A Randomized Trial of the Effect of Community Pharmacist Intervention on Cholesterol Risk Management

The Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP)

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Background: Despite clear evidence for the efficacy of lowering cholesterol levels, there is a deficiency in its real-world application. There is a need to explore alternative strategies to address this important public health problem. This study aimed to determine the effect of a program of community pharmacist intervention on the process of cholesterol risk management in patients at high risk for cardiovascular events.

Methods: A randomized controlled trial conducted in 54 community pharmacies (1998-2000) included patients at high risk for cardiovascular events (with atherosclerotic disease or diabetes mellitus with another risk factor). Patients randomized to pharmacist intervention received education and a brochure on risk factors, point-of-care cholesterol measurement, referral to their physician, and regular follow-up for 16 weeks. Pharmacists faxed a simple form to the primary care physician identifying risk factors and any suggestions. Usual care patients received the same brochure and general advice only, with minimal follow-up. The primary end point was a composite of performance of a fasting cholesterol panel by the physician or addition or increase in dose of cholesterol-lowering medication.

Results: The external monitoring committee recommended early study termination owing to benefit. Of the 675 patients enrolled, approximately 40% were women, and the average age was 64 years. The primary end point was reached in 57% of intervention patients vs 31% in usual care (odds ratio, 3.0; 95% confidence interval, 2.2-4.1; $P<.001$).

Conclusions: A community-based intervention program improved the process of cholesterol management in high-risk patients. This program demonstrates the value of community pharmacists working in collaboration with patients and physicians.

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I N CANADA and the United States, approximately 40% of all deaths are attributed to cardiovascular disease, and this is expected to continue to increase with the aging of society.[1,2] The modifiable risk factors for cardiovascular disease are well-known, and randomized trials have conclusively demonstrated the efficacy of lowering blood pressure, controlling blood glucose levels, and managing dyslipidemia in reducing mortality and morbidity from cardiovascular disease.[3]

Despite the incontrovertible evidence of the efficacy of dyslipidemia management,[4-8] our group and others[9-25] have demonstrated that this evidence is poorly applied in real-world practice. In a review of 3304 consecutive hospitalized, high-risk patients, we observed that only 28% had documentation of serum cholesterol measurement during their hospital admission or within the previous 5 years, and only 8% were prescribed a cholesterol-lowering medication.[9] In addition, it seems that even patients who are prescribed a cholesterol-lowering medication often do not reach the recommended target low-density lipoprotein cholesterol levels.[16,26,27] This represents a treatment gap between research evidence and clinical practice that has significant public health implications.

One reason for this deficiency in application of research findings may relate to the health care system, which is illness driven rather than prevention driven. A survey of 480 Canadian family physicians identified several barriers to the provision of preventive care.[28] The most com-

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PARTICIPANTS AND METHODS

Detailed methods of this study have been published previously (**Figure 1**).[32] The SCRIP was a randomized, multicenter trial comparing a program of pharmacist intervention with usual care in 54 community pharmacies in the provinces of Alberta and Saskatchewan. Patients were approached for entry into the study if they were at high risk for cardiovascular events. This included patients with atherosclerotic vascular disease, including previous myocardial infarction, unstable angina, stable angina, coronary revascularization, or cerebral or peripheral vascular disease. Patients with diabetes mellitus and at least 1 other cardiovascular risk factor were also included. This definition of high risk is similar to that used in the Heart Outcomes Prevention Evaluation study[34,35] and represents a group of patients with an annual cardiovascular event rate of at least 5% per year. Patients receiving cholesterol-lowering drugs were eligible for the study.

Patients were excluded if they (1) were currently enrolled in a cholesterol study or in a formal cardiac rehabilitation program, (2) had a terminal illness that would preclude them from aggressive cholesterol management, or (3) did not provide written informed consent.

Patients were identified by community pharmacists through their knowledge of the patient's medical history or the use of "indicator" medications, which are markers of high-risk status (eg, use of nitroglycerin for the presence of coronary artery disease[36] or use of insulin or oral hypoglycemic medications for the presence of diabetes mellitus). Written informed consent was obtained from all participants.

Patients were randomized to receive either intervention or usual care via a telephone call to the project coordinating center, the Epidemiology Coordinating and Research (EPICORE) Centre, Division of Cardiology, University of Alberta. Randomization was conducted via a computer-generated sequence using block randomization (block size of 4) with stratification by study center (pharmacy). Patients randomized to the intervention group were interviewed by the pharmacist to obtain complete information on their modifiable and nonmodifiable cardiovascular risk factors. Pharmacists measured the patient's serum total cholesterol level using a point-of-care cholesterol testing device (Accutrend GC; Roche Diagnostics, Laval, Québec). This value was documented and discussed with the patient. Education on cardiovascular risk factors was provided by the pharmacist using a patient brochure produced by the Alberta Medical Association and the Clinical Quality Improvement Network. The patient was encouraged to make an appointment with his or her primary care physician for further cardiovascular risk assessment, if necessary. To facilitate this, the pharmacist completed and faxed a single-page form to the physician. This form documented the patient's modifiable and nonmodifiable risk factors, medications, serum total cholesterol level, blood pressure, and any suggestions for further testing or management.
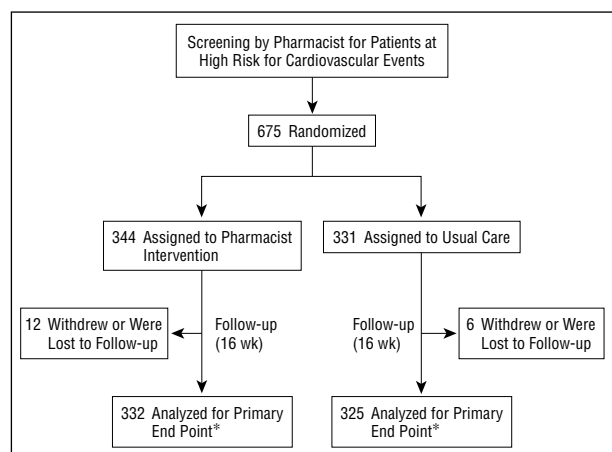

Figure 1. Trial profile. Asterisk indicates intention-to-treat analysis used.

mon reasons cited for not providing preventive care were that "healthy" patients do not seek preventive care and that when patients do visit, priority is given to the presenting problem. Respondents also believed that patients may not be interested in or would not comply with preventive measures and identified the need for systems to alert patients and physicians about the provision of preventive care.[28] To overcome these barriers, steps must be taken to educate patients about the benefits of preventive cardiovascular care and to provide a reminder system for patients and physicians.

Community pharmacists are well placed to assist in the provision of preventive cardiovascular care[29-32] because they are highly accessible and are often the first point of entry into the health care system. Pharmacists have computerized records of medications (often including information about concurrent disease states) and therefore are in an excellent position to recognize patients at high risk for cardiovascular events, to collaborate with patients and primary care physicians to improve cardiovascular care,[32,33] and to close the treatment gap between research evidence and clinical practice. The purpose of the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP) was to evaluate the efficacy of a program of intervention by community-based pharmacists to improve the process of cholesterol risk management in patients at high risk for cardiovascular events.

RESULTS

The first patient was randomized in the spring of 1998. After a planned review of the first 400 patients, the External Monitoring Committee (see the list at the end of the article) recommended early termination of the study because of striking evidence of benefit in the intervention group compared with the usual care group (using $P<.0001$, set a priori by the committee). By this time, a total of 675 patients were recruited by the SCRIP investigators (see the list at the end of the article). Eighteen patients withdrew or were lost to follow-up (these were included in all analyses).

Randomization resulted in a balance of patient demographics (**Table 1**). The average age was about 64

The intervention group received follow-up visits at 2, 4, 8, 12, and 16 weeks. These visits were performed either in person or by telephone (at the discretion of the pharmacist) and were intended to ensure that the patients had visited their physician, to provide further education on cardiovascular risk factors, to make further suggestions to the patient or physician, to assess and reinforce adherence to medications, to answer any questions from the patient, and to determine whether study end points had been reached. The final visit (at 16 weeks) was conducted in person to measure the patient's cholesterol level and blood pressure and to perform close-out procedures.

Patients randomized to the usual care group received a copy of the same patient information booklet and general advice only. Patients received minimal follow-up, with a telephone call at 8 weeks (to determine outcome events) and a close-out visit at 16 weeks.

The primary end point was a composite measure representing improvement in the process of cholesterol risk management. It consisted of measurement of a complete fasting cholesterol panel by the primary care physician or prescription of a new cholesterol-lowering medication or an increase in dosage of a cholesterol-lowering medication. As a composite end point, only the first event attained in the cluster was counted. End points were validated by obtaining a copy of the patient's laboratory report, a copy of the prescription(s), or both. Secondary end points included individual components of the primary end point and the humanistic impact of pharmacist intervention, assessed using the General Satisfaction With Pharmacy Services Scale[37-39] and the 12-Item Short Form Health Survey.[40,41]

Sample size was estimated assuming a primary event rate of 30% in the control group, as suggested by a previous study.[9] Assuming an increase to 40% in the intervention group, a 2-sided α of .05, and 85% power, a sample size of 814 patients was estimated. To allow for dropouts and loss to follow-up, the sample size was adjusted upward to 1000, with 500 patients in each treatment group.

All analyses were based on intention-to-treat principles. Primary and secondary dichotomous outcome variables were compared between the intervention and usual care groups using the Fisher exact test. Planned subgroup analyses included the effect of the intervention by sex, age, urban vs rural practice, and presence of diabetes mellitus. The Breslow-Day test for homogeneity of odds ratios (ORs) was used to compare outcome variables in subgroup analyses. The satisfaction scores were linearly transformed to a scale from 0 to 100 for analysis purposes.[42] Change in humanistic outcomes was assessed using analysis of covariance models. For humanistic outcomes, the 4-month follow-up scores were used as the dependent variable compared between groups, with baseline scores as a covariate. For all analyses, a threshold of statistical significance of $P<.05$ was used.

The study was approved by the research ethics boards of the University of Alberta, Edmonton; the University of Calgary, Calgary, Alberta; and the Regina Health District, Regina, Saskatchewan.

years, with approximately 40% of patients being women. About 40% of patients had a history of myocardial infarction; 29%, unstable angina; 40%, stable angina; 29%, previous revascularization procedures; and 18%, peripheral vascular disease or cerebrovascular disease. Almost half of the patients enrolled had diabetes mellitus (all figures are not mutually exclusive).

The primary end point was reached in 196 patients (57%) in the intervention group vs 102 (31%) in the usual care group (unadjusted OR, 3.0; 95% confidence interval, 2.2-4.1; $P<.001$) (**Figure 2**). The secondary end point of measurement of a fasting cholesterol panel performed by the primary care physician was attained in 53% of patients in the intervention group vs 29% in usual care group (OR, 2.8; 95% CI, 2.0-3.7; $P<.001$) (**Table 2**). The end point of new prescription for a cholesterol-lowering medication was attained in 10% of patients in the intervention group vs 4% in the usual care group (OR, 2.5; 95% CI, 1.3-4.6; $P<.003$) (Table 2). The end point of increased dose of an existing cholesterol-lowering medication was attained in 3% of patients in the intervention group vs 1% in the usual care group (OR, 3.0; 95% CI, 0.99-8.8; $P=.07$) (Table 2). There was no difference in the primary end point in subgroups of patients aged <70 vs ≥70 years or by urban vs rural pharmacy practices (Table 2). There was a significantly greater effect of the intervention in women vs men and in patients with diabetes mellitus vs those without (Table 2).

There were no statistically significant changes in satisfaction with pharmacy services or health status as a result of the intervention (**Table 3**). Comparing the sat-

isfaction scale scores, it seemed that respondents were less satisfied with the communication between their pharmacist and physician (mean score, 75 of 100) than with pharmacy services in general (mean scale score, 84).

Table 1. Patient Demographics by Randomized Groups*

Variable	Usual Care Group (n = 331)	Intervention Group (n = 344)
Age, mean ± SD, y	64.6 ± 11.3	64.2 ± 12.2
Females	124 (38)	141 (41)
Eligibility†		
Myocardial infarction	128 (39)	138 (40)
Unstable angina	95 (29)	97 (28)
Stable angina	140 (42)	131 (38)
Revascularization	95 (29)	97 (28)
Peripheral vascular disease	54 (16)	65 (19)
Cerebrovascular disease	59 (18)	61 (18)
Diabetes mellitus + ≥1 other risk factors	138 (42)	156 (45)

*All data are given as numbers (percentages) unless otherwise indicated.
†Not mutually exclusive.

COMMENT

The inconsistent application of research evidence into practice represents a significant public health problem, especially in the area of cardiovascular disease prevention and treatment.[43,44] The results of the SCRIP conclusively demonstrate the value of community pharmacist interven-

tion on the process of cholesterol risk management in patients at high risk for cardiovascular events. In addition, an economic evaluation, published separately,[45] has shown that the marginal cost of providing the intervention (from a government payer perspective) is reasonable, approximately $7 per patient per 4 months. Although the study was terminated early because of benefit, to our knowledge, the SCRIP is the largest randomized trial of pharmacist intervention in cardiovascular disease.

The community-based pharmacist has been an underused resource. In general, patients see their pharmacists more frequently than other health care providers, and because of the nature of their practice, pharmacists are more accessible to the public.[29-32] The practice of pharmacy has been evolving toward a more clinical, patient-centered (vs product-centered) role during the past decade, and evidence of the value of pharmacists' clinical activities is beginning to accrue.[46-51] The enhanced role of the pharmacist in preventive medicine has been advocated by the American Heart Association,[52] the British National Health Service,[53] a joint statement by the Canadian Medical Association and the Canadian Pharmacists' Association,[54] and others.[30,55,56] Pharmacists have successfully implemented preventive health programs in cholesterol management,[57-61] hypertension,[62] and other areas,[47,63] but often without comprehensive evaluation. Pharmacists may act as a link between the patient and the primary care physician, thus addressing many of the reported barriers to preventive care described by Hutchison et al.[28]

Project ImPACT was a nonrandomized observational study[61] of pharmacists' care of patients with hyperlipidemia carried out in 26 pharmacies that followed 397 patients for an average of 24.6 months. They observed a persistence (refill) rate of 93.6% and a compliance rate of 90.1%, with 62.5% of patients achieving National Cholesterol Education Program goals. The lack of a control group and the fact that only 69% of patients completed follow-up limit the conclusions that can be drawn from this study. Shibley and Pugh[57] reported on 25 patients managed for 12 months at 2 community pharmacies using a before-and-after design. Using point-of-care technology, they reported statistically significant reductions in total and low-density lipoprotein cholesterol levels at 6 and 12 months of follow-up. The main weakness of these 2 studies is the use of a before-and-after design, thus limiting causal inference.

Examination of the separate components of the primary end point shows that most events were attributed to the measurement of a fasting cholesterol profile by the primary care physician (Table 2). This is not surprising, as it represents an important first step in the process of cholesterol risk management. In a previous study,[9] less than one third of high-risk patients had any cholesterol
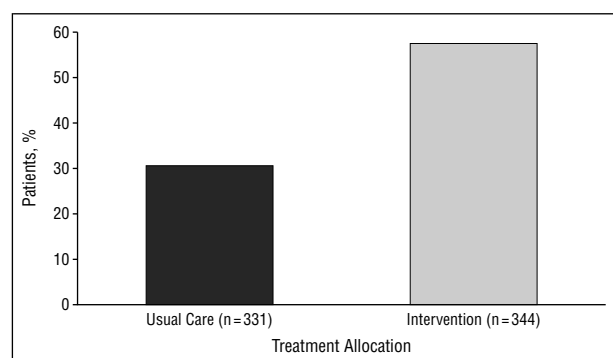

Figure 2. Percentage of patients in each group reaching the primary end point (odds ratio, 3.0; 95% confidence interval, 2.2-4.1; $P<.001$).

Table 2. Primary and Secondary Outcomes*

Outcome	Usual Care Group (n = 331)	Intervention Group (n = 344)	Odds Ratio (95% CI)	P Value
Primary end point	102 (31)	196 (57)	3.0 (2.2-4.1)	<.001
Secondary end points				
Performance of a cholesterol panel	96 (29)	181 (53)	2.8 (2.0-3.7)	<.001
New prescription of a cholesterol-lowering medication	14 (4)	34 (10)	2.5 (1.3-4.6)	<.003
Increase in dose of cholesterol-lowering medication	4 (1)	12 (3)	3.0 (0.99-8.8)	.07

	Usual Care Group	Intervention Group	P Value†	Odds Ratio (95% CI)	P Value‡
Subgroups of primary end point, No./Total No. (%)					
Women	33/124 (27)	88/141 (62)	<.001	4.6 (2.7-7.7) ⎤	.04
Men	69/207 (33)	108/203 (53)	<.001	2.3 (1.5-3.4) ⎦	
Age <70 y	68/216 (32)	126/219 (58)	<.001	2.9 (2.0-4.4) ⎤	.93
Age ≥70 y	34/115 (30)	70/125 (56)	<.001	3.0 (1.8-5.2) ⎦	
Urban pharmacy practice	87/281 (31)	170/291 (58)	<.001	3.1 (2.2-4.4) ⎤	.46
Rural pharmacy practice	15/50 (30)	26/53 (49)	.070	2.2 (1.0-5.0) ⎦	
Diabetes mellitus	35/138 (25)	97/156 (62)	<.001	4.8 (2.9-8.0) ⎤	.01
No diabetes mellitus	67/193 (35)	99/187 (53)	<.001	2.1 (1.4-3.2) ⎦	

*Data are given as number (percentage) of patients unless otherwise indicated. CI indicates confidence interval.
†Between the usual care and intervention groups.
‡For heterogeneity of odds ratios between subgroups (eg, females vs males).

measurement within the past 5 years. By design, this trial entered all high-risk patients regardless of their cholesterol level. Not all high-risk patients will require treatment for dyslipidemia; however, this will not be known if cholesterol is not assessed. Although the intervention group received more prescriptions for cholesterol-lowering medications or increases in doses of their cholesterol-lowering medication, the absolute number of these events is relatively few. This too, is not surprising given the short follow-up of the study (4 months) (ie, it may take longer to properly assess cholesterol, implement nonpharmacologic treatments, and then add or titrate medications).

It seems that the effect of the intervention was somewhat greater in women than in men, with relatively fewer end points reached in the usual care group (27% in women vs 33% in men) and more reached in the intervention groups (62% in women vs 53% in men). Because women often receive less cholesterol-lowering therapy,[9] this suggests that pharmacists should target this population for intervention. By design, about half of the patients enrolled had diabetes mellitus, a major risk factor for cardiovascular events.[64] The intervention was about twice as efficacious in patients with vs without diabetes mellitus. Again, this suggests that there is much to be gained by targeting this high-risk group of patients.

In general, respondents were satisfied with pharmacy services at baseline, leaving little room for improvement. This is not unlike results from previous research[38,39,42,65-68]

Table 3. Changes in Patient Satisfaction With Pharmacy Services and Health Status*

Variable	Baseline	Follow-up	P Value†
General satisfaction with pharmacy services			
Intervention group	82.8 (18.2)	84.2 (16.5)	.84
Control group	82.3 (18.5)	84.0 (20.0)	
Satisfaction with pharmacist-physician communication			
Intervention group	73.3 (22.5)	75.6 (22.2)	.54
Control group	72.7 (23.6)	76.6 (23.1)	
Physical health status (PCS12)			
Intervention group	39.8 (11.1)	39.2 (11.1)	.27
Control group	40.2 (11.3)	41.8 (10.9)	
Mental health status (MCS12)			
Intervention group	51.1 (9.5)	51.1 (10.2)	.57
Control group	51.6 (9.7)	51.3 (9.8)	

*Data are given as mean (SD). PCSI2 indicates the physical component score; MCS12, mental component score.
†From an analysis of covariance model comparing follow-up scores between groups after adjusting for baseline scores.

Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP) Participants

External Monitoring Committee
L. Brent Mitchell, MD (*Chairperson*) (University of Calgary); Timothy Stratton, PhD, RPh (University of Montana, Missoula); Diane Catellier, DrPh (University of North Carolina, Chapel Hill).

Investigators
Alberta: Donna Galvin and Catherine Biggs (*Area Monitors*); Apple Drugs, Peace River (Mike Kinshella); Broadmoor Pharmacy, Sherwood Park (Catherine Biggs and Rosemarie Biggs); Co-op Pharmacy, Red Deer (Gordon Matthies, Gloria Wright, and Susan Proctor); Crescent Rexall, Edmonton (Sylvie Généreux and Karen Schultz); Crestwood Apothecary, Edmonton (Mike Wolowyk); Grandin Prescription Center, St Albert (Merose Stelmaschuk, Carolyn Eastwick, and Karen Dyck); Medicine Shoppe, 118th Avenue, Edmonton (Laurie Reay and Michelle VanDerMolen); Medicine Shoppe, Fort Saskatchewan (Mark Sigurdson); Medicine Shoppe, Meadowlark, Edmonton (Terese Tsuruda); Medicine Shoppe, Whitemud Crossing, Edmonton (Pam Lavold); Myros Pharmacy, Edmonton (Dwayne Samycia and Mohib Samnani); Nolan Drugs, Edmonton (Zaher Samnani); Shoppers Drug Mart, Heritage Square, Edmonton (Roland Coppens); Shoppers Drug Mart, Kingsway Garden Mall, Edmonton (Rick Hackman, Anita Brown, and Pam Davis); Shoppers Drug Mart, Riverbend Square, Edmonton (Paul Readman, Eric Yu, and Robert Wojtas); Shoppers Drug Mart, Sherwood Park (Sandy Campbell and Catherine Chevalier); Shoppers Drug Mart, Tudor Glen Market, St Albert (Holly Paget, Shawn Cripps, and Jody Shkrobot); Shoppers Drug World, Edmonton (Donald Makowichuck); Southgate Mall Rexall, Edmonton (Willi Wangert and Joel Ghitter); Value Drug Mart, Devon (Dave Burwash); Value Drug Mart, Peace River (Patrick Kinshella and Vanda Bilous-Kinshella); Britannia Pharmacy, Calgary (Debbie Boyle); Central Care Medical Pharmacy, Calgary (Dean Myers); Kenron Pharmacy, Calgary (Martha Nystrom, Kim Johnson, Tamara Bresee, and Adrian Azim); Professional Centre Pharmacy, Calgary (Audrey Fry); Safeway, Centre Street, Calgary (Jenny Mancenido and Kee Goh); Safeway, Montgomery, Calgary (Nadine Velasco, Tracy Marsden, and Don Wickford); Safeway, North Hill, Calgary (Betty Wishloff, Michelle Borysko, and Rishma Damji); Safeway, Southland, Calgary (Kathy Hayward, Ian Churchill, Dana Fraser, and Noorani Ramji); Safeway, Westbrook, Calgary (Todd Read); Shoppers Drug Mart, Northland Drive, Calgary (Don Saby and Marlene Gukert); Signature Drugs, Calgary (Susan Younggren); Telstar Drug Ltd, Calgary (Olga Dmytrisin). **Saskatchewan:** Bill Semchuk and Arlene Kuntz (*Area Monitors*); College Avenue Drugs, Regina (Jack Mullock and Michelle Lesy); Co-op Pharmacy, Meadow Lake (Linda LaBar); COSTCO Pharmacy, Regina (Ed Toth, Cynthia Wegner, and Susan Wasylyshyn); Estevan Pharmasave, Estevan (Rob Rogers and David Jeske); Lorne Drugs, Regina (Chris Perentes and Rhonda Woods); Melfort Pharmasave, Melfort (Kirk Spicer and Darren Thirsk); Moose Jaw Pharmasave, Moose Jaw (Lena Hartman and Patricia Giesinger); Prescription Plus, General Hospital, Regina (Chris Semenchuck); Shaunavon Pharmasave, Shaunavon (Leigh Fehr-Little and Bruce Pearson); Shoppers Drug Mart, Gordon Road, Regina (Wendy Davidson and Spiro Kolitsas); Shoppers Drug Mart, Normanview Mall, Regina (Scott Szabo, Myra Allen, and Cathy Klatt); Shoppers Drug Mart, Park Street, Regina (Arlene Kuntz, Pat Laturnas, Sherry Gray, and Tom Chen); Shoppers Drug Mart, Victoria Square, Regina (Darla Cook and Carol Pannell); Townsend's Central Drugs, Wynyard (Dallas Townsend and Kendra Townsend); Wakaw Pharmacy, Wakaw (Mike Stan and Colette Stan); Wynyard Pharmacy, Wynyard (Walter Peterson).

and may also reflect the selection of highly motivated pharmacists (a ceiling effect). In contrast, respondents seemed to be less satisfied with communication between pharmacists and physicians, with no improvements in the intervention group. It is unclear why patients did not perceive any difference in the service provided, since the interaction between health professionals was an integral part of the intervention. It is likely that patients were not aware of the degree of communication that occurred and therefore could not base any assessment of satisfaction on the enhanced level of care. Further research on this topic is required, perhaps addressing the expectations of pharmacy services as an antecedent to satisfaction.[37,69]

The limitations of the present study have been outlined elsewhere.[32] Briefly, a possible limitation of this study is that it measured process rather than clinical outcomes. Given the weight of evidence for efficacy of cholesterol-lowering therapy, it would be inappropriate (and impractical) to follow patients to the point of clinical outcomes. Furthermore, it is well accepted that process outcomes are appropriate for trials of health care delivery and in fact are considered more sensitive indicators of quality than clinical outcomes because poor outcomes do not always result from poor processes.[70] The SCRIP was performed by highly selected pharmacists, thus raising the issue of the generalizability of our findings. Finally, the current health care system, which focuses on product delivery and acute care, makes such comprehensive programs difficult (although not impossible).

This study was conceived to address a major public health problem and a treatment gap between research evidence and clinical practice. It provides proof of concept that community pharmacists, working in partnership with patients and primary care physicians, can have a major beneficial impact on cholesterol risk management. It is hoped that these methods can be adapted for use in other disease states as another tool in our quest to provide the best care to the patients we serve.

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