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Aiding Screening, Diagnosis, and Management of Prediabetes Among High-Risk Medicare Patients in a Primary Care Setting

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Abstract

Purpose: Encourage prediabetes screening, testing, and referral to a CDC-recognized Diabetes Prevention Program (DPP) as a first-line treatment. **Background:** The prevalence of diabetes and prediabetes incidence is highest among Medicare-eligible Washingtonian patients, with 19% and 16%, respectively. DPP results in a 71% reduction of diabetes incidence in 65 years and older. However, only 3% of healthcare sites screen, test, and refer to DPP. **Design**: Quality assessment with a descriptive quantitative evaluation method was conducted using Retrospective Chart Review for patients who visited Franciscan primary clinics from 08/31/2019 to 08/31/2020. A total of 1250 Medicare patients were extracted from a convenient sample. Risk factors for prediabetes were identified for 224 patients, including, a first-degree family history of diabetes, history of hypertension, age, race/ethnicity, physical activity, sex, history of gestational diabetes, height, and weight and were entered into the online American Diabetes Association prediabetes risk-test. The number of patients who fulfilled the criteria for a diagnosis of prediabetes based on Fasting Plasma Glucose, Glycated Hemoglobin A1c and Random Glucose was 685. Four patients had mixed laboratory results and were excluded; the remaining 681 were considered for prediabetes management. The number of patients who did not fulfill laboratory criteria for prediabetes was 565. **Results**: All the 224 patients (100%) had risk-test scores of at least 5. The prevalence of misdiagnosis of blood glucose was 45.2%. All of the 681 patients (100%) meeting requirements of prediabetes were not referred to DPP. Only 26 patients (3.8%) were managed by either metformin (3.1%) or referral to diabetes education (0.7%). **Conclusion**: Medicare patients at high risk are not routinely screened, tested, and managed by DPP, metformin, or diabetes education. **Implication**: Practice change needs assessment of PCP awareness about diabetes risk-test, prediabetes laboratory parameters, and management by referral to DPP.

Key Words: Diabetes Prevention Program, Diabetes Risk-test, Prediabetes Lab Parameters.

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Introduction

Diabetes is a chronic disease that affects how the body metabolizes carbohydrates resulting in hyperglycemia. The condition is the seventh leading cause of death in the United States (Centers for Disease Control and Prevention, 2020). There are three main types of diabetes: type 2 accounting for 90 to 95%, type 1 accounting for 5-10%, and gestational diabetes. More than 122 million Americans live with diabetes (34.2 million), 20% of whom are unaware of their diagnosis, "and whereas 88 million live with prediabetes, nearly 85% of whom are unaware of their diagnosis" (Centers for Disease Control and Prevention, 2020). The lost wages, time at work, and medical costs in individuals with diabetes are twice as high as those without diabetes, accounting for $327 billion in health care costs each year (Centers for Disease Control and Prevention, 2020). Ultimately, the prevention of diabetes saves costs incurred for treating diabetes and its complications, including retinopathy, peripheral neuropathy, kidney disease, and cardiovascular diseases (Bansal, 2015). Additionally, early intervention in older adults prevents or slows the risk of all-cause dementia, Alzheimer disease and vascular dementia (American Diabetes Association, 2021).

Prediabetes is a precursor state of high blood sugar with glycemic parameters above normal but not high enough to diagnose diabetes (Bansal, 2015). The definition of prediabetes lacks uniformity between international organizations. The American Diabetes Association (ADA) defines prediabetes as impaired fasting plasma glucose level (100-125mg/dl), impaired 2-hour oral glucose tolerance test (140-200mg/dl), glycated hemoglobin A1c of 5.7-6.4%, and random glucose ≥140-199mg/dl (American Diabetes Association, 2014). The World Health Organization (WHO), on the other hand, defines prediabetes with the same cut-off value for impaired 2-hour oral glucose tolerance test (140-199 mg/dl) but a higher cut-off value for impaired fasting glucose (110-125mg/dl) (World Health Organization, 2006). WHO does not consider random glucose and glycated hemoglobin A1c

as a practical diagnostic test; the latter has potential interference with other hemoglobin variants such as sickle cell hemoglobin and fetal hemoglobin (World Health Organization, 2006). Like the before ADA, Diabetes Canada 2018 Clinical Practice Guideline defines prediabetes based on FPG and A1c but with a higher cuff-value (110-125mg/dl) and 6.0-6.4%, respectively (Punthakee, Goldenberg & Katz, 2018). To confirm the diagnosis of prediabetes after the initial abnormal test, providers need to repeat testing with the original screening test, run a different screening test with the initial specimen or collect another sample (American Diabetes Association, 2014) and rescreen the patient with repeat testing in 3-6 months. If the screening test is within normal range, repeat testing in three years is recommended (American Diabetes Association, 2021).

The United States Preventative Services Taskforce (USPSTF) recommends screening for abnormal blood glucose levels between the age of 40 and 70 years in individuals who are overweight or obese (United States Preventative Services Task Force, 2015), whereas ADA recommends screening starting at age 45 in all adults regardless of body weight. If screening is positive for prediabetes, the Centers for Disease Control and Prevention (CDC), International Diabetes Federation (IDF), ADA, and USPSTF recommend providers offer or refer patients to an intensive behavioral counseling intervention that promotes a healthful diet and physical activity. If left unscreened, prediabetic patients develop type II diabetes in 3-8 years (Herman *et al*., 2015), 50% of which remain undiagnosed and untreated until they develop complications later in life (International Diabetes Federation, 2017).

Overwhelming evidence from worldwide studies indicates lifestyle intervention with diet, exercise, or a combination of diet and exercise enhanced by prediabetes education prevents or delays the risk of developing diabetes. For example, lifestyle intervention reduced the risk by 46% with exercise alone, by 42% with diet and exercise, and 31% with diet alone in 577 Chinese individuals over the Da Qing Study's six-year period (Pan et al., 1997).

Another diabetes prevention study conducted in Europe, among Finish individuals, showed lifestyle intervention with significant reduction in weight, glycemia, and lipemia over three years (Lindström et al., 2003). The diabetes prevention program (DPP), a randomized clinical trial that compared lifestyle intervention with metformin and placebo in multiethnic groups in 3234 US adults with prediabetes, reinforces the importance of lifestyle change in the Chinese and Finnish studies. The DPP study involved 68% women and 45% minorities. After followed up for 2.8 years, the DPP reduced the incidence of diabetes by 58% in the lifestyle intervention group and 31% in the metformin group (Knowler et al., 2002). The reduction of incidence of diabetes by DPP was highest (71%) in US adults age 65 and older with prediabetes. However, 90% of older adults are unaware that they have prediabetes (Kalyani, Corriere, Donner, & Quartuccio, 2018). If a DPP is not available in the area, or patients are not willing to participate in the program, providers can refer patients to diabetes educators (Sherr & Lipman, 2013). Primary care providers can also initiate metformin treatment in prediabetic patients younger than 60 years, or BMI ≥35 kg/m2, and in women with gestational diabetes mellitus (American Diabetes Association, 2021). Alternatively, they can refer to medical nutrition therapy or provide a point of care brief counseling (American Medical Association, 2018).

Problem Statement

In Washington State, diabetes prevalence increased from 4% in 1993 to 9% in 2016, with the highest (19%) among Medicare eligible patients (Washington State Health Assessment, 2018). The same survey showed an increase in prediabetes incidence during 2011-2016 from 7 to 8%, with the highest (16%) among Medicare eligible patients. Unfortunately, the incidence of prediabetes is highest among adults 65 years and older despite their high awareness of prediabetes in this age group (Washington State Health Assessment, 2018). One-third of all people in Washington have prediabetes, 70% of which

could proceed to type 2 diabetes in five years, however most of them are unaware of their prediabetes status (Diabetes Epidemic and Action Report, 2019).

Background

Diabetes affects more than 25% of Americans aged 65 years and above (Andes et al., 2019). Among Medicare beneficiaries, diabetes prevalence increased from 23% in 2001 to 32% in 2012 and remained stable until 2015 (Centers for Disease Control and Prevention, 2020). Incidence of diabetes among Medicare patients increased from 3.4% in 2001 to 4 % in 2007 and then steadily declined to 3% in 2015 (Andes et al., 2019). The decline in the incidence of diabetes in older population is attributed to reduced consumption of dairy products and sugar-added beverages, and improved physical activity (Kit, et al., 2013; Ussery et al., 2017). In the last two decades, however, prevalence of diagnosed diabetes in adults doubled with aging and increased obesity (Center for Disease Control and Prevention, 2020). Approaches proven to curb progression of prediabetes to diabetes are CDC-approved DPP, metformin treatment, medical nutrition therapy, diabetes education, or point-of-care brief counseling on lifestyle change (American Medical Association, 2018).

The National DPP is the most effective evidence-based lifestyle change program that reduces the incidence of diabetes by 71% among individuals age 65 years and above when they attain a minimum of 5% weight loss (Kalyani, Corriere, Donner, & Quartuccio, 2018). The USPSTF found no evidence that the lifestyle change interventions will harm the DPP participants (US Preventive Services Task Force, 2016). However, over 60% of primary care providers are not aware of the DPP (Nhim et al., 2018).

In May 2017, the Washington State Institute for Public Policy analysis predicted that the net benefit from the DPP is $13,000 per participant, including $4,875 of benefit for taxpayers for each program participant (Diabetes Epidemic and Action Report, 2017). However, only 8 (3%) healthcare sites out of 243 routinely screen for prediabetes, order lab

tests, and refer to the DPP in the state of Washington (Diabetes Epidemic and Action Report, 2019), indicating that primary care providers in the rest 97% of healthcare sites do not refer their patients to DPP.

More than one-quarter of adults with prediabetes express interest in participating in a diabetes prevention programs, but few are being referred by their primary care providers (Venkataramani et al., 2019). There is a need to further assess existing practices of prediabetes screening, testing and referral to the CDC-recognized lifestyle change program (Nhim et al., 2018) and enhance program referral and access to diabetes prevention programs (Venkataramani et al., 2019). Practices that used retrospective chart review (RCR) identified more Medicare-eligible patients with prediabetes and increased referral to DPP than those using a routine point of care testing alone (Holliday et al., 2019). Additionally, creating a clinical registry to screen and track patients with prediabetes has resulted in more individuals with prediabetes being referred to diabetes prevention programs (American Medical Association, 2017).

Purpose and Aim

The purpose of this project is to encourage screening, testing, and referral to a DPP as a first-line treatment for prediabetes. The aims of the project through a retrospective chart review are 1) to determine prediabetes risk-test scores by assessing risk factors for prediabetes; 2) to determine the prevalence of misdiagnosis of blood glucose levels; and 3) to assess types of prediabetes management ordered by providers at the Franciscan Primary care clinics.

Theoretical Framework

The Donabedian model of quality assessment was applied as a conceptual framework for the project (Donabedian, 1988). An electronic medical record system was used as a resource to represent the structure of patient care delivery. The providers' routine practice to

assess for prediabetes risk, order laboratory tests for abnormal glucose, and management of prediabetes was used as the framework's process. The outcomes of the framework were misdiagnosis of prediabetes and untreated prediabetes.

Methodology

Study Design

A quality assessment project with a descriptive quantitative evaluation method was conducted using a RCR (Matt & Matthew, 2013) for patients who visited Franciscan Medical Group (FMG) primary clinics between 08/31/2019 to 08/31/2020.

Setting

Catholic Health Initiative (CHI) Franciscan Healthcare System of Washington has 29 primary care clinics served by an estimated 205 primary care providers of FMG (Franciscan Medical Group). Out of which 165 of the providers are physicians, and the remaining 40 are nurse practitioners and physician assistants. The number of diabetes educators who serve within the healthcare system is estimated to be 8-10. The total number of Medicare patients who visited the primary clinics within the healthcare system between 2013-2020 was 18752, with an average annual patient number of 2344.

Sample

The inclusion criteria included age 65 years and above, body mass index (BMI)≥25 kg/m2 (≥23 kg/m2, if Asian), Medicare or Medicare Advantage health plan, and laboratory test results within the last one year of Fasting Plasma Glucose (FPG) range within 100-125mg/dl, or A1c range within 5.7%-6.4%, or 2-hour Oral Glucose Tolerance Test (OGTT) range within 140-200 mg/dl), or history of gestational diabetes, and both sexes of all racial/ethnic groups. Exclusion criteria included those individuals with type 1 or type 2 diabetes, end-stage renal disease or long-term (current) use of insulin (Appendix A; Center for Medicare and Medicaid Services, 2018). Published literature indicates a minimum of 5-10

chart reviews per variable is required to obtain results that are likely to be both valid and clinically useful (Johnston et al., 2019). Johnson et al. further indicated that 100 retrospective chart reviews are sufficient for summarizing prediabetes management categories.

Demographic

The majority of 1250 Medicare patients reviewed in this quality assessment project were White or Caucasian, 1066 (85.28%), followed by Asians, Blacks, and Native Hawaiian, and they were overweight, obese, or extremely obese (Table 1).

Table 1.0

Health and Demographic Characteristics of Medicare Patients (n=1250)

Characteristics		**n**	**%**
Sex	Female	679	54.32
	Male	571	45.68
Race	White/Caucasian	1066	85.28
	Asians	47	3.76
	Blacks	42	3.36
	Declined	38	3.04
	Unable to determine	25	2
	Other	21	1.68
	Native Hawaiian	7	0.56
Ethnicity	Not Hispanic or Latino	1175	94
	Hispanic	33	2.64
	declined	25	2
	Unable to determine	17	1.36
Body Max Index	Overweight (25-29.9)	560	44.8
	Obese (30-34.9)	405	32.4
	extremely Obese (≥35)	285	22.8

A convenience sample of 18,752, Medicare patient data was retrieved from Epic, an electronic charting system. Out of 18,752 Medicare patients, 17,502 were excluded for test results older than one year, diagnosis of type 1 or type 2 diabetes, long-term (current) insulin

use, or end-stage renal disease. The remaining 1,250 Medicare patients who sought care at CHI Franciscan Primary Care Clinics within the last year between 08/31/2019 to 08/31/2020.

Out of 1,250 Medicare patients, 565 were excluded from consideration for prediabetes management because they had either normal A1c (<5.7%, n=323), A1c within diabetes range (>6.4%, n=17), or were not tested by A1c (n=225). None of the 565 patients were tested with 2-hour OGTT for prediabetes. Out of the 225 patients not tested by A1c, only one patient was tested by FPG and had normal blood glucose result; the remaining, 224 patients were tested only with random glucose and assessed for CDC prediabetes risk-test score. Samples collected to assess for prediabetes risk were first-degree family history of diabetes, history of hypertension, age, race/ethnicity, physical activity, sex, height, and weight.

A total of 685 out of the 1250 patients fulfilled laboratory inclusion criteria for prediabetes defined as FPG 100-125mg/dl or A1c 5.7%-6.4%. Four patients were excluded for having A1c levels within the diabetes range; the remaining 681 patients were considered for prediabetes management. None of these patients were tested with 2-hour OGTT for prediabetes.

Data Collection Procedure

Before collection of data, the Institutional Review Board (IRB) exempt approval was obtained from the CHI Franciscan Healthcare System to protect human subjects. The retrospective health record data was collected anonymously with no patient data identifiers. With data analysts' help at the CHI healthcare system, inclusion and exclusion criteria were entered into the Epic electronic health record system. The data analyst exported the data into an excel spreadsheet, coded the medical record number (MRN) of each patient with a specific identification number, and then removed patient identifiers.

Data on, 1250, Medicare patients who visited primary care clinics of the CHI Franciscan health care system within the last year between 08/31/2019 and 08/31/2020 was

filtered using an excel spreadsheet. Medicare patients (n=681) who fulfilled the inclusion criteria for prediabetes management were filtered within excel by the provider's plan and categorized into prediabetes management types: DPP, Metformin, diabetes education, or medical nutrition therapy (figure 1 & figure 2).

Medicare patients (n=565) who did not fulfill laboratory inclusion criteria for prediabetes were identified by laboratory test as having A1c in diabetic range, normal A1c, no A1c test, normal fasting plasma glucose, random glucose within diabetes range, or no laboratory glucose test within the last one year. However, these patients were assessed for misdiagnosis of prediabetes by filtering based on the laboratory test result and International Classification of Diseases -Tenth Revision (ICD-10 codes) such as R73.01, R73.02, R73.03, R73.09 which were retrospectively entered into Epic by providers. Out of the 565 Medicare patients, 224 were tested only by random glucose or were not tested (figure 1). The 224 were filtered within Excel by the risk factors for prediabetes, and the risk factors were entered into the online CDC prediabetes risk-test calculator (appendix B), and online scores from https://www.diabetes.org/risk-test were manually entered into an excel spreadsheet (figure 1 & figure 2).

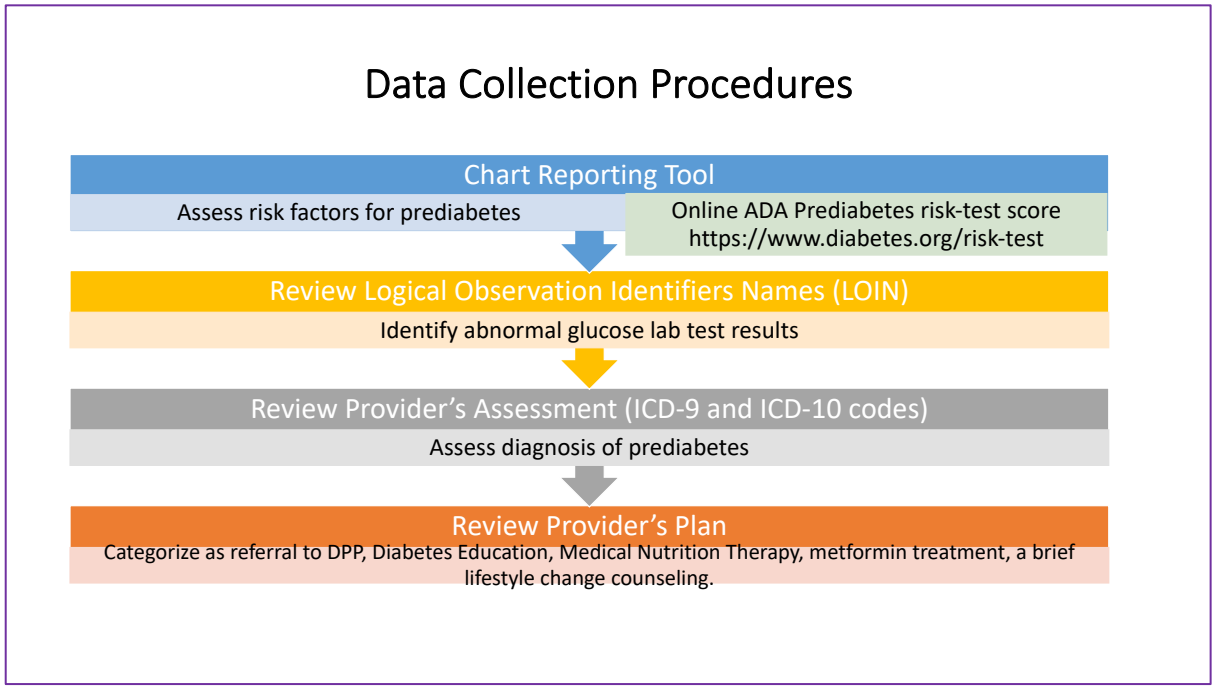

Figure 1. Steps in Data Collection Procedure.

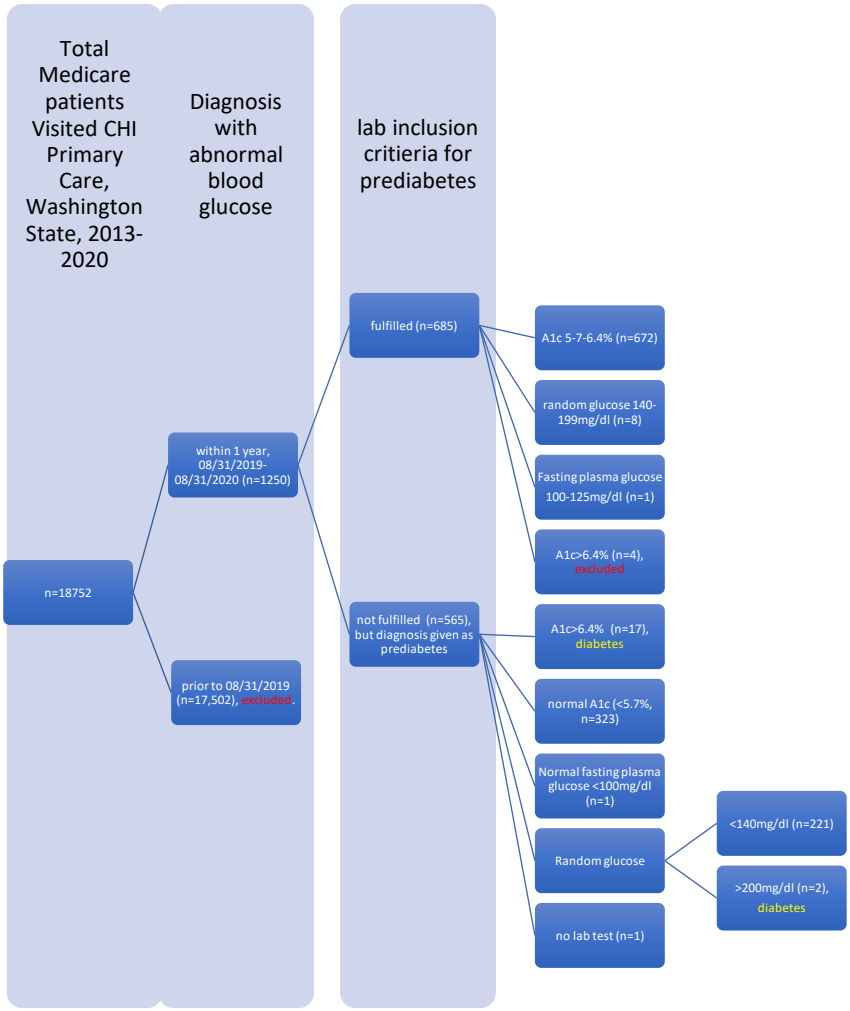

Figure 2. Flowchart of sample collection procedure

Data Analysis

Data was exported from Epic into an Excel spreadsheet. All study subjects with missing data and outliers were removed from data analysis during the cleaning process. Mode and weighted average scores as central tendency measures were calculated for prediabetes risk-test score by demographic characteristics of gender and race/ethnicity. Frequency and percentage of Medicare patients with prediabetes risk-test score of 5 or more for whom providers ordered laboratory screening tests (A1c, FPG, or 2hr-OGTT) were calculated. Mode as a measure of central tendency and percentages were calculated for prediabetes management types (DPP, Metformin, Diabetes Education, or a brief lifestyle counseling) ordered by providers. Similarly, mode as a measure of central tendency and percentage of

misdiagnosis of prediabetes by ICD-10 and laboratory test categories were calculated. The prevalence of misdiagnosis by ICD-10 codes and glucose laboratory tests was calculated.

Result

Prediabetes Risk-Test Score

All 224 (100%) Medicare patients were found to have CDC-prediabetes risk-test scores of 5 or more with 7.2, 6.8, and 7.5 weighted average scores for both sexes, females, and males respectively (table 2). None of the 224 patients (100%) were laboratory screened for prediabetes by A1c, FPG, or 2hr-OGTT (Table 2). The frequency of prediabetes score steadily increases as a score increases from 5 to 7 and decreases as the score increases from 7 to 9 in both genders with mode score of 7 (figure 3). As the prediabetes risk-test score increases from 7 to 9, within the same score, a greater number of males than females tend to be at risk for developing diabetes (figure 4). The majority of Medicare patients with scores 5 or more are white (n=197, 87.95%) followed by Asian (n=8, 3.57%), other race (n=6, 2.68%), declined (n=6, 2.68%), black (n=4, 1.79%), unable to determine race (n=3, 1.34%) (table 3, appendix D).

Table 2.0

Medicare Patients Eligible for Prediabetes Screening by Laboratory Test

Number eligible for prediabetes Risk-Test Score	Number with Prediabetes risk-test score ≥5	% eligible for screening by A1c, FPG, or OGTT-2hr	% screened by A1c, FPG, and 2hr-OGTT
224	224	100	0

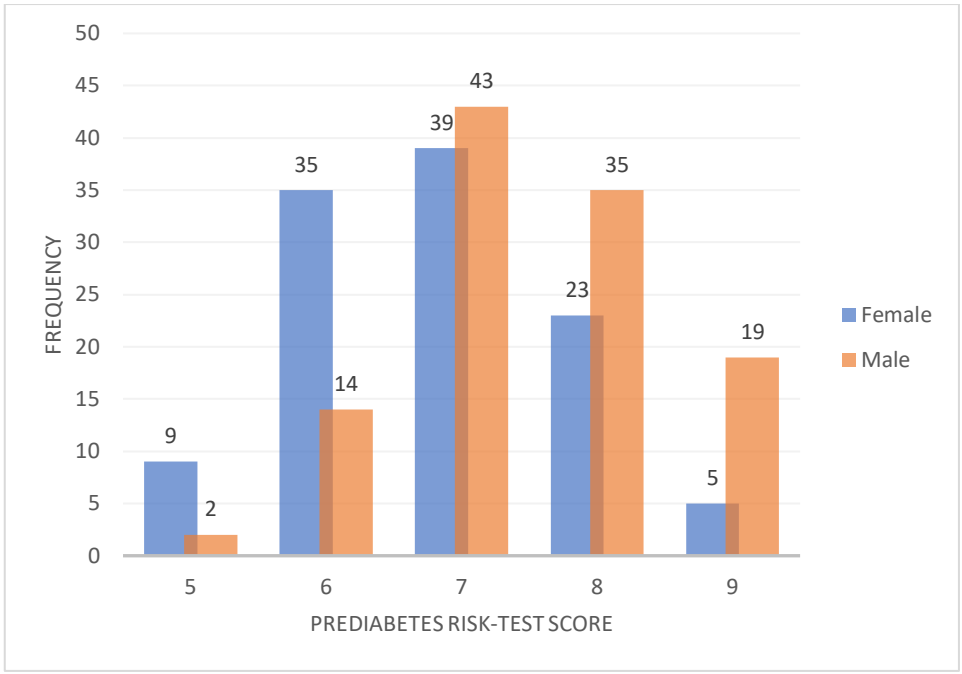

Figure 3. Frequency of Prediabetes Risk-Test Score Comparison Between Male and Female Medicare Patients.

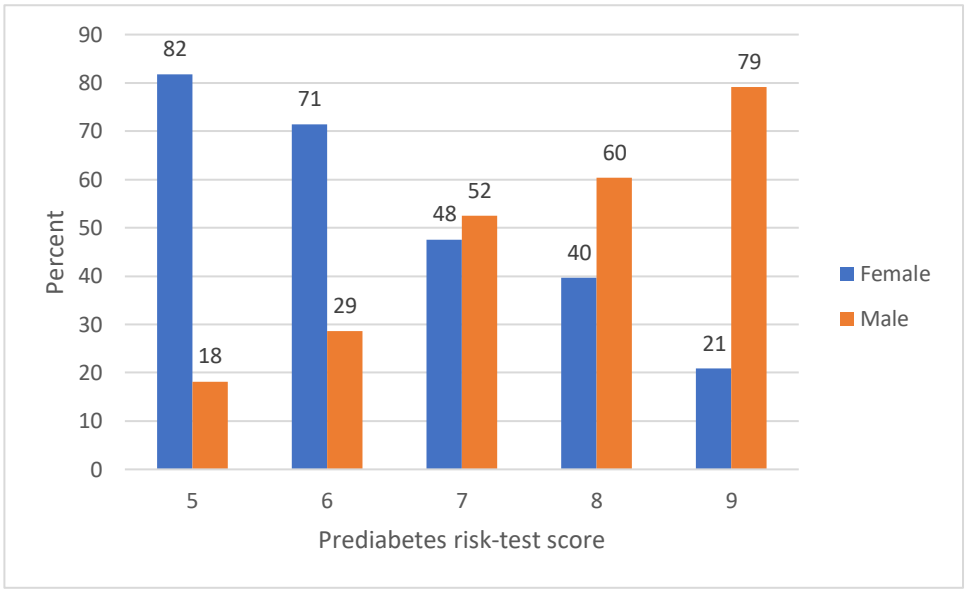

Figure 4. Percentage of Medicare Patients for each prediabetes risk-test score by gender

Table 3.0

Prediabetes Risk-Test Score by Race

	Prediabetes risk-test score	Asian	White	Black	unable to determine	other	declined	total	%
	5	1	8	0	1	1	0	11	4.9
	6	2	45	1	0	0	1	49	21.9
	7	4	69	1	1	4	3	82	36.6
	8	1	52	2	1	0	2	58	25.9
	9	0	23	0	0	1	0	24	10.71
Total		8	197	4	3	6	6	224	
%		3.5	87.95	1.79	1.34	2.68	2.68		
Weighted average	7.2	6.6	7.2	7.3	6.7	7.0	7.2		

Misdiagnosis of Blood Glucose Level

The prevalence of misdiagnosis of blood glucose level by either ICD-10 code or laboratory test was 45.2% (n=565). Most (n=201, 35.58%) of the misdiagnosis of blood glucose level was labeled as impaired fasting glucose with ICD-10 code R73.01, followed by other abnormal glucose (n=173, 30.62%, R73.09), prediabetes (n=163, 29.03%, R73.03), and impaired oral glucose (n=27, 4.78%, R73.02) (table 4, figure 5). Normal A1c level was the most (n=323, 57.17%) laboratory test misdiagnosed as abnormal blood glucose followed by normal random glucose (n=221, 39.02%), A1c>6.4% (n=17,3.01%), normal fasting plasma glucose (n=1, 0.18%) and diagnosis without laboratory test (n=1, 018%) (table 4, figure 6).

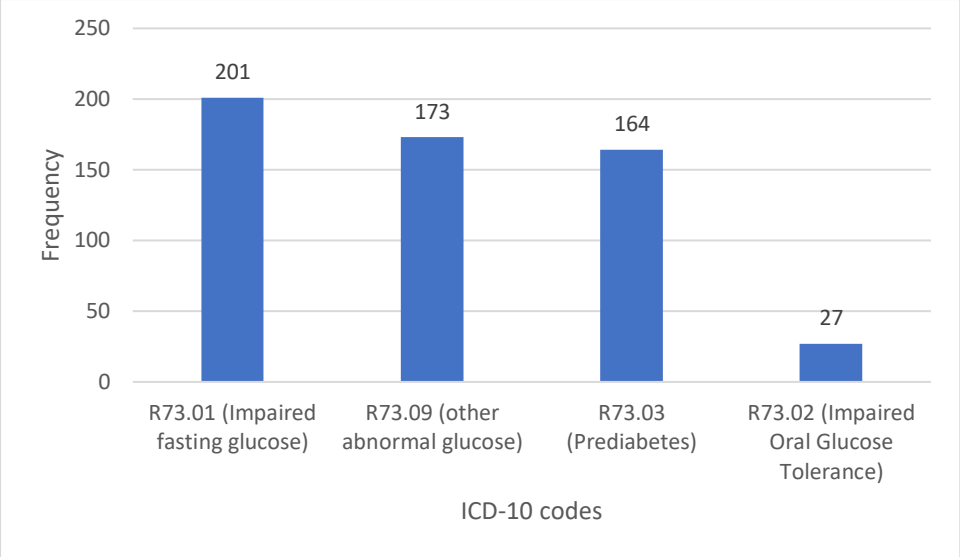

Figure 5. Frequency Distribution of Misdiagnosis of Blood Glucose Level by ICD-10 Codes (n=565).

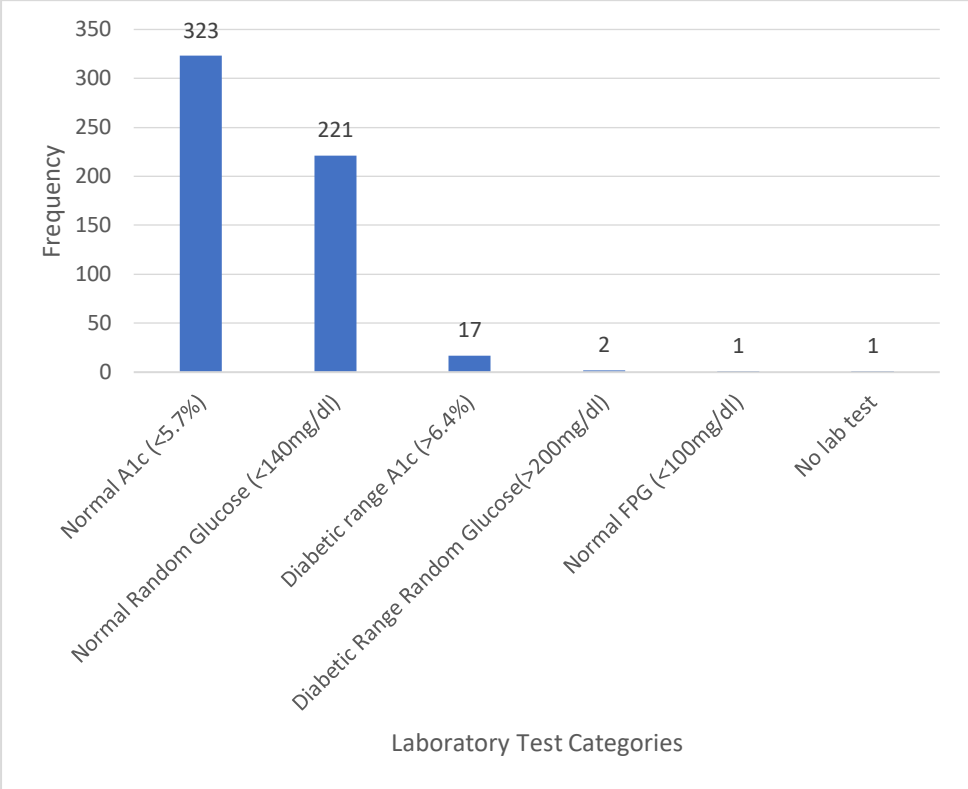

Figure 6. Frequency Distribution of Misdiagnosis of Blood Glucose Level by Laboratory Test (n=565).

Table 4.0

Misdiagnosis of Blood Glucose Level in Medicare Patients by ICD-10 and Laboratory Test Categories.

Lab Categories		ICD-10 codes					
		R73.01	R73.02	R73.03	R73.09	Total	%
A1c test	Normal A1c (<5.7%)	108	20	70	125	323	57.17
	Diabetic range A1c (>6.4%)	8	1	1	7	17	3.01
No A1c test	Normal FPG (<100mg/dl)	0	1	0	0	1	0.18
	Normal Random Glucose (<140mg/dl)	85	5	91	40	221	39.12
	Diabetic Range Random Glucose(>200mg/dl)	0	0	1	1	2	0.35
	No lab test	0	0	1	0	1	0.18
	Total	201	27	164	173	565	
	%	35.58	4.78	29.03	30.62		

Note. R73.01, Impaired fasting glucose; R73.09, other abnormal glucose; R73.03, Prediabetes; R73.02, Impaired Oral Glucose Tolerance.

Management of Prediabetes

All of Medicare patients (n=681, 100%) with prediabetes, as determined by, were not referred to a DPP, or individualized medical nutrition therapy. Only 21 patients (3.08%) were treated with metformin and 5 patients (0.73%) were referred to Diabetes Education (table 5). Due to restricted access to patients' charts, the number of Medicare patients who received a brief lifestyle counseling could not counted (table 5).

Table 5.0.

Categories of prediabetes Management

		Prediabetes Management Categories					comment
Eligible for management of prediabetes		DPP	Metformin	Diabetes Education	Medical Nutrition	Brief lifestyle counseling	
Number	681	0	21	5	0	unable to determine	excluded 4 out of 685 for having A1c>6.4 %
% managed	3.8	0	3.1	0.7	0		

Note. Laboratory criteria to be eligible for management of prediabetes are A1c 5.7-6.4%, FPG 100-125mg/dl, or Random glucose 140-199mg/dl.

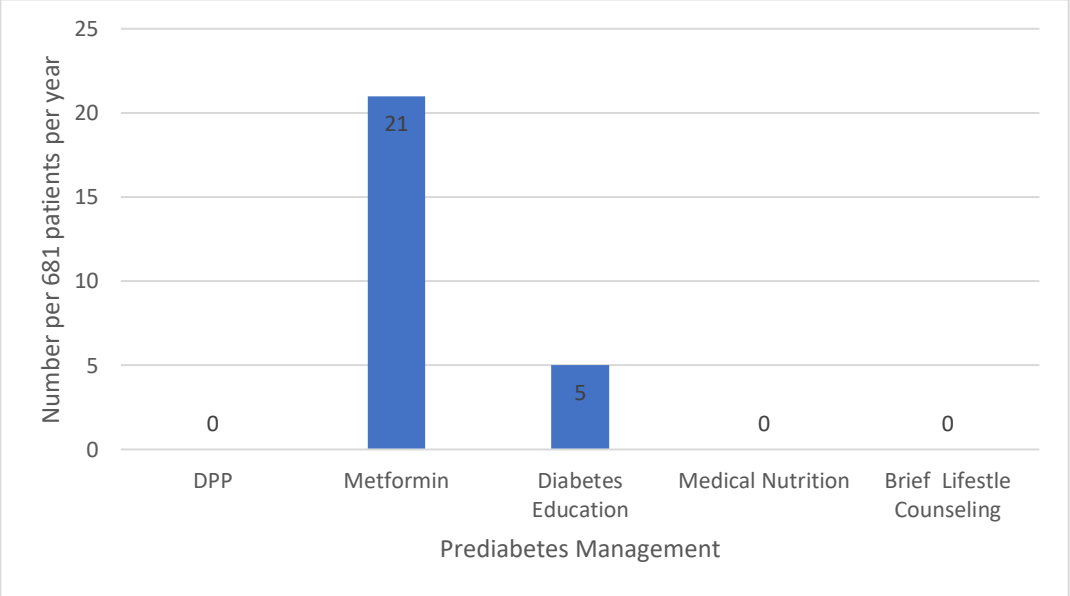

Figure 8. Medicare patients who received prediabetes management between 08/31/2019 to 08/31/2020.

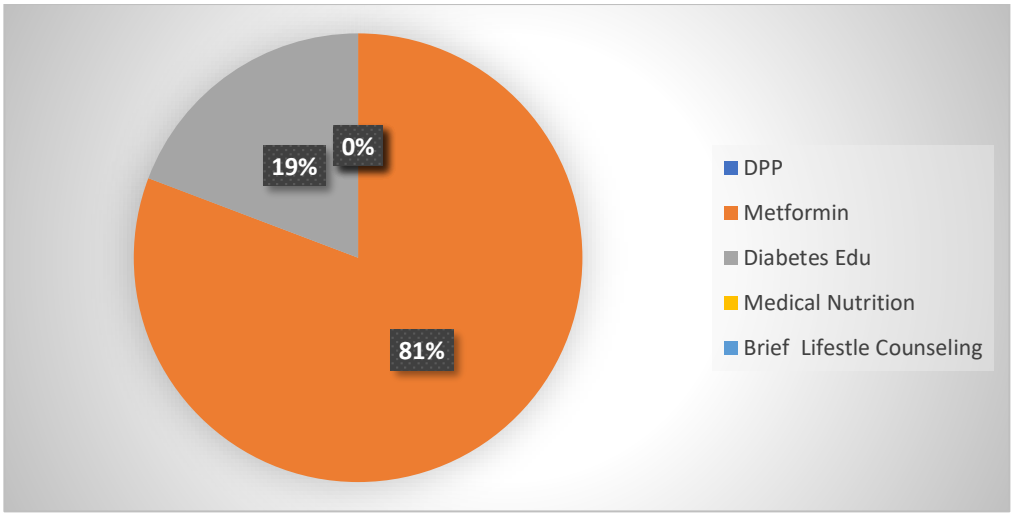

Figure 9. Medicare Patients (n=26) who received prediabetes management in primary care setting between 08/31/2019 to 08/31/2020.

Discussion

Prediabetes Risk-Test Score

The current quality assessment project's data indicates that all 224 high-risk Medicare patients who visited CHI Franciscan primary clinics were not screened for prediabetes with the CDC/ADA diabetes risk test. This finding reflects a national survey report that only 27% of primary care providers (n=1256), including MDs and ARNPs, use the risk test to screen for prediabetes (Nhim et al., 2018) and only 6% of PCPs correctly identified all the risk factors that warrants prediabetes screening (Tseng et al., 2017). More than 50% (112 out of 224) of the Medicare patients with the ADA Diabetes Risk test score of 5 or more, were not diagnosed with prediabetes (Ward, Hopkins & Shealy, 2021). This finding is in-line with the previous study that showed lack of screening in a primary care setting is one reason for delays in initiation or intensification of evidence-based treatment for diabetes (Grant et al., 2004). The low screening for prediabetes indicates an urgent need to use the CDC/ADA diabetes risk test to help primary care providers identify high-risk patients to curb epidemics of diabetes (Ward, Hopkins & Shealy, 2021).

Misdiagnosis of Blood Glucose Level

The high prevalence (45.2%) of misdiagnosis of prediabetes could be due to the lack of knowledge around recommended laboratory parameters of prediabetes and incorrect use of ICD-10 codes as demonstrated by high misinterpretation of normal blood glucose level per ADA criteria (Alc<5.7% and random glucose<140mg/dl) as abnormal. The high prevalence (45.2%) of misdiagnosis of prediabetes found in this project is supported by another study where a survey regarding PCP knowledge indicated that only 17% correctly identified laboratory parameters for prediabetes based on FPG and A1c (Tseng et al., 2017). The lack of knowledge of PCPs about laboratory parameters could be due to inadequate preparation of undergraduate medical students (Khan, Wozniak, & Kirley, 2019). Moreover, the lack of uniformity in laboratory cut-off values of prediabetes between various organizations such as WHO and ADA (Bansal, 2015) and Diabetes Canada (Punthakee, Goldenberg & Katz, 2018) could add inconsistency in interpreting laboratory parameters and use of ICD-10 codes. Misdiagnosis may unnecessarily result in overdiagnoses that could burden society in return for limited clinical value (Yudkin & Montori, 2014).

Management of Prediabetes

The majority (96.2%) of the Medicare patients with prediabetes were not managed by referral to a DPP, metformin, referral to diabetes education, or medical nutritional therapy. All these patients were eligible for in-person or online DPP, the most effective evidence-based lifestyle intervention known to prevent progression of prediabetes into diabetes. It is important to note that Medicare part B and Medicare Advantage cover costs related to glucose laboratory test screenings twice year and participation in the Medicare DPP (Center for Medicare and Medicaid Services, 2019). The lack of prediabetes management is consistent with a previous survey with 36 clinicians in a family medicine clinic where none referred patients with prediabetes to a DPP (Keck et al., 2019). The current zero referral is

also supported by a national study that showed more than 75% of primary care providers do not refer to a DPP. This is attributed to a lack of awareness about the program's existence (Nhim et al., 2018) and the role of lifestyle change in prevention of diabetes (Khan, Wozniak & Kirley, 2019). The national survey by Nhim et al. showed 62% of primary care providers are not aware of the DPP, and 81% are not knowledgeable about the STAT (Screen, Test, Act Today) toolkit, use of which is associated with increased referral to the lifestyle change program.

Once started, based on the Diabetes Prevention Program Outcome Study (DPPOS), metformin therapy should continue for the long-term, especially in prediabetic patients with a higher cut-off value of FPG 110-125 mg/dl and A1c 6.0-6.5% (Davidson, 2020). Providers should be aware that withdrawal of metformin treatment for a 1-to 2-week period may result in 64% more at risk of developing diabetes than those who have not started it (Diabetes Prevention Program Research Group, 2003).

Conclusion

This quality assessment project indicates potential need to improve clinical practice related to referral for prediabetes and patient outcomes within the CHI primary care clinics. The data showed that FMG primary care providers do not routinely screen for prediabetes using ADA/CDC prediabetes risk-test, order recommended laboratory tests for high-risk patients, refer confirmed prediabetes patients to the CDC-approved DPP suppliers, treat with metformin, and/or refer to diabetes education. As a result, 100% of CHI Medicare patients eligible for screening remained unscreened, making them at risk for undetected prediabetes or diabetes and its complications. FMG providers need to use consistent laboratory tests recommended by ADA with the correct interpretation of the results and correct ICD-10 codes to avoid the current high rate of misdiagnosis of prediabetes. Finally, FMG is encouraged to use these findings from the quality assessment to raise awareness of PCPs about the practice

gap, use of DPP as a first-line treatment for prediabetes in Medicare patients. The FMG is also encouraged to start a pilot quality improvement project with selected providers and primary care clinics to implement a trial of the Plan-Do-Study-Act cycle (Knudsen et al., 2019) of routine prediabetes screening, testing, and clinic-to-DPP referral (Appendix C). Providers can take advantage of the already established memorandum of understanding and business associate agreement between CHI Franciscan medical clinic and YMCA, the DPP supplier.

Limitations

The project has some limitations:

1. The investigator could not detect undiagnosed cases, patients who fulfilled laboratory criteria for prediabetes but not given the diagnosis, because ICD-10 codes used to extract diagnosis of abnormal blood levels resulted only in diagnosed cases.
2. The restricted access to patient charts limited access to provider's note on brief lifestyle counseling for prediabetes.
3. Most patient charts extracted retrospectively did not contain physical activity information. It is unclear whether a history of physical activity was not asked or not documented during the patient visit. As a result, the investigator could not find physical activity details in terms of duration per session and number of sessions per week in the patient's chart.
4. A survey might have been helpful to assess providers' knowledge and awareness on ADA/CDC risk-test, laboratory parameters of prediabetes, and DPP's availability. However, a follow-up survey was not part of the study protocol.
5. Although 2hr-OGTT is the best diagnostic test for prediabetes diagnosis, based on a total of 7412 randomly selected undiagnosed adults from the National Health and Nutrition Examination Survey (Tucker, 2020), the current findings heavily relied on

results of A1c, FPG, and random glucose tests. None of the study subjects had laboratory values for OGTT, even though the test agreement with A1c is only 25% and with FPG, 33.4% (Tucker, 2020). To avoid under or over-diagnosis of prediabetes, combining two of the three tests (A1c, OGTT-2hr, and FPG) produces a reliable diagnostic result (Gonzalez et al., 2020).

6. Data on medical nutrition therapy was not found likely due to lack of reimbursement from Medicare for Medicare patients with prediabetes unless A1c is 6.4 or greater.
7. Finally, this project's findings are not generalizable as the samples are not representative of all Medicare patients of all races, ethnicity, or gender.

Implications

The findings indicate that FMG primary care providers are not fully utilizing the best evidence-based diabetes prevention strategies. FMG needs to encourage their providers to screen, test, and refer high-risk prediabetes patients to DPP suppliers within their area. The lack of routine screening and testing for prediabetes contributes to the underutilization of diabetes educators who are skilled professionals able to reduce the risk of developing type II diabetes. The high prevalence of misdiagnoses of prediabetes blood glucose levels, suggests that-reviewing current guidelines and reference ranges for fasting plasma glucose, A1c, oral glucose tolerance test, and random glucose tests would be beneficial for providers. Assigning the correct ICD-10 codes during the patient visit for abnormal blood glucose levels specific to the laboratory test would further improve diagnosis. Increasing provider's awareness of identifying high-risk patients using ADA/CDC prediabetes risk-test tool, preferably a screening tool embedded within the Epic, would prompt providers to place an order for specific recommended prediabetes blood glucose tests and increase referral of those Medicare patients with prediabetes to DDP suppliers, ultimately decreasing the incidence of diabetes at CHI.

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Appendix A. Eligibility Criteria

Medicare Diabetes Prevention Program (MDPP)

Beneficiary Eligibility Fact Sheet

This checklist contains a summary of MDPP beneficiary eligibility requirements, as well as tips that MDPP suppliers can use to determine beneficiary eligibility. A full list of the beneficiary eligibility requirements can be found in the CY18 Medicare Physician Fee Schedule final rule at 42 C.F.R. 410.79(c).

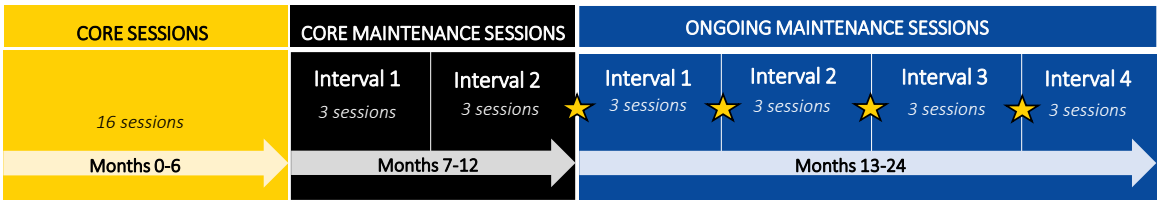
REQUIREMENTS TO START SERVICES

To start MDPP services, beneficiaries must have:

- ❑ **Medicare Part B coverage** through Original Medicare (Fee-for-Service) or a Medicare Advantage (MA) plan.
- ❑ Results from one of three **blood tests** conducted within one year before the first core session:
  - **Hemoglobin A1c test with a value of 5.7-6.4%**
  - **Fasting plasma glucose test with a value of 110-125 mg/dl**
  - **Oral glucose tolerance test with a value of 140-199 mg/dl**
- ❑ **A body mass index (BMI)** of at least 25, 23 if self-identified as Asian.
- ❑ **No history of type 1 or type 2 diabetes**, with the exception of gestational diabetes.
- ❑ **No End Stage Renal Disease** (ESRD).
- ❑ **Not received MDPP services previously.**

REQUIREMENTS TO CONTINUE SERVICES

★ *Represents when a beneficiary must meet a specific performance goal (i.e., attendance, weight loss) to be eligible to continue having coverage of services.*



Eligibility for Coverage of Core and Core Maintenance Sessions

- Eligible beneficiaries can participate in core and core maintenance sessions in the first 12 months regardless of attendance or weight loss.

Eligibility for Coverage of Ongoing Maintenance Sessions

- *Interval 1*: Beneficiaries must attend at least one in-person core maintenance session during months 10-12 and achieve or maintain 5% weight loss to proceed to interval 1.
- *Intervals 2-4:* Beneficiaries must attend at least two sessions (at least one in-person) in the previous interval and maintain 5% weight loss to go on to the next interval.

Note: An interval is a 3-month period tied to beneficiary performance and payment.

1

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Appendix B. Prediabetes Risk Test

Prediabetes Risk Test

NATIONAL DIABETES PREVENTION PROGRAM

1. How old are you?

Write your score in the boxes below

Younger than 40 years (0 points)
40–49 years (1 point)
50–59 years (2 points)
60 years or older (3 points)

2. Are you a man or a woman?

Man (1 point) Woman (0 points)

3. If you are a woman, have you ever been diagnosed with gestational diabetes?

Yes (1 point) No (0 points)

4. Do you have a mother, father, sister, or brother with diabetes?

Yes (1 point) No (0 points)

5. Have you ever been diagnosed with high blood pressure?

Yes (1 point) No (0 points)

6. Are you physically active?

Yes (0 points) No (1 point)

7. What is your weight category?

(See chart at right)

Total score:

Height	Weight (lbs.)		
4'10"	119-142	143-190	191+
4'11"	124-147	148-197	198+
5'0"	128-152	153-203	204+
5'1"	132-157	158-210	211+
5'2"	136-163	164-217	218+
5'3"	141-168	169-224	225+
5'4"	145-173	174-231	232+
5'5"	150-179	180-239	240+
5'6"	155-185	186-246	247+
5'7"	159-190	191-254	255+
5'8"	164-196	197-261	262+
5'9"	169-202	203-269	270+
5'10"	174-208	209-277	278+
5'11"	179-214	215-285	286+
6'0"	184-220	221-293	294+
6'1"	189-226	227-301	302+
6'2"	194-232	233-310	311+
6'3"	200-239	240-318	319+
6'4"	205-245	246-327	328+
	1 Point	2 Points	3 Points
	You weigh less than the 1 Point column (0 points)		

Adapted from Bang et al., Ann Intern Med 151:775-783, 2009. Original algorithm was validated without gestational diabetes as part of the model.

If you scored 5 or higher

You are at increased risk for having prediabetes and are at high risk for type 2 diabetes. However, only your doctor can tell for sure if you have type 2 diabetes or prediabetes, a condition in which blood sugar levels are higher than normal but not high enough yet to be diagnosed as type 2 diabetes. Talk to your doctor to see if additional testing is needed.

If you are African American, Hispanic/Latino American, American Indian/Alaska Native, Asian American, or Pacific Islander, you are at higher risk for prediabetes and type 2 diabetes. Also, if you are Asian American, you are at increased risk for type 2 diabetes at a lower weight (about 15 pounds lower than weights in the 1 Point column). Talk to your doctor to see if you should have your blood sugar tested.

You can reduce your risk for type 2 diabetes

Find out how you can reverse prediabetes and prevent or delay type 2 diabetes through a CDC-recognized lifestyle change program at https://www.cdc.gov/diabetes/prevention/lifestyle-program.

Risk Test provided by the American Diabetes Association and the Centers for Disease Control and Prevention.

American Diabetes Association. CDC Centers for Disease Control and Prevention

CS300699-A

Appendix C. Diabetes Prevention Program Referral Template

National Diabetes Prevention Program (National DPP) lifestyle change program referral template

This resource can be used as a guide for creating a form to refer patients from clinical settings to a National DPP lifestyle change program provider. The elements noted comprise key information to include in a referral and a sample template is also displayed below.

- Patient information: Name, contact information (address, phone, email), birth date/age, gender, health insurance, employer, preferred method of contact, preferred time to contact.
- Health care provider information: Physician/provider name, practice name, practice contact name, practice information (address, phone, fax, etc.)
- Other information: Date of referral, authorization information (language that meets your organization's specific legal requirements for privacy and security, etc.), eligibility for program information (patient body mass index, medical history and blood test results), signatures of physician/ordering provider and patient OR patient representative.

This resource is provided for informational purposes only and does not constitute legal advice. Please consult with a qualified legal advisor to create a resource for use within your organization.

Send to (program name): Fax/Email:

Patient information	
Name	Address
Gender	City
Birth date (mm/dd/yy)	State
Employer	ZIP code
Preferred me d of conta	Phone
Preferred tim contact	Health Insurance
Health care pr der informa n	
Physician/NP/PA	Address
Practice name	City
Phone	State
Fax	ZIP code

Date: _____ Health c e provi signatu _____

Authorization for release of health informatio sert your o s specific legal language here.]

Referral eligibility information:

Criteria	Referen nge	Result
☐ Body Mass Index (BMI)	Eligibility = ≥25 (≥22 sian)	_____
☐ Blood test		
• Hemoglobin A1C	5.7-6.4%	_____
• Fasting plasma glucose	100-125 mg/dL	_____
• 2-hour oral glucose tolerance test	140-199 mg/dL	_____

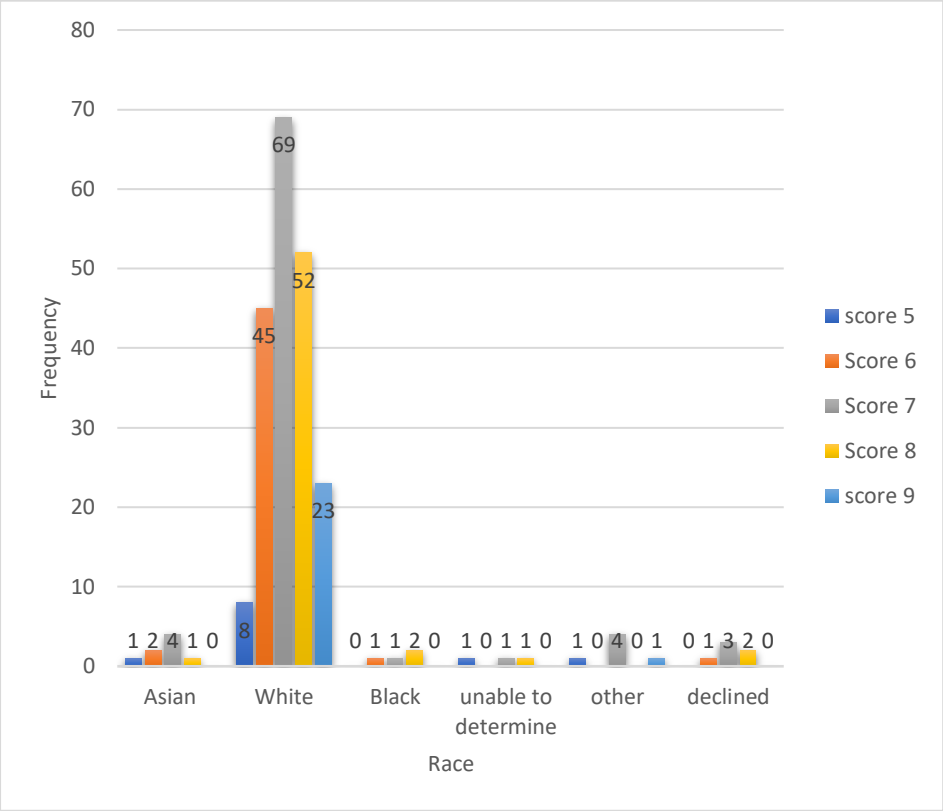
Date of blood test (mm/dd/yy): _____

☐ History of Gestational Diabetes

Date: _____ Patient or representative signature: _____

(Basis of representative's authority to sign on behalf of patient: _____)

Appendix D. Prediabetes Score Frequency by Race



Frequency of Prediabetic Score Among Racial/Ethnic Groups (n=224)