Real-world application of MedsCheck opportunities: The Costco pharmacists intervention trial for reduction of cardiovascular risk

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Introduction

Despite the observation that age-specific mortality rates from coronary artery disease have declined by nearly 40% in Canada over the past several decades, this disease continues to be the leading cause of death and morbidity for Canadians.¹

Advances in pharmacy practice, the expectation that pharmacists take a more active role in and responsibility for medication management and patient health outcomes, and high patient accessibility provide an important opportunity for pharmacists to identify and manage cardiovascular risk factors. Indeed, numerous trials have clearly demonstrated the positive impact of pharmacist care in managing patients with hypertension, hyperlipidemia and diabetes.²⁻⁸

In light of the changing pharmacist scope of practice and remuneration opportunities, we sought to implement a community pharmacists' heart health risk assessment program using MedsCheck and subsequent interventions on surrogate heart health outcomes in patients with moderate to high Framingham Risk Scores (FRS).

Methods

We implemented a community pharmacy-based MedsCheck program with an emphasis on cardiac risk reduction in Ontario. We based our cardiovascular risk reduction program on an adaptation and expansion of the 2009 Canadian Cardiovascular Society position statement.⁹

Prior to trial initiation, each participating pharmacy enlisted 2 lead pharmacists to receive training on the program protocol. Pharmacist training included 5 webinar-based sessions, which consisted of a FRS calculation; CardioChek training; patient intervention scripts; standardized pharmaceutical opinion forms with predetermined therapeutic regimens established by our medical director (see Appendix 1 at www.cpjournal.ca for the sample form); and patient program evaluation surveys. Structured dialogues counselling on various risk factors for cardiovascular disease were also incorporated into the protocol to ensure the standardization of care provided by the pharmacists. Piercing of the dermis for the CardioChek device was completed with the aid of an authorized medical directive. Upon completion of training, pharmacies were divided into control and intervention groups, with 12 pharmacies being selected as control and 12 as intervention.

Control pharmacies delivered usual care and performed 2 consults of up to half an hour each, which consisted of assessing FRS through point-of-care cholesterol and blood pressure readings, and performing medication reviews and lifestyle counselling, once at the beginning and once at the end of the study period (12 months).

Intervention pharmacies provided intensive care and performed the same consult every 3 months, with the additional opportunity to send a standardized pharmaceutical opinion to the prescribing physician at each visit as necessary, based on FRS factors. Pharmaceutical opinions

were provided on standardized forms suggesting regimen changes to improve surrogate FRS factors such as blood pressure, lipids or smoking status (see Appendix 1 at www.cpjournal.ca for a lipid pharmaceutical opinion sample form). Documentation for the pharmacist interventions (see Appendix 2 at www.cpjournal.ca) was either entered on the spot by the pharmacist through an online documentation tool or afterwards by an assistant. Participants were also provided with an informational brochure with their recorded results. Further information on the methods and tools used is available from the author.

Recruitment was completed through screening of over 600 patients during a series of Heart Health clinic days, with an additional pharmacist dedicated to the task as well during prescription dispensing over a period of 12 weeks. The Heart Health clinic, which was advertised through the use of bagstuffers given with heart-related prescriptions (see Appendix 3 at www.cpjournal.ca), took place at 3-month intervals at each intervention group pharmacy and was run by a dedicated pharmacist over a 5-hour time slot. During each clinic event, the pharmacist spent up to half an hour with each participant in a private counselling room, checking blood pressure, cholesterol panel, blood sugar, fat composition and body mass index, followed by a calculation of the participant's FRS. Participants identified as having a moderate to high FRS were asked to provide consent to enrol in the study. Follow-up consultations happened on dedicated Heart Health clinic days or at prenegotiated appointment times during periods of pharmacist overlap. In addition, both control and intervention groups conducted a patient satisfaction survey at the completion of the trial.

Results

A total of 455 patients (252 in control pharmacies and 203 in intervention pharmacies) were enrolled over 3 months. Unfortunately, losses to follow-up were high, with only 108 (43%) returning for a follow-up visit at 1 year in control pharmacies and 97 (48%) in intervention pharmacies.

Patient characteristics in each group did not differ substantially from each other and are shown in Table 1.

Reductions were seen in virtually all end points in the intensive care group over the usual

care group, although none reached statistical significance (Table 2).

Regardless of whether participants saw their pharmacist for 2 consults or 5 consults over the period of a year, patients were quite satisfied with their experience and appreciated the pharmacists' interest in their health.

Discussion

Pharmacists need to take a more active role in chronic disease management. We demonstrated that it was feasible to use MedsCheck as the starting point for a cardiovascular risk reduction intervention. We also successfully used medical directives to overcome restrictive point-of-care testing laws in Ontario at the time and preprepared pharmaceutical opinions to standardize the interventions. While our results showed only nonsignificant trends in cardiovascular risk reduction, our 24 pharmacies did enrol 455 patients in only 12 weeks. Importantly, we also showed how MedsCheck reviews could be the springboard for pharmacist intervention programs.

The strengths of our study include a real-world implementation of an important new opportunity for pharmacist's MedsCheck, with over 450 patients enrolled in the program. It was also a novel approach to not only calculate the FRS and report the findings to the physician but to also recommend an action plan for therapeutic regimen change in a standardized manner a full year before the Pharmaceutical Opinion Program was launched in Ontario. Limitations include a nonrandomized design and high losses to follow-up (as in many community pharmacy programs), which would have biased the results towards the null hypothesis. Despite providing appointment reminders to participants, losses to follow-up were high and may have been in part due to the lack of technology available to pharmacists to schedule appointments, as well as staffing resources to ensure the proper timing of follow-ups with patients. The small effect size on blood pressure, cholesterol and smoking perhaps shows the limitation of making unsolicited recommendations to physicians at a time when this was not commonplace. Stronger pharmacist-physician relationships may be necessary for future trials of this nature to have a more significant impact.

TABLE 1 Demographic and risk factors of study population at baseline

	Usual care (n = 108)	Intensive care (n = 97)
Age, mean (SD), y	64.1 (7.8)	63.4 (8.0)
Female sex	38 (35.2)	32 (33.0)
Treatment of hypertension	81 (75.0)	63 (65.6)
Diabetes	44 (40.7)	40 (42.1)
Smoker	10 (9.3)	8 (8.2)
Total cholesterol, median (IQR)	4.2 (3.3-5.7)	4.1 (3.1-5.3)
HDL-C, median (IQR)	1.2 (1.0-1.5)	1.2 (1.0-1.6)
LDL, median (IQR)*	2.1 (1.6-3.4)	2.0 (1.2-2.6)
Triglycerides, median (IQR)**	1.7 (1.3-2.9)	1.9 (1.4-2.8)
Systolic BP, median (IQR)	132 (123-141)	135 (126-146)
Diastolic BP, median (IQR)	75 (70-80)	77 (72-81)
Patient risk level		
High	59 (54.6)	54 (55.7)
Intermediate	48 (44.4)	43 (44.3)
Low	1 (1.0)	0
Framingham Risk Score, median (IQR)	15.0 (14.0-18.0)	16.0 (13.5-17.0)
10-year risk %, median (IQR)	21.6 (13.7-29.4)	21.5 (13.7-29.4)

Values are presented as number (%) unless otherwise indicated. BP, blood pressure; HDL-C, high-density lipoprotein cholesterol; IQR, interquartile range; LDL-C, low-density lipoprotein cholesterol.

*Based on 49 and 66 observations reported for usual and intensive care, respectively.

**Based on 55 and 81 observations reported for usual and intensive care, respectively.

TABLE 2 Average change in main outcomes from baseline to 1 year ($\Delta_{1\text{yr} - \text{Baseline}}$) in usual and intensive care using random effects models

	Change in usual care (UC)		Change in intensive care (IC)		Comparison of changes between UC and IC	
	Δ_{UC}	p-value	Δ_{IC}	p-value	$\Delta_{\text{IC}} - \Delta_{\text{UC}}$	p-value
Total cholesterol	0.02	0.90	-0.15	0.30	-0.17	0.40
HDL-C	-0.01	0.91	-0.05	0.34	-0.04	0.54
LDL-C	-0.03	0.86	-0.18	0.15	-0.15	0.42
Triglycerides	-0.02	0.90	0.05	0.70	0.07	0.73
Systolic BP	-3.57	0.02	-4.20	0.01	-0.63	0.78
Diastolic BP	0.08	0.93	-0.45	0.65	-0.53	0.69
Framingham Risk Score	-0.47	0.10	-0.53	0.08	-0.06	0.88
10-year risk %	-1.00	0.12	-1.51	0.02	-0.51	0.58

BP, blood pressure; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

The program demonstrates that it is feasible to use MedsCheck, MedsCheck follow-up, point-of-care testing and pharmaceutical opinion as the starting point for a cardiovascular risk reduction. The profession of pharmacy has a role to play in filling the accessibility and care gaps in primary care for Canadians, especially

those without a regular family physician. Further study is warranted with a larger sample size and a greater emphasis on improving patient follow-up to more fully understand the effect that community pharmacists' interventions can have on improving patient health outcomes in cardiovascular health and beyond. ■

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