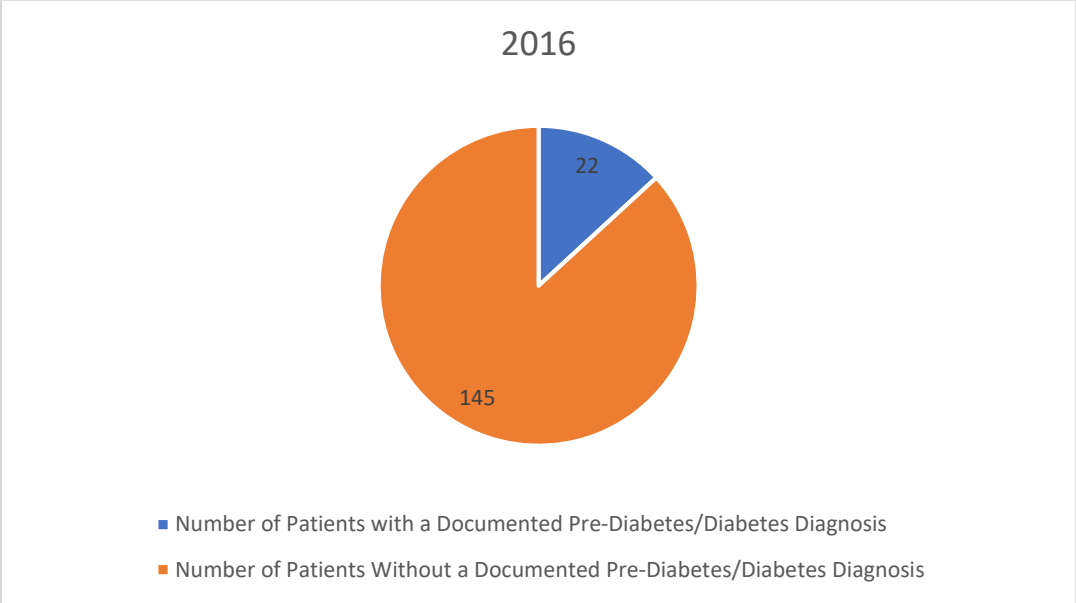

Figure 5. Surveyed patients with a documented pre-diabetes or diabetes diagnosis versus ones without for 2016.

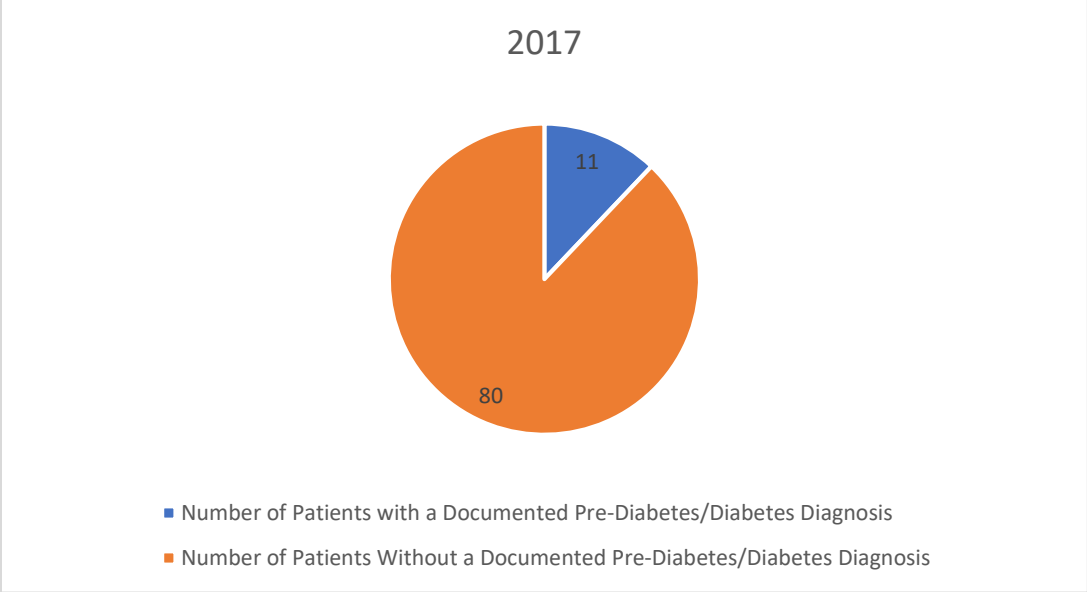

Figure 6. Surveyed patients with a documented pre-diabetes or diabetes diagnosis versus ones without from January 1 through June 30, 2017.

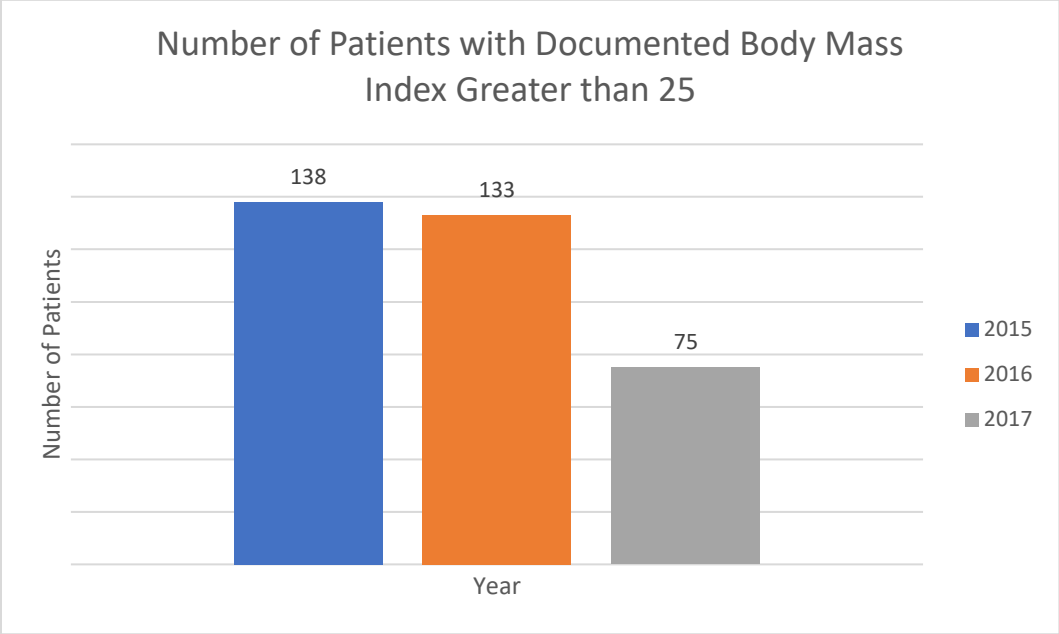

Figure 7. Number of patients seen with a documented body mass index greater than 25.

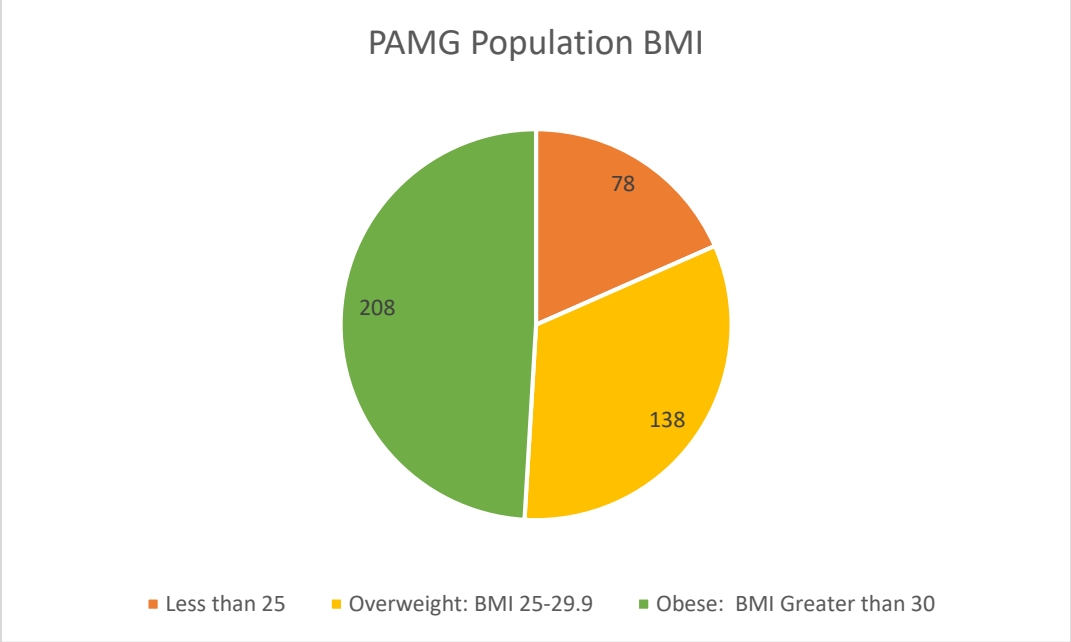

Figure 8. Body mass index of surveyed population at Park Avenue Medical Group.

Risk factors associated with a diabetes diagnosis were evaluated in 55 diabetic patients in the chart review process. Surprisingly, none of the patients with diabetes had a documented history of cardiovascular disease. Conversely, only 3.6% did not have any risk factors. A BMI over 25 was the most significant risk factor in common with 96.4% of the diabetic patient population seen at PAMG, followed by hyperlipidemia (52.7%), hypertension (41.8%), and high-risk ethnicity (30.9%). Of the 55 diabetic patients included in the chart review, over 81% of them had two or more risk factors (see Figures 9 through 14).

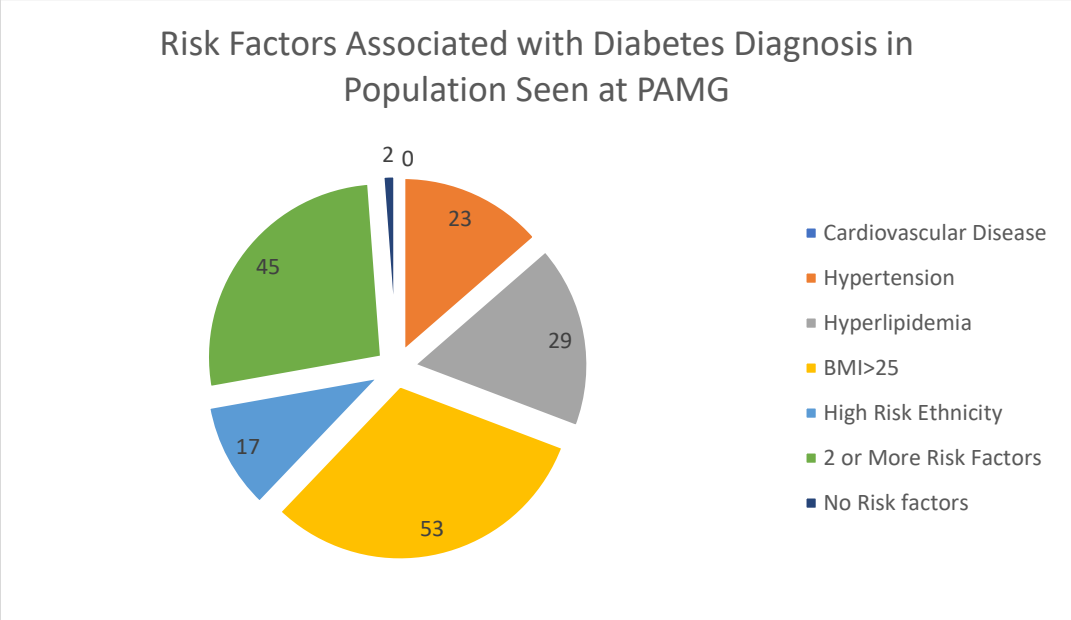

Figure 9. Risk factors associated with a diabetes diagnosis in the population seen at Park Avenue Medical Group.

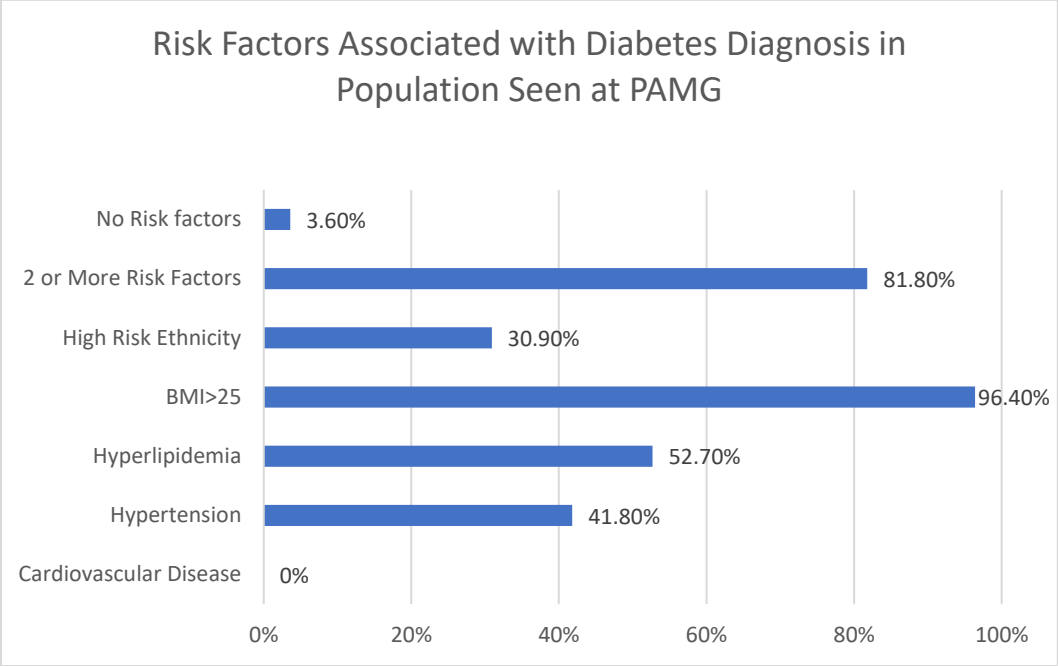

Figure 10. Differentiation of risk factors associated with a diabetes diagnosis in the patient population at Park Avenue Medical Group.

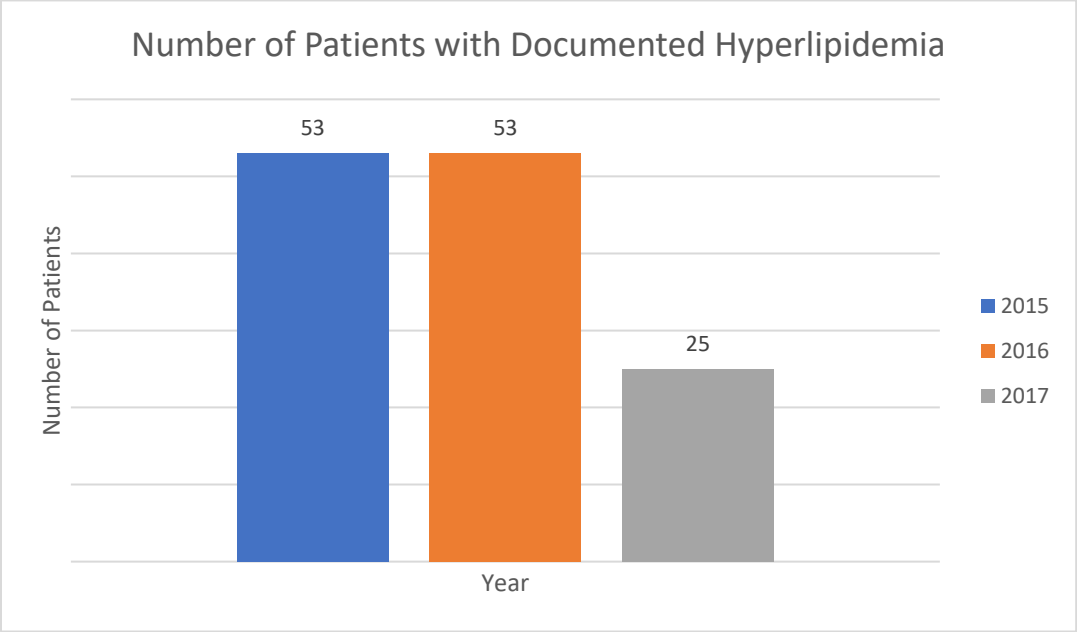

Figure 11. Patient population with documented hyperlipidemia by year.

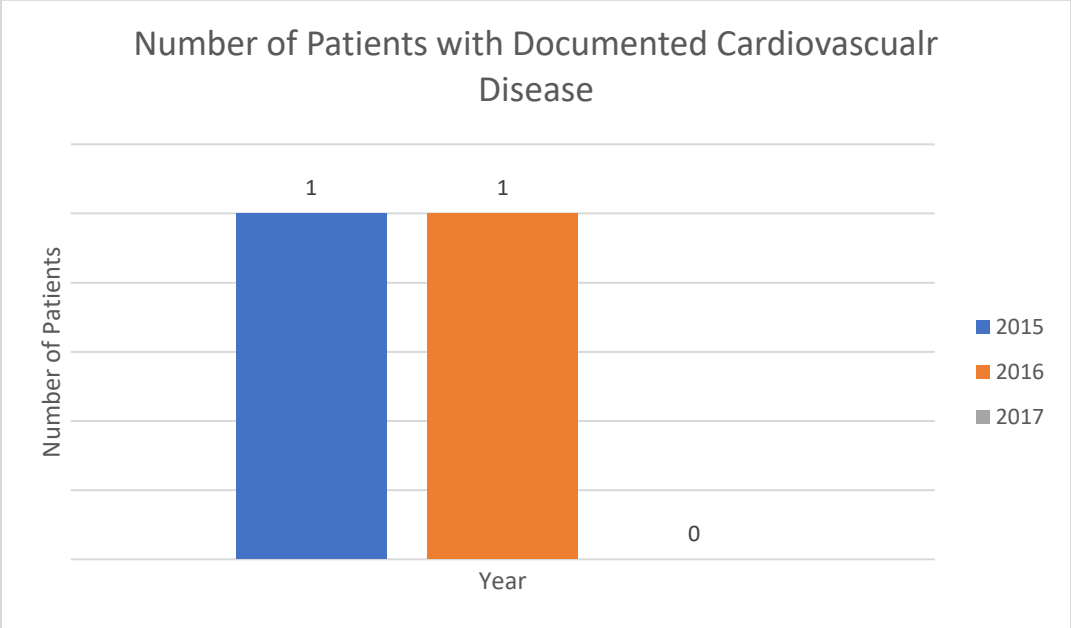

Figure 12. Patient population with documented cardiovascular disease by year.

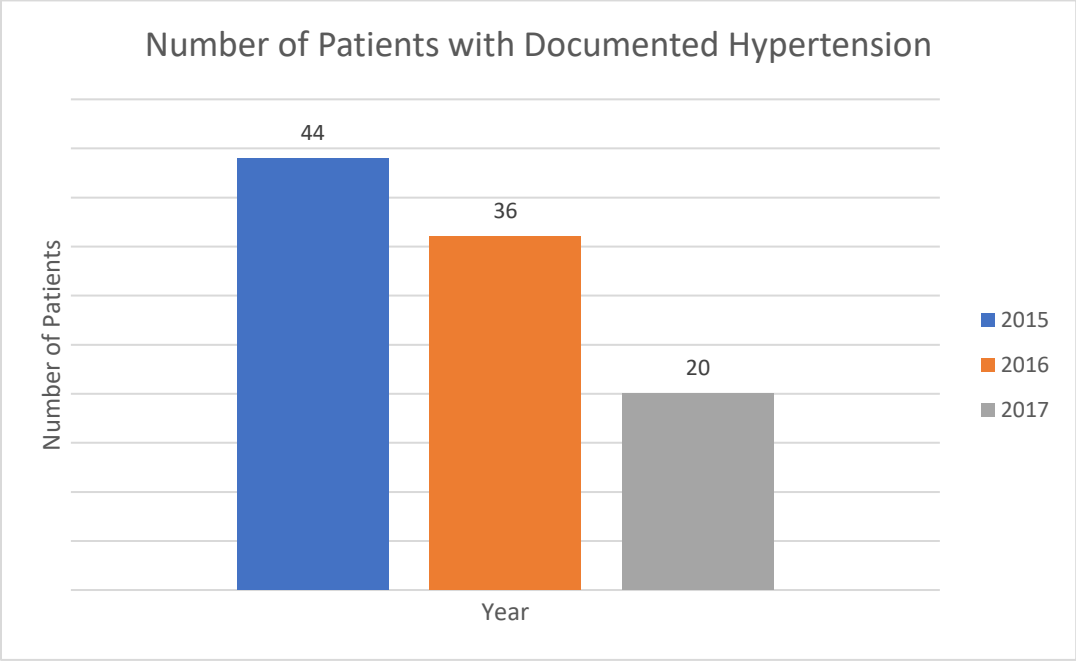

Figure 13. Patient population with documented hypertension by year.

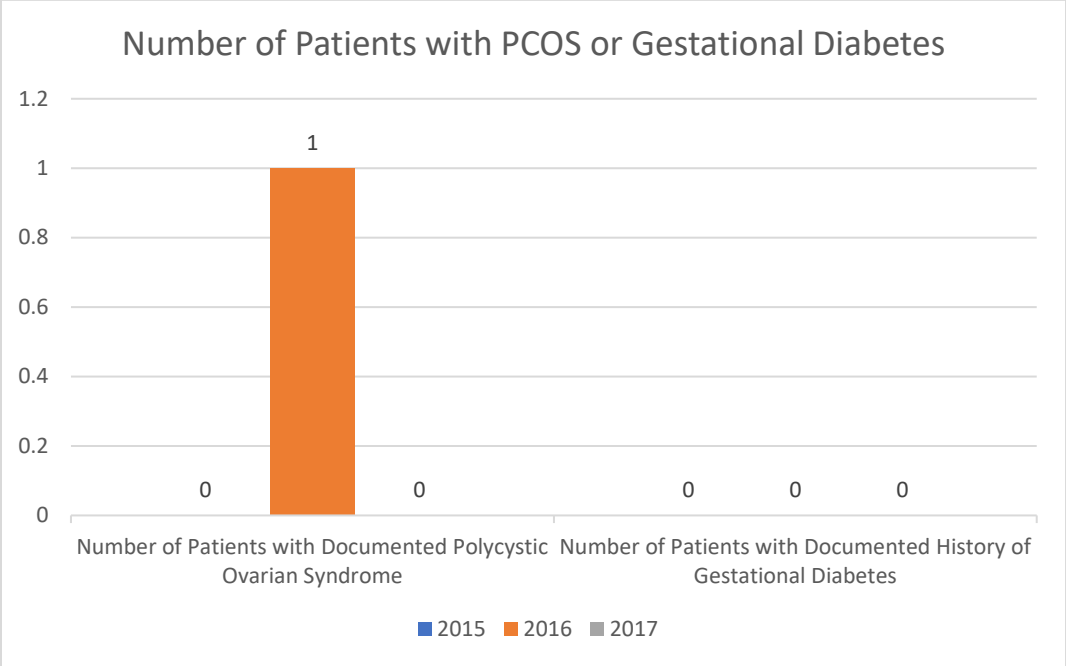

Figure 14. Patient population with polycystic ovarian syndrome or gestational diabetes by year.

To improve sensitivity and specificity in the screening process, the data were analyzed to identify patients without an existing prediabetes, or diabetes diagnosis with and without fasting, or random glucose levels at or greater than 100 mg/dL. In total, 28 non-diabetic patients were identified as having blood sugars equal to or greater than 100 mg/dL and have a hemoglobin A1c level falling in the diabetes or prediabetes range (at or above 5.7). Interestingly, only five individuals were identified in 2015, 10 in 2016, and 13 in the first six months of 2017. These data suggested the providers identified these patients as "at risk" for diabetes and appropriately screened with a hemoglobin A1c. An additional 15 patients were identified in 2017 with A1c levels falling in the diabetes or pre-diabetes range who had a fasting or random glucose level less than 100. These 15 patients were identified when the providers at PAMG began routinely screening with a hemoglobin A1c as part of their annual wellness blood work and would have been missed

using the ADA (2017), WHO (2011b), and USPSTF (2017) screening guidelines. Using Bowen et al.'s 2017 recommendation to screen all patients with a fasting or random blood glucose level equal to or greater than 100 mg/dL would have screened an additional 76 patients who were seen at PAMG for a wellness visit and did not carry a diabetes diagnosis. Of the 76 identified patients, 39 were not screened with an A1c in 2015, 33 were not screened in 2016, and only four were not screened in 2017 after the providers modified their screening practices to routinely include a screening A1c in the adult population, indicating routinely screening with an A1c would capture nearly 10 times more patients with the potential to have an elevated hemoglobin A1c than screening with a fasting blood glucose alone (see Figure 15).

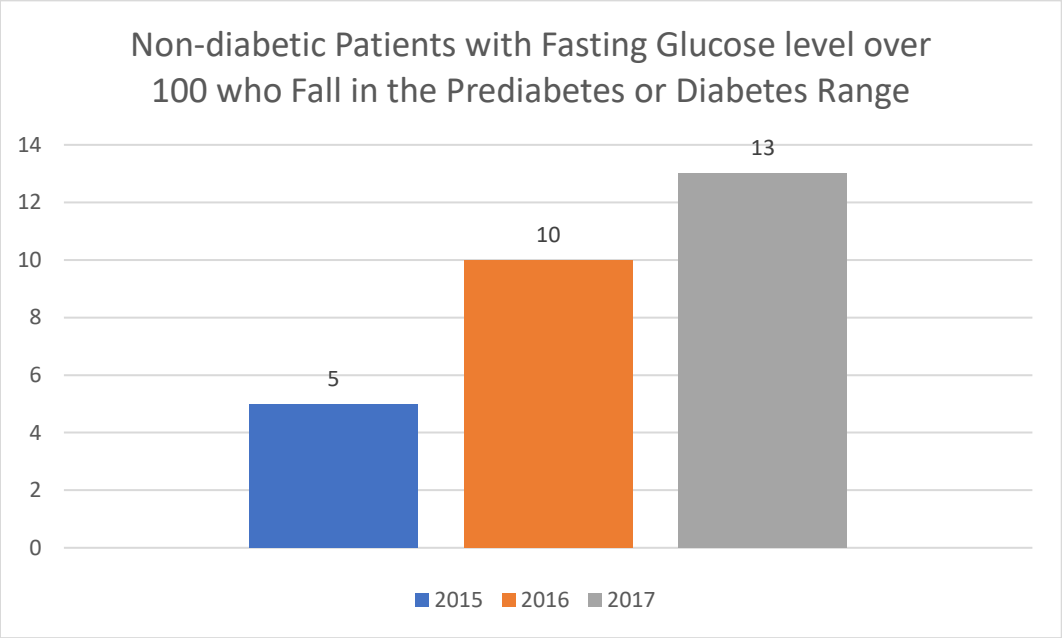

Figure 15. Non-diabetic patients with fasting plasma glucose levels over 100 mg/dL who fall within the pre-diabetes or diabetes range.

Objective One Outcome Statements

This retrospective study was valuable for statistically describing the population seen by the providers at PAMG as well as to stratify the risks associated with diabetes in relationship to non-diabetic, prediabetic, and diabetic populations. While many of the results paralleled the findings in the research offered by the ADA (2017), some of the results in the specific patient population at PAMG were not representative of the literature. For example, the research presented by Bowen et al. (2017) suggested random blood glucose levels over 100 mg/dL were more predictive of undiagnosed DM than traditional risk factors; however, the retrospective study identified only 28 individuals or less than 7% of the selected population with fasting or random blood glucose levels ≥ 100 mg/dL who had an A1c level falling within the diabetes or prediabetes range. Although more closely related, out of the 106 individuals of a high-risk ethnicity, only 17 individuals or 16% carried a diabetes diagnosis compared to 38 individuals or 11.95% of the sampled White population with diabetes, indicating a true increased propensity for individuals from a high-risk ethnicity to develop Type 2 diabetes mellitus.

The data examined in the retrospective study included the entire calendar year of both 2015 and 2016 and only six months of 2017. The results extracted in each of the full years were statistically similar and it was anticipated the results for all of 2017 would also mirror the two previous years. Early in 2017, the providers at PAMG changed their diabetes screening practices to include routinely screening adult patients with a hemoglobin A1c. As previously stated, this change in procedure resulted in the recognition of 15 patients with fasting blood sugars under 100 mg/dL with A1c levels falling within the diabetes or prediabetes range. In the absence of any other additional

risk factors recognized by the ADA (2017), WHO (2011b), and USPSTF (2017), this population of patients would not have been screened utilizing the existing recommendations, thus delaying interventions aimed at minimizing cardiovascular effects and end organ damage caused by diabetes. Although respectively small, this group of patients is representative of the need for changes to the existing recommendations.

The Reach, Efficacy, Implementation and Maintenance Framework

The reach, efficacy, implementation and maintenance (RE-AIM) framework is a method used to analyze the strengths and weaknesses of interventions. It can be used to plan new interventions, change existing interventions or evaluate the impact of interventions (RE-AIM, 2017). The RE-AIM framework evaluates the reach of an intervention or the participation rate within the target population; the efficacy, which is the impact of an intervention on specified criteria; the adoption or percentage of representativeness of organizations adopting the intervention; the implementation, which evaluates the quality and integrity of the intervention in a clinical setting; and maintenance, which evaluates how well the intervention holds up long term (Glasgow, McKay, Piette, & Reynolds, 2001). The practice of routinely screening adult patients with a hemoglobin A1c at PAMG was evaluated using the RE-AIM framework to evaluate the impact of the intervention introduced early in 2017.

Reach. The target population of the screening process initiated in 2017 was all of the adult patients who presented to PAMG for a wellness exam. The providers, a medical doctor and a nurse practitioner, began screening all adults in the clinic for a wellness exam and also began screening patients with symptoms indicative of diabetes. As a result, 15 patients were newly diagnosed with diabetes or prediabetes and were initiated

on antihyperglycemic agents or educated on lifestyle or behavioral modifications to promote risk reduction of diabetes related complications. Additionally, the introduction of routinely screening adults resulted in a nearly10-fold decrease in the number of patients with a glucose level falling in the impaired fasting glucose range who were not previously screened with an A1c.

Efficacy. As previously stated, the impact of initiating the new diabetes screening practice resulted in the identification of patients with diabetes and prediabetes who would not have been screened using the ADA (2017), WHO (2011b), and USPSTF (2017) recommendations unless multiple risk factors were present. Screening all adult patients with an A1c did indeed effectively screen more patients.

Adoption. Both providers at PAMG adopted the new screening practice, creating a 100% adoption rate.

Implementation. The degree to which the providers at PAMG consistently implemented the intervention on the desired population was difficult to determine by examining the data from the retrospective study alone. Given the results of the study, screening more patients with an A1c did capture 15 patients with elevated A1c results falling within the diabetes or prediabetes range in the first six months, suggesting any degree of implementation improved patient outcomes.

Maintenance. Since the introduction of the diabetes screening practice using the hemoglobin A1c is in its infancy, more time is required to determine if the intervention is sustainable over a long period of time. Given the perceived benefit of routinely screening adults with a hemoglobin A1c, it was anticipated the intervention would be sustained at PAMG as long as the literature supported the screening practice.

Evaluation

The use of the hemoglobin A1c as a screening technique on adult patients with complaints suggestive of a diabetes diagnosis and as a routine intervention at wellness visits requires a simple and relatively inexpensive blood test. Since many providers use routine blood testing to screen for a variety of conditions, it is reasonable to adopt the utilization of the A1c as a screening practice without inconveniencing patients for additional testing. The obvious benefits include early interventions to modify behavior and reduce the cardiovascular effects and end organ damage caused by diabetes and elevated glucose levels.

Other Considerations

The data extracted from the chart review supported the need for more aggressive Type 2 diabetes screening and risk management. The strongest data derived from the retrospective chart review supported the use of the hemoglobin A1c as the primary screening intervention for Type 2 DM. The question of insurance reimbursement and coverage of the A1c test as a screening method remains at the forefront of discussions and promotes the underutilization of the A1c for screening purposes. In a publication released by the Centers for Medicare and Medicaid Services (CMS) in 2016 specifically addressing Medicare's coverage of diabetes supplies and services, screening for diabetes was addressed. Medicare's diabetes screening coverage previously allowed screening exclusively with a fasting blood sugar and oral glucose tolerance test. The updated version allows for up to two screening tests per year for Medicare insured individuals and covers "fasting blood sugar tests and other tests approved by Medicare as appropriate" (CMS, 2016, p. 18), dispelling previous language and allowing screening tests beyond a

fasting glucose level and OGTT. Additional resources were explored to verify equal insurance coverage through several other large insurance companies. Kaiser Permanente (2015) also covers fasting blood sugars and hemoglobin A1c tests for screening purposes. Cigna (2016) follows the guidelines recommended by the USPSTF (2017), which includes the use of the A1c for screening purposes; similar coverage was documented for Anthem Blue Cross Blue Shield (Anthem Blue Cross Blue Shield, 2016) and United Healthcare (UHC; 2015), although with more limitations. United Healthcare's coverage of the hemoglobin A1c as a preventative screening test is only covered if the individual has a history of hypertension with a sustained blood pressure of 135/80.

Objective Two

The second plan objective included a survey of a panel of experts using the Delphi method to gather information on the utility of a clinical practice guideline. The expert panel for round one included two physicians, two nurse practitioners, one of which was a doctor of nursing practice, and a physician's assistant--all working in family practices. They were queried about their current screening methods, familiarity of the ADA (2017), WHO (2011b), and USPSTF (2017) guidelines and about their suggestions to improve diabetes screening practices.

Participants

The first round Delphi questionnaire was administered to the providers through SurveyMonkey, an internet survey platform that collects and analyzes data from the questionnaire and allows the participants' responses to remain anonymous. The survey consisting of 18 multiple choice, multiple selection, and short answer questions was sent to the participants' email addresses directly from SurveyMonkey. In total, six providers;

two physicians (MD), three nurse practitioners (APRNs and DNP), and one physician's assistant (PA) were invited to participate (see Table 4). The data were not available for review until the survey closed. Responses were received from 83.3% of the participants (5/6) and all five responding participants answered all 18 questions. The questionnaire was open and available for responses for 30 days--opening August 28 and closing September 28.

Table 4

Delphi Questionnaire Round One Participant Demographics

Participant	Title/Role	Type of Practice	Area Served
#1	MD	Family Medicine	Rural Northern Colorado
#2	APRN, DNP	Family Medicine	Rural Eastern Colorado
#3	PA	Family Medicine	Rural Eastern Colorado
#4	MD	Family Medicine	Rural Northern Colorado
#5	APRN	Family Medicine	Rural Northern Colorado

Results

Results of the first round of the Delphi questionnaire indicated 100% of the providers considered impaired fasting glucose levels, relatives with diabetes, and history of gestational diabetes when screening for DM. Eighty percent felt BMI was an important consideration and 40% of the surveyed participants felt impaired random glucose levels, age, and ethnicity were also important considerations. One hundred percent of the participants' organizations did not use a clinical guideline to screen for

diabetes and one participant reported personally using the CDC's (2016) clinical practice guideline. Sixty percent of the respondents were familiar with each of the ADA (2017), WHO (2011b), and USPSTF (2017) recommendations for diabetes screening. The participants were advised to consider the ADA, WHO and USPSTF recommendations, and to discuss which recommendations they preferred and rationale behind their choice (see Table 5). The responses were varied and included responses such as "results of the hemoglobin A1c" and "prefer one or more." Participants were queried about their personal preferences for diabetes screening. Eighty percent preferred the hemoglobin A1c and 20% preferred fasting glucose levels. None of the respondents preferred random glucose levels or the oral glucose tolerance test. The participants were surveyed with a question asking if they felt the patient population at their organization was adequately screened for diabetes. Four of the five responded favorable, stating they were adequately screened and one participant responded with "no- some at risk patients refuse screening labs; cost may be a factor."

Table 5

American Diabetes Association, World Health Organization and United States Preventative Services Task Force Recommendations: Provider Preference

Participant	Recommendation Preference (ADA, WHO or USPSTF)	Reasoning
#1	Prefer more than one	ADA. More Parameters
#2	ADA	ADA seems to be most used by endocrinology & is an easy one to reference
#3	ADA, WHO	Legitimate
#4	USPSTF	USPSTF-comprehensive review of studies evaluating benefits/harms of screening
#5	Results of hemoglobin A1c	A1C, seems to be the most reliable

The participants were additionally questioned about the utility of a clinical guideline and if screening/diagnosis would improve if a practice guideline was available for use. Four of the five participants responded with "yes" and one responded with "no- I already screen A1c for physicals and patients at risk." The provider participants were surveyed about the factors they felt were important to include in a clinical practice guideline and if there were a perfect guideline, what components would be included. The participants' responses included the following:

- Fasting glucose level
- A1c
- Symptoms
- Past medical history
- Family history

- Age
- BMI
- Lab test results
- Genetic, familial, environmental indications for screening
- Presence of cardiovascular disease
- History of gestational diabetes
- History of elevated lipids
- All risks

The final question in the survey requested their recommendations on the format of the clinical guideline. Eighty percent (4/5) preferred a written guideline with an algorithm and 20% or one participant preferred a written guideline.

Objective Two Outcome Statements

The results of the round one Delphi survey indicated a clear need and desire for a single clinical practice guideline to assist providers with diabetes screening. The screening methods preferred by the providers as well as consideration of risk factors and preferred guideline components were consistent enough to justify the creation of a clinical practice guideline. Given the similarity in the participants' responses, the creation of a clinical guideline simplistic enough to be used by all family practice disciplines, containing the elements surveyed as important to the providers, and remaining consistent with the research and current guidelines should pose no difficulty to implement.

Objective Three

Objective three included the creation of the clinical guideline utilizing the current literature, data collected from the retrospective study, and the expert opinions of the participants in the first round of Delphi questionnaires. The feedback from the providers who participated in the Delphi survey played an essential role in the construction of the clinical guideline. Expert opinion was necessary to ensure the clinical guideline was user friendly and contained components important to the providers who will utilize the clinical guideline. The second part of objective three included a second round Delphi questionnaire designed to query the same group of participants about the usefulness of the clinical guideline and ensure the components they felt were important were included in the algorithm and written guideline. Because the majority of queried providers preferred the elements included in the ADA's (2017) recommendations, the ADA recommendations provided the foundation for the development of the clinical guideline.

Elements of Guideline

In addition to ensuring the clinical guideline for this capstone project included the research from the literature review, data from the retrospective chart review and expert opinion garnered from the first round of Delphi questionnaire, insurance coverage for diabetes screening was also considered. As previously addressed, most of the larger insurance companies and Medicare cover diabetes screening as part of a wellness or preventative visit. The clinical practice guideline was comprised of a suggested algorithm, overview, and procedure including recommendations dependent on the results of a fasting glucose level, A1c, or both.

Procedure Highlights

To ensure adequate insurance coverage for the patient and provider reimbursement, the ICD-10 code Z00.00 (encounter for general medical examination without abnormal findings) or code Z00.01 (encounter for general medical examination with abnormal findings) should be used (NuMed ICD-10 Lookup, n.d.). Screening labs including a fasting blood glucose level should be drawn prior to exam or during the wellness visit. A lipid panel could also be drawn to further stratify the patient's risk for developing Type 2 diabetes beginning at age 35 in men and 45 in women (Siu, 2015). Adults over the age of 40 can have a screening A1c drawn, per the USPSTF recommendations (Siu, 2015), which are followed by Anthem Blue Cross Blue Shield (2016), Cigna (2016) and United Healthcare (2015) with an additional hypertension diagnosis using ICD-10 code Z13.1 (diabetes screening; NuMed ICD-10 Lookup, n.d.).

Adults between the ages of 18 and 44 who have an impaired or abnormal fasting blood glucose level and have one additional risk factor should also be screened with a hemoglobin A1c using ICD-10 code R73.09 for abnormal FPG or ICD-10 code R73.01 for impaired FPG (NuMed ICD-10 Lookup, n.d.). An informal risk assessment should be used in adults ages 18-44 to assist with risk stratification and appropriate use of the hemoglobin A1c as a screening and diagnostic tool in the diagnosis of Type 2 diabetes (WHO, 2011a). Individuals in this age group with an impaired fasting glucose level and one of the following additional risk factor should be routinely screened with an A1c:

- Impaired Fasting Glucose (100-125 mg/dL)
- Impaired Random Glucose (126-199 mg/dL)
- BMI $\geq$ 25

- Age ≥ 45
- Native American, Black, Hispanic or Asian Ethnicity
- Hypertension, hyperlipidemia, or cardiovascular disease
- Relative with diabetes
- Personal history of polycystic ovarian syndrome (PCOS) or gestational diabetes
- Physical inactivity.

Patients with an impaired fasting glucose level should be screened with an A1c if they are over the age of 45 or at or under the age of 44 and have one additional risk factor. For individuals with an impaired fasting glucose level and no other additional risk factors, age appropriate recommendations and annual fasting glucose levels should be followed. Adults ages 18-44 with an impaired fasting glucose level and normal A1c should be screened annually with a fasting blood glucose if no other risk factors are present and they have not previously had an impaired fasting glucose level and an A1c every three years. Individuals with at least one additional risk factor regardless of age should have an A1c repeated every three to six months until it becomes abnormal or repeated glucose levels fall within the normal range. Individuals with an elevated hemoglobin A1c should be diagnosed with prediabetes or diabetes, managed appropriately, and retested with an A1c in three to six months. Adults over the age of 45 with normal fasting glucose and A1c levels should have annual fasting blood work including a lipid panel. Hemoglobin A1c testing should be repeated every three years. The clinical guideline also contains a statement suggesting patients with hemoglobinopathies be screened with a two-hour glucose tolerance test instead of the

A1c. The algorithm offers two clinical pathways depending on age and covers all major elements addressed in the written clinical guideline on a single page for convenience and accessibility.

Results of the Round Two Delphi Questionnaire

Round two of the Delphi questionnaire asked the participants to study and evaluate the quality of the proposed Diabetes Screening in Adults Clinical Practice Guideline and Algorithm. The second Delphi questionnaire was administered to the same panel of expert providers as the first-round questionnaire excluding the one participant who did not respond to the invitation for the first survey. The participants were given two weeks to complete the second survey and were queried about the utility and comprehensiveness of the proposed clinical guideline. The participants were asked eight "*yes"* or "*no*" questions with the goal to obtain at least 70% consensus on the comprehensiveness and practical use of the proposed guideline and algorithm. Participants were also encouraged to comment on each of the eight questions and to offer their opinions about insurance coverage and reimbursement if the clinical practice guideline was used.

Five of the original participants were invited to complete the second round of surveys and four of the five finished the questionnaire (80%). The results were unanimously in favor of the quality and comprehensiveness of the clinical guideline with one question providing the only exception: "Looking at the written clinical guideline only, do you feel it is easy to follow?"; 75% of the participants responded "yes" (3/4) and one participant answered "no" with the following statement: "Algorithms are always easier to follow." Included in the second round of questionnaires were questions about

insurance coverage and reimbursement. All of the provider experts felt the clinical practice guideline was supportive enough to ensure coverage through the largest insurance providers. A table was included on both the algorithm and written guideline listing the aforementioned specific diabetes risk factors to consider for the informal assessment process. Again, all provider participants felt the table was helpful. Question 7 on the survey asked the participants,

> The written guideline offers a statement about the use of the hemoglobin A1c in patients with sickle cell disease and other hemoglobinopathies (pregnancy, hemodialysis, recent transfusion or erythropoietin therapy). Were you aware the 2-hour glucose tolerance test is the preferred screening method in this population?

Surprisingly, all of the providers answered "no" to this question, indicating a strong need for additional education on hemoglobinopathies and use of the A1c.

Objective Three Outcome Statements

The creation of the Diabetes Screening in Adults Clinical Practice Guideline and Algorithm proved to be a challenging and worthwhile undertaking. The results of the second Delphi survey indicated the guideline and algorithm contained the elements important to the providers, the recommendations of the ADA (2017), and data supported by the literature review and retrospective study conducted for this project. Participant provider experts in the Delphi study felt the guideline and algorithm were easy to use and comprehensive, supporting the objective in the guideline development process.

Objective Four

The plan for implementation was the fourth objective for this DNP capstone project. Physical implementation was not a defined goal of this objective; however, objective four included providing the staff at PAMG with the final clinical practice

guideline for utilization. No formal training was provided as the guideline is comprehensive and the results of the Delphi survey did not indicate a need for additional training. The providers were sent the guideline with instructions to contact this researcher with any questions. If the providers at PAMG decide to implement the diabetes screening clinical practice guideline, a second retrospective study is recommended to evaluate pre- and post-implementation results and edit as clinically necessary or as new evidence dictates.

Facilitators and Barriers to Project Objectives

Key Facilitators

A key advantage to the completion of this capstone project was the ability to use the EMR system at PAMG. The comprehensive retrospective study portion of this project would not have been possible without the use of the EMR. The EMR allowed the researcher to search for individuals who visited the clinic during a specific period of time for a wellness visit. Additionally, the utilization of the EMR promoted the ability to examine past medical history and co-morbidities, all which were invaluable in the risk stratification of the patient population at PAMG. A second key facilitator to this project was the change made internally to the screening processes in 2017 at PAMG. The practice of routinely screening adult patients seen for a wellness visit or had multiple risk factors allowed the researcher to contrast the difference screening with a hemoglobin A1c made in the same patient population from 2016 when the providers were not routinely screening with an A1c to 2017. A third key facilitator was the support and participation from the providers who completed rounds one and two of the Delphi questionnaire. The responses from the provider participants helped focus the development of the clinical

practice guideline into an evidence-based, simplistic, and user-friendly tool for diabetes screening in family practice.

Using the Delphi method to query provider participants through SurveyMonkey was beneficial in facilitating the completion of project objectives. The responses remained anonymous; thus, the integrity of the questionnaire results was not questioned. Providing anonymity for the participants might have played a role in the willingness of providers to participate. Over 80% of the providers invited to participate completed the surveys. The SurveyMonkey website application analyzed the results from the Delphi surveys, taking away some of the data analysis process that was cumbersome. The risk of data analysis errors was also eliminated with the use of SurveyMonkey's services.

Key Barriers

Time was the most prominent barrier to the completion of this capstone project. Objective four included the actual implementation of the guideline, which was not completed for this project due to time constraints. Following the implementation from infancy to one-year post-initiation would have allowed the researcher to perform a post-implementation study to observe the effects of the guideline on the practice, providers, and patient population. Improvements would have been made to the guideline to ensure it continues to be valuable in evidence-based diabetes screening practices. A second barrier to the objectives, although also beneficial, was the change to the diabetes screening practices within PAMG to include screening with a hemoglobin A1c in 2017. Because a large portion of the proposed clinical practice guideline included screening with an A1c at various intervals, the effectiveness of the utilization of the guideline on the providers and patient population could be questioned. Park Avenue Medical Group is

also a small practice in a rural area with only two providers. The effects of diabetes screening with the implementation of the guideline created for this project might be improved if piloted with a larger family practice.

Unintended Consequences

No notable unintended consequences were observed as a result of the completion of the DNP project objectives; however, the seventh question in round two of the Delphi questionnaire indicated more provider education is necessary on specific hemoglobinopathies and the use of the A1c, not only for screening purposes but also for diabetes management. None of the four participants were aware the hemoglobin A1c should not be used on certain populations with accuracy; the two-hour OGT test is the preferred method for diabetes screening and management in this small patient population.

CHAPTER V

RECOMMENDATIONS AND IMPLICATIONS FOR PRACTICE

Information garnered from the review of literature described the lack of congruency in diabetes screening practices nationwide. The recommendations made by the ADA (2017), WHO (2011b), and USPSTF (2017) are all remarkably similar and evidence-based, yet rarely used. While there is no clear answer as to why family practice providers are not following the diabetes screening recommendations made by one or all three organizations, the results of this project's Delphi questionnaire indicated a strong desire to have a single clinical practice guideline to follow within their organizations. Phase four of this project using the Stetler (2001) model was to physically implement the clinical guideline. The following recommendations are provided in lieu of the physical implementation as it was not part of this capstone project.

Recommendations

Results of the literature review, retrospective study, and Delphi surveys supported the need for a practical tool for diabetes screening in family practice; therefore, it is the researcher's recommendation to move forward with the project. The clinical practice guideline was provided to the providers at PAMG to support their current screening practices. The timeframe to implement the guideline if desired at PAMG will be left to the providers' discretion. The diabetes screening guideline was created to be

comprehensive enough to include the recommendations of the ADA (2017), WHO (2011b), and USPSTF (2017), the literature review, and include the preferences of the providers obtained through the results of the Delphi surveys. Very little training is required to follow the guideline; however, it is the researcher's recommendation that new providers and students be trained on its application to ensure proper use, insurance coverage, and reimbursement. Periodic review of the ADA, WHO, and USPSTF recommendations are recommended to ensure the clinical practice guideline is congruent with the latest evidence-based research. If no changes are made to the guideline, the researcher recommends an informal retrospective study to ensure this high-risk population is adequately screened for diabetes and changes are made appropriately. Consistent adherence to the guideline and algorithm will be necessary to adequately assess the usefulness of the clinical practice guideline.

As education continues to move toward evidence-based models of study, the researcher recommends disseminating the clinical practice guideline to other primary care providers, students, and educational institutions if the information contained in the practice guideline remains current. Because it is evidence-based and comprehensive enough to include recommendations from the ADA (2017), WHO (2011b), and USPSTF (2017), it could be used as a practical tool for understanding current standards of practice. It is the desire of the researcher for the community of family practice providers to screen and treat diabetes aggressively to decrease the complications and comorbidities of a diabetes diagnosis. While the cardiovascular and end organ damaged caused by DM is irreversible, Type 2 diabetes is one of the few chronic diseases that is reversible. Early screening and appropriately diagnosing patients with prediabetes allow for initiation of

lifestyle modifications and behavioral therapy before irreversible physiological damage ensues. Medicare now covers diabetes self-management training for newly diagnosed diabetics, diabetics with other risk factors, or poorly managed diabetics. The coverage allows up to 10 hours of initial training and two additional hours annually if indicated and teaches patients how to successfully manage their diabetes. Diabetes self-management training must be prescribed by a provider and can be completed at many federally qualified health centers (CMS, 2016). Finally, intensive diabetes education is recommended for patients at risk for developing diabetes as well as newly diagnosed prediabetics and diabetics. Educating patients is empowering; with empowerment, providers can help control the information their patients receive, ensure it is accurate, and limit the amount of bad information received from other sources. This could effectively place patients in control of their health and lifestyle choices.

Ongoing Evaluations Necessary for Phases Outside the Scope of the Doctor of Nursing Practice Project

Phase five of the Stetler (2001) model addresses the evaluation of the intervention. The evaluation process does not need to be completed formally and should include a cost-benefits analysis (Stetler, 2001). Since this capstone project does not cover implementation or evaluation, it would be of value for the staff at PAMG to consider re-evaluating the effectiveness of the diabetes screening guideline after an informal pilot study. Costs associated with additional blood work, insurance reimbursement for the facility, and additional out-of-pocket costs absorbed by the patients should be examined during the evaluation process. Strict adherence to the guideline is recommended to accurately evaluate the effectiveness of the guideline intervention.

Personal Goals and Contributions to Advanced Practice Nursing

Improving the practice of screening for diabetes in primary care was the principal goal of this project. It was the researcher's vision to uncover something uniquely brilliant in the retrospective study that could facilitate more research in diabetes diagnostic and screening practices performed in the primary care setting. While that did not occur, the creation of a comprehensive clinical practice guideline that included existing research and components of the research completed during this project could be used to improve screening practices. Proper utilization of the clinical practice guideline would capture and screen all patients at a high risk for developing Type 2 diabetes. The specific population for which this guideline would be most beneficial is individuals who do not have wildly abnormal fasting glucose levels (100-105mg/dL) and a single diabetes risk factor. This population would be screened with an A1c using criteria outlined in the guideline created for this DNP capstone project and would have likely been missed using traditional screening methods, thus delaying treatment. As mentioned previously, prediabetes carries the same cardiovascular risk as diabetes and microvascular changes might occur consequentially to unintentional delays in treatment. In an article by Ghody, Shikha, Karam and Bahtiyar (2015), it was suggested even mildly elevated blood glucose levels could cause microvascular complications like retinopathy, neuropathy, and nephropathy (Ghody et al., 2015). Engaging at-risk individuals in treatment options including lifestyle changes, behavioral modifications, and in some instances pharmaceutical interventions would minimize cardiovascular changes associated with diabetes.

In recent years, there has been a push for higher degrees of education, especially in health care. The Doctor of Nursing Practice was created to address challenges within health care and translate knowledge into practice, more specifically evidence-based practice. The knowledge garnered from DNP programs allows advanced practice nurses to thrive in leadership roles that improve nursing practice and patient outcomes. The American Association of Colleges of Nursing (AACN; 2006) released a publication addressing the essentials of a doctoral education for advanced practice nurses. Within the AACN's document is the delineation between research-focused doctoral degrees and practice-focused. While both doctoral degrees are rigorous and arduous terminal degrees, the practice-focused degrees rely less on theory and more on practical experiences. The DNP capstone project is an integrative, immersion experience that challenges DNP candidates to translate knowledge into practice (AACN, 2006).

The AACN (2006) document includes the following eight competencies that must be present for attainment of the Doctor of Nursing Practice degree in addition to specialty competencies advanced practices nurses must complete:

- Essential I: Scientific Underpinnings of Practice. The scientific underpinnings of DNP education reflect doctoral level complexities foundational in nursing including a holistic approach to life processes, patterns of human interaction with normal life events and the environment, and nursing processes that create positive changes (AACN, 2006). Within this essential, doctoral-prepared nurses learn to develop and evaluate new approaches to practice. Creation of a clinical guideline demonstrated this competency.

- Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking. According to the AACN (2006), a DNP graduate who possesses this essential is not only focused on improving health outcomes but also understands principles of practice management, assesses policies and procedures, and addresses improvement strategies that are cost effective and sustainable. Competency was demonstrated within this essential by the ability of this DNP candidate to assess risks and manage through collaboration with others using principles of economics, business, and healthcare policy. The final tenet of this competency is accountability. The DNP candidate is not only accountable for managing ethical dilemmas but also ensures the quality of healthcare delivery (AACN, 2006). Although not always evident, these principles were applied throughout the production of the project.
- Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice. This competency is arguably the most important concept of a DNP education. Bridging the gap between knowledge and practice is the fundamental tenet of this competency. A DNP graduate must be able to investigate and synthesize data, isolate facts, and make connections that hold validity across disciplines (AACN, 2006). Problem solving is achieved through application of knowledge and shared through dissemination of such knowledge through projects such as this capstone research project.
- Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care. Information

systems education and the use of technology to improve healthcare is instrumental to DNP education. The application of information systems and technology spans outside the realm of academia and into patient care for evaluating quality and safety standards, programs of care, and outcomes of care. This technology is used to perform cost benefits analyses, allow tools for budgeting, and evaluate consumer health information (AACN, 2006). Application of this essential was demonstrated through the use of internet-based research and EMR utilization.

- Essential V: Health Care Policy for Advocacy in Health Care. Healthcare policy on a broad scale would cover changes in legislation or through other government actions; while it is necessary for DNPs to be on the forefront of legislative policy changes, the actions of a DNP educated nurse could also be witnessed on a smaller scale within organizations. A DNP graduate is often called upon to facilitate changes in healthcare financing, access, safety, efficacy, and quality by advocating for policy changes impacting social justice and equity in health care. Demonstrating leadership and strength in knowledge of healthcare policy allows the DNP graduate to influence and implement change at the institutional, local, state, and national and international levels (AACN, 2006).
- Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes. The Agency for Healthcare Research and Quality (2016) recently mandated six domains of healthcare quality, which require a multidisciplinary approach to providing safe, effective, patient-

centered, timely, efficient, and equitable care. Doctor of Nursing Practice graduates possess a unique set of skills that allow them to effectively participate in a collaborative interdisciplinary team and lead when appropriate. Effective communication and collaborative skills allow the DNP graduate to lead changes in the delivery of healthcare congruent with the AACN's (2006) goals to improve patient outcomes.

- Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health. Population health, health promotion, and disease prevention are required coursework for the DNP graduate. These classes place emphasis on promoting health through lifestyle choices and healthcare decisions, risk reduction and illness prevention, and improving the health of the community. Many of these skills are taught through evidence-based recommendations, social determinants of health, and cultural sensitivity. Doctor of Nursing Practice graduates use their knowledge to evaluate care delivery models influenced by the community, occupational and environmental conditions, as well as socioeconomic and cultural dimensions of health to influence changes geared to improve the health of the population (AACN, 2006).
- Essential VIII: Advanced Nursing Practice. The AACN's (2006) publication acknowledged the complexity of specialization in advanced practice nursing. Doctor of Nursing Practice prepared graduates are all specialists in one or several areas, making their contribution to nursing the hallmark of the Doctor of Nursing Practice. Experiential opportunities

gained from each nursing specialty allows the advanced practice nurse to assess health and illness parameters in complex situations using a holistic approach, implement therapeutic interventions based on nursing sciences, create and maintain relationships with patients and other disciplines, and guide and mentor other nurses to uphold excellence in care delivery (AACN, 2006). Evidence-based care delivery models are fundamental to nursing practice and are encouraged throughout all levels of nursing education.

Summary

As diabetes continues to grow at epidemic proportions, evidence-based diagnostic and screening interventions are necessary to prevent the concurrent physiological damage caused by a diabetes diagnosis. Early screening and detection could help minimize the negative effects of the disease by encouraging early treatment interventions. The coherence of recommendations made by the ADA (2017), WHO (2011b), and USPSTF (2017) supported the need for more comprehensive screening in the at-risk population. Development of a simple, yet comprehensive clinical practice guideline for this DNP capstone research project was created to facilitate early detection of diabetes or prediabetes to foster interventions aimed at preventing end organ damage and the cardiovascular consequences caused by diabetes. Proper guideline utilization would help identify individual risk factors and stimulate diabetes screening to promote early lifestyle, behavioral, and pharmacological interventions.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	August 18, 2017
TO:	Vera Pillitteri, BSN, RN, DNP-S
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[1104482-1] Screening for Diabetes in At-Risk Populations in Primary Care
SUBMISSION TYPE:	New Project
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	August 18, 2017
EXPIRATION DATE:	August 17, 2021

Thank you for your submission of New Project materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

Vera -

Thank you for a thorough and clear IRB application for your Doctoral capstone project. There are no requests for any modifications or additional materials. Your protocols and documents are verified/approved exempt and you may begin this study.

Best wishes with your research.

Sincerely,

Dr. Megan Stellino, UNC IRB Co-Chair

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX B

STATEMENT OF MUTUAL AGREEMENT

Statement of Mutual Agreement
University of Northern Colorado
Doctorate of Nursing Practice Capstone Project

Vera L. Pillitteri, BSN, RN, DNP-S
August 3, 2017

The purpose of the "Statement of Mutual Agreement" is to describe the shared view between Park Avenue Medical Group and Vera L. Pillitteri, DNP Candidate from University of Northern Colorado, concerning her proposed capstone project.

Proposed Project Title:
Screening for Diabetes in At-Risk Populations in Primary Care

Brief Description of Proposed Project:
In an effort to improve consistency in screening practices for diabetes in primary care, this capstone project will develop an evidence-based clinical practice guideline for diabetes screening in adult patients presenting at Park Avenue Medical Group for annual wellness visits. The Delphi Method will be utilized to survey providers on current screening practices, high risk populations, guideline utilization and risk factors associated with a diabetes or pre-diabetes diagnosis. The survey information will be compiled along with the most current literature and demographic information from a retrospective chart review to develop a clinical practice guideline. The Stetler Model will be utilized to translate the research into practice.

Goal of Capstone Project:
The objectives for this capstone project include the creation of an evidence-based clinical practice guideline to assist providers at Park Avenue Medical Group with appropriately and consistently screening at-risk adult patients for diabetes to promote early interventions designed to prevent or delay the onset of diabetes related complications, comorbidities and mortality.

Proposed On-site Activities:
The on-site activities for this capstone project include the conduction of a retrospective study evaluating adult patients who were seen in the clinic for annual wellness visits between January of 2015 through June of 2017. A minimum of two Delphi questionnaires will be administered to qualified providers to assist with the creation of a simplistic clinical practice guideline designed specifically for the providers at Park Avenue Medical Group.

Confidentiality of Patient Records:
The retrospective portion of this capstone project will be performed by reviewing patient charts. No specific patient identification information will be collected. The information collected will be related to demographic characteristics such as gender, age and specific diabetes related risk factors such as weight, race/ethnicity and blood pressure and specific lab results. The purpose of this project is to foster a better understanding of diabetes screening practices. The information gathered from the study will provide enhanced knowledge about risk factors associated with a diabetes diagnosis and the benefits and implications of implementation of a diabetes screening practice guideline.

Regarding the utilization of the Delphi questionnaire, all responses will be kept anonymous. The DNP candidate and capstone chair/research advisor only will have access to the completed questionnaires to protect the respondents' opinions and confidentiality.

The designated Capstone Community/Agency member will agree to participate in the review and approval of the proposal and presentation of the final version of the project. He/she will attend (on campus or remotely) the meetings for both.

The DNP Capstone project will include a final report, an abstract, potential publication or oral presentation of the report. No personal identifiers will be included and all data will be reported in aggregate form. The author welcomes any comments or suggestions from the Agency, but reserves the right to publish findings and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the Author agrees to follow the Agency preferences in how it is to be named (or not) in the work.

Signature of DNP Student Date 8/8/17

Signature of Agency Member Date 8/8/17

Signature of DNP Capstone Chair Date Aug 14, 2017

APPENDIX C

ROUND ONE DELPHI SURVEY AND CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH

Phase One: Delphi Study, Round One Questionnaire

The following questionnaire will take approximately 10 – 15 minutes to fill out.
If you think that a colleague would be interested in filling out this questionnaire, please feel free forward to them the introductory email about this study.

1. What is your current title or role? (You may indicate more than one if applicable)
MD_____ DO _____ APRN _____ PA_____

2. In what kind of practice do you primarily work?
Family Medicine _____
Internal Medicine _____

3. What ages of patients do you *primarily* see? (You may indicate more than one)
Children (Birth to 12) _____ Adolescents (13-18) _____ Adults (19-39) _____
Adults (40-64) _____ Older Adults (>65) _____

4. What area do you primarily serve?
Denver Metro _____
Rural Northern Colorado _____
Rural Eastern Colorado _____
Other _____ Please Name _____
_____

5. Which risk factors do you consider when screening for diabetes?
Impaired fasting blood sugar _____ Impaired random blood sugar _____ Age _____
BMI _____ Gender _____ Ethnicity _____ Blood pressure _____
Relative with diabetes _____ History of gestational diabetes _____ Physical inactivity _____
History of polycystic ovarian syndrome _____ History of cardiovascular disease _____
Other _____ (please list) _____
6. Do providers at your location utilize any clinical guidelines pertaining to the screening/diagnosis of diabetes?
Yes _____ No _____
If yes, what do you think are the key components of the clinical guidelines most often used?
_____
_____
_____
_____
7. Do you follow any specific clinical practice guideline pertaining to the screening/diagnosis of diabetes?
No _____
Yes _____ If so, which do you use (please name) _____

8. Are you familiar with any of the following diabetes screening recommendations?
American Diabetes Association (Updated 1/2017)? _____
World Health Organization (Updated 2016)? _____
United States Preventative Services Task Force (Updated 12/2015)? _____
Note the information attached for each. Would you prefer to follow 1 or more of these, if so which one(s):
_____
_____
_____
If you prefer to follow one, tell me which one and why?
_____
_____
_____
_____
_____

If you prefer to follow parts of one or more of the above standard guidelines please elaborate (if possible please be specific) :

_____
_____
_____
_____
_____

9. If there were a perfect guideline what components would it contain?

_____
_____
_____
_____
_____

10. Which method do you prefer for screening for diabetes?
Fasting blood sugar _____
Random blood sugar _____
Hemoglobin A1c _____
Oral glucose tolerance test _____
Other _____ (please name) _____

11. What factors do you believe should be considered in a diabetes screening guideline?

_____
_____
_____
_____
_____

12. Do you feel the patient population at your organization is adequately screened for diabetes?
Yes _____
No _____
If you checked *no* above why are your patients not adequately screened? Please be specific.

_____
_____
_____
_____
_____

13. If a comprehensive diabetes screening clinical guideline were available to you or other providers in your organization, do you think it would improve or increase screening/diagnosis practices?
Yes _____
No _____
If you checked *no* above why do you think it would not improve or increase screening/diagnosis practices?

_____
_____
_____
_____
_____

14. What guideline format do you prefer?
Written guideline _____
Algorithm only _____
Guideline with an algorithm _____
Other _____ please explain _____

15. Are there any comments about the above questions you would like to make?

_____
_____
_____
_____
_____

Thank you for your participation.

American Diabetes Association Recommendations 2017

Test	Value	Description
Fasting Plasma Glucose	≥ 126 mg/dL	Fasting is defined as no caloric intake for > 8 hours
2-hour Plasma Glucose	≥ 200 mg/dL	Using WHO guidelines and glucose load of at least 75 g of anhydrous glucose
A1c	≥ 6.5%	Lab tested using method that is NGSP certified and standardized
Random Plasma Glucose	≥ 200 mg/dL	With classic symptoms of hyperglycemia

The diagnosis of diabetes is made only after repeat confirmation, unless there is a clear clinical diagnosis of random plasma glucose level ≥ 200 mg/dL in a symptomatic individual (polyuria, polyphagia, polydipsia). The second test should be conducted as soon as possible and questionable results should be repeated in 3-6 months.
Screen overweight or obese individuals (BMI>25) with one or more risk factors (A1c ≥ 5.7%, impaired glucose tolerance test (IGT), impaired fasting glucose level (IFT), 1st degree relative with type 1 DM, high risk ethnicity, women with history of gestational DM, history of cardiovascular disease, hypertension, history of PCOS or other diseases causing insulin resistance, physical inactivity)
Routine testing for everyone beginning at age 45 and repeated every 3 years for individuals with normal results.
More frequent testing is recommended based on risk stratification and prediabetes status.
Yearly monitoring for individuals with a prediabetes diagnosis.

World Health Organization Recommendations 2016

Test	Value
Fasting Plasma Glucose	≥ 7.0 mmol/L (126 mg/dl)
2-hour Plasma Glucose	≥ 11.1 mmol/L (200 mg/dl)
HbA1c	≥ 6.5%

Diagnosis of DM in an asymptomatic individual:
Should not be based on a single abnormal plasma glucose or A1c level.
A second test with values within the diabetic range is a requirement for diagnosis according to the WHO standards using fasting, random or oral glucose tolerance testing in a stringently controlled testing or lab environment.
Periodic retesting is recommended for individuals having a singular positive diagnostic test and negative second test until DM status is clear.

United States Preventative Services Task Force Recommendations 2015

Test	Value
Hemoglobin A1c Level	≥ 6.5%
Fasting Plasma Glucose Level	≥ 7.0 mmol/L ≥ 126 mg/dl
2-hour Oral Glucose Tolerance Test	≥ 11.1 mmol/L ≥ 200 mg/dl

Screening Recommendations:
Screen only adult patients ages 40-70 who are asymptomatic and overweight or obese.
Screen individuals with additional at least one risk factors such as family history of diabetes, history of gestational diabetes, polycystic ovarian syndrome, or persons of high risk ethnicities earlier.
Screening Tests:
HbA1c
Fasting plasma glucose level
Oral glucose tolerance test
Screening Interval:
Every 3 years for initial normal levels
Annual Risk assessment to identify risk factors for abnormal glucose metabolism such as obesity, physical inactivity, smoking, hypertension and hyperlipidemia
Diagnosis:
Repeat testing with the same test on a different day

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

INFORMED CONSENT-NO SIGNATURE DOCUMENT

Project Title: Screening for Diabetes in At-Risk Populations in Primary Care

Student Researcher: Vera L. Pillitteri, BSN, RN, DNP-S
Research Advisor: Kathleen N. Dunemn, PhD, APRN, CNM, School of Nursing
Co-Research Advisor: Vicki Wilson, PhD, MS, RN, School of Nursing
Committee Member: Deborah Green, M.D.

Expert Consensus: A Delphi Study

The purpose of the following Doctor of Nursing Practice Research Translation Project is to develop an evidence-based clinical practice guideline for improved screening methods in the diagnosis of diabetes in the adult population with one or several risk factors, or those individuals considered to have an increased risk for the development of type 2 diabetes. Evaluation of current screening practices in the family practice setting will be conducted. Participation from advanced practice healthcare providers throughout Colorado will be requested to develop expert consensus in the creation of a user friendly and simplistic clinical practice guideline.

The Delphi Method originally developed in the 1950's is a widely used research tool for surveying expert opinion and consensus on a specific topic or field of study using a questionnaire. The Delphi method was created to address what could or should be done in practice and has been fundamental in the development of clinical guidelines. For the purposes of this project, two rounds of questioning will be administered to the panel of experts (participants), first addressing observed or utilized diabetes screening practices using the Delphi Method. The second round of questions will address the proposed screening guideline, ease of use and prospective utilization. It is anticipated that each participant will complete each round of the Delphi survey in under 20 minutes. Two rounds of questioning will be required for this capstone project.

The responses gathered from the surveyed material will be recorded anonymously and only the student researcher and the research advisor will have access to the original responses. All Delphi questionnaires will be sent and returned electronically through private email on a secure server. **Participation is voluntary and all responses will be kept anonymous.** The responses will be kept on a password protected USB flash drive and in the possession of the DNP student. Access will only be granted to the student researcher and research advisor. Since participation is voluntary and this is a quality improvement project, there are no foreseeable risks to the participants.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision

will be respected and will not result in loss of benefits to which you are otherwise entitled. If you have questions, please contact a member of the research team.

Having read the above and having had an opportunity to ask any questions, please complete the questionnaire "Phase One: Delphi Study, Round One Questionnaire" if you would like to participate in this research. By completing the questionnaire and returning it to the student researcher, it will be assumed that you have communicated consent in participation. Please print a copy of this form to retain for future reference. Please return the completed survey to verapillitteri@gmail.com

If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Sponsored Programs, 25 Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

Student Researcher: Vera L. Pillitteri, BSN, RN, DNP-S
E-mail: verapillitteri@gmail.com
Phone: 303-517-2981

Research Advisor: Kathleen N. Dunemn, PhD, APRN, CNM
E-mail: Kathleen.Dunemn@unco.edu
Phone: 970-351-3081/303-649-5581

Co-Research Advisor: Vicki Wilson, PhD, MS, RN
E-mail: Vicki.Wilson@unco.edu
Phone: 970-351-1295

Committee Member: Deborah Green, M.D.
Address: Park Avenue Medical Group
315 Park Avenue
Ft. Lupton, CO 80621
E-mail: dgreen.pamg@hotmail.com
Phone: 303-857-6111

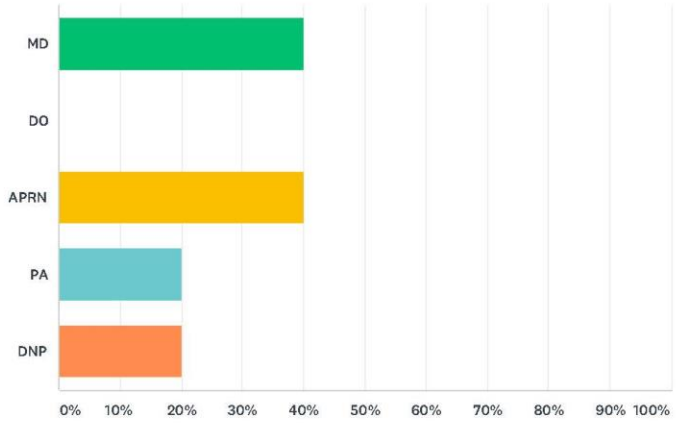
APPENDIX D

SUMMARY AND RESPONSES TO DELPHI ROUND ONE SURVEY

Phase One: Delphi Study, Round One Questionnaire

Q1 What is your current title or role? (You may indicate more than one if applicable)

Answered: 5 Skipped: 0

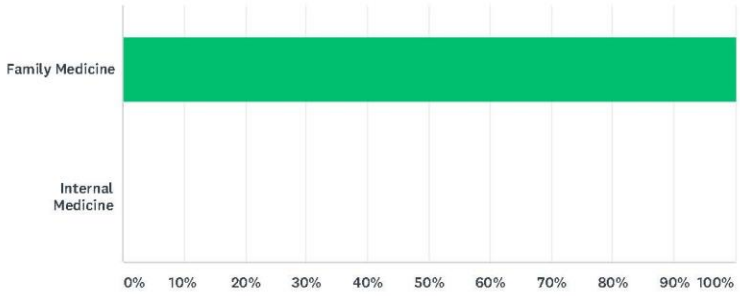


ANSWER CHOICES	RESPONSES	
MD	40.00%	2
DO	0.00%	0
APRN	40.00%	2
PA	20.00%	1
DNP	20.00%	1
Total Respondents: 5		

Phase One: Delphi Study, Round One Questionnaire

Q2 In what kind of practice do you primarily work?

Answered: 5 Skipped: 0

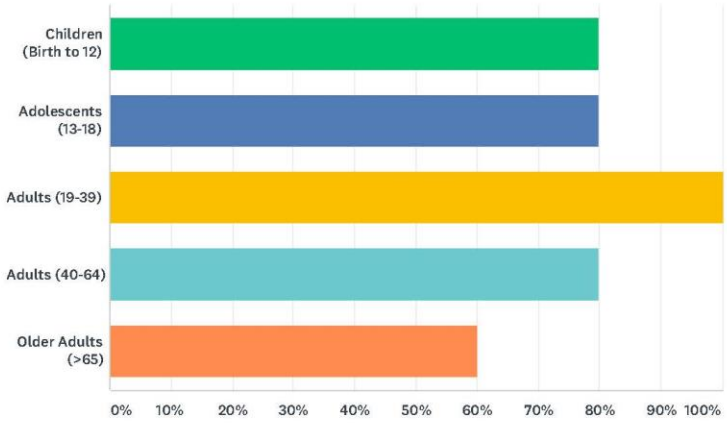


ANSWER CHOICES	RESPONSES	
Family Medicine	100.00%	5
Internal Medicine	0.00%	0
TOTAL		5

Phase One: Delphi Study, Round One Questionnaire

Q3 What ages of patients do you primarily see? (You may indicate more than one)

Answered: 5 Skipped: 0

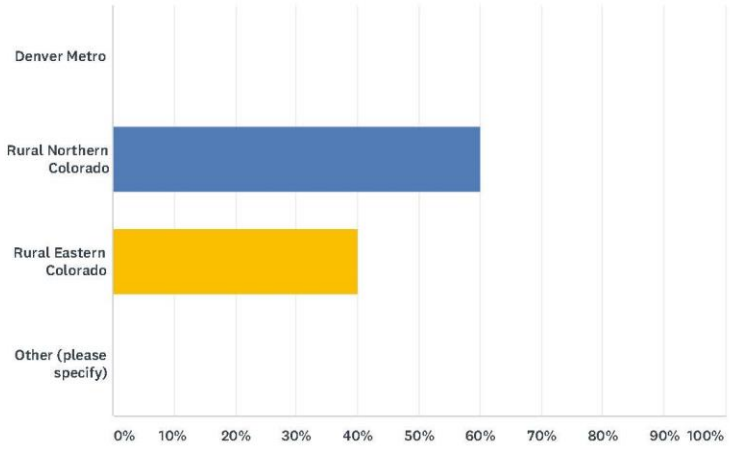


ANSWER CHOICES	RESPONSES	
Children (Birth to 12)	80.00%	4
Adolescents (13-18)	80.00%	4
Adults (19-39)	100.00%	5
Adults (40-64)	80.00%	4
Older Adults (>65)	60.00%	3
Total Respondents: 5		

Phase One: Delphi Study, Round One Questionnaire

Q4 What area do you primarily serve?

Answered: 5 Skipped: 0



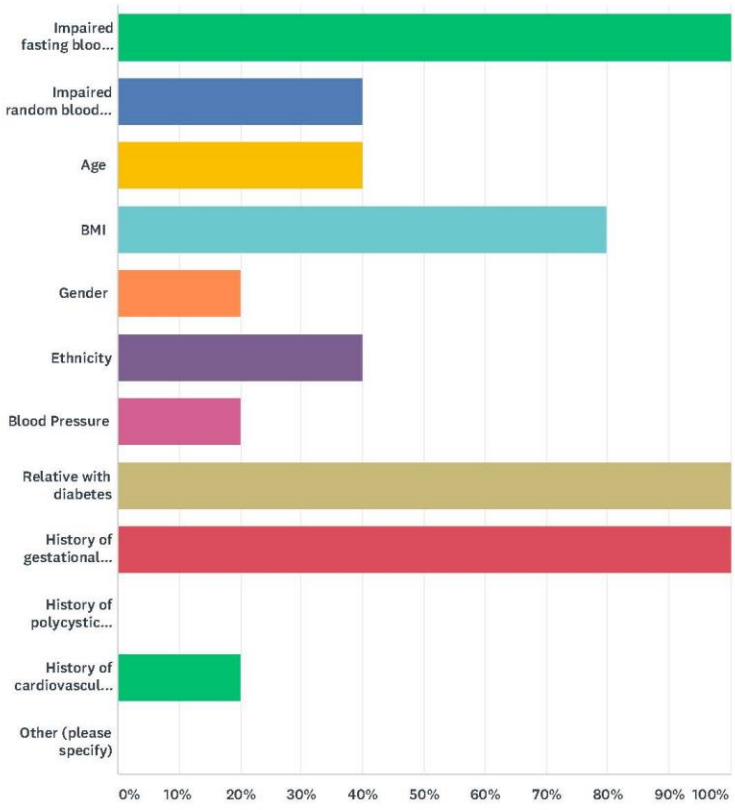
ANSWER CHOICES	RESPONSES	
Denver Metro	0.00%	0
Rural Northern Colorado	60.00%	3
Rural Eastern Colorado	40.00%	2
Other (please specify)	0.00%	0
TOTAL		5

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Phase One: Delphi Study, Round One Questionnaire

Q5 Which risk factors do you consider when screening for diabetes? (Choose all that apply)

Answered: 5 Skipped: 0



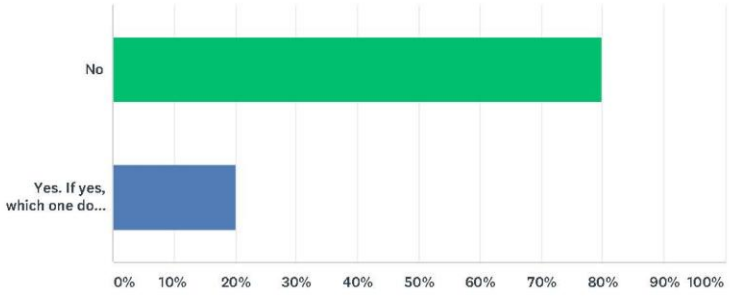
ANSWER CHOICES	RESPONSES	
Impaired fasting blood sugar	100.00%	5
Impaired random blood sugar	40.00%	2
Age	40.00%	2
BMI	80.00%	4
Gender	20.00%	1
Ethnicity	40.00%	2
Blood Pressure	20.00%	1

Relative with diabetes	100.00%	5
History of gestational diabetes	100.00%	5
History of polycystic ovarian syndrome	0.00%	0
History of cardiovascular disease	20.00%	1
Other (please specify)	0.00%	0
Total Respondents: 5		

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q7 Do you follow any specific clinical practice guideline pertaining to the screening/diagnosis of diabetes?

Answered: 5 Skipped: 0



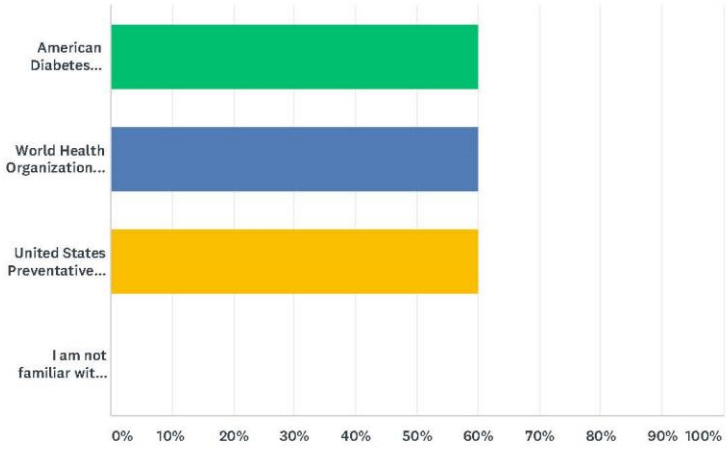
ANSWER CHOICES	RESPONSES	
No	80.00%	4
Yes. If yes, which one do you use? (please specify)	20.00%	1
TOTAL		5

#	YES. IF YES, WHICH ONE DO YOU USE? (PLEASE SPECIFY)	DATE
1	Cdc	9/3/2017 6:03 PM

Phase One: Delphi Study, Round One Questionnaire

Q8 Are you familiar with any of the following diabetes screening recommendations?

Answered: 5 Skipped: 0



ANSWER CHOICES	RESPONSES	
American Diabetes Association (Updated 1/2017)?	60.00%	3
World Health Organization (Updated 2016)?	60.00%	3
United States Preventative Services Task Force (Updated 12/2015)?	60.00%	3
I am not familiar with any of the above	0.00%	0
Total Respondents: 5		

Phase One: Delphi Study, Round One Questionnaire

Q9 Note the information attached for each recommendation. Would you prefer to follow 1 or more of these, if so which one(s):

Answered: 5 Skipped: 0

#	RESPONSES	DATE
1	result of hemoglobin A1C	9/26/2017 5:57 PM
2	USPSTF	9/18/2017 12:54 PM
3	1 and 2	9/3/2017 6:03 PM
4	ADA	8/31/2017 9:13 AM
5	More	8/29/2017 6:34 PM

Phase One: Delphi Study, Round One Questionnaire

Q10 If you prefer to follow one, tell me which one and why?

Answered: 5 Skipped: 0

#	RESPONSES	DATE
1	A1C, seems to be the most reliable	9/26/2017 5:57 PM
2	USPSTF--comprehensive review of studies evaluating benefits/harms of screening	9/18/2017 12:54 PM
3	Legitimate	9/3/2017 6:03 PM
4	ADA seems to be most used by endocrinology & is an easy one to reference.	8/31/2017 9:13 AM
5	ADA. More parameters	8/29/2017 6:34 PM

Phase One: Delphi Study, Round One Questionnaire

Q11 If you prefer to follow parts of one or more of the above please elaborate:

Answered: 3 Skipped: 2

#	RESPONSES	DATE
1	n/a	9/18/2017 12:54 PM
2	As much as possible	9/3/2017 6:03 PM
3	ADA contains all parameters	8/29/2017 6:34 PM

Phase One: Delphi Study, Round One Questionnaire

Q12 If there were a perfect guideline what components would it contain?

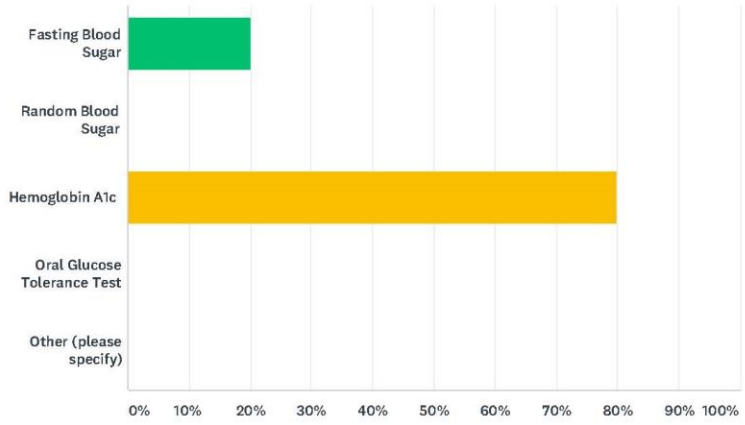
Answered: 5 Skipped: 0

#	RESPONSES	DATE
1	lab tests - fasting glucose & A1C, symptoms & past medical history, family history,	9/26/2017 5:57 PM
2	age, BMI, co-morbidities	9/18/2017 12:54 PM
3	Brief concise	9/3/2017 6:03 PM
4	1)laboratory values indicative for further screening 2) genetic, familial, environmental indications for screening	8/31/2017 9:13 AM
5	A1C, fasting glucose, family history, elevated BMI	8/29/2017 6:34 PM

Phase One: Delphi Study, Round One Questionnaire

Q13 Which method do you prefer for screening for diabetes?

Answered: 5 Skipped: 0



ANSWER CHOICES	RESPONSES	
Fasting Blood Sugar	20.00%	1
Random Blood Sugar	0.00%	0
Hemoglobin A1c	80.00%	4
Oral Glucose Tolerance Test	0.00%	0
Other (please specify)	0.00%	0
TOTAL		5

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Phase One: Delphi Study, Round One Questionnaire

Q14 What factors do you believe should be considered in a diabetes screening guideline?

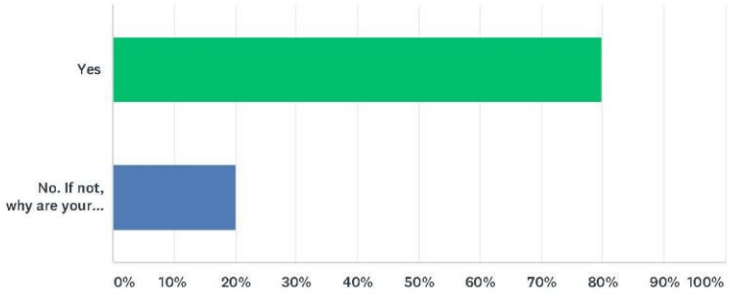
Answered: 5 Skipped: 0

#	RESPONSES	DATE
1	A1C result, symptoms	9/26/2017 5:57 PM
2	BMI, presence of cardiovascular disease, h/o gestational diabetes, h/o elevated lipids,	9/18/2017 12:54 PM
3	All risks	9/3/2017 6:03 PM
4	FBS, RBS, BMI, family hx, symptoms	8/31/2017 9:13 AM
5	A1C, BMI family history	8/29/2017 6:34 PM

Phase One: Delphi Study, Round One Questionnaire

Q15 Do you feel the patient population at your organization is adequately screened for diabetes?

Answered: 5 Skipped: 0



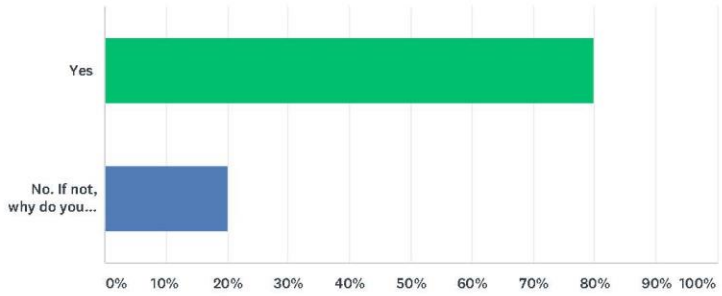
ANSWER CHOICES	RESPONSES	
Yes	80.00%	4
No. If not, why are your patients not adequately screened?	20.00%	1
TOTAL		5

#	NO. IF NOT, WHY ARE YOUR PATIENTS NOT ADEQUATELY SCREENED?	DATE
1	some at risk patients refuse screening labs; cost may be a factor	9/18/2017 12:54 PM

Phase One: Delphi Study, Round One Questionnaire

Q16 If a comprehensive diabetes screening clinical guideline were available to you or other providers in your organization, do you think it would improve or increase screening/diagnosis practices?

Answered: 5 Skipped: 0



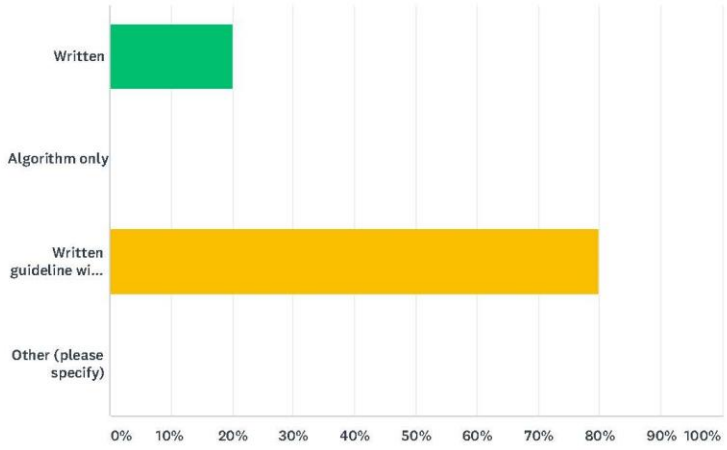
ANSWER CHOICES	RESPONSES	
Yes	80.00%	4
No. If not, why do you think it would not improve or increase screening/diagnosis practices?	20.00%	1
TOTAL		5

#	NO. IF NOT, WHY DO YOU THINK IT WOULD NOT IMPROVE OR INCREASE SCREENING/DIAGNOSIS PRACTICES?	DATE
1	I already screen A1C for physicals and patients at risk	8/29/2017 6:34 PM

Phase One: Delphi Study, Round One Questionnaire

Q17 What guideline format do you prefer?

Answered: 5 Skipped: 0



ANSWER CHOICES	RESPONSES	
Written	20.00%	1
Algorithm only	0.00%	0
Written guideline with an algorithm	80.00%	4
Other (please specify)	0.00%	0
TOTAL		5

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Phase One: Delphi Study, Round One Questionnaire

Q18 Are there any comments about the above questions you would like to make?

Answered: 4 Skipped: 1

#	RESPONSES	DATE
1	no, thanks	9/18/2017 12:54 PM
2	No	9/3/2017 6:03 PM
3	no	8/31/2017 9:13 AM
4	Some questions vague	8/29/2017 6:34 PM

Phase One: Delphi Study, Round One Questionnaire

#1

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Tuesday, August 29, 2017 6:27:37 PM
Last Modified:	Tuesday, August 29, 2017 6:34:24 PM
Time Spent:	00:06:46

Page 1

Q1 What is your current title or role? (You may indicate more than one if applicable)	**MD**
Q2 In what kind of practice do you primarily work?	**Family Medicine**
Q3 What ages of patients do you primarily see? (You may indicate more than one)	**Children (Birth to 12)** , **Adolescents (13-18)** , **Adults (19-39)** , **Adults (40-64)** , **Older Adults (>65)**
Q4 What area do you primarily serve?	**Rural Northern Colorado**
Q5 Which risk factors do you consider when screening for diabetes? (Choose all that apply)	**Impaired fasting blood sugar** , **Impaired random blood sugar,** **Relative with diabetes,** **History of gestational diabetes**
Q6 Do providers at your location utilize any clinical guidelines pertaining to the screening/diagnosis of diabetes?	**No**

Phase One: Delphi Study, Round One Questionnaire

Q7 Do you follow any specific clinical practice guideline pertaining to the screening/diagnosis of diabetes?	**No**
Q8 Are you familiar with any of the following diabetes screening recommendations?	**American Diabetes Association (Updated 1/2017)?, World Health Organization (Updated 2016)?**

Q9 Note the information attached for each recommendation. Would you prefer to follow 1 or more of these, if so which one(s):

More

Q10 If you prefer to follow one, tell me which one and why?

ADA. More parameters

Q11 If you prefer to follow parts of one or more of the above please elaborate:

ADA contains all parameters

Q12 If there were a perfect guideline what components would it contain?

A1C, fasting glucose, family history, elevated BMI

Q13 Which method do you prefer for screening for diabetes?	**Hemoglobin A1c**

Q14 What factors do you believe should be considered in a diabetes screening guideline?

A1C, BMI family history

Q15 Do you feel the patient population at your organization is adequately screened for diabetes?	**Yes**
Q16 If a comprehensive diabetes screening clinical guideline were available to you or other providers in your organization, do you think it would improve or increase screening/diagnosis practices?	No. If not, why do you think it would not improve or increase screening/diagnosis practices?: I already screen A1C for physicals and patients at risk
Q17 What guideline format do you prefer?	**Written**

Phase One: Delphi Study, Round One Questionnaire

Q18 Are there any comments about the above questions you would like to make?

Some questions vague

Phase One: Delphi Study, Round One Questionnaire

#2

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Thursday, August 31, 2017 9:05:23 AM
Last Modified:	Thursday, August 31, 2017 9:12:51 AM
Time Spent:	00:07:27

Page 1

Q1 What is your current title or role? (You may indicate more than one if applicable)	**APRN,** **DNP**
Q2 In what kind of practice do you primarily work?	**Family Medicine**
Q3 What ages of patients do you primarily see? (You may indicate more than one)	**Children (Birth to 12) ,** **Adolescents (13-18) ,** **Adults (19-39) ,** **Adults (40-64) ,** **Older Adults (>65)**
Q4 What area do you primarily serve?	**Rural Eastern Colorado**
Q5 Which risk factors do you consider when screening for diabetes? (Choose all that apply)	**Impaired fasting blood sugar ,** **Impaired random blood sugar,** **Age,** **BMI,** **Relative with diabetes,** **History of gestational diabetes**

Phase One: Delphi Study, Round One Questionnaire

Q6 Do providers at your location utilize any clinical guidelines pertaining to the screening/diagnosis of diabetes?	**No**
Q7 Do you follow any specific clinical practice guideline pertaining to the screening/diagnosis of diabetes?	**No**
Q8 Are you familiar with any of the following diabetes screening recommendations?	**American Diabetes Association (Updated 1/2017)?,** **World Health Organization (Updated , 2016)?** **United States Preventative Services Task Force (Updated 12/2015)?**

Q9 Note the information attached for each recommendation. Would you prefer to follow 1 or more of these, if so which one(s):

ADA

Q10 If you prefer to follow one, tell me which one and why?

ADA seems to be most used by endocrinology & is an easy one to reference.

Q11 If you prefer to follow parts of one or more of the above please elaborate:	**Respondent skipped this question**

Q12 If there were a perfect guideline what components would it contain?

1)laboratory values indicative for further screening 2) genetic, familial, environmental indications for screening

Q13 Which method do you prefer for screening for diabetes?	**Hemoglobin A1c**

Q14 What factors do you believe should be considered in a diabetes screening guideline?

FBS, RBS, BMI, family hx, symptoms

Q15 Do you feel the patient population at your organization is adequately screened for diabetes?	**Yes**
Q16 If a comprehensive diabetes screening clinical guideline were available to you or other providers in your organization, do you think it would improve or increase screening/diagnosis practices?	**Yes**

Phase One: Delphi Study, Round One Questionnaire

Q17 What guideline format do you prefer? **Written guideline with an algorithm**

Q18 Are there any comments about the above questions you would like to make?

no

Phase One: Delphi Study, Round One Questionnaire

#3

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Sunday, September 03, 2017 5:59:09 PM
Last Modified:	Sunday, September 03, 2017 6:03:03 PM
Time Spent:	00:03:54

Page 1

Q1 What is your current title or role? (You may indicate more than one if applicable)	**PA**
Q2 In what kind of practice do you primarily work?	**Family Medicine**
Q3 What ages of patients do you primarily see? (You may indicate more than one)	**Adults (19-39)**
Q4 What area do you primarily serve?	**Rural Eastern Colorado**
Q5 Which risk factors do you consider when screening for diabetes? (Choose all that apply)	**Impaired fasting blood sugar** **Age,** **BMI,** **Gender,** **Ethnicity,** **Blood Pressure** **Relative with diabetes,** **History of gestational diabetes** **History of cardiovascular disease**
Q6 Do providers at your location utilize any clinical guidelines pertaining to the screening/diagnosis of diabetes?	**No**

Phase One: Delphi Study, Round One Questionnaire

Q7 Do you follow any specific clinical practice guideline pertaining to the screening/diagnosis of diabetes?	Yes. If yes, which one do you use? (please specify): Cdc
Q8 Are you familiar with any of the following diabetes screening recommendations?	**American Diabetes Association (Updated 1/2017)?,** **World Health Organization (Updated 2016)?**

Q9 Note the information attached for each recommendation. Would you prefer to follow 1 or more of these, if so which one(s):

1 and 2

Q10 If you prefer to follow one, tell me which one and why?

Legitimate

Q11 If you prefer to follow parts of one or more of the above please elaborate:

As much as possible

Q12 If there were a perfect guideline what components would it contain?

Brief concise

Q13 Which method do you prefer for screening for diabetes?	**Hemoglobin A1c**

Q14 What factors do you believe should be considered in a diabetes screening guideline?

All risks

Q15 Do you feel the patient population at your organization is adequately screened for diabetes?	**Yes**
Q16 If a comprehensive diabetes screening clinical guideline were available to you or other providers in your organization, do you think it would improve or increase screening/diagnosis practices?	**Yes**
Q17 What guideline format do you prefer?	**Written guideline with an algorithm**

Phase One: Delphi Study, Round One Questionnaire

Q18 Are there any comments about the above questions you would like to make?

No

Phase One: Delphi Study, Round One Questionnaire

#4

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Monday, September 18, 2017 12:36:46 PM
Last Modified:	Monday, September 18, 2017 12:54:04 PM
Time Spent:	00:17:18

Page 1

Q1 What is your current title or role? (You may indicate more than one if applicable)	**MD**
Q2 In what kind of practice do you primarily work?	**Family Medicine**
Q3 What ages of patients do you primarily see? (You may indicate more than one)	**Children (Birth to 12)** , **Adolescents (13-18)** , **Adults (19-39)** , **Adults (40-64)** **Older Adults (>65)**
Q4 What area do you primarily serve?	**Rural Northern Colorado**
Q5 Which risk factors do you consider when screening for diabetes? (Choose all that apply)	**Impaired fasting blood sugar** , **BMI,** **Relative with diabetes,** **History of gestational diabetes**
Q6 Do providers at your location utilize any clinical guidelines pertaining to the screening/diagnosis of diabetes?	**No**

Phase One: Delphi Study, Round One Questionnaire

Q7 Do you follow any specific clinical practice guideline pertaining to the screening/diagnosis of diabetes?	**No**
Q8 Are you familiar with any of the following diabetes screening recommendations?	**United States Preventative Services Task Force (Updated 12/2015)?**

Q9 Note the information attached for each recommendation. Would you prefer to follow 1 or more of these, if so which one(s):

USPSTF

Q10 If you prefer to follow one, tell me which one and why?

USPSTF--comprehensive review of studies evaluating benefits/harms of screening

Q11 If you prefer to follow parts of one or more of the above please elaborate:

n/a

Q12 If there were a perfect guideline what components would it contain?

age, BMI, co-morbidities

Q13 Which method do you prefer for screening for diabetes?	**Fasting Blood Sugar**

Q14 What factors do you believe should be considered in a diabetes screening guideline?

BMI, presence of cardiovascular disease, h/o gestational diabetes, h/o elevated lipids,

Q15 Do you feel the patient population at your organization is adequately screened for diabetes?	No. If not, why are your patients not adequately screened?: some at risk patients refuse screening labs; cost may be a factor
Q16 If a comprehensive diabetes screening clinical guideline were available to you or other providers in your organization, do you think it would improve or increase screening/diagnosis practices?	**Yes**
Q17 What guideline format do you prefer?	**Written guideline with an algorithm**

Phase One: Delphi Study, Round One Questionnaire

Q18 Are there any comments about the above questions you would like to make?

no, thanks

Phase One: Delphi Study, Round One Questionnaire

#5

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Tuesday, September 26, 2017 5:49:51 PM
Last Modified:	Tuesday, September 26, 2017 5:57:09 PM
Time Spent:	00:07:17

Page 1

Q1 What is your current title or role? (You may indicate more than one if applicable)	**APRN**
Q2 In what kind of practice do you primarily work?	**Family Medicine**
Q3 What ages of patients do you primarily see? (You may indicate more than one)	**Adults (19-39),** **Adults (40-64),** **Adolescents (13-18),** **Children (Birth to 12)**
Q4 What area do you primarily serve?	**Rural Northern Colorado**
Q5 Which risk factors do you consider when screening for diabetes? (Choose all that apply)	**Impaired fasting blood sugar,** **BMI,** **Ethnicity,** **Relative with diabetes,** **History of gestational diabetes**
Q6 Do providers at your location utilize any clinical guidelines pertaining to the screening/diagnosis of diabetes?	**No**
Q7 Do you follow any specific clinical practice guideline pertaining to the screening/diagnosis of diabetes?	**No**

Phase One: Delphi Study, Round One Questionnaire

Q8 Are you familiar with any of the following diabetes screening recommendations?	**United States Preventative Services Task Force (Updated 12/2015)?**

Q9 Note the information attached for each recommendation. Would you prefer to follow 1 or more of these, if so which one(s):

result of hemoglobin A1C

Q10 If you prefer to follow one, tell me which one and why?

A1C, seems to be the most reliable

Q11 If you prefer to follow parts of one or more of the above please elaborate:	**Respondent skipped this question**

Q12 If there were a perfect guideline what components would it contain?

lab tests - fasting glucose & A1C, symptoms & past medical history, family history,

Q13 Which method do you prefer for screening for diabetes?	**Hemoglobin A1c**

Q14 What factors do you believe should be considered in a diabetes screening guideline?

A1C result, symptoms

Q15 Do you feel the patient population at your organization is adequately screened for diabetes?	**Yes**
Q16 If a comprehensive diabetes screening clinical guideline were available to you or other providers in your organization, do you think it would improve or increase screening/diagnosis practices?	**Yes**
Q17 What guideline format do you prefer?	**Written guideline with an algorithm**
Q18 Are there any comments about the above questions you would like to make?	**Respondent skipped this question**

APPENDIX E

DELPHI SURVEY ROUND TWO

Phase Three: Delphi Study Round Two Questionnaire

Thank you for your participation in the Delphi Study Round Two Questionnaire. The purpose of this questionnaire is to obtain consensus regarding the proposed clinical guideline developed for utilization by the providers at Park Avenue Medical Group. The objective of this guideline is to obtain at least 70% participant consensus on the ease of use and clinical utility of the proposed guideline and algorithm.
The information gathered from the Delphi Study Round One and the results from a retrospective chart review utilizing the electronic medical record (EMR) at Park Avenue Medical Group were used in conjunction with the current evidence-based recommendations to develop the proposed guideline. The chart review process evaluated current screening practices, risk factors identified by the American Diabetes Association, World Health Organization and United States Preventative Services Task Force and the demographic information on the patient population at Park Avenue Medical Group. Additionally, random and fasting blood glucose levels at or above 100 mg/dL were considered and utilized to improve sensitivity and specificity of the diabetes screening process. Please use the attached information to answer the following questions.

1. 100% of the participants responded that impaired fasting blood glucose levels, a relative with diabetes or a past history of gestational diabetes are the most important factors to consider when screening for diabetes, and BMI (80%), impaired random glucose levels, age and ethnicity (40%) were also important considerations. Do you feel the attached algorithm adequately considers these factors?

   Yes _____ No _____
   If you answered no, what do you feel is missing?
   _____

2. 80% of the Phase One participants do not follow any clinical guideline for diabetes screening, however prefer the parameters addressed by the American Diabetes Association's recommendations (fasting glucose levels, A1c, symptoms, family history, co-morbidities and BMI). Do you feel the attached algorithm correctly reflects the ADA's recommendations? (See the attached ADA recommendations if you are unfamiliar with them).

   Yes _____ No _____
   If you answered no, what ADA recommendations do you feel were not addressed?
   _____

3. The algorithm utilizes the A1c as a screening method in various stages depending on age and risk factors. Do you feel using the algorithm would allow adequate insurance coverage and reimbursement for diabetes screening?

   Yes _____ No _____
   If you answered no, what additional factors should be considered?
   _____

4. Looking at the written clinical guideline only, do you feel it is easy to follow?

   Yes _____ No _____
   If you answered no, what areas require clarification?
   _____

5. Again, looking at only the written guideline, do you feel Table 1 is helpful?

   Yes _____ No _____

6. Do you feel the inclusion of the ICD 10 codes and CPT codes will be helpful for ensuring insurance coverage and reimbursement?

   Yes _____ No _____
   If you answered no, please explain
   _____

7. The written guideline offers a statement about the use of the hemoglobin A1c in patients with sickle cell disease and other hemoglobinopathies (pregnancy, hemodialysis, recent transfusion or erythropoietin therapy). Were you aware the 2-hour glucose tolerance test is the preferred screening method in this population?

   Yes _____ No _____

8. Do you have any additional recommendations about the ease of use or comprehensiveness of the clinical practice guideline and algorithm?

   Yes_____ No _____
   If so, what recommendations do you have?
   _____

APPENDIX F

SUMMARY AND RESPONSES TO DELPHI ROUND TWO SURVEY

Phase Three: Delphi Study Round Two

#1

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Monday, October 02, 2017 3:18:21 PM
Last Modified:	Monday, October 02, 2017 3:28:47 PM
Time Spent:	00:10:26

Page 1

Q1 100% of the participants responded that impaired fasting blood glucose levels, a relative with diabetes or a past history of gestational diabetes are the most important factors to consider when screening for diabetes, and BMI (80%), impaired random glucose levels, age and ethnicity (40%) were also important considerations. Do you feel the attached algorithm adequately considers these factors?	**Yes**
Q2 80% of the Phase One participants do not follow any clinical guideline for diabetes screening, however prefer the parameters addressed by the American Diabetes Association's recommendations (fasting glucose levels, A1c, symptoms, family history, co-morbidities and BMI). Do you feel the attached algorithm correctly reflects the ADA's recommendations? (See the attached ADA recommendations if you are unfamiliar with them).	**Yes**
Q3 The algorithm utilizes the A1c as a screening method in various stages depending on age and risk factors. Do you feel using the algorithm would allow adequate insurance coverage and reimbursement for diabetes screening?	**Yes**
Q4 Looking at the written clinical guideline only, do you feel it is easy to follow?	**Yes**
Q5 Again, looking at only the written guideline, do you feel Table 1 is helpful?	**Yes**
Q6 Do you feel the inclusion of the ICD-10 codes and CPT codes will be helpful for ensuring insurance coverage and reimbursement?	**Yes**

Phase Three: Delphi Study Round Two

Q7 The written guideline offers a statement about the use of the hemoglobin A1c in patients with sickle cell disease and other hemoglobinopathies (pregnancy, hemodialysis, recent transfusion or erythropoietin therapy). Were you aware the 2-hour glucose tolerance test is the preferred screening method in this population?	**No**
Q8 Do you have any additional recommendations about the ease of use or comprehensiveness of the clinical practice guideline and algorithm?	**No**

Phase Three: Delphi Study Round Two

#2

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Monday, October 02, 2017 7:31:48 PM
Last Modified:	Monday, October 02, 2017 7:34:03 PM
Time Spent:	00:02:14

Page 1

Q1 100% of the participants responded that impaired fasting blood glucose levels, a relative with diabetes or a past history of gestational diabetes are the most important factors to consider when screening for diabetes, and BMI (80%), impaired random glucose levels, age and ethnicity (40%) were also important considerations. Do you feel the attached algorithm adequately considers these factors?	**Yes**
Q2 80% of the Phase One participants do not follow any clinical guideline for diabetes screening, however prefer the parameters addressed by the American Diabetes Association's recommendations (fasting glucose levels, A1c, symptoms, family history, co-morbidities and BMI). Do you feel the attached algorithm correctly reflects the ADA's recommendations? (See the attached ADA recommendations if you are unfamiliar with them).	**Yes**
Q3 The algorithm utilizes the A1c as a screening method in various stages depending on age and risk factors. Do you feel using the algorithm would allow adequate insurance coverage and reimbursement for diabetes screening?	**Yes**
Q4 Looking at the written clinical guideline only, do you feel it is easy to follow?	**Yes**
Q5 Again, looking at only the written guideline, do you feel Table 1 is helpful?	**Yes**
Q6 Do you feel the inclusion of the ICD-10 codes and CPT codes will be helpful for ensuring insurance coverage and reimbursement?	**Yes**

Phase Three: Delphi Study Round Two

Q7 The written guideline offers a statement about the use of the hemoglobin A1c in patients with sickle cell disease and other hemoglobinopathies (pregnancy, hemodialysis, recent transfusion or erythropoietin therapy). Were you aware the 2-hour glucose tolerance test is the preferred screening method in this population?	**No**
Q8 Do you have any additional recommendations about the ease of use or comprehensiveness of the clinical practice guideline and algorithm?	**No**

Phase Three: Delphi Study Round Two

#3

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Wednesday, October 04, 2017 2:16:40 PM
Last Modified:	Wednesday, October 04, 2017 2:26:16 PM
Time Spent:	00:09:36

Page 1

Q1 100% of the participants responded that impaired fasting blood glucose levels, a relative with diabetes or a past history of gestational diabetes are the most important factors to consider when screening for diabetes, and BMI (80%), impaired random glucose levels, age and ethnicity (40%) were also important considerations. Do you feel the attached algorithm adequately considers these factors?	**Yes**
Q2 80% of the Phase One participants do not follow any clinical guideline for diabetes screening, however prefer the parameters addressed by the American Diabetes Association's recommendations (fasting glucose levels, A1c, symptoms, family history, co-morbidities and BMI). Do you feel the attached algorithm correctly reflects the ADA's recommendations? (See the attached ADA recommendations if you are unfamiliar with them).	**Yes**
Q3 The algorithm utilizes the A1c as a screening method in various stages depending on age and risk factors. Do you feel using the algorithm would allow adequate insurance coverage and reimbursement for diabetes screening?	**Yes**
Q4 Looking at the written clinical guideline only, do you feel it is easy to follow?	**No,** If you answered no, what areas require clarification?: Algorithms are always easier to follow
Q5 Again, looking at only the written guideline, do you feel Table 1 is helpful?	**Yes**
Q6 Do you feel the inclusion of the ICD-10 codes and CPT codes will be helpful for ensuring insurance coverage and reimbursement?	**Yes**

Phase Three: Delphi Study Round Two

Q7 The written guideline offers a statement about the use of the hemoglobin A1c in patients with sickle cell disease and other hemoglobinopathies (pregnancy, hemodialysis, recent transfusion or erythropoietin therapy). Were you aware the 2-hour glucose tolerance test is the preferred screening method in this population?	**No**
Q8 Do you have any additional recommendations about the ease of use or comprehensiveness of the clinical practice guideline and algorithm?	**No**

Phase Three: Delphi Study Round Two

#4

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Wednesday, October 11, 2017 5:46:06 AM
Last Modified:	Wednesday, October 11, 2017 5:50:45 AM
Time Spent:	00:04:38

Page 1

Q1 100% of the participants responded that impaired fasting blood glucose levels, a relative with diabetes or a past history of gestational diabetes are the most important factors to consider when screening for diabetes, and BMI (80%), impaired random glucose levels, age and ethnicity (40%) were also important considerations. Do you feel the attached algorithm adequately considers these factors?	**Yes**
Q2 80% of the Phase One participants do not follow any clinical guideline for diabetes screening, however prefer the parameters addressed by the American Diabetes Association's recommendations (fasting glucose levels, A1c, symptoms, family history, co-morbidities and BMI). Do you feel the attached algorithm correctly reflects the ADA's recommendations? (See the attached ADA recommendations if you are unfamiliar with them).	**Yes**
Q3 The algorithm utilizes the A1c as a screening method in various stages depending on age and risk factors. Do you feel using the algorithm would allow adequate insurance coverage and reimbursement for diabetes screening?	**Yes**
Q4 Looking at the written clinical guideline only, do you feel it is easy to follow?	**Yes**
Q5 Again, looking at only the written guideline, do you feel Table 1 is helpful?	**Yes**
Q6 Do you feel the inclusion of the ICD-10 codes and CPT codes will be helpful for ensuring insurance coverage and reimbursement?	**Yes**

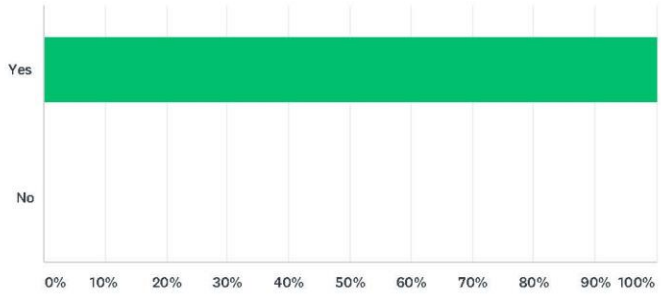
Phase Three: Delphi Study Round Two

Q7 The written guideline offers a statement about the use of the hemoglobin A1c in patients with sickle cell disease and other hemoglobinopathies (pregnancy, hemodialysis, recent transfusion or erythropoietin therapy). Were you aware the 2-hour glucose tolerance test is the preferred screening method in this population?	**No**
Q8 Do you have any additional recommendations about the ease of use or comprehensiveness of the clinical practice guideline and algorithm?	**No**

Phase Three: Delphi Study Round Two

Q1 100% of the participants responded that impaired fasting blood glucose levels, a relative with diabetes or a past history of gestational diabetes are the most important factors to consider when screening for diabetes, and BMI (80%), impaired random glucose levels, age and ethnicity (40%) were also important considerations. Do you feel the attached algorithm adequately considers these factors?

Answered: 4 Skipped: 0

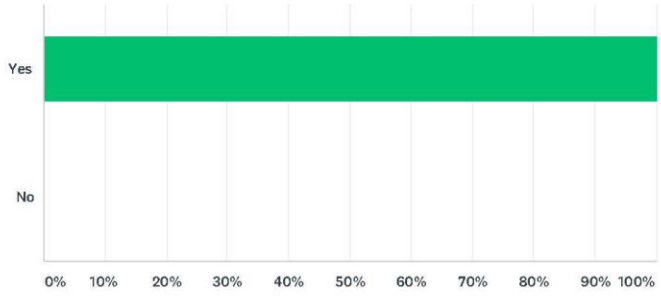


ANSWER CHOICES	RESPONSES	
Yes	100.00%	4
No	0.00%	0
TOTAL		4

Phase Three: Delphi Study Round Two

Q2 80% of the Phase One participants do not follow any clinical guideline for diabetes screening, however prefer the parameters addressed by the American Diabetes Association's recommendations (fasting glucose levels, A1c, symptoms, family history, co-morbidities and BMI). Do you feel the attached algorithm correctly reflects the ADA's recommendations? (See the attached ADA recommendations if you are unfamiliar with them).

Answered: 4 Skipped: 0

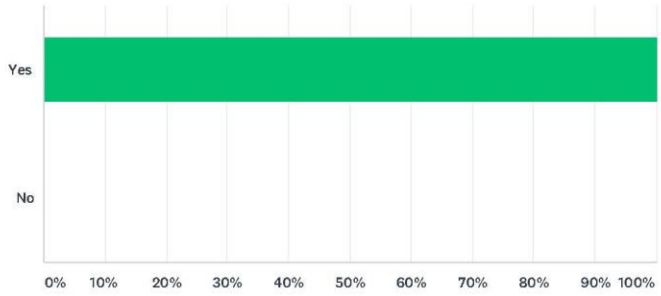


ANSWER CHOICES	RESPONSES	
Yes	100.00%	4
No	0.00%	0
TOTAL		4

Phase Three: Delphi Study Round Two

Q3 The algorithm utilizes the A1c as a screening method in various stages depending on age and risk factors. Do you feel using the algorithm would allow adequate insurance coverage and reimbursement for diabetes screening?

Answered: 4 Skipped: 0

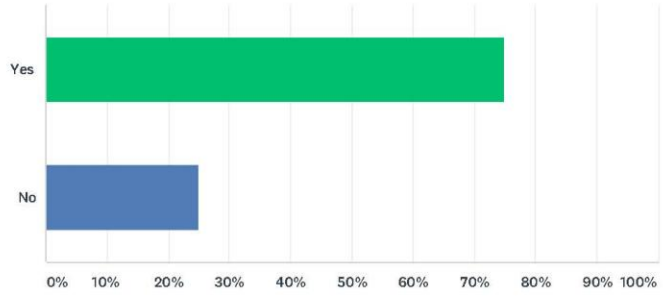


ANSWER CHOICES	RESPONSES	
Yes	100.00%	4
No	0.00%	0
TOTAL		4

Phase Three: Delphi Study Round Two

Q4 Looking at the written clinical guideline only, do you feel it is easy to follow?

Answered: 4 Skipped: 0

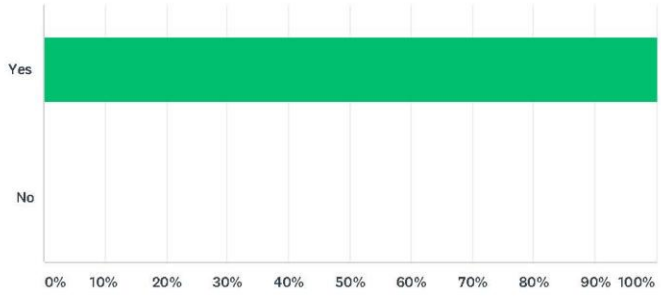


ANSWER CHOICES	RESPONSES	
Yes	75.00%	3
No	25.00%	1
TOTAL		4

Phase Three: Delphi Study Round Two

Q5 Again, looking at only the written guideline, do you feel Table 1 is helpful?

Answered: 4 Skipped: 0

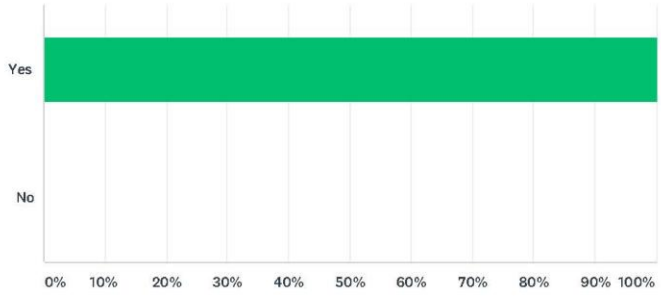


ANSWER CHOICES	RESPONSES	
Yes	100.00%	4
No	0.00%	0
TOTAL		4

Phase Three: Delphi Study Round Two

Q6 Do you feel the inclusion of the ICD-10 codes and CPT codes will be helpful for ensuring insurance coverage and reimbursement?

Answered: 4 Skipped: 0

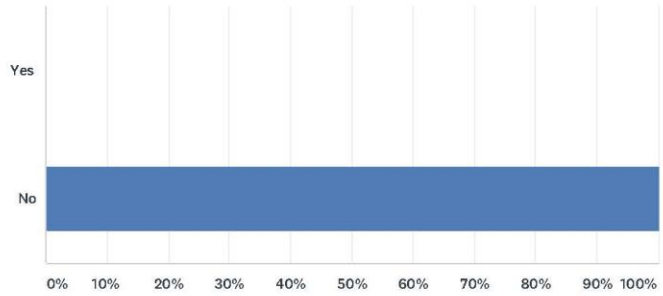


ANSWER CHOICES	RESPONSES	
Yes	100.00%	4
No	0.00%	0
TOTAL		4

Phase Three: Delphi Study Round Two

Q7 The written guideline offers a statement about the use of the hemoglobin A1c in patients with sickle cell disease and other hemoglobinopathies (pregnancy, hemodialysis, recent transfusion or erythropoietin therapy). Were you aware the 2-hour glucose tolerance test is the preferred screening method in this population?

Answered: 4 Skipped: 0

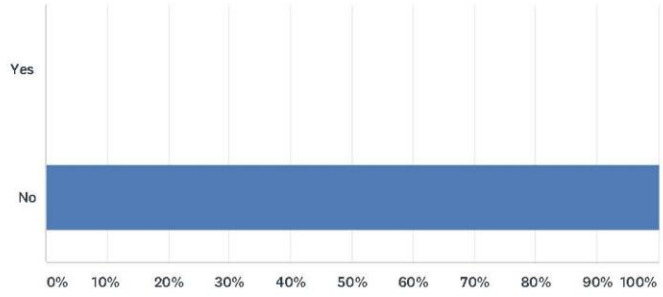


ANSWER CHOICES	RESPONSES	
Yes	0.00%	0
No	100.00%	4
TOTAL		4

Phase Three: Delphi Study Round Two

Q8 Do you have any additional recommendations about the ease of use or comprehensiveness of the clinical practice guideline and algorithm?

Answered: 4 Skipped: 0

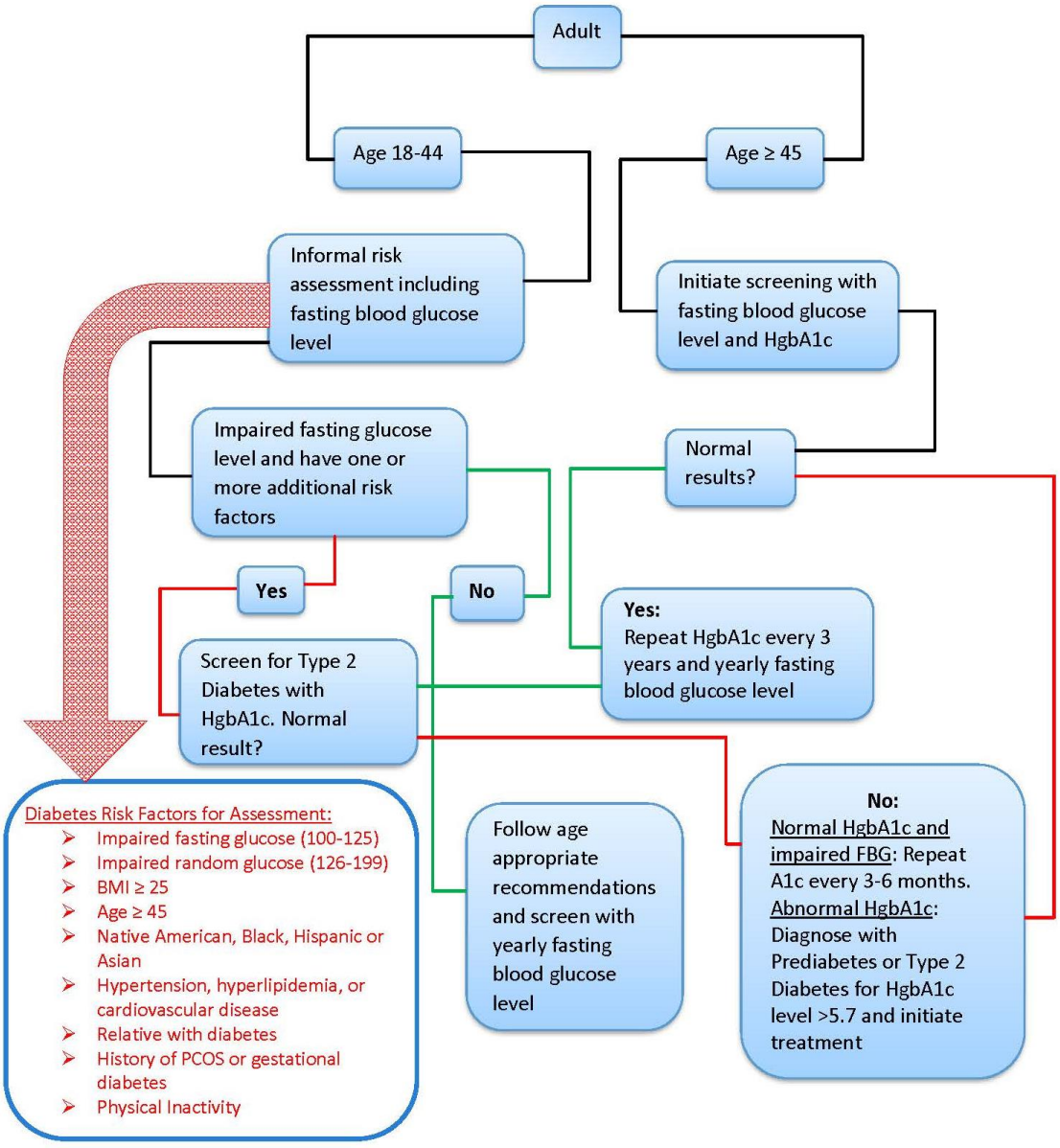


ANSWER CHOICES	RESPONSES	
Yes	0.00%	0
No	100.00%	4
TOTAL		4

APPENDIX G

SCREENING FOR TYPE 2 DIABETES IN ADULTS GUIDELINE AND ALGORITHM

Screening for Type 2 Diabetes in Adults Guideline & Algorithm



CLINICAL PRACTICE GUIDELINE

TITLE: Screening for Type 2 Diabetes Mellitus in the Adult Population Clinical Practice Guideline
Author: Vera L. Pillitteri BSN, RN, DNP-S
Reviewed: October 2017
Target Population: All adult patients over the age of 45 and adult patients ages 18-44 with one or more risk factor
Rationale: The following practice guideline will assist with differentiating at-risk populations and model screening practices for type 2 diabetes mellitus in the primary care setting.

Overview

Screening for type 2 diabetes has been the focus of ongoing efforts to minimize the cardiovascular consequences and long-term effects of diabetes, however there has not been consensus on screening practices. A recent survey indicated that while providers are familiar with the American Diabetes Association, World Health Organization and the United States Preventative Services Task Force recommendations, they are not being used to screen for diabetes in the primary care setting.

A retrospective study was conducted to evaluate the screening practices and risk stratification at a rural family practice. The data was examined to quantify the number of diabetes related risk factors in the patient population as well as to analyze screening methods used for a wellness visit in diabetic and non-diabetic patients. The results indicated routinely screening with only a fasting blood glucose level would fail to capture a significant number of individuals with a normal fasting glucose level and potentially elevated hemoglobin A1c results falling within the prediabetes or diabetes range. Additionally, individuals with impaired fasting glucose levels were either sent for additional testing, did not follow up or were lost to follow up causing a delay in treatment. Based on the data collected in the retrospective chart review, performing both, a fasting blood sugar and hemoglobin A1c on all patients during their annual wellness visit on adults ages 45 and older, and on adults ages 18-44 with impaired fasting glucose levels and one additional risk factor would capture nearly 10 times more patients with the potential to have elevated A1c levels.

The purpose of this practice guideline is to provide a simplistic, yet comprehensive tool to assist with screening for type 2 diabetes in the primary care setting using the latest research based evidence from the retrospective study as well as the American Diabetes Association, World Health Organization and United States Preventative Services Task Force.

Procedure

For all patients presenting to the clinic for a wellness exam (ICD 10 code Z00.00 or Z00.01), screening labs including a fasting blood glucose level should be drawn prior to exam or during the wellness visit. A lipid panel can also be drawn to further stratify the individual's risk for the development of type 2 diabetes. Individuals ages 40 and older should additionally have a screening hemoglobin A1c drawn with fasting labs using the diabetes screening ICD 10 code Z13.1 and CPT code 82947 for insurance reimbursement. Adults ages 18-44 who have an impaired fasting blood glucose level (100-125 mg/dL) or abnormal fasting blood glucose level which includes glucose levels less than 60 mg/dL

and have at least one of the following additional risk factors should also be screened with a hemoglobin A1c using ICD 10 code R73.09 for abnormal fasting glucose level or R73.01 for impaired fasting glucose.

Diabetes Related Risk Factors for Informal Risk Assessment

- Impaired Fasting Glucose (100-125 mg/dL)
- Impaired Random Glucose (126-199 mg/dL)
- BMI ≥ 25
- Age ≥ 45
- Native American, Black, Hispanic or Asian Ethnicity
- Hypertension, hyperlipidemia or cardiovascular disease
- Relative with diabetes
- Personal history of polycystic ovarian syndrome (PCOS) or gestational diabetes
- Physical Inactivity

An informal risk assessment using the above mentioned risk factors should be used in adults ages18-44 to assist with risk stratification and appropriate use of the hemoglobin A1c as a screening and diagnostic tool in the diagnosis of type 2 diabetes. Individuals with an impaired fasting glucose level and one additional risk factor should be routinely screened with an A1c.

Impaired Fasting Glucose Level: Adult individuals with an impaired fasting glucose level should be screened with an A1c if they are over the age of 45, or at or under the age 44 and have one additional risk factor. For individuals at or under the age of 44 who have an impaired fasting glucose level and no other additional risk factors, age appropriate recommendations and annual fasting glucose levels should be followed.

Impaired Fasting Glucose Level and Normal Hemoglobin A1c: Adult individuals ages 18-44 with an impaired fasting glucose level and normal A1c should be screened annually with a fasting blood glucose if no other risk factors are present and they have not had an impaired fasting glucose level in the past, and every three years with a hemoglobin A1c. For individuals with at least one additional risk factor, regardless of age, an A1c should be repeated every 3-6 months until it becomes abnormal (5.7 or higher) or repeated glucose levels fall within the normal range (60-99 mg/dL).

Abnormal (elevated) Hemoglobin A1c: Adult individuals with an A1c level within the abnormal range (5.7 or higher) should be diagnosed with prediabetes or diabetes, managed appropriately and retested with an A1c in 3-6 months.

Normal Fasting Blood Glucose and Hemoglobin A1c Level in the 45 and Older Population: Adults age 40 and older with normal fasting blood glucose levels and hemoglobin A1c should have annual fasting blood work including a lipid panel, and a hemoglobin A1c should be repeated every three years.

Individuals with Sickle Cell Trait or Other Hemoglobinopathies: Adults with sickle cell disease or other disorders of the red blood cells should be screened with the 2-hour glucose tolerance test instead of the hemoglobin A1c.

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