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Description of a pharmacist-led diabetes prevention service within an employer-based wellness program

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Abstract

Objective—To describe a pharmacist-led diabetes prevention service piloted within an employer-based wellness program.

Practice Description—A pharmacist-led, ambulatory care clinic within a school of pharmacy that provides wellness services to university employees.

Practice Innovation—Implementation of a diabetes prevention service utilizing opportunistic A1C screening within a biometric screening program. Patients with a prediabetes-level A1C were invited to participate in the National Diabetes Prevention Program (NDPP) in July 2016-March 2019.

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Conflicts of interest: None of the authors has anything to disclose.

Evaluation—Comparison of baseline characteristics of participants with normal and elevated A1C. Evaluation of participation in the NDPP and changes in clinical values at the subsequent biometric screening appointment for individuals with a prediabetes-level AlC.

Results—A1C testing of 740 individuals identified sixty-nine (9.3%) participants with a prediabetes-level, and seven (1.0%) with a diabetes-level A1C. Compared to those with a normal A1C (<5.7%), participants with an elevated A1C were more likely to be older, non-white, obese, physically inactive, have a sibling with diabetes, higher random blood sugar (RBS), lower high-density lipoprotein (HDL), and more likely to have hypertension. Twelve patients participated in the NDPP, though most attended only one session. Attenders had a significantly lower baseline weight and body mass index (BMI). There were no significant differences in the changes in A1C, BMI, weight, RBS, or HDL between attenders and non-attenders approximately one year later.

Conclusion—This pilot demonstrated that opportunistic A1C testing could be incorporated into an ambulatory care clinic within a pharmacist-led, employer-based wellness program. Uptake and retention of the NDPP were poor. Barriers to NDPP participation need to be investigated and addressed to improve service impact.

According to recent estimates, approximately 34% of American adults have prediabetes, though only 12% are aware.[1] Prediabetes is the condition of impaired glucose regulation that immediately precedes the onset of type 2 diabetes (T2D). It is diagnosed by an A1C of 5.7–6.4%, fasting plasma glucose (FPG) of 100–125 mg/dL, or 2-hour plasma glucose after a 75-gram oral glucose tolerance test (OGTT) of 140–199 mg/dL followed by confirmatory testing via one of the previous methods.[2] Individuals aged 45 years and older with prediabetes have an estimated 70% lifetime risk for the development of T2D.[3] Those with prediabetes are also at higher risk than those with euglycemia for the development of cardiovascular disease and coronary heart disease.[4] T2D is a significant and growing public health concern that places a significant burden on the nation's healthcare system and contributes to extensive morbidity and mortality nationwide.[5] Timely treatment and preventative efforts are essential for improving population health and tempering the impact of T2D on healthcare spending and utilization.[6]

The Diabetes Prevention Program Research Group demonstrated that progression to T2D from prediabetes can be delayed or prevented through an intensive lifestyle intervention that emphasizes healthy eating and increasing physical activity leading to a loss of 5–7% of baseline body weight.[7] This intervention has been adapted and provided for public use as the National Diabetes Prevention Program (NDPP).[8] Research has shown that the health benefits of the NDPP are retained at least 15 years after program participation.[9] The potential impact of prevention efforts has been recognized by the HealthyPeople2020 initiative and included within the diabetes objectives. Objective D-16 seeks to increase the proportion of individuals with prediabetes that are engaged in the preventive behaviors of increasing physical activity, trying to lose weight, and/or decreasing calories.[10] A proposed objective for HealthyPeople2030 (D-2030–09) is to decrease the number of adults with undiagnosed prediabetes.[11] Bullard and colleagues previously demonstrated that only half of individuals meeting guideline criteria reported blood sugar testing within the last 3 years (2007–2012).[12] In order to meet the goals of the HealthyPeople initiative and to improve screening and intervention rates, changes in identification procedures are needed.

National efforts to improve the identification and intervention for prediabetes have been recently endorsed by the nation's leading health organizations. A collaboration between the Centers for Disease Control (CDC), the American Diabetes Association (ADA), the American Medical Association (AMA), and the Ad Council launched a series of public service announcements focused on increasing prediabetes awareness in order to encourage individuals to learn about their personal risk and to take action.[13] In 2018, the CDC published a guide for community pharmacists that outlined how to implement and sustain a diabetes prevention service in the community pharmacy setting.[14] This guidance followed the 2018 implementation of the Medicare Diabetes Prevention Program (MDPP), which established a payment model for all organizations, including pharmacy practices, providing the NDPP to eligible Medicare beneficiaries.[15] Though guidance materials about the implementation of the MDPP and NDPP are available for community pharmacy practices, data are lacking about implementation in ambulatory care pharmacy settings, specifically in employer-based programs. Given that pharmacists are uniquely positioned to identify individuals with prediabetes and to provide intervention in the populations they serve, the potential exists to make a large impact in the campaign to lower the incidence of T2D nationwide.

OBJECTIVE

The purpose of this report was to describe the implementation of a pharmacist-led diabetes prevention service that leveraged an existing biometric screening program within an employer-sponsored wellness program.

SETTING

The Auburn University Pharmaceutical Care Center (AUPCC) is a pharmacist-led ambulatory care clinic that provides services to university employees, their dependents, and the local community. The mission of the clinic is to develop and provide innovative services to its patients and to serve as a training site for student and resident pharmacists. The AUPCC is staffed by one full-time pharmacist, one eight-hour per week faculty pharmacist, two to three fourth year student pharmacists on advanced pharmacy practice experience (APPE) rotations, and one ambulatory care resident. A faculty-level dietician sees patients eight hours per week. Offered services include immunizations, medication therapy management (MTM), diabetes self-management, weight loss, smoking cessation, and anticoagulation. The clinic has five patient rooms, a CLIA-waived laboratory, a conference room, and several offices. This study made use of the laboratory for clinical testing and the conference room for delivery of the NDPP. The clinic is funded through a combination of negotiated services billable to the university insurance program and out-of-pocket costs to patients. This research was approved by the Institutional Review Board of Auburn University.

PRACTICE DESCRIPTION AND INNOVATION

In 2010, the AUPCC began to offer an incentivized, biometric screening program for adult subscribers to the university's employee health insurance program. Subscribers are eligible

for a monthly insurance premium deduction if they complete an annual screening and complete follow-up on abnormal values as outlined in the program. The clinic screens approximately 5,000 individuals per year, the majority of which return to the clinic for annual screenings. The goal of the program is to provide early identification and intervention for uncontrolled and/or undiagnosed chronic disease. During the screening appointment, blood pressure (BP), random blood sugar (RBS), cholesterol (total, high density lipoprotein (HDL), and non-HDL via the Cholestech-LDX 300®), and body composition (bioelectrical impedance analysis (BIA); Tanita TBA-300A®) are measured and evaluated. Participants are educated on their results and behavioral counseling and referrals to primary care are made, as appropriate.

This pilot was conducted from July 2016 to March 2019. All patients reporting to the clinic for a regularly scheduled biometric screening appointment from July 2016 to March 2017 were invited to have their A1C measured via the A1C Now Plus® point-of-care device (POC) using a finger stick blood sample. POC A1C testing was used due to the ease of testing within the clinic setting, reliability of the instrument used, the inability to obtain fasting or 2-hour post-prandial blood sugar readings for the population due to appointment scheduling and logistical barriers, and the lack of criteria for use of RBS as a predictor of prediabetes.[2] Participants were counseled based on A1C value: normal A1C (< 5.7%): told that he/she did not have an A1C indicative of prediabetes and counseled on personal risk factors; prediabetes-level A1C (5.7%−6.4%): counseled about prediabetes and patient-specific risk factors and invited to participate in the clinic-delivered NDPP curriculum; diabetes-level A1C (≥ 6.5%): counseled on personal diabetes risk and referred to a primary care provider for follow-up. Individuals were excluded from testing if they were less than 19 years of age, pregnant, or had a pre-existing diagnosis of diabetes.

All participants with a prediabetes-level A1C were invited to participate in the NDPP. They received a flyer that defined prediabetes and provided information about the associated health risks and information about participating in the NDPP in the clinic. The NDPP curriculum is freely available online at the CDC's website and was delivered as outlined in the materials.[16,17] The NDPP core sessions, 16 classes spanning 6 months, were delivered in the clinic, free of charge, in 1-hour sessions by the part-time pharmacist or dietitian, depending on the session topic. Sessions covered healthy eating, physical activity, and behavioral topics and required participants to make session-specific goals.[16] The recommended attendance schedule in our clinic was one session every other week for 24 weeks and completion of four pre-recorded sessions online. Participants could take the courses in any order after completing the introductory session. Each session was offered at multiple and varied times, and all eligible participants received bi-weekly email updates of the weekly schedule. At each session, participants received a participant guide and session-associated goals were developed with aid from the session facilitator. Weight and activity level were assessed at the beginning of each session.

EVALUATION

The prevalence of prediabetes and undiagnosed diabetes, based on A1C results, was determined. A comparison of characteristics for participants with a normal versus elevated

(prediabetes- or diabetes-level) A1C was made using t test and chi-square analyses. For participants found to have a prediabetes-level A1C, clinical data including A1C, BMI, RBS, and HDL were reassessed approximately 1-year later when participants returned for their subsequent biometric screening appointment. Participation in the NDPP was assessed. Changes in A1C, weight, BMI, RBS, and HDL across years and stratified by NDPP participation, were compared utilizing t test analysis.

Results

During the study period, 740 individuals met inclusion criteria and consented to participate. The participant population was 45.0 ± 11.5 years of age, 54.7% female, 81.5% white, and 61.8% overweight or obese (average BMI = 27.5 ± 6.1 kg/m^2). The prevalence of prediabetes was 9.3%. Seven individuals had an A1C ≥ 6.5% (1.0%), an average of 7.2%, suggesting undiagnosed diabetes. This gave a combined prevalence of elevated A1C of 10.3%. Individuals with a diabetes-level A1C were referred to primary care for follow-up. Individuals with an elevated A1C differed significantly from those with a normal A1C based on known risk factors. (Table 1) Twelve participants with a prediabetes-level A1C attended at least one session of the NDPP, though only 3 met the minimum requirement of 4 sessions attended and most attended only the introductory session.[18] The average class attendance was 3 sessions. One participant was released from classes due to being underweight and highly physically active.[17]

Follow-up data was available for 55 participants with a prediabetes-level A1C. The average time to follow-up was 441 ± 124 days. Participants that attended at least one session of the NDPP (“attenders”) demonstrated a significantly lower weight and BMI than individuals who did not participate in the sessions (non-attenders) at baseline (Table 2). Attenders experienced nonsignificant decreases of 0.01%, 0.34%, and 0.11kg/m^2 for A1C, weight, and BMI, respectively while non-attenders experienced non-significant increases of 0.1%, 0.47%, and 0.003 kg/m^2 for A1C, weight, and BMI, respectively. There were no significant changes in A1C, BMI, RBS, or HDL within or between groups. Two non-attenders and one attender experienced an elevation in A1C into the diabetes range and were referred to primary care (+0.7% and +0.6%, respectively). Two attenders and five non-attenders experienced an A1C decrease into the normal range (−0.6% and −0.4% average decrease, respectively). Follow-up A1C data was only available for 22 of the 43 non-attenders.

PRACTICE IMPLICATIONS

This pilot demonstrated that opportunistic screening for prediabetes and undiagnosed diabetes could be integrated into an employer-based wellness program within a pharmacist-led ambulatory care clinic. A1C testing and counseling resulted in an increase in appointment time of less than five minutes. There was no need for an additional fingerstick or copay since the testing was integrated into an existing clinical appointment. The cost for testing supplies was approximately $9 per patient. Acceptance of A1C testing by patients was high.

Early identification and intervention for the three patients with a diabetes-level A1C at follow-up had the potential to decrease their risk for future complications. Though

participation was low in this pilot, the NDPP can be provided in the ambulatory care setting in order to create a comprehensive diabetes prevention service. Higher participation rates have been reported previously[14], so the low participation found in this study may not be representative of other settings or populations. This service was temporarily halted in order to investigate methods to improve participation in the NDPP intervention. Barriers to participation and retention in this setting are currently under investigation. Interestingly, attenders of the NDPP had a significantly lower baseline body weight and BMI than non-attenders. Though the change in percent of baseline body weight was not significant between groups, the NDPP attenders' average percent weight loss was consistent with what was expected based on an average attendance of 3 sessions and previous findings.[18]

DISCUSSION

The aim of this study was to describe the implementation of a diabetes prevention service within an employer-based wellness program in a pharmacist-led ambulatory care clinic. Adams and colleagues previously demonstrated that an employer-based wellness program could be used to retrospectively identify individuals at risk for T2D through review of electronic health records (EHR). Identified individuals were invited, by mail, to receive additional testing to determine their glycemic status, but only one-third returned to clinic for blood sugar testing. The authors concluded that the time and infrastructure needed to identify, contact, test, and follow-up with at-risk patients via this method was not economically feasible. Further, neither time frame nor process for secondary review of patient records was proposed.[19] We sought to improve the rate of laboratory testing for patients at risk for elevated A1C and lower the cost of identifying at-risk patients by implementing a prospective, rather than retrospective, screening program. Our service did not require an additional appointment, payment of a copay, or a significant increase in appointment time.

Interestingly, the prevalence of A1C-positive prediabetes in this population was significantly lower than national averages and recent reports.[20, 21, 22] This could be due to average population age, sensitivity of A1C[2], the employer emphasis on wellness, or the activity level of the population. Nearly 55% of all participants reported at least 150 minutes of weekly physical activity. According to the CDC, only about 20% of U.S. adults meet this goal.[23]

Participation in the NDPP was low despite removing the barriers of cost and a rigid class schedule. Barriers to participation are currently being investigated and may include perceived lack of time to attend in-person sessions, personal motivation, the work-site setting, scheduling sessions during normal work hours, perception of personal risk, perceived importance, lack of incentivization, or self-efficacy for improving health or health behaviors.[24,25,26]

In a small subset (32 participants), repeat A1C testing in the second year revealed that half of the patients experienced an increase in A1C and that approximately 10% progressed to T2D, consistent with previous findings.[27] This reinforces the need for improving participation in the NDPP.

Limitations.

Limitations in this study include the low prevalence of prediabetes and low participation in the NDPP. Another limitation includes an inability to measure behavioral changes patients made outside of our program, such as changes in eating habits, physical activity, or seeking classes or support through another program or organization as a result of this study.

Though POC A1C testing is commonly used for research and screening in the ambulatory care setting,[28,29,30,31] there are some disadvantages and controversy associated with its use. A1C is known to be less sensitive for detecting diabetes using the threshold of 6.5%, missing approximately one-third of individuals who would have been identified by a fasting plasma glucose of ≥126 mg/dL. This could decrease the number of patients identified to have prediabetes. A1C is also affected by conditions that affect hemoglobin such as anemia, hemolysis, blood transfusion, genetics, pregnancy, HIV treatment, and erythropoietin therapy.[2] According to the manufacturer of the A1C Now Plus® meter used in this study, the meter has demonstrated a 99% accuracy (confidence intervals (CI) = −1.0 – 0.8%) with fingerstick samples and 99.7% accuracy (CI= −0.8% to 0.7%) when compared to venous sampling.[32] Meter accuracy combined with low sensitivity and natural fluctuations may have resulted in misclassification for patients with a reading near the classification thresholds. Confirmatory testing via a second A1C test, FPG, or OGTT could be used to verify A1C results as recommended by the 2019 Standards of Care in Diabetes.[2] Patients with an A1C ≥6.5% were referred to primary care for confirmatory testing and those with an A1C of 5.7–6.4% were not re-tested due to the associated time, cost, and low benefit of repeat testing in the context of our program. Participation in the NDPP has a low risk for harm and high potential for benefit, even for patients with prediabetes risk factors that do not include elevated A1C.

CONCLUSION

An ambulatory care pharmacy clinic serving an employer-based wellness program was found to be a viable setting to perform opportunistic screening for prediabetes and undiagnosed diabetes. A minority of individuals identified to have prediabetes participated in a no-cost offering of the National Diabetes Prevention Program. Barriers to participation need to be elucidated in order to improve the impact of the prevention service.

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Key Points

Background

1. Approximately one-third of American adults currently have prediabetes and most are unaware of their increased risk for the development of type 2 diabetes. Early identification and intervention for individuals with prediabetes is a goal shared by the HealthyPeople2020 initiative, American Diabetes Association (ADA), American Medical Association (AMA), and Centers for Disease Control (CDC).
2. The CDC endorses enhanced screening for prediabetes by pharmacists and has published recommendations for developing screening services in the community pharmacy setting.

Findings

1. Opportunistic A1C testing can be successfully integrated into an ambulatory care pharmacy practice and employer-sponsored wellness program.
2. Despite providing a no-cost, evidence-based intervention for diabetes prevention, the majority of patients with prediabetes did not participate. Barriers to participation in the National Diabetes Prevention Program should be further investigated.

Table 1.

Participant demographics

	Normal n=664[a]	PreDM/DM n=76	p value[b]
Average age ±SD	44.4 ± 11.5	50.5 ± 10.5	<.001
Sex			0.011
Male	311	24	
Female	353	52	
Race/Ethnicity			<0.001
White	560	43	
African American	45	22	
Asian	39	8	
Hispanic	13	0	
Other	7	3	
Average BMI ±SD	27.1 ± 5.8	31.0 ±7.0	<.001
RBS ± SD	98.2 ± 17.2	107.9 ± 28.4	0.005
HDL ± SD	55.1 ± 17.2	50.8 ± 14.3	0.016
Parent with DM	175	28	0.054
Sibling with DM	34	11	0.001
Inactivity	286	48	0.002
Baby > 9lbs	33	4	.916
HTN	97	21	0.003
Smoker	17	3	0.489

PreDM = prediabetes; DM = diabetes; SD = standard deviation; BMI = body mass index in kg/m^2; RBS = random blood sugar; HDL = high-density lipoprotein; HTN = hypertension

[a] Complete data is not available for all parameters

[b] Two-sided T-test was used for I/R data and Chi-square analysis was used for nominal data

Table 2.

Comparison of outcomes stratified by class attendance

	Attenders n=11	Non-attenders n=43[a]	p value[b]
Average age ±SD	48.8 ± 9.9	50.7 ± 9.9	0.58
Sex			0.54
Male	3	16	
Female	8	27	
Race/Ethnicity			0.25
White	5	26	
African American	3	12	
Asian	3	3	
Hispanic	0	0	
Other	0	2	
Average BMI ±SD	26.8 ± 5.8	33.0 ±7.2	<0.01
BMI change ±SD	−0.04 ±0.61	0.003 ±1.8	0.93
Average weight ±SD	166.9 ±30.7	211.8 ±48.5	<0.01
% Weight change ±SD	−0.34 ± 2.2	0.47 ±5.0	0.60
Baseline activity Level			
Active	7	15	0.08
Inactive	4	28	
Average A1C ±SD	5.8 ± 0.5	5.9 ±0.2	0.97
A1C change[c]	−0.01 ±0.4	0.1 ± 0.4	0.66

SD = standard deviation; BMI = body mass index in kg/m^2

[a] Data is only included for participants for which follow-up data was available

[b] Two-sided T-test was used for I/R data and Chi-square analysis was used for nominal data

[c] Data was available for only 10 of the attenders and 22 of the non-attenders