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The roles of community pharmacists in cardiovascular disease prevention and management

George J,[1] McNamara K[1,2], Stewart K[1]

1. Centre for Medicine Use and Safety, Monash University, Australia

2. Greater Green Triangle University Department of Rural Health, Flinders University and Deakin University, Australia

REVIEW

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Corresponding Author:
A/Prof Kay Stewart
Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, 381 Royal Parade, Parkville, VIC 3052, Australia
Kay.Stewart@monash.edu

Abstract

There is ample evidence in the international literature for pharmacist involvement in the prevention and management of cardiovascular disease (CVD) conditions in primary care. Systematic reviews and meta-analyses have confirmed the significant clinical benefits of pharmacist interventions for a range of CVD conditions and risk factors. Evidence generated in research studies of Australian community pharmacist involvement in CVD prevention and management is summarised in this article.

Commonwealth funding through the Community Pharmacy Agreements has facilitated research to establish the feasibility and effectiveness of new models of primary care involving community pharmacists. Australian community pharmacists have been shown to effect positive clinical, humanistic and economic outcomes in patients with CVD conditions. Improvements in blood pressure, lipid levels, medication adherence and CVD risk have been demonstrated using different study designs. Satisfaction for GPs, pharmacists and consumers has also been reported. Perceived 'turf' encroachment, expertise of the pharmacist, space, time and remuneration are challenges to the implementation of disease management services involving community pharmacists.

Key Words
Cardiovascular, community pharmacy, outcomes, pharmacist, primary care

Introduction

Pharmacists in Australia have long undertaken roles in the prevention and management of CVD that extend beyond the traditional dispensing of medicines. These roles range from provision of educational materials, through screening and monitoring of conditions such as blood pressure, to interventions in areas such as smoking cessation, lifestyle modification, medicines management and medicines adherence. These expanded roles are often informal in nature, implemented to varying extents between pharmacies, and usually are neither remunerated nor systematically integrated within the broader primary care setting.[1-2] This article summarises the evidence generated in research studies regarding community pharmacist involvement in CVD prevention and management.

International evidence

International scientific evidence for pharmacist involvement in CVD interventions has increasingly emerged in recent decades. Consequently, systematic reviews and meta-analyses of randomised controlled trial (RCT) evidence can now confirm the significant clinical benefits of pharmacist interventions for a range of major disease states and preventive health activities related to diabetes (significant HbA1c reductions),[3] smoking cessation (improved cessation rates),[4-5] hyperlipidaemia (significantly reduced total cholesterol, and within-group significant LDL cholesterol reductions),[6] and hypertension (reduced systolic and diastolic levels).[7] While this demonstrates the benefits of pharmacist intervention for several individual risk factors, it must be acknowledged that management of patients often requires concurrent consideration of multiple risk factors and interventions. To address this gap in evidence for pharmacy, more recent studies have examined the clinical effectiveness of pharmacists delivering multi-faceted interventions and addressing multiple cardiovascular risk factors. For

example, Lee et al.[8] implemented a randomised clinical trial (RCT) in the United States involving individualised medication education, medication dispensing using medication aids, and regular follow-up with clinical pharmacists. Compared with usual care, pharmacist interventions significantly improved systolic blood pressure (BP, -6.9 mmHg), medicine adherence and medicine persistence for an elderly population taking multiple medications. Medication adherence measured via pill count increased markedly from 61% to 97% (P<0.001).

Wu et al.[9] provided RCT data to demonstrate significantly reduced patient mortality following delivery of a pharmaceutical care programme by telephone to patients in Hong Kong receiving polypharmacy (five or more drugs). The Number Needed to Treat (NNT) to prevent a single death in this clinically stable, elderly outpatient population was just 16 – equivalent to a 41% relative risk reduction. It is important to note that while this was a general patient population, the greatest cause of mortality was from CVD and changes to cardiovascular medications following the intervention appear to have had a substantial association with improved risk profile. This intervention also reduced the median number of days spent in hospital each year (zero days versus three days, P=0.018), and fewer patients remained non-compliant with medications (7% versus 18%; P<0.001). Secondary analysis shows a clear and significant association between worsening non-compliance with medications and mortality, highlighting the importance of this role for pharmacists.

Pharmacists have also engaged extensively in the specific management of more complex patients with CVD, most notably those with heart failure. A systematic review of 12 RCTs indicates that pharmacist care is associated with a significantly reduced rate of all-cause hospitalisations and heart failure hospitalisations, and non-significant reductions in mortality.[10] Included trial settings were hospital outpatient departments, ambulatory care and community pharmacies.

While contributing to medicines management, recent international studies provide good reasons to suggest pharmacists can also contribute to broader CVD management as part of a primary care team. Notable examples include the Canadian SCRIP trial, which examined management of lipids in 675 patients at high risk of vascular events and demonstrated a 13.4% relative reduction in LDL-cholesterol among high-risk patients with uncontrolled LDL-cholesterol, equivalent to an average reduction of 0.5 mmol/L.[11] The intervention aimed to implement lipid management guidelines through patient education, investigation of other modifiable CVD risk factors, and referral to physicians, if necessary with written documentation and recommendations.

Several studies have assessed the capacity of community pharmacies to increase their involvement in screening activities. Liu et al.[12] found that pharmacists could competently identify patients at medium-high risk of CVD and reliably assess their 10-year absolute risk using a validated scoring tool derived from the Framingham Heart Study. Other studies suggest that community pharmacists can identify significant numbers of people at risk of CVD, but also that screening programmes in community pharmacies are a useful way of targeting some hard to reach groups such as males, ethnic minorities and socially deprived communities.[13-14] It is important to note that these screening and clinical intervention programmes were not designed to supplant the important role of the GP in patient cardiovascular care. Pharmacists appear to have acted within their competencies, and case detection programmes generally resulted in a large proportion of screened individuals being referred for in-depth medical examination or treatment.[13-14] The desire to work *with* medical practitioners rather than *to compete*, is underlined by an increasing number of studies highlighting the benefits of collaborative care processes. Collaborative management of heart failure has been found to produce even greater improvements in clinical outcomes than pharmacist-directed care.[10] The clinical benefits of team-based collaborative care compared with pharmacist- or GP-only care are becoming increasingly apparent.[15-16]

Evidence from Australia

Over the past five to ten years, the community pharmacy profession across Australia has been engaged in generating hard evidence of the benefits of such roles in Australia. Funding from the Commonwealth-supported Community Pharmacy Agreements and other sources has enabled a concerted drive for research to establish the feasibility and effectiveness of new models of primary care involving community pharmacy. Pharmacy interventions have been shown to lead to improved clinical, humanistic and economic outcomes in patients with cardiovascular conditions. Full reports of projects funded under the Community Pharmacy Agreement Research and Development Program are available at: http://www.5cpa.com.au/The key cardiovascular health findings of Australian studies carried out through community pharmacies are as follows:

Hughes et al.[17] carried out the first Australian community pharmacy-based hypertension management research at six community pharmacies located in the Perth metropolitan area. Patients (25 years or older) were

recruited at the time of presentation of their first prescription for an antihypertensive medication. Enrolment was ceased after 12 months with a final cohort of 34 patients (11.3% of projected). Of the 34 patients enrolled, 13 participants – four in the control group, three in the low intervention (three monthly follow-up) and six in the high intervention (six monthly follow-up) – were lost to follow up. Only 21 participants (seven in each group) completed the trial. Less than 50% of the patients enrolled in the study were aware of the BP reading on which their doctor had based their diagnosis of hypertension. The majority of subjects enrolled had Grade 1 or 2 hypertension as classified by the National Heart Foundation.

All groups showed a reduction in BP with time. The mean BP in the control group decreased from 163/99 mm Hg to 137/87 mm Hg (+/- 14.3/12.1); mean change: 26/12. In the low intervention group mean BP decreased from 147/86 mm Hg to 138/83 mm Hg (+/- 4.9/9.0); mean change: 9/3 mm Hg. In the high intervention group it decreased from 131/82 mm Hg to 126/73 mm Hg (+/- 13.9/6.6); mean change: 5/9 mm Hg. The number of participants at target BP increased in all groups during the trial (0 to 2; 2 to 3; and 4 to 6 in the control, low intervention and high intervention groups, respectively). Overall 42.9% of patients' adherence was rated as very good and 33.3% as excellent. Both intervention groups showed a trend towards better adherence compared to controls.[17]

Stewart et al.[18] tested an intervention package to enable community pharmacists to improve patient adherence and/or persistence with antihypertensive medications in a RCT with a view to improving BP control. Patients 18 years or above with primary hypertension who had been dispensed an antihypertensive in the previous six months were eligible to participate in the Hypertension Adherence Program in Pharmacy (HAPPY) Trial.[19] Pharmacies from three Australian states – Victoria, Western Australia and Tasmania – were randomised to Pharmacist Care Group (PCG; n = 29) or Usual Care Group (UCG; n = 26).

Following training, PCG pharmacists offered a multi-faceted intervention to their patients (n=207) at baseline, three and six months. The intervention included home BP monitoring; training on self-monitoring of BP; motivational interviewing; medication use review; and prescription refill reminders (by SMS, telephone or mail). Pharmacist-initiated home medicine reviews, dose administration aids, referral to a general practitioner and/or patient medication profile were offered, where necessary. UCG participants (n=188) received usual care. There were no significant differences between the groups at baseline. Numbers of participants completing the study were 176 in the PCG and 178 in the UCG.

In the HAPPY trial the number (%) of adherent patients as per Morisky scale[20] at baseline was 107 (57.5%) in the UCG and 112 (56.6%) in the PCG, which increased at six months to 111 (63.8%) and 127 (72.2%), respectively (p = 0.09).[18] Reduction in systolic BP was significantly better in the PCG than the UCG (–10.0 mm Hg versus –4.6 mm Hg; p = 0.02). Reduction in BP of this magnitude is known to be associated with reduced incidence of heart attacks, strokes and death from cardiovascular disease. The intervention was highly cost-effective as the cost per Quality Adjusted Life year (QALY) gain of $6,322.58 was far greater than the benchmark $70,000 accepted by the Australian government. This level of economic viability has also been demonstrated in other disease state management trial of diabetes and asthma care in Australia.[21-22]

Emerson et al.[23] tested the health impact of an inter-disciplinary Continuous Quality Improvement (CQI) approach in rural areas in a RCT using community Quality Use of Medicines (QUM) indicators. It involved a control group (six sites) which provided 'usual care', a low intervention group (one site) to test the impact of collaborative interventions without the use of indicators, and a high intervention group (two sites), to test the predictive validity of those indicators. Participants were aged between 40–65 years, on cardiovascular medication, and with a 10% or higher 10-year CVD risk. Recruitment and point of care testing for coronary heart disease (CHD) risk were undertaken through community pharmacies. The pharmacists and GPs were encouraged to collaborate to implement a range of evidence-based interventions to reduce CHD risk in the low intervention group over 12 months, whereas the control group continued to receive usual care. Regular meetings between pharmacists and GPs to discuss the results of all indicators complied from data collected prior to the meetings, and the delivery of interventions to increase the number of indicators met for enrolled patients occurred in the high intervention sites. Changes in key clinical results such as CHD risk, BP, lipids, weight, smoking and diabetes status were measured approximately 16 months after recruitment.

A total of 229 participants were recruited – 101 to the high intervention group, 60 to the low intervention group and 68 to the control group. Pharmacists provided 324 interventions (e.g. BP checking, medication compliance assessment, nutrition and exercise advice) to participants in the two intervention groups. The mean 10-year CHD risk change score for the high intervention group patients was a reduction in risk of -2.33 (a change from 18.3% to 16.0%; p=0.007), while the changes in control group and

low intervention groups failed to reach statistical significance (-0.17%; p=0.87 and +1.47%; p=0.23, respectively). The reduction in the high intervention group equated to a 13% reduction from baseline score. There was a significant difference in the effect between groups (p=0.04).

Aslani et al.[24] carried out a repeated-measures RCT to develop, implement and evaluate a new service in community pharmacy for conducting therapeutic outcomes monitoring in patients with dyslipidaemia and to promote adherence to medication therapy. Patients were eligible if they were 18 years or older, able to fluently speak and read English, and taking a lipid-lowering medicine for at least one month prior to enrolment in study. Pharmacists (*n*=38) were trained in study conduct, and given continuing professional education on ischaemic heart disease and lipid management. Intervention pharmacists were also trained on the intervention.

Intervention group patients attended the pharmacy at baseline and approximately every three months. At each visit, total blood cholesterol levels (non-fasting) were measured by pharmacists using a point of care testing device. After lipid levels were taken,results were provided to the patient. Pharmacists assessed each consumer individually, and developed a targeted strategy to address their barriers to adherence. Control group patients also attended the pharmacy, but only had their blood lipid levels measured and reported to them, and completed the questionnaire.

Seventeen pharmacists recruited 142 patients (97 completions: 49 control, 48 intervention). Most patients missed either the third or last visit, thus data at visits three and four were combined. Patients in the intervention group achieved a significantly greater reduction in total cholesterol levels (0.5 mmol/L) compared to those in the comparison group (0.01 mmol/L) over the study period (p<0.05). There was a 9% reduction in the total cholesterol levels of the intervention group. Intervention group patients lowered their total cholesterol level by an average of 6.7% over the study period, which translates to ~10% reduction in CHD mortality risk and an expected ~7% reduction in total mortality risk. No changes in medicine adherence scores were observed although there was an improvement in participants' exercise and eating habits. There were no differences between the two groups' hospital admissions and GP visits during the course of the study. For patients with an average blood lipid reading of ~5 mmol/L, the cost to achieve an average 10% lowering of cholesterol was between $293 and $356 including start-up costs, and approximately $178 for an ongoing service delivery.

Mc Namara et al.[25-26] tested a pilot model for primary prevention of CVD in community pharmacy aimed at improving quality of care. Pharmacists from 10 pharmacies received training in CVD risk factor management and facilitating patient lifestyle modification. They recruited 70 participants aged 50–74 years, taking medicines for BP or cholesterol, and without diabetes or CVD. At baseline, research assistants conducted a clinical assessment of risk factors, and conducted interviews to assess health behaviours, medicine use and related issues. Data was analysed by a consultant pharmacist (credentialed to undertake medication reviews) and summary reports produced, with recommendations and targets for risk reduction. These were addressed by patients and their community pharmacists over five monthly sessions.

At follow up, the relative risk reduction for CVD onset over the next five years was 24% (p<0.001), contributed to by reductions in mean systolic BP (7 mmHg), diastolic BP (5 mmHg), total:HDL cholesterol ratio (–0.2), waist circumference (–2 cm in males, –0.7 cm in females) and other risk factors. Several key health behaviours improved, including diet quality and physical activity levels. Prevalence of non-adherence to cardiovascular medicines dropped in absolute terms by 16% to 22%.

Hourihan et al.[27] developed a pharmacy based health promotion and screening model for a rural population at risk of CVD. A total of 204 participants attended the initial screening; 89% had at least one modifiable risk factor for CVD and 80% received healthy lifestyle advice from the pharmacist. Dietary advice was delivered to 70% of participants, exercise advice to 42% and smoking cessation advice to 8%.

Peterson et al.[28] carried out CVD risk profiling of individuals aged 30 years and older without diagnosed heart disease. The risk profiling was performed by three trained research pharmacists in a convenience sample of 14 community pharmacies, predominantly in rural areas of Tasmania and Northern Queensland. Six hundred and forty subjects with a median age of 54 years were screened for CVD risk factors. Participants were considered at risk of CVD because of an estimated 10-year CVD risk greater than 15%, or because of detection of one or more abnormal test results (i.e. systolic BP greater than or equal to 140 mmHg; diastolic BP greater than or equal to 90 mmHg; total cholesterol greater than or equal to 5.5 mmol/l; HDL cholesterol below 1.0 mmol/l or random blood glucose greater than or equal to 8 mmol/l), were asked to see their GP for further assessment or

management. A copy of the results was sent to the nominated GP with any necessary recommendations.

The estimated 10-year CVD risk of the subjects screened ranged from 0.2% to 61.0% (median = 9.5%). More than a quarter (28.1%) of the subjects was considered to be at increased risk of cardiovascular events. A total of 467 individuals (73% of those screened) who were considered at increased risk because of their estimated 10-year CVD risk (*n* = 180) or because of one or more abnormally high test results (*n* = 287) were advised to consult their doctor. Overall, the survey participants had a reasonable knowledge of CVD risk factors, with a mean score of 15.8 ± 2.2 (maximum score = 20) in the pre-consultation quiz. At the three-month follow-up, there was a small, but significant, improvement in the mean risk factor knowledge score (16.7 ± 2.4) for the 346 participants who returned questionnaires ($p< 0.0001$). The advice provided during the pharmacy consultation, or the screening itself, also appeared to have behavioural benefits, with 191 subjects (55% of respondents) reporting one or more lifestyle changes; 31.8% reported increased exercise, 16.4% weight loss, 29.8% improved diet and 3.6% had quit smoking.

In general, the process was well accepted by participants, with 71% of the 346 respondents regarding the screening as worthwhile, and 98% rating the consultation as good (30%) or excellent (68%). The majority regarded community pharmacy as an appropriate place for cardiovascular risk screening (97%) and felt that this could be a routine service offered by community pharmacists (90.5%). Assuming approximately 10 subjects per pharmacy would be screened per week, this programme in one community pharmacy over five years would screen 2,500 people at a cost to the pharmacy of $62,864. Of the 2,500 screened individuals, 700 (with risk of CVD exceeding 15% over 10 years) would be referred and 315 would receive an intervention, potentially averting 10 cardiovascular events over five years. In one pharmacy, the screening program would thereby prevent three premature deaths during five years. Against the previously described international backdrop, in 2005 Peterson et al.[29] developed the Pharmacy Cardiovascular Health Model in Australia to identify how the community pharmacy profession could optimise its contribution to the prevention, detection and management of CVD in Australia. The Pharmacy Cardiovascular Health Care Model proposed by Peterson et al.[29] has the following priority areas:

- Public/preventive health promotion.
- Continuum of care.
- High-risk patient referral.
- Compliance with therapy.
- Medication management and reviews.

To assist in developing the model, a 15-minute computer-assisted telephone survey of 505 households was conducted across Australia (metropolitan, rural and remote) to gauge public willingness to embrace involvement of community pharmacists in CVD prevention/management. The sample (aged over 29 years) was screened to include only those who had visited a pharmacy in the previous month, and had a quota of 50% with CVD. There was a high level of satisfaction with the quality of service provided by regularly visited pharmacies; however, there appeared to be a lack of awareness amongst consumers about the skills and capabilities of pharmacists and of services available through pharmacies. Not surprisingly, the most accepted role for community pharmacists was the optimisation of medicines use, with 90% willing to seek advice on medication use from pharmacists. Many respondents believed that pharmacists are capable of providing screening or testing for hypertension, diabetes and cholesterol, with the majority indicating that they would be likely to use these screening services if provided. The value of this risk factor and disease screening role in community pharmacies has been confirmed in other studies.[30-31] A majority also believed pharmacists to be competent to provide advice on lifestyle changes (weight loss, smoking, alcohol intake etc.) and information about CVDs and their management. Overall, these findings suggest sufficient public support for the profession to start engaging broadly in different activities supporting the roles listed above.

In developing and implementing disease state management programmes, including those directed at improving cardiovascular health, many researchers have consulted stakeholders to ascertain opinions regarding feasibility and acceptability of such programmes. Stakeholders have commonly included GPs, community pharmacists and consumers. Opinions are generally consistent across the various programmes. The general consensus is that both pharmacists and general practitioners have reservations about the feasibility of such programmes prior to the trials. Recurring themes include perceived need for the service, potential 'turf' encroachment, expertise of the pharmacist, space, time and remuneration.[17-18, 32]

GPs have emphasised that they would like to be assured that patients would be referred back to them for issues that are beyond the pharmacists' capabilities. Hypertension largely being an asymptomatic condition, consumers may not be motivated to have regular GP consultations unless encouraged by their health

professionals. BP monitoring between GP visits, either at the pharmacy or at home by the patient, might also be beneficial. Lack of adequate space within some pharmacies to conduct private consultations was mentioned as a major barrier to offering any pharmacy service focusing on chronic disease management, and needs to be addressed within this setting to ensure patient confidentiality.

Pharmacist and consumer satisfaction with pharmacy services in studies (e.g. HAPPY trial[18]) has been high; most could not think of any ways to improve the service. It was thought appropriate that pharmacists should provide the service as it was commonly recognised that GP resources were stretched and extension of their current services may be not be possible. Pharmacies were seen as a relaxing environment, and pharmacists seen as approachable. For the same reason, expecting substantial pharmacist–GP collaboration in delivering such an intervention, although ideal, may not be feasible. However, while GPs generally believed that a pharmacist-led educational programme would be beneficial to patients, it was suggested that a more formal, personalised communication between the pharmacist and the GP would be helpful e.g. via referral slips, preferably by fax to facilitate entry of information into the patient record. Consumers rated the most important components as monitoring their own BP regularly and the education they received from the pharmacists. Most consumers felt they had been given the tools to have a greater input into their BP management. The main facilitator for successful implementation of a community pharmacy disease state management programme was seen to be remuneration for pharmacists. Without this, pharmacy staff would not have time available for prolonged consultations. Team work involving consumers, GPs, other health professionals and pharmacists was also thought to be essential for the success of collaborative disease state management programmes.

Conclusion

There is mounting clear evidence of the positive potential for collaborations between GPs and community pharmacists in the management and prevention of CVD. The evidence involves improvement in clinical markers, improvements in quality of life in some conditions, satisfaction for GPs, pharmacists and consumers – and all at an economically viable cost. The challenges that lie ahead, in the climate of primary healthcare reform include fostering of the team approach and development of a sustainable funding model.

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CONFLICTS OF INTEREST

The authors were lead investigators on some of the studies included in this manuscript.

PEER REVIEW

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