1. Introduction

In 2013 the American College of Cardiology (ACC) and American Heart Association (AHA) released updated cholesterol guidelines for the prevention of atherosclerotic cardiovascular disease (CVD) (Stone et al., 2014). These guidelines eliminated cholesterol goals and instead incorporated evidence-based CVD risk thresholds to guide clinician-patient decision-making for statin initiation in primary prevention, a shift that has been recognized as the next paradigm in “personalized” CVD prevention (Robinson and Ray, 2016). This approach requires estimating 10-year CVD risk from multiple traditional risk factors including laboratory values like total cholesterol and high-density lipoprotein cholesterol to guide risk assessment and treatment discussions. However, there are many practical barriers to risk-based prevention such as availability of blood test results at the time of consultation, time required for risk factor measurement and absolute risk estimation, and poor integration of these steps into clinic workflow (van Steenkiste et al., 2004). These barriers contribute to missed opportunities for optimal primary prevention, especially among adults at increased CVD risk (King et al., 2016). POCT provides rapid point-of-care testing (POCT) is a promising technology to promote personalized CVD prevention (King et al., 2016). POCT provides rapid blood test results at the time of physician consultation to facilitate integration of these results into clinical decision-making (Gialamas et al., 2010). Traditionally, studies evaluating POCT have focused on diagnostic test accuracy or acute care decision-making in emergency settings, but there is growing interest in their application to primary care (St John, 2010). Systematic reviews of the literature, however, identify limited high quality evidence to guide its application in primary care (Gialamas et al., 2010), and a recent Cochrane systematic review of strategies for implementing CVD risk scores in clinical practice identified no studies that utilized POCT for this purpose (Karmali et al., 2017).
In light of this limited evidence, we performed a study to determine the preliminary feasibility, acceptability, and efficacy of pre-visit POCT and quantitative CVD risk assessment immediately before a routinely scheduled primary care provider (PCP) visit among high-risk adults.

2. Methods

2.1. Study design

This was an uncontrolled study in which participants received pre-visit, quantitative CVD risk assessment facilitated by POCT between July–October 2014. Outcomes were assessed by manual chart review after the study visit. The Institutional Review Board of Northwestern University and the participating federally qualified health center’s (FQHC) research committee approved the study.

2.2. Settings and participants

We performed this study at the Northwestern Medicine faculty general medicine practice and a federally-qualified health clinic (FQHC) in Chicago, IL. Both sites had electronic health records (EHR) that could be used to calculate 10-year predicted CVD risk. We included men and women with: (1) age 40 to 75 years, (2) ≥2 clinic visits in the past 2 years, and (3) a scheduled PCP visit during the recruitment period, and (4) 10-year CVD risk ≥10% based on last measured risk factor levels in the EHR. For patients with measured lipid values in the past 2 years, we used the Pooled Cohort Equations (Goff et al., 2014) and for those with no measured lipid values during this period, we used the non-laboratory Framingham risk score (D’Agostino et al., 2008). We used this strategy to identify adults who were likely to meet current ACC/AHA risk thresholds for statin consideration when evaluated in clinic. Patients were excluded if they had an active statin prescription; were non-English speaking; had a history of stroke, congestive heart failure, coronary heart disease, angina, heart attack, or diabetes mellitus; were pregnant; or were marked as inappropriate for study by their PCP.

2.3. Participant recruitment

Study staff reviewed patient records at regular intervals to identify potentially-eligible adults with appointments 10–20 days in the future and obtained approval to contact them from their PCPs. Participants were recruited by mail and screened for eligibility by telephone call. A study visit was scheduled immediately prior to the patients’ PCP appointment. Study staff obtained written informed consent at the beginning of the study visit.

2.4. Study visit and CVD risk assessment

Participants were surveyed about medical history, lifestyle behaviors, and family history. A research assistant measured weight and blood pressure using standardized procedures (Pickering et al., 2005). Three blood pressures were measured, and the average of the last 2 was used for the study visit blood pressure. Finger sticks were used to obtain capillary blood for POCT. We used the Cholestech LDX (Alere, Hayward, CA) to measure total and high-density lipoprotein cholesterol and the Siemens DCA Vantage Analyzer (Siemens Healthcare Diagnostics, Deerfield, IL) to measure glycosylated hemoglobin (HbA1c) to detect undiagnosed diabetes mellitus. The research assistant then prepared and reviewed a “CVD Risk Assessment” form with the participant. This form listed the participant’s 10-year predicted atherosclerotic CVD risk as estimated by the Pooled Cohort Equations and provided personalized treatment recommendations and lifestyle modifications per current ACC/AHA prevention guidelines (Stone et al., 2014; Eckel et al., 2014). The research assistant then provided the completed form to the participant and his or her PCP prior to the office visit.

2.5. Measures and analysis

The primary efficacy outcomes were: physician documentation of CVD risk discussion and statin prescription at the time of the PCP visit. Both outcomes were assessed by manual chart review. We administered a questionnaire to assess acceptability of the intervention measured on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). We used descriptive statistics to characterize results.

3. Results

3.1. Characteristics

We identified 77 patients who met study eligibility criteria during the 4 month study period. From this group, we recruited and consented 18 participants (8 from Northwestern Medicine clinics and 10 from the local FQHC) for this study. All recruited participants completed the pre-visit POCT and quantitative CVD risk assessment. Participants’ characteristics at the time of the study visit are listed in Table 1.

3.2. Preliminary efficacy-testing

Outcomes are summarized in Table 2. After the intervention, 83% of participants discussed CVD risk with their PCP. Moreover, 47% of participants were recommended a moderate-intensity statin for primary prevention by their PCP; one participant discussed statins with their PCP but was not recommended treatment due to a potential drug-drug interaction. In total, 29% of all participants meeting ACC/AHA risk thresholds for consideration of statin therapy received a new statin prescription during their PCP visit after the POCT intervention.

3.3. Preliminary acceptability of the intervention

Participants who were surveyed after the intervention deemed it highly acceptable (Table 2).

4. Discussion

This study provides initial data to suggest that pre-visit POCT and quantitative CVD risk assessment appears to be a feasible intervention for increasing guideline-recommended statin use in primary prevention. The positive feedback from participants also supports the

Table 1

| Characteristic | N (%) |
|---------------|-------|
| Mean age, y   | 64.7 (8.5) |
| Female sex    | 13 (72.3%) |
| Race/ethnicity|       |
| Non-Hispanic white | 5 (27.8%) |
| Black         | 8 (44.4%) |
| Hispanic      | 1 (5.6%)  |
| Other, unknown| 4 (22.2%) |
| Drug-treated hypertension | 10 (55.6%) |
| Current smoker| 7 (38.9%) |

| Ten-year cardiovascular disease risk | 14.7 (7.2) |
| Total cholesterol, mg/dL | 201 (40) |
| HDL-cholesterol, mg/dL | 56 (20) |
| Systolic blood pressure, mm Hg | 132 (12) |
| Diastolic blood pressure, mm Hg | 78 (10) |

* Risk is estimated by the ACC/AHA Pooled cohort risk equation that predicts 10-year risk of an atherosclerotic cardiovascular disease event (defined as nonfatal myocardial infarction, nonfatal stroke, or cardiovascular disease death). Risk is calculated from age, sex, race/ethnic group, total cholesterol level, high-density lipoprotein (HDL) cholesterol level, systolic blood pressure level, diabetes mellitus status, smoking status, and presence or absence of blood pressure medications (Goff et al., 2014).
intervention’s acceptability in both an academic medical center and FQHC.

Among the participants who met absolute CVD risk thresholds for consideration of statin therapy based on ACC/AHA cholesterol guidelines, the finding that 83% discussed CVD risk reduction with their PCP and that 29% received a new statin prescription during their PCP visit is noteworthy. The magnitude of these rates compares favorably with a recent randomized controlled trial conducted by our group that also included only 17 participants because 1 participant had a potential drug-drug interaction.

Table 2

| Chart review outcomes | N (%) |
|-----------------------|-------|
| Documented discussion of CVD risk | 15 (83.3%) |
| Drug treatment for cholesterol recommended at office visit | 8 (47.1%) |
| Statin prescribed at office visit* | 5 (29.4%) |

| Acceptability statement | Mean (SD) |
|-------------------------|-----------|
| The Cardiovascular risk factor review session strengthened my relationship with my doctor. | 4.3 (0.8) |
| I felt more motivated to look after my cardiovascular health after the risk factor review session. | 4.5 (0.8) |
| The CVD Risk Assessment form was difficult to understand. | 1.6 (1.0) |
| The CVD Risk Assessment form helped me talk with my doctor about things I could do to prevent heart attacks and strokes. | 4.8 (0.6) |
| My doctor did not follow the recommendations outlined on the CVD Risk Assessment form | 4.5 (0.8) |
| The finger-stick required to get blood tests during the risk factor review session was bothersome. | 1.3 (0.9) |
| I have confidence in the accuracy of the blood test obtained by finger prick. | 4.5 (0.8) |
| It was helpful to know my numbers before I met with the doctor. | 4.8 (0.6) |

* Of 17 participants because 1 participant had a potential drug-drug interaction.
CVD = cardiovascular disease.

In conclusion, this study provides preliminary data about the effects of pre-visit POCT and quantitative CVD risk assessment in primary care. These findings suggest that use of POCT prior to primary care visits appears to be feasible, acceptable, and may promote guideline-recommended statin initiation in high-risk adults. Future research with an adequately powered randomized controlled clinical trial is warranted to determine the effectiveness of this approach in primary prevention.

5. Conclusions

In conclusion, this study provides preliminary data about the effects of pre-visit POCT and quantitative CVD risk assessment in primary care. These findings suggest that use of POCT prior to primary care visits appears to be feasible, acceptable, and may promote guideline-recommended statin initiation in high-risk adults. Future research with an adequately powered randomized controlled clinical trial is warranted to determine the effectiveness of this approach in primary prevention.

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Conflicts of interest

Dr. Persell receives grant support from Pfizer, Inc. for research unrelated to this study. The other authors have no competing interests to report.
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