KANSAS JOURNAL of MEDICINE

Identifying Opportunities for Impact of Community-Based Pharmacist-Led Biometric Health Screenings on ASCVD Risk

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Received Sept. 16, 2022; Accepted for publication March 7, 2023; Published online April 24, 2023
https://doi.org/10.17161/kjm.vol16.18514

ABSTRACT

Introduction. Community-based pharmacists are positioned uniquely to assist in the early detection of underlying cardiovascular disease (CVD) which affects approximately 50% of adults in the United States. Organizations utilize community-based pharmacists to conduct annual biometric health screenings to help employees identify health risks previously undetected. The goal of this study was to evaluate how community-based pharmacists could impact lifetime atherosclerotic cardiovascular disease (ASCVD) risk for a large population.

Methods. This study was a retrospective analysis of annual pharmacist-led 15-minute biometric health screening data from a large regional community-based pharmacy chain. Employees between the ages of 20 and 79 who had completed at least three biometric health screenings between July 1, 2015 and June 30, 2020 were included. Incomplete biometric health screening records were excluded. To calculate lifetime ASCVD risk and identify perceived gaps in care, prescription fill history of study participants was used. The pharmacists did not make clinical interventions; however, education was provided with the information found.

Results. A total of 10,001 patients were included. Median baseline ASCVD risk was 1.5% and increased to 1.8% ($p < 0.001$). Additionally, 1,187 patients with an elevated ASCVD risk ≥ 7.5%, showed statistically significant improvements in blood pressure, body mass index, and cholesterol.

Conclusions. Improvements for high-risk patients were seen in several biometric health screening parameters including blood pressure, body mass index, and cholesterol. Community-based pharmacists were well positioned to intervene clinically to support reduction of ASCVD lifetime risk. ***Kans J Med 2023;16:88-93***

INTRODUCTION

Cardiovascular disease (CVD) is one of the most prevalent disease states in the United States (U.S.), affecting nearly half of the adult population.[1] Early detection and management of the underlying causes of CVD, such as hypertension (HTN), dyslipidemia, and tobacco use, are key in the prevention and treatment of myocardial infarctions and strokes. The U.S. Centers for Disease Control and Prevention (CDC) reported in 2019 that 11.5% of adults surveyed older than 20 years-of-age had a total cholesterol greater than 240 mg/dL noting the increased risk for CVD.[2] Underlying causes of CVD are highly prevalent with approximately one in two adults in the U.S. having a diagnosis of HTN and approximately 20.8% of U.S. adults using tobacco products.[3]

According to the CDC, many individuals within the U.S. do not have a primary care provider.[4] Approximately 21% of the adults in the U.S. indicated they have not had their cholesterol checked, and close to 17% are estimated to have undiagnosed hypertension.[5] Additionally, a trend was noted that there is a decrease in adults seeking medical care from a primary care provider, except for those who were 80 years of age and older.[4,5]

With CVD being an ongoing health concern, employer-sponsored biometric health screenings for employees continue to expand looking to identify health risks that previously had gone undetected.[6] As community-based pharmacists are one of the most accessible health care providers in the U.S., with millions of people visiting the pharmacy daily, they are positioned to assist in the early detection of CVD through point-of-care screening.[7-11] Additionally, not all patients routinely visit their primary care provider due to numerous reasons, including cost, time, and health literacy.[12] Pharmacists are trained and positioned to perform biometric screenings, identify risk factors, provide counseling/interventions (if needed), and refer patients completing employer-sponsored biometric health screenings to the primary care provider, if screening data is abnormal.[7,13,14] While biometric health screenings are a useful tool to identify atherosclerotic cardiovascular disease (ASCVD) risk, they are not a replacement for medical evaluation from a primary care provider for diagnosis.[6]

The Atherosclerotic Cardiovascular Disease Risk Estimator Plus, created by the American College of Cardiology, is utilized as a tool for calculating patients' risk of a cardiovascular event.[15] The risk estimator utilizes patient age, gender, race, systolic blood pressure (SBP), total cholesterol (TC), high-density lipoprotein (HDL), patient history of diabetes, patient's tobacco use status, and whether the patient is on treatment for HTN to calculate either a 10-year or lifetime risk of an ASCVD event. Additional information that can individualize advice for the patient is diastolic blood pressure (DBP), low-density lipoprotein (LDL), and if the patient is on a statin or aspirin therapy. The ASCVD risk score facilitates a discussion between health care providers and patients on lowering their cardiovascular risk, specifically identifying appropriate statin intensity based on cardiovascular risk, if indicated.[16,17] While this calculator application can evaluate one patient at a time, others have been developed to perform batch calculations based on Pooled Cohort Equations.[15,18,19] Community-based pharmacists are educated to utilize this tool during biometric health screenings and refer patients on to primary care. The goal of this study was to

evaluate how community-based pharmacists could impact ASCVD risk for a large population.

METHODS

Study Site. A large regional community-based pharmacy chain offers annual biometric health screenings to employees within its large parent grocer organization of approximately a half million employees. A sub-set of these employees, based on classified employment location, are incentivized by the employer sponsored health insurance plan to seek a biometric health screening at least once per year. Employees are offered insurance incentives for completing a biometric health screening at one of the community-based pharmacies within the organization or with a primary care provider. The University of Kansas Medical Center institutional review board approved this research.

Study Design. This study was a retrospective analysis that collected biometric health screening data from 24 divisions across 18 states within a large regional community-based pharmacy chain from July 1, 2015 to June 30, 2020. In the 15-minute biometric health screening, the pharmacist was tasked with obtaining the patient's name, date of birth, gender, race, blood pressure, lipid panel, height and weight, and tobacco use status, recording the data, and counseling the patient about the screening results. For this analysis, the first biometric health screening during the specified period was classified as "baseline", although this may not be the first screening visit a patient has had with a community-based pharmacist. The intermediary screening was defined as the middle screening for a patient during the study period. For patients who had more than three screenings, the intermediary screening was the middle screening which occurred in a unique year. The last screening was defined as the last screening obtained for each patient during the study period. The pharmacists did not make clinical interventions with the information found; however, education over the obtained results was provided.

The lifetime ASCVD risk was calculated utilizing an online calculator created by clincalc.com developed from the 2013 ASCVD Risk Estimator Plus Pooled Cohort Equations.[18] To validate results from clincalc.com, a sample data file of 100 patients' records was processed by the online calculator and compared to the ASCVD Risk Estimator Plus calculator. Prescription fill history data, specifically HTN and diabetes medications, were collected from the same large regional community-based pharmacy chain and utilized to calculate lifetime ASCVD risk answering the questions "On hypertension treatment?" and "History of diabetes?". The history of HTN and diabetes questions were answered using the prescription fill history data for medications filled with known Food and Drug Administration labeled indications, not known patient diagnosis. Additionally, the prescription fill data extracted was applied to all three screening time periods for analysis: baseline, intermediary, and last. Statin prescription filling history was utilized to determine a patient's eligibility for statin therapy, therefore the opportunity for clinical intervention by a community-based pharmacist. Data gathered initially as identifiable was stored on an encrypted and password-protected organization laptop utilizing secured software and was de-identified prior to analysis.

The primary endpoints were change in lifetime ASCVD risk (elevated ASCVD risk defined as ≥ 7.5%) and health screening parameters. A post-hoc analysis was completed to determine where changes in health screening parameters occurred during the study period. Secondary endpoints were number of patients at the last screening who qualified for but were not receiving statins, and those who were classified as current tobacco users. Based on American College of Cardiology and American Heart Association guidelines, qualification for statin therapy included those with one or more cardiovascular disease risk factors, including dyslipidemia, diabetes, hypertension, or smoking.[20]

Population. Patients were included in the study if they were at least 20 years old at the beginning of the study period, had completed at least three biometric health screenings during the study period, and were an employee of the organization. Patients over the age of 79, those with incomplete biometric health screening records (missing lipid panel, blood pressure, or tobacco use), or those with biometric health screening parameters outside of prespecified ranges by the calculator (SBP 90-200 mmHg, DBP 60-130mmHg, TC 130-320mg/dL, and HDL 20-100mg/dL) were excluded. The lower age cutoff of 20 years was selected to comply with the calculator requirements for accurate calculation to identify ASCVD lifetime risk.

Statistical Analysis. Patient demographics were assessed using descriptive statistics. Change in ASCVD risk was assessed using repeated measures ANOVA. Post-hoc analyses were completed with the Bonferonni correction. The need for clinical interventions was assessed between demographic groups (gender, tobacco status) using chi-square. These same analyses were conducted on patients with ASCVD risk ≥ 7.5%. The Statistical Package for Social Sciences program, version 27 (SPSS v.27) was utilized with an a-priori α of 0.05. SPSS adjusts p values for Bonferonni comparisons so they also may be interpreted based on the established a-priori α.

RESULTS

Baseline Characteristics. After applying exclusion criteria, 10,001 eligible patients with three biometric health screenings in the five-year period were included, and 2,642 patients were excluded. Included patients had an average of 3.4 screenings during the study period. Baseline demographics are displayed in Table 1.

Primary Outcome. The results demonstrated an overall statistically significant increase in ASCVD risk from 1.5% at baseline to 1.8% at the last biometric health screening ($p < 0.001$) during the study period. There was a statistically significant increase in HDL from the intermediary to last screening ($p = 0.03$). There were no statistically significant changes observed in SBP, DBP, BMI, TC, LDL, triglycerides, or blood glucose. Primary outcome results are shown in Table 2.

Table 1. Baseline demographics.

Demographic	N = 10,001
Gender, n (%), Female	4,975 (49.7)
Age (years), median (IQR)	47 (37 - 55)
Race, n (%)	
White	1,598 (16)
African American	149 (1.5)
Not Specified	8,134 (81.3)
Tobacco Use, n (%)	
Yes	1,544 (15.4)
No	8,321 (83.2)
Former	136 (1.4)
Body Mass Index, median (IQR)	28.8 (25.1 - 33.8)
History of Diabetes, n (%)	178 (1.8)
Receiving Treatment for Hypertension, n (%)	440 (4.4)
Receiving Statin Therapy, n (%)	279 (2.8)
Total Cholesterol, median (IQR)	179.2 mg/dL (157.8 - 204.4)
Triglycerides, median (IQR)	117 mg/dL (82 - 171)
HDL Cholesterol, median (IQR)	49 mg/dL (40 - 62)
LDL Cholesterol, median (IQR)	100 mg/dL (82 - 123)
Blood Glucose, median (IQR)	95 mg/dL (87 - 104)
Systolic Blood Pressure, median (IQR)	125 mmHg (117 - 134)
Diastolic Blood Pressure, median (IQR)	81 mmHg (75 - 87)

n = population; HDL = high-density lipoprotein; LDL = low-density lipoprotein; IQR = interquartile range

Table 2. Change in ASCVD lifetime risk.*

	Baseline	Last Screening	Change	p Value
ASCVD Risk, median (IQR) N=10,001	1.5% (0.7% - 3.5%)	1.8% (0.8% - 4.2%)	0.3%	< 0.001

*ASCVD = atherosclerotic cardiovascular disease; p value < 0.05 was considered significant

Secondary Outcome. Of the 1,187 patients who qualified for statin therapy based on elevated ASCVD risk (ASCVD risk ≥ 7.5%) and 2013 American College of Cardiology and American Heart Association guidelines, 1,025 (86.4%) were not receiving statin therapy at their last screening in the study period. Additionally, 1,573 patients (15.7%) of the entire study population still used tobacco products at the last biometric health screening. These patients represented the potential clinical interventions community-based pharmacists could make to decrease ASCVD risk. Secondary outcomes are displayed in Table 3. Additional analyses were performed on all patients with an elevated ASCVD risk (Table 4).

Table 3. Patients eligible for clinical intervention by community-based pharmacist.

	At Last Screening
ASCVD Risk ≥ 7.5%, n	1,187
Receiving Statin Therapy, n (%)	162 (13.6)
Not Receiving Statin Therapy, n (%)	1,025 (86.4)
Current Tobacco Users, n (%)*	1,573 (15.7)

*out of 10,001 patients
n = population; ASCVD = atherosclerotic cardiovascular disease

Among patients with elevated ASCVD risk, statistically significant improvements were discovered in all parameters (ASCVD risk, SBP, DBP, BMI, total cholesterol, triglycerides, HDL, and LDL) from baseline to intermediary screening and from baseline to last screening. From intermediary to last screening, statistically significant improvements were demonstrated from ASCVD risk, SBP, DBP and HDL. At baseline, there were 145 patients with elevated ASCVD risk who utilized tobacco products. By the last screening, six patients had quit using tobacco products.

DISCUSSION

To the authors' knowledge, this is the largest study of this type. Over the past two decades, community-based pharmacies have worked to implement ASCVD risk reduction initiatives.[21-24] The Asheville Project, comprising of 565 patients in one city, was instrumental in defining the value of community-based pharmacists in the management of chronic disease.[21,22] The clinical services provided by community-based pharmacists, including disease state education, clinical assessments, monitoring and collaborative drug therapy management, significantly improved the health of study participants with type 2 diabetes, HTN, and dyslipidemia. More than 50% of study participants displayed improvements in cholesterol and hemoglobin A1c at every measurement. While groundbreaking efforts were made in the Asheville Project, there was a limited geographical impact in comparison to this study. This study incorporated a larger patient population for evaluation and increased generalizability across 18 states versus one city. Further, if this study had been able to make clinical interventions to the concerns found, similar health improvements would have been expected on a larger scale.

Additionally, in Mississippi, a small community-based pharmacy chain performed biometric health screenings for union employees.[23] The screening event took place on a single day and allowed 452 employees and family members to self-select blood pressure or cholesterol screenings. Although analyzed data were inconsistent per patient, 13% of participants had elevated blood pressure (defined as a SBP ≥ 140 mmHg and a DPB ≥ 90 mmHg), 24% had high TC, and 16.4% had low HDL. Again, the aforementioned study was limited geographically in sample size while our study was spread regionally across 18 states incorporating more diversity. The Mississippi screenings were limited within scope to a one-time screening of blood pressure or cholesterol and not tracked over time. Our study, over a period of time, evaluated the impact of change of multiple screening data points tracking the potential for impact of the community-based pharmacist.

Table 4. Mean differences in health screening parameters among patients with elevated ASCVD risk (≥ 7.5%).

	Baseline Minus Intermediary Screening (N=1,187)	p Value	Intermediary Minus Last Screening (N=1,187)	p Value	Baseline Minus Last Screening (N=1,187)	p Value
ASCVD Risk	0.7%	< 0.001	-0.3%	0.076	0.4%	0.027
Systolic Blood Pressure	4.7 mmHg	< 0.001	1.8 mmHg	0.006	6.4 mmHg	< 0.001
Diastolic Blood Pressure	2.1 mmHg	< 0.001	0.9 mmHg	0.015	3.1 mmHg	< 0.001
Body Mass Index	0.797	0.01	0.073	0.24	0.870	0.02
Total Cholesterol	8.5 mg/dL	< 0.001	0.297 mg/dL	0.83	8.8 mg/dL	< 0.001
Triglycerides	13.8 mg/dL	< 0.001	-0.25 mg/dL	0.94	13.6 mg/dL	0.001
HDL	-4.8 mg/dL	< 0.001	-1.6 mg/dL	0.012	-6.3 mg/dL	< 0.001
LDL	9.7 mg/dL	< 0.001	2.0 mg/dL	0.1	11.7 mg/dL	< 0.001

ASCVD = atherosclerotic cardiovascular disease; high-density lipoprotein, LDL = low-density lipoprotein. p value < 0.05 was considered significant.

In the study published by DiDonato et al.[24], a small independent community-based pharmacy chain in Northwest/Central Missouri created a pharmacist-led wellness coaching program. In the coaching program, pharmacists performed baseline screenings and stratified 81 patients into focused monitoring groups, cholesterol, HTN, diabetes, and weight. Patients met with their pharmacist coach for 5 to 60 minutes every one to two months for education, goal setting and monitoring, or physical assessment. At the end of the one year coaching program, statistically significant improvements were observed in TC, LDL, HDL, total-to-HDL ratio, and DBP. There were no statistically significant changes observed in mean triglycerides, SBP, weight, BMI, and waist circumference. The coaching program provided no direct clinical medication interventions, but provided physicians, as necessary, a visit summary note communication. In contrast, patients included in our study only met with a community-based pharmacist one time each year for up to 15 minutes, however, patient data were tracked across a five-year time frame. Furthermore, the obtained screening data within our study were provided to the patient at the conclusion of the screening and encouraged to be shared with the primary care provider for additional follow-up, as needed.

The strictly timed schedule of our biometric health screenings limited an in-depth conversation over a patient's screening results and ways to improve their health. The limited time spent with our community-based pharmacists could be one explanation behind the slight increase in lifetime ASCVD risk over time and potentially the lack of change in smoking status as well. If the pharmacists had been able to make clinical interventions or provide education, it would be projected that a decrease would have been noted. Despite these studies, gaps still exist regarding the impact of community-based pharmacists on ASCVD risk in a large patient population, beyond that of an employer group.

Our retrospective analysis examined biometric health screening data from a large patient population within a large regional community-based pharmacy chain of 10,001 patients. As the biometric health screenings are completed annually, the ability to follow the patient over time was beneficial. There was a statistically significant increase in ASCVD risk from baseline to most recent biometric health screening in the overall study population. However, as a patient ages, the risk of an ASCVD event naturally increases.[17,25-27] Because of the low baseline ASCVD risk, the increase from 1.5% to 1.8% could be attributed to the natural aging process and may not be a clinically significant finding.

Analyses performed on the 1,187 patients with an ASCVD risk ≥ 7.5% showed many statistically significant improvements in biometric health screening parameters. Theoretically, the patients in this subgroup were those who could benefit the most from clinical education and intervention. Although almost all biometric health screening parameters were discovered to be statistically significant, the statistically significant changes of 0.4% from baseline to final screening (Table 4) itself is not clinically significant. In contrast, mean SBP and DBP from baseline to last screening decreased 6.4 mmHg and 3.1 mmHg, respectively, which are clinically significant reductions, and has been estimated to reduce cardiovascular events by approximately 10%.[28] Additionally, a statistically significant reduction in triglycerides (14 mg/dL) was seen between both baseline to intermediary and baseline to last screening.

A statistically significant increase of 0.61 mg/dL in HDL was discovered among all 10,001 patients from intermediary to last biometric health screening. In comparison, DiDonato et al.[24] also demonstrated a statistically significant improvement in HDL by 3.2mg/dL over 12 months. Although both findings were statistically significant, the improvements in HDL were slight and would not be considered clinically relevant.

Lastly, clinical interventions determination by the community-based pharmacists is the last step that could be taken to reduce ASCVD risk of the biometric health screening patients. Although community-based pharmacists were not diagnosing dyslipidemia with annual biometric health screenings, communicating the findings and making recommendations for treatment were done via medication therapy management services within community-based pharmacies. The 1,025 patients identified in our study as potentially qualifying for statin therapy but not currently receiving it represented the number of opportunities the pharmacist had to communicate with the patient's primary care team. Additionally, pharmacists are well trained to implement these

interventions with a collaborative practice agreement. Community-based pharmacists within the organization were not required to communicate the findings of biometric health screenings to a patient's primary care provider and typically did not initiate clinical interventions after screenings were completed. This was an identified area for enhancement in the future.

Limitations. Because the employees were given the option to obtain both biometric health screening and prescription filling services outside of the organization, there was limited ability to capture the outside data. Due to prespecified cholesterol and blood pressure parameters in the ASCVD Risk Estimator, patients with extreme readings who may have higher ASCVD risk were excluded in analysis. The biometric screening analyzer used to provide the cholesterol panel did not measure LDL directly, instead it calculated this value utilizing the patient's triglycerides, HDL, and TC numbers which may result in a potential error. Other limitations included discrepancies in record keeping across divisions, stores, and between pharmacists regarding tobacco use status and race/ethnicity in a patient's prescription record.

CONCLUSIONS

This study identified areas of impact opportunity for pharmacist-led biometric health screenings within a large regional community-based pharmacy chain, specifically with statin therapy and tobacco use. A statistically significant increase in ASCVD risk from a baseline was discovered in this study. Although, this increase was likely due to the natural aging process and was not a clinically significant finding. Among those patients with an elevated baseline ASCVD risk of ≥ 7.5%, a statistically significant improvement was seen in nearly all biometric health screenings. However, if community-based pharmacists were to intervene through enhanced counseling with direct clinical interventions under a collaborative practice agreement with this population, there is potential for greater improvement in the lifetime ASCVD risk score and other screening parameters.

ACKNOWLEDGEMENT

Partial support for this project was provided by a 2021 APhA Foundation Incentive Grant.

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Keywords: cardiovascular diseases, community pharmacy services, heart disease risk factors, mass screening, diagnostic techniques and procedures