University of Alberta

Pharmacist Management of Hypertension: An Examination of Clinical and Economic Outcomes and Remuneration for Expanded Services

by

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This thesis is dedicated to the memory of my grandmother, Barbara, who encouraged me from a very young age to study hard and dream big.

Abstract

Background: One-third of Canadian adults with hypertension remain uncontrolled. As drug therapy experts, pharmacists can play a role in addressing this challenge, particularly when utilizing prescribing authorization in Alberta. However, the clinical effectiveness of pharmacist management of hypertension, particularly prescribing, has not yet been established, and remuneration strategies for these services need to be determined.

Methods: This thesis consists of five studies. The first estimates the cost-saving potential of pharmacist care for hypertension resulting from reduced cardiovascular events. The second study reports on the current worldwide remuneration landscape for pharmacists' clinical care services, including eligible services, fees, and data on uptake and outcomes. Then, we examine the business implications of performing case finding and medication management activities in community pharmacy, to quantify the potential magnitude of revenue that these services can generate. The fourth study delves into the clinical effectiveness of pay-for-performance (P4P) versus other pay strategies, to determine if this novel approach results in improved quality of care as hypothesized. Finally, we report on the results of a randomized controlled trial of pharmacist prescribing for patients with uncontrolled hypertension, specifically comparing outcomes achieved when pharmacists were paid by P4P versus flat fees.

Results: A pharmacist prescribing intervention lowered systolic BP by 7.0 (SE 2.5) mmHg versus usual care. Since cost-savings has been established following BP lowering of 5.6 mmHg, the added benefit from pharmacist prescribing is likely both clinically- and cost-effective. However, BP lowering achieved under P4P was not significantly different than observed under fee-for-service, although this study was under-powered. This is

consistent with research among P4P physicians, where uncontrolled studies suggested benefit, but subsequently not substantiated by controlled trials. Pharmacists are increasingly being paid for clinical care services worldwide, and all programs follow the fee-for-service model. Outcomes of pharmacist remuneration suggest that uptake is suboptimal, despite evidence of patient benefit and cost-effectiveness.

Conclusion: Pharmacist prescribing offers significant blood pressure lowering benefit, and a gain over recommendation-based intervention. To ensure uptake and sustainability, remuneration needs to consider the changing pharmacy business model. P4P is unlikely to result in improved care quality and is therefore not recommended at this time.

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LIST OF ABBREVIATIONS

ACE: Angiotensin converting enzyme

APA: Additional Prescribing Authorization

BMI: Body mass index

BP: Blood pressure

BPLTTC: Blood Pressure Lowering Treatment Trialists' Collaboration

CAD: Canadian dollars

CACP: Comprehensive Annual Care Plan

CHD: Coronary heart disease

CHEP: Canadian Hypertension Education Program

CI: Confidence interval

CIHI: Canadian Institute of Health Information

COPD: Chronic obstructive pulmonary disease

CV: Cardiovascular

CVD: Cardiovascular disease

DM: Diabetes mellitus

DRP: Drug-related problem

DTP: Drug therapy problem

FFS: Fee-for-service

FOBT: Fecal occult blood test

GERD: Gastroesophageal reflux disease

HbA1c: Hemoglobin A1c (glycosylated hemoglobin)

HF: Heart failure

HOPE: Heart Outcomes Prevention Evaluation

HTN: Hypertension

IHD: Ischemic heart disease

LDL: Low-density lipoprotein

MCID: Minimal clinically important difference

MTM: Medication therapy management

NA, N/A: Not applicable

NHS: National Health Service

NRT: Nicotine replacement therapy

P4P: Pay-for-performance

PACT: Partnership to Assist with Cessation of Tobacco

PART2: Prevention of Atherosclerosis with Ramipril Trial

PCT: Primary Care Trust

PREVENT: Prospective Randomized Evaluation of the Vascular Effects of Norvasc Trial

PROGRESS: Perindopril Prevention of Recurring Stroke Study

QALY: Quality-adjusted life year

QOF: Quality and Outcomes Framework

RENAAL: Reduction of Endpoints in NIDDM with the Angiotensin II Antagonist Losartan

RRR: Relative risk reduction

RxACTION: Alberta Clinical Trial in Optimizing Hypertension

SBP: Systolic blood pressure

SCAT: Simvastatin/enalapril Coronary Atherosclerosis Trial

SCOPE: Study on Cognition and Prognosis in the Elderly

SCRIP-*HTN*: Study of Cardiovascular Risk Intervention by Pharmacists-Hypertension

SD: Standard deviation

SE: Standard error

SMBG: Self-monitoring of blood glucose

SMMA: Standard Medication Management Assessment

SYST-EUR: Systolic Hypertension in Europe

CHAPTER 1: Overview

1.1 INTRODUCTION

1.1.1 Pharmacist prescribing – a step forward

In April 2007[1], Alberta became the first Canadian province and the second jurisdiction worldwide to authorize independent prescribing by pharmacists. This authorization is one of three types of prescribing legislated in Alberta, as described in Table 1-1.

Table 1-1. Types of prescribing authorized by Section 16 of the Pharmacists and Pharmacy Technicians Profession Regulation[1]

Type of Prescribing	Description
Adapting a prescription	• Altering the dosage, formulation or regimen, • Renewing a prescription to ensure continuity of care, or • Substituting another drug that is expected to have the same or a similar therapeutic effect.
Prescribing in an emergency	Prescribing when there is an immediate need for drug therapy and it is not reasonably possible for the patient to see a prescriber.
Initial access prescribing or managing ongoing therapy	Prescribing based on: • The pharmacist's own assessment of the patient, • A recommendation from a regulated health professional who is authorized to prescribe, or • Consultation with another regulated health professional.

While all pharmacists on the clinical register may adapt a prescription or prescribe in an emergency when appropriate, initial access prescribing requires pharmacists to successfully apply for Additional Prescribing Authorization (APA). This application process involves an evaluation of competence to prescribe in the anticipated clinical area(s), an assessment of the pharmacist's practice environment, and the submission of patient cases demonstrating the pharmacist's care processes.[2] Pharmacists may legally prescribe any drug or blood product with the exception of narcotics and controlled substances,[3] provided that they are competent to prescribe in each scenario.

Pharmacist prescribing and other scope of practice expansions (i.e., ordering of laboratory tests, administration of injections) are being increasingly adopted across Canada, the United States, Europe, Australia, and New Zealand. In addition to Alberta, independent prescribing by pharmacists is now also legislated in Saskatchewan (limited to minor ailments), Ontario (limited to smoking cessation therapy), and Nova Scotia (limited to minor ailments), with pending legislation in Manitoba, Québec, and New Brunswick.[4] Such scope of practice expansions are in line with the vision for the profession set out in the Blueprint for Pharmacy initiative, which states that pharmacists will:[5]

- "Practice to the full extent of their knowledge and skills," and
- "Initiate, modify and continue drug therapy (e.g., through collaborative agreements, delegated or prescriptive authority), and order tests."

The need for pharmacy practice change has been called for since the first definition of pharmaceutical care was published over 20 years ago,[6] but progress has been slow. Recent renewal of interest has occurred due to the confluence of a number of factors including, but not limited to:

- An aging population,[7]
- Increasing incidence and prevalence of chronic diseases[8] that are largely managed through lifestyle modification and drug therapy,
- Escalating healthcare costs,[9,10]
- Need to improve access to primary care services,[11,12]
- Robust evidence of clinical benefit when pharmacists are added to patient care teams or perform direct patient care activities,[13-15] and
- Reduced community pharmacy revenues from dispensing activities.[16]

Pharmacist prescribing and related clinical services therefore provide an effective and accessible means to address changing population demographics, and may indeed evolve into a significant additional source of revenue for community pharmacies required for long-term sustainability.

1.1.2 Remuneration for professional services

Historically, community pharmacist remuneration has been dependent on the dispensing of prescriptions in the form of a professional/dispensing fee. Additionally, rebates from pharmaceutical manufacturers had been utilized to supplement dispensing revenues and support the provision of 'free' care and advice; however, such rebates have since been banned across Canada, beginning with the implementation of Bill 102 in Ontario in 2006.[17] Therefore, alternative pay models for pharmacists' services have been required and have since been introduced in most provinces as reported in Chapter 3.

However, health professional salaries and fees constitute one of the key drivers of increasing healthcare costs in Canada.[10] Therefore, in order for provincial governments to justify paying for pharmacists' clinical services, cost-benefit as a result of improved patient health outcomes and/or reduced utilization of other more costly health services (e.g., physician consultations or emergency department visits) must be realized. From the payer's perspective, this can be achieved by paying the lowest fee for these services that the market can bear. However, from the provider's perspective, fees must be sufficient to encourage the provision of these clinical services in addition to traditional dispensing activities and generate sufficient revenue for this new pharmacy business model to remain viable.

In an effort to improve care quality and ensure optimal use of limited financial resources, incentive-based (pay-for-performance, P4P) models have been piloted and implemented in the United Kingdom, the United States, and, to a lesser extent, in Canada. Proponents of this model suggest that it may shift focus to care quality rather than quantity (a concern with fee-for-service [FFS] remuneration), and can be used to shape clinicians' behaviour towards evidence-based activities. With efforts underway in Canada and in Alberta to shift physicians from FFS billing to other models such as salary, capitation, or P4P,[18-20] one should consider whether fees offered for pharmacists' clinical services should adopt a similar approach.

Chapter 2 presents an economic model estimating health system cost-savings potential from pharmacist intervention based on the findings of the SCRIP-*HTN* study.[21] Current remuneration programs for pharmacists' clinical care services worldwide are described

in Chapter 3, the business potential of billing for clinical services from a community pharmacy perspective is posed in Chapter 4, and a review examining the effect of P4P on patient health outcomes is presented in Chapter 5.

1.1.3 The clinical and economic burden of hypertension

Hypertension has been identified as the leading risk factor for premature death worldwide according to the World Health Organization.[22] It is well known that hypertension, left uncontrolled, contributes to a number of major complications affecting patients' quality of life and contributing to significant direct costs for health services and indirect costs such as lost productivity or loss of participation in leisure activities. Such complications include, but are not limited to, myocardial infarction, stroke, heart failure, chronic kidney disease, dementia, retinopathy, and premature mortality.[22-23] Physician, medication, and laboratory costs related to hypertension were estimated at $2.3 billion in 2003,[24] and total annual costs (direct and indirect) associated with cardiovascular disease were estimated at over $18 billion over a decade ago.[25] With 1 in 5 Canadian adults currently diagnosed with hypertension and increasing prevalence with age,[26] optimizing the accessibility and quality of hypertension care now can translate to enormous patient-level and societal gains for years to come.

Despite having one of the highest rates of blood pressure control worldwide, room for improvement remains in Canada, since one-third of Canadian adults with diagnosed hypertension remain uncontrolled,[27] increasing to almost half among patients with concomitant diabetes.[28] One method proposed by the Canadian Hypertension Education Program (CHEP) to address this need is greater utilization of multidisciplinary team-based care for patients with hypertension, with all team members functioning at their full scope of practice.[29] Pharmacist prescribing is therefore in alignment with this vision.

1.1.4 Evidence supporting pharmacist care of patients with hypertension

A number of randomized controlled trials support the role of the pharmacist in treating hypertension. Prior to the introduction of pharmacist prescribing in Alberta, the SCRIP-*HTN* study provided evidence supporting the role of community pharmacist/nurse teams in hypertension management.[21] This study enrolled 227 patients with diabetes and BP

>130/80 mm Hg from 14 pharmacies in Edmonton, and randomized them to usual care or pharmacist/nurse enhanced care. Enhanced care consisted of education on cardiovascular risk reduction, communication of drug therapy recommendations to the patient's primary care physician, and 4 follow-up visits over 6 months. Control patients received general diabetes advice and continued receiving usual care from their physician. After 6 months, enhanced care patients saw a systolic BP (SBP) reduction of 5.6 mm Hg (SE 2.1) more than usual care patients (p=0.008), with even greater effects seen in patients with baseline SBP >160 mm Hg (difference = 24.1 mm Hg versus usual care, p=0.001).

Three meta-analyses of randomized controlled trials have been published in recent years on the outcomes achieved by pharmacists performing clinical care activities, and reported on blood pressure reduction achieved. A 2010 paper by Chisholm-Burns *et al.*[30] was limited to studies conducted in the United States. The descriptive review included studies providing evidence of pharmacist involvement in direct patient care, employing comparison group(s), and reporting patient-related outcomes (therapeutic, safety, or humanistic), regardless of study design. However, only randomized controlled trials were included in the meta-analysis. Studies had to be randomized at the individual patient level, report the number of individuals in the intervention and control groups, and report outcomes as either a mean with standard deviation or as a proportion.

Santschi et al. published two systematic reviews with meta-analyses - one including patients of all types (excluding only those studies conducted exclusively in patients with diabetes),[31] and the other specifically examining the effectiveness of pharmacist intervention in patients with diabetes.[32] Neither review was limited by country as with the paper described previously. Included studies had to have a randomized controlled design, evaluate the impact of pharmacist-provided care, and had to be conducted among adult outpatients with modifiable cardiovascular disease (CVD) risk factors, which may include hypertension, dyslipidemia, diabetes, smoking, or obesity. Studies meeting these criteria were included irrespective of whether patients were receiving pharmacologic treatment. The results of all 3 reviews related to blood pressure interventions are presented in Table 1-2.

Table 1-2. Blood pressure outcomes reported in meta-analyses

Paper	No. of Studies	No. of Patients	Result (Pharmacist care vs. control)
Systolic blood pressure			
Chisholm-Burns *et al*., 2010[30]	14	9 357	-7.8 mm Hg (SD=1.5; p<0.001)
Santschi *et al.,* 2011[31]	19	10 479	-8.1 mm Hg (SD=1.1; p<0.001)
Santschi *et al.,* 2012[32]	12	1 894	-6.2 mm Hg (SD=0.8; p<0.001)
Diastolic blood pressure			
Chisholm-Burns *et al.,* 2010[30]	13	9 208	-2.9 mm Hg (SD=0.7; p=0.001)
Santschi *et al.,* 2011[31]	19	10 479	-3.8 mm Hg (SD=0.8; p<0.001)
Santschi *et al.,* 2012[32]	9	1 496	-4.5 mmHg (SD=0.9; p<0.001)

The paper by Chisholm-Burns *et al.* reported that the p-values observed were not impacted following the removal of any one study from the analysis, but did not report conducting any further sensitivity analyses.[30] Santschi *et al.* found no appreciable differences in BP reduction in either of their reviews after sensitivity analyses based on study quality or size, and after excluding one study in their 2011 review where the pharmacist did not have direct contact with patients.[31-32] Post-hoc subgroup analyses based on type of care (pharmacist-directed vs. collaborative), the type and number of interventions, and the inclusion of strictly uncontrolled or a combination of controlled and uncontrolled hypertensive patients also did not significantly affect the outcomes observed.

All three papers acknowledged a high degree of heterogeneity among studies regarding the type and/or intensity of the intervention(s) applied, the inclusion criteria for subjects, whether care was pharmacist-directed or performed collaboratively, and follow-up parameters. Therefore, while likely generalizable to a broader setting, one cannot ascertain which intervention(s) were most specifically correlated with improved systolic or diastolic blood pressure outcomes observed. Likewise, it is also possible that unintentional co-interventions had occurred, which may not have been detected.

1.1.5 Alberta Clinical Trial in Optimizing Hypertension (RxACTION) Study

Legislation for pharmacist prescribing in Alberta therefore presents a unique opportunity to study a number of the factors outlined above, including clinical- and cost outcomes in the management of hypertension, and an examination of how these activities should be funded. Such data can play a key role in the further expansion of pharmacist prescribing activities worldwide and the development of appropriate remuneration strategies to ensure the uptake and sustainability of this type of care.

To that end, the first randomized controlled trial of pharmacist prescribing has been performed in Alberta. The complete study protocol has been published elsewhere[33]. In brief, pharmacists from across Alberta with Additional Prescribing Authorization were invited to participate in the study, which enrolled patients with uncontrolled BP as defined by CHEP. Randomization occurred at the level of the patient in a 2:1 ratio to enhanced care or usual care. Usual care consists of BP measurement at 3 month intervals, a BP wallet card for the patient to record readings on, and written information on cardiovascular disease. Enhanced care added a complete cardiovascular risk assessment, provision of personalized lifestyle advice, prescribing/titration of antihypertensive drugs by the pharmacist, and follow-up at 4-week intervals until BP target was reached. All patients were followed for 6 months. Enhanced care patients were further randomized in a 1:1 ratio to either fee-for-service or pay-for-performance remuneration strategies for the pharmacist, in order to study the impact of incentive pay on outcomes achieved. The primary outcome was the difference in systolic BP reduction achieved between the groups, with secondary outcomes including diastolic BP reduction, the proportion of patients achieving target BP, systolic BP reduction achieved between FFS and P4P groups, the type and number of prescribing activities performed, and the proportion of patients initiated on ASA or a statin by the pharmacist.

Enrolment into the study concluded on May 31, 2013, with the study results presented in Appendix 2. A total of 248 patients were enrolled into the study. After adjusting for age, sex, diabetes status, history of myocardial infarction, and BMI, the mean (SE) difference in change in systolic BP was 7.0 (2.5) mm Hg (p=0.005). The mean (SE) difference in change in diastolic BP was 3.5 (1.3) mm Hg (p=0.007). Target BP was

reached by an absolute difference of 23.9% more patients in the enhanced care compared to usual care group (p=0.001).

The results of the remuneration sub-study comparing systolic BP reduction achieved between enhanced care and usual care groups are presented in Chapter 6.

1.2 THESIS OBJECTIVE

The broad intent of this thesis is to examine the clinical and economic effectiveness of pharmacist care, including prescribing, in the management of hypertension in the community. In doing so, the objectives of this thesis are:

1. To estimate the cost impact of pharmacist provided care for hypertension from a health system perspective, with the expectation that any cost-savings from reduced complications can be invested into paying pharmacists for providing this direct patient care;
2. To identify how pharmacists worldwide are currently paid for non-dispensing activities and the potential business implications of scaling-up the provision of these activities in community pharmacies; and
3. To determine whether payment models for pharmacists' clinical care activities should consider incentive payments related to the magnitude of outcome(s) achieved.

1.3 THESIS OUTLINE

Chapter 2: An economic model estimating health system cost implications as a result of pharmacist and nurse intervention for hypertension management in the community, based on avoided major cardiovascular events.

Chapter 3: A systematic review to identify the current status worldwide of payment for pharmacists' clinical care activities.

Chapter 4: An examination of the business potential of utilizing blood pressure kiosks in community pharmacies to identify patients eligible for remunerable clinical care services.

Chapter 5: A systematic review to assess whether performance-based remuneration is associated with improved patient health outcomes.

Chapter 6: A sub-study of the RxACTION randomized controlled trial, evaluating blood pressure reduction achieved via pharmacist care including prescribing, comparing subjects whose pharmacist was paid by performance-based remuneration versus a flat fee irrespective of outcome.

Chapter 7: Overall summary, opportunities for future research, and the clinical and economic implications of the results.

Appendix 1: Additional table data for chapters 1-7.

Appendix 2: Results of the Alberta Clinical Trial in Optimizing Hypertension (RxACTION) randomized controlled trial of pharmacist prescribing for hypertension management.

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CHAPTER 2: Effect of a pharmacist-managed hypertension program on health system costs: an evaluation of the Study of Cardiovascular Risk Intervention by Pharmacists-Hypertension (SCRIP-*HTN*)

2.1 INTRODUCTION

Hypertension is a common condition affecting approximately 20% of adults in North America, with prevalence increasing with age to more than 70% of those aged 80 years and older.[1,2] Poorly controlled hypertension contributes to cardiovascular events such as myocardial infarction, stroke, and heart failure. Furthermore, individuals with hypertension have been shown to have a 34–44% higher rate of all-cause mortality than those without hypertension.[1] Heart disease and stroke contribute to a significant portion of North American health care costs from direct costs—such as drug therapy, costs of major cardiovascular events attributable to elevated blood pressure, and outpatient and hospital visits for treatment of hypertension—and indirect costs such as lost productivity.[3,4] Although hypertension control rates are improving, in more than one third of patients with the condition, hypertension remains poorly controlled.[1]

There is a growing body of evidence that intervention programs by health care professionals such as community pharmacists are effective at preventing and managing cardiovascular disease, including a recently published meta-analysis on pharmacist intervention programs for cardiovascular risk reduction.[5,6] It has been argued that pharmacists are ideally suited to provide preventive care and chronic disease intervention for a number of reasons. Community pharmacists are highly accessible health professionals in both rural and urban communities and are often available without an appointment and beyond the hours of operation of many primary care medical clinics. In addition, patients see their pharmacist more frequently than their physician.[7] As drug therapy experts, pharmacists are capable of providing pharmacotherapeutic and educational interventions and are well positioned to play a greater role in primary health care.

A recent randomized controlled trial, the Study of Cardiovascular Risk Intervention by Pharmacists—Hypertension (SCRIP-*HTN*), demonstrated that compared with usual care, community pharmacy intervention for patients with diabetes mellitus and

uncontrolled hypertension led to a 5.6 mm Hg greater reduction in systolic blood pressure over 6 months.[5] Thus, we sought to quantify the potential cost savings of a community pharmacy–based hypertension management program based on the results of the SCRIP-*HTN* study in terms of avoided cardiovascular events over a 1-year period.

2.2 METHODS

An economic model was developed to estimate the potential cost avoidance in direct health care resources achievable over a 1-year period as a result of reduced major clinical adverse events—myocardial infarction, stroke, and hospitalization for heart failure—if systolic blood pressure were lowered by 5.6 mm Hg in patients with uncontrolled hypertension.

2.2.1 The SCRIP-HTN Study

Details on the intervention provided in the SCRIP-*HTN* study are reported elsewhere.[5] In brief, the study population consisted of Canadian residents with diabetes and uncontrolled hypertension (blood pressure > 130/80 mm Hg) as defined by the Canadian Hypertension Education Program.[8] Patients randomized to the intervention group received cardiovascular risk reduction counseling by a pharmacist-nurse team along with a hypertension education brochure. Patients were provided a wallet card documenting their blood pressures and were encouraged to visit their primary care physician for cardiovascular risk assessment. To facilitate this, the pharmacist-nurse team faxed the physician documentation on the patient's modifiable and non-modifiable risk factors, current blood pressure reading and drug therapy, and recommendations for further testing or management, supplemented with a one-page summary of the evidence for blood pressure management and current Canadian guidelines signed by local opinion leaders in hypertension. Patients were followed up every 6 weeks, with results of these assessments sent to each patient's primary care physician. In contrast, patients receiving usual care received a blood pressure wallet card, a pamphlet on diabetes, and general diabetes counseling from the nurse or pharmacist. A total of 227 patients were enrolled in the study: 115 randomized to the intervention group and 112 to the usual care group. Both groups were similar at baseline with regard to age (mean age 63.7 years in the intervention group and 66.2 years in the usual care group) and the presence of

cardiovascular risk factors (with the exception of alcohol consumption and history of previous stroke, transient ischemic attack, or carotid revascularization, all having a higher proportion in the intervention group). Patients in the intervention group were also significantly more likely to be male than those randomized to usual care (65.2% versus 54.5%). At study end (6 months), patients in the intervention group had a greater mean ± SE reduction in systolic blood pressure of 5.6 ± 2.1 mm Hg than those patients receiving usual care.

2.2.2 Model Perspective

Our model takes the perspective of a provincial Ministry of Health (a single payer providing universal access to health care). Indirect costs (e.g., days absent from work) and direct nonmedical costs (e.g., travel costs and caregiver costs) were excluded from the analysis. We excluded the cost of outpatient prescription drugs since data on prescription drug costs associated with similar hypertension management programs were not available and there are potentially limitless combinations of antihypertensive drug therapies available at highly varying costs.

2.2.3 Time Period

Economic outcomes are expressed as cost avoidance/patient over 1 year. This time period was chosen because of its convenience and its applicability to health system budgeting. Sensitivity analyses explored the possibility of dwindling effectiveness in the final 6 months of the time frame, since the duration of the SCRIP-*HTN* intervention was 6 months. Details on the parameters used in the sensitivity analysis are provided below.

2.2.4 Sources of Inputs

2.2.4.1 Clinical Outcomes

We derived estimates of the effect of blood pressure lowering on clinical outcomes in patients at high cardiovascular risk (such as those in SCRIP-*HTN*) by using data from the Blood Pressure Lowering Treatment Trialists' Collaboration (BPLTTC).[9] This meta-analysis of 29 randomized trials included patients with hypertension and additional

cardiovascular risk factors such as diabetes or peripheral artery disease. The BPLTTC studies were excluded from our model if they did not meet the following criteria: were double-blind and placebo-controlled, and reported on the systolic blood pressure difference between the treatment and control groups. For those articles in which the presence or absence of these criteria was unclear, the study authors were contacted for additional information. A total of 18 studies were excluded for not meeting all criteria, and an additional three studies were excluded because the authors did not reply to our requests for additional information. Thus, eight studies were used for our analysis and are described in Table A.1-1 (**see Appendix 1**).[10–18]

From these studies, we extracted the following information: sample sizes of treatment and control groups, duration of follow-up, number of events (myocardial infarction, stroke, and heart failure exacerbation requiring hospitalization) in the treatment and control groups, and the mean systolic blood pressure reduction realized. Studies were then weighted so that the studies with larger sample sizes would have greater influence. This was done by multiplying the following results from each study by that study's sample size, summing those values across each study, and then dividing this sum by the total sample size across all applicable studies to determine the average outcomes: systolic blood pressure reduction, study duration, and event counts within the intervention and control groups. The absolute risk reduction was calculated for each event by taking the difference in clinical event rates between the control patients and the intervention patients. To determine the 95% confidence intervals (CIs), we calculated the SD of the difference and assumed the results followed a normal distribution. The absolute risk reductions calculated for each event were then adjusted to a 6-month period using an exponential survival curve function.

2.2.4.2 Clinical Outcome Rate Reduction

Between the intervention and control groups in the included studies, the overall absolute risk reduction was 2.00% (95% CI 0.65–3.44%) for myocardial infarction, 2.40% (95% CI 1.11–3.70%) for stroke, and 2.20% (95% CI 0.86–3.57%) for development of heart failure symptoms or hospitalization for heart failure (Table A.1-2)(**see Appendix 1**).[10–18]

The mean duration of follow-up across all studies was 3.7 years, and the weighted mean systolic blood pressure reduction was 5.7 mm Hg. These absolute risk reductions were then adjusted to a 6-month period using an exponential survival function and then repeated with adjusting to a 3.5- and 7.7-mm Hg mean systolic blood pressure reduction (corresponding to ± 1 SE of the mean reduction in systolic blood pressure from the SCRIP-*HTN* study), assuming a linear relationship between systolic blood pressure reduction and cardiovascular risk.[19] The larger of the two SEs calculated for the 3.5- and 7.7-mm Hg systolic blood pressure reductions was added to the SE of the absolute risk reductions from the cardiovascular event data for use in the sensitivity analysis. This accounted for the variability associated with the event data and the variability around the mean systolic blood pressure reduction achieved in SCRIP-*HTN*. Summation of SEs was employed since these terms were assumed to be independent.

2.2.4.3 Event Costs

Event costs adjusted to 2011 Canadian dollars were applied to all outcomes.[20] Average inpatient costs for myocardial infarction, stroke, and heart failure hospitalization were obtained from the Canadian Institute of Health Information (CIHI)[21] and included direct costs for the initial hospitalization (nursing, laboratory tests, diagnostic imaging, pharmaceuticals, allied health professionals, and overhead). Physician billing costs were excluded because records of those costs are submitted directly by the physicians to their respective province's department of health for reimbursement and not documented on the administrative systems used to collect data for CIHI. Therefore, the event costs presented were an underestimate of true cost. Also excluded were outpatient costs for continued care and follow-up as a result of the event. Costs were also transformed by CIHI to approximate a normal distribution, and regression was used to adjust for varying patient complexity. Unit cost data used in the model are provided in Table 2-1.

Table 2-1. Average Inpatient Costs for Major Cardiovascular Events.

Cost Parameter	**Cost/Event[21]**
Myocardial infarction	$13,737 ± $81.64
Stroke	$17,741 ± $144.43
Heart failure hospitalization	$12,185 ± $93.68

Data are mean ± SE.
Costs were adjusted to 2011 Canadian dollars.[20]

2.2.4.4 Program Costs

Actual program cost data were not available in the SCRIP-*HTN* study.[5] However, another study quantified the time spent by a pharmacist in providing pharmaceutical care for 25 patients with essential hypertension.[22] This study enrolled patients with uncontrolled hypertension who were cared for by physicians belonging to a particular medical group in the United States and who had monthly consultations with a pharmacist in his community pharmacy for 5 months. At these consultations, the pharmacist documented patient history, measured blood pressure, assessed drug therapy utilization and adherence, provided patient education, identified drug-related problems, and communicated recommendations to the patient's physician. In addition, the pharmacist visited the urban health center where the patients' physicians practiced to review medical records and make recommendations directly to the physicians. In this study, the pharmacist spent, on average, 25 minutes to complete the initial consultation and 6 minutes for monthly follow-up consultations. Based on the results of this study and acknowledging the high number of antihypertensive drugs introduced into practice since this study was conducted in 1973, we assumed that initial visits in SCRIP-*HTN* took 30 minutes and follow-up visits every 6 weeks took 15 minutes. Using the average hourly wage for pharmacists in Alberta, Canada ($50.16 in 2011 Canadian dollars),[20,23] personnel costs would approximate $75.24/patient in pharmacists' wages alone over the 6-month program. If a 20% fringe rate was applied for nonwage benefits, the total personnel cost would be $90.29/patient for the 6-month program. If follow-up visits continued every 6 weeks for a total duration of 1 year, personnel costs including fringe benefits would be $150.48/patient/year.

We acknowledge that the above-mentioned study[22] may not accurately represent usual community pharmacy practice today for two key reasons: pharmacists rarely visit the practice site of patients' physicians to review complete medical records, and the complexity of antihypertensive drug treatment has expanded considerably with the addition of new drugs to the market since the study was conducted. Therefore, we also tested scenarios in which twice the amount of time is required for the pharmacist to provide care for the first 6 months (i.e., 1 hour for the initial assessment and 30 minutes for follow-up visits), and for programs continuing for 1 year, 15 minutes/visit is required for the last 6 months. We believe that this approach is rational, since other

hypertension studies conducted in community pharmacies have estimated 15–60 minutes/consultation.[24–26]

Although both a pharmacist and nurse were used in SCRIP-*HTN*, it is unlikely that 30 minutes of both the pharmacist's and nurse's time would be necessary for the initial visit, and one health professional could likely perform the intervention. To be conservative, we used the average hourly wage for pharmacists, since it is higher than the average hourly wage for nurses in Alberta.

2.2.5 Sensitivity Analysis

Multiway probabilistic sensitivity analyses were performed to estimate expected cost avoidance and associated variability through 10,000 Monte Carlo simulations using the distributions and SEs listed in Table A.1-3 (**see Appendix 1**).

During each simulation, for each input with a fitted distribution, a value was randomly sampled from the distribution, and the costs were calculated for the simulation (probabilistic sensitivity analysis). Based on the 10,000 sample sets, a distribution of expected costs was generated, from which the degree of variability was assessed.

In addition, improvements in blood pressure levels noted during hypertension programs often dwindle after a program's discontinuation and patients return to usual care (Table A.1-4) (**see Appendix 1**).[22,27,28]

From these studies, it appears that approximately two thirds of the blood pressure reduction realized as a result of an intervention, including pharmacist care, dwindles after program discontinuation. Therefore, the sensitivity analyses also incorporated the potential for decline of clinical effectiveness for the last 6 months of the model's time frame, during which time the pharmacy program would have ended and patients returned to receiving usual care. This was done by assuming a random non-distributed loss of up to two thirds of the improvement noted in the program in the 6 months after the program's end in each of the 10,000 Monte Carlo simulations performed. To determine annual absolute risk reduction, the risk reduction calculated from the 6

months of the program was added to the risk reduction modeled for the 6-month follow-up period after the program's end.

In addition, a one-way sensitivity analysis was performed to test the conclusions of the model against the situation in which consultations would take community pharmacists more time for the first 6 months of care for a patient (as described above).

2.3 RESULTS

Based on 10,000 Monte Carlo simulations estimated, mean cost avoidance in a program like SCRIP-*HTN* as a result of reduced cardiovascular events was $265 (95% CI $63–467) annually/patient, assuming that the blood pressure reductions achieved in the 6-month program persisted for 6 months after the program end (total of 1 year). If the effectiveness achieved during the program declines during the 6 months after the end of the program as described, mean cost avoidance was calculated to be $221 (95% CI $72–371) annually/patient.

As described earlier, assuming that the initial assessment takes 30 minutes to complete, with follow-up visits of 15 minutes every 6 weeks, the personnel costs, including benefits, for the pharmacist to provide the service would be $90.29/patient for the program period alone, or $150.48/year if follow-up by the pharmacist continued at 6-week intervals for a total of 1 year. Therefore, the annual net total cost savings/patient were estimated to be $130.98 for a program lasting 6 months or $114.74 for a program lasting 1 year.

Assuming that these consultations require more time for community pharmacists to perform than reported in the 1973 study[22] (for the reasons discussed above), doubling of the time required to perform visits for the first 6 months (1 hour for initial consultation and 30 minutes for follow-up visits) followed by 15-minute consultations for the remainder of the year, we estimated pharmacist costs of $180.58 for a 6-month program or $240.77 for a program lasting 1 year. This results in annual net total cost savings/patient of $40.69 for a 6-month program or $24.45 for a 1-year program, showing that such programs are at least cost neutral even when using these longer time parameters.

Our model finds that, on average, a program like SCRIP-*HTN* should be at least cost neutral if not cost saving in terms of personnel costs as a result of avoided major cardiovascular events alone, whether the program ends after 6 months or continues with regular follow-up for a total of 1 year.

2.4 DISCUSSION

This study presents the results of an economic model developed to quantify the potential cost avoidance as a result of a 6-month community pharmacy–based hypertension management program like SCRIP-*HTN*, targeting individuals with elevated cardiovascular risk and achieving a mean ± SE systolic blood pressure reduction of 5.6 ± 2.1 mm Hg/patient compared with usual care. From this model, we estimated that the costs to provide such services in terms of pharmacist time are offset by savings to the health care system from reduced cardiovascular events and, in fact, that cost savings can be realized to the health care system as a result of paying pharmacists to provide cognitive services to reduce blood pressure in patients with hypertension and diabetes.

The risk reductions for major cardiovascular events used in our model are consistent with those from other work. A meta-analysis of 147 randomized controlled trials of blood pressure–lowering drugs and their association with cardiovascular event rates estimated that for a 6-mm Hg reduction in systolic blood pressure, the relative risk reduction was 15% (95% CI 11–19%) for myocardial infarction, 27% (95% CI 20–34%) for stroke, and 24% (95% CI 19–28%) for a heart failure hospitalization.[29] Relative risk reductions from our model using the BPLTTC trials were 20% for myocardial infarction, 28% for stroke, and 23% for heart failure. It must also be noted that although the SCRIP-HTN trial studied individuals with concurrent hypertension and diabetes, our model focused on those with uncontrolled hypertension regardless of their diabetes status (although by using data from BPLTTC trials in patients with hypertension and elevated cardiovascular risk, our resulting estimates of clinical outcomes are for higher risk individuals). Our assumption that cardiovascular risk is linearly related to magnitude of systolic blood pressure reduction within the range of systolic blood pressure encountered in individuals with hypertension in clinical practice is substantiated by a meta-analysis of more than 1 million people by the Prospective

Studies Collaboration, which found that when plotting cardiovascular risk on a logarithmic scale versus blood pressure on an arithmetic scale in every age group, the resulting graph was well fitted by straight lines above a systolic blood pressure of 115 mm Hg, with no strong evidence of an upper threshold.[19]

The main limitation of our model is that it does not account for outpatient costs of prescription drugs used in patients enrolled in an intervention program versus those not enrolled in such a program but does include inpatient prescription drug costs for patients experiencing a cardiovascular event. Not only is there a lack of studies reporting actual outpatient drug utilization or costs associated with a particular systolic blood pressure reduction achieved, but there is also such a wide range of antihypertensive drugs available of highly variable costs with potentially limitless combinations that estimation of such costs would be impossible. Because the perspective of the study was that of a provincial ministry of health (insurer), which covers the cost of inpatient drugs for all patients but only for a small subset of the population's outpatient drugs (i.e., the elderly and the disabled), this approach of including inpatient drug costs but not outpatient drug costs is consistent with our perspective. In addition, potential costs avoided as a result of reduced physician visits or emergency room visits for hypertension assessment or management were not considered in the model, as these data were not collected in SCRIP-*HTN* or were not available from other sources. Such costs may be substantial, as was found in a 5-month, pharmacist intervention study that included 25 patients with hypertension; these patients scheduled 34 appointments with physicians over the study period versus 44 appointments over the same time period before the study.[22] The authors hypothesized that this difference in number of physician visits may have reflected the improved blood pressure readings seen throughout the study period and the receipt of regular follow-up by the pharmacist. Therefore, our estimate of cost savings estimated from SCRIP-*HTN* may be a significant understatement of the true cost-benefit if all other factors are considered. Although pharmacist training and overhead costs were not included in our model, since these data were not collected in SCRIP-*HTN*, we feel that these costs are likely to be reasonably offset by the net cost savings from reduced cardiovascular events as well as additional cost savings from reduced utilization of other health services, such as family physician or emergency department visits for routine management of chronic hypertension.

Other limitations with the available data may have also affected our results. For example, inpatient cost data from the CIHI does not include fee-for-service payments to the physicians providing inpatient care. The perspective taken for the analysis was that of payer or insurer, excluding costs incurred by the patient (e.g., expenses associated with travel, or time at a community pharmacy or physician's office) and to sectors outside of the health system (e.g., lost productivity from unemployment and/or disability from stroke). In addition, other factors such as diabetes control and drugs for prevention of cardiovascular disease (e.g., antiplatelet or lipid-lowering therapy) are unknown from the published studies used in determining cardiovascular event risk reduction, yet they may have also played a contributing role in the outcome rates observed.

Univariate sensitivity analysis demonstrated robust findings in terms of time spent by the pharmacist providing care for patients with hypertension, being at least cost neutral if not cost saving, even if the initial consultation takes up to 1 hour, followed by 30 minutes/consultation every 6 weeks over the next 6 months and 15 minutes/consultation every 6 weeks for the remaining follow-up for up to 1 year total. However, all time estimates are likely overestimated given that available data are based on time pharmacists spent providing patient care within a study environment, which may be inflated because of time spent on documentation and additional study procedures not undertaken in routine practice. It is important to note that all pharmacists providing care as part of the SCRIP-*HTN* study were community pharmacists with a baccalaureate degree and no additional formal training (Doctor of Pharmacy degree or hospital pharmacy residency). Therefore, the results obtained in SCRIP-*HTN* were obtained by typical community pharmacists with standard training. It is possible that the clinical results achieved may differ if care had been provided by clinical pharmacy specialists; however, this was beyond the scope of this study.

Strengths of our study include the use of published data for all variables, and determination of absolute risk reductions for each of the major cardiovascular events as a result of systolic blood pressure reduction from randomized controlled trial data from a published meta-analysis, adjusted to coincide with the blood pressure reduction realized in SCRIP-*HTN*. Thorough probabilistic sensitivity analyses were also

conducted to incorporate the high levels of variability seen from both clinical and economic perspectives, and the evaluations of a 6-month intervention versus follow-up for 1 full year resulted in similar conclusions of cost neutrality and potential cost savings.

SCRIP-*HTN* studied the effects of care provided by both a pharmacist and nurse in a community pharmacy setting. However, we believe that these services could be provided solely by a pharmacist (or solely by a nurse) as would be done in usual practice. This is substantiated by a published meta-analysis that found that pharmacists' interventions alone can reduce patients' systolic blood pressure by a mean ± SD of 7.0 ± 12.9 mm Hg over 7.6 ± 5.5 months compared with usual care.[30] This result remained virtually unchanged when studies including multiprofessional interventions were included in the analysis (mean ± SD reduction of 6.9 ± 12.0 mm Hg). Therefore, in estimating personnel costs, the higher hourly wage paid to pharmacists in Alberta, Canada, was used within the model rather than the average hourly registered nurse wage. Furthermore, our model may also be conservative in estimating personnel costs by assuming a 30-minute initial assessment and 15-minute follow-up visits based on a study from nearly 30 years ago,[22] as it is possible that health professionals have become more efficient in performing these assessments as a result of prevalent time constraints. Although the study did not differentiate the effectiveness of the interventions in patients with concomitant diabetes versus those without diabetes, it did find that the clinical effect of the interventions was greater in those patients with higher baseline blood pressure, suggesting that pharmacist interventions may be more effective in more complex or high-risk patients. Indeed, in SCRIP-*HTN*, patients with a baseline systolic blood pressure greater than 160 mm Hg who were exposed to the intervention exhibited a 24-mm Hg greater reduction in systolic blood pressure compared with those receiving usual care.[5]

Although the intent of this study was to quantify the potential cost savings associated with a community pharmacy–based hypertension management program, one must also consider the potential for new interventions to increase resource use and perhaps increase costs. Without input cost or long-term resource use information available, we were unable to determine whether this may be an unintended consequence of such a program. We anticipate this to be unlikely, since the costs of pharmacist consultations

and care are likely similar to the costs of physician consultations and care; however, we were unable to rule this out as a possibility with the available data. Evidence from other studies also point toward cost-effectiveness of hypertension programs involving pharmacist care.[31–33] Opportunities also exist for pharmacists to bill for such cognitive services,[34] for example, through Medicaid Part D, to help offset the costs to the pharmacy and justify the pharmacist's time away from the dispensary, and should be explored when developing a clinical program.

We believe (and are testing in an ongoing clinical trial [ClinicalTrials.gov identifier NCT00878566]) that the pharmacist intervention will potentially be even more effective in reducing blood pressure if pharmacists prescribe drugs and adjust dosages at the time of patient assessment,[35] rather than simply faxing recommendations to primary care physician offices as done in SCRIP-*HTN*. This study is also capturing program costs, prescription drug costs, and data on health resource utilization including physician visits and hospitalizations. More than 2 million Canadians have poorly controlled hypertension.[1] Extrapolating our findings in this economic model to even 25% of this population could result in potential cost savings of up to $70 million annually to the Canadian health care system.

2.5 CONCLUSION

Community pharmacist hypertension care is cost saving to payers and insurers, and reduces major cardiovascular events if systolic blood pressure is lowered by an average of 5.6 mm Hg in patients with diabetes and hypertension as realized in the SCRIP-HTN study. Wider adoption of pharmacist-provided cognitive services for patients with diabetes and hypertension is therefore encouraged.

2.6 FOOTNOTE

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CHAPTER 3: Paying Pharmacists for Patient Care: A Systematic Review of Remunerated Pharmacy Clinical Care Services

3.1 INTRODUCTION

Since the first definition of pharmaceutical care was published over twenty years ago[1], the pharmacy profession has aimed to transition from a distributive focus to a patient care focus. In particular, the last decade has seen a significant expansion of the pharmacists' role through the implementation of services such as minor ailments schemes, prescribing, medication therapy management programs, and the authorization to administer drugs and vaccines by injection. The implementation of the MedsCheck program in Ontario and the Medicare Part D Medication Therapy Management Program in the United States are two recent examples of government programs remunerating pharmacists for clinical activities in North America.

The Blueprint for Pharmacy, a Canadian strategy for improving the provision of patient-centered care by pharmacists, identifies obtaining remuneration for professional services as a key area of action to support such activities.[2] Indeed, lack of remuneration for services has been cited by community pharmacists as a key barrier preventing the greater provision of clinical services.[3-4] As the pharmacy practice literature reporting the clinical benefits of pharmacist cognitive services continues to grow[5-6] and pharmacy revenues from dispensing alone decrease in light of generic drug price reductions and other factors, the profession is advocating for appropriate payment for clinical services.

A systematic review published by members of our group in 2008 identified 28 programs worldwide wherein pharmacists received remuneration for clinical care services, most often funded by government payers.[7] Medication therapy management, a type of clinical care service defined as a medication review with resolution of drug-related problems, was the most common remunerated service, ranging from $27-170 depending on the number of problems resolved and the time spent, among other factors. While only 14 of these programs reported clinical or economic outcomes, these services were consistently associated with improved chronic disease control and cost-effectiveness. Since its publication, many additional remuneration systems have been developed, implemented, and evaluated. This article therefore aims to serve as an update to the previous

publication, presenting the current status of pharmacist remuneration for clinical care activities worldwide.

3.2 METHODS

The QUORUM process for the conduct and reporting of systematic reviews was followed.[8] As with the previous review, pharmacist clinical care services were defined as "those that enhanced a patient's medication therapy or overall health and did not include medication preparation, distribution, or any tasks that could be delegated to a typical Canadian pharmacy technician with basic training."[7] The provision of routine medication counseling upon dispensing was excluded from this review, as was routine clozapine monitoring without intervention or care plan development, and the administration of drugs or vaccines by injection, which is reported separately.[9]

In consultation with a medical librarian, we performed searches in Ovid Medline, Ovid Embase, International Pharmaceutical Abstracts, the Cochrane Library, EconLIT, Scopus, and Web of Science. The searches combined relevant keywords and subject headings (when available) including *fees, reimbursement, community pharmacy services, medication therapy management, pharmaceutical care*, and *direct patient care*, among others. The complete search strategy can be obtained from the authors on request. The search strategy was derived from that employed in the 2008 review by Chan and Grindrod *et al.*,[7] but significantly expanded the number of terms used with regard to specific types of cognitive services offered including home visits and medication therapy management. Explosion of subject headings, adjacency searching, and truncation of terms were used where appropriate. The Ovid searches were peer-reviewed by a second health sciences librarian to ensure accuracy and comprehensiveness. To identify additional relevant articles, the bibliographies of included studies were manually reviewed, and tables of contents for pharmacy practice journals were reviewed for additional citations.

Grey literature searches were conducted using the same search terms in the Web of Science Conference Proceedings Citation Index and ProQuest Dissertations and Theses. Following the identification of articles and grey literature, comprehensive online searches were performed to seek additional information on programs described in the

citations identified, and to identify additional programs not reported in the literature by accessing websites of governments and regional pharmacy associations in North America, Australia, Europe, and any other regions reporting active pharmacist cognitive services programs.

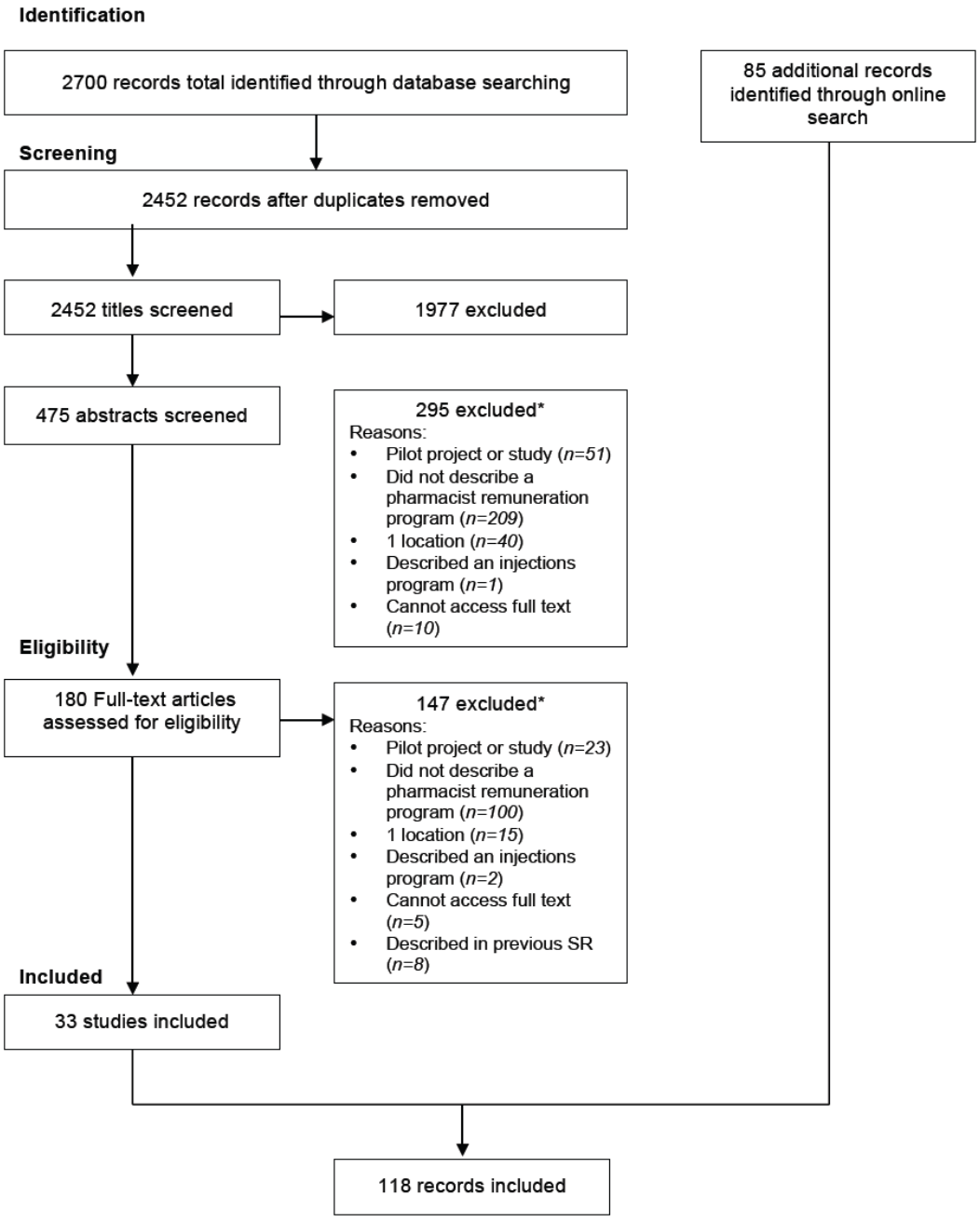
Citations were included if they described remuneration programs for pharmacist clinical care services in any setting, were introduced before December 2012, and were not included in the previous review. Included articles had to be published in English, and had to report on a program where remuneration for these services was provided by a third-party payer such as a government, employer, or insurance plan, and must be separate from dispensing fees. Programs or services paid for directly by patients were excluded, as were programs that existed solely within the context of a funded research study or pilot project, or involved fewer than three pharmacies. We used this approach in order to focus on the long-term support of pharmacists' clinical care services from a broad healthcare system perspective, rather than through individual pharmacy contracts with private insurers or patients or through short-term demonstration projects.

Two authors independently screened titles and abstracts for inclusion. Disagreement was resolved by discussion and consensus. Data extraction was performed by one author, and then independently verified by a second author. To facilitate comparison, all reported remuneration amounts and cost outcomes were converted to Canadian dollars using the Bank of Canada currency conversion rates as of September 16, 2013. Due to expected heterogeneity in this subject area and among different health systems, data were collected descriptively.

3.3 RESULTS

As reported in Figure 3-1, 33 articles and 85 web resources describing 60 programs met our inclusion criteria and are therefore included in this review. Programs were identified across Canada, the United States, Europe, Australia, and New Zealand, ranging in complexity from emergency contraception counseling, to minor ailments schemes and comprehensive medication management. While many programs operate at a regional level, nation-wide programs exist in all countries with the exception of Canada.

Figure 3-1. Flow diagram.



* The sum of studies included per reason exceeds the number of articles excluded since multiple criteria applied to some excluded articles

The identified programs and associated fees, with information on patient eligibility criteria, payers, implementation dates, and additional pharmacist training requirements are presented in Table A.1-6 (**see Appendix 1**). Additional remuneration programs identified, but lacking information on fee amounts, are presented in Table A.1-7 (**see Appendix 1**).

3.3.1 Payers

The majority (73%) of remunerated clinical care services identified are paid for by government agencies, with the remainder funded by private third party insurance plans. All third party-funded programs, with the exception of the General Motors Smoking Cessation Program in Canada, were based in the United States.

3.3.2 Types of Service and Remuneration Schedules

The most common remunerated service identified was for completion of a medication review with or without care plan development, with 38 programs identified. Of these, 18 had limitations on the patients who qualified for the service, described in Table 3-1. The average fee in North America for a medication review – determined by taking the flat fee offered for medication reviews where applicable, or assuming a 30-minute duration for those where payment was time-dependent – is $68.86 (SD $27.42), and pharmacists are eligible for, on average, $23.37 (SD $6.80) for performing a follow-up visit after the completion of a medication review. North American programs were selected specifically for this determination since pharmacist wages and, therefore, fees provided, were more likely to be comparable.

Table 3-1. Eligibility restrictions placed on medication review programs.

Criterion	Number of Programs
Minimum number of drugs taken (range: 2-11)	n=13
Multiple chronic conditions	n=8
Recent discharge from hospital	n=4
Presence of specific chronic conditions: Asthma *(n=4)* Cardiovascular disease (including hypertension, heart failure, ischemic heart disease, dyslipidemia) *(n=4)* Mental health disorder (including addiction) *(n=3)* Diabetes *(n=4)* COPD (n=3) Others: Chronic kidney disease, obesity, gastroesophageal reflux disease, sickle cell anemia *(n=1 for each)*	n=5
Patient age	n=3
Multiple prescribers	n=3
Drugs requiring laboratory monitoring	n=2
Need for compliance packaging	n=2
Minimum annual drug costs	n=1

Other common remuneration programs identified were for contacting prescribers about drug therapy problems identified (*n=13*), smoking cessation counseling (*n=9*), diabetes management (*n=5*), emergency hormonal contraception counseling (*n=2*), and device training for inhaled medications (*n=2*). Minor ailments programs are operational in Saskatchewan, England and Northern Ireland.[23,114-116] Seven programs paid pharmacists for prescription adaptation services, including therapeutic substitution, dose or dosage form changes, emergency prescribing, or extending refills. The fee for prescription adaptation services (currently offered only in North America) averages $15.16 (SD $9.12) per service. When remuneration was provided based on a pre-specified time increment, this fee was found to be on average $1.68 (SD $0.75) per minute.

3.3.3 Additional Pharmacist Training Requirements

Thirteen programs (22%) required pharmacists to complete additional training or certification to provide services, including basic training on administration of the program[22,83-85,99-102], attendance at a workshop or completion of an online module on the disease state involved[22,23,55-58,82,103-108], credentials of a Certified Diabetes Educator of Board Certified Pharmacotherapy Specialist[30-33,42-46], or completion of a residency or

certificate program[30-33,79-80]. In Alberta, pharmacists with Additional Prescribing Authorization can claim higher fees for medication reviews and follow-ups than those without this authorization,[10] and in Saskatchewan pharmacists with PACT (Partnership to Assist with Cessation of Tobacco) training can claim for smoking cessation counseling visits of longer duration than those without PACT training.[23] One program restricted program participation to pharmacists graduating after 1996.[52-53]

3.3.4 Evaluation of Outcomes

Uptake data, clinical or economic outcomes, and barriers preventing further expansion or service provision were identified for 16 programs, representing 27% of all programs identified, and is presented in Table A.1-8 (**see Appendix 1**).

Concerns with low uptake by pharmacists were reported across multiple studies. For example, only 22% of eligible pharmacists provided smoking cessation services as part of the General Motors Smoking Cessation Program[25], and the Wisconsin Medicaid Pharmaceutical Care Program found that 37% of pharmacies participated in the program for only one year.[88] Similarly, in New Zealand, only half of pharmacists accredited to perform medication use reviews were actually performing that service regularly.[103]

Patient uptake of pharmacist clinical care services was also highly variable. At the lower end, only 17% of patients eligible for the Iowa Priority program and with prescription drug claims received a brown bag medication review.[41] Conversely, 12 pharmacists in Texas saw 500 diabetic patients within 6 months,[80] and Scottish pharmacists provided smoking cessation services to 12,000 patients per year.[104-105]

When provided, pharmacist services were effective for smoking cessation,[25,104-105] identifying and resolving drug-related problems,[50,51,66,94,139,141] and improving clinical parameters such as glycosylated hemoglobin (HbA1c), cholesterol, and blood pressure.[45,50,51,69,81,95] However, one study of Medicare Part D medication therapy management services found mixed clinical outcomes.[147] Pharmacist services were also widely considered to have a net cost benefit,[50,66,70,71,80-81,94,140,145-147,151] with estimated returns on investment ranging from $1.29 per dollar spent within the Minnesota

Medication Therapy Management Program[50] to $2.50 per dollar spent in a Medicare Part D Medication Therapy Management Program.[140]

Patient satisfaction, when measured, was high,[50,144,147,150] as was job satisfaction among U.K. pharmacists performing Medication Use Reviews.[112] Barriers identified by pharmacists as impeding the uptake and success of remunerated clinical care services include low reimbursement rates, cumbersome billing processes, time constraints, lack of privacy in the pharmacy, insufficient publicity regarding the availability of services, and lack of interest among physicians and patients.[42,88,103,112,149] Patients noted lack of privacy to be a barrier to seeking minor ailments advice from pharmacists in England.[149]

3.4 DISCUSSION

We identified 118 records describing 60 remunerable pharmacist clinical care services across North America, Europe, Australia, and New Zealand. Remunerated services included medication reviews, chronic disease management, prescription adaptations, emergency hormonal contraception counseling, smoking cessation counseling, and minor ailment programs. Some regions in the United States also paid pharmacists for contacting prescribers to resolve drug therapy problems or to authorize the substitution of more cost-effective therapies.

In the five years since our previous review,[7] the number of remunerated pharmacist clinical care services programs have doubled. Consistent with previous findings, nearly three-quarters of programs are paid for by government payers, with the remainder being supported by private insurance companies. One disturbing finding is that the proportion of programs reporting uptake and outcome data has declined from 50% to 27% in the current review. Although these findings may be limited by the few programs collecting such data internally, to remain sustainable the collection of uptake and outcome data is critical to demonstrate a return on investment in these services from a payer perspective, to encourage expansion of remunerated programs, and to demonstrate the impact of pharmacist care on patient care and health system outcomes. Processes to both collect and publish this information should therefore be built into every remuneration program.

Although lack of remuneration is a commonly expressed barrier preventing pharmacists providing more clinical care services, outcome data presented here suggest that the mere presence of a remuneration scheme is insufficient to ensure uptake in practice. For example, pharmacist participation in the remuneration programs described herein was found to vary considerably, with some programs reporting very low numbers of participating pharmacies,[51,142-143] and others reporting a high initial expression of interest but short persistence or very low patient enrollment over time..[25,87-89,103,112]

Payers should consider the commonly reported barriers to uptake, including insufficient remuneration for services offered, cumbersome paperwork and complicated claims submission processes when designing and evaluating programs. Practicing front-line pharmacists should be invited to these discussions, and processes should be pilot tested prior to roll-out to identify and resolve administrative issues. For other barriers such as insufficient privacy in the pharmacy, time constraints, and insufficient public awareness of services, employers and payers should expect that there may be some changes needed to the pharmacy layout, workflow and marketing strategy. However, one cannot rule out that some pharmacists may report the presence of a number of external barriers when motivation and other internal barriers are the primary issue. As pharmacists often lack confidence and are risk averse,[152] social cognitive theories may offer insight into the resistance to change, as they have been shown to reliably explain intention and predict the behaviour of health professionals.[153] For example, Herbert *et al*. used the Theory of Planned behavior to predict pharmacist uptake of Medicare medication management services. The theory helped identify that the most significant predictor of uptake was the "subjective norm", or the pharmacist's perception of whether others think the service should be delivered.

Due to the high degree of heterogeneity among programs, this study was limited to the descriptive review of remunerated clinical care programs described in the literature or online. Given that over 70% of references identified describing such programs are online resources, and the large number of potential government and private insurance payers, it cannot be assured that our review captured all programs in existence worldwide. Additionally, heterogeneity among fee schedules, patient eligibility, and outcomes collected precluded the meta-analysis of outcomes achieved and whether a relationship exists between the payment models and/or remuneration amount and the

uptake of programs or outcomes. While the limited outcome data identified suggests that pharmacist-provided clinical care services can improve patient adherence and markers of chronic disease, future research should consider whether improvements in these surrogate outcomes are translated into improvements in hard outcomes such as major cardiovascular events, hospitalizations, or mortality. The effect of these clinical care services on patient quality of life has also been insufficiently studied to date. To address these knowledge gaps, we recommend that rigorous outcome reviews by a third party be included in programs' implementation plans, utilizing regular cycles of evaluation and revision to improve program effectiveness.

With diminishing revenues from dispensing, remuneration models for clinical care services should also consider pharmacies' changing business models from primarily dispensing-based revenues to a blend of dispensing and patient care reimbursement income. Pharmacist opinion surveys have suggested that pharmacists often consider the fees to be insufficient, considering the time required to provide patient care.[42] Only three programs reported the mean time spent by pharmacists providing patient care,[95,103,147] with medication use reviews in New Zealand taking twice as long to perform on average (57 minutes) than the expected duration of 30 minutes stated in the payment policy.[103] More research is therefore needed to establish if fees are commensurate with the cost to provide the service from the pharmacy's perspective or, perhaps, if pharmacists need to provide services a more time-efficient manner. Opportunities to streamline processes and improve the efficiency should also be explored. Reported returns on investment of $1.29-$2.50 per dollar spent by these programs[50,145] suggest that there is room to more fairly compensate pharmacists for these services and encourage greater uptake while still remaining cost-saving.

3.5 CONCLUSION

Despite a doubling in the worldwide number of remunerated pharmacy clinical care services offered since 2006, the types of services included and the fees offered continue to vary significantly even within similar geographic areas, and evaluation data remains sparse, and inconsistently collected and reported. Expanding pharmacist scopes of practice worldwide and diminishing revenues from dispensing activities suggest that these programs will take on a larger role in pharmacy business models in the future. In

addition to ensuring that payers adequately reimburse pharmacists for time spent providing this cost-effective care and that patient inclusion criteria are sufficiently broad to ensure access to care, pharmacists must also make both physical and workflow-related changes to their practices to be able to accommodate these increasingly important activities.

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CHAPTER 4: Blood pressure kiosks for medication therapy management programs: Business opportunity for pharmacists

4.1 INTRODUCTION

Hypertension affects 20% to 30% of North American adults and approximately one-half remain uncontrolled.[1–3] Uncontrolled hypertension causes major cardiovascular events, including myocardial infarction, stroke, heart failure, and kidney disease. It is the leading global risk for mortality[4] and is a core chronic disease within Medicare Part D Medication Therapy Management (MTM) programs.[5] The evidence for the benefit of pharmacist care regarding hypertension outcomes is strong.[6–8]

MTM allows for the remuneration of pharmaceutical care services worldwide.[9] Pharmacists are ideally suited to provide these interventions, particularly pharmacists practicing in community pharmacies, which are generally visited by patients more frequently than a physician's office. However, pharmacists historically do not take full advantage of remuneration opportunities, partly because they often lack a system for finding patients.[10] Blood pressure kiosks may help in this regard because they are used frequently by patients and because newer generation kiosks can provide printed messages to patients or on-screen messages to pharmacists that could drive patients to pharmacists for appropriate hypertension care.

4.2 OBJECTIVE

The purpose of this study was to analyze the economic potential of using newer-generation blood pressure kiosks to identify patients who were eligible for remunerable pharmacist care in Ontario, Canada.

4.3 METHODS

Pharmacists in Ontario, Canada, can bill the provincial government for the provision of two types of pharmaceutical care: MedsCheck[11] and Pharmaceutical Opinion.[12] Ontario residents can receive an annual MedsCheck medication review by a pharmacist at no charge if they possess a valid Ontario Health Care card and take at least three

prescription medications for chronic disease or have a type 1 or type 2 diabetes diagnosis regardless of the number of prescription medications they are taking.

A MedsCheck follow-up review can be conducted if considerable changes occur to an existing patient medication profile, nonadherence is documented, a change in residence occurs and prescriptions are transferred to another pharmacy, patients are referred for a MedsCheck follow-up from a physician or nurse practitioner, or a planned hospital admission occurs.

The Pharmaceutical Opinion program enables pharmacists to bill the provincial government for identifying and resolving a drug-related problem during the course of dispensing a medication or when conducting a MedsCheck review. Pharmaceutical Opinion program services can be provided to all Ontario residents (Figure 4-1).

Figure 4-1. Equations Used for Economic Model.

1. Size of population with elevated blood pressure and eligible for MedsCheck and Pharmaceutical Opinion program:

Number of blood pressure kiosk readings taken per month per pharmacy
×
Proportion of blood pressure kiosk readings from "unique" users (to account for multiple measurements per month by the same patients)
×
Proportion of all adults eligible for MedsCheck and Pharmaceutical Opinion
×
Proportion of blood pressure kiosk results that are elevated (>130/80 mm Hg)
×
Eligible billable amount for MedsCheck (CAD $60) and Pharmaceutical Opinion (CAD $15)

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2. Subset of above population that would be expected to receive more than one MedsCheck and Pharmaceutical Opinion program intervention per year:

Population defined in step 1
×
Proportion of patients with hypertension who are hospitalized each year
×
Eligible billable amount for MedsCheck (CAD $60) and Pharmaceutical Opinion (CAD $15)

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3. Proportion of blood pressure kiosk users who do not meet MedsCheck criteria but are on at least one antihypertensive drug and may receive a Pharmaceutical Opinion program intervention tied to a dispensing activity each year:

Same calculation as step 1 above, except incorporating the proportion of all adults *not* eligible for MedsCheck
×
Proportion of patients who are taking antihypertensive medication therapy
×
Eligible billable amount for Pharmaceutical Opinion (CAD $15)

---

4. Net revenue = sum of steps 1, 2, and 3

4.3.1 Patients eligible for MedsCheck and Pharmaceutical Opinion program

Number of blood pressure kiosk readings per month per pharmacy. More than 7.5 million PS-2000 blood pressure kiosk (PharmaSmart Inc., Surrey, Canada) readings were taken from 341 pharmacies between January 2010 and September 2011 (J. Sarkis and L. Goodwin, PharmaSmart Inc., written communication, September 2011). A mean (±SD) of 964 ± 26.8 kiosk readings were taken per pharmacy per month.

Proportion of blood pressure kiosk readings from "unique" users. Some patients may check their blood pressure multiple times per month at a single kiosk or once at multiple kiosks. In the absence of verified patient-specific data, we assumed that up to one-half of blood pressure kiosk readings are multiple readings from the same users.

Eligibility for remunerable pharmacist care. Estimates for the model are based on an adult population (consisting of those ≥25 years) because adults are most likely to use the blood pressure kiosks. All patients qualify for the Pharmaceutical Opinion program; however, MedsCheck reviews are limited to those with diabetes or those taking three or more chronic medications. In Ontario, a total of 519,495 (6.2%) adults qualify based on diabetes status alone (Table 4-1).

Table 4-1. Ontario Population 25 Years of Older with a Diagnosis of Diabetes.

Age Group (years)	No. Population[13]	Diabetes Prevalence (%)[14]	No. Population with Diabetes
25-34	1,535,645	0.90	13,759
35-54	3,777,770	3.21	120,415
55-64	1,356,510	9.95	133,376
65-74	898,190	16.66	145,587
≥75	780,990	18.03	106,458
Total	8,349,105	-----	519,495

For the remainder of the population without diabetes, data suggest that 62% of all Canadians older than 65 years take medications from at least five different drug classes,[15] and U.S. data suggest that approximately one-half of patients younger than 65 years take at least three unique prescriptions.[16] Therefore, we assumed that 50% to 62% of the adult population qualifies for MedsCheck reviews, including the 6.2% of adults with diabetes. Canadian diabetes guidelines advocate for at least one oral hypoglycemic

medication or insulin therapy (acknowledging that combination therapy with two or more agents often is required). Moreover, most patients with diabetes have concomitant hypertension[17] and may require drug therapy to achieve target blood pressure. Therefore, adult patients with diabetes are likely to be on three or more chronic medications to control their diabetes and cardiovascular risk factors. The proportion of patients with diabetes is subtracted from the total eligible for MedsCheck review, as they are automatically eligible. We estimated that 43.8% to 55.8% of the general population qualifies for MedsCheck based on the number of prescriptions criteria. The midpoint was used for the model (49.8%).

Elevated blood pressure kiosk readings. From PS-2000 usage data, we determined that 27% of readings were 130–139/80–89 mm Hg, 29% were 140–159/90–109 mm Hg, and 7% were 160/110 mm Hg or greater. Canadian hypertension guidelines recommend a treatment target of less than 130/80 mm Hg for those with diabetes or chronic kidney disease and less than 140/90 mm Hg otherwise.[18] Therefore, because diabetes and kidney disease status cannot be assessed by the kiosk, we assumed that patients with a blood pressure kiosk reading of 130/80 mm Hg or more (63%) were appropriate for pharmacist intervention, realizing that a portion will not meet the hypertension guideline criteria. Pharmacists completing an annual MedsCheck medication review are eligible for CAD $60 in payment for the 20- to 30-minute in-person consultations, including preparation and documentation time.[11] Pharmacists also can bill the provincial government CAD $15 for Pharmaceutical Opinions if a drug-related problem is identified.[12] Pharmacists who conduct a MedsCheck review for their patients with elevated blood pressure are likely to submit a recommendation to the patient's physician if appropriate. Therefore, we assumed that each annual MedsCheck also included a Pharmaceutical Opinion for the primary physician who qualified for payment.

4.3.2 Patients eligible for more than one annual MedsCheck and Pharmaceutical Opinion

To estimate the number of follow-ups provided between annual MedsCheck reviews, we consulted the 2007 Canadian Community Health Survey. It is a cross-sectional national survey of approximately 65,000 Canadians aged 12 years or older.[19] Based on the survey results, we determined that 14.5% of respondents reporting a diagnosis of

hypertension also reported being an overnight patient in a hospital or related health setting and therefore would be eligible for a MedsCheck follow-up. However, all of these patients receiving a follow-up would be unlikely. In addition, patients could receive a follow-up for another reason. Therefore, we assumed that 14.5% represented the total proportion of patients with high blood pressure who were eligible for a follow-up review from all sources. These follow-up reviews also were assumed to include a Pharmaceutical Opinion. Pharmacists completing a follow-up MedsCheck review are eligible for a CAD $25 payment and CAD $15 for their Pharmaceutical Opinion, as required.[11]

4.3.3 Pharmaceutical Opinions tied to medication dispensing

All Ontario residents qualify for the Pharmaceutical Opinion program. Even residents who do not qualify for MedsCheck are eligible for a reimbursable Pharmaceutical Opinion that is tied to the dispensing of a new or repeat prescription if a drug-related problem is identified. The proportion of kiosk users who take blood pressure medications is unknown. Therefore, we estimated eligible patients using the following rationale. Of Canadians with hypertension, 80% are treated.[3] A fraction of these patients are likely controlled and use the kiosks to monitor their blood pressure. We assumed that 50% of those using the kiosk who have blood pressure greater than 130/80 mm Hg are on at least one antihypertensive drug and eligible for a Pharmaceutical Opinion upon dispensing of their medication(s), if required. Pharmacists can request payment of CAD $15 per Pharmaceutical Opinion regardless of a patient's eligibility for MedsCheck.[12]

4.3.4 Program costs

Costs for pharmacist time and overhead for the service were not factored into the model. The Government of Ontario conducted an analysis of personnel and overhead costs to ensure that the payment rate was sufficient to offset the service cost. The cost of leasing the blood pressure kiosk also was not factored into the model because it varies based on the pharmacy location (distance for company representatives to travel for regular calibration and maintenance) and service options selected, among other factors (J. Sarkis, written communication, PharmaSmart Inc., October 2011). Finally, most pharmacies currently lease a blood pressure kiosk. Therefore, it is an overhead cost

already borne by most pharmacies regardless of whether it is used to identify patients for cognitive services.

4.3.5 Sensitivity analysis

Sensitivity analysis incorporates variability for parameters having a range of potential values. A Monte Carlo simulation repeated the model 10,000 times using different values for each variable; each sample was taken from a predetermined distribution around the known average (Table 4-2).

Table 4-2. Sensitivity Analysis Parameters.

Parameter	Point Estimate	Variability	Distribution
Blood pressure kiosk readings taken per month per pharmacy	964	SE 26.8	Gamma[a]
Proportion of blood pressure kiosk readings that correspond to unique patients (to account for multiple readings per patient per month)	--	Range 50-75%	Uniform[b]
Proportion of the population qualifying for MedsCheck[13-16]	49.8%	Range 43.8-55.8%	Uniform[b]
Proportion of blood pressure kiosk readings ≥130/80 mm Hg	63%	±10%	Uniform[b]
Proportion of patients receiving a MedsCheck follow-up review and additional Pharmaceutical Opinion intervention annually[19]	14.5%	±10%	Uniform[b]
Proportion of patients not eligible for MedsCheck with elevated blood pressure kiosk readings and on drug therapy who could receive a Pharmaceutical Opinion program intervention tied to a dispensing activity[3]	50%	±10%	Uniform[b]

[a] Gamma distribution samples values following a normal distribution with the point estimate as the mean and with a lower limit of zero so that negative values cannot be sampled.
[b] Uniform distribution assumes an equal probability for sampling among the entire range specified.

Monte Carlo simulation is preferred because only one variable is sampled for each model using one-way sensitivity analysis. The Monte Carlo method simultaneously incorporates variability around each estimate for each of the 10,000 calculations, producing more robust results.[20,21]

Two distributions were used to incorporate variability around the point estimates in the model depending on the presence or absence of observed variance parameters. Uniform distributions were used when observed variance parameters were unavailable. We assumed that the sampled values for each of the 10,000 iterations would fall within the prespecified range but with an equal probability of being sampled, unlike a normal distribution in which the probability of sampling is higher for values closer to the mean. When observed variance parameters were available, a gamma distribution was used. Gamma distributions model the normal distribution with the point estimate as the mean of the distribution, with a lower bound of zero.

4.4 RESULTS

On average, 189 patients with elevated blood pressure who would qualify for a MedsCheck annual drug review and Pharmaceutical Opinion were identified per month using blood pressure kiosk readings. Of these, 28 patients likely would require a follow-up MedsCheck assessment and Pharmaceutical Opinion within 1 year. On average, 95 patients would be identified as qualifying for Pharmaceutical Opinion but not for MedsCheck. Assuming pharmacists successfully completed the medication review(s) and Pharmaceutical Opinions for all eligible patients, a mean (±SD) of $12,270 ± 3,854 in revenue could be generated by the pharmacy annually. Of important note, these results assume that case-finding efforts and patient identification occur for 1 month of the year only. Continued case finding each month would further increase possible annual revenue.

After the Monte Carlo simulations, the results remained robust, with a range of $4,523 to $24,420 in revenue estimated if this care was provided to all eligible patients. Assuming that not all patients will agree to and receive a complete medication review, even completing these reviews for one-half of the potentially eligible patients could generate an average of $6,135.

4.5 DISCUSSION

Community pharmacists face many barriers to widespread incorporation of pharmaceutical care into practice, including remuneration,[22] dispensary support to allow time to provide cognitive services,[22] and proactive identification of eligible patients.[23]

The MedsCheck and Pharmaceutical Opinion programs allow pharmacists in Ontario, Canada, to bill the government for time spent providing pharmaceutical care to qualified patients. Public use blood pressure kiosks can serve as an effective case-finding tool to identify patients who would benefit from pharmacist intervention or triage. These kiosks are used frequently—more than 900 times per month in an average community pharmacy—providing daily opportunities for pharmacists to become involved in assisting patients. Pharmacies must legally have a pharmacist on duty at all times to provide patient care and oversee the dispensing process. Consequently, the cost to use the pharmacist(s) may be partially offset by revenues generated from billing for cognitive services, rather than having the pharmacist(s) tied to the dispensary. Such revenues could be reinvested into automated dispensing technology or to obtain additional technician support to address dispensing demands.

Although improvement in patients' health status and reduced risk of adverse events is the primary goal of pharmacist medication reviews and other cognitive services, additional benefits from a business perspective also may result from the provision of these services. Such benefits may include increased customer loyalty, potentially higher prescription volumes, and improved adherence to prescription drugs, which should be examined in future research. Patients may remain loyal to pharmacies that they feel provide a value-added care service compared with other pharmacies. Pharmacists spending one-on-one time to review a patient's individual medication regimen and achieve clinical targets can be anticipated to provide such a value-added service. Further, with documentation of consultations and medication reviews by the pharmacist and the patient's current medication regimen on file at a particular pharmacy, patients can be educated on the importance of maintaining a consistent pharmacy to ensure the highest quality care and best ability for the pharmacist to recognize any actual or potential drug-related problems with their existing medications. Recognition of potential untreated or undertreated medical conditions through the MedsCheck and Pharmaceutical Opinion program reviews also may result in adding new therapies by the patient's physician to better control these conditions. Adherence also can be expected to improve as a result of such services by educating patients on the importance of their medications and addressing any barriers to adherence,[8] which would be expected to result in additional revenue for the pharmacy.[24]

Pharmacist care for hypertension has been shown to have a positive effect on patient outcomes in randomized controlled trials. SCRIP-*HTN* (Study of Cardiovascular Risk Intervention by Pharmacists–Hypertension) found that patients who saw a pharmacist/nurse team every 6 weeks for blood pressure assessment, education, and communication of treatment recommendations to the patients' physician experienced a 5.6–mm Hg greater decrease in systolic blood pressure after 6 months compared with patients receiving usual care. If sustained, this would be expected to reduce stroke risk by 30%.[6] A recently published systematic review on pharmacist interventions for cardiovascular risk factor reduction also demonstrated positive clinical outcomes for patients receiving pharmacist care for hypertension.[7] Although one certainly cannot expect community pharmacies conducting annual MedsCheck assessments to provide the same comprehensiveness of care, these studies provide evidence that pharmacist involvement in patient care is associated with improved patient outcomes.

4.6 LIMITATIONS

A number of assumptions were incorporated into the model when published information was lacking and must be considered when interpreting the results. Because patients may use a blood pressure kiosk more than once per month, a broad range was applied in estimating the proportion of all readings from individual users, estimating that up to one-half of the readings were multiple readings from the same users. In doing so, it was assumed that these multiple readings followed the same distribution of results as all readings, as available data were unable to distinguish whether people with higher blood pressure results were more likely to take multiple monthly readings than those with lower blood pressure results. In addition, the best estimate of the proportion of patients requiring more than one MedsCheck review and Pharmaceutical Opinion annually was applied based on hospitalization rates for patients with hypertension. Without actual data on the proportion of patients receiving more than one annual review/intervention, one cannot be sure whether this is an under- or overestimate.

The accuracy of certain models of public use blood pressure kiosks has been questioned[25,26]; however the PS-2000 model has been well validated against the standards of the Association for the Advancement of Medical Instrumentation and a modified British Hypertension Society protocol.[27] However, because blood pressure

kiosks are not used in a supervised setting, patients may not use the proper technique (e.g., incorrect arm position, not resting before test, talking during testing), therefore resulting in falsely high results. Therefore, measurement on the kiosk should be repeated under observation to ensure proper technique. During this assessment, patients should take three consecutive tests, 1 minute apart, with the first reading discarded and the latter two averaged to minimize the effect of blood pressure variability, as recommended for clinic and home blood pressure monitoring.[18] Even in situations in which results were found to be falsely elevated as a result of suboptimal technique, valuable education can be provided to the patient on the proper measurement of blood pressure and their individual target blood pressure and a medication review for appropriateness and efficacy can be offered.

The results of this model are likely conservative, as Ontario is in the process of developing a chronic disease management remuneration strategy through which all patients with hypertension will be eligible for pharmacist MTM. This would ensure that all hypertensive patients are eligible for MedsCheck services, even those who currently are ineligible because they do not take three or more medications or have concurrent diabetes. This program will expand the size of the eligible population considerably, contributing to even higher revenue potential. In addition, other remunerable programs in Ontario such as the Pharmacy Smoking Cessation Program offer pharmacists additional opportunity to claim remuneration for activities related to smoking cessation, which is another intervention that can be identified at the time of providing MedsCheck or Pharmaceutical Opinion program services.[28] Billable at CAD $40 for the first smoking cessation consultation, $15 for the first three follow-up consultations per calendar year, and $10 for each follow-up consultation thereafter, this program offers pharmacists the ability to combine billable smoking cessation initiatives with existing pharmaceutical care programs. These additional opportunities were not factored into this economic model, but they do portend additional opportunities for sustainable sources of revenue for pharmacy services, including MTM.

Actual revenues achievable as a result of billing for cognitive services may vary depending on each community pharmacy's patient demographics, ability to offer cognitive services because of personnel or infrastructure limitations, or other factors. The intention of this model was to make a business argument for better integration of

the blood pressure kiosk into pharmaceutical care services. Increasingly, these services can be billed in certain situations to governments or third-party payers. Although Ontario, Canada, was used as the setting for this analysis, such an approach also could be used for patients qualifying for MTM through Medicare Part D and other existing remuneration frameworks. Each jurisdiction will have its own remuneration models in place with unique inclusion criteria and billing amounts, potentially affecting the generalizability of our results. However, the overall conclusion is the same. By *actively* identifying patients who may qualify for and benefit from these services, pharmacy blood pressure kiosks could be used as a tool to generate revenue through available MTM remuneration strategies.

4.7 CONCLUSION

Blood pressure kiosks could be a valuable strategy for identifying patients eligible for remunerable cognitive services by pharmacists, providing an evidence-based service for patients, and affording a unique business opportunity for community pharmacies.

4.8 FOOTNOTE

A version of this chapter has been published. Houle 2012. Journal of the American Pharmacists Association. 52(2): 188-194.

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CHAPTER 5: Does Performance-Based Remuneration for Individual Health Care Practitioners Affect Patient Care? A Systematic Review

5.1 INTRODUCTION

Pay-for-performance (P4P) is one of many potential remuneration strategies for clinicians (Table 5-1) and is increasingly touted as a method to improve the quality of health care.[1,2]

Table 5-1. Definitions of Reimbursement Models

Model	Definition
Fee-for-service	Practitioner is paid fees for each service delivered
Pay-for-performance	Any compensation system that links pay to quality of care provided and/or outcomes achieved
Capitation	Practitioner is paid a set amount per patient to provide care over a specified time; patients are allocated to only 1 practitioner or clinic that must often provide them with both clinical care and medication out of that budget
Salary	Basic salary is received for providing care
Mixed/blended remuneration	A government/organization signs a contract with practitioners to pay in accordance with a predetermined blended formula involving multiple remuneration strategies (e.g., salary with fee-for-service for select services).

The Affordable Care Act even calls for an expansion of P4P programs within U.S. health care. The P4P programs targeting hospitals or group practices (such as the Premier Hospital Quality Incentive Demonstration project in the United States) have been found to have marginal effects on process of care measures and little or no effect on harder outcomes, such as mortality.[3,4] As a result, interest is now focusing on P4P programs that specifically target individual practitioners.

An earlier review published in 2006[5] discussed 6 studies evaluating the effect of physician-level P4P programs, but only 2 of these studies compared P4P with other remuneration models; both were small and inconclusive. A recent Cochrane review[6] on the effect of financial incentives for primary care physicians included 7 studies and concluded "there is insufficient evidence to support or not support the use of financial incentives to improve the quality of primary health care." However, many studies have been published since both of these reviews, and we thus conducted this systematic review to determine the current state of the evidence base.

5.2 METHODS

5.2.1 Data Sources and Searches

The following electronic databases were searched, with librarian assistance, from inception until 8 June 2012: PubMed, MEDLINE, EMBASE, Cochrane Library, OpenSIGLE, Canadian Evaluation Society Unpublished Literature Bank, and New York Academy of Medicine Library Grey Literature Collection. The following Medical Subject Headings were used: payment, salary, fee-for-service, payment-for-performance, reimbursement, clinic, clinical outcome, clinical, and outcome. No limitations were placed in terms of patient characteristics, remuneration scheme variables, study duration, or outcomes, and both experimental and observational studies were considered. Bibliographies of identified studies were also manually searched.

5.2.2 Study Selection

Two authors independently screened citations and determined eligibility; disagreements were resolved by consensus. We included original research studies (randomized, controlled trials; interrupted time series; uncontrolled and controlled before–after studies; and controlled/uncontrolled cohort comparisons) that compared P4P with at least 1 other payment model or compared performance before and after initiation of P4P on such quality-of-care measures as target blood pressure or glycosylated hemoglobin or such outcomes as morbidity and mortality. To be eligible for our review, P4P incentives had to target individual practitioner performance and provide payment to individual health care practitioners on the basis of their achievement of quality indicators in patients under their direct care. Thus, P4P programs aimed at hospitals or group practices were excluded. Study authors were contacted to clarify the type of remuneration method or unclear outcome data. Study types were defined according to standard definitions from the Cochrane Effective Practice and Organisation of Care Group (http://epoc.cochrane.org). Because this review focuses on patient-relevant outcomes, any process measures not related to patient outcomes (such as documentation of patient risk factors in their chart) were excluded.

5.2.3 Data Extraction and Quality Assessment

Two authors independently extracted study data; disagreements were resolved by consensus, and a third reviewer validated all data extractions. Quality of included studies was evaluated by using the Cochrane Collaboration tool for assessing risk of bias[7], with particular attention to features highlighted by the Cochrane Effective Practice and Organisation of Care Group (allocation concealment, similar baseline characteristics/outcomes, complete outcome reporting, and protection against contamination).[8]

5.2.4 Data Synthesis and Analysis

Because of substantial heterogeneity between studies, meta-analysis was deemed impossible and results are presented descriptively.

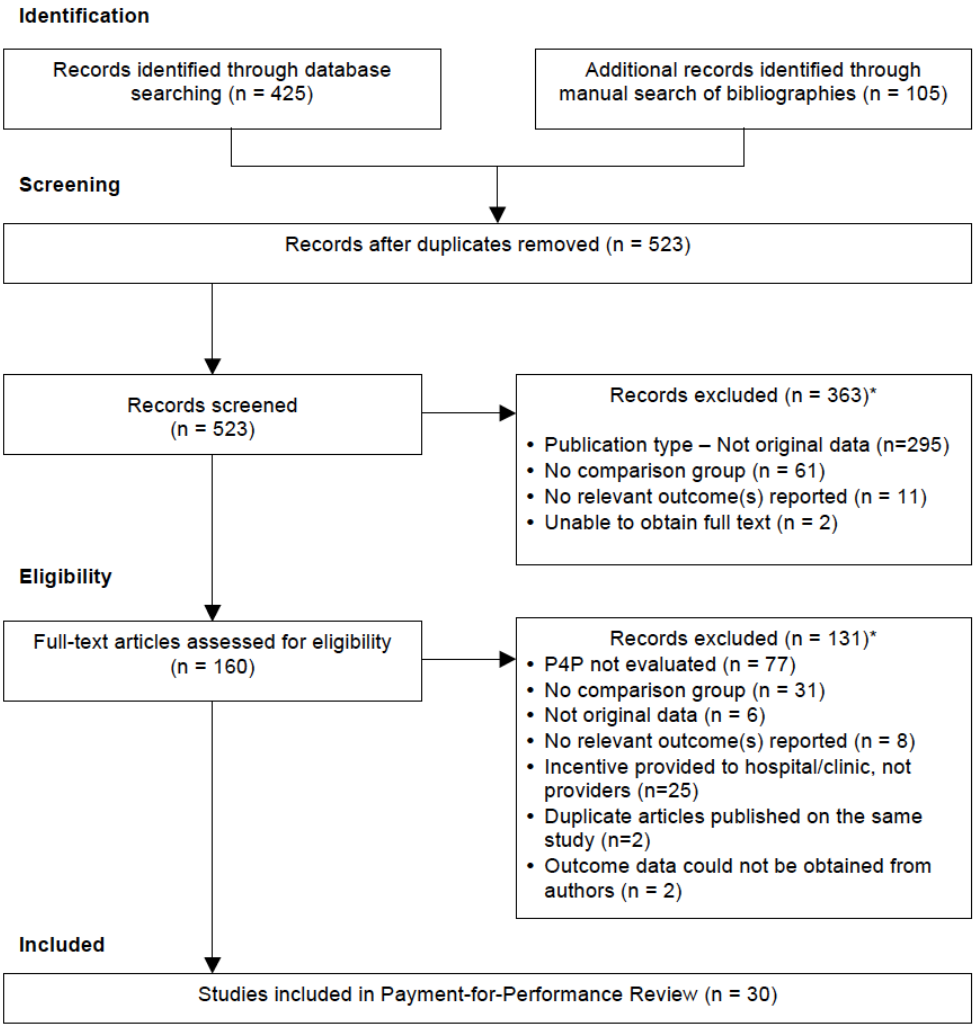
5.2.5 Role of the Funding Source

The study received no external funding. Salary support was provided by the Interdisciplinary Chronic Disease Collaboration, Alberta Innovates—Health Solutions, Hypertension Canada, and the Canadian Institutes for Health Research. The funding sources had no role in the design, completion, or reporting of this study or in the decision to submit the manuscript for publication.

5.3 RESULTS

The literature search yielded 523 records, of which 30 met our inclusion criteria (Figure 5-1 and Table A.1-9, **see Appendix 1**): 4 randomized, controlled trials; 5 interrupted time series; 3 controlled before–after studies; 1 nonrandomized, controlled study; 15 uncontrolled before–after studies; and 2 uncontrolled cohort studies.

Figure 5-1. Summary of evidence search and selection

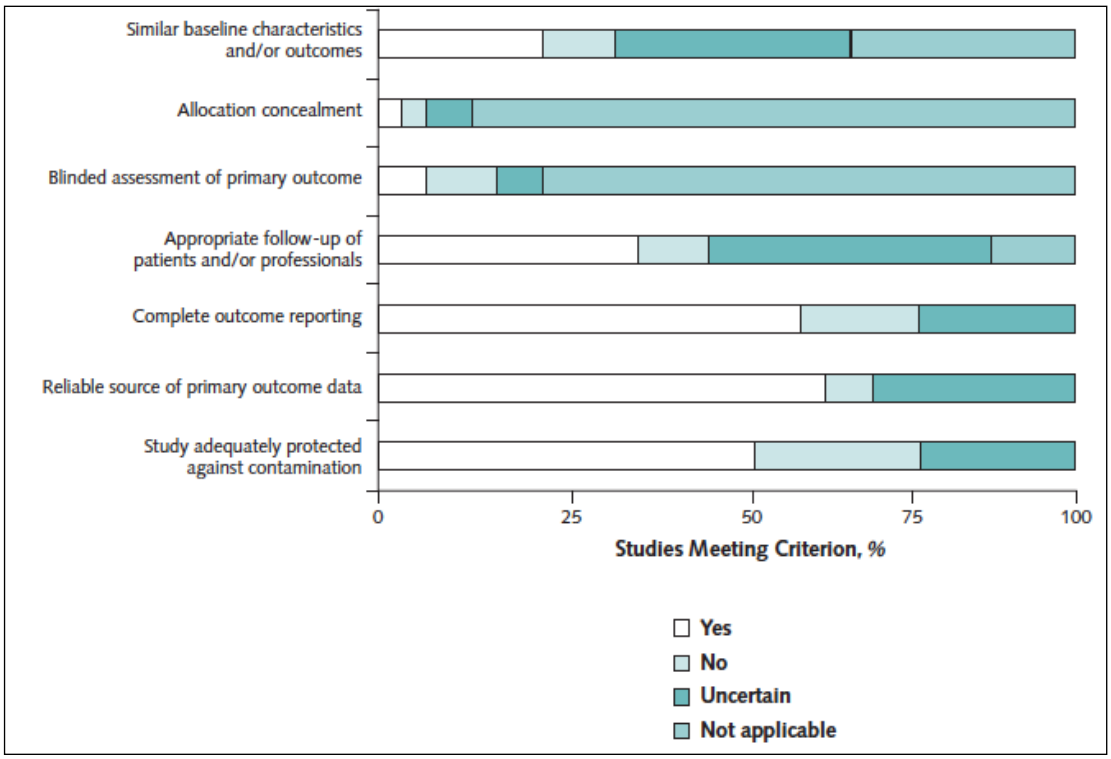


Nine studies evaluated the effect of P4P on preventive care or screening, 20 studies explored care for chronic medical conditions, and 1 study evaluated effect on both preventive and long-term care. Of these 30 studies, 8 were included in the previous reviews.[5,6]

5.3.1 Quality of Included Studies

The quality of the included studies varied (Table A.1-10, **see Appendix 1**) but was generally low to moderate (Figure 5-2).

Figure 5-2. Risk of Bias Across All Included Studies



In particular, studies without contemporaneous control groups were at particularly high risk for spurious results because there is no possibility of controlling for secular trends. Furthermore, because study participants were aware of their remuneration scheme in all studies, any benefits may have been due simply to an alteration of behavior as a result of being under study rather than the P4P intervention itself. In terms of other sources of potential bias, all of the randomized, controlled trials but few of the other studies reported similar comparison groups or baseline measurements. Furthermore, only 1 study[9] ensured concealment of patient allocation (for patients or health care providers within the randomized, controlled trials, or for data analysts for the other study types), and only 2[10,11] reported that outcomes were ascertained in blinded fashion. Failure to meet these 3 key quality criteria introduces substantial potential for positive bias in the results reported. Approximately half of these studies reported adequate follow-up of patients and outcome ascertainment to protect against detection bias, although the other half did not. Admittedly, this is difficult to interpret for studies that used administrative data because documentation of outcomes evaluated may be incomplete. Finally, although most of these studies were believed to be adequately protected against

contamination, this is arguably a less important source of potential bias in studies assessing systems of care than the first 3 named above.

5.3.2 Studies on the Effect of P4P on Preventive Care or Screening (n = 10)

5.3.2.1 Randomized, Controlled Trials

Although Fairbrother[9] and Kouides[10] and their colleagues found statistically significant improvements in immunization rates with P4P versus fee-for-service (FFS), the absolute effect sizes in both trials were small (Table A.1-11, **see Appendix 1**).[9-18] In contrast, Grady and coworkers[12] found no improvement in mammography referral or performance rates for women seeing P4P physicians.

5.3.2.2 Controlled Before-After Studies

Rosenthal and colleagues[13] demonstrated that although cervical cancer screening improved significantly more in P4P practices compared with contemporaneous peer practices without P4P, mammography and glycosylated hemoglobin monitoring did not significantly differ between groups. Stratification of practices by baseline performance found that practices with the poorest baseline performance improved the most yet received the smallest bonus payments, whereas those already at or near the performance targets showed negligible improvement but captured the majority of bonus payments paid out. Fagan and associates[14] reported that although a new care system for patients with diabetes mellitus that included a practice-base care coordinator and a P4P program for physicians was associated with a statistically significant increase in influenza vaccination rates, no significant changes occurred in other P4P-incentivized quality indicators, such as glycosylated hemoglobin or nephropathy screening, and low-density lipoprotein cholesterol screening decreased significantly. Moreover, they found that nonincentivized quality indicators, such as angiotensin-converting enzyme inhibitor prescriptions or visits to the emergency department, did not differ between patients being cared for P4P physicians and those receiving care from other physicians.

5.3.2.3 Nonrandomized, Controlled Study

In their study comparing quality of care in 6 primary care centers under P4P versus 5 centers within the same health maintenance organization that did not use P4P, Gavagan and colleagues[15] did not detect any statistically significant differences in secular trends in rates of Papanicolaou smears, mammography, or childhood immunizations between the 2 groups.

5.3.2.4 Uncontrolled Before-After Studies

Although 3 uncontrolled studies suggested substantial benefits with P4P programs (for such indicators as measles/ mumps/rubella vaccination rates, colorectal cancer screening, or frequency of glycosylated hemoglobin monitoring), lack of a control group seriously hampers interpretation of their results given the inability to adjust for temporal trends in each study.[11,16,17]

5.3.2.5 Multivariate Analysis of an Uncontrolled Cohort Study

Ettner and colleagues[18] examined care for patients with diabetes treated in 10 managed care organizations. Although rates for several process-of-care measures (frequency of monitoring glycosylated hemoglobin, proteinuria, lipid panel, dilated eye examination, foot examination, advice to take acetylsalicylic acid, and influenza immunization) were higher among patients cared for by physicians paid by salary or capitation compared with those receiving care in a FFS program, no statistically significant differences were associated with P4P bonus schemes, irrespective of baseline remuneration method.

5.3.3 Studies on the Effect of P4P on Quality of Care for Chronic Conditions (n = 20)

5.3.3.1 Randomized, Controlled Trial

Twardella and Brenner[19] reported low success rates for smoking cessation in both groups of their study, with no difference in the P4P group.

5.3.3.2 Interrupted Time Series

Interrupted time series examine data trends before and after an intervention to determine whether an intervention has an effect greater than expected given the underlying secular trend—a key benefit of interrupted time series over before–after studies. Interpretation of interrupted time series results include consideration of whether there is a change in level (difference between the expected result extrapolated from preintervention trends at the time of the intervention versus the first postintervention reading) or a change in trend (change in slopes of the postintervention regression line versus the preintervention regression line).[39]

Five interrupted time series studies have examined outcomes in the United Kingdom after the 2004 introduction of the Quality and Outcomes Framework (QOF). Before QOF, primary care practices were paid by capitation with additional FFS payments for certain procedures. Under QOF, practitioners were eligible for annual bonuses of up to 25% of their base pay depending on achievement of 146 specified quality indicators. Campbell and colleagues[20] reported statistically significant improvements after adjusting for baseline trends in composite quality scores for diabetes and asthma (but not coronary disease) in 2005 compared with 2003 among 42 primary care practices. They also noted no further improvements between 2005 and 2007. Given the rapid improvements seen between 1998 and 2003 before QOF introduction, that finding suggested at best a dissipation of effect. Improvements were seen only for indicators specifically incentivized in the QOF and were not seen for all aspects of care for the target conditions; indeed, another analysis of 429 quality indicators suggested small but measurable detrimental effects on aspects of primary care that were not incentivized in the QOF.[27] There was another unintended consequence in that patients reported a decline in continuity of care after introduction of the QOF (which incentivized rapid access to care at the expense of continuity of care) in 2004.[20] Serumaga and associates[21] analyzed hypertension end points for more than 470 000 patients in the United Kingdom between January 2000 and August 2007. After adjustment for pre-P4P trends, no statistically significant changes were attributable to P4P for incentivized (frequency of blood pressure measurement) or nonincentivized (rate of initiating antihypertensive treatment, number of antihypertensive drugs prescribed per patient) indicators. Serumaga and colleagues[21] also reported no discernible effect of P4P on the proportion

of patients with controlled blood pressure or the incidence of hypertension-related events (myocardial infarction, stroke, heart failure, renal failure). Vamos and colleagues[22] reported statistically significant improvements in achievement of blood pressure and total cholesterol targets in individuals with diabetes but reduced achievement of glycosylated hemoglobin targets in the year after P4P introduction versus trends before P4P. Similar findings were published by Alshamsan and associates[23] in a different sample of English patients before and after the QOF.

It is important to note that the General Practice Research Database used by Vamos and colleagues contains information from nearly twice as many general practices as the Health Improvement Network database used by Serumaga and coworkers, although an unknown proportion of practices contribute to both databases. In their examination of prescribing practices in Scotland, MacBride-Stewart and colleagues[24] found that neither QOF-incentivized drugs nor nonincentivized drugs improved after the QOF; indeed, they noted that the use of QOF-incentivized drugs increased more slowly after P4P implementation than before.

5.3.3.3 Controlled Before-After Studies

Beaulieu and Horrigan[25] reported greater improvements in lipid panels, retinal examinations, and nephropathy testing in diabetic patients cared for by P4P physicians (compared with those whose physicians were reimbursed by FFS or capitation), along with substantially larger improvements in the proportion of their patients with glycosylated hemoglobin levels of 9.5% or less and low-density lipoprotein cholesterol levels of 130 mg/dL (3.37 mmol/L) or less. However, this study is at high risk of bias because physicians volunteered to participate in the P4P group and outcomes were collected by physician self-report.

5.3.3.4 Uncontrolled Before-After Studies

Although these 13 studies reported mixed results, most reported improvements in quality of care after implementation of P4P. However, the lack of contemporaneous control groups makes it impossible to draw firm conclusions because of the inability to adjust for temporal trends in these studies.

5.3.3.5 Multivariate Analysis of a Nonrandomized, Uncontrolled Study

Pourat and colleagues[38] reported no difference in self-reported adherence to sexually transmitted disease guidelines between physicians paid by FFS, capitation with P4P provisions, or salary with P4P provisions.

5.4 DISCUSSION

Our review identified 30 original research articles comparing P4P programs that target individual performance with other remuneration models for health care practitioners. Although uncontrolled before–after studies suggested that P4P improves adherence to quality-of-care indicators for chronic illnesses (such as the ordering of laboratory tests in patients with diabetes, measurement and achievement of target blood pressure, adherence to prescribing guidelines for patients with heart failure),[13,17,20] higher-quality studies with contemporaneous control groups or analyses that considered secular trends failed to confirm these benefits. Most important, 4 large interrupted time series analyses conducted in the United Kingdom to evaluate the effect of their primary care P4P scheme introduced in 2004[20-23] found that quality scores for incentivized indicators were increasing for patients with such target conditions as asthma, diabetes, hypertension, and coronary disease before P4P began; there was no convincing evidence that the quality of care increased at a faster rate in the 3 years after P4P implementation than before. Moreover, no improvements were seen for nonincentivized indicators even for target conditions in any P4P studies.

In contrast to the relative paucity of empirical studies on P4P, more than 200 commentaries or editorials about P4P have been indexed in MEDLINE in the past decade. As noted by Mannion and Davies, "evaluation of pay for performance initiatives has not kept pace with the rush to implement them".[40] Despite the attention being lavished on P4P as a potential means to improve quality and cost of health care, on the basis of our review we believe the evidence base is not yet robust enough to support widespread implementation into health policy. Although evidence suggests modest effectiveness for P4P in improving preventive activities, such as immunization rates, there is little evidence that P4P is effective for other outcomes at this time. Thus,

we believe implementation of P4P models in health care should be considered experimental and not yet evidence-based. Randomized, controlled trials may not be feasible or generalizable to study the effects of P4P; however, quasi-experimental study designs, such as interrupted time series with a concurrent comparison group or controlled before–after studies, are feasible, have generalizable findings, and provide high-quality evidence (as recognized by the Cochrane Effective Practice and Organization of Care group [http://epoc.cochrane.org]). Future research in this area should also move beyond the simple examination of change in practice patterns to also evaluate the role of organizational factors in facilitating or impeding the implementation and effectiveness of P4P, as well as the best motivators to change professional behavior.

Performance incentives arose from the principal agent theory in economics and have been shown in some instances to affect behavior (for example, annual bonuses tied to sales or cost-savings in the business sector), although the benefits tend to be specific to the remuneration scheme and the setting.[41] The optimal P4P scheme for health care remains an unresolved question, although our review provides some insights. For example, the targets chosen for incentive payments should not be too narrow because even the studies with positive results have shown improvement only for incentivized targets, with no spillover effect for nonincentivized targets.[24,27,36] In addition, careful consideration must be taken in deciding whether to base incentives on process or outcome measures because process measures are more easily modifiable by the professional and may therefore be more achievable, but they may not always translate into improvements in clinical outcomes. The size of the financial incentive relative to the effort required is another consideration, although we found evidence that even small incentives (worth less than 5% of annual income) seemed sufficient to modify practice in some settings[10,13,15,17,26,28,35] and that much larger incentives were ineffective in other settings. Furthermore, programs must consider whether to reward absolute or relative changes in performance and whether comparisons are made against one's peers or an individual's past performance.

Given the lack of evidence supporting claims about the effectiveness of P4P, it seems appropriate to consider the potential for unintended consequences. Campbell and Colleagues[20] noted that patient perception of continuity of care declined after P4P implementation in the United Kingdom (where rapid access to care rather than

continuity with the same physician was incentivized), which raises concerns given the known negative effect of care fragmentation on patient satisfaction and outcomes.[42] In addition, the potential negative effect of P4P remuneration schemes on the job satisfaction of clinicians should be considered; at least 1 study has documented reduced satisfaction among physicians in a P4P program as a result of increased administrative responsibilities.[43] The potential to change health care provider focus from quality of care to quality of record-keeping, and the potential for gaming through such methods as exception reporting (that is, exclusion of patients from denominators to improve percentage target achievement), falsifying of data, and measurement fixation has also been raised.[44] Although Doran and coworkers found that exception reporting was not widespread in the United Kingdom after implementation of their primary care P4P program (median, 6%), they did find that the rate of exception reporting was the strongest predictor of target achievement and that 1% of all practices excluded more than 15% of their patients from target calculation denominators.[27] Furthermore, as P4P schemas emphasize selected target indicators, it is unknown whether P4P-remunerated clinicians may preferentially avoid caring for patients with complex multisystem disease in whom hitting a target for one of their conditions would be more difficult than in patients with single-system disease. We believe it would be important to determine whether P4P programs actually accentuate inequity in health care by making it more difficult for disadvantaged or sicker patients to access care.

The opportunity costs of implementing P4P programs must also be considered because substantial costs can be incurred to develop targets and monitor performance. In a closed cost system, such as health care, the use of resources in one area must necessarily be balanced by a reduction in other areas. Thus, if P4P is ineffective in improving care, "given the expense of collecting and reporting data, [this] represents failure".[44] Indeed, Kralewski and associates[45] examined administrative data from 86 U.S. primary care clinics and reported that after adjustment for patient age, sex, and morbidity, P4P was not associated with any statistically significant changes in patient care costs.

Some limitations with our review must be acknowledged. This paper focused specifically on P4P programs whose incentives were based on the performance of individual practitioners—we excluded programs in which achievement of target indicators was based on the overall performance of a hospital or group practice.

However, studies of hospital or clinic-based P4P programs (such as the Premier Hospital Quality Incentive Demonstration project in the United States) have also found marginal effect on process-of-care measures and little or no effect on mortality.[3,4] All of the published data we found evaluated the effect of P4P schemes targeting physicians; however, other health care providers, such as nurses and pharmacists, are increasingly providing patient care, and research into the effect of P4P schemes with these professional groups is urgently needed.

Although P4P seems to be useful in business settings and may serve as a means to signal which elements of care are valued within a participating health care organization, the current evidence for P4P targeting individual practitioners is insufficient to recommend wholesale adoption in health care systems at this time. Additional high-quality research is required to fully evaluate the potential of P4P to affect patient care, outcomes, and the cost of health services. Organizations currently using P4P as a remuneration method are encouraged to perform formal clinical and economic evaluations of their programs (which could be done using an interrupted time series or controlled before–after methods if contemporaneous control groups can be identified) and publish their findings to enhance the literature base and aid in future decision making on performance-based remuneration. We believe the enthusiasm for P4P as a driver of quality improvement is disproportionate to the amount and quality of the current evidence.

5.5 FOOTNOTE

A version of this chapter has been published. Houle 2012. Annals of Internal Medicine. 157: 889-899.

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CHAPTER 6: Pay-for-performance remuneration for pharmacist prescribers' management of hypertension: A sub-study of the Alberta Clinical Trial in Optimizing Hypertension (RxACTION)

6.1 INTRODUCTION

Pharmacy practice is shifting from a focus on drug distribution to direct patient care in an effort to better utilize pharmacists' drug therapy expertise and respond to a societal need. This shift is evident from a number of practice scope expansions worldwide including policies allowing pharmacist adaptations of prescriptions, refill extensions, prescribing in an emergency or under collaborative practice agreements, the ordering and interpretation of lab tests and, in some instances, initiating drug therapy.

Alberta is the first Canadian province and the second jurisdiction worldwide to authorize some pharmacists to independently prescribe drug therapy for patients across a variety of disease states. This ability, termed Additional Prescribing Authorization, is granted to pharmacists following the successful completion of a comprehensive application process. This application requires pharmacists to demonstrate their competence to prescribe and the safety of prescribing in their current practice environment, as well as their current patient care and documentation processes through the submission of actual patient care cases.[1] Once granted, pharmacists can initiate or modify drug therapy across any disease state or drug class with the exception of narcotics and controlled drugs. However, pharmacists must prescribe in areas of their personal competence, and take legal responsibility for the outcomes of their prescribing activities.

To ensure the provision of expanded scope activities, including prescribing, remuneration strategies have been developed to compensate pharmacists for providing care. Such payments are in addition to professional fees payable upon dispensing prescription medications, and are intended to offset the cost for the pharmacist to be away from the dispensary. A 2006 review was the first to systematically identify the remuneration programs in existence worldwide,[2] and has since been recently updated (Chapter 3). Across all programs identified, pharmacists were paid on a fee-for-service (FFS) basis, whereby a flat rate is offered for each service offered regardless of the outcome.

Recently, there has been interest in linking health professionals' payment to outcomes achieved. This model, known as pay-for-performance (P4P) has been implemented in some regions of the United States, Canada, and Europe and has generally been limited to physician providers. A systematic review published by members of our team found that, despite its popularity, it is premature to conclude that P4P is associated with improved patient care outcomes, as current programs publishing outcome data had highly variable results or demonstrated improvements of a small magnitude.[3] Given the high cost of designing and maintaining these programs, concerns with gaming or focused efforts on incentivized outcomes at the expense of other disease states, and potential negative effects on job satisfaction due to increased documentation requirements, P4P should still be considered investigational until more high-quality studies have been conducted on its effectiveness. Since the publication of that review, two additional randomized controlled trials were published finding similar modest effects for cardiovascular risk factors[4] and hypertension specifically.[5] In the accompanying editorial, it was stated that "[both] studies suggest that even with elegant incentives applied at the practice level, gaps in clinical performance still remain."[6]

Additionally, one cannot assume that pharmacists' response to P4P will match that of physicians. As billing for pharmacist-provided care becomes more widespread, it is worth exploring if P4P is an effective option for this group of care providers. As such, a sub-study on the recently completed Alberta Clinical Trial in Optimizing Hypertension (RxACTION) examined this by randomizing those patients in the pharmacist care arm to either fee-for-service or P4P remuneration for the pharmacist. Clinical outcomes observed throughout the trial, described briefly below, can therefore be compared between the two payment strategies. Historically, in Alberta, professional fees collected for dispensing paid for community pharmacists' wages. In July 2012, a Pharmacy Services Framework was introduced, allowing pharmacies to bill the government for prescription adaptations, medication reviews, administering injections, and assessments leading to pharmacist prescribing.[7] All fees are flat rates per service, without any incentives for attaining specified outcomes.

This study's objective is to determine whether blood pressure outcomes achieved in the RxACTION study differed between patients whose pharmacist was paid by FFS or P4P. This represents the first evaluation of P4P among pharmacists, within the first

randomized controlled trial of pharmacist prescribing. Results of this study will help inform policy decisions regarding optimal payment strategies for pharmacists' clinical activities.

6.2 METHODS

The methods of the RxACTION study (Clinicaltrials.gov NCT00878566) have been published in detail elsewhere.[8] Briefly, individuals were eligible for the study if they were identified as having uncontrolled blood pressure following multiple screening visits in accordance with the Canadian Hypertension Education Program guidelines.[9] To be enrolled, subjects had to be 18 years of age or older, have uncontrolled blood pressure (BP), could not be pregnant, and had to provide consent to participate. Ethics approval was obtained from the University of Alberta Health Research Ethics Board.

Upon enrollment, patients were randomized in a 2:1 ratio to enhanced care or usual care. Enhanced care consisted of a BP wallet card for recording of measurements, written and verbal information on hypertension, medication review and adherence assessment, implementation of strategies to reduce blood pressure (non-pharmacologic and pharmacologic, including pharmacist prescribing of antihypertensive therapy and ordering of laboratory tests, as appropriate), and follow-up at 4-week intervals until BP is at target for 2 consecutive visits, and at 3-month intervals thereafter until study completion. Patients' primary care physicians received faxed documentation of actions taken. Usual care consisted of a wallet card to record BP, written information on cardiovascular disease, and usual follow-up by the patient's physician. All patients were followed for 6 months.

Those patients randomized to enhanced care were further randomized in a 1:1 ratio to either P4P or FFS payment for the pharmacist. Under both models, pharmacists received CAD $150 for the initial visit (estimated to take 1 hour) and $75 per follow-up visit every 4 weeks (estimated to take 30 minutes). Under P4P, pharmacists were eligible for an additional $125 if the patient reached 50% of their target (i.e., a 50% reduction from baseline towards reach their target BP), or $250 if target BP was achieved. The primary outcome of the remuneration sub-study was a reduction in systolic BP between P4P and

FFS groups. Secondary outcomes were reduction in diastolic BP between groups, and the proportion of patients in each group who achieved target BP after 6 months.

The sample size of this sub-study was designed to detect a 6 mm Hg change in systolic BP between FFS and P4P groups, with 80% power and a 2-sided α of 0.10, for a sample size of 224 for the primary outcome. To account for attrition, the sample size was increased to 250, with 125 patients per group.

All analyses were conducted using IBM SPSS Statistics, version 21 (IBM Corp., Armonk, NY) and followed the intent-to-treat principle, with *P* set at 0.05. Multivariate linear regression with change in systolic BP as the dependent variable was performed to adjust for baseline imbalances between groups (defined as those characteristics with $p>0.20$). We adjusted for age, sex, and family history of myocardial infarction. Missing values were imputed using the last-observation carried forward method.

6.3 RESULTS

Between July 2009 and May 2013, 248 patients were enrolled into the RxACTION study. Of those, 181 were allocated to enhanced care, with 92 randomized to the fee-for-service and 89 to the P4P arm. Recruitment in the study was halted before attainment of the full sample size due to financial pressures.

6.3.1 Baseline Characteristics

FFS and P4P groups were similar at baseline, as described in Table 6-1, except that the P4P group had a higher proportion of patients with a positive family history of myocardial infarction (MI). Patients' average (SD) age was 63.5 (12.7) and 48.8% were male. Three-quarters (77.8%) were on antihypertensive drug therapy, taking 1.7 medications on average.

Table 6-1. Patient Characteristics.

Variable	Fee-for-Service (n=92)	Pay-for-Performance (n=89)
Demographics:		
Male sex	42 (45.7)	47 (52.8)
Age, mean (SD) in years	62.8 (13.6)	63.1 (12.9)
Cardiovascular risk factors:		
Systolic BP at baseline, mean (SD) in mm Hg	148.3 (13.7)	150.3 (15.0)
Diastolic BP at baseline, mean (SD) in mm Hg	83.3 (12.1)	84.4 (12.1)
1st degree relative history of MI	49 (53.3)	38 (42.7)*
1st degree relative history of angina	19 (20.7)	28 (31.5)
1st degree relative history of stroke	28 (30.4)	29 (32.6)
BMI, mean (SD)	31.9 (7.5)	31.7 (6.4)
Waist circumference, mean (SD) in cm	106.4 (17.3)	106.4 (16.3)
Elevated waist circumference (>102 cm in men, >88 cm in women)	63 (68.5)	63 (70.8)
Smoking		
Current	15 (16.3)	17 (19.1)
Ex-smoker	37 (40.2)	41 (46.1)
Never	38 (41.3)	30 (33.7)
Alcohol consumption		
One or more servings per day	14 (15.2)	14 (15.7)
Occasional	49 (53.3)	41 (46.1)
Salt added to food		
Often/always	16 (17.4)	15 (16.9)
Sometimes	23 (25.0)	18 (20.2)
Self-reported cardiovascular comorbidities:		
Diabetes	37 (40.2)	34 (38.2)
Chronic kidney disease	15 (16.3)	16 (18.0)
History of MI	4 (4.3)	4 (4.5)
History of angina	11 (12.0)	12 (13.5)
History of heart failure	0	2 (2.2)
History of atrial fibrillation	12 (13.0)	10 (11.2)
History of stroke	4 (4.3)	6 (6.7)
Dyslipidemia	50 (54.3)	43 (48.3)
Peripheral artery disease	3 (3.3)	8 (9.0)
Prior revascularization procedure	8 (8.7)	3 (3.4)
On antihypertensive drug therapy at baseline	68 (73.9)	69 (77.5)
Number (SD) of drugs taken	1.6 (1.2)	1.7 (1.1)

Abbreviations: SD, standard deviation; MI, myocardial infarction; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

All data are given as numbers (percentages) unless otherwise indicated.
* Baseline differences between groups at $p<0.20$

6.3.2 Blood pressure reduction and attainment of target

After adjusting for age, sex, and family history of MI, systolic BP decreased in both groups over the 6-month trial, the reduction in the P4P group was 19.0 (SD 17.0) mm Hg and in the FFS group was 16.4 (SD 17.1) mm Hg. The difference in change of SBP

was 2.6 mm Hg (p=0.32). Diastolic BP also decreased in both groups, by 8.0 (SD 7.8) mm Hg in the FFS group and 7.7 (SD 8.6) mm Hg in the P4P group. The resulting difference of 0.3 mm Hg was not statistically significant (p=0.8). The proportion of patients achieving CHEP-recommended target BP increased in both groups, with 63.0% of patients in the FFS group reaching target after 6 months versus 53.9% in the P4P group (by design, none were at target at enrolment). The absolute difference of 9.1% was not statistically significant (p=0.22).

6.3.3 Antihypertensive medication use and modifications

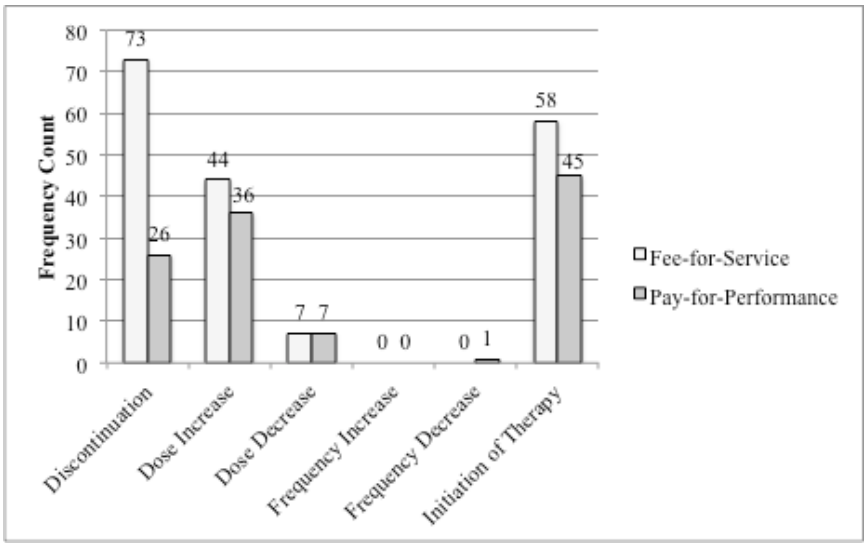
Antihypertensive medication use by class for each group at baseline and at the end of the study is provided in Table 6-2, and the number and type of drug changes made are summarized in Figure 6-1. Additionally, 11 patients in the FFS group were initiated on low-dose ASA and 10 were initiated on a statin during the study, compared to 7 and 11, respectively, in the P4P group.

Table 6-2. Use of antihypertensive medications.

	Fee-for-Service, No. (%) (n=92)		**Pay-for-Performance, No. (%) (n=89)**	
	Baseline	**6 Months**	**Baseline**	**6 Months**
Thiazide diuretic	40 (43.5)	46 (50.0)	37 (41.6)	50 (56.2)
ACE inhibitor	32 (34.7)	36 (39.1)	33 (37.1)	32 (36.0)
Beta blocker	17 (18.5)	16 (17.4)	17 (19.1)	19 (21.3)
Calcium channel blocker	25 (27.2)	35 (38.0)	27 (30.3)	32 (36.0)
Angiotensin receptor blocker	30 (32.6)	36 (39.1)	33 (37.1)	40 (45.0)
Other	5 (5.4)	4 (4.3)	8 (9.0)	8 (9.0)

Abbreviation: ACE, angiotensin-converting enzyme

Figure 6-1. Frequency of drug therapy changes made between fee-for-service and pay-for-performance group.



6.3.4 Outcomes between pharmacists eligible for direct financial benefit from P4P versus those without personal benefit.

Recognizing that not all pharmacists may have seen direct personal benefit from incentive payments (for example, payments went to the pharmacy and they were not an independent pharmacy owner, or if they were salaried pharmacists not practicing in community pharmacies) and therefore may not have been influenced by P4P to the same extent as those with direct benefit, a subgroup analysis was performed. Pharmacists were asked whether they received any direct financial benefit related to P4P payments, and reductions in systolic and diastolic BP and the proportion of patients achieving target BP were compared between these subgroups. Of the 89 patients randomized to P4P, 46 (51.7%) received care from a pharmacist who personally benefitted from the performance payments, while the remaining 43 (48.3%) received care from a pharmacist without a personal financial interest in the BP outcome.

Systolic BP reduction was greater in those without personal benefit (19.9 mm Hg vs. 18.2 mm Hg, p=0.65), as was diastolic BP reduction (8.1 mm Hg vs. 7.4 mm Hg, p=0.71), but neither of these reached statistical significance. The proportion of patients

reaching target BP by study end was higher in those whose pharmacist did directly benefit from performance payments, and this was statistically significant (71.1% vs. 40.0%, p=0.005).

6.4 DISCUSSION

This randomized controlled trial of pharmacist prescribing for patients with uncontrolled hypertension found no appreciable difference in the magnitude of blood pressure reduction seen among those whose pharmacist was paid by pay-for-performance versus fee-for-service, although both groups did experience reduced BP (19.0 vs. 16.4 mm Hg, respectively). Even accounting for whether the pharmacist was an owner with potential for personal gain (versus a salaried employee without personal gain), P4P showed no greater reduction in systolic BP reduction, although patients of pharmacists with direct benefit were more likely to reach target BP. To our knowledge, this is the first known study of performance-based incentives among pharmacists.

This study is not without limitations. First, the study ended prior to enrollment of the full sample size of subjects, therefore resulting in the study being under-powered to detect the outcome of interest. Additionally, one must consider that pharmacist investigators for this study came from a variety of practice settings, ranging from independently owned pharmacies to chain pharmacies, hospital practice, or family health team practice. Therefore, performance payments in the P4P arm may not have always been directed to the pharmacist investigator. Indeed, over half of the patients randomized to the P4P arm received care from a pharmacist who did not personally receive any financial benefit linked to performance outcomes. Since performance-based incentives are designed to influence the behaviour of individuals,[10] one must consider that this had the potential to underestimate the potential benefits of P4P. However, subgroup analyses comparing outcomes among those pharmacists receiving direct financial benefit versus those not individually benefitting from the achievement of BP targets failed to support this hypothesis. Additionally, due to the nature of the study, pharmacists could not be blinded to their remuneration allocation for each patient. Furthermore, with only a small proportion (approximately 5%) of practicing pharmacists in Alberta having Additional Prescribing Authorization (personal communication, Alberta College of Pharmacists), one cannot assume that those early

adopters participating in our study are representative of the general population of pharmacists in terms of their motivation to provide patient care including prescribing. Future work will include conducting focus groups with the RxACTION study pharmacists to elucidate their motivation for obtaining APA and participating in the study, and their perception of whether P4P payments influenced the magnitude of intervention applied.

Despite being under-powered to detect a statistically significant difference, the small magnitude of difference in systolic and diastolic BP observed is consistent with the results of our previous systematic review examining the impact of P4P on patient health outcomes provided by physicians.[3] Previous work has also suggested the potential for P4P programs to incite gaming (i.e., exclusion of patients from denominators to improve percentage target achievement), falsifying of data, or a fixation on measurable values rather than patient-centered goals.[11] While rates of such activities have been found to be generally low among physicians,[12] policy makers should keep this in mind if P4P is pursued among pharmacists. Policy makers should also consider that most pharmacists are paid by salary, and may therefore be unaffected by performance-based payment offerings. Our prior systematic review on this topic also concluded that the size of the incentive offered wasn't necessarily directly related to the magnitude of effect observed, as some very small incentive payments were observed to have a significant impact on outcomes observed.[3] However, it is important to recognize that the incentive amounts for this study were set arbitrarily, and it is possible that they were insufficient to influence the pharmacists' clinical decisions.

Given the cost of developing targets, measuring outcome attainment, and processing P4P payments, one must also consider whether the clinical benefits and/or cost-savings realized as a result are sufficient to offset these operational expenses. Indeed, a U.S. study conducted using administrative data from 86 primary care clinics found that P4P was not associated with any statistically significant change in patient care costs, after adjusting for patient age, gender, and morbidity.[13] An economic model conducted by our group based on the SCRIP-*HTN* study found that pharmacist-provided care resulting in a systolic BP reduction of 5.6 mm Hg over 6 months is likely cost-neutral if not cost-saving, when considering reduced rates of myocardial infarction, stroke, and heart failure hospitalization secondary to inadequate hypertension control.[14] However, in

SCRIP-*HTN*, intervention patients were seen in 6-week intervals rather than monthly intervals as in RxACTION, which may impact the intervention's cost-effectiveness. Additionally, since pharmacist time providing care was not captured in SCRIP-*HTN*, this information was captured in the RxACTION study to allow for a more accurate cost-effectiveness estimation to be made, and will be reported in future work. An additional sub-study of RxACTION will be performed to compare patients' utilization of emergency rooms, primary care physician offices, and laboratory services before and during the study between the enhanced care and usual care groups, to identify potential cost-savings from a health system perspective.

The implications of this study's results are two-fold: to inform future policy related to pharmacist remuneration strategies to ensure best use of limited healthcare funds, and to start a discussion on the motivating factors that may influence the quality of care provided by pharmacists under an expanding scope. Our results suggest that P4P may not significantly impact pharmacists' treatment approaches related to the management of patients with hypertension, but this needs to be studied across a larger sample and across a variety of disease states. Therefore, future remuneration programs including a P4P component for pharmacists are encouraged to consider the use of P4P to be experimental, and include a robust evaluation strategy to assess the effectiveness of this approach. Additionally, P4P is one of many approaches tried among physicians and other health professionals to improve care quality, including self-assessment, practice audits with feedback, public results reporting, and peer rankings.[14] As pharmacists increasingly take on patient-centered versus product-centered roles, similar approaches should be considered and tested in this population.

To ensure the sustainability of pharmacist-provided patient care, fees provided must be sufficient to offset the costs of providing these services. Therefore, future research will examine the time pharmacists spent providing care for RxACTION enhanced care patients and compare this to the fees provided. As mentioned above, administrative data on patients' use of other health resources during the intervention period will be examined to identify the effect of pharmacist-provided care on health system utilization. Focus groups and interviews will also be conducted to determine pharmacists' opinions on P4P remuneration and the perceived effect it had on their clinical decision-making, professional satisfaction, and workload.

6.5 CONCLUSION

This study, the first to examine pay-for-performance remuneration for pharmacists' clinical care services, demonstrated no clinically or statistically significant impact of P4P on blood pressure reduction after 6 months when compared to fee-for-service pay. Although our study was somewhat underpowered, the point estimate of SBP reduction suggests that the impact of P4P, if any, might be clinically insignificant. Therefore, future research on the potential role, if any, for P4P in pharmacy practice is warranted before widespread implementation of P4P programs occurs in the pharmacy profession.

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CHAPTER 7: Summary, Conclusions, and Implications

7.1 SUMMARY

Hypertension is one of the most common chronic diseases in Canada, affecting approximately 1 in 5 adults[1], and is largely managed through lifestyle modification and drug therapy.[2] Pharmacists, the medication experts of the healthcare team, are also highly accessible. For example, Canadian patients with diabetes have been found to see their pharmacist twice as often as a physician per year.[3] Given pharmacists' expanding scope of practice and an aging population creating capacity pressures on the existing model of providing healthcare, an opportunity exists for pharmacists to play a larger role in tackling the increasing burden of chronic disease in Canada. The goal of this thesis was to examine the clinical and economic outcomes of pharmacist care of patients with uncontrolled hypertension, and to examine remuneration strategies that will support the provision of high-quality patient care in community pharmacies while remaining cost-effective to the health system.

Despite recent improvements in treatment and control rates in Canada, room for improvement remains in how hypertension is managed. One-third of diagnosed hypertensives remain uncontrolled[4], and 15% of Canadians do not have a regular family physician.[5] While pharmacist prescribing is not intended to replace medical care, when utilized as an adjunctive measure, gains in hypertension control can be realized, and limited physician resources can be focused on more acute or specialized needs. Furthermore, with reducing profit margins for community pharmacy dispensing activities, the provision of remunerable patient care services represents another potential revenue stream for pharmacies to remain viable.

While prescribing by pharmacists has been in place for the past decade in the United Kingdom, no work has been done to examine the clinical effectiveness of these activities. The majority of published research on pharmacist prescribing to date reports on barriers and facilitators related to providing the service, and attitudes towards pharmacist prescribing among pharmacists, physicians, and patients.[6] Therefore, the work presented in this thesis represents some of the first quantitative research on clinical and economic outcomes of pharmacist prescribing. While not a randomized controlled

trial, the Pharmacist Intervention for Glycaemic Control in the Community (RxING) study found that pharmacist prescribing and titration of insulin glargine for Alberta patients with uncontrolled diabetes resulted in an absolute reduction in glycosylated hemoglobin of 1.8% (95% CI 1.4 to 2, $p<0.001$). In addition, the recently completed Pharmacist Prescribing to Achieve Cholesterol Targets (RxACT) study (ClinicalTrials.gov NCT01581372) will provide the first randomized trial evidence of pharmacist prescribing in the management of dyslipidemia. Through these and future studies, a high-quality evidence base supporting pharmacists' direct patient care activities can be established and utilized for policy development, knowledge translation activities, and integration into clinical practice guidelines for chronic disease management.

7.2 MAIN FINDINGS

As elucidated above, the goal of my thesis was to establish early evidence to support and facilitate the uptake and expansion of pharmacists clinical care services, including prescribing, as part of a hypertension management strategy. With evidence on the cost-effectiveness of pharmacy-based care, positive business implications, and clinical improvements in blood pressure from pharmacist prescribing, it is my vision that this largely untapped resource can be increasingly drawn upon to help address the increasing burden of chronic disease in Canada and improve patients' health outcomes.

In Chapter 2, we established that community pharmacy-based care as provided in the SCRIP-*HTN* study is cost-neutral if not cost-saving. This was done by comparing health system cost avoidance secondary to prevented major cardiovascular events associated with a systolic BP reduction of 5.6 mm Hg annually to personnel costs to provide the service. However, this is likely an underestimation of true cost avoidance as outpatient care cost savings and lost productivity costs were not included in the model, and it was hypothesized that pharmacist prescribing has the potential to result in even greater BP reduction by removing the ceiling effect associated with providing recommendations to be implemented by patients' primary care physicians. Indeed, the RxACTION study (Appendix 2) resulted in a systolic BP reduction of 7.0 (SE 2.5) mm Hg.

Chapter 3 presented an update to a 2008 systematic review of remuneration offered worldwide for pharmacists clinical care services. Between June 2006 and December

2012, 60 programs were identified, ranging from remuneration for medication reviews to chronic disease education and management, minor ailments schemes, and prescription adaptation services. Programs were identified in Canada, the United States, Europe, Australia, and New Zealand, and nearly two-thirds of programs identified were paid for by government agencies. Most importantly, all programs operated on a fee-for-service basis with no performance-based incentive offerings, and many placed limitations on patients qualifying for remunerable services. When compared to all programs identified, Alberta's current Pharmacy Services Framework[7] is among the most comprehensive, with remuneration offered on adaptation and prescribing services for all Alberta residents, and minimal restrictions for eligibility for Comprehensive Annual Care Plan (CACP) or Standard Medication Management Assessment (SMMA) medication reviews.

Of note, only 27% of programs included in the review reported on uptake data, barriers, clinical outcomes, or economic outcomes, and multiple studies reported low uptake by pharmacists. When such information was collected, patient satisfaction was high, net cost benefit was realized, and improvements were noted in smoking cessation, drug therapy problem resolution, and chronic disease management. A need for greater incorporation of outcomes research and knowledge translation activities into remuneration programs is therefore apparent.

In Chapter 4, the perspective of a community pharmacy was adopted to determine the potential role of remunerated clinical services in a pharmacy's business plan. As previously discussed, with revenues from dispensing activities declining in light of numerous factors including competition, reduced generic prices, and stagnant professional fees, pharmacies will need to generate alternate forms of revenue to remain viable. As the Alberta Pharmacy Services Framework was not yet announced at the time this study was completed, the perspective of an Ontario pharmacy participating in the MedsCheck program was adopted. Using a pharmacy's automated blood pressure kiosk to identify patients with uncontrolled hypertension we estimated that, on average, 189 patients could be identified monthly who would qualify for a MedsCheck service, with an additional 95 not qualifying for a MedsCheck but eligible for a Pharmaceutical Opinion due to their uncontrolled hypertension. Assuming that active case finding with the kiosk occurred for only 1 month, a pharmacy could generate on average over

$12,000 in revenue if all eligible patients received the MedsCheck or Pharmaceutical Opinion services they qualified for. Therefore, pharmacies should consider the role of patient care services as more than 'additional services' but rather as a key component of the business model. This strategy may form a useful exercise for knowledge translation when identifying facilitators of practice change, with the goal of improving the uptake of expanded pharmacist scopes of practice by community pharmacies.

With pay-for-performance (P4P) gaining in popularity in North America and Europe, Chapter 5 examined whether this enthusiasm is supported by improved patient health outcomes. This review identified 30 studies comparing P4P to another payment modality in terms of clinical outcomes. Of these 30 studies, only 4 were of randomized controlled trials, with the remainder consisting of interrupted time series, controlled or uncontrolled before-after studies, and uncontrolled cohort studies. As such, the heterogeneity in quality of these studies, their methods, and their outcomes precluded meta-analysis. Three main points were identified in this study:

1. The need for more high-quality outcomes research on P4P before its widespread adoption can be advocated;
2. Existing evidence suggests that P4P has generally not resulted in clinically or statistically significant improvements in patient outcomes, with higher-quality controlled studies reporting neutral outcomes compared to the more positive observations from uncontrolled studies;
3. P4P programs and evaluation studies should consider potential unintended consequences such as gaming, effect on health professionals' job satisfaction, and whether incentivized indicators are favored over non-incentivized diseases and outcomes.

A key limitation of the review in Chapter 5 that is relevant to this thesis is that none of the programs evaluated P4P among pharmacists. As indicated in Chapter 3, this is because programs for paying pharmacists for the provision of patient care services have all followed the fee-for-service (FFS) model. Therefore, Chapter 6 addressed this knowledge gap by being the first randomized trial of P4P versus FFS in pharmacy practice. As a sub-study of the RxACTION randomized controlled trial (**Appendix 2**), we were able to study the impact of P4P on blood pressure lowering achieved by

patients receiving care from pharmacists with Additional Prescribing Authorization. While the main study found that enhanced care including pharmacist prescribing resulted in clinically and statistically significant reductions in systolic and diastolic blood pressure when compared to usual care, the remuneration sub-study failed to identify an association between the remuneration strategy used and BP reduction. However, this sub-study was limited by not reaching the pre-specified sample size, and therefore was under-powered to detect the minimal clinically important difference (MCID) in systolic BP of 6 mm Hg between groups as specified in the study protocol.[7] While consistent with the findings among physicians presented in Chapter 5, further research is warranted to confirm these results.

7.3 LIMITATIONS

This thesis has demonstrated the potential value, clinically and economically, of pharmacist prescribing for hypertension management. However, the work is not without limitations, which must be considered when interpreting the results and conclusions herein.

Limitations specific to each study are acknowledged in that chapter's discussion section and will not be re-stated here. Rather, I will limit this section to the acknowledgement of the broader and most significant limitations related to this body of work as a whole, including:

1. **Lack of data on time required for providing care.** In Chapter 2, we were unable to identify a recent study estimating the time pharmacists require to comprehensively provide care for patients with uncontrolled hypertension. A single study from 1973 formed the basis of our estimate, but we acknowledge this is likely not accurate in current practice. Three studies in Chapter 3 reported on pharmacist time spent conducting medication reviews or providing chronic disease management, but none were specific to hypertension. The SCRIP-*HTN* study also did not capture this data. However, estimates of time spent with patients at each visit were collected in the RxACTION study and will be examined as part of a complete economic analysis in the future.

2. **Inability to determine medication costs of patients receiving hypertension care from pharmacists.** Neither SCRIP-*HTN* nor RxACTION captured information on the actual drug regimens used by patients pre- and post-intervention. Therefore, any economic analyses of these interventions will be missing this important contributor to overall care costs (or savings). Therapeutic classes of drugs utilized were collected in RxACTION, which will allow the potential determination of whether prescribing activities were concordant with guideline recommendations, but dose optimization outcomes cannot be determined as this information was not collected.

3. **Early termination of the RxACTION study.** Due to funding limitations and the long enrollment period of the RxACTION study, randomization of new patients was terminated before achievement of the pre-specified sample size. While the final sample of 247 patients was sufficient to satisfy the requirements for analysis of the study's primary outcome of systolic BP reduction, the sub-study on P4P versus FFS remuneration (Chapter 6) was significantly under-powered. Therefore, one cannot be certain that the non-significant results observed genuinely reflect the absence of a significant association. The observed absolute difference in systolic BP between groups of 2.6 mm Hg is, however, well below the MCID utilized in the sample size calculation of 6 mm Hg.[7]

4. **Early adopters of pharmacist prescribing in Alberta.** As of December 17, 2013, 394 Alberta pharmacists have successfully received Additional Prescribing Authorization.[8] With over 4400 licensed pharmacists in Alberta[9], less than 10% of registrants have APA. Furthermore, only 26 pharmacists were involved in the RxACTION study. One cannot assume that this group is representative of all pharmacists in Alberta, as there may be significant confounding factors contributing to their decision to be an early adopter of pharmacist prescribing. Therefore, as APA continues to expand in Alberta and independent pharmacist prescribing is established in other jurisdictions, additional research should be conducted to evaluate the outcomes achieved by a more general population of pharmacists.

5. **Use of surrogate outcomes.** Given the short duration (6 months) of RxACTION, surrogate outcomes in terms of systolic and diastolic BP were evaluated. Neither study included a long-term follow-up strategy beyond the intervention to assess whether these outcomes persist following the intervention period, and whether pharmacist-provided care is associated with reduced rates of major complications such as heart attack, stroke, heart failure, or chronic kidney disease. Similarly, SCRIP-*HTN* and most other studies of pharmacist interventions were not of long enough duration to examine the effect on major events. However, blood pressure has been found, through large meta-analyses, to have a log-linear relationship with cardiovascular mortality, and BP lowering is closely associated with the primary and secondary prevention of major cardiovascular events.[10-11] Regardless, future research should consider incorporating long-term monitoring in the analysis plan to address this limitation.

6. **Impact of pharmacologic vs. non-pharmacologic interventions.** Hypertension can be effectively lowered through both pharmacologic and lifestyle measures, and a treatment plan incorporating both approaches is recommended in clinical practice guidelines.[12] In accordance with the guidelines, pharmacists in RxACTION were encouraged to employ both approaches when managing patients' hypertension in the enhanced care group. Data on the type and frequency of lifestyle advice provided was collected (but is not reported in this thesis as it will form future work), and may have had an impact on the results observed. Therefore, the results presented in this thesis reflect the overall achievement of BP lowering regardless of the specific strategy employed. It is possible that some patients achieved target BP strictly through lifestyle modification without the need for pharmacists to utilize their Additional Prescribing Authorization.

7.4 IMPLICATIONS FOR PRACTICE AND POLICY

This thesis provides data relevant to both healthcare professionals and policy makers. Clinically, we have established that pharmacist prescribing results in additive benefits when applied as a supplement to usual physician care for patients with uncontrolled hypertension. Community pharmacies offer a unique opportunity to identify patients requiring intervention as patients visit them more frequently than physicians' offices[3]

and pharmacists are often available for consultation without an appointment and across broad operating hours. Electronic pharmacy records can also be utilized to systematically identify patients at risk of a disease or of suboptimal control of a disease, a process known as case finding.[13] Therefore, great public health potential exists if community pharmacies systematically identify at-risk patients and offer disease management services as provided in the RxACTION study.

Despite the observation that the majority of RxACTION patients were already on antihypertensive drug therapy at baseline, the clinically and statistically significant blood pressure reductions observed following pharmacist intervention suggest that clinical inertia, non-adherence, or suboptimal dosing of antihypertensive therapy may be contributing factors. Therefore, the role of pharmacist prescribers may be both in the detection of incident hypertension and in the optimization of existing therapy. Extrapolating the results of RxACTION based on data obtained from large population-based epidemiologic studies, a sustained 8 mm Hg reduction in systolic BP is predicted to reduce stroke mortality by approximately 35% and mortality from ischemic heart disease or other vascular causes by approximately 25% during middle age, decreasing only slightly at older age.[14]

From a health policy perspective, evidence on the clinical effectiveness as well as the potential cost-savings resulting from pharmacist care supports expansions in pharmacists' scope of practice and the availability of remuneration for clinical care services. However, high heterogeneity between jurisdictions in terms of scope of practice legislation and remuneration programs limits the generalizability of our findings. Decision-makers are called on to optimize upon the drug therapy expertise of pharmacists and work towards pharmacist prescribing authorization, and to ensure these services are fairly remunerated to encourage uptake. As noted in Chapter 3, community pharmacy is a profession with a complex business model, so pharmacists must be involved in program planning and evaluation to ensure fees are fair and documentation requirements are attainable in practice. Additionally, Chapter 3 noted that fewer than 1 in 3 remuneration programs have published any type of uptake or outcome data, so government and third-party funders are strongly encouraged to incorporate multifaceted evaluation plans into program budgets and timelines. As determined in Chapters 5 and

6, pay-for-performance is not recommended for widespread use and should still be considered experimental, with rigorous evaluation strategies employed concurrently.

7.5 FUTURE RESEARCH

In addition to the pre-specified sub-studies of RxACTION, areas for future research regarding pharmacist prescribing and remuneration for professional services include, but are certainly not limited to:

1. **Examination of which aspect(s) of the intervention in RxACTION were most likely to be associated with improved blood pressure outcomes.** For the main analysis and the remuneration sub-study of this intervention, we were only interested in the overall outcomes achieved rather than the specific means by which those outcomes were facilitated. Information on adherence, lifestyle advice, patient ownership of a home blood pressure monitor, and distance for the patient to access their pharmacy and their physician were also collected but not included in these analyses. Since RxACTION was initially limited to rural communities, perhaps patient access to their pharmacist was much more convenient than to their usual physician who may have been in a neighboring town. Additionally, it is possible that some patients achieved their BP target as a result of improved adherence and introduction of lifestyle modifications, with the pharmacist never needing to utilize their prescribing authority. Such confounding factors may be significant and should be accounted for.

2. **The influence of pay-for-performance on pharmacists' treatment strategies.** While we did not observe a significant difference in results achieved between the two payment models utilized in the RxACTION sub-study, the actual and perceived influence of P4P on the pharmacists' treatment plans may shed light on whether it had any impact on their clinical decision-making. For example, were patients randomized to P4P initiated on new drug therapy or prescribed a higher dose of existing therapy sooner in the intervention period than fee-for-service patients where lifestyle measures may have been trialed first? Such observations can then be correlated with pharmacists' reports of whether they perceived an influence based on remuneration allocation to see if such decisions were conscious or more reflexive decisions.

3. **A comprehensive economic analysis should be undertaken, incorporating a societal perspective.** An examination of administrative databases to evaluate the use of health system resources between usual care and enhanced care patients is a planned sub-study of RxACTION. This information can then be incorporated into an economic analysis where cost inputs include pharmacist time, drug therapy costs (based on dispensing records via Alberta NetCare), and laboratory test costs, and outputs include hospital/emergency department/physician visits, patient quality of life, and travel and time considerations for patients, among others. The societal perspective is recommended for economic analyses in Canada[15] as it provides the most comprehensive analysis of the net effect of a technology or intervention. Analyses can then be further broken down into separate perspectives (community pharmacy, Ministry of Health, or patient perspective) as required. The results of this analysis will be useful in determining the net cost effect of paying pharmacists for comprehensive patient care activities in hypertension management.

4. **Knowledge translation (KT) requirements to facilitate greater provision of pharmacist prescribing activities in daily practice.** While the work in this thesis has demonstrated clinical and economic benefits of pharmacist prescribing for chronic disease management, the existence of supporting evidence alone is not sufficient to ensure uptake into practice. As indicated in the Knowledge to Action Framework (Figure 7-1)[16] and the Promoting Action on Research Implementation in Health Services (PARiHS) framework (Figure 7-2),[17] active efforts to understand the context of the current practice environment, identify barriers to uptake, and facilitate change processes are required for successful integration into practice. As such, future research should examine these needs related to pharmacy practice to design KT strategies to operationalize the vision for pharmacy practice and chronic disease management proposed in this thesis.

Figure 7-1. Knowledge to Action Framework

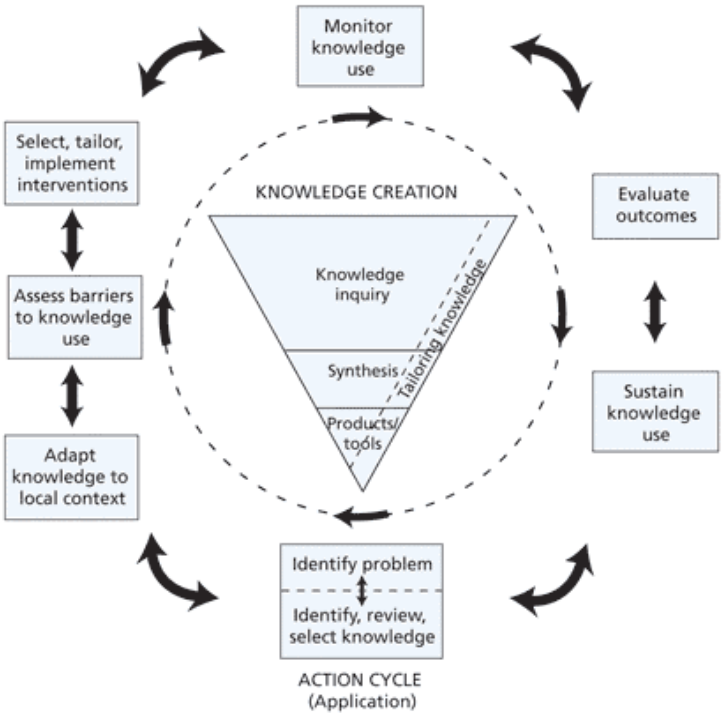

Figure 7-2. The PARiHS Framework

7.6 CONCLUSION

Our work has demonstrated that pharmacist prescribing offers a clinically effective and likely cost-saving strategy for addressing uncontrolled hypertension among community-dwelling adults. Furthermore, the changing business landscape for Canadian community pharmacy practice necessitates the integration of remunerated clinical care services as a key component of the pharmacy business model. Indeed, the number of pharmacist remuneration programs worldwide is increasing, but consistency is lacking in the type of services remunerated and the fees offered, and we were unable to identify any work relating fees provided to the cost of providing care. Despite the popularity of pay-for-performance in healthcare in the past decade, evidence among physicians and the pharmacist prescribers in our study suggest that widespread adoption of this model is premature and may not result in any significant improvement in care quality. Therefore, we advocate for an expansion of pharmacist prescribing legislation across all jurisdictions, involvement of front-line pharmacists in policy and program development, and collaboration among programs to standardize the services that patients can receive from their pharmacist to ensure all patients have access to this largely untapped drug therapy expertise.

7.7 REFERENCES

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APPENDIX 1. Additional Tabulated Data

Table A.1-1. Characteristics of the Eight Studies Included in the Analysis.

	HOPE (n=9297)[10, 11]	PART2 (n=617)[12]	PROGRESS (n=6105)[13]	SCAT (n=460)[14]	SYST-EUR (n=4695)[15]	RENAAL (n=1513)[16]	SCOPE (n=4937)[17]	PREVENT (n=825)[18]
Treatment group (no. of patients)	4645	308	3051	229	2398	751	2477	417
Control group (no. of patients)	4652	309	3054	231	2297	762	2460	408
Comparison groups	Ramipril vs placebo	Ramipril vs placebo	Perindopril (± indapamide) vs placebo	Enalapril vs placebo	Nitrendipine vs placebo	Losartan vs placebo	Candesartan vs placebo	Amlodipine vs placebo
Patient characteristics	CVD, CHD, or DM ± otherCV risk factors	CHD or CVD	Cerebrovascular disease	CHD	HTN	DM + nephropathy	HTN, elderly (70–89 yrs)	CHD
Duration of follow-up (yrs)	4.5	4.7	3.9	4	2	3.4	3.7	3
Myocardial infarction events (no.)								
Treatment group	459	18	60	8	33	50	70	19
Control group	570	19	96	13	45	68	63	20
RRR (95% CI)	0.19 (0.09–0.28)	0.05 (−0.77–0.49)	0.38 (0.14–0.55)	0.38 (−0.47–0.74)	0.30 (−0.10–0.55)	0.25 (−0.06–0.48)	−0.10 (−0.54–0.21)	0.07 (−0.72–0.50)
Stroke events (no.)								
Treatment group	156	7	307	2	47	–	89	5
Control group	226	4	420	9	77	–	115	5
RRR (95% CI)	0.31 (0.16–0.43)	−0.76 (−4.94–0.48)	0.27 (0.16–0.36)	0.78 (−0.03–0.95)	0.42 (0.16–0.59)	–	0.23 (−0.08–0.41)	0.02 (−2.35–0.72)
Heart failure events (no.)								
Treatment group	418	7	–	–	37	89	–	1
Control group	535	9	–	–	49	127	–	5
RRR (95% CI)	0.22 (0.12–0.31)	0.22 (−1.07–0.71)	–	–	0.28 (−0.10–0.53)	0.29 (0.09–0.45)	–	0.80 (−0.67–0.98)
Mean SBP difference, treatment vs control group (mm Hg)[a]	3	5	9	4	10	1	3	7

HOPE = Heart Outcomes Prevention Evaluation; PART2 = Prevention of Atherosclerosis with Ramipril Trial; PROGRESS = Perindopril Protection Against Recurrent Stroke Study; SCAT = Simvastatin/Enalapril Coronary Atherosclerosis Trial; SYS-EUR = Systolic Hypertension in Europe Trial; RENAAL = Reduction of Endpoints in NIDDM with the Angiotensin II Antagonist Losartan; SCOPE = Study on Cognition and Prognosis in the Elderly; PREVENT = Prospective Randomized Evaluation of the Vascular Effects of Norvasc Trial; CVD = cardiovascular disease; CHD = coronary heart disease; DM = diabetes mellitus; CV = cardiovascular; HTN = hypertension; RRR = relative risk reduction; CI = confidence interval; SBP = systolic blood pressure.

[a]Calculated by subtracting the changes from baseline SBP in the control group from the corresponding changes in the treatment group over the duration of the study.

Table A.1-2. Overall and Absolute Risk Reductions of Major Cardiovascular Events Between the Intervention and Control Groups.

Assumptions	Myocardial Infarction	Stroke	Heart Failure Exacerbation
Overall			
5.7-mm Hg SBP reduction, 3.7-yr follow-up period[a] (raw data)[10–18]	2.00% (0.65–3.44%)	2.40% (1.11–3.70%)	2.20% (0.86–3.57%)
Adjusted			
5.6-mm Hg SBP reduction, 6-mo follow-up period[b]	0.27% (0.08–0.47%)	0.33% (0.15–0.51%)	0.30% (0.12–0.49%)
3.5-mm Hg SBP reduction,[c] 6-mo follow-up period	0.18% (0.02–0.33%)	0.20% (0.07–0.35%)	0.19% (0.04–0.34%)
7.7-mm Hg SBP reduction,[c] 6-mo follow-up period	0.38% (0.17–0.61%)	0.45% (0.25–0.67%)	0.42% (0.20–0.64%)

Data are absolute risk reduction (95% confidence interval).
SBP = systolic blood pressure.
[a]Mean duration of follow-up across all studies included in the analysis.[10–18]
[b]Adjusted to 6 mo for the mean ± SE SBP reduction of 5.6 ± 2.1 mm Hg in SCRIP-*HTN*.[5]
[c]Corresponds to ± 1 SE of the mean systolic blood pressure reduction from SCRIP-*HTN*.[5]

Table A.1-3. Distribution Parameters for the Probabilistic Sensitivity Analysis.

Parameter	Mean ± SE	Distribution
Absolute risk reduction (after 6 mo of program)		
Myocardial infarction	0.54 ± 0.18%[a]	Beta
Stroke	0.66 ± 0.16%[a]	Beta
Heart failure exacerbation	0.60 ± 0.20%[a]	Beta
Absolute risk reduction (6 mo after end of program)		
Myocardial infarction	—	Uniform[b]
Stroke	—	Uniform[b]
Heart failure exacerbation	—	Uniform[b]
Cost/cardiovascular event		
Myocardial infarction	$13,737 ± $81.64	Normal
Stroke	$17,741 ± $144.43	Normal
Heart failure hospitalization	$12,185 ± $93.68	Normal

[a]Calculated as the sum of the SEs from cardiovascular event absolute risk reduction data and the largest SE when absolute risk reductions were calculated for a 3.5- and 7.7-mm Hg systolic blood pressure reduction (corresponding to ± 1 SE around the mean systolic blood pressure reduction from SCRIP-*HTN*[5]). Summation of SEs was used, since these variances are assumed to be independent.
[b]Absolute risk reductions observed as a result of the program were reduced by one third to two thirds following a uniform distribution in the sensitivity analysis to account for potential loss of benefit after program end.

Table A.1-4. Results of Hypertension Program Follow-Up Studies.

	Study 1[27]		Study 2[28]		Study 3[22, a]	
	Intervention Group (n=174)	Control Group	Intervention Group (n=65)	Control Group (n=39)	Intervention Group (n=24)	Control Group (n=24)
Systolic blood pressure (mm Hg)						
At baseline	133 ± 14.9	NA	153 ± 9.5	150 ± 9.6	157	163
At end of program	130 ± 16.0	NA	125 ± 10.7	132 ± 15.1	146	166
Change over duration of program	−3 ± 1.4 (n=83)[b]	NA (n=76)[b]	−28.0 ± 3.2 (n=65)	−18 ± 3.5 (n=39)	−11 (n=24)	+3 (n=19)[b]
At end of follow-up period	124 ± 14.0[c]	133 ± 21.5[c]	131 ± 12.2[d]	143 ± 17.5[d]	149[c]	168[c]
Change since end of program	−6 ± 2.4[c]	+3 ± 2.7[c]	+6 ± 2.8[d]	+11 ± 3.2[d]	+3	+2

Data are mean or mean ± SD.
NA = not applicable. All study patients received intervention care for the first phase of the study, with randomization into intervention or control groups only utilized for the follow-up period after the initial study.
[a] SDs or variances were not reported in this study.
[b] Numbers of patients at follow-up do not equal the total number of patients at the start of the program due to incomplete follow-up.
[c] Follow-up period of 6 mo.
[d] Follow-up period of 9 mo.

Table A.1-5. Search strategy utilized in Medline

#	Search terms
1	economics, pharmaceutical/ or exp "fees and charges"/ or exp reimbursement mechanisms/
2	"Salaries and Fringe Benefits"/
3	Employee Incentive Plans/
4	capitation fee/ or fee-for-service plans/ or fees, pharmaceutical/ or "rate setting and review"/
5	insurance, health, reimbursement/ or insurance, pharmaceutical services/ or Medicare Part D/ or exp managed care programs/
6	(capitat* or pay* or paid or fee* for service* or ffs or prospective payment* or income* or salar* or economic* or financi* or charge* or remunerat* or compensat* or comp or incentive* or reimburse* or funding or managed care or billing).ti.
7	Current Procedural Terminology/
8	(cpt cod* or Current Procedural Terminology).mp.
9	or/1-8
10	pharmaceutical services/ or community pharmacy services/ or exp drug information services/ or medication therapy management/ or pharmacy service, hospital/ or drug substitution/
11	Pharmacy/
12	adverse drug reaction reporting systems/ or clinical pharmacy information systems/
13	(pharmacy or pharmacies or pharmacist*).mp.
14	or/10-13
15	9 and 14
16	((cognitive adj2 service$) or patient educat$ or counsel$).mp.
17	medication therapy management/
18	Patient Education as Topic/
19	counseling/ or directive counseling/
20	"Drug Utilization Review"/
21	case management/
22	((drug or medication or medicine*) adj2 (manag* or therapy or review*)).ti,ab.
23	(prescription adaptation or therapeutic substitution or prescription renewal*).mp.
24	pharmaceutical case management.mp.
25	(clinical adj2 (care or service*)).mp.
26	(pharmaceutical care or disease state management).mp.
27	(pharmacist$ adj2 (prescribe or prescribes or prescribing)).mp.
28	((independent or supplementary or nonmedical or non-medical or repeat or collaborative) adj prescrib$).mp.
29	((advanced or enhanced) adj2 service*).mp.
30	expanded role.mp.
31	(pharmaceutical opinion* or "refusal to dispense" or "refusal to fill").mp.
32	direct patient care.mp.
33	nondistributive service*.mp.
34	medscheck.mp.
35	or/16-34
36	15 and 35

Table A.1-6. Pharmacist clinical care remuneration programs.

Program	Year Started	Location	Payer	Service	Eligible Patients	Fee
Canada						
Pharmacy Services Compensation Program[10-12]	2012	Alberta (AB)	Government of Alberta	Comprehensive Annual Care Plan (CACP)	AB resident. Two or more chronic diseases (HTN, DM, COPD, asthma, HF, IHD, mental health disorder) and 1 other risk factor (tobacco use, obesity, addiction)	$100, or $125 if pharmacist has Additional Prescribing Authorization (APA)
				Standard Medication Management Assessment (SMMA)	AB resident. One or more chronic disease(s) and be on ≥3 prescription drugs	$60, or $75 if pharmacist has APA
				CACP or SMMA follow-up	AB resident with CACP or SMMA completed. Require follow-up based on pharmacist assessment of need, physician referral, or recent hospitalization	$20, or $25 if pharmacist has APA
				Prescription adaptation (alteration of dosage or regimen, therapeutic substitution, prescription renewal, or emergency prescribing)	AB resident.	$20
				Initiation of therapy (pharmacist must have APA)		$25
PharmaCare Clinical Services Plan[13]	2011	British Columbia (BC)	Government of British Columbia	Medication Review – Standard	BC resident. On ≥5 different medications, and with clinical need.	$60
				Medication Review – Pharmacist Consultation (includes resolution of DRPs identified)		$70
				Renewal, or changing of dose, formulation, or regimen	BC resident.	$10
				Therapeutic substitution		$17.20

				Emergency contraception counseling		$15
				Refusal to fill		2x usual dispensing fee
PharmaCheck[14]	2012	New Brunswick (NB)	New Brunswick Prescription Drug Program	PharmaCheck (20-30 min. medication review)	NB resident on the Plan A (senior) program. On ≥3 chronic prescription drugs.	$52.50
Medication Review, Medication Management, and Refusal to Fill[15-17]	2012	Newfoundland and Labrador (NL)	Newfoundland and Labrador Prescription Drug Program	Medication Review (minimum duration 20-30 minutes)	NL Prescription Drug Program beneficiary	$52.50
				Refusal to fill		$21.80
				Medication management (interim supply, extending prescription, adaptation of dosage form/regimen/quantity, completion of missing information, or non-formulary generic substitution)		$10.90
Pharmacare Insured Professional Services[18]	2011	Nova Scotia (NS)	Government of Nova Scotia	Advanced Medication Review Service	NS resident, beneficiary of seniors Pharmacare program. Have ≥1 chronic disease and be on ≥4 prescription medications (or 1 high-risk drug). Not residing in nursing home or care facility, and not receiving compliance packaging.	$150
				Basic Medication Review Service	NS resident on ≥3 chronic prescription medications.	$52.50
				Therapeutic substitution	NS resident.	$26.25
				Prescription adaptation (includes alteration or refusal to fill)		$14
MedsCheck[19]	2007	Ontario (ON)	Ontario Ministry of Health and Long-Term Care	MedsCheck	ON resident on ≥3 prescription medications for a chronic condition.	$60
				MedsCheck for Diabetes	ON resident with Type I or II diabetes.	$75

				MedsCheck at Home	As for MedsCheck, but for home-bound patients.	$150
				MedsCheck LTC	As for MedsCheck, but for patients residing in long-term care facilities	$90 for annual interdisciplinary review, $50 for quarterly follow-ups
				MedsCheck Follow-Up	Patients already receiving a MedsCheck but requiring a second one due to hospitalization, referral from physician or nurse, or pharmacist assessment of need.	$25
Pharmaceutical Opinion Program[20]	2011			Pharmaceutical Opinion (identification of DRP and recommendation to prescriber)	ON resident receiving provincial drug benefits (seniors, social services)	$15
Pharmacy Smoking Cessation Program[21]				Readiness assessment and first consultation		$40
				Primary follow-up (first 3 follow-up sessions)		$15
				Secondary follow-up (follow-up sessions 4-7 within 1 year of first consultation)		$10
ColonCancerCheck[22]	2008			ColonCancerCheck (provision of FOBT kit and referral of those with positive results)	ON resident. Age 50-74 without a primary care provider and without symptoms indicative of colon cancer. Have not had colonoscopy in past 10 years or completed FOBT in past 2 years.	$7
Pharmacy Services Compensation Program[23]	2012	Saskatchewan (SK)	Saskatchewan Ministry of Health	Medication Assessment	SK resident receiving home care or mental health services, live in own home, and receive compliance packaging.	$60
				Emergency contraception counseling	SK resident.	2x usual dispensing fee

				Refusal to dispense		1.5x usual dispensing fee
				Seamless care (medication reconciliation within 1 week of discharge)		1.5x usual dispensing fee
				Minor ailments program (acne, cold sores, insect bites, allergic rhinitis, diaper dermatitis, oral aphthous ulcers, oral thrush)		$18
				Adaptation (dosage form, interim supply, continuing existing supply)		$6
				Emergency extension		$10
				Prescription alteration because of missing information		$6
Partnership to Assist with Cessation of Tobacco (PACT)[24]	2009			Smoking cessation counseling		$2 per minute
General Motors Smoking Cessation Program[25]	2006	Multiple provinces	General Motors Canada Limited	Smoking cessation counseling (initial assessment and 6 follow-up visits over 6 months)	General Motors Canada Limited health plan enrollees, retirees, and their dependents who smoke	$115
United States						
Alaska Medicaid Program[26]	2011	Alaska	State of Alaska Department of Health and Social Services	Tobacco cessation counseling	Alaska Medicaid beneficiaries	$19.84
Alameda Alliance for Health CompleteCare MTM Program[27]	2008	California	Alameda Alliance for Health CompleteCare	Comprehensive medication review	Alameda Alliance for Health CompleteCare members	$76.70
				Prescriber consultation (cost-efficacy or DTP management)		$20.45
				Patient compliance consultation		$20.45
				Patient education and monitoring		$10.23

Health Plan of San Joaquin Pharmacy Cognitive Services Compensation Program[28]	2009	California	Health Plan of San Joaquin	Non-formulary to formulary change	Health Plan of San Joaquin beneficiary	$5.11
				Extended education		$10.23
				Contacting a prescriber		$20.45
Health Plan of San Mateo Medication Therapy Management Program[29]	2006	California	Health Plan of San Mateo	Comprehensive medication review	Subgroup of Health Plan of San Mateo members (not specified)	$76.70
				Prescriber consultation (cost-efficacy or DTP management)		$20.45
				Patient compliance consultation		$20.45
				Patient education and monitoring		$10.23
Partnership Healthplan of California Medication Therapy Management Program[30]	2007	California	Partnership Healthplan of California	Comprehensive medication review	Subgroup of Partnership Healthplan of California Medicare Advantage Plan members (not specified)	$51.13
				Prescriber consultation		$20.45
				Patient compliance consultations		$20.45
				Patient education and monitoring		$10.23
Rx Review Program[31-34]	2007	Colorado	Colorado Department of Health Care Policy and Financing (Medicaid)	Medication review	Colorado Medicaid beneficiaries on ≥5 medications over 3 consecutive months	$76.70 if face-to-face, $51.13 if via telephone
Florida Medicaid Program[35-36]	2004	Florida	Florida Agency for Health Care Administration (Medicaid)	Comprehensive medication review	Florida Medicaid beneficiaries	$51.13
				Identification and management of quality-related events		$20.45 if prescriber consultation required, $15.34 if patient non-compliance
				Patient education and monitoring (includes follow-up call after dispensing)		$10.23
Smoking Cessation	1999	Indiana	Indiana	Smoking cessation	Indiana Medicaid beneficiaries	$22.58 per 15

Treatment Services[37]			Medicaid	counseling		minutes
CarePro Health Services MTM Program[38]	1999	Iowa	CarePro Health Services	Comprehensive medication review	CarePro plan members	$51.73
				Prescriber consultation		$20.45
				Patient compliance consultation		$20.45
				Patient education and monitoring		$10.23
City of Ames Medication Therapy Management Program[39]	2000	Iowa	City of Ames	Comprehensive medication review	City of Ames members	$76.70
				Prescriber consultation (cost-efficacy or DTP management)		$20.45
				Patient compliance consultation		$20.45
				Patient education and monitoring		$10.23
Pharmacists Mutual Insurance Companies MTM Program[40]	2004	Iowa	Pharmacists Mutual Insurance	Comprehensive medication review	Pharmacists Mutual employees and health plan members	$51.50
				Prescriber consultation		$20.45
				Patient compliance consultation		$20.45
				Patient education and monitoring		$10.23
Iowa Priority Prescription Program[41-42]	2002	Iowa	Iowa Department of Public Health	Brown bag medication review	Medicare-eligible Iowans with no insured drug benefit and not enrolled in Medicaid	$25.57
Diabetes Self-Management Training[43-44]	2011	Louisiana	Louisiana Department of Health and Hospitals (Medicaid)	Diabetes self-management training	Medicaid beneficiaries with diabetes and 1 of: newly diagnosed, pregnant, not yet received diabetes education, HbA1c >7, severe hypo- or hyperglycemia in past 12 months, diagnosis of complication or co-morbidity, or new order for insulin pump	$50.31 per 30 minutes of individual education, $13.53 per patient per 30 minutes for group education
Maryland Patients Pharmacists Partnerships (P^3)		Maryland	Six Maryland self-insured employers (not	Diabetes management	Insurance program enrollees and their dependents with diabetes	Varies by employer, averages $2.05

Program[45-47]			specified)			per minute[a]
Priority Health Medication Therapy Management Program[48]	2010	Michigan	Priority Health	Comprehensive medication review	Priority Health members	$76.70
				Prescriber consultation (cost-efficacy or DTP management)		$20.45
				Patient compliance consultation		$20.45
				Patient education and monitoring		$10.23
Medicaid Medication Therapy Management Program[49-53]	2006	Minnesota	Minnesota Department of Human Services (Medicaid)	Medication therapy management	Outpatient, not eligible for Medicare Part D, taking ≥3 prescriptions for ≥1 chronic condition(s)	$53.18 for first 15 minutes of first encounter, $34.77 for first 15 minutes of follow-up encounter, and $24.54 per additional 15-minute increments for either first or follow-up encounters
HealthPartners RxCheckup[53-54]	2008	Minnesota	HealthPartners	Medication therapy management (face-to-face)	HealthPartners employees, Medicare members with HealthPartners prescription drug coverage, and beneficiaries of the Minnesota General Assistance Medical Care, Medical Assistance, MinnesotaCare, Minnesota Senior Health Options, and Minnesota Senior Care programs	Up to $153.41 for planning, initial visit, and follow-up
Missouri Medicaid Disease State Management Program[34]	2002	Missouri	Missouri Medicaid	Initial assessment	Missouri Medicaid beneficiaries with asthma, DM, HF, or depression	$76.70

				New problem assessment		$40.91 for initial assessment and per follow-up
				Preventative follow-up assessment		$25.57
MO HealthNet Medication Therapy Management[55]	2008 (ended 2010)	Missouri	MO HealthNet (Medicaid provider)	Medication therapy management	Missouri Medicaid beneficiary with ≥1 of: asthma, COPD, DM, CVD, GERD, or sickle cell anemia	$51.13 for first 15 minutes of initial visit, $10.23 for first 15 minutes of a follow-up visit, $5.11 for each additional 15 minutes for either initial or follow-up visits
PharmAssist Program[35,56-57]		Montana	State of Montana Department of Public Health and Human Services	Medication therapy management	Montana resident	$51.13 for first 15 minutes of initial encounter, $25.57 for additional 15 minute increments at either initial encounter or follow-up encounters
Pharmacist tobacco cessation counseling program[58-59]	2008	Nebraska	Nebraska Medicaid	Smoking cessation counseling (must be ordered by primary care provider)	Nebraska Medicaid beneficiary age ≥18 and participating in Tobacco Free Quitline	$13.49 for visit of ≤10 minutes, or $23.13 for visit lasting >10 minutes
New York Medication Therapy Management Program[60]		New York	New York Medicaid	Medication therapy management		$35.79 initial consultation, $25.57 follow-up consultation
ChecKmeds Program[61-63]	2007 (ended 2011)	North Carolina (NC)	State of North Carolina	Comprehensive medication review	NC resident age ≥65, part of Medicare Prescription Drug Plan	$51.13
				Prescriber consultation (cost-efficacy of DTP management)		$20.45

				Patient compliance consultation		$20.45
				Patient education and monitoring		$10.23
Focused Risk Management (FORM) Program[64-66]	2006		North Carolina Department of Health and Human Services	Medication therapy management	NC Medicaid beneficiary age ≥21 and taking ≥11 medications per month. Must live in own home.	$30.68 per patient per 3 months
Smoking and Tobacco Cessation Counseling for Pregnant Women Program[67-68]	2012	North Dakota (ND)	North Dakota Medicaid	Smoking and tobacco cessation counseling	ND Medicaid beneficiaries who are pregnant or up to 60 days postpartum	$18.97 for counseling ≤10 minutes duration, $35.71 for counseling >10 minutes
Oregon Medication Therapy Management[69-77]		Oregon	Oregon Medicaid	Medication therapy management	Oregon Medicaid beneficiaries	$28.86 for first 15 minutes of initial encounter and $13.47 for each 15 minutes thereafter, $26.94 for first 15 minutes of follow-up and $13.47 for each 15 minutes thereafter
Tobacco Cessation Services[78]	2002	Pennsylvania (PA)	Pennsylvania Department of Public Welfare	Tobacco cessation counseling	PA Medical Assistance recipient	$15.34 per 15 minute increment
HealthSpring and John Deere MTM Program[79]		Tennessee	HealthSpring and John Deere Health Care programs	Comprehensive medication review	All HealthSpring Medicare Prescription Drug Plan members and a subgroup of John Deere Health Care members (not specified)	$51.13
				Prescriber consultation		$20.45
				Patient compliance consultation		
				Patient education and monitoring		$10.23
Scott & White Health Plan[80-81]		Texas	Scott & White Health Plan	Diabetes medication management	Enrollees with DM and HbA1c >7.5%	$107.38 for initial visit, $56.25 for follow-up visits
Washington Medicaid		Washington	Washington	Emergency contraception	Washington Medicaid	$13.81

Prescription Drug Program[82]			Medicaid	counseling	enrollees	
Face to Face (F2F) Diabetes Program[83]	2010	West Virginia	West Virginia Public Employees Insurance Agency	Diabetes assessment	Plan members with DM (including secondary causes of DM or gestational DM)	$51.13 initial assessment, $20.45 per 15 minutes for follow-up assessments
Medication Therapy Management and Intervention-Based Services[84-86]	2012	Wisconsin	Wisconsin Medicaid and BadgerCare	Comprehensive medication reviews and assessments	Medicaid, BadgerCare, SeniorCare, Program for All Inclusive Care of the Elderly, and FamilyCare program beneficiaries with 1 or more of: taking ≥4 medications for ≥2 chronic conditions, DM, multiple prescribers, recent discharge from hospital or care facility, health literacy issues, referral from physician	$76.70 for initial review, $35.79 for follow-up
				Cost-effectiveness intervention	Medicaid, BadgerCare, SeniorCare, Program for All Inclusive Care of the Elderly, and FamilyCare program beneficiaries	$30.68
				Change in dose, dosage form, or duration		
				Focused adherence consultation		
				Medication addition or deletion		
				Medication device instruction		
Wisconsin Medicaid Pharmaceutical Care Program[87-89]	1996 (ended 2012)	Wisconsin	Wisconsin Medicaid	Pharmaceutical care service	Wisconsin Medicaid and SeniorCare recipients	$9.66 for 0-5 minutes, $15.01 for 6-15 minutes, $22.66 for 16-30 minutes, and $41.02 for ≥31 minutes
PharmAssist Program[35,90]	2004 (ended 2009)	Wyoming	Wyoming Department of Health	Medication consultation	Wyoming resident	Up to $129.82
Medicare Part D	2006	Multiple states	Centers for	Varies between	Medicare Part D enrollee with	Varies

Medication Therapy Management Program[91-97]			Medicare and Medicaid Services	pharmacy and part D sponsor	multiple chronic diseases (defined by each program), taking multiple Part D covered drugs, and likely to incur annual costs of ≥$3,000 for Part D drugs	
Humana Medication Therapy Management Program[98]	2011	Multiple states	Humana	Comprehensive medication review	Humana members	$51.13
				Prescriber consultation		$20.45
				Patient compliance consultation		
				Patient education and monitoring		$10.23
Medi-CareFirst Medication Therapy Management[99]	2008	Multiple states	Medi-CareFirst BlueCross BlueShield	Comprehensive medication review	Medi-CareFirst BlueCross BlueShield members in Delaware, Maryland, and Washington, D.C.	$76.70
				Prescriber consultation (cost-efficacy or DTP management)		$20.45
				Patient compliance consultation		
				Patient education and monitoring		$10.34
New Zealand						
New Zealand National Pharmacist Services Framework[100-103]	2007	Nation-wide	District Health Boards of New Zealand	Medications use review and adherence support	≥1 of: taking ≥3 medicines and/or ≥12 doses/day, multiple prescriber, recent hospitalization, high-risk medication use, presence of a DRP, non-adherence, sensory/language/cognitive deficiencies, on narrow therapeutic index drug, or on a drug suspected of being inappropriately used	$86.38 for initial consultation, $21.60 for follow-up
				Medicines therapy assessment (as part of multidisciplinary team)	≥1 chronic disease, ≥2 comorbidities, and ≥4 medicines and/or ≥12 doses/day or at risk of an adverse effect	$103.66 for initial consultation, $51.83 for follow-up
				Comprehensive medicines management		$138.21 for initial consultation,

				(as part of multidisciplinary team, including future pharmacist prescribing)		$69.10 for follow-up
United Kingdom						
Starting Fresh and Smoke Free Pharmacy Services[104-108]	2008	Scotland	National Health Service Greater Glasgow & Clyde	Behavioral smoking cessation counseling (may include prescribing of NRT or drug therapy)		$7.81 for baseline visit, $21.86 for weeks 1-4 visits, $15.62 for weeks 5-8, $9.37 for weeks 9-12[b]
Community Pharmacy Heart Failure Service[109]	2005	Scotland	National Health Service Scotland	Heart failure service		$57.53 for initial review, $16.44 for follow-up
Medication Use Reviews[110-112]	2008	Scotland, England, Wales	National Health Service	Medication use review		$42.16
Discharge Medicines Review Service[113]		Wales	National Health Service Wales	Discharge medicines review (includes 2 visits)	Recently discharged plus 1 of: medications changed during hospitalization, on ≥4 medicines, requires compliance packaging, or pharmacist assessment of patient benefit from service	$57.78 per visit
Minor Ailments Scheme[114-116]	2005	England	National Health Service	Minor ailments consultation (eligible conditions vary)	England resident.	Varies by primary care trust, range from $4.68-10.93
	2009	Northern Ireland	Health and Social Care in Northern Ireland	Minor ailments consultation (coughs and colds, hay fever, head lice, athlete's foot, threadworms, vaginal thrush, diarrhea, and Dhobie itch)	Patients receiving free prescriptions from the state	$15.68 for the first 500 consultations per pharmacy, $12.55 for next 1000, and $10.21 per consultation thereafter
Appliance Use Review[117-118]		England	National Health Service	Appliance use review		$46.36 if performed in a pharmacy, $89.40 if

						performed in patient's home. $46.36 for subsequent reviews for same patient within a 24-hour period
New Medicine Service[118-120]	2011	England	National Health Service	New medication service consultation	Newly prescribed drug for asthma, COPD, type II DM, HTN, or antiplatelet/anticoagulation therapy	$33.11-46.36 depending on the total number of patients who receive the service in the month per pharmacy
Europe						
Inhaler Technique Assessment Service[121]	2005	Denmark	Danish Ministry of Health	Inhaler technique assessment service	Asthma or COPD	$11.87
Polymedications Check[122-123]	2010	Switzerland	Swiss Federal Office of Public Health	Polymedications check	Swiss resident on ≥4 prescribed drugs taken for ≥3 months	$50.00[c]
Australia						
Medication Management Review Program[124-126]	2005	Nation-wide	Australia Government – Department of Human Services	Residential medication management review	Resident of government-funded aged care facility, if requested by general practitioner	$99.93
	2012			MedsCheck	Medicare or Department of Veterans Affairs cardholder, living at home, taking ≥5 prescriptions or with recent significant medical event	$60.02
				Diabetes MedsCheck	Diagnosed with Type II DM in past 12 months, or who are uncontrolled and unable to access an existing diabetes education/health service	$90.03

Abbreviations used: HTN, hypertension; DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; HF, heart failure; IHD, ischemic heart disease; DRPs, drug-related problems; FOBT, fecal occult blood test; DTP, drug therapy problem; HbA1c, glycosylated hemoglobin; CVD, cardiovascular disease; GERD, gastroesophageal reflux disease; NRT, nicotine replacement therapy

a. University of Maryland School of Pharmacy, personal communication, May 20, 2013.
b. NHS Greater Glasgow and Clyde, personal communication, June 4, 2013.
c. University of Basel, personal communication, May 22, 2013.

Table A.1-7. Remuneration programs with incomplete information available.

Program	Year Started	Location	Payer	Service	Eligible Patients
United States					
MaineCare Medication Therapy Management Services[127]	2012	Maine	Maine Department of Health and Human Services	Medication therapy management	MaineCare beneficiary with ≥1 chronic disease, prescribed multiple drugs, and designated by their primary care provider as eligible for medication therapy management services
Community Pharmacy Cognitive Care Initiative[128-129]	2011	New Mexico	State of New Mexico	Action plan development	State of New Mexico employees/dependents with adherence issues or therapeutic omissions related to CVD, DM, pulmonary disease, immunology, women's health, or neurology
About the Patient Program[130-131]	2008	North Dakota	North Dakota Public Employees Retirement System, North Dakota Workplace Safety & Insurance	Medication therapy management	Plan enrollees with ≥2 chronic conditions, on ≥2 medications, and with annual drug costs of ≥$3000 USD
				Diabetes management program	
				Pain management program	
Lucas County Prescription Drug Use Review Program and Diabetes Case Management Program[132-134]	NA	Ohio	Lucas County Employer Group	Drug use review	Enrollees of the Lucas County employee prescription drug program
				Diabetes case management	
Medication therapy management[135]	NA	Wisconsin	Unity Health Insurnace, Dean Health Plan, and State of Wisconsin Employee Trust Fund	NA	NA
Diabetes Prevention and Control Alliance[136-138]	NA	Multiple states	UnitedHealth Group and Medica	Diabetes control program	UnitedHealth Group members with DM
United Kingdom					
Emergency hormonal contraception program[139-140]	NA	Wales and Scotland	Bridgend Local Health Group	Emergency hormonal contraception counseling	Females age ≥13

Abbreviations used: CVD, cardiovascular disease; DM, diabetes mellitus; NA, not available

Table A.1-8. Uptake and outcomes of identified pharmacist remuneration programs.

General Motors Smoking Cessation Program[25]

Design: Analysis of prescription claims data and self-reported quit rates by participating pharmacies.

Objectives: To determine smoking cessation quit rates and the mean duration of therapy for nicotine patches.

Uptake: Of 217 pharmacies eligible to participate, 47 provided services. Between November 4, 2006 and December 17, 2006, 80 patients received the service. 23 were lost to follow-up.

Clinical Outcomes: 30 patients (37.5%) smoke-free after 6 months, with men having a higher quit rate than women (42.6% versus 21.2%, p = 0.034).

Economic Outcomes: Mean duration of therapy for those using the nicotine patch was 61.2 days.

Barriers: A high loss to follow-up rate was observed (28%).

Iowa Priority Prescription Program[41-42,141]

Design: Retrospective cohort study using enrollment, claims, and provider data[41]

Objectives: To assess whether member characteristics and their provider access affected the probability of the member to obtain the service.

Uptake: Of the 24,044 eligible members of the Iowa Priority program as of June 30, 2002, 3071 (12.76%) received a brown bag review. Among the members with prescription claims for that same time period (14,051), 2434 (17.32%) received brown bag reviews.

Objectives: To characterize the number and types of patient safety issues identified among patients receiving a Brown Bag medication review.[141]

Uptake: 2,780 Brown Bag medication review claims were filed through mid-2002.

Clinical Outcomes: 33% of patients receiving a Brown Bag medication review had at least one patient safety issue identified (16.2% of patients had a drug interaction issue, 6.6% had a duplication of therapy issue, and 17.1% had other issues). Requiring a medication not currently taken was the most commonly-identified 'other' issue.

Uptake: Of ~800 Iowa retail pharmacies, 748 (93.5%) have joined Iowa Priority. As of July 17, 2002, 3,675 enrollees had taken advantage of the free Brown Bag Assessments. While either the patient's physician or pharmacist can complete assessments, over 95% of assessments have been done by pharmacists.[42]

Barriers: Some pharmacists have reported that the low dispensing fee offered to Iowa Priority enrollees ($2.50 for brand-name drugs and $3.25 for generic drugs) when combined with the discount given to enrollees makes the cost of doing business too high.

Maryland Patients Pharmacists Partnerships (P^3) Program[45]

Design: Retrospective chart review (January 2009 – December 2010).

Objectives: To examine HbA1c control rate (measured as the percentage of participating employees achieving the target HbA1c levels), LDL cholesterol levels, and blood pressure among 449 patients with two or more HbA1c values during the study period.

Uptake: Currently >300 pharmacist providers participating. During the evaluation period, the program had served ~500 employees and engaged six self-insured employers.

Clinical Outcomes: On average, the HbA1C was reduced by over 0.5% for all

participants during the study interval. Proportion of participants at LDL <100 mg/dL increased from 53% to 65%, and the proportion at LDL <70 mg/dL also increased from 22% to 29.1%. BP was also reported to have improved, but actual data not provided.

Economic Outcomes: Actual cost savings of $495 and $3,281 per patient in 2008 were reported by two participating employers. The authors reported modest, but positive cost savings by the end of 2008 for employers when compared to baseline costs (actual data not provided). Per employee out-of-pocket costs decreased for participants in the sites where economic data were available.

Minnesota Medication Therapy Management Program[50-51,142]

Design: Retrospective analysis of administrative data over the 10-year period from September 1998 to September 2008 in 1 health system with 48 primary care clinics.[50]

Objectives: To present the clinical, economic, and humanistic outcomes of the program.

Uptake: 33,706 documented encounters with 9,068 patients in 10 years, averaging 3.72 visits per patient.

Clinical Outcomes: 38,631 drug therapy problems identified and addressed, with 7,708 (85%) of patients having 1 or more drug therapy problem at the first visit, and 2,630 (29%) having 5 or more. Among 110 patients with diabetes, 47 (42.7% reached all 5 goals of therapy set out (HbA1c <7%, blood pressure <130/80 mm Hg, LDL cholesterol <100 mg/dL, no tobacco use, and daily aspirin use) compared to only 19 (17.3%) at baseline.

Economic Outcomes: Estimated direct savings were $2,913,850 ($86.45 per encounter for 33,706 encounters). The average cost of an MTM visit was $67.00 for a total program cost of $2,258,302 and an estimated return on investment of $1.29 per $1 spent.

Patient Satisfaction: Patient satisfaction was very high, with >95% of 317 survey respondents agreeing or strongly agreeing that the pharmacist provided education helpful in achieving goals of therapy, that their health and well-being had improved as a result of the program, they would recommend the service to their family and friends, and that the pharmacist helped them understand how to take their medication(s) safely and correctly. 98% of patients agreed or strongly agreed that health care benefits should include the program.

Uptake: 34 pharmacists billed the state for providing MTM services to 259 patients from April 1, 2006, to March 31, 2007.[51]

Clinical Outcomes: Pharmacists resolved an average of 3.1 drug therapy problems per patient, most commonly issues of inadequate therapy. Of patients with diabetes, 36% met all five of the state's standards for diabetes care after starting to receive the service compared to 6% of patients meeting these standards statewide in 2004.

Economic Outcomes: The pharmacists received an average of $92.50 per patient visit, with the payment based on the complexity of care for the given patient.

Design: Retrospective medical chart review and administrative data analysis.[142]

Objectives: To evaluate patient care, quality of care and health expenditure outcomes of the program in the first year of the program (April 2006 to March 2007).

Uptake: 34 pharmacists provided medication therapy management services to 259 recipients across 431 encounters.

Clinical Outcomes: A total of 789 drug therapy problems were identified and resolved, with dosage too low, non-compliance, and need for additional therapy representing 73% of problems identified. 82% of problems did not require the direct involvement of a physician while 18% were resolved through collaboration with a physician or other primary care professional. Goals of therapy achieved improved from 76% to 87% in the first year of the program.

Economic Outcomes: $39,866 was paid to pharmacists (average $92.50 per encounter). Total health care claims (including payments for MTM) were $3,027 per person per month in the pre-intervention period compared to $3,271 per person per month in the post-intervention period for an 8.0% difference in expenditures. Additionally, expenditures increased for prescriptions (+24.3%), inpatient care (+11.2%), home and community-based services (+4.9%), and extended and residential care services (+12.7%). A decrease in expenditures was observed among prescribing providers (-9.3%), non-prescribing providers (-36.5%), ambulatory care (-20.6%), other care and services (-24.3%), and lab and diagnostic procedures (-69.7%).

Missouri Medicaid Disease State Management Program[143]

Uptake: 175 claims for services submitted by 15 pharmacists for 148 patients in 6 months.

Clinical Outcomes: Pharmacists resolved the most health recommendations for hypertension (n=69), followed by dyslipidemia (n=51), and smoking cessation (n=36)

North Carolina Medicaid Medication Therapy Management Program[66]

Design: Retrospective analysis of pharmacy documentation

Objectives: To determine the prescriber acceptance rate of pharmacists' recommendations and implementation rate of accepted recommendations, and to estimate the cost-effectiveness of MTM activities at Kerr Drug pharmacies in North Carolina.

Clinical Outcomes: Of 352 quarterly reviews performed for 88 randomly sampled beneficiaries, the most common recommendations were for prescription to over-the-counter changes or brand to generic drug changes. From a clinical perspective, 11.4% of recommendations pertained to medication monitoring, 11.4% were to discontinue unnecessary medications, 5% were regarding adherence concerns, and 4.8% were to initiate new medications. The prescriber acceptance rate of recommendations averaged 52.8%. Of the 88 patients included in the analysis, 56 had recommendations that were both accepted and implemented by the pharmacist.

Economic Outcomes: Of the 56 patients with accepted and implemented recommendations, pharmacists were paid $6,720, and their recommendations led to $9,444 in savings. Net savings is therefore $2,724. However, when considering savings for these 56 patients versus the costs of providing medication therapy management for all 88 patients, the program resulted in a net loss of $1,116. Pharmacists were found to make cost-saving recommendations for 96% of beneficiaries, including switching from prescription to non-prescription drugs, or the use of generic drugs in place of brand name products.

Lucas County Prescription Drug Use Review Program and Diabetes Case Management Program (Ohio)[69-71]

Design: A retrospective-prospective study of a cohort receiving pharmacist provided MTM services in Northwest Ohio.[69]

Objectives: Impact of pharmacist intervention on A1c, systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI). self-monitored blood glucose (SMBG) and caffeine intake per day among patients with diabetes and hypertension and an A1c >7.

Clinical Outcomes: Within one year of starting the MTM program, patients' mean A1c values decreased from 8.21 to 7.41 (p=0.000), SBP decreased from 130.72 to 127.84 (p=0.006) and DBP decreased from 81.75 to 80.03 (p=0.004). Caffeine consumption and SMBG decreased significantly ($p<0.05$ for each), while BMI decreased non-significantly.

Design: Longitudinal study using medical claims.[70]

Objectives: To determine costs and utilization incurred by employees following enrollment in the program, and to assess the impact of attrition from the program on

health expenditures.

Economic Outcomes: Among 361 enrollees between January 2005 and July 2010, office visit expenses decreased 22.4% ($71,442), emergency room visits increased by $12,597.16, and total expenditure on inpatient visits went up by approximately $7600 but the amount spent on each visit went down from $7,746. The number of employees who had an inpatient visit increased from 3 to 7. A decrease in total health care expenditures by over 14% was observed. On average, employees spent $407 per patient per year more when they dropped out of the program than if they stayed enrolled.

Design: Prospective pre-post longitudinal study.[71]

Objectives: To determine health care utilization and potential cost savings among patients with diabetes, hypertension, hyperlipidemia, or a combination of the three.

Clinical Outcomes: Over 70% of employees received a flu shot at least once over the 24 months. Alcohol and tobacco consumption decreased by 50% and 55%, respectively. Caffeine use decreased by 26.47%. Patient-reported exercise increased by 39%.

Economic Outcomes: Visits to specialty physicians increased (podiatrist by 24%, ophthalmologist by 41%, and dentist by 26%). Average cost-savings for employees who improved or maintained appropriate utilization of health resources ranged from $932-$1438 per employee over two years. Approximately 90% of employees either took less or had the same amount of sick days, and those with fewer sick days saved $1231 per employee while those who took more sick days spent $2147 per employee.

Texas – Scott & White Health Plan[80-81]

Uptake: 12 pharmacists saw 500 diabetic patients in 2011.[80]

Clinical Outcomes: Patients receiving pharmacist care experienced an improvement in medication adherence and a trend toward lower glycosylated hemoglobin (HbA1c) values (actual results not provided).

Economic Outcomes: The plan saved $1,800 per patient in the diabetes program compared with a control group. Given that 500 health plan members participated, the annual savings to the Scott & White plan was $900,000.

Objectives: To compare medication adherence, diabetes control, and healthcare costs between patients enrolled in the program and matched control patients.[81]

Uptake: 144 patients were enrolled in the program for at least 2 years and included in the analysis.

Clinical Outcomes: Average HbA1c decreased by 0.8 in controls and 1.5 in program patients ($p<0.01$). However, both groups declined in adherence to oral antidiabetic drugs (program patients by 10%, control patients by 19%, $p=0.009$).

Economic Outcomes: After two years, the average per member per month costs increased by 16% and 36% in program and control groups, respectively, with the increase mainly attributable to growth in diabetes-related drug and outpatient claims in the program group. Inpatient costs decreased by 38% in program patients versus an increase of 159% in the control group.

Wisconsin Medicaid Pharmaceutical Care Program[87-89]

Design: Retrospective, longitudinal analysis of paid claims from the Wisconsin Medicaid program

Objectives: To characterize claims from July 1996 to June 2007

Uptake: There were 51,543 paid claims to 601 pharmacies, ranging from a low of 806 in 1999 to 9,742 in 2004. An average of 87.7 claims were paid per pharmacy. There was a 12-fold increase in claims between 1999-2005, and after 2005 claims dropped by 22.6% in 2006 and 30.6% in 2007. 334 pharmacies were paid for 10 or fewer claims, with 111

paid for only one claim. Over one-third (37%) of pharmacies participated in the program for 1 year only.

Clinical Outcomes: Since 2002, prescription adjustments trended upward in frequency while providing patient information remained flat (actual data not reported).

Economic Outcomes: The majority of claims were paid at the 31-60 minutes level, with 55% of claims falling in the time categories of 0-5 minutes and 6-15 minutes. For more than 86% of paid claims, the actual dollar amount paid per claim to the pharmacy was paid at the maximum allowable reimbursement amount (actual data not reported).

Barriers: Potential explanations cited for low participation include low reimbursement rates, billing difficulties, time constraints, and the loss of dual-eligible patients to enrollment in Medicare Part D plans.

Wyoming PharmAssist[144]

Uptake: The program enrolled 15-20 state residents annually during the program's last two years (2007-2009), after the introduction of Medicare Part D pharmacy benefits.

Economic Outcomes: The program saved participants approximately $1,100 in medication costs per year, on average.

Barriers: Patient participation in the program declined significantly following introduction of Medicare Part D pharmacy benefits.

Medicare Part D Medication Therapy Management[94-95,145-147]

Design: Retrospective observational study conducted at 20 pharmacies from January 1 to December 31, 2010.[94]

Objectives: Primary objective was to determine the net financial impact on patient out-of-pocket prescription medication expense as a result of pharmacist interventions. The secondary objective was to evaluate the patient and physician acceptance rates of the pharmacists' recommendations.

Uptake: 284 patients were eligible for the service, of which 128 (45%) participated.

Clinical Outcomes: Pharmacists attempted 732 interventions, of which 53% were approved by both the patient and physician.

Economic Outcomes: 87 patients (68%) did not see a direct financial impact from the program, while 34 (27%) saw a decrease in medication expenses and 7 (5%) saw an increase in expenses. Net financial impact for all patients was a savings of $102.83 (SD $269.18) per patient per year.

Design: Retrospective quasi-experimental study using administrative data[95]

Objectives: To study the impact of the program on LDL cholesterol levels and achievement of LDL treatment goal.

Clinical Outcomes: Following intervention, mean LDL levels among control patients were significantly higher than those receiving MTM (90.8 ± 31.0 mg/dL among non-participants versus 83.4 ± 31.1 mg/dL among participants. 69% of MTM participants had an LDL <100 mg/dL versus 50% of control group patients ($p<0.001$).

Economic Outcomes: Pharmacists spent an estimated 1-3 hours for each patient served during the course of the intervention. The average savings in one year was $49 per member per month in those not receiving the service, but $77 in program participants. The amount spent out of pocket for copayments was $11.28 per member per month lower in program non-participants versus $7.36 lower among participants.

Design: Case-control study[145]

Objectives: To determine per member per month medication savings in the first year of a

medication therapy management program.

Uptake: 4,259 case interventions were performed

Economic Outcomes: Projected medication costs for the control group assuming no intervention was $665 whereas actual costs were $613, representing a savings of $52 per member per month. Average monthly drug savings of $221,468 minus average monthly pharmacist fees for the intervention of $89,336 resulted in a return on investment of $2.50 per $1 spent.

Design: Analysis of administrative data.[146]

Objectives: To evaluate Medicare Part D drug costs, use, and generic dispensing ratio between pre- and post-medication therapy management (MTM) periods (service provided from May to December 2007).

Uptake: Of 73,793 patients eligible and analyzed, 21,336 (29%) received MTM services from a community pharmacist.

Economic Outcomes: Patients who received MTM services from a community pharmacist had a decline in mean monthly drug costs of $35 (from $669 to $634). Those patients who had a face-to-face session had a decline in mean monthly drug costs of $29 (from $658 to $629), while drug costs decreased by $40 (from $677 to $637) when the community pharmacist provided the services over the telephone. The mean number of prescriptions used per month decreased by 5% (from 9.79 to 9.29). The proportion of generic drugs dispensed per patient per month also increased by 9.4% (from 60.1% to 65.7%).

Design: Retrospective case-control study of patients receiving MTM versus those declining the service.[147]

Objectives: To compare clinical and economic outcomes among recipients and non-recipients of MTM.

Uptake: In 2006, 1388 patients were eligible and offered enrollment in the program, of which 307 (22%) accepted enrollment. In 2007, 1308 were eligible and 228 (17%) accepted enrollment.

Clinical Outcomes: 60% relative reduction was seen in gastrointestinal bleeds for patients with arthritis 6 months post-enrollment compared to 6 months pre-enrollment ($p=0.007$). An even greater reduction was seen among those enrolled in the program versus those declining enrollment ($p=0.001$). The proportion of patients receiving MTM with coronary artery disease with LDL cholesterol <100 mg/dL decreased by 5% over 6 months versus an increase of 7% in those declining MTM. Adherence to ACE inhibitor or angiotensin receptor blocker therapy increased by 10% in patients receiving MTM versus a decrease of 1% in those declining. Beta-blocker adherence decreased 2% in those receiving MTM versus decreasing by 8% in those declining. The proportion of patients with diabetes and HbA1c <7% increased by 3% among those receiving MTM versus increasing by 7% in those declining. The use of insulin among diabetic patients increased by 4% in those receiving MTM versus decreasing by 1% in those declining.

Economic Outcomes: Each pharmacist spent between 2-2.5 hours per patient case (included researching medication therapy, contacting physicians for additional data, collaboration, development of the care plan, and patient education). Rate of decline in per member per month drug costs was significantly steeper in the accepted group versus the declined group ($p = 0.001$), while the rate of decline in medical costs was not significantly different between groups. Patients enrolling in 2006 saw a sustained positive effect in lowered drug costs in 2007, while medical cost savings realized in 2006 were not sustained in 2007. For enrollees, the overall use of generic drugs increased by 6%, versus only 3% among those declining the service.

Patient Satisfaction: Over 95% of the enrollees responding to a survey found the program helpful, and over 90% of the 2006 enrollees and nearly 90% of the 2007 enrollees agreed that the telephone discussion with their pharmacist was convenient and provided the necessary education.

New Zealand National Pharmacist Services Framework[103]

Uptake: Of 66 pharmacists accredited to perform medication use reviews surveyed in May 2008, 39 (57%) were undertaking these reviews while the remainder were not.
Economic Outcomes: Initial interview takes a median of 57 minutes (range 30-120), and follow-up interviews take a median of 15 minutes (range 5-90). Pharmacists report that payment for the service ranged from $101-150 for three interviews, to $181-200 for four interviews, plus subsequent documentation.
Barriers: Pharmacists not performing reviews reported the following barriers: no current contract agreed upon with funders (contracts must be negotiated with individual district health boards), insufficient time, personal circumstances (unemployment, family leave), GPs and/or patients were not interested, and the claims process is too complex.

Scotland – Starting Fresh and Smoke Free Pharmacy Services[104-105,108]

Design: Observational study of administrative information linked with survey data.[104-105]

Objectives: To compare smoking cessation outcomes of users accessing pharmacy-based versus group smoking cessation treatment.

Uptake: At the time of the study, >200 pharmacists were participating and treating more than 12,000 smokers each year.

Clinical Outcomes: 18.6% of patients receiving pharmacy-based care were carbon monoxide-validated non-smokers after 4 weeks, versus 35.5% of patients receiving group counseling outside of the pharmacy. After 1 year, group service participants retained an abstinence rate of 6.3% versus 2.8% among pharmacy program participants (p=0.001).

Economic Outcomes: Economic model assumed cost per client of £79 for pharmacy clients and £368 for group clients. In comparison to self-quit attempts, economic modeling estimated that the pharmacy service resulted in a cost per quality-adjusted life-year (QALY) of £2,600 for pharmacy care, versus £4,800 for group services.

Barriers: Patients could obtain orders for bupropion or varenicline from a physician as part of the group counseling service, but could only receive nicotine replacement therapy through the pharmacy program at the time of the study. However, when group service clients receiving pharmacotherapy were excluded, 5.7% of group participants were quitters after 1 year (p=0.015 versus pharmacy program participants).

Design: Economic analysis of observational study data and information from National Health Service (NHS) Greater Glasgow and Clyde smoking cessation services.[108]

Objectives: To estimate short-term cost-effectiveness (cost per quitter) among a sample of 1374 pharmacy and 411 group service participants.

Economic Outcomes: 4-week cost of £53.31 per patient and £772 among quitters for those receiving pharmacy-based care, versus £338.54 per patient and £1612 per successful quitter in the group program.

Scotland, England, and Wales – Medication Use Reviews[112]

Design: Telephone interview of 30 community pharmacists.

Objectives: To assess community pharmacists' experiences and opinions of medication review services in England, Wales and Scotland.

Uptake: One-third of interviewees reported currently providing medication review services.

Professional Outcomes/Satisfaction: Perception that providing medication reviews enhanced relationships between patients and their pharmacist, and improved the image of

the profession. Job satisfaction was also reported to be increased.

Barriers: Unnecessary bureaucracy, lack of sufficient privacy in the work environment, and an inappropriate link between medication reviews and remuneration rather than patient needs.

England and Northern Ireland – Pharmacy Minor Ailments Scheme[116,148-151]

Design: Analysis of claims data between August 2008 and January 2009.[116]

Objectives: To examine the uptake and cost of the minor ailments scheme in Cheshire.

Uptake: The Central and Eastern Cheshire Primary Care Trist (CECPT) provided 6,933 consultations across 92 pharmacies, and the Western Cheshire Primary Care Trust (WCPCT) provided 2,261 consultations across 29 pharmacies. 80% of service recipients said they would have visited a GP clinic if the minor ailments service were unavailable, and 15% said they would have self-selected a non-prescription product without advice.

Clinical Outcomes: 1% of CECPT and 0.7% of WCPCT consultations were referred to a physician.

Economic Outcomes: The average cost per consultation was less than £7, which is reported to compare favorably to the cost of general practitioner consultations (fees not provided).

Uptake: In June 2007, almost one-quarter of patients presenting to community pharmacies with minor ailments received treatment through the minor ailments service. In the Heart of Birmingham Primary Care Trust (PCT), the scheme is offered by 82 of 84 pharmacies and 140,000 consultations were conducted in 2007. By comparison, the Sheffield PCT has 101 of 114 pharmacies participating, with 38,000 consultations provided in 2007-2008.[148]

Patient Satisfaction: 9 out of 10 Heart of Birmingham PCT patients reported the scheme saved them a visit to the GP. In Sheffield PCT, 8 out of 10 patients reported they would have otherwise visited their GP if the service wasn't available, and patient and GP satisfaction with the service is high.

Design: Semi-structured interviews with 26 pharmacists within Nottingham City Primary Care Trust[149]

Objectives: To investigate pharmacists' perspectives about the acceptability of the scheme, barriers to the use of the scheme, and potential improvements.

Uptake: 6 respondents reported performing ≤200 consultations between December 2003 and September 2006, 9 reported performing 201-800 consultations, and 10 reported performing >800 consultations.

Professional Satisfaction: Most respondents reported that the scheme had not affected their relationships with physicians. Patient benefits such as improved access to medicines, greater choice of where to receive care, and convenience were cited.

Barriers: Patient restriction to accessing the service from the pharmacy where they first registered with the scheme, insufficient remuneration for the increased work involved, time consuming and overly bureaucratic paperwork, lack of privacy, formulary restrictions, the need to provide a specimen louse for head lice treatment according to protocol, insufficient publicity of the scheme to promote greater use, abuse and overuse of the scheme by patients to obtain free non-prescription drugs.

Design: A mixed-methods study was conducted, including semi-structured interviews with key stakeholders, a patient survey, and an analysis of the Nottingham City Primary Care Trust data.[150]

Objectives: To evaluate whether the scheme achieved its objectives in terms of

improving access to medicines and reducing doctor workload for minor ailments

Uptake: More than 40,000 consultations were carried out through the scheme during the first 3 years of the operation (December 2003–November 2006), with a steady increase in the volume of consultations over time.

Clinical Outcomes: Only a very small proportion of consultations (0.4%) were referred to GPs.

Patient Satisfaction: All parents interviewed who accessed the service for their child were satisfied with the scheme in terms of gaining access to the service, the medicine supplied and advice given as well as the conduct of providers. The convenience of the service was a benefit highlighted. Mean satisfaction scores for the 24 items of opinion ranged from 3.0 to 4.8 (where 1 indicated the most negative level of satisfaction and 5 indicated the most positive level of satisfaction). The highest satisfaction was reported for access/convenience and the lowest satisfaction for the physical environment.

Design: Prospective study[151]

Objectives: To assess the cost effectiveness of minor ailments schemes in 5 primary care organizations.

Uptake: 1044 patients attended pharmacies with a minor ailment over a 1-month period.

Economic Outcomes: The total cost of running the scheme for the 1044 patients was £4,100. Using standard general practitioner (£36 per consultation) and emergency department (£111) costs, it is estimated that the scheme saved £14,602 over one month.

Table A.1-9. Results of Included Studies on the Effect of P4P on Quality of Care for Chronic Conditions

Study, Year (Reference)	Outcome(s) Measured	Results*		
		Control	Intervention	Comparison
Randomized, controlled trial				
Twardella and Brenner, 2007 (19)	Proportion of patients smoke-free as validated by a negative blood cotinine level after 1 y	2.7%	3.5%	$P = 0.75$
Interrupted time series		**Pre-P4P**	**Post-P4P**	**ITS Analyses**
Campbell et al, 2009 (20)	Mean scores for processes of care quality indicators:			
	Coronary heart disease	Improved from 58.6% in 1998 to 76.2% in 2003	Improved to 85.0% in 2005 and 84.8% in 2007	$P = 0.06$ for greater than expected change in 2005 given secular trends before; $P = 0.02$ for less than expected improvement in 2005–2007 versus 1998–2003
	Asthma	Improved from 60.2% in 1998 to 70.3% in 2003	Improved to 84.3% in 2005 and 85.0% in 2007	$P = 0.001$ for greater than expected change in 2005 given secular trends before; $P = 0.16$ for less than expected improvement in 2005–2007 versus 1998–2003
	Diabetes	Improved from 61.6% in 1998 to 70.4% in 2003	Improved to 81.4% in 2005 and 83.7% in 2007	$P < 0.001$ for greater than expected change in 2005 given secular trends before; $P = 0.91$ for less than expected improvement in 2005–2007 versus 1998–2003
Serumaga et al, 2011 (21)	Proportion of patients with blood pressure controlled to ≤150/90 mm Hg	70%	67.3%	Level change: −1.19 (CI, −2.06 to 1.09) percentage points Trend change: −0.01 (CI, −0.06 to 0.03) percentage points
	Proportion of patients with blood pressure measured	47.7%	53.2%	Level change: 0.85 (CI, −3.04 to 4.74) percentage points Trend change: −0.01 (CI, −0.24 to 0.21) percentage points
	Proportion of patients who began receiving new drug treatment	0.05% per month	0.05% per month	Level change: 0.67 (CI, −2.37 to 3.81) percentage points Trend change: 0.02 (CI, −0.23 to 0.19) percentage points
	Occurrence of hypertension-related outcomes (myocardial infarction, stroke, heart failure, renal failure, death)	NR	NR	Level change: 0.07% (CI, −0.13 to 0.28) percentage points Trend change: 0.05% (CI, −0.02 to 0.07) percentage points
Vamos et al, 2011 (22)	Rate of improvement per year in achieving the following targets for diabetic patients:			
	Blood pressure	2.2% (CI, 1.9% to 2.6%)	3.8% (CI, 2.7% to 4.9%)	$P < 0.001$ for improvement after P4P
	Total cholesterol level ≤5 mmol/L (193.05 mg/dL)	4.9% (CI, 4.3% to 5.3%)	7.4% (CI, 6.0% to 8.8%)	$P < 0.05$ for improvement after P4P
	Hemoglobin A_{1c} value ≤7.0%	2.0% (CI, 1.3% to 2.7%)	−0.2% (−2.0% to 1.6%)	$P < 0.01$ for worsening after P4P
Alshamsan et al, 2012 (23)	Hemoglobin A_{1c}	NR	NR	Level change: 0.04 (CI, −0.04 to 0.12) percentage points Trend change: 0.19 (CI, 0.15 to 0.22) percentage points
	Total cholesterol	NR	NR	Level change: −0.12 (CI, −0.18 to −0.06) mmol/L Trend change: 0.03 (CI, 0.01 to 0.05) mmol/L
	Systolic blood pressure	NR	NR	Level change: −1.95 (CI, −2.87 to −1.02) mm Hg Trend change: −1.04 (CI, −1.42 to −0.64) mm Hg
MacBride-Stewart et al, 2008 (24)	Percentage increase in the defined daily dose prescribed per patient:			
	Drugs incentivized by the Quality and Outcomes Framework	1.3% (CI, 1.2% to 1.4%)	1.0% (CI, 0.9% to 1.1%)	$P < 0.001$ for less than expected change in prescribing between 2004–2006 versus 2002–2004, taking into account secular trends
	Drugs not incentivized by the Quality and Outcomes Framework	0.2% (CI, 0.2% to 0.3%)	0.3% (CI, 0.3% to 0.4%)	$P = 0.09$, meaning no significant difference in rate of change in prescribing for 2004–2006 versus 2002–2004

Continued on following page

Study, Year (Reference)	Outcome(s) Measured	Results*		
		Control	Intervention	Comparison
Controlled before–after study		**Pre-P4P**	**Post-P4P**	**Between-Group Difference**
Beaulieu and Horrigan, 2005 (25)	Performance of tests/examinations:			
	Hemoglobin A_{1c}	Intervention: 80.3% Control: 87.1%	Intervention: 83.4% Control: 86.5%	2.5 percentage points
	Lipid panel	Intervention: 68.5% Control: 88.8%	Intervention: 86.8% Control: 91.0%	16.1 percentage points
	Diabetic retinal examination	Intervention: 37.4% Control: 50.3%	Intervention: 63.0% Control: 51.5%	24.4 percentage points
	Nephropathy test	Intervention: 41.8% Control: 48.5%	Intervention: 78.8% Control: 51.6%	33.9 percentage points
	Outcome measures:			
	Hemoglobin A_{1c} value ≤9.5%	Intervention: 61.8% Control: 72.4%	Intervention: 75.6% Control: 74.2%	12.0 percentage points
	LDL cholesterol level ≤130 mg/dL (3.4 mmol/L)	Intervention: 46.0% Control: 60.4%	Intervention: 69.5% Control: 59.7%	24.2 percentage points
Uncontrolled before–after studies		**Pre-P4P**	**Post-P4P**	**Between-Group Difference**
Chung et al, 2003 (17)	Patients with heart failure prescribed ACE inhibitor or angiotensin-receptor blocker	40.8%	64.2%	$P < 0.001$
Coleman et al, 2007 (26)	Provision of brief smoking cessation advice to smokers			Rate ratio, 3.03 (CI, 2.98 to 3.09)
Doran et al, 2011 (27)	Percentage change in prescribing rates above projected trends:			
	For post-P4P year 2004–2005			Incentivized prescriptions: 4.3% (CI, 3.3% to 5.3%) Nonincentivized prescriptions: −0.9% (CI, −1.9% to 0.2%)
	For post-P4P year 2006–2007			Incentivized prescriptions: 2.9% (CI, 2.0% to 3.7%) Nonincentivized prescriptions: −1.7% (CI, −2.7% to −0.0%)
Greene et al, 2004 (28)	Number of exceptions (care decisions deviating from the recommended treatment algorithm) per 1000 episodes:			
	Of any type	326	261	$P < 0.005$
	For prescribing of less appropriate or ineffective antibiotics	199	136	$P < 0.005$
	For inappropriate radiologic studies	15	12	$P < 0.005$
Kiran et al, 2012 (29)	Proportion of diabetic patients receiving 1 retinal eye examination, 4 hemoglobin A_{1c} tests, and 2 cholesterol tests in the previous 2 y	38%	45%	Improvement in 2 y after P4P similar to improvement in 2 y before P4P (relative risk, 1.22 [CI, 1.21 to 1.23] versus 1.31 [CI, 1.30 to 1.32])
McGovern et al, 2008 (30)	Percentage of diabetic patients with hemoglobin A_{1c} ≤7.4%	45.0%	52.7%	$P < 0.05$
	Percentage of diabetic patients with blood pressure ≤145/85 mmHg	63.2%	69.5%	$P < 0.05$
	Percentage of diabetic patients with total cholesterol ≤5 mmol/L (193.05 mg/dL)	67.5%	66.2%	$P < 0.05$ (reduction)
McGovern et al, 2008 (31)	Proportion of patients with coronary heart disease with:			
	Smoking cessation advice (if smoker)	81.0%	96.2%	$P < 0.05$
	Blood pressure controlled to ≤150/90 mm Hg	79.3%	80.0%	$P < 0.05$
	Total cholesterol level ≤5 mmol/L (193.05 mg/dL)	86.3%	75.5%	$P < 0.05$ (reduction)
	Antiplatelet or anticoagulant therapy	65.8%	90.3%	$P < 0.05$
	β-blocker therapy	42.6%	70.0%	$P < 0.05$
	ACE inhibitor therapy	66.4%	77.9%	$P < 0.05$
	Influenza vaccination up to date	57.4%	85.5%	$P < 0.05$
Millett et al, 2007 (32)	Percentage of diabetic smokers given cessation advice	48.0%	83.5%	$P < 0.001$

Continued on following page

Study, Year (Reference)	Outcome(s) Measured	Results*		
		Control	Intervention	Comparison
Simpson et al, 2011 (33)	Change (2006 versus 2001) in proportion of patients:			
	Blood pressure ≤140/90 mm Hg			Difference, 18.9% (CI, 18.5% to 19.4%)
	With hypertension who were treated with at least 1 antihypertensive drug			Difference, 9.2% (CI, 9.0% to 9.5%)
Simpson et al, 2006 (34)	Percentage of stroke patients with:			
	Advice on smoking cessation (if smokers)	79.0%	95.9%	Difference, 17.0% (CI, 15.7% to 18.3%)
	Total cholesterol level controlled to ≤5 mmol/L (193.05 mg/dL)	65.8%	66.1%	Difference, 2.3% (CI, 0.6% to 2.3%)
	Blood pressure controlled to ≤150/90 mm Hg	75.2%	76.5%	Difference, 1.3% (CI, 0.4% to 2.2%)
	Antiplatelet or anticoagulant therapy	55.9%	88.2%	Difference, 32.3% (CI, 31.5% to 33.1%)
	Influenza vaccination	47.1%	81.3%	Difference, 34.2% (CI, 33.4% to 35.0%)
St. Jacques et al, 2004 (35)	Mean number of cases per physician delayed by inappropriately excessive anesthesiology procedure, induction, or emergence time	14.9 (SD, 2.9)	3.34 (SD, 1.0)	$P < 0.001$
Steel et al, 2007 (36)	Percentage of quality indicators achieved:			
	Asthma (incentivized)	59% (SD, 24%)	73% (SD, 23%)	$P < 0.001$
	Hypertension (incentivized)	58% (SD, 17%)	70% (SD, 16%)	$P < 0.001$
	Depression (nonincentivized)	37% (SD, 14%)	38% (SD, 14%)	$P = 0.22$
	Osteoarthritis (nonincentivized)	36% (SD, 19%)	38% (SD, 22%)	$P = 0.43$
Young et al, 2007 (37)	Difference in rate of change for adherence to targets of:			
	2 hemoglobin A_{1c} measurements per year	0.0176	0.0262	P = NS
	Annual LDL cholesterol measurement	0.0439	0.0472	P = NS
	Annual urinalysis/microalbumin measurement	0.0278	0.0105	P = NS
	Annual eye examination	0.0195	0.0713	$P < 0.001$
Regression analysis of administrative data		**Adjusted Odds Ratio (CI)†**		
Pourat et al, 2005 (38)	Association between reimbursement method and self-reported:			
	Screening sexually active females aged 15–19 y for chlamydia annually:			
	FFS	0.96 (0.58 to 1.59)		
	Capitation with P4P	1.32 (0.65 to 2.72)		
	Salary with P4P	1.45 (0.66 to 3.15)		
	Screening sexually active females aged 20–25 y for chlamydia annually			
	FFS	1.32 (0.55 to 3.15)		
	Capitation with P4P	0.87 (0.43 to 1.75)		
	Salary with P4P	1.37 (0.50 to 3.74)		
	Provide chlamydia drugs to affected patients for treatment of partner			
	FFS	0.59 (0.30 to 1.15)		
	Capitation with P4P	0.93 (0.49 to 1.77)		
	Salary with P4P	0.78 (0.51 to 1.20)		

ACE = angiotensin-converting enzyme; FFS = fee-for-service; ITS = interrupted time series; LDL = low-density lipoprotein; NR = not reported; NS = not significant; P4P = pay-for-performance.

* All CIs are 95% CIs.

† Adjusted for practice characteristics (practice setting, volume of Medicaid patients, number of Medicaid HMO contracts, number of medical group contracts with Medicaid business), individual physician characteristics (sex, specialty, years in practice), having sexually transmitted disease guidelines from the Centers for Disease Control and Prevention and U.S. Preventive Services Task Force, having ever received feedback on sexually transmitted disease screening from the contracted Medicaid HMO or medical group, and the type of contracted Medicaid managed care health plan.

Table A.1-10. Risk of Bias Summary, by Study

Study, Year (Reference)	Baseline Characteristics and/or Outcomes Similar?	Allocation Concealment?	Blinded Assessment of Primary Outcome?	Appropriate Follow-up of Patients and/or Professionals?	Complete Outcome Reporting?	Reliable Source of Primary Outcome Data?	Study Adequately Protected Against Contamination?
Randomized, controlled trials							
Fairbrother et al, 2001 (9)	Yes	Yes	NA	Yes	Yes	Yes	Yes
Kouides et al, 1998 (11)	Yes	NA	Yes	Yes	Yes	Yes	Yes
Grady et al, 1997 (12)	Yes	Unknown	No	Yes	Yes	Yes	Yes
Twardella and Brenner, 2007 (19)	Yes	NA	NA	Unknown	Unknown	Yes	No
Interrupted time series							
Campbell et al, 2009 (20)	Unknown	NA	No	Unknown	Yes	Unknown	Yes
Serumaga et al, 2011 (21)	Unknown	NA	NA	Unknown	Unknown	Yes	Unknown
Vamos et al, 2011 (22)	Unknown	NA	NA	NA	Yes	Yes	Yes
Alshamsan et al, 2012 (23)	Unknown	NA	NA	NA	Unknown	Yes	Yes
MacBride-Stewart et al, 2008 (24)	NA	NA	NA	Yes	Yes	Yes	Yes
Controlled before–after studies							
Rosenthal et al, 2005 (13)	Unknown	NA	Unknown	No	Yes	Yes	Yes
Fagan et al, 2010 (14)	No	NA	NA	Unknown	Unknown	Yes	Unknown
Beaulieu and Horrigan, 2005 (25)	Unknown	NA	NA	No	No	No	No
Nonrandomized, controlled study							
Gavagan et al, 2010 (15)	Unknown	NA	NA	Unknown	Yes	Yes	Yes
Uncontrolled before–after studies							
Morrow et al, 1995 (16)	Yes	NA	NA	Unknown	Yes	Yes	Unknown
Chung et al, 2003 (17)	Unknown	NA	NA	Unknown	No	Yes	Unknown
Armour et al, 2004 (11)	No	NA	NA	No	Yes	Yes	No
Coleman et al, 2007 (26)	NA	NA	NA	Unknown	Yes	Unknown	Yes
Doran et al, 2011 (27)	Unknown	NA	NA	Unknown	No	Yes	No
Greene et al, 2004 (28)	NA	NA	NA	Yes	Yes	Yes	No
Kiran et al, 2012 (29)	Yes	NA	NA	Unknown	Yes	Yes	Yes
McGovern et al, 2008 (30)	NA	NA	NA	Yes	Yes	Yes	Unknown
McGovern et al, 2008 (31)	NA	NA	NA	Unknown	Unknown	Unknown	Yes
Millett et al, 2007 (32)	NA	NA	NA	Yes	Yes	Unknown	Yes
Simpson et al, 2011 (33)	NA	NA	NA	Unknown	Yes	Yes	No
Simpson et al, 2006 (34)	NA	NA	NA	Yes	Yes	Unknown	Yes
St Jacques et al, 2004 (35)	Yes	NA	NA	Yes	Yes	Unknown	Unknown
Steel et al, 2007 (36)	No	No	No	Unknown	Unknown	Unknown	Unknown
Young et al, 2007 (37)	NA	NA	NA	Yes	Unknown	Unknown	Yes
Nonrandomized, uncontrolled studies							
Ettner et al, 2006 (18)	Unknown	Unknown	Yes	Yes	No	Unknown	Yes
Pourat et al, 2005 (38)	Unknown	NA	Unknown	Unknown	No	No	No

NA = not applicable.

Table A.1-11. Results of Included Studies on the Effect of P4P on Preventive Care or Screening

Study, Year (Reference)	Outcome(s) Measured	Results*		
		Control	Intervention	Comparison
Randomized, controlled trials				
Fairbrother et al, 2001 (9)	Change in percentage of children receiving recommended vaccinations over 1 y	−2.5 percentage points	5.9 percentage points	$P < 0.05$
Kouides et al, 1998 (10)	Change in mean influenza immunization rates over 1 y	2.5 percentage points	10.3 percentage points	$P = 0.03$
Grady et al, 1997 (12)	Change in mean rate (per practice, over 1 y) of:			
	Mammography referral	25.0 percentage points	26.0 percentage points	$P = 0.46$
	Mammography completion	30.2 percentage points	28.2 percentage points	$P = 0.14$
Nonrandomized, controlled study		**Control**	**Intervention**	**Interaction Term Comparing Trends**
Gavagan et al, 2010 (15)	6-y linear trend models for achievement of performance thresholds for:			
	Papanicolaou smears	Slope, −0.004	Slope, 0.005	$P = 0.053$
	Mammography	Slope, 0.0015	Slope, 0.003	$P = 0.076$
Controlled before–after studies		**Pre-P4P**	**Post-P4P**	**Between-Group Difference†**
Rosenthal et al, 2005 (13)	Cervical cancer screening	Intervention: 39.2% Control: 55.4%	Intervention: 44.5% Control: 57.1%	3.6 ± 1.8 percentage points ($P = 0.02$)
	Mammography	Intervention: 66.1% Control: 72.4%	Intervention: 68.0% Control: 72.6%	1.7 ± 1.5 percentage points ($P = 0.13$)
	Hemoglobin A_{1c} testing	Intervention: 62.0% Control: 80.0%	Intervention: 64.1% Control: 82.1%	0.0 ± 3.5 percentage points ($P = 0.50$)
Fagan et al, 2010 (14)	Influenza vaccination	NR	NR	OR, 1.79 (CI, 1.37–2.35)
	Hemoglobin A_{1c} testing	NR	NR	OR, 0.44 (CI, 0.30–0.65)
	LDL cholesterol screening	NR	NR	OR, 0.62 (CI, 0.44–0.86)
	Retinopathy screening	NR	NR	OR, 0.98 (CI, 0.61–1.58)
	Nephropathy screening	NR	NR	OR, 0.95 (CI, 0.62–1.46)
Uncontrolled before–after studies		**Pre-P4P**	**Post-P4P**	**Between-Group Difference**
Morrow et al, 1995 (16)	Measles/mumps/rubella immunization in children	78.1% (CI, 73.9%–82.1%)	95.6% (CI, 93.5%–97.7%)	$P < 0.001$
	Cholesterol screening in adults	91.9% (CI, 87.8%–94.4%)	95.4% (CI, 91.7%–97.4%)	$P < 0.001$
Chung et al, 2003 (17)	Patients with diabetes receiving hemoglobin A_{1c} test annually	51.5%	79.6%	$P < 0.001$
	Children receiving measles/mumps/rubella vaccine	83.2%	87.3% (year 2); 81.8% (year 3)	$P = 0.061$ (year 2); $P < 0.001$ (year 3)
Armour et al, 2004 (11)	Colorectal cancer screening	23.4%	26.4%	$P < 0.01$
Multivariate analysis of cohort study		**Adjusted Relative Risk (CI)‡**		
Ettner et al, 2006 (18)	Proportion of patients receiving the following when P4P bonuses were based on quality or patient satisfaction scores:			
	Hemoglobin A_{1c}	0.99 (0.90–1.11)		
	Proteinuria assessment	0.86 (0.71–1.13)		
	Lipid panel assessment	1.05 (0.90–1.25)		
	Dilated eye examination	1.00 (0.89–1.14)		
	Foot examination	1.02 (0.91–1.18)		
	Advice to take daily aspirin	1.19 (0.99–1.48)		
	Influenza immunization	1.06 (0.90–1.29)		
	Proportion of patients receiving the following when P4P bonuses were based on patients' outpatient utilization or care costs:			
	Hemoglobin A_{1c}	0.99 (0.88–1.05)		
	Proteinuria assessment	1.13 (1.03–1.24)		
	Lipid panel assessment	1.01 (0.87–1.11)		
	Dilated eye examination	1.02 (0.93–1.09)		
	Foot examination	1.01 (0.88–1.08)		
	Advice to take daily aspirin	0.87 (0.71–1.04)		
	Influenza immunization	1.02 (0.89–1.14)		

LDL = low-density lipoprotein; NR = not reported; OR = odds ratio; P4P = pay-for-performance.
* All CIs are 95% CIs.
† Values expressed with a plus/minus sign are SEs.
‡ Adjusted for sociodemographic (age, sex, ethnicity, education, household income, source of insurance) and clinical (type of diabetes treatment [insulin, oral agents, diet only], years since diabetes diagnosis, Charlson comorbidity index, and Short-Form-12 physical and mental component summary score) characteristics of patient population.

APPENDIX 2. Abstract – A randomized trial of the effect of pharmacist prescribing on improving blood pressure in the community: the Alberta clinical trial in optimizing hypertension (RxACTION) study

Background: Hypertension is a leading contributor to cardiovascular disease and premature death, and blood pressure control rates remain suboptimal. In Alberta, Canada, pharmacists may receive authorization to prescribe drugs including those for hypertension and other chronic diseases. This study, the first randomized controlled trial of pharmacist prescribing, aimed to determine the effectiveness of pharmacist care for improving blood pressure (BP) in patients with uncontrolled hypertension in the community.

Methods: We performed a randomized controlled trial in 22 communities in Alberta, utilizing pharmacists with the authorization to prescribe and practice in community, hospital, and primary care clinic settings. Patients were eligible for the study if they had above-target BP across multiple measurements. Intervention consisted of a pharmacist assessment, wallet card of BP measurements, written and verbal education on hypertension, pharmacist prescribing of antihypertensive drugs and laboratory monitoring, and follow-up visits monthly. Patients achieving BP control across 2 consecutive visits were able to drop down to 3 month follow-up intervals. Control group patients received a wallet card for BP recording, written hypertension information, and usual care from their physician. The primary outcome was the difference in change in systolic BP between the intervention and control groups at 6 months.

Results: A total of 248 patients were randomized to intervention and control arms between September 2009, and May 2013. The mean (SD) patient age was 63.5 (12.7) years, 48.8% were male, and the mean (SD) baseline systolic/diastolic BP was 149.7(13.6)/83.4(11.5) mm Hg at baseline. The intervention group had an adjusted mean (SE) reduction in systolic BP at 6 months of 18.0 (1.4) mm Hg compared with 11.0 (2.1) mm Hg in the control group (p=0.005).

Conclusion: Pharmacist prescribing for patients with uncontrolled hypertension resulted in a statistically and clinically significant reduction in systolic blood pressure when added to usual care practice.