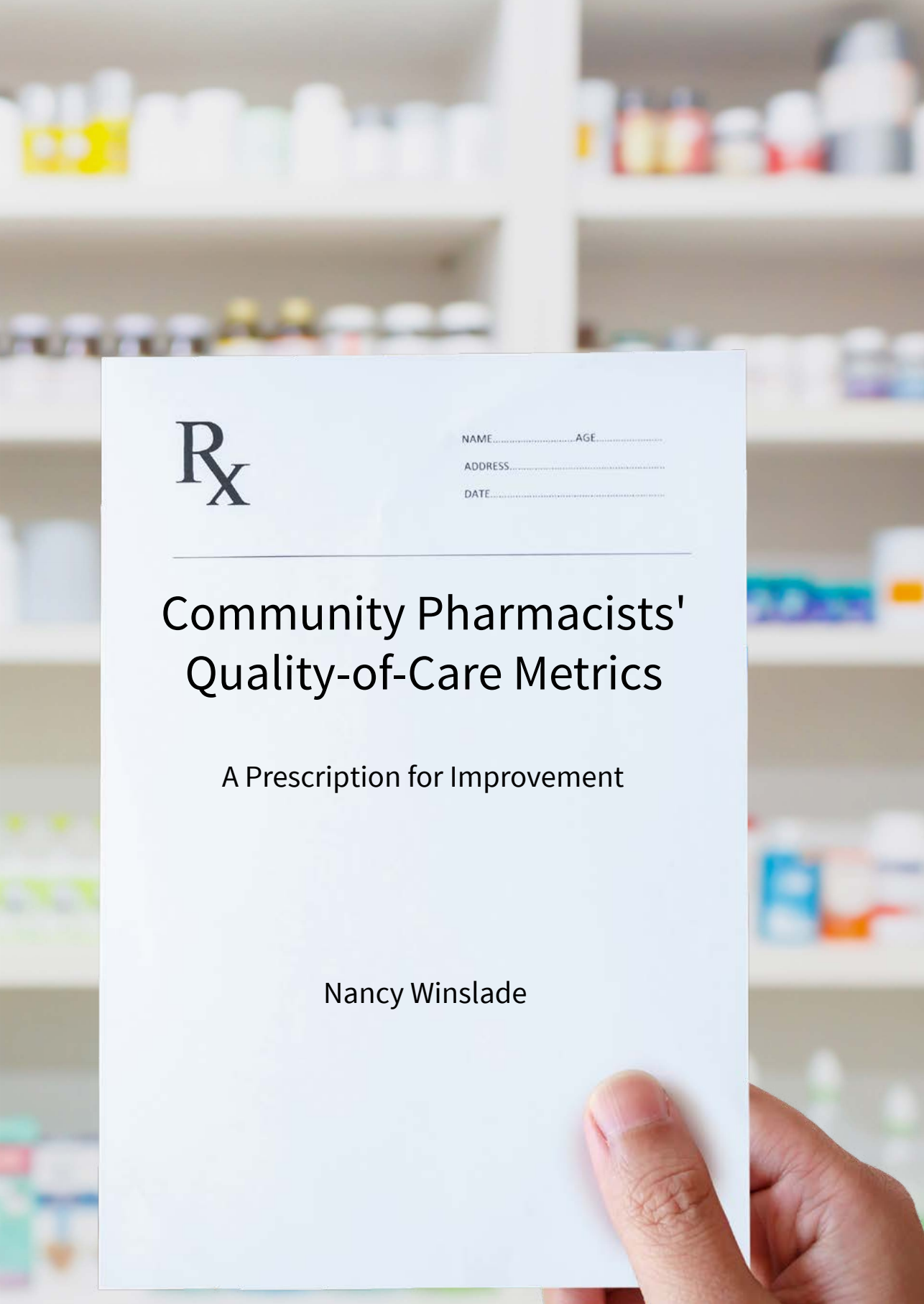
Community Pharmacists' Quality-of-care Metrics



Community Pharmacists' Quality-of-Care Metrics

A Prescription for Improvement

Nancy Winslade

The research reported in this dissertation was carried out at

Maastricht University

in the School of Health Professions Education

School of Health Professions Education

in the context of the Clinical and Health Informatics Research Unit, Faculty of Medicine, McGill University, Montreal, Quebec, Canada

McGill

with funding for the randomized controlled trial and analysis of quality determinants from the Quebec Order of Pharmacists and Green Shield Foundation of Canada.

ORDRE DES PHARMACIENS DU QUÉBEC

gsc green shield canada FOUNDATION

ISBN: 978-94-6380-015-0

Layout: Datawyse
Cover illustrations Shutterstock
Printed by Datawyse | Universitaire Pers Maastricht

UNIVERSITAIRE PERS MAASTRICHT

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DISSERTATION

to obtain the degree of Doctor at the Maastricht University,
on the authority of the Rector Magnificus,
Prof. dr. Rianne M. Letschert
in accordance with the decision of the Board of Deans,
to be defended in public
on Tuesday 23rd October 2018, at 10:00 hours

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Confucius said that wisdom, compassion, and courage are the three universally recognized moral qualities of (wo)men. I am fortunate to have been surrounded by wise, compassionate, courageous women and men throughout the completion of my dissertation. My supervisors added patience to these qualities, while Nuria and Alida (my children) and Brian (my partner) taught me the power of believing and the impact of happiness. I am grateful to you all.

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Chapter 1

Introduction

Introduction

Among patients with chronic illness, approximately 50% do not take their medications as prescribed.

World Health Organization 2003 (1)

Preventable medication-related adverse events account for 4% of hospitalizations.

Howard et al, British Journal of Clinical Pharmacology 2006 (2)

The pharmacist is responsible for optimal drug therapy outcomes for Canadians through patient-centred care.

Vision for Pharmacy,
Canadian Pharmacist Association,
Blueprint for Change 2008 (3)

Background

Problems with drug therapy remain a common source of preventable morbidity and health-related cost in most developed countries (4- 10). Community pharmacists are easily-accessed healthcare professionals, educated in the rational use of medications whose role has transitioned over the decades. In the 1950s, the growth of medication-production by the pharmaceutical industry led pharmacists to shift from a role of medication preparation towards a role focused on ensuring the quality of medications supplied to individual patients. Although hospital pharmacists expanded their role to include clinical pharmacy, into the 1990s community pharmacists remained focused on quality medication supply. In 1989, Hepler and Strand's seminal paper on pharmaceutical care proposed that pharmacists refocus their practice on providing the care required by patients to minimize their preventable drug-related morbidity and mortality (11). Pharmaceutical care proposed pharmacists moving from ensuring safe and effective supply of medications (by ensuring the 5 Rs, the Right drug, at the Right dose, in the Right format, at the Right time to the Right patient), towards ensuring safe and effective use of medications by patients. The 5 Rs were replaced by seven categories of drug-related problems (DRP) defining undesirable signs or symptoms experienced by patients that are due to patients:

1. taking a drug they did not need to be taking,
2. not taking a drug that they should be taking,
3. taking the wrong drug because an alternative drug would be better for them,
4. taking too little of a drug,
5. taking too much of a drug,
6. suffering adverse effects from a drug, or
7. not taking the drug as prescribed (12).

The pharmacists' responsibility in pharmaceutical care, regardless of their practice site, was to provide the care necessary to identify and resolve patient's DRP. Although there was significant overlap between Hepler and Strand's DRPs and the 5 Rs, pharmaceutical care's focus on the patient and his/her overall medication-related needs added the responsibilities of identifying unneeded medications, identifying additional needed medications and monitoring the patient to ensure that his/her medications were achieving the desired effects. Pharmaceutical care also offered a clear vision of the pharmacists' role and a structured approach and language for fulfilling, documenting, and, perhaps most importantly, communicating this role (11). For patients, the role was easily described as the pharmacist working with them and their health care providers to ensure that none of their preventable health problems were related to their medications.

Worldwide, pharmaceutical care was rapidly adopted as the ideal practice philosophy for the profession of pharmacy (13). Across North America, hospital pharmacists were the most common early adopters of pharmaceutical care. In Canada, transition to the community occurred initially through pharmacists' clinics at community health centres (14) and subsequently through Family Health Team Pharmacists (15). Occasional community pharmacists also tried to expand their practice (16) but, despite nearly two decades of focus on transitioning community pharmacy practice towards pharmaceutical care, there has been little success (17-19).

Initially it was rationalized that practice change could not occur because pharmacists were not educated or competent to provide pharmaceutical care. In response, in the 1990s emphasis was placed on revising the undergraduate/baccalaureate pharmacy programs (20). In Canada, clinical reasoning processes were defined to guide pharmacists' identification of patient's DRP and served as the basis for revision in pharmacy pharmacotherapeutics curricula (21-23). The educational outcomes required of graduates were also revised to focus on the provision of pharmaceutical care and these outcomes were incorporated into the accreditation requirements for pharmacy curricula across Canada (24). Post-baccalaureate Doctor of Pharmacy (PharmD) programs were also introduced in Canada in the early 1990s. The University of Toronto program specifically admitted practicing community pharmacists with the goal of educating leaders in transitioning community pharmacy practice towards the provision of pharmaceutical care (25). Entry-to-practice competencies for pharmacists were updated by the National Association of Pharmacy Regulatory Authorities (NAPRA) and the Pharmacy Examining Board of Canada's qualification exams reformatted using these competencies as the exam blueprint (26, 27).

Despite these early transformations, practice change remained limited as a range of barriers were identified that prevented community pharmacists from altering their practice on a consistent, long term basis (28, 29). Focus, therefore, shifted from pharmacy students to supporting practicing pharmacists. NAPRA introduced their *National Model Continuing Competence Program for Canadian Pharmacists* (30, 31). This program was designed to ensure that practicing pharmacists acquired and maintained

their ability to provide pharmaceutical care as defined in NAPRA's pharmacists' competencies. Originally based on a self-assessment of competence this model was revised in 2002, removing reliance on self-assessment and proposing a sequential performance assessment program (32, 33). An initial screen was proposed that used administrative health data (e.g. community pharmacy billing data for dispensed medications and pharmacists' professional services) to evaluate pharmacists' performance in daily practice. The revised continuing competency framework acknowledged that substantial research was necessary to determine the assessment formats and tools most appropriate for evaluating community pharmacists' quality of care via practice performance (34). Research was also needed to determine the barriers / facilitators affecting competent pharmacists' abilities to provide quality care in daily practice. The revised program also focused on maintenance of competence as consistent with the mandate of the regulatory authorities. Although less desirable philosophically than a program combining continuing competence (CC) and continuing professional development (CPD), at that time no evidence of successful, functioning joint CC / CPD programs could be located. Recommendations, however, encouraged the development and evaluation of models that both supported CDP and ensured CC. The revised CC framework was also constrained by the regulatory authorities' perspective that they should evaluate only the performance of individual pharmacists. This perspective did not include evaluation of the performance of a practice where a number of pharmacists and support staff functioned as a team to provide care. The lack of consideration of the impact of factors beyond the individual pharmacist emphasized the then dominant theory that it was primarily the individual pharmacist's competence that drove performance in practice. However, literature emerging from physician assessment was identifying the practice and system-based determinants of physician practice performance – a concept equally applicable to community pharmacists' performance assessment (35, 36).

Research Questions

The challenges faced by NAPRA in developing a national CC / CPD framework served as the starting point for this thesis. The over-arching goal was to support community pharmacists' integration of caring practices that effectively improved patients' use of medications, principally focusing on pharmaceutical-care practices as defined at the University of Toronto Faculty of Pharmacy (21). Provincial pharmacy regulatory authorities were already concentrating on supporting practice change with interest in the use of administrative health data to assess the performance of community pharmacists within the context of CC/CDP programs. These stakeholders, therefore, were considered the partners who could most effectively translate research findings into practice. Based on this interest, the following over-riding research question was developed for this thesis:

Within the context of an integrated CC/CPD program, how would the use of routinely collected administrative health data for performance measurement contribute to the improvement in quality of care by community pharmacists?

Four more detailed research questions were defined to investigate this over-riding question:

1. Research Question 1 focused on the challenge of developing an integrated CC / CPD model:

   Is there sufficient evidence from the health professions' literature to create a theoretical model of an integrated CC/CDP program that is based on using administrative health data to assess community pharmacists' quality of care?

2. Research Question 2 further investigated the use of database derived performance indicators as metrics of community pharmacists' quality of care:

   Is it feasible for pharmacy regulatory authorities to use administrative health / pharmacy claims data to evaluate community pharmacists' performance as a screening measure within a CC/CPD program?

3. Research Question 3 focused on the audit and feedback of performance on quality-of-care indicators:

   Does the provision of individualized, comparative practice-performance feedback on community pharmacists' quality-of-care metrics increase community pharmacists' provision of patient-oriented services and improve patient's use of medications?

4. Research Question 4 identified the structures/inputs important to the provision of quality pharmacist care:

   Can linked administrative health data be used to determine the dispensing, patient and pharmacy-level characteristics that are consistently associated with higher quality of pharmacists' care across pharmacies in Quebec?

Overview of Studies

Chapter 2 addresses the first research question, reviewing the literature and proposing an evidence-based CC / CPD model that is performance-based, applies to all community pharmacists, recognizes the powerful influence of external factors on an individual

pharmacist's ability to perform to his/her highest level of capability, incorporates the team-based nature of care provision at community pharmacies and is effectively integrated with CPD (37). Use of community pharmacy claims databases is the starting point for the model, serving to identify pharmacies underperforming on a number of pharmacists' quality-of-care metrics.

Chapter 3 translates the results of the first research question into practice, demonstrating how the integrated CC/CPD model supports pharmacy practice change (38). This paper was completed in collaboration with a community pharmacy leader knowledgeable in both the realities of daily community pharmacy practice and the market conditions under which pharmacy is practiced in Canada. The framework of barriers and facilitators published in the integrated CC/CDP program (37) was used to analyze the processes followed by this pharmacist when developing, implementing, sustaining and growing the pharmacy's travel health services.

Chapter 4 addresses the second research question, assessing the feasibility of pharmacy regulatory authorities using pharmacy claims / administrative health data as a starting point for screening pharmacists' quality of care through performance assessment. We used the Canadian province of Quebec's public insurance system health administrative data (RAMQ) for pharmaceuticals and pharmacists' service to calculate pharmacy-specific performance on four quality-of-care indicators and determined whether results met requirements for use for high-stakes decisions by regulatory authorities (39, 40). Results indicated that it is feasible to use routinely collected pharmacy claims data to evaluate the quality of care provided in community pharmacies. Further, this methodology is useful both in identifying underperforming pharmacy-teams and measuring the impact of policy changes that enable an expanded scope of pharmacists' practice through provision and funding of new pharmacists' services.

Chapter 5 evaluates the third research question, addressing the potential for using audit and feedback of performance on quality-of-care indicators to improve pharmacists' performance (41). As pharmacists are directly responsible for evaluating prescriptions for appropriateness of the medication therapy prescribed and working with patients to ensure their appropriate use of medications, pharmacists are increasingly being reimbursed separately from the dispensing fee to provide these services (42). Like many other provinces currently, Quebec pharmacists are authorized to bill for recommendations to physicians regarding patient non-adherence or for refusing to dispense a medication for safety or effectiveness reasons. Unlike other provinces, however, in Quebec billings are coded by the drug class and specify the DRP the pharmacists' professional service is addressing. Fundamentally all community pharmacies in Quebec were randomized sequentially to 'control' or 'receipt of relative performance feedback' on two indicators measuring dispensings to patients who were nonadherent to their chronic medications for hypertension or asthma. Using relatively

real-time access to Quebec's RAMQ pharmacy administrative health data, the impact of performance feedback was measured on both pharmacists' provision of pharmaceutical opinions to improve patient's adherence and on the changes in nonadherence (i.e. the outcome defined for provision of these pharmaceutical opinions).

Results confirmed that community pharmacists' billing data are useful to evaluate both the provision and impact of billable pharmacists' services on appropriate patient use of medications. However, pharmacists' provision of the targeted service was ineffective at improving patients' adherence. It was hypothesized that the format and requirements of the pharmacists' services required redesign to increase the effectiveness of the service on appropriate patient use of medications.

Chapter 6 addresses the fourth research question, making use of the data from the feedback study to evaluate the structures/inputs important to the provision of quality pharmacists' care (43). The analysis used the administrative billing data for community pharmacists' dispensings and provision of services, linked to additional RAMQ databases containing patient and pharmacy information, to directly measure the dispensing, patient and pharmacy characteristics for each dispensing of an antihypertensive medication. Each dispensing was classified as adherent or non-adherent based on whether the patient had received more than 80% of the prescribed antihypertensive therapy within the previous three months. Results validated the use of the methodology to determine known characteristics associated with nonadherence with antihypertensive medications including male sex, decreasing age, new to treatment, multiple prescribers and multiple dispensing pharmacies. Results also confirmed the findings from the audit and feedback study that pharmacists' services targeting antihypertensive nonadherence were not associated with patients' adherence. However, pharmacy-teams providing more total professional services and those with better continuity of care had higher quality-of-care results, and there was a trend for higher quality of care in pharmacies with higher overlap of pharmacists.

Chapter 7 integrates the results of the five research papers and compares them with current best practices in measurement of healthcare professionals' quality of care and ongoing work in pharmacists' quality-of-care metrics.

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Chapter 2

Integrating Performance Assessment, Maintenance of Competence, and Continuing Professional Development of Community Pharmacists.

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American Journal of Pharmaceutical Education, 2007;71(1)
Footnotes updating information added

Introduction

The self-regulating health professions in Canada are mandated to ensure that licensed practitioners provide safe and effective care. To fulfill this mandate, regulatory authorities have been established within the provinces, with coordination of policies at the national level. For the profession of pharmacy, the provincial organizations are known as the Colleges of Pharmacists while the national organization is the National Association of Pharmacy Regulatory Authorities (NAPRA). This situation in Canada is similar to that in many westernized countries, including the United States, where there are State Boards of Pharmacy and the National Association of Boards of Pharmacy. Other countries have more centralized regulatory authorities such as the Royal Pharmaceutical Society of Great Britain.

Historically, health professions regulatory authorities focused on fulfilling their public protection mandate by ensuring that health care professionals were competent at the time of entry to practice. For Canadian pharmacists, the requirements for licensure include the need for candidates to have graduated from a pharmacy program accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP) (1), passed the Pharmacy Examining Board of Canada's (PEBC) Qualifying Examinations (2) and a Jurisprudence Examination, and completed a NAPRA-approved structured internship (3)*. Substantial effort and resources continue to be dedicated to ensuring that these requirements remain current and effective. This has resulted in modifications in the CCAPP accreditation criteria to include pharmaceutical care-based educational outcomes and teaching strategies that encourage lifelong learning (1) while the PEBC has expanded beyond written assessments to include competency-based objective structured clinical examinations (OSCE) (2).

In parallel to these enhancements in entry-to-practice requirements, regulatory authorities also developed systems to ensure the continuing provision of safe and effective care by practitioners. Initially such programs were limited to investigating and managing patient complaints against members. As the discovery of health-related information grew, however, new methods were needed to ensure that practitioners' knowledge was continuously updated and incorporated into practice. Continuing education (CE) was introduced to address this need, with a range of professions in multiple countries introducing mandatory CE as a requirement to maintain licensure or certification (4-6). The goal of mandatory CE was to assure the public of the continuing quality of care provided by practitioners (7). As experience was gained with mandatory CE, however, research evidence documented that mandatory CE was ineffective at influencing practice performance (8, 9). This led the professions, including pharmacy, to pose questions such as: "Is a better system possible? Could a different model produce

* NAPRA licensure requirements in 2018 include completion of a structured practical training program rather than an internship and adds a language requirement.

the desired, or better, outcomes? How, and by whom, can professional competence be assured?" (10). The purpose of this article is to present a new model for assurance of continuing competency of practicing pharmacists and to describe the research needed to validate this model.

One approach that has been suggested as a better method of ensuring maintenance of competence relative to mandatory CE is continuing professional development (CPD) (10, 11). Many international, national, and provincial pharmacy organizations, including several Canadian Colleges of Pharmacists, have supported CPD programs for this purpose (12-15). Rouse defines CPD for pharmacists as "an ongoing, self-directed, structured, outcomes focused cycle of learning and personal improvement" (16). The International Federation of Pharmacy (FIP) directly linked CPD to maintenance of competence in their 2002 statement that CPD is "the responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional, throughout their careers" (13). A fundamental aspect of CPD is that it is self-directed, with 2 steps in the traditional CPD cycle involving self-assessment and development of self-directed learning plans to redress learning needs. Many authors acknowledge the challenges practitioners face in these self-directed tasks. Rouse recognizes that pharmacists will require third-party assistance for both self-assessment and self-directed learning within the CPD cycle (16). National and provincial pharmacy organizations have responded to this need by developing self-assessment programs that pharmacists can use to identify learning needs for CPD (14, 15). Critics of CPD, however, point to increasing evidence that practitioners continue to have limited ability to accurately identify and rectify practice deficiencies (17-19). Norman, in writing about CPD-based continuing competency programs in medicine in Canada, also emphasizes the lack of evidence that self-directed CPD is effective at ensuring maintenance of competence or improving practice performance (18). His conclusion is that, until such evidence exists, maintenance of competence programs must include a component of external judgmental assessment. The Citizen's Advocacy Coalition draws similar conclusions in their report on Maintaining and Improving Health Professional Competence (4). They comment that, although self-assessment is likely to predominate in nascent continuing competency programs, the goal is to move to independent, third-party assessment over a period of time. The American Institute of Medicine's report on Health Professions Education is even stronger in its recommendations, calling for legislation obliging all health professions boards to require their members to periodically demonstrate continued competency, and recommending that the boards move towards requiring rigorous tests for this purpose (20).

In Canada such legislative changes began as early as 1991, when new health professions legislation in the province of Ontario required the regulatory authorities for all health professions to develop programs to assure the quality of practice of its members and to promote continuing competence (21). The Ontario College of Pharmacists responded by developing a peer review-based continuing professional

development program that includes a mandatory third-party assessment of both knowledge and practice competence (14). As early as 1977, the College of Pharmacists of British Columbia also contained a third-party assessment in its original competency assessment program (5). The current program at the College of Pharmacists of British Columbia (15) and the program for pharmacists in the province of Alberta (22) continue to include third-party assessments ranging from written examinations to on-site assessments. In 1999, NAPRA's Model Continuing Competence Program Framework for Canadian Pharmacists incorporated the need for third-party assessments (23). Two of the principles of this national program were that, in order to fulfill the public protection mandate of the provincial Colleges of Pharmacists, a continuing competency program must:

1. include an assessment component that judges whether individual pharmacists have maintained their competence to practice, and;
2. assess all practicing pharmacists on a regular, cyclical basis.

The NAPRA model also identified a number of assessment formats that could be used within a continuing competency assessment program, but acknowledged that research was needed to determine the most appropriate structure and assessment formats.

NAPRA's recommendations recognized that in pharmacy, as well as other health professions, the design of third-party assessments of practicing professionals has been challenging and implementation attempts have been met with substantial resistance by practitioners (24-27). Part of this resistance is because the external assessments used for practicing professionals often focus on practitioner's competence rather than their performance (27, 28). There is a critical difference between these 2 concepts: competence is defined as what health professionals are able to do in artificial, testing situations; performance is defined as what health professionals do during daily practice (29-32). These differences are important for development of assessment programs for practicing professionals for two reasons. First, the primary purpose of assessment of practicing professionals is to ensure the continuing quality of their practice. Therefore, these assessments should focus on practitioners' daily performance, rather than their underlying competence (32, 33). This differs from the situation at entry-to-practice, where it is not possible to assess candidate's daily performance. This is because, prior to licensure, candidates cannot perform their responsibilities independently on a day-to-day basis. Only after they receive initial licensure can they begin independent practice and perform their daily activities. Entry-to-practice assessments, therefore, require the use of competency-assessment methods in testing environments that function as surrogate measures and predictors of performance in "real life" practice. These surrogate measures include written assessments of candidates' knowledge or ability to apply their knowledge, their ability to demonstrate skills in simulated environments, and their competency at providing integrated care to standardized patients (such as via OSCEs) (34-41). This situation differs from that which has been traditionally termed continuing

competency assessment in which the focus is on assessing **practicing** health care professionals. Despite the term, the focus of continuing competency assessment is not competence but performance. In this situation, assessment of daily performance is possible and does not require the reliance on surrogate, competency-based assessments. These performance-based assessments have traditionally included practice audits, on-site assessments, evaluation of videotaped patient encounters, and the introduction of simulated patients into practice settings. If practitioners are to be assessed on a periodic basis, then such performance-based assessment formats allow them to be evaluated on their ability to put knowledge into practice, and are perceived as inherently more acceptable to practitioners (42).

Balanced with this preference toward performance assessment rather than competence assessment is a second issue that differentiates these concepts: the recognition that practice performance is influenced by more than simply the competence of health professionals. Although it is readily acknowledged that competence is a prerequisite to good performance, recent literature has documented additional determinants of the performance of health professionals (29-44). Issues such as facilities and access to equipment, practice organization, government programs and initiatives, patient expectations, and policies developed by the practice facility have all been identified as determinants of the quality of performance of family physicians (30, 45-47). Therefore, although the goal of third-party assessments of practicing health care professionals should be to evaluate the daily performance of practitioners, these assessment programs must also differentiate among the determinants of practice performance. Farmer applies these principles in his theoretical model of performance assessment for practicing doctors, recognizing that poor performance may arise from three areas: the health care professional; the team/practice in which the health care professional works; or the overall health care system in which the health care professional practices (44). Farmer provides only general statements about the types of performance-based assessments that could be used to differentiate these determinants of practice. Therefore, the initial challenge is to identify performance-based assessments that are feasible for assessment of practicing health care professionals on a regular basis and that can be structured into an assessment program that identifies external influences on pharmacists' performance that are important determinants of practice quality.

The second challenge is to incorporate these performance-based assessments into a CPD framework, a task not undertaken in the programs described by NAPRA (23), Rethans (30) or Farmer (44). Within a CDP framework, results of performance-based, third-party assessments could serve as a valid starting point for individual reflection-on-practice, followed by identification of specific learning needs. The following model addresses these two challenges by integrating 21st century performance assessment techniques with continuing professional development for community pharmacists.

Framework for Professional Practice Assessment

Figure 1 incorporates the principles of performance-based assessment, application to all practicing community pharmacists on a regular basis, differentiation of competence and performance, and acknowledgement of the team-based nature of care, all integrated into a CPD-based framework. The model assessment program begins with a third-party auditing and assessment of care and services provided in community pharmacies. Data obtained from this audit would identify pharmacies with high, acceptable, and below standard levels of performance (Figure 1, A). Staff at high and acceptable performing pharmacies would require no further mandatory third-party performance-based assessment until the subsequent assessment cycle was initiated. Pharmacists employed at these pharmacies would enter a CPD cycle (Figure 1, B and C). Performance-based feedback would be provided to these pharmacists to support further enhancement of their performance or to re-align areas of below-average performance. Staff at higher performing pharmacies would also be requested to undergo on-site assessments to establish determinants of quality performance and benchmarks for these determinants. These benchmarks would inform the diagnostic assessments required at pharmacies with lower than acceptable performance (Figure 1, D). This diagnostic assessment would determine if the measured performance level was related to the pharmacists' competence and/or to external determinants. This in turn would allow the development of specific strategies to resolve the performance problems. These include strategies aimed at remediation for target pharmacists (Figure 1, E), those addressing pharmacy-specific factors such as management systems or inappropriate resource allocation (Figure 1, F), and those focusing on global barriers such as limitations in scope of practice, reimbursement procedures, or patient resistance to pharmacists' provision of specific services (Figure 1, G) (48-50). The cycle would be complete when the outcome of these strategies is evaluated as pharmacists re-enter the screening phase of the assessment program.

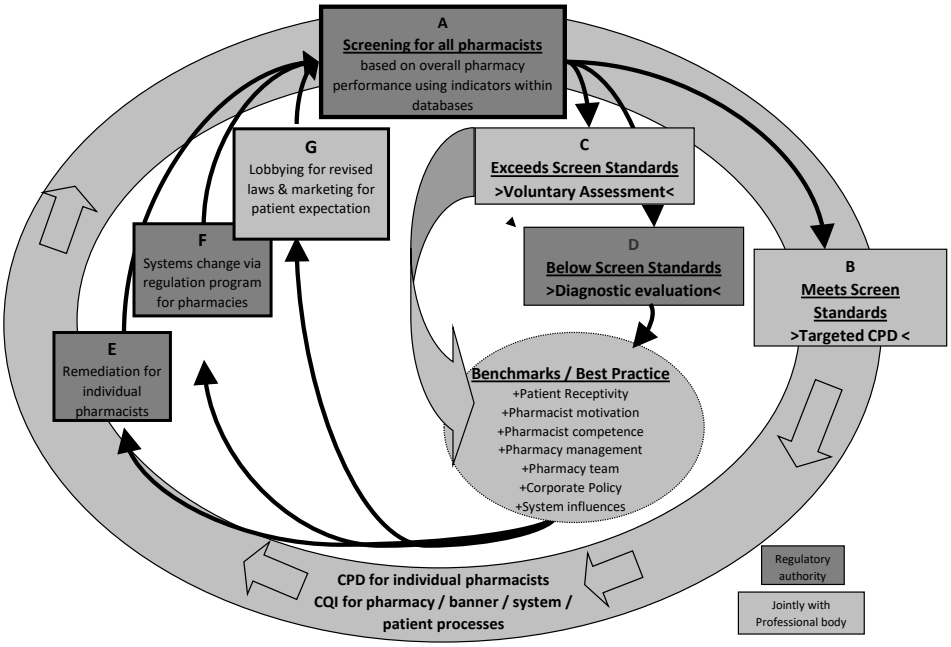

Figure 1. Framework for professional practice assessment.

Performance Based Screening: All Practicing Community-based Pharmacists

A third-party, performance-based assessment of the care and services provided by all pharmacists and support staff practicing in community pharmacies begins the assessment process (Figure 1, A). Traditional performance assessments such as on-site assessments are not recommended at this screening point as they are too resource intensive to be used for regular review of large numbers of practitioners. Instead, the screening assessment uses performance-based information contained in a range of administrative databases currently available within many provinces, states and/or countries (51). These databases are often generated as a by-product of reimbursement for health and pharmacy services. For example, in the province of Quebec in Canada, the government's health insurance plan maintains a database recording payment for all physician and emergency room visits, including unique patient and physician identifiers and the reason for the visit. A second database is maintained with all prescription medications dispensed at community pharmacies to government-covered patients. Again, this database contains unique patient, pharmacy and pharmacist identifiers and the date and quantity of each medication dispensed. In the Canadian province of British Columbia, the Pharmanet database also contains information on all prescription

medications received by patients via both community pharmacies and emergency rooms. In the USA, private databases such as RxHub and public databases such as Medicare contain similar records. Each of the separate databases contains substantial information related to services and patient care. However, for the purposes of assessing quality of care the greater value is created when these databases are merged. Tamblyn et al evaluated the usefulness of integrated databases as a source of information for measurement of the quality of care provided by community-based physicians (52, 53). Within Tamblyn's research environment, information related to diagnoses, medical procedures, medical and emergency room visits, and prescription medications allowed for measurement of indicators of physician's performance such as mammography screening rates, continuity of care, disease-specific prescribing rates, and contraindicated prescribing rates.

For pharmacy, indicators have been developed to identify patients at risk for drug-related morbidity or mortality (54-57). The Quebec Order of Pharmacists also uses performance indicators during their on-site inspections of the quality of care provided by community pharmacists (58). However, the use of databases to access and measure indicators of pharmacist's quality of care has not been reported. Current work with the databases used by Tamblyn et al is evaluating the feasibility and validity of measuring indicators of pharmacist's quality of practice (52, 53). Indicators being considered for measurement on a pharmacy basis include, for example:

1. the proportion of patients on HMG-Co reductase inhibitors who appear to be noncompliant with their therapy,
2. the proportion of patients on antibiotics that were dispensed with an inappropriate label instruction regarding the frequency of doses,
3. the proportion of patients whose medication history indicates overuse of beta two agonists.

Once measured, performance on these indicators could be compared among pharmacies with similar characteristics. Although no conclusions about pharmacist's performance should be drawn based only on these indicators, consistent underperformance could be used to identify pharmacies requiring further evaluation. Since the data required to measure these performance-based indicators are routinely collected, these data could be used to routinely screen the quality of performance of all community pharmacists without mandated participation in structured assessment programs (59). However, the validity of using such indicators as measures of quality of pharmacy practice remains to be evaluated, as does the validity of using pharmacy-based measures to reflect the performance of individual pharmacists employed at these pharmacies. Although the principle that high-quality individual pharmacist's performance is a prerequisite for the provision of quality care at community pharmacies is sound, this principle must be validated through further empirical research.

Practice Performance Meets Required Standards: Targeted CPD

The premise of using a performance-based screening assessment is that the majority of pharmacists would be employed at pharmacies where the quality of performance meets standards established by provincial or national organizations (23). Based on evidence from the third-party performance-based screen these pharmacists could be "revalidated" (29). From a regulatory perspective, these pharmacists would require no further assessment for the duration of the cycle, but would be re-screened on a regular basis. From a professional perspective, however, it is at this point that CPD programs could offer invaluable opportunities for pharmacists to continue to improve their practice performance beyond the minimum standard required to provide safe and effective care (Figure 1, B). Performance-based feedback would provide an opportunity for individual pharmacists to develop targeted CPD. This would be particularly useful for those pharmacists' whose performance was identified as satisfactory overall, but with deficiencies on individual indicators. For example, using the example database indicators described earlier, overall performance could be judged adequate, with above-standard performance on the indicators related to antibiotic frequencies and compliance with statin therapies, while performance on the indicator related to overuse of β2 agonists might be borderline. If this feedback were provided to pharmacists, it could serve as stimulus for reflection within the CPD cycle, resulting in learning directed towards asthma management or re-engineering of systems that support pharmacists' provision of care to asthma patients.

Practice Performance Meets Required Standards: Setting of Benchmarks

Before the root causes of performance problems at underperforming pharmacies could be identified, the determinants of quality practice would have to be identified and benchmarks for these determinants established (43, 47). To accomplish this, pharmacists at higher performing pharmacies would be requested to undergo detailed, diagnostic assessments (Figure 1, C). This step in the framework recognizes the differences between competence and performance, and measures the influence on pharmacist's performance of determinants beyond competence.

Although a number of studies have investigated determinants of pharmacists' performance, none has estimated the contribution of these determinants according to their source and nature (60-63). Factors influencing pharmacists' performance can readily be grouped into categories such as those defined by Van de Hombergh (45, 46), Ram (47) and Rethans (30), or those used to characterize barriers and facilitators to knowledge translation (48-50, 64). Grimshaw and Eccles define 4 levels of interventions related to the quality of health care (47, 49). These are the level of the individual health professional; the healthcare group or team; the organization providing health care; and the larger healthcare system or environment in which individual organizations are

embedded. Using these basic levels, along with Green's (65) predisposing, enabling, or reinforcing categories, qualitative interviews with pharmacy stakeholders identified theoretical determinants of the quality of pharmacists' practice (Figure 2). According to the principles of Green's PRECEDE model, determinants classified as motivating often relate to perceptions such as a pharmacist's perception of patient receptivity to expanded services or perceptions of the ease of reimbursement for these services (63, 65). Enabling or reinforcing determinants relate to, for example, the patient's true receptivity for these services and the actual ease of reimbursement. Each of these determinants could support or undermine whether a pharmacist provides a service and the quality of the service provided, both of which contribute to the quality of care provided by the pharmacist. For example, a patient nonreceptive to a pharmacist providing warfarin dosage adjustment could both discourage the pharmacist from offering this service to the patient and influence the quality of service by providing incomplete information to the pharmacist.

Figure 2. Model for Analyzing and Assessing Factors Influencing Pharmacists' Practice Performance*.

	Motivating Factors	Enabling Factors	Reinforcing Factors
The patient	Perception of patients' receptivity to pharmacists' services.	Patient willingness to provide time and information.	Patient feedback or willingness to pay.
Individual Pharmacist	Pharmacist motivation to provide services.	Pharmacist competence.	Pharmacist reward for services (e.g. pay / support for education).
Team / Pharmacy • Pharmacy technicians • Pharmacy owners	Perception of team / owner support of pharmacist provision of services.	Team / management systems support of pharmacist provision of services (e.g. # of support staff, job descriptions, work flow, physical layout, training).	Pharmacy / pharmacy staff reward for pharmacist provision of services.
Organization • Chain (corporate policies)	Perception of corporate management support of pharmacist provision of services.	Corporate management support of pharmacists providing the services (e.g. vision, mission, advertising, recruiting).	Chain reward for pharmacist provision of services (e.g. increased clientele / profit).
Health Care System • Profession of pharmacy • Other health care providers • Regulators • Policy makers	Perception of profession and health care system support of pharmacist provision of services.	Health care system support of pharmacists (e.g. laws, regulations, reimbursement, access to information such as therapeutic indication for prescribed medications).	Health care system reward (e.g. lower costs, improved patient outcomes, increased physician time for care provision).

* Shading represents different assessment tools that could be used to evaluate each of these factors as follows:

Questionnaires[69,70]	Assessments of knowledge, clinical reasoning & skill.	Time & motion analysis (on site assessment)	Practice management assessment[45]

Ongoing elucidation of the determinants of quality pharmacy practice would be followed by development of assessment tools to measure the degree of impact of these factors on pharmacists' performance. Tools could range from patient surveys to pharmacy practice management assessment (33, 45, 66). Based on current literature primarily from the profession of medicine, Figure 2 also provides broad suggestions for primary assessment tools that could be used for each of the factors (67, 68). Although a number of these tools have been developed for use in pharmacy (69, 70) or other professions, substantial research is necessary to modify and validate these tools for use in a performance practice assessment program for community pharmacists.

Once these assessment tools have been validated, they may be used to develop benchmarks of quality practice and standards for minimum practice for each of the specific determinants of pharmacists' performance. The benchmarks would be used for CPD, while the standards for minimum practice would be used in the diagnostic assessment of pharmacists employed at community pharmacies with measurable performance problems.

Practice Performance Does Not Meet Required Standards: Diagnostic Assessment

Point D in Figure 1 indicates the point at which pharmacists employed at community pharmacies with measurable performance problems would be required to undergo diagnostic assessment (30). The goal of this assessment would be to determine the root cause(s) of performance problems and would use the minimum standards and tools from the benchmarking process (32). Recognition of the influence of external determinants avoids presuming that performance problems are caused solely by pharmacist incompetence. Efficient use of remedial resources also requires that the nature of the performance problem be identified, followed by determination of the most effective strategies to overcome the specific problems.

Remediation and Pharmacy Systems Change

The APhA recognizes the importance of differentiating the contributions of pharmacists' competence and external factors on overall performance, arguing that they are not convinced that errors are necessarily due to incompetent practitioners. Maine suggests that "in addition to continuing a dialogue about practitioner competence assessment, we need to think seriously about the adequacy of site practice inspection and regulation" (71). This identifies a key opportunity within the profession of pharmacy in that it is one of the few, if not only, professions that regulates both practitioners and practice sites. Points E and F in Figure 1 emphasize this critical opportunity. At present, pharmacy

inspectors are an accepted part of community pharmacy practice. If critical practice or management-based determinants of performance could be identified, then the role of these existing pharmacy inspectors could be expanded to assess overall performance and the relative influences of these determinants. Regulatory authorities could effect change in pharmacists' performance through both remediation of individual pharmacists, and creation and enforcement of expanded regulations for pharmacies.

External Systems Change

In addition to the pharmacist and pharmacy specific determinants, Figures 1 and 2 also identify influences related to patients and the health care system. Solutions to overcome barriers from these sources would involve actions and organizations beyond the regulatory authorities (Figure 1, G). Marketing by pharmacy chains or professional organizations could help improve receptivity of patients towards pharmacists' provision of services such as disease state monitoring or primary care. In a similar manner, receptivity of physicians, scope of practice regulations, and reimbursement policies could be modified by joint efforts of regulatory authorities and professional organizations. The assessment cycle would be complete when the impact of the strategies selected could be evaluated, and the outcomes of the assessment program documented, as pharmacists re-enter the performance-based screening phase of their performance-based assessment program.

Summary

Although a number of regulatory authorities are developing programs intended to ensure that health professionals continue to practice in a safe and effective manner, the design and implementation of these programs has been challenging. For the pharmacy profession, a novel framework is proposed that is performance based, applies to all community pharmacists, recognizes the powerful influence of external factors on an individual pharmacist's ability to perform to his/her highest level of capability, and can be effectively integrated with CPD. The framework expands upon current best practices in health professions assessment, and in doing so identifies a number of research questions. First, the use of databases as a source of performance data is central to the proposed framework and the validity of using such indicators as measures of quality of pharmacy practice remains to be evaluated, as does the validity of using pharmacy-based measures to reflect the performance of individual pharmacists employed at these pharmacies. Second, further research is needed to gain a better understanding of the varied source and nature of determinants of quality community pharmacy practice. Third, the tools and formats to assess the impact of these determinants on the daily practice of community

pharmacists must be developed or modified from those used by other health professions. Fourth, the most effective strategies to overcome specific barriers documented to impact quality community pharmacy practice require evaluation. Finally, as with any assessment program, the efficiency and outcomes of the program must be evaluated to determine the impact on the quality and safety of community pharmacists' practice.

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Chapter 3

Planning new pharmacist services that last: The Prescription Shop's travel medicine clinic.

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Canadian Pharmacists Journal, 2009;142(4):178-83.

Introduction

As we travel the path to professional change in community pharmacies, we can expect to encounter new professional challenges and opportunities. It has been suggested that a single cataclysmic event, such as the recent generic pricing changes, could be used to create a sense of urgency that would provide the stimulus to drive change in our profession. For most pharmacists, however, one single event is unlikely to move us forward to a new type of practice or professional role. Success more likely depends on establishing a management plan that not only capitalizes on opportunities, but also anticipates facilitators and barriers to change. Such a plan, which recognizes investment requirements (both time and financial), workflow issues, required professional competencies and above all, patient needs, significantly increases the potential for a new professional service to thrive beyond the first weeks and months. Indeed, initiating new professional services without considering facilitators and barriers in the planning phase can lead pharmacists to select services that are doomed to failure.

In this article we present an analysis of the planning process used during the implementation of travel clinic services at The Prescription Shop (1). Our goals were to identify the range of facilitators and barriers encountered during different phases of implementation and to create a planning process that could be used by other pharmacists who are developing and implementing innovative services.

Current travel clinic service

The travel clinic service was introduced in 2002 at The Prescription Shop, an independent pharmacy located on the campus of Carleton University in Ottawa, Ontario (1). The student health clinic had recently discontinued its travel clinic service, choosing instead to send patients to designated travel clinics off-campus. Pharmacists at The Prescription Shop had been providing travel health information to students on an informal basis, but when the student health clinic's travel service was discontinued, they recognized that providing assessments using a more formal consultation approach would better meet the needs of students. The service in the pharmacy is currently offered by appointment, with fee-for-service payment by patients. Consultations, which typically run 15 to 30 minutes, are provided in a private counselling area. Pharmacists providing the assessment have completed a certification exam in travel health. The service is offered via a collaborative framework, through which pharmacists are authorized to prescribe travel medications according to a medical directive. Physicians are not involved in the assessment process, but nurses in the adjacent student health clinic administer vaccines, and assessment information is added to the patient's electronic file at the clinic. Demand for the service varies depending on the time of year, ranging from 2 to 15 patients per week.

A framework for management planning

We organized our analysis according to a traditional business model of 3 phases of product development: introduction, growth and maturation (2). For each phase, we identified the nature and source of the barriers and facilitators influencing pharmacists' practice change. This organization by source enabled us to identify who we needed to communicate with in order to address the barriers to successful implementation of the travel clinic service. As a starting point, we used a practice change framework that identified five sources of barriers and facilitators and separated them into those that motivate, enable or reinforce pharmacists' attempts to provide professional services (3). This framework was developed to focus specifically on evaluating barriers and facilitators to pharmacists' professional practice and draws together principles from assessment of health care professionals (4, 5), knowledge translation (6), determinants of quality of health care (7) and change management (8, 9). With permission, we adapted this framework to focus on key questions to be addressed when selecting and implementing pharmacists' services, when supporting sustained provision of these services during growth phases, and when maintaining provision of these services once they became part of daily practice (Table 1). As we traced the history of the travel clinic service, we added detail to the framework, listing very specific questions for each of these phases. Table 2 provides highlights of this framework for the patient level; full details are available in Appendix 1 (available at www.cpjournal.ca). Finally, we integrated the insight gained through responses to these questions into a management plan for implementing new pharmacy services.

Table 1. Framework for analyzing barriers and facilitators to community pharmacists' provision of travel services

Source of barrier/facilitator	Questions to identify potential barriers and facilitators		
Patient	Why would patients want/need me to provide this service in my pharmacy?	What do I need from patients to provide this service?	What do I need from patients to reinforce my commitment to providing this service?
Pharmacist	Why would I want to provide this service in my pharmacy?	What do I need to know or be able to do to provide this service?	What do I need as a professional to reinforce my commitment to providing this service?
Team/pharmacy	Why would staff want to provide this service in our pharmacy?	What support from staff or physical resources do I need to provide this service?	What support from pharmacy staff or physical resources do I need to reinforce my commitment to providing this service?
Organization	Why would head office want me to provide this service in my pharmacy?	What do I need from head office to provide this service?	What do I need from head office to reinforce my commitment to providing this service?
Health care system • Pharmacy profession • Regulators • Other health care providers	Why would the profession/other health care providers/the health system want/need me to provide this service in my pharmacy?	What do I need from the profession/other health care providers/the health care system to provide this service?	What do I need from the profession/other health care providers/the health care system to reinforce my commitment to providing this service?

Modified with permission from Winslade et al (3)

Table 2. Sample section of the detailed model for analyzing barriers and facilitators to community pharmacists' provision of travel clinic services: The patient

Phase	Why would patients want/need me to provide this service in my pharmacy?	What do I need from patients to provide this service?	What do I need from patients to reinforce my commitment to providing this service?
Introduction phase	When selecting a service to provide: • Are there sufficient numbers of patients who require this service? • Do the patients recognize the need for and the value of this service? • Will patients accept these services/do they want these services from me (a pharmacist) or do they see this as a service better provided by a different health care professional? • Are patients willing to pay me (adequately) to provide these services (if there isn't an alternate source of reimbursement)?	As I start providing the service: • Do patients know enough about their conditions/ medications, etc., to provide me with the information I need to provide the service? • Are patients willing to accept a delay in filling prescriptions to accommodate the provision of this service?	As I start providing the service: • Have patients been receptive to the first attempts to provide the service? If not, how will I incorporate change to gain receptivity? • Are patients paying for the service? If not, how will I need to adjust my implementation plan? • Have I received feedback from patients regarding the value of the travel service?
Growth phase	What opportunities exist for me to increase patient's requests for this service? • Are there patients who need these services and don't realize it? • Are there patients who realize their need but don't know about or accept the service from me as a pharmacist?	What do I need from patients to be able to provide this service in an efficient manner? • Do I need to rely on patients for the required information or can I access it via other routes, such as health care providers or patient records? What would it take to obtain this information via these sources? • Are patients willing to schedule appointments to increase efficiency?	As demand for the service grows: • Are patients referring others to the pharmacy for travel services? If not, why not, and how do I plan to encourage this? • Am I actively pursuing patient feedback on the value of the travel services (to support/market the value)?
Maturation phase	What do I need to do to ensure that patients continue to use this service from me? • Are there new/potential service providers or products that may diminish patients' use of my service (e.g., plans to offer travel medicine at the student health clinic)? If yes, what is the degree of threat?	What do I need from patients to be able to continue to provide this service?	Once the service is an accepted part of daily practice: • Are patients returning to make use of the service on a regular/expected basis? If not, why not, and how do I plan to encourage this?

The introduction phase

Prior to and during start-up, our focus was on determining patient need/demand for travel services and ensuring that we were able to meet this need through recommendations for vaccinations and education about travel safety. Establishing patient need required us to consider questions that ranged from whether our patients travelled, to whether patients had travel needs that were not currently being met, to whether patients would be receptive to receiving and paying for travel clinic services from pharmacists. Answers to these questions became clear when, despite considerable requests for services, the student health clinic discontinued its travel consultation service due to staff limitations. Patient agreement to pay for the services was not anticipated to be a barrier, as travel clinic services were not covered by the Ontario Health Insurance Plan (OHIP), so patients would have had to pay a fee regardless of where or from whom they received the service.

Motivation of our pharmacists was considered a facilitator, as we had been searching for a professional service to provide to patients, and travel clinic services offered a substantial opportunity to increase patient continuity of care. Instead, our focus was on potential barriers, such as ensuring that our pharmacists had the knowledge and skills required to assess and manage patients' travel risks. Although competence in patient assessment was an initial concern, investigation of the nature of the assessment required for travel clinic services clarified that pharmacists would not be required to make diagnoses; recommendations would be based on an assessment of country-specific health risks. A search of online resources enabled us to locate the references needed to provide timely and comprehensive assessments. We were also encouraged since most travel education focused on medications, including nonprescription medications, so pharmacists' knowledge of drug interactions was relevant. We were, therefore, confident in our pharmacists' competence and in the fact that this type of assessment fell within pharmacists' scope of practice.

Barriers relating to either management or pharmacy team support were minimal during the implementation phase, in part because the owner planned the service. Some staffing issues did need to be considered, however, since the travel clinic service introduced appointment-based activities into the pharmacy workflow. Pharmacist overlap was not always available during travel clinic appointments, and pharmacy technicians had to manage the requests of other patients seeking to speak to the pharmacist during appointments.

Corporate support was not relevant, as our pharmacy is independent. However, we anticipate that for pharmacies that are a part of chains or banners, opportunities may exist via, for example, corporately sponsored education for pharmacists. Corporate-based barriers may also be encountered, in the form of centrally determined priorities for professional services that could conflict with services planned for specific pharmacies.

We also realized that the value of our service to patients depended on clinic physicians accepting our prescribing recommendations so that patients could receive all travel-related services without going off-campus. We worked with selected salaried physicians to gain acceptance of both the service and our competence to provide prescribing recommendations. Salaried physicians were selected because during the implementation phase a physician appointment was needed to authorize our prescription recommendations. This would have been a barrier for fee-for-service physicians, since the visit would not have been billable to OHIP. Acceptance of the service was also facilitated by a lack of overlap or competition for these services, since no physicians at the student health clinic specialized in travel medicine. In addition, a short referral form was developed that provided the rationale for pharmacist prescription recommendations and documentation of the information reviewed with patients during the consultation. This provided clear support of our competence to provide travel health recommendations.

Finally, communication and collaboration with nursing staff were also priorities, since nurses were responsible for administering vaccines. The nurses were very supportive, as they found our referral forms straightforward. Since the student health clinic charged a fee to patients for nurse administration of travel vaccines, this was also an income-generating service for the clinic.

The growth phase

Within 6 months of introducing the service, there was significant growth in demand, exposing new barriers that threatened the sustainability of the service. Efficiency was needed to decrease the time spent preparing for patient consultations. Auto-population of the referral form via programming modifications decreased preparation time by half. Efficiency was also increased when pharmacists gained knowledge and experience by completing an internationally recognized travel medicine certification.

The growing demand for the service also required increasing time commitments for the physicians who authorized prescriptions. Some physicians questioned why they were required to co-sign prescriptions written by travel medicine–certified pharmacists, when the physicians themselves did not have this type of expertise. This certification was, therefore, important in paving the way toward a medical directive that delegated prescribing authority. The tipping point came when the coach of the varsity basketball team requested the pharmacy travel clinic service for the entire team for a tournament in Southeast Asia. An agreement was reached that members of this group would be assessed and provided with prescriptions without a routine visit to a physician, provided they met certain criteria. Based on the success of this trial group, the medical directive was developed using the Ontario College of Pharmacists guidelines to ensure that it conformed to regulatory requirements.

Other barriers faced during this growth phase related to acceptance of the travel clinic service by pharmacy support staff and the time needed to clarify the extent of services that pharmacists could provide. To address this latter issue and to support the growth of travel clinic services, we became more active in-patient education initiatives. In particular, we identified an opportunity to present our services to students who were participating in a study-abroad program organized by the university.

While staffing issues in the introduction phase altered workflow and responsibilities, changes during the growth phase focused on efficiency. For example, we began to shift responsibility for handling inquiries about the travel clinic service to the pharmacy technicians. Where possible, we also spread out appointments and scheduled them during off-peak dispensary times to reduce the need for pharmacist overlap. Pharmacy staff offered strong support during this growth phase as technicians accepted new roles related to the travel clinic service. It is recognized, however, that such changes can be difficult for some staff (including pharmacists), especially if the culture of the pharmacy is shifting toward more professional services. On occasion, staff may recognize that the changes required are too demanding and decide to relocate to pharmacies where expectations are more consistent with previous roles.

The maturation phase

Once this second set of barriers and facilitators was addressed, the travel clinic service entered a phase of relative predictability. During this period, barriers tended to be less dramatic in terms of challenging the sustainability of the service, but they continued to relate to critical issues. The barrier that caused the greatest amount of concern related to the renewal of the medical directive. We had always anticipated that at some point the medical directive would not be required based on our sense that pharmacist prescribing would expand to Ontario. However, early in 2008, the director of the student health clinic retired, and the university replaced him with a non-physician who did not have the authority required for our medical directive. The part-time medical staff raised a number of questions focusing on liability, conflict of interest and documentation of the quality of services we provided. For liability, we confirmed our own insurance coverage, and information provided by lawyers proved vital to assuring the signing physician that liability could be reasonably addressed within the framework of our medical directive. Conflict-of-interest questions focused on the fact that we dispensed the medications that we prescribed. Our clear, consistent, well-documented assessment process allowed us to rationalize this aspect of our service.

One barrier relating to the renewal of the medical directive was the need for data supporting the impact of our service. Although we had anticipated the need for documentation, we had not considered how to collate this documentation to evaluate the service and create evidence supporting its value. In the absence of such data, we

focused on the need for the service in our community and the theoretical value it offered to patients. Data showing evidence of the impact of our service would have greatly strengthened our case for renewal, and this lack of data continues to be a barrier facing our service. Although the travel clinic service has grown and matured despite this lack of data, we are currently planning systems to evaluate the quality and impact of the service.

A final key barrier during this maturation phase was vaccine shortage. Since certain vaccines are made available only to more established clinics, we occasionally had to refer patients or rely on professional relationships with other clinics to purchase required vaccines directly. The absence of a yellow fever designation for our travel clinic also limited our ability to provide complete travel services. Eligibility for the designation requires a health care practitioner who is authorized to administer vaccinations. Since Ontario pharmacists do not have this authorization*, we worked with the medical and nursing staff to clarify the nursing, physician and pharmacist roles for yellow fever vaccination. A joint application was submitted in January 2009, and the university medical clinic and pharmacy received approval for the yellow fever designation in February 2009.

A management plan for new pharmacy services: Putting theory to work

The process below outlines how the framework we have developed can be used to select and plan the implementation of a pharmacist's professional service in a community setting. It is provided in chronological order so that it can be used in a step-by-step approach. While the outline is based on a business-management approach and we strongly support the principle of appropriate financial reimbursement for services, it is emphasized that a proper financial plan is needed to address the varying financial requirements of different services and practice settings.

1. Create an outline of the service being considered. This step should start with writing a brief description of the service. It should answer the following questions: "What is my vision of my role in providing this service?" and "What benefits will patients receive?" The description of the service should also define success, including areas such as expected annual revenue, number of patients and impact on the pharmacist's role.
2. Review the questions in Table 2 to identify barriers and facilitators across the phases of service implementation. Determine what information is needed, activities to be undertaken or relationships to establish to accurately identify and address barriers and facilitators across the phases. Prioritizing at this point is essential. Each service and each practice setting is likely to have its own

* Effective December 15, 2016, pharmacists in Ontario were authorized to administer vaccines to any patient older than five years for 13 vaccine-preventable diseases under specified conditions.

combination of barriers, not all of which need be resolved before offering a new service. Determine which barriers are critical to success and address them.

3. Once you tentatively select a service, establish communication, marketing and other activities for each phase according to the source of key barriers/ facilitators. The goal in this step is to determine communication messages (including both marketing and education information) that need to be directed at the different sources.
4. Outline financial costs. Financial costs may include training, marketing, physical changes to the workplace, increased staffing costs and technology. It should be anticipated that there may be relatively high start-up and variable ongoing maintenance costs. From a business standpoint, however, the product life cycle of a professional service is likely to be longer than that of a retail product. Also, workplace changes made while developing one new professional service, such as staffing and workflow changes, establish a system that can more readily incorporate other new professional services.
5. Develop an action plan and timeline for implementing the service and for moving it through the introduction, growth and maturation phases.

Summary

Analysis of the travel clinic service experience allowed for the development of a detailed planning framework for implementing practice change (see Appendix 1). Using this planned approach, potentially cataclysmic events, such as a potential loss of our medical directive, were manageable and used as facilitators to gain additional support for the clinic. Validation of this planning framework continues as we work to improve the travel clinic service and identify new professional services to offer at The Prescription Shop.

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Appendix 1 Complete detailed model for analyzing barriers and facilitators to community pharmacist's provision of travel clinic services

Patient	Why would patients want me to provide this service in my pharmacy?	What do I need from patients to provide this service?	What do I need from patients to reinforce my commitment to providing this service?
	When selecting a service to provide: • Are there sufficient numbers of patients who require this service? • Do the patients recognize the need for and the value of this service? • Will patients accept these services/do they want these services from me (a pharmacist) or do they see this as a service better provided by a different health care professional? • Are patients willing to pay me (adequately) to provide these services (if there isn't an alternate source of reimbursement)?	As I start providing the service: • Do patients know enough about their conditions/medications, etc., to provide me with the information I need to provide the service? • Are patients willing to accept a delay in filling prescriptions to accommodate the provision of this service?	As I start providing the service: • Have patients been receptive to the first attempts to provide the service? If not, how will I incorporate change to gain receptivity? • Are patients paying for the service? If not, how will I need to adjust my implementation plan? • Have I received feedback from patients regarding the value of the travel service?
	What opportunities exist for me to increase patient's requests for this service? • Are there patients who need these services and don't realize it? • Are there patients who realize their need but don't know about or accept the service from me as a pharmacist?	What do I need from patients to be able to provide this service in an efficient manner? • Do I need to rely on patients for the required information or can I access it via other routes, such as health care providers or patient records? What would it take to obtain this information via these sources? • Are patients willing to schedule appointments to increase efficiency?	As demand for the service grows: • Are patients referring others to the pharmacy for travel services? If not, why not, and how do I plan to encourage this? • Am I actively pursuing patient feedback on the value of the travel services (to support/market the value)?
	What do I need to do to ensure that patients continue to use this service from me? • Are there new/potential service providers or products that may diminish patients' use of my service (e.g., plans to offer travel medicine at the student health clinic)? If yes, what is the degree of threat?	What do I need from patients in order to be able to continue to provide this service?	Once the service is an accepted part of daily practice: • Are patients returning to make use of the service on a regular/expected basis? If not, why not, and how do I plan to encourage this?

Pharmacist	Why would I want to provide this service in my pharmacy?	What do I need to know or be able to do to provide this service?	What do I need as a professional to reinforce my commitment to providing this service?
	When selecting a service to provide: • Is this a service that is important for me, as a pharmacist, to provide? • Is the service within my scope of practice? • Is this service sufficiently important to take priority over the provision of other services that I currently provide (or that I am thinking of providing)? • How much change will be required in the way I practice to provide this service? • Is there evidence that community pharmacists similar to me can provide this service on a sustainable basis?	As I start providing the service: • Do I already possess the basic knowledge and skills required to provide the service? • Is the service relatively straightforward and consistent for most patients? • Are there tools available to guide me in the provision of the services (forms, guidelines, step-wise process)? • Is there a simple way to ensure/document that I have provided quality service?	As I start providing the service: • Do I see informal proof that providing the service is improving patients' health (or other desired outcomes)? • Am I being financially rewarded by patients/the pharmacy for providing this service?
	What opportunities exist for me to increase provision of the service? • Are there clearly defined goals that are easily measured to evaluate success of the service? • How much effort will it take to collect this data so I can use it to justify expansion of the service?	What do I need to know or be able to do to provide this service in an efficient manner? • Is there a way for me to improve my competence to provide this service (and, therefore, efficiency)? • Are there recognized training/certification programs? • Are there simple systems available for documenting/analyzing patient outcomes?	As demand for the service grows: • Have I actively sought out proof of positive effect on patients? • Am I being recognized within the pharmacy/chain/profession/other health care professionals/health care system for providing the service (e.g., professional practice awards, publications, speaking requests)?
	What do I need to do to motivate myself to continue to provide this service once it is established? • Have the collection of outcome data been systematized so we can easily monitor the quality and impact of service?	What do I need to know or be able to do to continue providing this service? • Are there easy-to-access resources to stay up-to-date in this field?	Once it is an accepted part of daily practice: • Do the outcome data document the impact of the service on patients? On the pharmacy's financial success?

Team/ pharmacy	Why would staff want to provide this service in our pharmacy?	What support from staff or physical resources do I need to provide this service?	What support from pharmacy staff or physical resources do I need to reinforce my commitment to providing this service?
	When selecting a service to provide: • Do pharmacy staff members support the value of the pharmacist providing this service? • Does the owner/manager support the value of pharmacists providing professional services? • Is the service financially sustainable (adequate fee to support the pharmacist's time and other resources)?	As I start providing the service: • Does the physical setting of the pharmacy enable provision of the service? • Are there new roles/tasks that staff must accept to provide this service? Are staff members willing to accept these roles? • Do I have access to the information resources necessary (Internet access, drug information resources, experts, guidelines)? • Are there systems within the pharmacy to document the provision of the services?	As I start providing the service: • Are staff members willingly fulfilling their roles to accommodate provision of this service?
	What would motivate staff to provide this service to more patients? • Am I passing along informal feedback from patients to staff that demonstrate the value of the service? • Am I seeking staff input as to the impact of the service on their work? Are their suggestions for improvements in workflow/job responsibilities being considered? • Am I providing training support for new responsibilities?	What support do I need from staff or physical resources to increase the efficiency of this service? • Are there changes in structure/workflow needed to increase efficiency? • Does the staffing framework facilitate an appointment system for the service? • Can I automate any aspect of the service provision or documentation? • Are there changes in the physical layout that would streamline the service?	As demand for the service grows: • Is the pharmacy's profitability increased via provision of the service? • Are my responsibilities being shifted to accommodate provision of this professional service?
	What would motivate staff to continue providing this service once it is established? • Is the pharmacy team receiving increased salary/bonus to recognize their role in the service?	What support do I need from staff or physical resources to continue providing the service? • Have documentation systems become routine and easy?	Once the service is an accepted part of daily practice: • Are staff members comfortable with/accepting of the provision of this service as being routine?

Organization • Chain (corporate policies) •	Why would head office want me to provide this service in my pharmacy?	What do I need from head office to provide this service?	What do I need from head office to reinforce my commitment to providing this service?
	When selecting a service to provide: • Does head office support the value of pharmacists providing this specific service?	As I start providing this service: • Does head office provide support for education necessary to provide this service?	As I start providing the service: • Does head office actively encourage pharmacists to seek / develop innovative practices (e.g. is the culture supportive of change)?
	What would motivate head office to support providing this service to more patients? • Have I documented the value of this service to patients, including their willingness to pay? • Have I focussed on the pharmacy receiving recognition from the profession, health care system or lay press for the service?	What do I need from head office to increase the efficiency of this service? • Does head office provide support for certification programs necessary for efficiency in providing this service? • Does head office provide marketing support to help promote the service?	As demand for the service grows: • Does head office recognize pharmacists who develop innovative practice services? • Does head office actively seek ways to promote the service (proactive versus reactive)?
	What would motivate head office to continue providing this service once it is established? • Have I documented that the service has become the expected standard of care by patients or referring physicians? • Have I determined if there is a financial gain to providing this service?	What do I need from head office to continue providing this service? • Will head office modify staffing assigned / productivity targets to accommodate provision of the service?	Once the service is an accepted part of daily practice: • Does head office market the service as an ideal for other pharmacies to emulate?

Health care system • Profession of pharmacy • Regulators • Other health care providers	Why would the profession/other health care providers/the health system want/need me to provide this service in my pharmacy?	What do I need from the profession/other health care providers/the health care system to provide this service?	What do I need from the profession/other health care providers/the health care system to reinforce my commitment to providing this service?
	When selecting a service to provide: • Does this service fulfil an unmet health care need? Is it within my scope of practice? • Does the system reimburse me to provide this service (recognizing the value/ appropriateness of pharmacists providing the service)?	As I start to provide this service: • Do I have the required relationship with key physicians or other professionals whose support I need? • Do I have simple, consistently effective ways of communicating with the required professionals?	As I start providing the service: • Are physicians/other professionals willingly fulfilling their required roles? • Is physician feedback positive?
	What would motivate the profession/other health care providers/the health care system to support providing this service to more patients? • Can I document the impact on patients' health/access to services to the profession/other professionals/health care system?	What do I need from the profession/other health care providers/the health care system to increase the efficiency of this service? • Are there regulatory systems in place to support me providing this service? – Delegation or medical directives – Access to patient information • Can I streamline communication systems?	As demand for the service grows: • Are key physicians and other health care professionals referring patients to me?
	What would motivate the profession/other health care providers/the health care system to continue providing this service once it is established? • Do we routinely report outcome data to the profession/other health care providers/regulators?	What do I need from the profession/other health care providers/the health care system to continue providing this service? • Are regulatory/scope of practice changes being made to facilitate the provision of the service?	Once the service has become an accepted part of daily practice: • Am I routinely involved with educating the profession/other health care providers/health care officials on pharmacists' provision of the service?

Shading represents the 3 phases of introduction, growth and maturity.

Chapter 4

Monitoring Community Pharmacists' Quality of Care: A feasibility study of using pharmacy claims data to assess performance.

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BMC Health Services Research, 2011;11:12.

Background

Although medications are a mainstay of modern medical treatment, their use is associated with both benefit and harm (1-3). Preventable drug-related morbidity and mortality (DRM) now accounts for 8% to 23% of hospital admissions in seniors (4-6). In North America in the early 1990s, professional pharmacy organizations recognized the extent of this problem and recommended that pharmacists expand their role to include a focus on minimizing preventable DRM (7-9). This recommendation was based on the assertion that pharmacists are both educated to manage patients' drug-therapy problems and readily accessible within the majority of communities in North America. Indeed, the average Canadian adult visits a community pharmacy once or twice per month (10). This situation provides an ideal opportunity for community pharmacists to minimize patient's preventable DRM.

As pharmacists have incorporated this role of minimizing DRM into their practice, university-based educational programs have been modified to emphasize these responsibilities and standards of practice have been revised (11, 12). Increasing public emphasis on the need for assurance that health practitioners remain competent to provide quality care throughout their careers has lead pharmacy regulatory authorities to update their programs for monitoring pharmacist's performance to ensure compliance with these revised standards of practice (personal communications Quebec Order of Pharmacists and Nova Scotia College of Pharmacists). These quality assurance programs are being updated based on modern frameworks for regulatory review that include proactive routine surveillance of practice performance, followed by more in-depth assessment of potentially under-performing practices (13-16). Such frameworks acknowledge the collaborative nature of current health care provision and that the quality of care provided by the health care team is dependent on the quality of care provided by each team member (14, 17). These frameworks are appropriate for use in community pharmacies, where multiple pharmacists and pharmacy technicians contribute to the care and services provided to an individual patient (18, 19). Therefore, the proactive surveillance phase of regulatory programs recommended for community pharmacists measures performance on a pharmacy-specific basis rather than on a pharmacist-specific basis (14).

Indicators are being developed to conduct routine surveillance of the quality of care provided in community pharmacies (20). To maximize efficiency, it has been recommended that performance on these indicators be assessed using pharmacy claims data that are routinely collected as part of daily provision of medications and services (14, 20). Preliminary studies have shown that the data required to measure performance on these indicators is available in pharmacy claims databases and that pharmacists find comparative performance information useful (21). What remains to be evaluated is whether routine use of information from these databases to measure performance at community pharmacies is feasible. Feasibility can be determined by evaluating whether

the database-derived performance measures meet the key requirements for use by regulatory authorities for quality assurance. Specifically, the target services need to be routinely provided at the majority of community pharmacies, care must be appropriately attributed, and there must be sufficient variability in performance across community pharmacies to warrant surveillance (22).

The purpose of this project was to determine the feasibility of routine use of information from these databases by regulatory authorities to screen the quality of care provided at community pharmacies.

Methods

Context: This study was conducted in the Canadian province of Quebec where the Order of Pharmacists, the governmental regulatory authority responsible for licensing pharmacists, monitors the performance of more than 5000 community pharmacists in 1800 community pharmacies. These pharmacists serve a population of 7.4 million patients, of whom approximately 50% receive government support for payment of their medications via the publicly-funded insurance program (Régie de l'assurance maladie du Québec - RAMQ). Similar to public and private insurance programs in the rest of the Canadian provinces and American states, medication-related data maintained by RAMQ for insured patients includes payments made for each dispensing of a reimbursable medication, the date, the name, strength, dosage form and quantity of the dispensed medication, and prescriber, pharmacist and pharmacy identification. Reimbursable medications include over 85% of medications available in Canada. In Quebec, medication supply policies support dispensing of chronic medications on a 30-day interval rather than encouraging a 90-day dispensing interval. Although this policy provides more opportunities for pharmacists to detect and intervene on medication use problems, dispensing on either a 30-day or 90-day interval provides regulatory authorities with the data required to measure performance on quality-of-care indicators.

Study Population: To assess the quality of care provided at community pharmacies, we used a random sample of 1.4 million patients who received medications from community pharmacies between January and December 2002. In addition to the routine medication-related information, for each dispensing a unique anonymized identifier was provided by RAMQ for each patient, prescriber and dispensing pharmacy. These unique identifiers were used to develop a longitudinal prescription history for each patient and a practice population for each pharmacy that could be used to measure quality of performance on each indicator on a pharmacy-specific basis. Ethics approval was obtained from the McGill Faculty of Medicine Institutional Review Board.

Assessing Feasibility: The feasibility of using pharmacy claims data to evaluate performance was assessed by calculating pharmacy-specific performance on four quality-

of-care indicators and determining whether results met requirements for use for high-stakes decisions by regulatory authorities (22). Specifically, we evaluated the proportion of community pharmacies where provision of services was frequent enough to allow reliable assessment on the performance indicators, the variability of performance across pharmacies and the proportion of pharmacies where performance was systematically poor on multiple indicators, indicating a need for further evaluation.

Selection and Measurement of Indicators: The Pharmacy Quality Alliance (PQA) in the United States has developed quality indicators for conditions where there are widely documented medication use problems, including noncompliance with anti-hypertensive medications, over-use of rescue inhalers in the treatment of asthma and use of contra-indicated/high risk medications (20). We used similar indicators to assess performance at community pharmacies in Quebec. Two of the indicators measured safety (the use of high risk medications) and two represented effectiveness of chronic treatments (hypertension and asthma) (Table 1). To produce comparable measures of performance among pharmacies, we restricted the denominator for each indicator to the "at-risk" patient population. This at-risk population was defined as patients who were treated for the respective problem (e.g. hypertension) or who had been dispensed medications within a specific therapeutic class. For example, for the medication safety indicator evaluating the dispensing of flurazepam to seniors, the at-risk population was defined as 'all seniors who were dispensed a benzodiazepine from the pharmacy' and not as 'all seniors dispensed a medication from the pharmacy' as most would not be using a benzodiazepine and would, therefore, not be at-risk. Details of the at-risk population used for each indicator are found in Table 1.

Number of dispensings was counted in the numerator and denominator because the number of dispensings provided the best measure of the opportunity for community pharmacists to detect and intervene on medication-use problems. For example, for the indicator evaluating non-compliance with anti-hypertensive medications, pharmacists had the opportunity to detect non-compliance each time a patient returned to the pharmacy for a refill of his/her medication. Therefore, each dispensing to a non-compliant patient represented an opportunity for intervention by the pharmacist.

Pharmacy-specific performance on each quality indicator was calculated using dispensings of medications from all community pharmacies. All dispensings were included because pharmacists are expected to inquire about all prescription therapies including dispensings from other pharmacies. Operationally this meant that for the dispensing of concomitant non-selective beta-blockers and inhaled short acting beta agonists (SABA), the medications could be dispensed from two different pharmacies and the performance was attributed to the pharmacy dispensing the non-selective beta-blocker to the patient. For the over-use of SABA and non-compliance with anti-hypertensive medications, all SABA's and anti-hypertensives dispensed to the patient from all pharmacies were counted. As medication discontinuation and switching are not well documented in databases and are

common in management of hypertension, the inclusion of all anti-hypertensives allowed us to eliminate the problems of over-estimation of non-compliance due to switching or changing dose of anti-hypertensive medications.

Table 1. *Quality-of-care* Indicators for Community Pharmacists

Indicator	Definition
Medication Safety	
Beta Blockers in Respiratory Patients	
Recommended Care: Patients receiving a SABA should not receive nonselective beta-blockers (NSBB)	*Measure:* proportion of dispensings of beta-blockers to patients dispensed SABA that are for NSBB*
	Denominator: # of dispensings of oral beta-blockers (selective or nonselective) to patients who received a SABA from any pharmacy within the previous 6 months (including dispensing on the same day)
	Numerator: # of dispensings of oral NSBB to patients who were dispensed a SABA from any pharmacy within the previous 6 months (including dispensing on the same day)
Benzodiazepines in the Elderly	
Recommended Care: seniors requiring a benzodiazepine should not receive long acting agents (flurazepam)	*Measure:* proportion of dispensings of benzodiazepines to patients > 65 years old that are for flurazepam*
	Denominator: # of dispensings of benzodiazepines to patients > 65 years old
	Numerator: # of dispensings of flurazepam to patients > 65 years old
Medication Effectiveness	
Over-use of Asthma Medications	
Recommended Care: patients should not use more than 250 doses of SABA in a 90 day period	*Measure:* proportion of dispensings of SABA that are provided to patients who had used more than 250 doses of these rescue medications over the previous 90 days*
	Denominator: # of dispensings of inhaled SABA
	Numerator: # of dispensings of an inhaled SABA that were provided to a patient who had been dispensed more than 250 doses of this same SABA from any pharmacy within the previous 90 days
Under-use of Anti-hypertensives	
Recommended Care: patients should take at least 80% of their medication prescribed for hypertension	*Measure:* proportion of dispensings of anti-hypertensive medications that are provided to patients who had received < 80% of their required supply of antihypertensive medications over the previous 90 days*
	Denominator: # of dispensings of any blood pressure medications
	Numerator: # of dispensings of any blood pressure medications that were to patients who had received < 80% of the prescribed amount of any blood pressure medications over the previous 90 days from any pharmacy

* The lower the score on the Quality of Care indicators the better the performance.

To ensure stable estimates of performance we required pharmacists at each pharmacy to dispense the relevant medication to the at-risk population (i.e. denominator group) five or more times over the one-year period (23). Such cut offs are recommended for use in measures of physician performance to improve the reliability of estimated performance while ensuring that potential poor-performers who provide a low volume of service are not excluded from evaluations (22, 24).

Data Analysis

To evaluate whether the performance on the quality indicator met the requirements established by regulatory authorities, we first determined the number of pharmacies where pharmacists provided the service frequently enough for reliable performance estimates to be calculated. We then used univariate statistics and the coefficient of variation to examine the distribution of the quality of performance across pharmacies. To determine if performance on one indicator influenced performance on another indicator, we estimated the Spearman Rank Order Correlation among indicators using the pharmacy as the unit of analysis. To estimate the proportion of pharmacies that would be in the worst-performing quartile in all indicators, and would likely be targeted for regulatory review, we cross tabulated performance by quartile on the four performance indicators.

Results

Our sample included 1,427,325 patients with an average age of 50 and a predominance of women (Table 2). Patients were dispensed on average 6.2 different medications per year, receiving these medications via, on average, 37.9 dispensings per year. The mean number of pharmacies visited per patient per year was 1.6, with 61.4% of patients using one pharmacy exclusively over the study period. Although within our study population the greatest number of patients demonstrated under-use of anti-hypertensive medications (42.5%, 220,179 of 517,656 at-risk patients under-used anti-hypertensives), patients taking SABA were more likely to demonstrate inappropriate use of these medications (57.0%, 39,895 of 70,021 at-risk patients over-used SABA).

Breadth and Frequency of Service Provision: The majority of pharmacies provided the services for the four indicators frequently enough to be included in the performance calculation (Table 3). The indicator that excluded the greatest number of pharmacies was the indicator measuring the concomitant use of SABA and non-selective beta-blockers, reflecting the low prevalence of at-risk patients in the population (Table 2). For the indicator related to under-use of anti-hypertensive medications, virtually all pharmacies

met the cut-off criteria of having dispensed anti-hypertensive medications five or more times over the study period. No pharmacy was excluded from the performance calculation on all four indicators.

Table 2 Characteristics of Pharmacy Practice Population (N=1,427,325 patients)

Patient Characteristics		
Patient Demographics	**N**	**%**
Female	849,989	59.6†
	Mean	**SD**
Age	50.0	24.2
Medication use	**Mean**	**SD**
Medications per year‡	6.2	5.2
Dispensings per year§	37.9	64.3
Health Services Use	**Mean**	**SD**
Prescribing physicians per year	2.7	2.0
Dispensing pharmacies per year	1.6	0.95
	N	**%**
Patients receiving all medications & services from a single pharmacy per year	877,038	61.4†
Population Prevalence of Quality-of-care Problems	**N (N at-risk)**	**%****
Medication Safety Indicators		
Seniors receiving flurazepam	11,453 (196,774)	5.8
Patients receiving non-selective beta blockers and SABA	5,200 (33,058)	15.7
Medication Effectiveness Indicators		
Patients over-using SABA	39,895 (70,021)	57.0
Patients under-using anti-hypertensives	220,179 (517,656)	42.5

Overall quality and variability in service provision: Overall the quality of performance was better for the medication-safety indicators than for the medication-effectiveness indicators (Table 3). The worst performance on the four quality-of-care indicators was exhibited for the SABA over-use indicator. On average, across all pharmacies, 43.3% of dispensings of SABA were to patients who had over-used these medications within the previous 90 days. Performance on the medication-safety indicator measuring pharmacist dispensing of flurazepam to seniors was the best with, on average, 4.3% of benzodiazepine dispensings to seniors being for flurazepam.

Variability of performance across the community pharmacies on each of the indicators is also provided in Table 3. Based on the coefficient of variation (CV), performance on the medication-safety indicators demonstrated the greatest variability. Across pharmacies the rate of inappropriate dispensing ranged from 0% to 42.5% for flurazepam with a CV of 0.72,

† Percent of 1,427,325 patients.
‡ Calculated by determining the average of the total number of medications per patient per year.
§ Total number of dispensings in one year period is 54,045,097.
** Percent of the population at-risk

and 0% to 100% for nonselective beta-blockers and SABA (CV = 0.73) (Figure 1). In comparison, for medication-effectiveness indicators, the CVs of the two indicators were lower (0.29 for SABA over-use and 0.37 for anti-hypertensive under-use).

Performance across indicators: Among the 1799 pharmacies, 86% provided a sufficient number of services to assess performance on all four indicators. The rank order correlation among indicators was modest, varying from -0.01 (nonselective beta-blockers concomitant with SABA and over-use of SABA) to a high of -0.13 (over-use of SABA and under-use of anti-hypertensive medications).

Nine pharmacies performed in the lowest quartile on all four indicators, with an additional 95 pharmacies performing in the lowest quartile on three of four indicators. These pharmacies represent those that, in all likelihood, would be targeted for further evaluation by regulatory authorities. By contrast, three pharmacies were in the top quartile for all four indicators with another 79 pharmacies in the top quartile for three of four indicators. These pharmacies would be useful to determine predictors of best practice.

Table 3 Pharmacy-Specific Performance on *Quality-of-care* Indicators

	Breadth / Frequency of Performance				Pharmacy-Specific Performance on *Quality-of-care* Indicators			
	Pharmacies dispensing 5 or more times per year		Dispensings per year (N=54,045,097)		Indicator	Mean Annual Pharmacy-specific Rate of Inappropriate Dispensings		
	N	%[††]	N	%[‡‡]		Mean	SD	Range
Medication Safety								
Dispensings of benzodiazepines to seniors	1763	98.0	1,885,484	3.5	Seniors receiving flurazepam	4.3[§§]	3.1	0-42.5
Dispensings of beta-blockers to patients taking SABA	1730	96.2	398,177	0.7	Patients receiving non-selective beta blockers and SABA	15.2[***]	11.1	0-100
Medication Effectiveness								
Dispensings of SABA	1775	98.7	527,955	1.0	Patients over-using SABA	43.3[†††]	12.4	0-91.6
Dispensing of anti-hypertensive medications	1793	99.7	10,838,986	20.1	Patients under-using hypertension medications	10.7[‡‡‡]	4.0	0-70.0

†† Of all pharmacies dispensing medications in our sample (1799)
‡‡ Of all dispensings of medications to our population during 2002 (54,045,097)
§§ Median annual dispensing rate for flurazepam is 4.0%, interquartile range 2.5%-5.7%
*** Median annual dispensing rate for SABA and non-selective beta-blockers is 14.2%, interquartile range 8.3%-20.4%
††† Median annual dispensing rate for SABA over-use is 43.6%, interquartile range is 36.4%-50.7%
‡‡‡ Median annual dispensing rate for HTN under-use is 10.2%, interquartile range is 8.4%-12.2%.

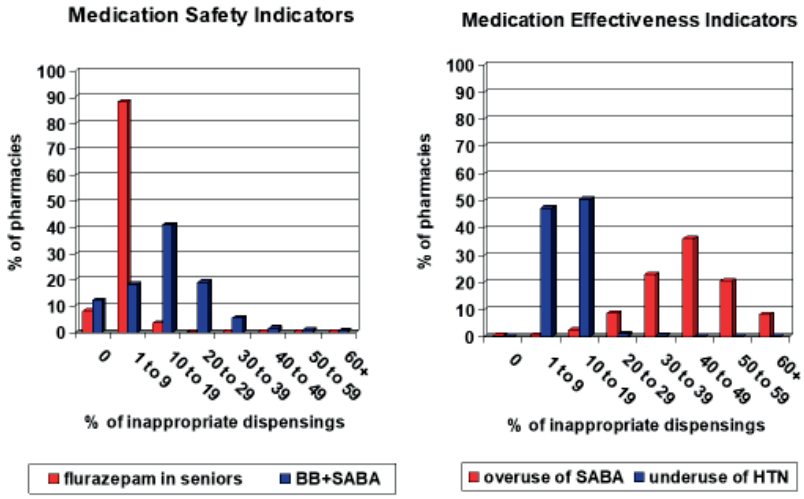

Figure 1: Distribution of Pharmacies by Performance on Safety and Effectiveness Indicators as Measured by Pharmacy Specific Percent of Inappropriate Dispensings

Discussion

This study evaluated all 1800 community pharmacies providing medications to 1.4 million people within the jurisdiction of one regulatory authority in Canada. We found that performance at community pharmacies could be measured on four quality-of-care indicators using pharmacy claims data. Over 85% of pharmacies provided services frequently enough to be reliably assessed on all four indicators. Proactive surveillance documented substantial variability in performance, with the best performance demonstrated on the indicator measuring rates of dispensing of contra-indicated benzodiazepines to the elderly, and the worst performance demonstrated on the dispensing of SABA to patients who were over-using this medication. Pharmacists at 5.3% (95/1799) of pharmacies underperformed on three of the four indicators.

This study is the first to be done in Canada that uses routinely available claims data to evaluate performance at community pharmacies. The PQA in the United States has completed a series of demonstration projects using administrative data from limited numbers of pharmacies (25 to 85 community pharmacies) to evaluate and report on pharmacy-based performance on quality indicators measuring similar medication use-problems (21). Similar to our results, these projects indicate that pharmacy claims data contain the information necessary to measure a number of quality-of-care indicators and that performance varies across pharmacies. Direct comparison of our results with those from the demonstration projects is difficult, since limited performance results have been published. However, differences in results are anticipated as our project used different definitions for some indicators. For example, for SABA over-use we used the Canadian

guidelines that define over-use as more than 250 doses in 90 days as prior research had shown that overuse of this magnitude is associated with an increased risk of asthma mortality (25-27). In contrast, the PQA defined over-use as more than 600 doses in 90 days. As a result of these differences in quality definitions, performance results would be worse in our study as compared to in the demonstration projects. To assess differences in jurisdictions and pharmacy policies, it will be essential to use common metrics for quality measurement.

Comparison of our results with those from the demonstration projects is also difficult as the PQA indicators use patients as the unit of analysis where we elected to use dispensings as the unit of analysis. Although number of patients could have been used in our study, by doing so we would have been unable to detect differences in pharmacies where, for example, a patient was compliant for 11 of 12 dispensings as compared to a pharmacy where the patient was compliant for none of the 12 dispensings. If patients had been used as the unit of analysis, both patients would have been classified as non-compliant for the year and the performance of the two pharmacies considered to be equal. To create a more sensitive measure of performance we, therefore, elected to use the number of dispensings as the unit of analysis. Use of dispensings versus patients would also be anticipated to result in a greater variability in performance across pharmacies, whereas use of patients as the unit of analysis would provide an estimate of the impact of pharmacy services in the population. Both approaches will be useful to evaluate in the future.

The results of our work have significant implications for regulatory authorities as the approach of using claims data to measure performance on quality-of-care indicators appears to be feasible and reveals substantial variability in the quality of care provided at community pharmacies. With greater demand for public accountability for the quality of health professional practice, regulatory authorities are moving from a passive complaints-based process for monitoring to proactive quality assurance. Currently, pharmacy regulatory authorities have adopted very resource-intensive processes such as on-site inspections or competence testing for assessing the quality of practice (28-30). Given limitations in availability of human resources, such processes are not able to ensure timely detection of potential performance problems that require further investigation. The ubiquitous availability of pharmacy claims data, and ultimately electronic health records, and the reliability of this data provides a new avenue for relatively inexpensive, proactive performance assessment by regulatory authorities (31). The methodologies for performance monitoring using billing and electronic health record data are being developed in a number of sectors such as pay-for-performance (32). Pharmacy regulatory authorities will be able to capitalize upon such advances while developing their performance assessment programs. These approaches may also be more acceptable to practitioners since they are based on actual performance data rather than artificial testing or inspection processes (16).

The main strengths of this study are the large and representative population of pharmacies studied and the measurement of quality indicators in comparable populations. Limitations that should be considered in interpreting the results are that only four indicators were evaluated that may not be representative of a pharmacy's quality of care, and the relationship between performance on the indicator and patient outcome was not ascertained. We were also missing data such as treatment indication, and patient age, sex and socioeconomic status, all of which could influence the types of drugs prescribed and their utilization. In future it would be preferable to retrieve information on these patient-related characteristics to statistically adjust for differences in clientele served by different pharmacies. In addition to these patient characteristics that may affect pharmacy-specific performance, pharmacy-level characteristics have also been shown to relate to the quality of care provided in community pharmacies (33). Future work should evaluate the influence of these pharmacy-level characteristics, such as pharmacy location, dispensing volume and staffing, on the quality of care provided at community pharmacies.

Our results confirm that patients present to community pharmacies with evidence of well-known medication use problems that are related to safe and effective use of medications. Patients at some pharmacies receive superior care and our methodologies could be used to evaluate the patient, pharmacy and prescriber-based characteristics that are associated with better care. There are many changes being made to the way services are being provided in community pharmacies such as regulation of pharmacy technicians, remote dispensing and deregulation of prescription medications. The utilization of pharmacy claims data provides unique opportunities to evaluate the influences of such policy changes.

Conclusion

Routinely collected pharmacy claims data can be used to monitor indicators of quality of pharmacy services, and may be useful in future to identify potentially underperforming pharmacists, measure the impact of policy changes and to determine predictors of best practices.

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Chapter 5

Optimising the changing role of the community pharmacist: a randomized trial of the impact of audit and feedback.

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BMJ Open, 2016;6:e010865

Introduction

Background: Policy makers continue to seek solutions that optimize the role of health care professionals in managing the increasing numbers of patients with medication-use problems and the health care costs associated with this misuse of medications (1). Internationally, community pharmacists are being recognized as a relatively untapped resource for improving patients' use of medications, leading to revisions in health care policies to expand the authority of pharmacists (2-4). As healthcare payers around the world implement schemes to reimburse community pharmacists for provision of these services, these payers are also seeking systems to evaluate both the quality of care provided and the impact of pharmacists' services on inappropriate use of medications (5-8). To enable such evaluations, nationally-endorsed quality of medication-use indicators have been developed for use as standardized measures of the outcomes of pharmacists' care (9-11). Systems are also being developed for pharmacists to be held accountable for achievement of defined performance on these indicators and healthcare payers are incorporating these performance measures into revised reimbursement schemes (12, 13). The Pharmacy Quality Alliance (PQA) in the USA has been instrumental in defining standardized quality of medication-use outcome measures that focus on patient adherence to medications, use of high-risk medications in the elderly, appropriate selection of medications for common diseases, management of drug interactions, appropriate dosing of high risk medications and completion of comprehensive medication reviews for at-risk patients (14). Methodologies have now also been developed to use community pharmacy billing data to measure and report community pharmacy-level performance on such quality of medication-use measures (14-16). Similarly, where there is appropriate documentation for reimbursement of pharmacists' service-provision, billing data-derived methodologies have been developed to objectively measure pharmacists' provision of expanded services in health care systems (16, 17).

Despite these advances, there is limited evaluation of the impact of pharmacists' expanded services on the quality of medication use (6). The Pennsylvania Collaborative project, a pioneer in this area, showed that pharmacists' screening of patients for risk of non-adherence and brief motivational counselling increased adherence to five classes of medications for management of chronic diseases (18). Pharmacists were supported by a combination of intensive direct training, audit and feedback of their performance on the quality of medication-use measures, regular on-site visits and telephone calls to support and sustain implementation of the service throughout the evaluation. Although the added costs of such resource intensive support can be maintained during research evaluations, it is challenging to incorporate these costs into a business model that enables sustainable, scalable provision of the service. Indeed, even with resource-intensive support during research trials, service provision by community pharmacists is often low and the limited numbers of new services delivered have been identified as a major challenge in community pharmacy research (19-22). It is, therefore, important to

evaluate if strategies that require less resources could both increase pharmacists' provision of expanded services and improve performance on quality of medication-use measures.

Audit and feedback to health care professionals of a summary of their clinical performance measured over a specified period of time has been shown to lead to small but potentially important improvements in care (23-25). For pharmacists, although feedback on performance with standardized patients has been piloted to improve quality of care, no studies have evaluated the use of audit and feedback alone to either increase pharmacists' provision of professional services or improve performance on standardized quality of medication-use measures (21, 26). If community pharmacy billing data are used to electronically provide real-time feedback, the use of such audit and feedback to community pharmacists is an attractive option. This is because electronic systems can be fully automated, reducing the resource requirements for adoption and sustainability. Such automated technologies have been introduced and adoption of these electronic performance dashboards has been rapid in the USA, with a wide range of pharmacies and health plans using the EQuIPP™ platform to audit and provide pharmacy-level performance feedback on PQA quality of medication-use measures (27-31). As there has been no evaluation of the impact of these technologies, what remains unknown is if performance feedback alone effectively improves both community pharmacists' provision of professional services and quality of medication use.

Objectives: The purpose of this study was to determine if comparative feedback to community pharmacists of their pharmacy's performance on quality of medication use by hypertensive and asthmatic patients increases provision of targeted pharmacists' services and performance on quality of medication-use measures.

Methods

Setting: This study was conducted in Canada, where the organizational structure of the health care system offers several advantages. First, all provinces offer publicly-funded health insurance programs that cover the drug costs and pharmacists' fees for prescription medications dispensed to seniors and the economically-disadvantaged. Second, consistent with healthcare policy trends in Australia, the UK and the Netherlands, over the past several years all Canadian provinces have expanded the authority and fee-for-service reimbursements for pharmacy services to community pharmacists (32, 33). Third, all provinces maintain central, electronic databases of information about the medications dispensed and services provided if they are reimbursed by the publicly-funded insurance program. Although varying in format and level of detail across the provinces, the information retained in the community pharmacy billing databases is sufficiently detailed to allow measurement of both the provision of reimbursable

pharmacists' services targeted at managing specific medication-use problems as well as the patients' quality of medication-use (15). These electronic databases provide ready access to the information required to both audit performance and prepare feedback reports to community pharmacists.

The province of Quebec is the largest in Canada, with a population of 8 million patients of whom approximately 3.5 million receive government support for payment of their medications via the Régie de l'Assurance Maladie du Québec (RAMQ). Medication-related data maintained by the RAMQ includes payments made for reimbursable medications and for provision of defined pharmacist services that aim to resolve specific medication-use problems. Similar to many developed countries, the date, name, strength, dosage form and quantity of the dispensed medication, prescriber, pharmacist and pharmacy identification, and associated costs are recorded. Reimbursable medications include over 85% of medications available in Canada. For reimbursable pharmacists' services, the date, type of pharmacists' service provided (e.g. refusal to dispense, review and recommendations for changes in therapy to the prescribing physician, initiation of therapy) and the medication-use problem the service was meant to resolve are recorded in a coded format. The Quebec Order of Pharmacists, the provincial authority who regulates the performance of more than 5000 community pharmacists in over 1800 community pharmacies, is authorized to access the information contained in the electronic databases as part of their mandate to ensure the quality of care provided by community pharmacists.

Trial Design: A single-blind, randomized controlled trial was conducted to determine the effect of comparative feedback of pharmacy-specific performance on two quality of medication-use measures related to medication adherence. Outcomes were measured and compared between the intervention and control groups in the 12 months post intervention. A 2X2 factorial design also allowed estimation of the cumulative effect of receiving sequential feedback on the two measures. There are approximately 1800 community pharmacies in the province of Quebec. A sample of this size was expected to detect an absolute difference of 7% in the pharmacy-level percentage of dispensings to nonadherent patients, assuming a Type I and II error of 5% and 20% respectively. The McGill University Faculty of Medicine Institutional Review Board provided ethics approval.

Data sources: To assess the impact of relative performance feedback, we received anonymized pharmacy billing data from RAMQ for all Quebec community pharmacies every six months starting January 2010 until September 2012. This data provided all billings for dispensings of antihypertensive and asthma medications and provision of community pharmacists' services over the time period of October 1, 2008 to April 30, 2012. Each pharmacy was assigned a unique encrypted identifier by RAMQ that enabled all activity within a pharmacy to be measured by the investigators, without revealing the identity of the pharmacy.

Participants: All community pharmacies were advised about the study through communications from the pharmacy regulatory authority and were provided with the opportunity to opt out of participating. Community pharmacies were eligible if they had dispensed the targeted medications more than five times during the baseline period.

Intervention: Pharmacy-specific performance on two quality of medication-use measures was calculated using previously-described methods (15). Quality measures included were pharmacy-specific rates of dispensing: 1. antihypertensive medications to non-adherent patients, defined as those who had used less than 80% of their required medication over the previous 90 days, and; 2: Short acting beta agonists (SABA) to patients with demonstrated over-use of these medications (defined as more than 200 doses of SABA over the previous 90 days). Feedback reports of comparative performance on each quality of medication-use measure were generated and mailed once to the intervention pharmacies. Reports provided a graphic and numeric display of performance at the pharmacy on the quality measure over a six-month baseline in relationship to the performance at all other pharmacies in the province (Figure 1a*). Specific colour coding was assigned for each quartile of performance and the report recommended how pharmacists could provide and bill for professional services to address the relevant medication-use problem (Figure 1b). Feedback reports were developed in conjunction with the Quebec Order of Pharmacists and included review by practising pharmacists. Design of the feedback reports was based, with permission, on the Pharmaceutical Society of Australia's Targeted Interventions publications (34). The graphical representation of performance was derived from the best practices used at the time by the Quebec College of Physicians within their practice enhancement program (35).

Outcomes: The impact of feedback was measured by two outcomes in the 12 months post intervention: 1) the pharmacy-specific number of billings for pharmacists' services for management of the specific medication-use problem and 2) the pharmacy-level percentage of dispensings to patients nonadherent with their hypertension and asthma medications respectively. Total numbers of all pharmacists' expanded services billed were also calculated to determine if the feedback lead to a general change in provision of pharmacists' services or a change in services targeting the specific medication use problems addressed in the feedback reports.

Randomization: Pharmacies that did not opt out were randomized sequentially, using a random numbers table by the statistician, starting with the hypertension non-adherence measure. Six months later pharmacies were randomized again to receive feedback or not on the asthma measure. Sequential randomization ensured that the dual intervention group was not receiving feedback on two quality indicators at the same time, which could have diluted pharmacists' efforts to improve their performance. Sequential randomization also allowed evaluation of the impact of repeated provision of feedback as pharmacies fell

* An English translation of the feedback reports, which were provided to pharmacies in French.

into one of four feedback groups: no performance feedback; hypertension alone; asthma alone, and; both hypertension and asthma feedback.

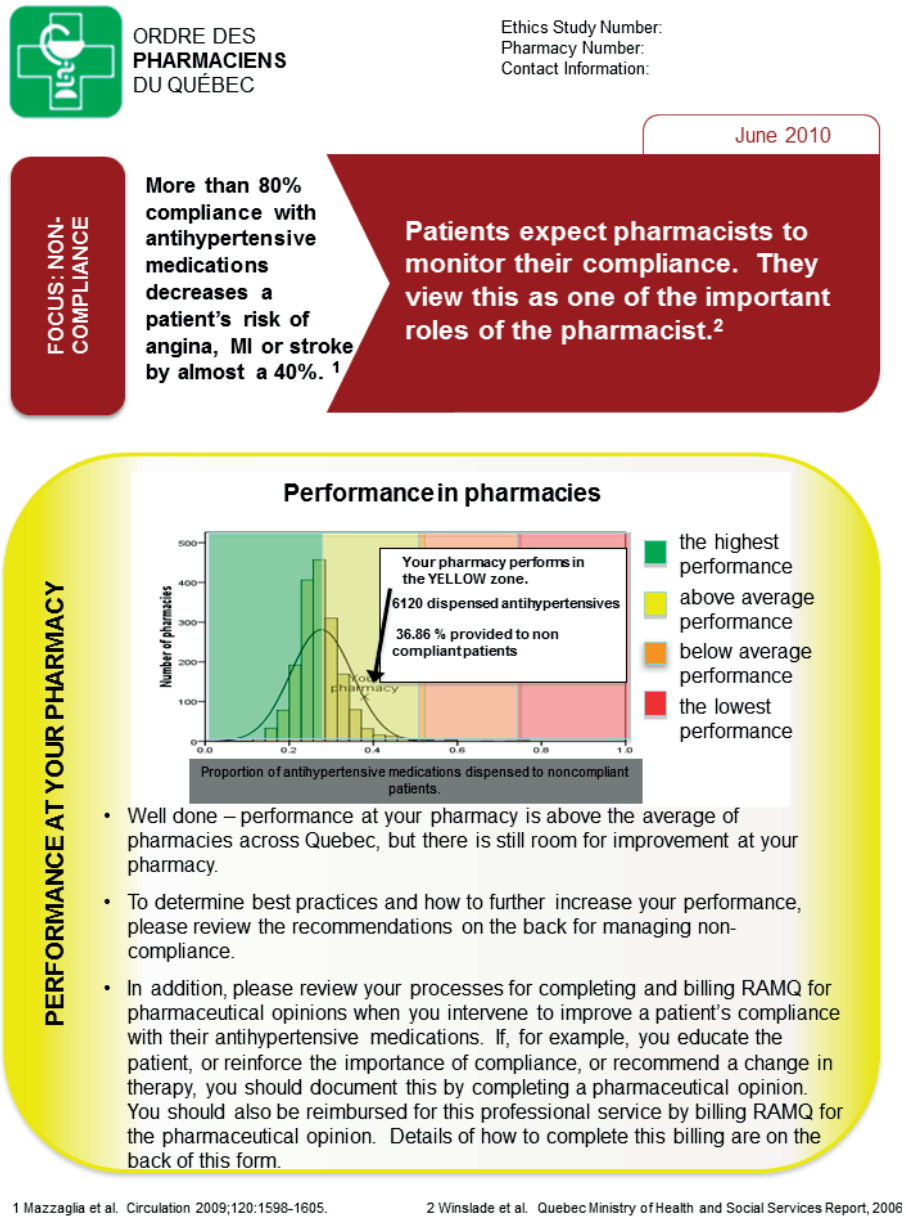
Blinding: Reports were prepared for each intervention pharmacy, identified to the research team by anonymized study pharmacy number only. The pharmacists' regulatory authority served as a trusted third party to retain the look-up codes provided by RAMQ that linked the anonymized pharmacy study number with the real pharmacy name and address. Feedback reports were provided to the regulatory authority in sealed envelopes labelled only with the anonymized study pharmacy number and in this manner confidentiality of results was maintained. Consistent with the ethics approval requirements, control pharmacies received their relative performance feedback reports upon completion of the study.

Statistical Methods: For each quality of medication-use measure, Poisson regression with the log link function and adjustment for baseline performance was used to determine the impact of performance feedback on the number of pharmacists' services billed for managing noncompliance with antihypertensive medications and SABA respectively, and the impact on the number of all pharmacists' services billed in the follow-up period. Setting control pharmacies as the reference, exponentiation of the estimate allowed calculation of the relative risk of intervention pharmacies billing for pharmacists' services during the follow-up period as compared to control pharmacies. Negative binomial regression was also used as a sensitivity analysis to correct for over-dispersion.

Generalized linear regression with adjustment for baseline performance was used to test for differences between pharmacies receiving performance feedback and controls in the percent of dispensings that were provided to nonadherent patients during the follow-up period. Given that results were bounded between 0 and 100, the binomial distribution was used. The log link function was selected to enable calculation of the relative risk of intervention pharmacies dispensing medications to nonadherent patients during the follow-up period as compared to control pharmacies (36). To test whether changes in performance in response to feedback were modified based on baseline level of performance, pharmacies were divided into quartiles according to their performance in the baseline period. Setting the lowest performing quartile as the reference (ie the quartile of pharmacies with the highest percent of dispensings provided to nonadherent patients), differences between intervention and control pharmacies were compared among quartiles. To determine if there was a cumulative effect of feedback we used a generalized linear regression model with binomial distribution, log link function and dummy variables to evaluate changes in performance on the asthma quality measure if pharmacies received no feedback, feedback only for hypertension, feedback only for asthma, or feedback for both asthma and hypertension. The four dummy variables represented the four intervention groups with the no feedback intervention being the reference. These analyses allowed determination of whether: feedback was effective in producing a change in performance; change in performance was greater depending on initial levels of

performance, and: if there was increasing change in performance in response to receipt of repetitive performance feedback on multiple quality of medication-use measures.

Figure 1a and 1b. Sample Feedback Report



ORDRE DES
PHARMACIENS
DU QUÉBEC

Ethics Study Number:
Pharmacy Number:
Contact:

GOOD PERFORMANCE

What is considered Best Practice?

Pharmacists should evaluate a patient's compliance each time (s)he requests a refill for a chronic medication. Every refill request by a non-compliant patient provides the pharmacist an opportunity, and an obligation, to intervene to improve compliance. In Quebec, for patients whose medications are paid for by RAMQ, pharmacists are reimbursed for completing pharmaceutical opinions to fulfill this professional role. You can bill a maximum of two opinions for non-compliance with antihypertensive medications per year per patient. POs can be provided to non-RAMQ insured patients but there is no reimbursement for these PO.

For RAMQ insured patients we have calculated the percentage of times that pharmacists in your pharmacy dispensed antihypertensive medications to non-compliant patients over a six month period. Your results are compared with the average results of the almost 1800 community pharmacies across Quebec. These results are shown on the graph.

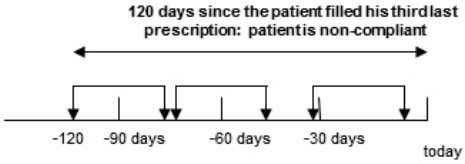
The performance at your pharmacy relative to other pharmacies provides a starting point for you and your team to identify factors that may be influencing the management of patient non-compliance in your pharmacy. Analyze these factors and develop a plan that aims a best practice.

SOLUTIONS FOR YOUR QUALITY OF CARE

What you can do to improve your performance?

1. Improve Detection of Non-compliant Patients

Each time a patient requests a refill for an antihypertensive medication, determine if (s)he has received at least 90 days worth of the required medication over the last 108 days (80% of required dose). For patients receiving 30 day supplies, the easiest way to do this is to determine the date that the patient was dispensed the **third previous** refill (3 x 30 days supply). If it has been more than 108 days since that date then the patient is considered non-compliant. In the example below, the patient requests a refill today and you last dispensed this same medication 32 days ago. The second last dispensing was 75 days ago, and the third last dispensing was 120 days ago. Therefore, since it has been more than 108 days since the third last refill, then he is considered non-compliant. **Important**: If the patient did not start taking the medication at least 108 days ago they are not eligible for a pharmaceutical opinion for management of non-compliance with this medication.



2. Provide the Relevant Professional Service

Talk with the patient to determine their reason for non-compliance and use your professional judgement to determine the most appropriate intervention to improve compliance. Common reasons include misunderstanding, adverse effects or belief that they do not need the medication. Provide them with appropriate documentation of your intervention.

3. Document and Bill

Complete a pharmaceutical opinion and send it to the prescribing physician.

Results

Study Participants: Of the 1833 eligible community pharmacies, 19 opted out of the audit and feedback study (e-Appendix Consort Flow Diagram). All 1814 pharmacies had sufficient dispensings of antihypertensive medications over the baseline period to be included in the hypertension intervention. Of the 1814 pharmacies, 1598 had sufficient SABA dispensings over the baseline to be included in the asthma randomization.

For the 12-month follow-up, 1422 of the 1814 pharmacies had complete information provided from RAMQ for the hypertension intervention (N=706 intervention, N=716 control), and 1301 of the 1598 pharmacies for the asthma intervention (N=657 intervention, N=644 control). Lack of complete data occurred when the coded pharmacy identifier was not found in the billing data during the follow-up period. Changes in pharmacy identifiers occur when pharmacies close or undergo a change in ownership or management, thereby accounting for attrition over time.

Baseline Characteristics: Intervention and control pharmacies had baseline patient populations that were comparable in their characteristics known to influence medication adherence such as patient age and sex, or in the use of multiple medications, multiple prescribing physicians or multiple dispensing pharmacies (Table 1) (37). Intervention and control pharmacies were also comparable in their baseline performance on the quality of medication-use measures and provision of pharmacists' services, including those targeted at managing the specific medication-use problems. The 216 pharmacies excluded from the asthma randomization due to dispensing of low numbers of SABA during the baseline period also had low total numbers of dispensings and pharmacists' services, and fewer pharmacists employed, over the six-month baseline period. Pharmacies without complete information during follow-up (hypertension n=392, asthma n=297) were comparable to the pharmacies with complete information for the respective intervention.

Table 1. Baseline characteristics of participating community pharmacies

	Managing Noncompliance in Hypertensive Patients		Managing Medications in Asthma Patients	
Number of Pharmacies	Control N=716	Intervention N=706	Control N=644	Intervention N=657
Characteristics	**N (%)**	**N (%)**	**N (%)**	**N (%)**
Total number of dispensings of targeted drugs during baseline	387,287 (50.1)	385,829 (49.9)	87,908 (48.9)	91,797 (51.1)
Pharmacy Clients[†]				
Sex				
Female	214,967 (55.5)	214,323 (55.5)	50,143 (57.0)	52,676 (57.4)
Male	172,320 (44.5)	171,506 (44.5)	37,765 (43.0)	39,121 (42.6)
Age				
< 65 years	385,589 (99.6)	384,168 (99.6)	74,467 (84.7)	77,905 (86.8)
65-69	593 (0.2)	646 (0.2)	2,388 (2.7)	2,642 (3.2)
70-79	860 (0.2)	768 (0.2)	4,709 (5.4)	2,872 (3.2)
>79	245 (0.1)	247 (0.1)	6,344 (7.2)	6,378 (6.9)
Drug Therapy for Condition				
New Therapy (< 6 months)	77,334 (20.0)	77,726 (20.1)	6,472 (7.4)	6,810 (7.4)
Chronic Therapy (≥6 months)	309,953 (80.0)	308,103 (79.9)	81,436 (92.6)	84,987 (92.6)
Single Drug	178,953 (46.2)	178,863 (46.4)	86,217 (98.1)	89,978 (98.0)
Multiple Drugs	208,334 (53.8)	206,966 (53.6)	1,691 (1.9)	1,819 (2.0)
Prescription duration < 2 months	374,740 (96.8)	373,609 (96.8)	87,059 (99.0)	90,852 (99.0)
Prescription duration ≥2 months	12,547 (3.2)	12,220 (3.2)	849 (1.0)	945 (1.0)
Single Pharmacy Dispensed	346,442 (90.4)	346,606 (89.8)	77,616 (88.3)	80,611 (87.8)
Multiple Pharmacies Dispensed	40,845 (9.6)	39,223 (10.1)	10,292 (11.7)	11,186 (12.2)
Single Prescriber	326,482 (84.3)	325,716 (84.4)	76,998 (87.6)	80,185 (87.4)
Multiple Prescribers	60,805 (15.7)	60,113 (15.6)	10,910 (12.4)	11,612 (12.6)
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Pharmacy characteristics				
Total number of Prescriptions/day	264 (189.2)	262 (189.9)	270 (186.5)	275 (204.5)
Number of pharmacists employed over 6 months	8.1 (5.7)	8.3 (5.9)	9.1 (6.4)	9.3 (6.7)
Pharmacists' Performance and Provision of Professional Services				
Performance on quality measure (% dispensings to nonadherent patients)	27.2 (4.6)	27.4 (5.1)	48.1 (12.0)	48.3 (11.9)
Number of pharmacist services for medication-use problem[‡]	0.7 (3.4)	0.7 (2.6)	0.1 (0.5)	0.2 (0.9)
Number of all pharmacist services per 100 prescriptions	0.2 (0.2)	0.2 (0.1)	0.2 (0.1)	0.2 (0.1)

† Considering all dispensings included in the calculation of performance on relevant indicator.

‡ As a majority of pharmacies did not bill any pharmacist services targeted at the medication-use problem, the average number billed is less than 1.

Impact of Audit and Feedback: For the first outcome measure of the number of pharmacists' services billed for managing the targeted medication-use problem, pharmacists receiving asthma feedback had 1.6 times the chance of billing for services recommending changes to patients' asthma medications as compared to pharmacists not receiving asthma feedback (control 0.2, intervention 0.4, RR 1.58 95% CI 1.02-2.46) (Table 2). Of interest, during the same period control pharmacies billed more pharmacists' services for all medications compared to intervention pharmacies (control 39.8, intervention 38.9, RR 1.17 95% CI 1.00-1.37), suggesting the intervention effect was specific to asthma management.

The same trends were seen for the hypertension feedback with intervention pharmacists billing more services to improve compliance with antihypertensive medications despite billing for fewer pharmacists' services overall, but the differences were not statistically significant (HTN pharmacist services, control 0.7, intervention 0.8, RR 1.25 95% CI 0.86-1.82; all pharmacist services, control 30.5, intervention 27.4, RR 1.05, 95% CI 0.89-1.23).

For the second outcome measure of the pharmacy-level percent of dispensings to non-adherent patients, baseline performance on each measure was a significant predictor of performance in the follow-up period, so all analyses were adjusted for prior performance (Table 3). Feedback on hypertension performance had no impact on the follow-up performance over 12 months (control 27.9%, intervention 28.0%, RR 1.0 95% CI 0.99-1.00) (Table 3). Similarly, for asthma performance, 12 month follow-up performance was virtually identical in control and intervention pharmacies (control 45.5%, intervention 44.6%, RR 0.99 95% CI 0.98-1.01). The impact of hypertension performance feedback differed significantly among the quartiles of pharmacies, but there was no trend for feedback to have a greater impact on pharmacies with lower initial levels of performance (Table 3). Although the quartile of pharmacies performing the worst on the asthma measure demonstrated the largest improvement in performance post feedback (control 55.5% of dispensings to SABA-overuse patients compared to intervention 52.9% of dispensings to SABA-overuse patients), there were no statistically significant differences in the response to asthma feedback among the quartiles.

There was no evidence of a cumulative effect of providing comparative feedback on more than one quality measure (Table 4). There were no significant differences in medication use measures among pharmacies who had received no feedback, feedback only on hypertension non-adherence, feedback only on the asthma management, or feedback on both. In relationship to asthma pharmacy services, the group receiving no feedback billed the lowest number of pharmacists' services for asthma management. Pharmacies who received feedback for both conditions did not bill for significantly more asthma services relative to the pharmacies who received no feedback. However, pharmacies who received only asthma feedback had more than a two-fold chance of billing for asthma services compared to no feedback (no feedback 0.18, asthma-only feedback 0.46, RR 2.28 CI 1.19-4.39). These higher billings for asthma services occurred

despite significantly lower billings for all pharmacists' services, again supporting that the intervention effect was specific to asthma management.

Discussion

Statement of Principal Findings: A population-wide randomized intervention trial of audit and feedback to more than 1400 community pharmacies documented that the provision of comparative performance feedback alone led to a significant increase in the number of pharmacists' services billed for management of asthma. However, audit and feedback had no impact on the provision of pharmacist services for managing noncompliance with antihypertensive medication, or on the overall performance on quality of medication-use measures related to nonadherence in patients with asthma or hypertension.

Table 2 Impact of Single Provision of Relative Performance Feedback on Provision of Pharmacists' Services over 12-month Follow-up

	Managing Noncompliance in Hypertensive Patients					Managing Medications in Asthma Patients				
	Control N=716	Intervention N=706		Poisson Regression		Control N=644	Intervention N=657		Poisson Regression	
	Mean Count (SD)	Mean Count (SD)	Difference	Relative Risk* (95% CI)	P value	Mean Count (SD)	Mean Count (SD)	Difference	Relative Risk* (95% CI)	P value
Pharmacists' Services for Targeted Medication Use Problem†	0.7 (3.3)	0.8 (2.7)	0.1	1.25 (0.86-1.82)	0.25	0.2 (1.0)	0.4 (1.6)	0.2	1.58 (1.02-2.46)	0.04
Pharmacists' Services for all Medication-Use Problems	30.5 (70.1)	27.4 (58.8)	-3.1	1.05 (0.89-1.23)	0.58	39.8 (80.7)	38.9 (70.6)	-0.9	1.17 (1.00-1.37)	0.05

* Relative Risk of intervention pharmacies billing for the service during the follow-up period as compared to control pharmacies.

† As a majority of pharmacies did not bill any pharmacist services targeted at the medication-use problem, the average number billed is less than 1.

Table 3 Impact of Single Provision of Relative Performance Feedback on Patient Quality of Medication Use over 12-month Follow-up

	Managing Noncompliance in Hypertensive Patients‡					Managing Medications in Asthma Patients§				
	Control N=716	Intervention N=706		GLR**		Control N=644	Intervention N=657		GLR**	
	Mean % (SD)	Mean % (SD)	Difference In percent	Relative Risk (95% CI)	P	Mean % (SD)	Mean % (SD)	Difference In percent	Relative Risk (95% CI)	P
All pharmacies	27.9 (5.1)	28.0 (4.4)	0.1	1.0 (0.99-1.00)	0.59	45.5 (12.9)	44.6 (13.2)	-0.9	0.99 (0.98-1.01)	0.42
By performance during baseline										
Worst quartile	31.8 (4.2)	32.2 (3.7)	0.6	reference		55.5 (11.3)	52.9 (14.0)	-2.6	reference	
Second quartile	28.6 (2.1)	28.5 (2.9)	-0.1	0.98 (0.97-1.00)	0.01	47.5 (8.7)	45.8 (10.8)	-1.7	0.98 (0.96-1.01)	0.28
Third quartile	26.3 (2.4)	26.9 (2.9)	0.3	0.97 (0.96-0.99)	<0.001	43.0 (10.7)	44.0 (8.5)	1.0	0.98 (0.95-1.02)	0.41
Best quartile	24.9 (7.4)	24.1 (3.3)	-0.8	0.94 (0.92-0.96)	<0.001	36.5 (12.6)	35.5 (12.3)	-0.9	0.97 (0.91-1.03)	0.29

‡ Calculated as percent of all dispensings of antihypertensive medications that were provided to patients documented to have taken less than 80% of the prescribed dose over the previous 90 days.

§ Calculated as percent of all dispensings of SABA that were provided to patients who had used more than 250 doses in the previous 90 days.

** Generalized linear regression using binomial distribution and log link function.

Table 4 Impact of Repeated Provision of Relative Performance Feedback on Patient Quality of Medication Use over 12-month Follow-up

	Pharmacies *N*	Managing Medications in Asthma Patients			Pharmacist Services billed for SABA Overuse			Total Pharmacist Services billed for all Medication-Use Problems		
		Mean % (SD)	Generalized Linear Model		Mean number Billed (SD)	Poisson Regression		Mean number Billed (SD)	Poisson Regression	
			Relative Risk†† (95% CI)	P value		Relative Risk‡‡ (95% CI)	P value		Relative Risk‡‡ (95% CI)	P value
No performance feedback	323	46.4 (12.5)	reference		0.18 (0.62)	reference		41.51 (83.28)	reference	
Performance feedback on Hypertension Non-compliance, asthma control	321	44.5 (13.1)	0.99 (0.97-1.02)	0.48	0.30 (1.19)	1.60 (0.80-3.20)	0.19	38.03 (78.12)	1.18 (0.94-1.48)	0.14
Performance feedback on asthma management, Hypertension Non-compliance control	328	44.1 (12.5)	0.99 (0.97-1.02)	0.64	0.46 (1.85)	2.28 (1.19-4.39)	0.01	40.35 (79.93)	1.33 (1.06-1.66)	0.01
Performance Feedback on both Hypertension Noncompliance and Asthma Management	329	45.1 (13.8)	0.98 (0.96-1.01)	0.18	0.34 (1.31)	1.84 (0.94-3.60)	0.08	37.37 (59.95)	1.22 (0.98-1.53)	0.08

†† Relative risk of pharmacies in the respective intervention group dispensing a SABA during follow-up to a patient who had used more than 250 doses in the previous 90 days relative to pharmacies receiving no feedback on either measure.

‡‡ Relative risk of pharmacies in the respective intervention group billing for provision of pharmacist services during follow-up relative to pharmacies receiving no feedback on either measure.

Strengths and Limitations: The main strengths of this study are the large sample of pharmacies and the use of objective outcome measures. In particular, the ability to objectively measure the pharmacists' provision of targeted services allowed evaluation of the value of pharmacists' provision of these services (21). At present there is little literature available that evaluates pharmacists' services, and in turn there is limited evidence to guide policy-decisions (6, 38). This has led to substantial variability across and within countries as to the services community pharmacists are authorized and reimbursed to provide (2, 6, 33). Mossialos and colleagues recognized the inherent difficulties of completing robust evaluations of the impact of expanded pharmacists' services and similar concerns lead to Patwardhan's conclusion that evaluations must include objective measures of both pharmacists' service provision and standardized outcome measures (6, 21). Since this study included these two objective measures, the impact of pharmacists' services could be evaluated. As many provinces and countries continue to expand the services pharmacists are authorized to provide, while creating and maintaining electronic databases to document and reimburse these services, the methodologies from this study could be used to evaluate the value and impact of these expanding services. Limitations include that we evaluated performance on only two quality of medication-use measures that differed in the medication-taking behaviours targeted (increased use of anti-hypertensive medications versus decreased use of asthma rescue medications). These two measures may not be representative of overall performance at a pharmacy and ongoing analysis is evaluating if the predictors of performance are consistent for the two different medication-taking behaviours targeted in our study. In addition, administrative databases are limited in the extent to which they can measure whether pharmacists provided a service but did not bill for it, if patients actually consumed dispensed medications or the impact of the feedback and pharmacist's services on patient health and wellbeing (39-41).

Interpretation: Our results of the impact of audit and feedback are similar to those reported for other health professions that indicate variable impact of provision of feedback on performance (23-25). Criteria for effective use of feedback to improve performance have been defined, and begin with the recipients having confidence that the performance being measured is important, within their professional scope of practice and amenable to change by the services or care they provide (42). Recipients must also be convinced that the feedback is based on valid, reliable measures of performance and be able to understand the feedback provided (23). The opportunity to discuss their relative performance with the feedback providers enables thoughtful reflection, which is proposed to be instrumental to the integration of external feedback with self-perceptions of performance, and subsequent acceptance, use and integration of feedback to improve performance (42, 43). These latter steps require that recipients believe that performance improvement is possible, understand how to improve their performance, set performance goals and plan/take action to improve performance (42).

For the current study, management of patient's adherence to antihypertensive and asthma medications is readily identified as important and a core responsibility of pharmacists, thereby supporting pharmacists' acceptance of the significance of the performance feedback (44). Confidence in the measures reported was increased through the use of objective measures from pharmacy billing databases, rather than subjective self-reports, of both service provision and patient outcome. Collaboration with the provincial regulatory authority also increased pharmacists' acceptance of the fairness and credibility of the outcome measures and reports. Initial work of the PQA documented that pharmacists are able to understand performance feedback that is based on medication-adherence reports, although they are less certain how they can improve their performance (27, 45). Feedback that is associated with increased acceptance and incorporation into practice improvement is timely, individualized, consequential but non-punitive and "actionable", which support recipients' understanding of how to improve their practice (23, 42). The asthma reports in our study provided specific advice to review the use of inhaled corticosteroids and prepare a recommendation for adding these medications if appropriate. It may be that this recommendation was more actionable, leading to the increase in billing of pharmacists' services for asthma management.

The low numbers of pharmacists' services billed during the follow-up period of our study is consistent with existing literature (21, 46). Both these low numbers and the overall limited impact of our performance feedback on billing of pharmacists' services targeted at managing patient nonadherence could be explained if pharmacists did not believe that the current process of providing written recommendations to the prescriber is an effective means of improving patient adherence (47). Our results that increasing numbers of asthma-related recommendations did not lead to improved adherence supports this notion. The origins of pharmacists billing for medication-related recommendations in Quebec dates back to 1978, with a goal of promoting the optimal use of medications (48). Pharmacists experienced in providing pharmaceutical opinions over the subsequent five years concluded that these written opinions were a good means of communication about a range of medication-related problems encountered in community pharmacy (49). Policy reviews in 1983 and 1992 aimed to focus the process on provision of patient-specific recommendations and to decrease the administrative burden for pharmacists (48). The current process requires that pharmacists send their written treatment recommendations to the original prescriber, who receives them at a variable time point after having seen the patient – and when the patient is not present for further consultation. As no direct discussion or follow-up between the pharmacist and prescriber is required, the prescriber's response to the recommendation, actions taken with the patient to address medication adherence, and the patient's response to these actions are not communicated to the pharmacist. These numerous steps, delays and lack of direct discussion all have the potential to decrease the likelihood that the pharmacist's written recommendations will have an impact on patient's medication use. It would be valuable to determine the impact of audit and feedback when pharmacists' services

involve direct communication with prescribers or where pharmacists are authorized and reimbursed to take direct actions with patients to resolve their medication-use problems (50). The recently expanding scope of practice in a number of jurisdictions, including Quebec, that authorizes pharmacists to modify prescription drug therapy offers rich combinations of advanced pharmacists' services and detailed administrative billing databases that could serve as an ideal site for such evaluations (51, 52).

An additional factor that could have led to low impact of the performance feedback is that the pharmacists were not provided the opportunity to discuss or reflect on their performance. Changes in the role of pharmacy practice inspectors to function primarily as practice mentors are providing opportunities for future studies to evaluate the impact of peer discussion in combination with performance feedback (53). Finally, when placed in the larger context of the factors known to influence pharmacists' provision of professional services, it may be that lack of awareness of their relative performance is not a primary factor influencing pharmacists' service provision. Consistent with the theory that there are multiple barriers and facilitators to provision of pharmacists' professional services, feedback of relative performance may be insufficient to overcome the more significant barriers related to, for example, relationships with prescribers, remuneration, insufficient time and lack of management support (46, 54-56).

Implications and Future Research: Given the evidence that provision of targeted pharmacists' services did not lead to improvements in medication use, modifications in the services provided by pharmacists and the associated required processes should be considered. Such modifications should be grounded in a conceptual framework that incorporates the theories of factors influencing pharmacists' professional practice and the evidence supporting these theories (57). To date, much of community pharmacy practice research has focused on single influencers such as pharmacist competence, pharmacist motivation or reimbursement (5, 58). Integrated frameworks that consider the range and source of influencers, including patient and context factors, may be more useful for understanding pharmacists' practice and developing services that are both effective at improving patients' medication use and sustainable within the community pharmacy environment (46, 59, 60). Future research should also focus on using objective measures and strong methodologies to evaluate the effectiveness of services that are reimbursed – both new and old – to optimize reimbursement of services that have a meaningful impact on health outcomes. Such research is of importance as provinces, countries and private insurers consider the value offered by community pharmacists' provision of targeted professional services.

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Chapter 6

Determinants of community pharmacists' quality of care: a population-based cohort study using pharmacy administrative claims data.

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BMJ Open, 2017;6: e015877.

Introduction

Background: Misuse of prescription medications, ranging from inappropriate prescribing to patient non-adherence, remains a significant and costly challenge to health systems (1). The medication-related expertise and accessibility of community pharmacists has led policy-makers to re-evaluate the role community pharmacists play in managing medication misuse (2, 3). Emphasis has been placed on the care provided by pharmacists both as part of medication-dispensing and via expanded professional services that target specific medication-misuse problems (4, 5). Although such care can improve patient's medication use, community pharmacists struggle to incorporate expanded professional services into their daily practice (6, 7). As a result, payers continue to seek evidence of the real-world impact of community pharmacists' services on medication misuse (4, 8, 9), and quality indicators of unsafe or interacting medications and management of non-adherent patients have been established as standardized outcome measures of pharmacists' quality of care (10-12). The services pharmacists provide to achieve high performance on these quality indicators can vary across jurisdictions (5). Developments in the use of community pharmacy administrative claims data have enabled the measurement of both pharmacy-level performance on these standardized quality indicators and the impact of pharmacists' professional services on patient outcomes (13, 14).

To date there has been no precise methods of determining pharmacy-level characteristics that consistently support high levels of pharmacists' performance and that could inform directions for pharmacy policy. Pharmacy characteristics such as workload, continuity of care, culture, workflow and overlap of pharmacists have been evaluated through self-report and with varying definitions of quality performance (15-17). The few studies that used standardized quality measures employed a potentially biased ecologic approach to estimate pharmacy characteristics by determining a population-based quality metric in the geographical area and then assigning these population-based results to all pharmacies within that area (18-21). More robust methodologies are needed to measure the characteristics of the patient, pharmacy and workload situation when the patient receives the medication (22).

One potentially powerful option is to use pharmacy administrative claims data to measure salient pharmacy characteristics. To date use of such data has been limited to identifying whether the pharmacy is a chain or independent, and the volume of dispensing (20, 23). This is primarily due to challenges in using the large volume of pharmacy administrative data to create accurate measures, as well as challenges linking pharmacy claims data to other health administrative databases to obtain information on patient and pharmacy characteristics. Increasingly these linkages have been enabled through interest by payers in monitoring performance and researchers in conducting population-based studies (24, 25). We developed a framework for pharmacists' services evaluation that uses linked pharmacy administrative claims and health administrative

data to measure and feedback pharmacy-level performance on quality indicators, followed by diagnostic on-site assessments of lower performing pharmacies (26). The objective of this study was to determine if the linked administrative health data used within this prototype pharmacists' services evaluation program could be used to identify characteristics of pharmacies providing higher quality of care.

Methods

Setting: This study was conducted in Quebec, with a population of 8 million patients of whom approximately 3.5 million receive government support for payment of their medications via the Régie de l'Assurance Maladie du Québec (RAMQ). Since the late 1970s Quebec pharmacists have been authorized to bill RAMQ for professional services such as refusals to dispense medications and written pharmaceutical opinions for management of specific medication-use problems (27, 28). RAMQ requires the date, hour, drug identification number, therapeutic drug class, dosage form, strength, quantity, duration of treatment, specific type and reason for the pharmacist service (e.g. previous adverse effect or management of under-use of antihypertensive medications), and costs to RAMQ, the patient and for the overall prescription. All data are coded and can be linked to other health administrative data using unique encrypted identifiers for patients, prescribers, pharmacists and pharmacies. For patients, age, sex, postal code and average household income are recorded. For pharmacies, the location (e.g. shopping centre), and type of pharmacy (independent or not) are maintained, along with the specific chain or banner to which the pharmacy belongs.

Study Design: A population-based prospective cohort of patients was assembled for whom Quebec pharmacists billed for dispensings of antihypertensive medications between November 1, 2009 to June 30, 2010. A dispensing was defined as the preparation and provision of medications to a patient pursuant to a prescription, regardless of quantity of medication dispensed. Each time there was a dispensing for an antihypertensive medication we determined whether the dispensing was to a patient who was adherent or not over the 90 days prior to the dispensing. Characteristics of each dispensing, the patient and the pharmacy were measured and a multi-level model used to identify predictors of dispensing to a non-adherent patient.

Participants: All 1891 pharmacies in Quebec were included unless they had opted out of participating in a previously reported randomized controlled trial, were open < 61 days, or had dispensed >165,317 prescriptions over the eight-month study period, which represented outliers with Z-scores >2.5 (14, 29). Pharmacies with shorter open-days did not have sufficient data for reliable calculation of characteristics and very high dispensing volumes were not representative of traditional community pharmacy practice in Quebec.

We had sufficient sample size to have 90% power to detect a difference in antihypertensive adherence of 5% for most potential predictors.

Primary Outcome: The primary outcome was whether a dispensing of an antihypertensive medication was provided to an adherent or non-adherent patient. Antihypertensive adherence was selected for this initial evaluation as antihypertensive medications are widely used and non-adherence is common (30). Our previous research had also documented that almost all community pharmacies in Quebec (99.7%) dispense antihypertensive medications, thereby allowing a population-based cohort for the current study (12).

For each antihypertensive dispensing, we created a record of all dispensings of the same antihypertensive medication to the same patient from all pharmacies in Quebec over the previous 180 days. 'Same medication' was defined as the same drug in the same dosage format, regardless of strength. Switches to a new medication in the same therapeutic class were treated as new therapies. Dispensings of antihypertensive medications were excluded if the patient had not been treated with the same medication for at least 90 days or had not had continuous insurance coverage over the previous 180 days. As dispensing pharmacists are responsible for obtaining information on medications supplied from other pharmacies when determining adherence, each eligible dispensing was attributed to the dispensing pharmacy. We calculated the proportion of previous 90 days covered (PDC) for the same medication using the previous dispensing dates and number of days of supply provided at each dispensing and adjusting for early refills. If the PDC over the 90 days prior to the dispensing was less than 72 days (80%), then the dispensing was to a non-adherent patient (31).

Potential Predictors: Dispensing-level characteristics: included the type of antihypertensive medication dispensed, the total prescription cost and the cost to the patient as these have been demonstrated to affect patient adherence (32). Although in Quebec the standard supply of medications is for 30 days, patients at risk for non-adherence can receive weekly medication supply and patients stabilized on chronic therapies can receive 90-day supplies. Adherence was, therefore, expected to be worse for patients receiving less than 30 days' supply and better for patients receiving more than 30 days' supply.

Potential Predictors: Patient-level characteristics: were those known to affect adherence such as sex, age and income, with older males and patients with higher income anticipated to be more compliant (20, 33). As our previous work indicated that patients within their first six months of antihypertensive therapy are less compliant as are those on single drug therapy or receiving their antihypertensive medications from more than one physician or pharmacist, these variables were also included (12, 34-36).

Potential Predictors: Pharmacy-level characteristics: included workload as higher numbers of prescriptions dispensed has been identified as a factor limiting community

pharmacists' ability to provide professional services (37) and predisposing to dispensing errors (15, 17, 38). Workload has been reported variously as prescriptions dispensed per year, which can readily be determined from administrative claims data, to prescriptions per pharmacist per hour, which has only been reported using self-reported estimates (17). We received from RAMQ the total number of billings and open days for each pharmacy over the 8-month study period and used the administrative claims data to calculate for each pharmacy the average number of: open hours per day, pharmacists billing per hour, prescriptions dispensed per hour, and prescriptions dispensed per pharmacist per hour. Related to workload, as medication dispensing errors occur more frequently when only one pharmacist is working, there have been calls for mandatory overlapping of pharmacists' schedules to allow one pharmacist to focus uninterruptedly on prescription verification while a second pharmacist provides professional services (16, 39). To measure pharmacist-overlap for each pharmacy, we created a matrix of the number of pharmacists billing each open hour over each open day during the 8-month study period. From this we calculated the average percent of each pharmacy's open hours where more than one pharmacist was billing (Pharmacist Overlap Index©). Finally, although continuity of care measuring whether patients received all antihypertensive medications from a single pharmacy was included as a patient-level variable, based on evidence from other health professions that care from the same health care professional is important in creating trusting, professional relationships, we determined the likelihood that a patient would be cared for by the same pharmacist on multiple visits (Within-pharmacy Continuity of Care Index©)(34). We calculated, for each pharmacy, the total number of pharmacists working over the 8-month study period (weighted to emphasize differences in high and low numbers of pharmacists) and divided this by the average number of pharmacists working per day at that pharmacy. The lowest value of the index is 1, representing the best within-pharmacy continuity of care when there is only one single pharmacist working in the pharmacy over the 8 months. Increasing indices indicate a lower chance that the patient would be cared for by the same pharmacist at multiple visits. To determine the culture within the pharmacy we calculated the total number of pharmacists' professional services billed per 100 prescriptions dispensed over the 8-month period, including refusals to dispense, pharmaceutical opinions, transmission of medication profiles and emergency contraception. We also counted the number of professional services billed specifically for management of under-use of antihypertensive medications.

Data sources/measurement: Baseline community pharmacy claims data for all dispensings of antihypertensive medications and pharmacist services were received from RAMQ for all Quebec community pharmacies for the period of October 1, 2008 to June 30, 2010 (14). Patient, pharmacy, pharmacy chain/banner group, pharmacist and

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prescriber identifiers were anonymized by RAMQ prior to data transfer. Data for the 8-month period of November 1, 2009 to June 30, 2010 were used to calculate dispensing, patient and pharmacy-level characteristics and estimate determinants of non-adherence.

Statistical Methods: Descriptive statistics summarized the characteristics of the dispensings, patients and pharmacies including the incidence of dispensing to non-adherent patients by type of antihypertensive, patient sex and age. Multivariate alternating logistic regression (ALR) estimated the association among the dispensing, patient and pharmacy-level characteristics and non-adherence. ALR allows analysis of dichotomous outcomes when observations have more than one level of clustering (40). For our results, ALR first measured the extent of clustering of non-adherence among multiple dispensings within the same patient and then for multiple patients receiving their medications from the same pharmacy. All analyses were completed using SAS, version 9.4 (SAS Institute, Cary, North Carolina), with ALR using PROC GENMOD.

Where multiple measures could be calculated to reflect a single construct, results for each measure were first compared with previously reported estimates (if available) to test the accuracy of the calculations. Next each measure was tested individually for association with non-adherence. A single measure of each construct was selected for inclusion based on the accuracy of the calculation, the strength of evidence supporting its use and the strength of association. Collinearity was evaluated for all variables considered for the final analysis using the variance inflation factor. When collinearity was present, variables that were calculated as interim steps were considered for exclusion and the variables retained were those most directly measuring the constructs of interest. To account for interactions between patient income and the cost of the medication to the patient, we divided both variables into low, medium and high categories and created dummy variables for each of the nine possible interactions, setting low income and low cost to the patient as the reference (41).

Results

Study Participants: 1872 pharmacies were enrolled in the study, after 19 (1%) opted out of the previous trial (Figure 1, Consort diagram). Ninety-one pharmacies open for < 61 days and 39 additional pharmacies dispensing >165,317 prescriptions over the 8-month period were removed from the analysis. 8,655,348 dispensings of antihypertensive medications to 760,700 patients in 1742 pharmacies were evaluated.

Population Characteristics: Angiotensin-receptor blockers (ARB) were the most commonly dispensed antihypertensive medications (23.2% of dispensings) with <1% of dispensings for each of alpha agonists, alpha blockers, potassium sparing diuretics and vasodilators (Table 1). Most prescriptions were dispensed in the morning and were for an approximate

one-month duration. 74.1% of patients were prescribed their antihypertensive medications by a single physician and 86.0% went to a single pharmacy for all their antihypertensive medications over the previous six months. Most patients had been taking antihypertensive medications for more than six months (98.5%) and were on multiple antihypertensive medications (79.4%). The majority of pharmacies were either chains or banners (89.9%). Pharmacists dispensed an average 18.4 prescriptions per pharmacist per hour, billing for 0.18 professional services for every 100 prescriptions dispensed. Most pharmacies did not have any billings for pharmacists' services for antihypertensive non-adherence, leading to an average of less than 1 billing over the 8 months (0.35 +/- 1.8). Pharmacies had more than 1 pharmacist billing for 15.5% of their open hours and an average of 9 different pharmacists worked in each pharmacy over the 8-month study period.

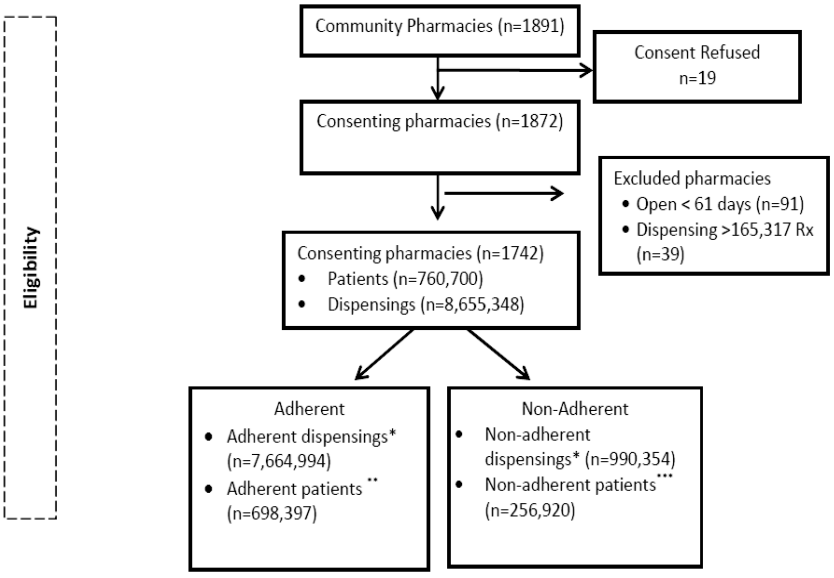

Figure 1. Consort diagram.

* Dispensings that were provided to patients who had been either adherent or non-adherent with their antihypertensive medication over the previous 90 days.

** Patients with at least one adherent dispensing over the 8 month study period.

*** Patients with at least one non-adherent dispensing over the 8 month study period. As patients received multiple dispensings, they could be counted as both adherent and non-adherent, therefore the total of adherent and non-adherent patients is more than 760,700.

Table 1. Characteristics of prescriptions dispensed, patients and their pharmacies.

Level of Characteristic	N (%)
Dispensed Prescription Level (n=8,655,348)	
Time of Day Dispensed	
Morning (>8-noon)	4,273,894 (49.4%)
Afternoon (>noon-16)	3,141,594 (36.3%)
Evening (>16-20)	1,065,102 (12.3%)
Overnight (>20-8)	174,758 (2.0%)
Number of Days of Medication Supplied	
<10 days	180,524 (2.1%)
10-32 days	8,241,026(95.2%)
>32 days	233,798 (2.7%)
Type of Antihypertensive Medication Dispensed	
Angiotensin Receptor Blockers	2,004,146 (23.2%)
Beta Blockers	1,853,835 (21.4%)
Calcium Channel Blockers	1,828,320 (21.1%)
Angiotensin Converting Enzyme Inhibitors	1,391,246 (16.1%)
Thiazide diuretics	672,041 (7.8%)
Loop diuretics	368,466 (4.3%)
Diuretic combinations	184,101 (2.1%)
Other diuretics	145,051 (1.7%)
Alpha Agonists	74,278 (0.9%)
Alpha Blockers	68,367 (0.8%)
Potassium sparing diuretics	56,693 (0.7%)
Vasodilators	8,804 (0.1%)
Cost	Mean (SD)
Total cost of the prescription (Canadian $)	$28.36($17.48)
Cost to the patient of the prescription (Canadian $)	$8.55 ($8.56)
Pharmacy Client Level† (n=760,700)	
Sex	
Female	4,858,885 (56.1%)
Male	3,800,463 (43.9%)
Age	
< 65 years	2,055,518 (23.8%)
65-69	1,595,657 (18.4%)
70-79	3,106,633 (35.9%)
>79	1,897,540 (21.9%)
Income	
Low (<$31,700 Canadian)	647,805 (7.5%)
Middle ($31,700-$80,000 Canadian)	7,096,041 (82.0%)
High (>$80,000 Canadian)	911,502 (11.5%)
Antihypertensive Therapy	

† Considering all patients who received eligible dispensings over 8 months' follow-up.

Level of Characteristic	N (%)
New Therapy (< 6 months)	126,812 (1.5%)
Chronic Therapy (≥6 months)	8,528,536 (98.5%)
Single Antihypertensive Drug	1,782,490 (20.6%)
Multiple Antihypertensive Drugs	6,872,858 (79.4%)
Continuity of Care	
Single Pharmacy Dispensed antihypertensives over previous 6 months	7,440,825 (86.0%)
Multiple Pharmacies Dispensed antihypertensives over previous 6 months	1,214,523 (14.0%)
Single Prescriber of antihypertensives over previous 6 months	6,412,928 (74.1%)
Multiple Prescribers of antihypertensives over previous 6 months	2,242,420 (25.9%)
Community Pharmacy Level (n=1742)	
Pharmacy Type	N (%)
Chain/banner	1,566 (89.9%)
Independent	176 (10.1%)
Pharmacy Location	
Neighborhood pharmacy	457 (26.2%)
Shopping Centre	281 (16.1%)
Medical Clinic	283 (16.2%)
Other	53 (3.1%)
Missing	668 (38.3%)
Professional Services Provided over 8 months	
Total pharmacist services billed per 100 prescriptions	
<0.12	544 (31.2%)
0.12-0.2	588 (33.8%)
>0.2	610 (35.0%)
Recommendations for non-adherence with antihypertensive medications	
0	1485 (85.3%)
1-5	237 (13.6%)
6-10	17 (0.1%)
>10	3 (0.2%)
Workload	Mean (SD)
Total prescriptions dispensed over 8 months	53,308 (36,749)
Total days open over 8 months	214 (42.8)
Hours open per day	14.4 (3.3)
Pharmacists working/day	1.8 (0.7)
Pharmacists working/hour	1.1 (0.1)
Prescriptions dispensed/day	244.6(156.6)
Prescriptions dispensed/hour	20.5 (13.0)
Prescriptions dispensed/pharmacist/hour	18.4 (10.5)
Pharmacist Overlap Index© (average percent of open hours with >1 pharmacist)	15.48 (9.14)
Within Pharmacy Continuity of Care	
Distinct Pharmacists employed over 8 months	9.0 (6.7)
Within Pharmacy COC Index© (weighted # of pharmacist in 8 months/# pharmacists per day)	17.3 (20.1)

Non-adherence: Over eight months, 9.2% of all dispensings of antihypertensive medications were provided to non-adherent patients (795,031 of 8,655,348 dispensings) (Table 2). Antihypertensive dispensings were provided to 760,700 distinct patients, 31% of whom were non-adherent to their antihypertensive medication at least once over the study period (235,885 of 760,700). The highest incidence of non-adherence occurred with alpha agonists (21.49%) and for dispensings provided in the evening (12.03%). The incidence of non-adherence was also higher if the patient was <65 years old (12.41%), new to therapy (18.29%) or on a single antihypertensive medication (12.47%).

When adjusted for the three levels of variables and clustering, the odds of non-adherence were significantly greater for medications supplied for less than 10 days and for medications dispensed at times other than morning ($p<0.05$) (Table 2). Relative to beta-blockers, the odds of dispensing an ARB or angiotensin-converting enzyme (ACE) inhibitor to a non-adherent patient were decreased by 17% (OR: 0.83; 95%CI: 0.82-0.84).

Older, female patients were less likely to be non-adherent at the time of receiving an antihypertensive medication, with a 41% decrease in the odds for patients ≥80 years relative to patients < 65 years old (OR: 0.59; 95%CI: 0.58-0.60). Patients newly started on their antihypertensive medication within the past six months experienced a 27% increase in odds of non-adherence at the time of dispensing. Patients with decreased continuity of care were also more likely to be non-adherent at the time of dispensing, with the odds of non-adherence increased by 10% if the patient had used multiple pharmacies and 16% if she/he had used multiple physicians for their antihypertensive medications over the past 6 months. The impact of cost of the medication to the patient was modified by the patient's income and, in contrast to the unadjusted incidence of non-adherence where increasing out-of-pocket costs lead to higher non-adherence, when adjusted for all three levels of characteristics, higher out-of-pocket costs resulted in a decreased odds of non-adherence within all of low, middle and high income patients. High income patients with low out-of-pocket medication costs were 15% more likely to be non-adherent at the time of dispensing as compared to low income patients with low medication costs (OR: 1.15, 95%CI: 1.12-1.18).

At the pharmacy level, the odds of non-adherence decreased by 40% per 1 increase in the number of professional services billed per 100 prescriptions dispensed (OR: 0.60; 95%CI: 0.57-0.62). Neither the number of billings for pharmacists' services targeted at managing non-adherence with antihypertensive medications nor the percentage of open-hours with overlapping pharmacists influenced non-adherence. However, pharmacist overlap was highly correlated with dispensing volume (Pearson correlation coefficient 0.51, $p<.0001$). Higher workload decreased the odds of non-adherence by 4% per 10 prescription increase in number of prescriptions dispensed per pharmacist per hour (OR: 0.96; 95%CI: 0.96-0.97). Higher scores on the Within-Pharmacy Continuity Care Index©, indicating a decreased chance of patients being cared for by the same pharmacist, slightly but significantly increased the odds of non-adherence (OR: 1.003; 95%CI: 1.001-1.005). There was significant variability in the odds of non-adherence

among pharmacies belonging to various banners or chains and the odds of non-adherence were significantly higher for chains/banners relative to independent pharmacies (OR: 1.02; 95%CI: 1.00-1.05).

Table 2. Dispensed prescription, patient and pharmacy characteristics associated with risk of non-adherence with antihypertensive medications.

	N	Non-Adherence	Multivariate Alternating Logistic Regression		
		(%)	Odds Ratio	95% Confidence Interval	P-Value
Dispensed Prescription Level					
All dispensings	8,655,348	9.19			
Time of Day Dispensed					
Morning (8-noon)	4,273,894	7.89	Reference		
Afternoon (noon-16)	3,141,594	9.86	1.03	1.03-1.04	<.0001
Evening (16-20)	1,065,102	12.03	1.06	1.05-1.06	<.0001
Overnight (20-8)	174,758	11.37	1.03	1.02-1.05	<.0001
Number of Days Supplied					
10-32 days	8,241,026	9.10	Reference		
<10 days	180,524	8.12	1.16	1.12-1.19	<.0001
>32 days	233,798	13.13	0.84	0.82-0.86	<.0001
Type of Antihypertensive					
Beta Blockers	1,853,835	9.16	Reference		
Angiotensin Receptor Blockers	2,004,146	8.63	0.83	0.82-0.84	<.0001
Calcium Channel Blockers	1,828,320	8.93	0.98	0.97-0.99	<.0001
ACE Inhibitors	1,391,246	8.13	0.83	0.83-0.84	<.0001
Thiazide diuretics	672,041	9.51	0.98	0.97-0.99	<.0001
Loop diuretics	368,466	12.70	1.50	1.48-1.52	<.0001
Diuretic combinations	184,191	12.23	1.19	1.17-1.22	<.0001
Other diuretics	145,051	8.28	0.89	0.87-0.91	<.0001
Alpha Agonists	74,278	21.49	2.71	2.63-2.79	<.0001
Alpha Blockers	68,367	8.72	1.12	1.08-1.15	<.0001
Potassium sparing diuretics	56,693	13.44	1.28	1.24-1.32	<.0001
Vasodilators	8,804	15.19	1.87	1.70-2.05	<.0001
Patient Characteristics					
Sex					
Male	3,800,463	9.69	Reference		
Female	4,854,885	8.79	0.90	0.90-0.92	<.0001
Age					
<65	2,055,518	12.41	Reference		
65-69	1,595,657	8.70	0.66	0.64-0.66	<.0001
70-79	3,106,633	8.02	0.60	0.59-0.61	<.0001
≥80	1,897,540	8.00	0.59	0.48-0.60	<.0001

	N	Non-Adherence	Multivariate Alternating Logistic Regression		
		(%)	Odds Ratio	95% Confidence Interval	P-Value
Patient Income*patient cost interaction					
Low income & low cost	301,826	8.67	Reference		
Low income & middle cost	184,565	9.59	0.93	0.91-0.95	<.0001
Low income & high cost	161,414	9.89	0.88	0.87-0.90	<.0001
Middle income & low cost	2,286,651	8.47	0.99	0.97-1.01	0.241
Middle income & middle cost	2,459,139	9.28	0.97	0.95-0.99	0.003
Middle income & high cost	2,350,251	9.27	0.95	0.93-0.97	<.0001
High income & low cost	210,972	10.31	1.15	1.12-1.18	<.0001
High income & middle cost	339,456	10.53	1.07	1.04-1.09	<.0001
High income & high cost	361,074	10.50	1.01	0.99-1.04	0.336
Antihypertensive Therapy					
Chronic Therapy (≥6 months)	8,528,536	9.05	Reference		
New Therapy (< 6 months)	126,812	18.29	1.27	1.25-1.30	<.0001
Multiple Antihypertensive Drugs	6,872,858	8.33	Reference		
Single Antihypertensive Drug	1,782,490	12.47	1.04	1.04-1.05	<.0001
Continuity of Care					
Single Dispensing Pharmacy	7,440,825	8.86	Reference		
Multiple Dispensing Pharmacies	1,214,523	11.16	1.10	1.08-1.11	<.0001
Single Prescriber	6,412,928	8.65	Reference		
Multiple Prescribers	2,242,420	10.72	1.16	1.15-1.17	<.0001
Pharmacy Characteristics					
Pharmacy Type					
Independent	444,956	9.69	Reference		
Chain/banner	8,210,392	9.16	1.02	1.00-1.05	0.034
Anonymized Pharmacy Chain/Banner/Independent					
UUU	2,495,701	9.68	Reference		
VVV	1,071,922	8.01	0.84	0.80-0.83	<.0001
TTT	572,422	8.83	0.91	0.89-0.93	<.0001
SSS	840,234	10.46	1.04	1.02-1.06	<.0001
HHH	657,249	8.12	0.84	0.83-0.86	<.0001
EEE	1,104,215	9.06	0.94	0.93-0.96	<.0001
Other	1,913,605	9.18	0.94	0.92-0.95	<.0001
Pharmacy Location					
Shopping Centre	1,912,484	9.39	Reference		
Neighborhood pharmacy	2,704,536	9.17	1.01	1.00-1.02	0.139
Medical Clinic	1,300,939	8.41	0.96	0.95-0.98	<.0001
Medical Offices	73,561	7.99	0.98	0.93-1.03	0.461
Other	180,417	8.34	0.96	0.93-1.00	0.047
Missing	2,483,411	9.54	1.01	1.00-1.03	0.081

	N	Non-Adherence	Multivariate Alternating Logistic Regression		
		(%)	Odds Ratio	95% Confidence Interval	P-Value
Workload					
Prescriptions/pharmacist/hour					
<12	947,400	11.0			
12-<22	2,755,796	31.8			
22-<34	3,668,952	42.4			
≥34	1,283,200	14.8			
Odds per 10 increase			0.96	0.96-0.97	<.0001
Professional Services					
Total Pharmacist Professional Services					
<0.11	2,519,258	10.13			
0.11-0.22	3,118,481	9.05			
≥0.22	3,017,609	8.54			
Odds per 1/100 Rx increase			0.60	0.57-0.62	<.0001
Hypertension adherence services					
0	6,936,363	9.23			
1-5	1,553,820	8.95			
6-10	145,393	9.80			
≥10	19,772	8.74			
Odds per 1 per 8 month increase			1.00	1.00-1.00	0.083
Pharmacist Overlap Index					
<10%	1,242,727	14.4			
10%-<16%	2,780,707	32.1			
16%-<22%	1,532,245	17.7			
≥22%	3,099,669	35.8			
Odds per 1% increase			0.95	0.90-1.00	0.068
Within Pharmacy Continuity of Care Index					
1-5	1282931	8.75			
>5-10	2554425	8.93			
>10-20	2331227	9.37			
>20	2486765	9.50			
Odds per 10 increase			1.003	1.001-1.005	0.012

Discussion

Statement of Principal Findings: This study is the first to document that linked community pharmacy claims and health administrative data can be used to directly measure a range of pharmacy-level characteristics and quality measures. It is also the first study that investigated the association between the provision of pharmacists' professional services and better within-pharmacy continuity of care with adherence, showing that each of these pharmacists' practices are associated with a decreased odds of dispensing antihypertensive medications to non-adherent patients.

Strengths and Limitations: The main strengths of this study are the direct measurement of pharmacy characteristics from administrative claims data and the use of an objective, validated quality-of-care measure of adherence (10-12). As significant variability in results has been reported from studies using differing measures of adherence, use of standardized methods for measuring adherence is particularly important in determining predictors of non-adherence (10). As only 1% of community pharmacies in Quebec did not consent to participate (18 of 1891), a second strength is that the sample approximated a population-based cohort and selection-bias was minimized. Limitations include that we evaluated performance on only one quality of medication-use measure and results cannot be generalized to other measures of pharmacists' quality of care. Although underuse measures of other therapeutic categories such as lipid-lowering or diabetes may show similar results, determinants of performance on quality indicators measuring medication overuse (eg rescue inhalers for asthma) or unsafe dispensing may differ as the professional services pharmacists provide to detect and manage these medication-use problems differ from those provided for medication underuse. Evaluation of performance on additional quality indicators measuring both adherence and unsafe dispensing is required to determine if results are generalizable. In addition, our methodology for calculating adherence did not allow for detection of primary non-adherence or non-adherence / non-persistence within the first 90 days of therapy. As these types of non-adherence are problematic with antihypertensive medications, our results may have underestimated non-adherence and measures of these additional types of non-adherence should be evaluated. Finally, administrative claims data are limited in the extent to which they can measure whether pharmacists provided a service but did not bill for it (42-, 43, 44).

Interpretation: Our overall rate of non-adherence is consistent with previous reports that utilize community pharmacy administrative claims data and similar measures of non-adherence (10, 45). Calculation of pharmacy-level characteristics required multiple steps and complex analysis and for characteristics that had previously been estimated via self-report, such as prescriptions per pharmacist per hour, our results were higher (18.4 +/- 10.5 our study vs 14.1 +/- 4.9) (17). This is consistent with national reports documenting higher total prescriptions dispensed in Quebec relative to other provinces (37). Results of

the drug and patient characteristics affecting non-adherence agree with previous research documenting that there is higher adherence to antihypertensive medications with fewer side effects, such as ARB and ACE, and that increasing age is associated with increased adherence to antihypertensive medications (32, 46). However, given the variability in results of non-adherence rates and predictors from studies that used differing measurement methodologies, our results should be compared with studies using pharmacy administrative claims data and standardized methods for measuring non-adherence (10). To our knowledge, this literature is limited to the study that used an ecological approach to measuring pharmacy and patient characteristics (20). Our results differ from this ecological study for the impact of patient sex and income, and independent pharmacy ownership on the odds of dispensing to a non-adherent patient. Our results demonstrate the impact of measuring these characteristics directly for each dispensing and adjusting for clustering. When only considering whether the pharmacy is independent vs a chain/banner, the incidence of non-adherence is higher in independent pharmacies. However, when adjusted for clustering and the remaining dispensing, patient and pharmacy characteristics, this association reverses with chain / banner pharmacies demonstrating a greater odds of non-adherence. The same is true for the impact of patient costs relative to income. Without adjustment, the incidence of non-adherence increases as cost to the patient increases. However, when adjusted for all characteristics, this relationship reverses. As higher patient cost typically occurs with second-line treatments for hypertension, this may represent patients who required switches or additions to their therapies due to side or insufficient effects from their initial treatments, which has been shown to increase adherence (47).

The most striking results of our analysis are the reductions in the odds of non-adherence with both an increasing rate of provision of pharmacists' professional services and improved within-pharmacy continuity of care. It is hypothesized that the relationship between the rate of provision of these services and lower non-adherence indicates that improved quality of care is provided at pharmacies where pharmacists prioritize provision of professional services vs involvement in technical distributive functions (48, 49). The relationship between improved within-pharmacy continuity of care and decreased odds of non-adherence supports such a hypothesis as patients can more easily develop trusting relationships with their pharmacist when continuity of care is improved. Our findings that increased workload is associated with lower odds of non-adherence would not appear to support that increased workload challenges pharmacists' provision of quality care. However, we had removed very high-volume pharmacies so we did not see the previously reported results of lower quality of care in pharmacies with both very low and very high dispensing volumes (15). The strong positive correlation between workload and pharmacist-overlap suggests that pharmacists are not being scheduled to provide professional services but to enable increased number of prescriptions to be processed. As both culture and workflow are determined predominantly by the pharmacist owner, greater freedom to emphasize professional pharmacists' practice by owners of

independent pharmacies could account for their lower odds of non-adherence relative to chains / banners (50). Similarly, differences in practice philosophy among the chains / banners could account for the variability in performance among the different banners and chains.

Implications and Future Research: Our results indicate that emphasis on the caring role of pharmacists both during dispensing and via provision of professional services appears key to improving patients' use of medications. Results also support policies that encourage continuity of care and that focus adherence strategies on younger males, new to treatment and taking single antihypertensive therapy. Pharmacy administrative claims data can be used to directly measure dispensing, patient and pharmacy characteristics, thereby increasing the range and accuracy of pharmacy-level characteristics evaluated. Evaluation of additional measures both of non-adherence and dispensing of contraindicated medications is needed to determine if there is consistency across the measures of pharmacy-level characteristics identified in our study as being related to pharmacists' quality of care.

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Chapter 7

Discussion

This dissertation adds significantly to the pharmacy literature as there has been little work published that measures the quality of community pharmacists' care beyond: 1) practice visits to determine compliance with pharmacy regulations, 2) reporting systems for pharmacy errors and 3) pharmacy audits (1-3). Although the use of community pharmacy dispensing records to measure performance on pharmacists' quality-of-care metrics has recently been launched in the USA, this dissertation introduced the use of administrative health / pharmacy claims datasets that include billing data for community pharmacists' professional services. This allowed not only pharmacy dispensing claims to be used to measure quality indicators, but also provided the opportunity to develop methodologies to evaluate the impact of the community pharmacists' professional services on the quality of practice.

Research Question 1: A Continuing Competence/Continuing Professional Development Model for Pharmacists

The first research question asked if there was sufficient evidence from the health professions' literature to create a theoretical model of an integrated continuing competence (CC)/continuing professional development (CPD) program that is based on using administrative health data to assess community pharmacists' quality of care. Chapter 2 presented the evidence-based model that was developed, which integrated CC with CPD for pharmacists and continuing quality assurance (QI) for pharmacy management systems (Figure 1) (4). The value of such integrated systems has been highlighted in recent medical education literature (5). The model was also the first that could feasibly evaluate CC of all practicing pharmacists on a routine basis. This is possible via a screening assessment of pharmacy-team performance on quality-of-care indicators measured through routinely available administrative health / pharmacy claims data from community pharmacies. The model recognized that pharmacists practice within a team environment in the community pharmacy and acknowledged the impact of factors beyond the individual pharmacist's competence on their daily performance. These factors included those arising from pharmacists themselves such as motivation, from patients, corporate pharmacy management, health care policies / legislation, reimbursement and other health care professionals.

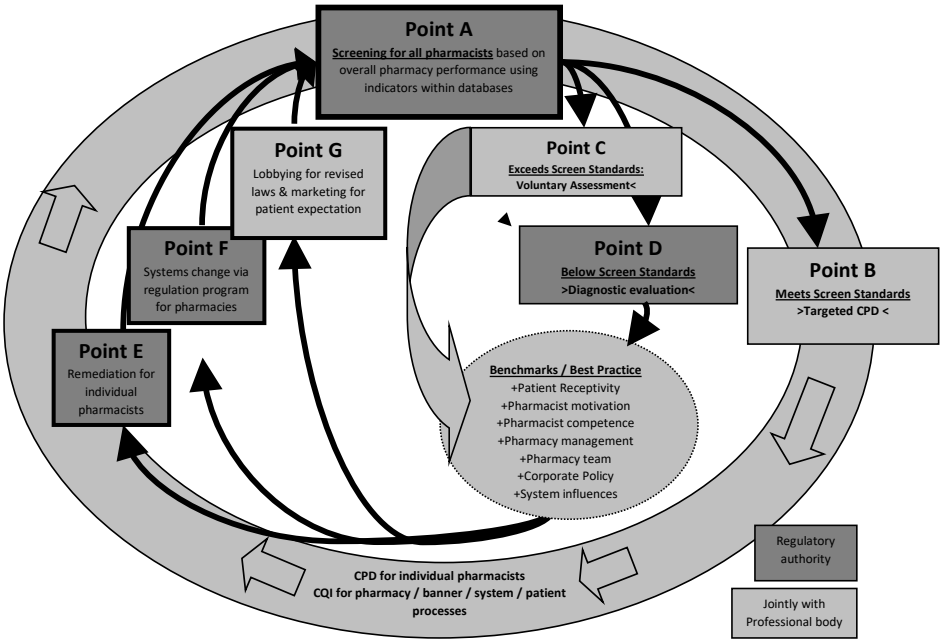

Figure 1. Proposed CC/CPD model for community pharmacists (4)

Research Question 2: Figure 1Point A Screening assessment for all pharmacists

The second research question addressed the feasibility of pharmacy regulatory authorities using administrative health / pharmacy claims data to evaluate community pharmacists' performance as a screening measure within the model CC/CPD program. Using Landon's criteria for performance measures of physicians (6), results documented that community pharmacy billing data could be used to measure pharmacy-team level performance on four sample indicators representing traditional perspectives of pharmacist quality of care (Chapter 4) (7). One hundred and four of 1799 (5.8%) pharmacies demonstrated consistently low performance with scores in the lowest quartile on all four or three of four indicators. On a yearly basis, 104 pharmacies would be a reasonable number for regulatory authorities to target for on-site inspections for further confirmatory / diagnostic evaluation of the quality of care provided, as required by pharmacy regulations for continuing competence and quality assurance.

During analysis of the overall results of this dissertation, the current criteria for selecting indicators for use as measures of pharmacy-team quality of care were reviewed. Four indicators had been selected that reflect traditional measures of pharmacists' responsibilities (8). Two represented safe dispensing (dispensing of contra-indicated medications) and two measured effective medication dispensing (dispensing to patients

non-adherent to their medications for chronic conditions). Two challenges were identified when reviewing the use of these four indicators as measures of pharmacists' quality of care. First, although the indicators selected met the technical criteria for use of performance indicators in high-stake assessments, it was necessary to determine if these measures met the broader requirements for use as quality measures within relevant health quality evaluation frameworks. Second, as there have been calls to increase the policy relevance of community pharmacists' quality initiatives, the consistency of these pharmacists' quality measures with those prioritized by relevant health care systems required evaluation (9). In Canada these questions required consideration of the health system quality models and indicators developed by the Canadian Institute of Health Information (CIHI) (10, 11) and provincial organizations such as Health Quality Ontario (HQO) (12). On an international level this related to health care quality models and indicators developed by, for example, the Organization for Economic Cooperation and Development (OECD) and Institute of Medicine (IOM) (13-15).

For the first question, criteria for selection of measures of health systems' quality have been developed and include the relevance and importance to stakeholders; significance (prevalence across the health system and degree of impact); controllability (capacity for improvement); attributability; reliability; validity, and; feasibility for measurement (16). Core to all of these criteria is the strength of evidence documenting that the quality of care provided by the health care professional independently and consistently leads to desired changes in priority health outcomes (14). For the profession of pharmacy, although the literature is replete with evaluations of pharmacists' services including numerous meta-analyses and literature reviews, evidence of the independent and consistent impact of pharmacists' services on health outcomes is sparse (8, 17- 23). In Canada, a 2016 review of the health and economic evidence of pharmacy services acknowledged the shortfall of evidence of the real-world value and impact of pharmacists' services (24). Provinces that expanded the scope of community pharmacists to include new services acknowledged that they had done so with a "leap of faith" that real-world evidence of health and economic impacts would follow. Mossialos emphasized this same challenge, documenting inconclusive evidence in 33 systematic reviews for policies expanding the role of community pharmacists (9).

Care must be taken, however, not to extrapolate results of these reviews to the conclusion that the pharmacists' services evaluated have no impact on patient outcomes. Such conclusions are unjustified due the challenges acknowledged in the reviews, including the use of differing outcome measures and difficulties in determining if the service had been provided, the specific components of the service provided, and the quality of the service provided. The majority of pharmacist-service studies have either not documented the provision of the service or relied on self-report by pharmacists, both of which lead to challenges in accuracy (25). In countries that reimburse pharmacists to provide these services, billing data can be used to measure provision of these services (25). In the absence of separate funding, systems such as Australian's Guildcare®

document the care provided by pharmacists during dispensing and facilitate evaluation of the impact of this care (26-28). Challenges remain, however, determining the specific components and quality of services provided by pharmacists, such as the types of patients who could benefit most from specific services, the most impactful timing of service provision and the characteristics of effective services (29). The ongoing Optimising Therapy to Prevent Avoidable Hospital Admissions in the Multimorbid Older People (OPERAM) is focusing on improving the consistency of outcomes reported in clinical trials evaluating pharmacists' services and has recently published a core outcome set to be reported for all clinical trials evaluating the impact of medication review services for older patients with polypharmacy (30).

The pharmacists' services measured within the projects for this dissertation included pharmacists' refusals to dispense a prescription for safety reasons and their provision of written pharmaceutical opinions to physicians to maximize patient adherence to appropriate therapies. Although these services were authorized and funded in Quebec more than two decades ago, there has been no evaluation of the effectiveness of these services on decreasing the use of contra-indicated medications or improving adherence. Separate reimbursement is provided to pharmacists for these services and billing requires submission of codes identifying the specific medication-use problem being addressed at a sufficient level of detail to determine the drug / drug category and whether, for example, the problem is under-use or over-use of the medication. For this dissertation, this resolved the challenge of lack of documentation of service provision, although it is recognized that pharmacists may provide the service and not bill for it for a variety of reasons (31). This documentation enabled us to count the number of pharmacists' services provided to address the medication-use problem being measured via our quality-of-care indicators. This was critical to our ability to evaluate the impact of these services on the targeted medication-use problem in our audit and feedback study (Chapter 5). We also evaluated the potential for using this documentation of service provision as a process-of-care measure, similar to measures of appropriate care provision for physicians such as disease screening rates (e.g. mammograms, colon cancer screening). Inclusion of indicators measuring pharmacists' service provision in health-care quality frameworks is rare with the exception of systems that include indicators measuring provision of medication reviews or medication reconciliation (although not necessarily by pharmacists) (12, 32). Results of our feasibility study (Chapter 4), however, documented that billings for the pharmacists' professional services targeting the specific medication-use problem were completed by only 2% of pharmacies over the year study period.*

* Over one year, of 1383 pharmacies dispensing a nonselective beta blocker to a patient taking a fast acting beta agonist, 33 pharmacies billed for a refusal to dispense the nonselective beta blocker; of 1662 pharmacies dispensing flurazepam to a senior, 34 pharmacies billed for a refusal to dispense the flurazepam; of 1707 pharmacies dispensing a fast acting beta agonist to a patient in an over-use situation, 36 billed for a refusal to dispense; of 1781 pharmacies dispensing antihypertensive medications to non-adherent patients, 376 bill for a pharmaceutical opinion to improve adherence.

Therefore, since indicators are only useful as measures of quality performance if they apply to the majority of health care providers (6), the low billing rate of these targeted services meant that a process of care indicator could not be developed based on provision of these services. This situation is not unique to Quebec and, in the additional Canadian provinces that provide reimbursement for similar pharmacist dispensing-related services, low service provision has been a consistent challenge (33).

In addition to the criteria established for selection of indicators, proposals from business management professionals have called for greater focus on indicators measuring outcomes that are important to patients (34, 35). These groups have developed standardized outcome measures covering a range of chronic illnesses (36, 37). Despite criticism that application of these standardized outcome measures minimizes the variability in individual patient priorities, there has been wide-spread adoption of the value-based health care models that have been developed based on these standardized outcomes (38- 42). Identification of outcomes important to patients is relevant to community pharmacists as there has been little focus on determining patients' expectations of care from community pharmacists. Although patients are satisfied with and trusting of community pharmacists, satisfaction considers patients' expectations relative to their service experience and the high patient satisfaction with pharmacy services has been interpreted as being due to low patient expectations (43). Patients are consistent in their expectation for pharmacists to ensure that no errors occur in the dispensing of their medications, but their desired outcomes of pharmacists' care and the changes in health status they expect as a result of receiving care from their community pharmacist have not been determined (44, 45).

This leads to the second question which calls for aligning of the outcomes evaluated in pharmacy quality initiatives with those prioritized by the relevant health authorities. In Canada, CIHI's *health outcomes* focus on improving health conditions, human functioning and/or well-being (10, 13, 46, 47). CIHI's *health-related outcomes* include several relevant to community pharmacists' care such as hospital admission rates for community-treatable conditions and use of potentially inappropriate medications in the elderly (11). Measures do not extend, however, to the distal surrogate outcomes that are typically focused upon in research-based evaluations of community pharmacists' services such as control of blood pressure, blood lipid levels or HBA1c, or improving adherence (8, 48- 53). Recent focus on adherence-related quality measures in pharmacy is being driven by the American Centers for Medicare and Medicaid Services (CMMS) quality rating system for health care plans which includes several quality measures of medication adherence as developed by the Pharmacy Quality Alliance (PQA) (54, 55). Green Shield Canada has recently adopted PQA's measures and feedback processes for use in Canada. However, unlike the American CMMS, European, UK, Australian[†] and Canadian health care systems

[†] Although Australia's 2009 health indicators reference proportion of patients treated for HTN that have controlled BP, this indicator is not included in reports on Australian Health (59, 60).

and public payers are not focusing on adherence-related measures such as those measured by PQA. Instead these payers are focusing on higher level *health outcomes / health-related outcomes* such as those defined by CIHI (11, 13, 16, 56- 60). Therefore, in contrast to the two measures of adherence used in the feasibility study for this dissertation (Chapter 4), the two measures of safe medication are more aligned with CIHI's indicators. Indeed, quality measures evaluating the prevention of use of potentially inappropriate prescriptions (PIP) through refusals-to-dispense or pharmaceutical opinions to taper/withdraw benzodiazepine would be consistent with these national indicators. Extension of the indicator to evaluate the impact of these refusals or pharmaceutical opinions on ER visits, adverse events or hospitalizations would make the pharmacist quality-of-care indicators even more relevant to CIHI's and OECD *health outcomes* indicators.

Once the supporting evidence and priority indicators measured by relevant health systems have been considered, the theories underlying health professionals' learning and behaviors must also be evaluated (61, 62). This would allow understanding of the factors determining pharmacists' performance on potential indicators and the potential consequences (both desirable and undesirable) of holding pharmacists' accountable to high performance on the selected indicators. Certain indicators may be particularly susceptible to, for example, gaming including indicators measuring adherence. For these metrics, corporate management can implement automatic refill policies that artificially inflate performance results (63, 64). Quotas and minimum wait-time guarantees are additional corporate strategies that have been employed to improve performance on indicators that focus on simply counting number of services without counter-balancing indicators that evaluate the quality of services (24, 65).

In summary, the feasibility study (Chapter 4) documented that routinely collected pharmacy claims data can be used to evaluate daily performance of community pharmacy teams on indicators that represent outcome measures often used in community pharmacists' health services research. However, adherence measures are not aligned with the outcome measures prioritized at the health system level of many countries. For the refusals to dispense medications, there is a lack of evidence that these refusals impact priority outcomes such as use of high risk medications in the elderly. Evaluation of existing indicators and literature linking provision of high-quality pharmacists' services to desired outcomes is needed to select relevant outcome measures, with theory-based evaluation of the pharmacists' services to gain understanding of their optimum design and potential impacts (61). Thus, the only change to Step A in the proposed CC/CPD model is to clarify the requirements for selection of quality-of-care measures.

Research Question 3: Figure 1, Point B Audit and Feedback for Pharmacists Meeting Screening Standards

The third research question focused on whether provision of individualized, comparative practice-performance feedback on quality indicators increased community pharmacists' provision of targeted professional services and improved patient's use of medications. Despite the low rates of provision of refusals to dispense and pharmaceutical opinions for management of non-adherence, the ability to count the provision of pharmacists' services targeted at managing specific medication-use problems was critical for this study. Counting allowed evaluation of both the impact of feedback on provision of these services and the impact of these services on patients' use of medications. With the detailed coding contained in the Quebec databases, we were able to determine in our audit/feedback trial that provision of feedback led pharmacists to increase provision of pharmaceutical opinions to improve patient's asthma treatment, but that this did not lead to desired improvements in use of asthma medications (Chapter 5) (66). For hypertension, feedback neither increased pharmacists' provision of pharmaceutical opinions nor improved patients' adherence to their medications.

These results required re-evaluation of the audit/feedback step proposed in the model CC/CPD program (Point B, Figure 1). The goal of this step is to support continuing improvement in performance of pharmacy-teams who meet or are above the screening phase performance requirements. The proposed model recommended that feedback be used by these pharmacy-teams to continue to improve their performance. This was based on the evidence that audit and feedback can result in small, but significant changes in performance (67). Further, audit/feedback was being considered by a range of regulatory and advocacy organizations to support continuous quality improvement in care provision (68). The inconsistent impact of audit and feedback has led recent research to focus not on determining if audit and feedback work, but how to design and implement audit and feedback systems to be most effective in improving performance (69-71). A number of recommendations are available as to how to optimize audit and feedback interventions (97), including clarification of the elements that can be modified (72) and the theories upon which audit and feedback are based (73, 74). In analysis of our feedback results, we used Sargeant's models to determine several changes that could potentially improve the impact of pharmacy-team performance feedback (75, 76). These include the provision of repeated feedback, inclusion of an opportunity for discussion and reflection, and provision of aggregated, anonymized reports to corporate managers for CQI of corporate policies. These are highlighted as changes to Point B in the proposed model CC/CPD program (Figure 2). However, the more fundamental challenges with the effectiveness of audit/feedback of pharmacists' performance relate to the lack of evidence documenting that the services pharmacists provide are effective at achieving desired changes in health outcomes. Without this evidence, pharmacists are appropriately skeptical about prioritizing provision of these services. And without evidence as to what constitutes an

effective, quality service, pharmacists have no guidance as to how to improve their performance. For example, reporting that pharmacists are providing too few medication reviews and are not focusing on quality reviews to the right patients is inappropriate when there is no understanding of what constitutes a quality medication review, which patients can benefit most from this service and what outcomes, if any, are achieved by provision of the service (77, 78).

The paucity of evidence supporting the link between pharmacy services and patient outcomes is the current situation for the majority of professional pharmacists' services. Robust evidence is needed of the impact of community pharmacists' care and services on outcomes valued by health care systems and that matter to patients, with particular focus on patient-rated outcome measures. The methodologies we developed in the audit and feedback trial (Chapter 5) will be useful in completing evaluations of the impact of other reimbursed community pharmacists' professional services on specific medication-use problems if billing data includes coding at a sufficiently detailed level. At present literature is appearing that uses data from billing databases from other jurisdictions to evaluate the impact of, for example, community pharmacists' provision of medication reviews (79). However, the information required for billing of these medication reviews does not allow determination of the particular medication-use problem the service was meant to address. This challenge is magnified by the unclear goals of the services when they were designed with some suggesting medication reviews were designed to decrease high-risk medication use while others suggest they aim to improve compliance (78, 79). These issues limit the ability to translate our methodologies into other jurisdictions but, given the strengths of our methodology, we have been able to establish the billing-criteria required to enable similar analysis in other provinces. Discussions are ongoing with a number of these provinces to make appropriate revisions to their billing requirements.

Research Question 4: Figure 1 Points C &D Analyzing the Determinants of Quality Pharmacist's Care

The final research question addressed the lack of evidence evaluating the characteristics of quality pharmacists' services. We determined whether linked administrative health data could be used to determine the dispensing, patient and pharmacy-level characteristics that are consistently associated with higher quality of pharmacists' care across pharmacies in Quebec (Chapter 6). Using the adherence indicator for hypertension medications as a sample indicator, new methodologies were developed to enable use of community pharmacy billing data to directly calculate pharmacy-level factors theorized to relate to the quality of pharmacists' care. These include two previously unmeasured constructs of within-pharmacy continuity of care and pharmacist-overlap (Chapter 6) (80). The former measured the chance that a patient would receive care from the same pharmacist on different visits to the pharmacy while the latter measured the proportion

of open hours that a pharmacy had more than one pharmacist working (theorized to represent an opportunity for one pharmacist to focus undisturbed on dispensing-related care while the second pharmacist focused on providing other patient care services). In our preliminary work with the hypertension nonadherence indicator, we demonstrated that increased continuity of care was significantly associated with improved adherence with increased overlap also trending to support improved medication adherence (Chapter 6). Our results also supported findings from the audit and feedback study that provision of pharmaceutical opinions targeted to improve adherence to antihypertension medications was not associated with increased adherence. However, provision of a higher number of total pharmacists' professional services including refusals to dispense medications, pharmaceutical opinions for a range of medication-use problems and new-medication dispensing services, was associated with improved adherence for anti-hypertensive therapy. This suggests that the culture and degree of independence of owners to prioritize professional services influence the quality of care provided in community pharmacies. However, validation of our findings with additional indicators is necessary.

The methodologies used in this determinants study also allowed us to measure and confirm drug and patient-level factors that are known to influence adherence and that must be adjusted for when calculating pharmacy-team level performance on adherence-related indicators (14). Patient characteristics such as age, sex, education, income, concomitant diseases, polypharmacy and multiple prescribers are known to affect medication adherence and non-medical determinants have been documented to have strong influence on overall health outcomes (81). To ensure comparability of pharmacy-level performance on quality indicators, differences in drug and patient characteristics must be accounted for so that pharmacists are not held accountable for performance differences due to dissimilarities in their pharmacy-practice population. Although such risk adjustment is a critical requirement for use of quality-of-care measures for comparative performance reporting, it has only recently been emphasized when comparing pharmacy-team level performance (82, 83). As outcome measures are identified that are consistently influenced by the quality of pharmacists' care, confounders will require identification and pharmacy-team level results adjusted accordingly. The methodologies used in our determinants study (Chapter 6) would be appropriate to use in these studies to identify relevant confounders (80).

Revision of the Proposed CC/CPD Model

Figure 2 provides a revised integrated CC/CPD model that incorporates the changes resulting from the research completed for this dissertation. Additional changes have also been recommended to the model based on review of overall results and consideration of additional evidence. The first change relates to the original proposal that pharmacy teams

exceeding the screening performance standards be requested to undergo voluntary on-site assessment to enable identification of the determinants of quality practice and to set benchmarks for quality standards. Reconsideration of this proposed step relates primarily to the need for such determinants and standards to be established prior to implementing a CC/CPD program as opposed to being included as a component within the program. Continuing competence assessment programs are highly stressful to practicing health care professionals and can neither expose them to psychometrically unsound assessments nor request them to complete additional tasks despite successful performance. The College of Pharmacists of British Columbia experienced significant challenges during the development of their CC program when they followed such a pattern, with pharmacists rebelling against the need for continued assessment despite satisfactory results (84). Although the importance of identifying the determinants of quality practice and benchmarks is paramount, this should be completed alongside the research required to establish valid quality indicators of pharmacists' care and not as part of the CC/CPD program.

A second modification to this model focuses on Point A being a screen of pharmacy-team level performance and that accuracy of the screening results must first be evaluated before a full diagnostic evaluation to determine causative factors would be completed by the regulatory authority. In theory, pharmacy-teams at pharmacies who fell below the screening standards but who could provide alternate evidence or for whom there was additional evidence that the quality of care provided met the required standard could move to the 'Point B: meets standards' point and proceed through supported, self-directed CPD/CQI. Those pharmacy-teams that continued to not meet the quality standard, however, would undergo diagnostic evaluation by the regulatory authority to determine the causative factors for low quality of care.

Finally, the process for identifying the determinants influencing the quality of care at each pharmacy was moved so that it could be applied either independently by pharmacists who had met the screening performance standard or by the regulatory authority for pharmacies where the quality of care was confirmed to be below the standard. The remaining steps are unchanged and a revised, proposed integrated CC/CDP model that is based on the results of this dissertation and evidence from relevant health systems is provided in Figure 2.

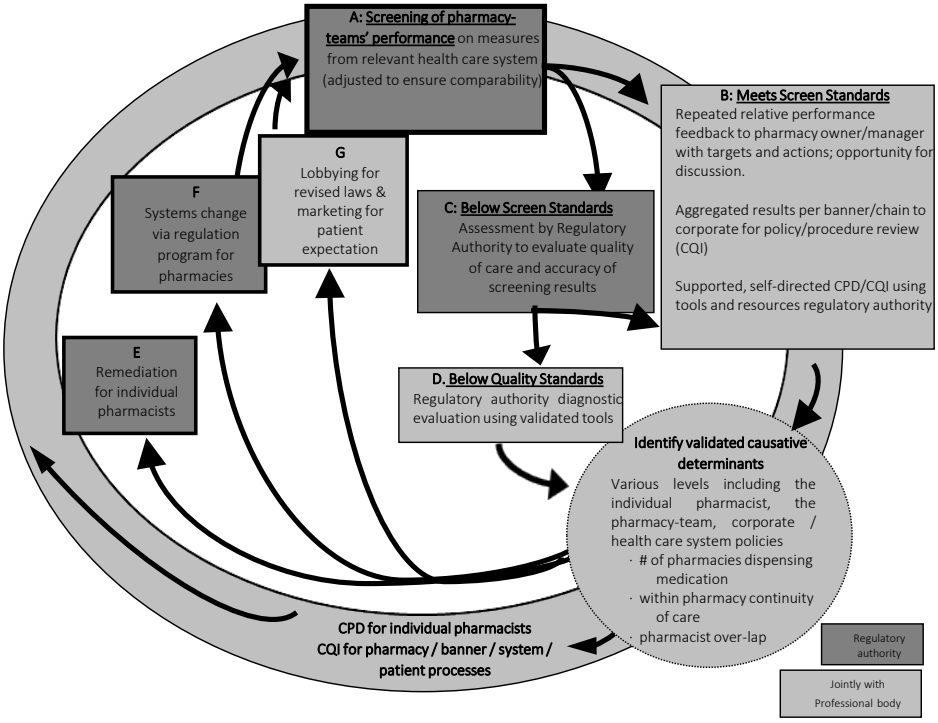

Figure 2. Revised integrated CC/CPD model

Strengths

The strengths of the studies reported in this dissertation include the large number of pharmacies and community pharmacists included, resulting in population-based studies rather than potentially biased samples of pharmacies. The nature of information retained in the Quebec administrative billing databases was an additional strength in that our feedback study was able to evaluate whether pharmacists' provision of pharmaceutical opinions for nonadherence improved subsequent adherence. Our methodologies also accounted for reversals of billings within 60 days, thereby minimizing any artificially high adherence calculation results due to automatically-filled repeat prescriptions. If methodologies do not account for automatic refills, the accuracy of database-derived performance on adherence measures cannot be relied upon. The capacity of the analysts completing the determinants calculations was another particular strength of our research, given the complexity of the analyses and the size of the data file. This capacity was fundamental to being able to calculate pharmacy characteristics directly from the data rather than relying on self-report or ecological estimates. Another strength of the studies related to our linkage across databases to identify determinants of high

performance on an indicator. There was also the capacity to link the databases we used with the hospital services databases to measure impact of pharmacists' services on patient health-related outcomes, such as ER visits for asthma-related events (85), but privacy concerns prevented us from making these linkages for our research studies.

A final strength of our work relates to translation of our results into pharmacy practice policy. This has been supported through joint work with the Ontario Pharmacy Evidence Network to develop a national pharmacist services evaluation framework (86) with emphasis on appropriate measuring of community pharmacists' care (87). Knowledge translation of research findings into practice / policy was also undertaken via both joint practitioner / researcher publications (Chapter 3) (88) and via consultations with pharmacy regulatory authorities in both Quebec and across Canada.

Weaknesses

Weaknesses of the research projects relate primarily to the limited number of indicators evaluated, particularly for the determinants study (Chapter 6). The four indicators initially measured in the feasibility study (Chapter 4) considered both safe dispensing by evaluating dispensings of contra-indicated medications and effective use of medications by evaluating dispensings to patients non-adherent to their therapies. The services provided by pharmacists in response to these medication-use problems differed with pharmacists expected to bill for refusals to dispense unsafe medications and to bill for pharmaceutical opinions to improve adherence. Pharmacists may have differing views on the effectiveness, appropriateness and value of these two services but our focus on only adherence-related indicators in the feedback and determinants study (Chapter 5) did not allow us to investigate these differences. There are also standard limitations when using billing data to evaluate care in that the data can only include services that were billed and omits services that were provided but not billed. For adherence, in particular, billing data can also be gamed via automatic refill polices because the methodologies consider only when the medication was dispensed and not if or when it was actually consumed by the patient.

Implications for Practice and Research

The overarching research question guiding the development of this dissertation was how, within the context of an integrated CC/CPD program, the use of routinely collected administrative health data for performance measurement could support improved quality of care by community pharmacists. Although an evidence-based integrated CC/CPD model using community pharmacist claims data was developed, results of our projects did not demonstrate a consistent, sustained impact of performance

measurement and feedback on pharmacists' quality of care. We did not evaluate all the component steps of the proposed CC/CPD model, however, and further evaluation of the determinants of quality pharmacists' care and interventions by the responsible organizations (Points E, F and G in the revised model, Figure 2) is required to evaluate the full process of use of performance measurement via administrative health data. Importantly, analysis of our results indicates that the greater challenge is the missing evidence supporting the impact of pharmacists' professional services, as they are currently defined, on outcomes important to health care systems and patients.

In future work, priority should be placed on identifying and selecting appropriate outcomes and indicators for use as measures of pharmacists' quality of care. In attempt to align pharmacy efforts with ongoing quality improvement efforts, review should be completed of the indicators identified by relevant health-system quality organizations to determine which indicators would be expected to measure either provision of pharmacists' services (i.e. process measures) or outcomes of quality pharmacists' care. In Canada, this would require review of outcomes defined by CIHI and relevant provincial health authorities such as Health Quality Ontario, along with the patient-rated outcome measures developed by the International Consortium Health Outcome Measures. For outcomes, the majority of these will be measures of *health-related outcomes* such as ER visits, admissions, adverse events or falls, health-related quality of life and patient-rated outcome measures. For care provision (process) measures, these will be limited to potentially pharmacists' provision of medication reviews or completion of medication reconciliation (12). However, the low provision rates of these services and the lack of evidence supporting that provision of these services leads to consistent changes in desired health outcomes limits the usefulness of these care process measures. Robust evidence of community pharmacists' care on outcomes valued by the Canadian health care system and that matter to patients is required. To achieve this, clarity should be sought on the policy-makers' and patients' desired impact of pharmacists' care and services on health outcomes. Although it would seem apparent that development of pharmacists' services would always include this step of defining the desired outcomes, in particular if these services are to be funded by public payers, evidence indicates that this is not always the case (89).

Our results showing the limited impact of relative performance feedback on adherence suggest that the approach being used by PQA through their subsidiary Pharmacy Quality Solutions (PQS) in the United States and adopted by Green Shield Canada in their Value-Based Pharmacy initiative will be ineffective in improving pharmacists' performance (90-92). PQS's performance reports for pharmacies are provided electronically, comparing the pharmacy's results with the pharmacy organization's average, state average and all-pharmacy average (90). The denominator for each measure is provided and performance is color-coded, and pharmacists can obtain graphical representations of their pharmacy's relative performance over time. Pharmacists can click on an improvement strategies button but, as few pharmacists'

professional services have been identified that are documented to improve performance on these indicators, the improvement strategies provided are quite general and focused on background information and synchronization, either with or without automatic refill systems (93-95). More recently, for certain organizations the system has begun offering a list of names and contact information for patients who are outliers on the performance indicator (96). A drop-down list of actions is available for each of these patients to guide pharmacist's attempts to manage the patient's situation. Again, the lack of evidence-based services limits the options available to general statements such as medication history check, patient consulted, prescriber consulted or adherence intervention. As such, the PQS feedback reports provide little guidance to the pharmacist as to the specific actions (s)he can undertake to improve performance. Green Shield Canada provides no recommendations or information to pharmacists as to how they can improve their performance. As with other health care professionals, without recommendations as to a specific service they can provide or action the health professional can undertake, such systems are bound to fail. Best practice policies for audit and feedback include that feedback provides targeted actions and action plans to facilitate improvement (97).

Perhaps the most important requirement to ensure impactful research on pharmacists' quality of care, however, is the need for an agreed upon definition of quality pharmacists' care. The metrics currently being used by PQS and Green Shield Canada as measures of quality pharmacists' care focus almost exclusively on the care pharmacists provide during the dispensing of new and repeat prescription medications. Indicators of contra-indicated, interacting or high-risk medications measure the core patient safety responsibilities of pharmacists when reviewing patients' prescriptions prior to dispensing. Indicators of adherence measure the core medication effectiveness responsibilities associated with refill dispensing. Indeed, although PQA now has more than 100 measures in their concept inventory, only one endorsed indicator measures pharmacists' services that are provided independently from dispensing (completion rates for comprehensive medication reviews) (98, 99). Similarly, only Green Shield Canada's Cardiovascular Health Coaching indicator measures dispensing-independent pharmacists' care. The assessment of pharmacist's quality of care via indicators that dominantly measure pharmacists' dispensing-related care is at distinct odds with the ongoing recommendations by international pharmacy leaders to remove pharmacists from the dispensing process and dispensary overall (100). Indeed, pharmacy leadership organizations and academia around the world have called for pharmacists to abandon their traditional roles involving medication dispensing in favor of medication-related and other health care services such as prescribing, health screening, medication reviews and vaccinations (101-103). Although the joint WHO/International Pharmaceutical Federation's (FIP) definition of medication dispensing includes the responsibility for evaluating a prescription and the provision of information and instructions to ensure the safe and effective use of the medication by the patient, both WHO and FIP have stated their view that dispensing is a purely technical function better completed by pharmacy technicians or machines (100). The opening quote

of the WHO/FIP 2006 Developing Pharmacy Practice document is clear: "Pharmacists should move from behind the counter and start serving the public by providing care instead of pills only. There is no future in the mere act of dispensing" (100). Canadian pharmacy academia and organizations have adopted this WHO/FIP definition and perspective on dispensing (104, 105), with criticism of pharmacists who choose to 'remain behind the counter' and involved with medication dispensing (101, 102, 106, 107).

This lack of clarity as to the definition of pharmacists' care, and in particular what care community pharmacists provide as part of dispensing, limits the ability to identify appropriate measures of quality pharmacists' care. Spanish, Portuguese or Brazilian models for defining the patient care pharmacists provide during dispensing should be considered for evaluation (108-110). If dispensing-related care is determined to be a priority, then research using our methodologies could evaluate dispensing-related care through administrative health data obtained through traditional pharmacy claims data or through documentation systems such as Australian's GuildCare®(26).

Conclusions

The four studies completed for this dissertation introduced an integrated CC/CPD model that used province-wide billing data from community pharmacies to evaluate pharmacy-team performance on proposed quality-of-care indicators. Lack of agreement on the definition of pharmacists' care and lack of literature documenting that provision of 'high-quality', well defined pharmacists' professional services leads to consistent, expected changes in patient health-outcomes make it difficult to identify appropriate quality indicators for use within our proposed model. Adherence-related indicators, although commonly-used as surrogate outcome measures, are easily gamed by policies such as automatic refills and do not align with quality outcomes defined for Canadian health care systems. Outcome indicators measuring patient use of potentially inappropriate prescription medications, such as our indicator measuring flurazepam use in the elderly, are not subject to gaming and align with priority health goals. Relevance would be further increased if there was evidence linking pharmacists' services with a decrease in use of such potentially inappropriate prescriptions and subsequent decrease in, for example, ER visits, falls or hospitalizations. Few process indicators measuring provision of pharmacists' services have been identified due primarily to challenges with low service provision and lack of evidence linking provision of these services with desired outcomes. Nationally and internationally our methodologies should be applicable for measuring pharmacy-level performance on indicators measuring the outcomes of pharmacists' care. However, the usefulness of our methodologies for the evaluation of the impact of specific pharmacists' services and determination of the factors affecting pharmacists' provision of quality care remain dependent on the type and detail of information maintained in the relevant databases.

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Chapter 8

Summary

Chapter 1 provides the background and context to this dissertation, focusing on the changing role of the community pharmacist. Although historically pharmacists have been responsible for medication preparation and supply, since the 1990s there has been increasing emphasis on the pharmacists' role in improving patients' use of medications. Around the world, the concept of pharmaceutical care was adopted that centred the pharmacists' role on identifying, managing and ensuring follow-up of patients with drug-therapy problems. Despite changes in education, regulation, scope of practice and reimbursement, implementation of the pharmacists' services required to provide this care has been limited. This is particularly true in community pharmacy. Focus, therefore, shifted to supporting community pharmacists in their provision of care and services that improved patients' use of medications. Continuing competence programs based on performance measurement were considered a possible vehicle for providing this practice change support. Challenges with the design of these programs included the identification of performance assessment methodologies that were both robust and feasible given the large numbers of practicing pharmacists in most jurisdictions. The concept of using routinely collected administrative health data, such as community pharmacists' billing data, to measure practice performance offered a potential solution that had not been evaluated. Therefore, the over-riding research question for this dissertation was:

> Within the context of an integrated CC/CPD program, how would the use of routinely collected administrative health data for performance measurement contribute to the improvement in quality of care by community pharmacists?

From this over-riding research question, four more detailed research questions were identified and addressed through four research projects as outlined in the chapters below. The studies were done in the Canadian province of Quebec, using data from the provincially-maintained databases for health services. These databases include information on patients, health care providers, dispensed medications and pharmacists' services provided to patients who were insured under Quebec's provincial health plan. Historically, Quebec pharmacists were the first to be authorized to bill for specific patient care services and the databases contain detailed information for each of these billings. All provinces across Canada now have similar authorizations, although the specific services and required billing information varies. Within Quebec, information from approximately 50% of the provinces 7.5 to 8 million residents is maintained within the pharmacy-specific databases. The province has more than 5000 community pharmacists provided care and service in roughly 1800 community pharmacies.

Chapter 2 addressed whether there was sufficient evidence from the health professions literature to create a theoretical model of an integrated CC/CDP program that was based on performance assessment of pharmacists' quality of care. The literature was reviewed and a model developed that applies to all community pharmacists, recognizes the powerful influence of external factors on an individual pharmacist's ability to perform to

his/her highest level of capability, incorporates the team-based nature of care provision at community pharmacies and is effectively integrated with CPD. The assessment cycle begins with a screening assessment of all community pharmacy-teams, using community pharmacy claims databases to calculate pharmacy-team performance on selected quality-of-care metrics. Factors that affected community pharmacists' performance beyond their individual competence were identified and structured into motivating, enabling and reinforcing factors.

Chapter 3 translates the results of Chapter 2 into community pharmacy practice. The framework of barriers and facilitators developed in the integrated CC/CDP program was used to analyze the processes followed when developing, implementing, sustaining and growing a community pharmacist's travel health services. This analysis allowed the development of a detailed planning framework for implementing sustainable community pharmacy practice change. Validation of this planning framework continues as new professional services are identified to be offered at The Prescription Shop and similar community pharmacies.

Chapter 4 addressed the feasibility of pharmacy regulatory authorities using pharmacy claims data to evaluate community pharmacists' performance as a screening measure within a CC/CPD program. We evaluated whether performance results on pharmacists' quality-of-care metrics met the requirements for use for high-stakes decisions related to licensure by regulatory authorities. Pharmacy-specific performance rates were calculated on four quality-of-care indicators, with performance at more than 85% of community pharmacies reliably assessed on all four indicators. One hundred and four of 1799 (5.8%) community pharmacy-teams demonstrated performance in the lowest quartile on three or four of four indicators. This is a manageable number of pharmacies that could be targeted for in-depth, diagnostic pharmacists' performance evaluation on an annual basis by pharmacy regulatory authorities. The validity of using database-derived indicators to measure pharmacy-team performance was supported by non-compliance results and data-base derived predictors consistent with literature-based expectations. Further, results met the requirements for use as a screening performance assessment within a CC/CPD program for community pharmacists. It was concluded that routinely collected pharmacy claims data can be used to monitor community pharmacy-team performance on quality-of-care indicators, and may be useful in future to identify potentially underperforming pharmacy-teams, measure the impact of policy changes and to determine predictors of best practices.

Chapter 5 investigated whether the provision of individualized, comparative practice-performance feedback on two medication effectiveness quality-of-care indicators increased community pharmacists' provision of patient-oriented services and improved patient's use of medications. Using provincial billing data to measure performance at more than 1400 randomized community pharmacies, mailed comparative feedback

reported the pharmacy-level percentage of dispensings to patients nonadherent to antihypertensive medications or overusing asthma rescue inhalers. Recommendations for improved performance were provided with focus on providing pharmaceutical opinions to physicians and were tailored to the pharmacy-team's performance level. Feedback on only the asthma overuse indicator led to increased provision of the pharmacists' opinions. This was hypothesized to relate to the more actionable nature of the feedback provided on this indicator relative to the antihypertensive medication underuse indicator. Feedback, however, did not result in improvements in patients' use of medications for either indicator. The lack of improvement in patients' use of asthma medications, despite increased pharmacists' pharmaceutical opinions to physicians to improve patient-use of these medications, lead to the conclusion that the quality process of providing pharmaceutical opinions to physicians was not linked to the quality outcome of improved patient use of medications. It was recommended that the format and requirements of the pharmacists' pharmaceutical opinion service be redesigned to increase the effectiveness of the service on patient-use of medications.

Chapter 6 made use of the data on adherence to antihypertensive medications from the feedback study to evaluate whether linked administrative health data could be used to determine the dispensing, patient and pharmacy-level characteristics that are associated with higher quality of pharmacists' care across pharmacies in Quebec. Results validated the use of the data to identify characteristics known to be associated with nonadherence including male sex, decreasing age, new to treatment, multiple prescribers and multiple dispensing pharmacies. Pharmacies providing more total professional services and those with better within-pharmacy continuity-of-care had higher quality of care results. Neither number of pharmaceutical opinions targeting antihypertensive nonadherence nor higher pharmacist overlap impacted a pharmacy team's quality of care. The impact of total professional services lead to the hypothesis that improved quality of care is provided at pharmacies where pharmacists prioritize their provision of professional services relative to involvement in technical distributive functions. The relationship between improved within-pharmacy continuity-of-care and decreased odds of non-adherence supports such a hypothesis as patients can more easily develop trusting relationships with their pharmacist when continuity of care is improved. Overall conclusions included that pharmacy administrative claims data can be used to directly measure dispensing, patient and pharmacy characteristics, thereby increasing the range and accuracy of pharmacy-level characteristics evaluated.

Chapter 7 discussed the results of the four research projects, revising the evidence-based model of integrated CC and CPD for community pharmacists. The model incorporates a screening performance evaluation of community pharmacists' quality of care that used pharmacy administrative claims data to measure pharmacy-level performance on proposed quality-of-care metrics. Although pharmacy-team level performance could be readily calculated on the proposed metrics, feedback of relative performance did not

improve follow-up scores on the indicators. Feedback did lead to increased provision of pharmacists' services aimed at improving medication management of patients with asthma, but these services were ineffective at changing medication mis-use. Determinants of higher pharmacy-team quality of care were identified via new methodologies that used linked administrative health data with results indicating better care in pharmacies with better continuity of care and higher billings for a range of pharmacists' services. Although results require validation with additional quality-of-care indicators, results suggest that culture and degree of independence of owners to prioritize professional services influence the quality of care provided in community pharmacies.

In review of the results of these studies, the lack of clear and accepted definition of what is meant by community pharmacist's quality-of-care was identified as a primary challenge in developing systems to assess community pharmacists' quality-of-care. For Canada, basing the definition of pharmacists' quality-of-care on the definitions of quality health care used by Canadian health policy organizations would align and embed future community pharmacist quality initiatives within existing Canadian frameworks. Once such a definition has been developed, existing quality-of-care indicators can be reviewed to identify potentially useful community pharmacist quality-of-care metrics. However, selection of appropriate pharmacist-metrics is further challenged by the lack of literature documenting the impact of pharmacists' services on health outcomes important to patients and health systems. The existing literature shows inconsistent findings and is frequently hampered by the selection of surrogate outcome measures that are not prioritized by health systems. Recognition of these challenges is being addressed through the development of core outcome sets for use in trials evaluating community pharmacists' services. Outcome indicators measuring patient use of potentially inappropriate prescription medications, such as our indicator measuring flurazepam use in the elderly, align with priority health goals. Relevance would be further increased if there was evidence linking pharmacists' services with a decrease in use of such potentially inappropriate prescriptions and subsequent decrease in, for example, ER visits, falls or hospitalizations. Collaboration with existing health quality organizations is critical to ensuring relevance of community pharmacists' quality-of-care metrics and to emphasizing community pharmacists' role as health care providers within high quality health systems.

Samenvatting (Dutch Summary)

Hoofdstuk 1 geeft de achtergrond en context bij dit proefschrift en richt zich daarbij op de veranderende rol van de openbaar apotheker. Hoewel apothekers van oudsher verantwoordelijk zijn voor de bereiding en voorziening van medicatie, ligt de nadruk sinds de jaren 90 steeds meer op de rol van de apotheker bij het verbeteren van medicijngebruik door patiënten. Wereldwijd werd het begrip "farmaceutische zorg" geadopteerd dat aan de apotheker een centrale rol toekende bij het identificeren, begeleiden en opvolgen van patiënten met farmacotherapeutische problemen. Ondanks veranderingen in de opleiding, regelgeving, bevoegdheden en vergoedingen, bleef de tenuitvoerlegging van de voor deze zorg vereiste dienstverlening door apothekers beperkt. Dit geldt met name voor de openbare farmacie. Daarom werd de focus verlegd naar het bieden van ondersteuning aan openbaar apothekers bij het verlenen van zorg en diensten ter verbetering van medicijngebruik door patiënten. Op prestatiemetingen gebaseerde nascholingsprogramma's werden gezien als een potentieel middel waarmee deze praktijkverandering kon worden ondersteund. Het bleek echter nog niet zo eenvoudig om dergelijke programma's te ontwerpen, getuige het probleem om prestatiemeetmethodes te vinden die zowel gedegen als uitvoerbaar waren gezien de grote aantallen praktiserende apothekers in de meeste districten. Het idee om gebruik te maken van routinematig verzamelde administratieve gezondheidsgegevens, zoals facturatiegegevens van openbaar apothekers, voor het meten van praktijkprestaties bood een potentiële oplossing die nog niet onderzocht was. De belangrijkste onderzoeksvraag voor dit proefschrift was dan ook:

> Hoe zou, in het kader van een geïntegreerd bij- en nascholingsprogramma*, het gebruik van routinematig verzamelde administratieve gezondheidsgegevens voor prestatiemetingen de kwaliteit van door openbaar apothekers verleende zorg kunnen helpen verbeteren?

Uit deze overkoepelende onderzoeksvraag werden vier meer specifieke onderzoeksvragen gedestilleerd die, zoals beschreven in de navolgende hoofdstukken, door vier onderzoeksprojecten werden beantwoord.

De studies werden in de Canadese provincie Quebec uitgevoerd, waarbij gebruik gemaakt werd van de door de provincie beheerde gezondheidszorgdatabanken. Deze databanken bevatten informatie over patiënten, zorgverleners, verstrekte medicatie en apothekersdiensten verleend aan patiënten in het bezit van Quebec's provinciale ziektekostenverzekering. Oorspronkelijk waren de apothekers van Quebec als eersten bevoegd om bepaalde patiëntenzorgdiensten in rekening te brengen en de databanken bevatten gedetailleerde informatie over elk van deze factureringen. Alle Canadese provincies hebben inmiddels vergelijkbare bevoegdheden, hoewel de specifieke diensten en vereiste factureringsinformatie per regio verschillen. In Quebec wordt de informatie

* Oorspronkelijke naam van bij- en nascholingsprogramma: Continuing Competence / Continuing Professional Development (CC/CPD) program.

van ongeveer 50% van de 7,5 tot 8 miljoen inwoners die de provincie telt bijgehouden in apotheek-gebonden databanken. De provincie kent meer dan 5000 openbaar apothekers zie zorg en diensten verlenen in ruwweg 1800 openbare apotheken.

Hoofdstuk 2 ging in op de vraag of er in de gezondheidszorgliteratuur voldoende bewijs te vinden was om een theoretisch model te kunnen ontwerpen voor een geïntegreerd bij- en nascholingsprogramma dat gebaseerd was op prestatiemeting van de kwaliteit van door apothekers verleende zorg. Er vond een literatuuronderzoek plaats aan de hand waarvan we een model ontwikkelden dat op alle openbaar apothekers van toepassing is, de grote invloed van externe factoren op het vermogen van een individuele apotheker om naar zijn/haar beste vermogen te presteren in acht neemt, rekening houdt met de teamgerichte aard van de zorgverlening in openbare apotheken en op effectieve wijze met nascholing is geïntegreerd. De meetcyclus start met een screening van alle openbare-apotheekteams, waarbij gebruik gemaakt wordt van databanken met openbare-farmaciedeclaraties om de prestaties van apotheekteams ten aanzien van geselecteerde zorgkwaliteitsindicatoren in kaart te brengen. We onderscheidden factoren die de prestaties van openbaar apothekers, los van hun individuele bekwaamheid, beïnvloedden en rangschikten deze naar motiverende, bevorderende en versterkende factoren.

Hoofdstuk 3 vertaalt de resultaten van Hoofdstuk 2 naar de openbare-farmaciepraktijk. Het schema van belemmerende en bevorderende factoren dat bij het geïntegreerde bij- en nascholingsprogramma werd ontwikkeld werd gebruikt om de bij de ontwikkeling, uitvoering, het onderhoud en de uitbreiding van openbare-farmaciereisgezondheids-diensten te volgen processen te analyseren. Dankzij deze analyse kon een gedetailleerd planningskader worden ontwikkeld voor de realisering van structurele verandering binnen de openbare-farmaciepraktijk. Validatie van dit planningskader wordt voortgezet, terwijl er nieuwe professionele diensten worden onderscheiden die bij *The Prescription Shop* en soortgelijke openbare apotheken verleend zullen gaan worden.

Hoofdstuk 4 behandelde de vraag of het mogelijk was dat apotheektoezichthouders farmaciedeclaratiegegevens gebruiken om de prestaties van openbaar apothekers te beoordelen als screeningsonderdeel binnen een bij- en nascholingsprogramma. We onderzochten of de prestatiescores van apothekers voor de zorgkwaliteitsindicatoren voldeden aan de voorwaarden voor het gebruik van deze resultaten voor *high-stakes*-besluiten over registratie door regelgevende instanties. Voor elke apotheek berekenden we prestatiescores voor vier zorgkwaliteitsindicatoren, waarbij van meer dan 85% van de openbare apotheken de prestaties ten aanzien van alle vier de indicatoren op betrouwbare wijze werden gemeten. Honderdenvier van de 1799 (5,8%) openbare-apotheekteams lieten bij drie van de vier indicatoren een prestatie in het laagste kwartiel zien. Dit is een overzichtelijk aantal apotheken dat in aanmerking zou kunnen komen voor jaarlijkse grondige, diagnostische prestatiemetingen door apotheektoezichthouders. De

validiteit van het gebruik van aan databanken ontleende indicatoren voor het meten van apotheekteamprestaties werd ondersteund door de ondermaatse-prestatieresultaten en de aan de databanken ontleende voorspellers die overeenkwamen met verwachtingen uit de literatuur. Voorts voldeden de resultaten aan de voorwaarden voor het gebruik ervan als prestatiescreening binnen een bij- en nascholingsprogramma voor openbaar apothekers. Er werd geconcludeerd dat routinematig verzamelde farmaciedeclaratiegegevens gebruikt kunnen worden om de prestaties van openbare-apotheekteams ten aanzien van zorgkwaliteitsindicatoren te controleren en dat deze in de toekomst tevens kunnen helpen om mogelijk ondermaats presterende apotheekteams te identificeren, de invloed van beleidsveranderingen te meten en voorspellers van best practices in kaart te brengen.

Hoofdstuk 5 onderzocht of het geven van individuele feedback op basis van vergelijkende praktijkprestaties op twee zorgkwaliteitsindicatoren omtrent medicatie-effectiviteit ervoor zorgde dat openbaar apothekers meer patiëntgerichte diensten verleenden en het medicijngebruik door patiënten verbeterde. De per mail verstuurde vergelijkende feedback, die gebaseerd was op provinciale facturatiegegevens waarmee de prestaties van meer dan 1400 gerandomiseerde openbare apotheken konden worden berekend, vermelde het percentage medicijnen dat verstrekt was aan patiënten die hun bloeddrukverlagende medicijnen niet innamen of die te vaak gebruik maakten van hun astma-inhalatoren. Er werden aanbevelingen voor prestatieverbetering gedaan waarbij de nadruk lag op het geven van farmaceutische adviezen aan artsen die waren toegespitst op het prestatieniveau van het apotheekteam. Feedback op enkel de overmatig-gebruik-bij-astma-indicator zorgde ervoor dat apothekers vaker advies gaven. Er werd verondersteld dat dit te maken had met het feit dat het eenvoudiger was om te handelen naar de feedback op deze indicator dan naar de feedback op de bloeddrukverlagende-therapieontrouw-indicator. De feedback leidde echter bij geen van beide indicatoren tot een verbetering van medicijngebruik door patiënten. Het uitblijven van een verbetering van het gebruik van astmamedicijnen door patiënten, ondanks de farmaceutische adviezen die apothekers gaven aan artsen om het gebruik van deze medicijnen door patiënten te verbeteren, leidde tot de conclusie dat kwaliteitsverbetering in de vorm van het geven van farmaceutische adviezen aan artsen geen verband hield met een zelfde verbetering in de vorm van beter medicijngebruik door patiënten. Er werd aangeraden om de vorm en vereisten waaraan de farmaceutische-adviesverstrekking door apothekers moest voldoen te herzien teneinde het effect van deze dienst op het medicijngebruik door patiënten te vergroten.

Hoofdstuk 6 maakte gebruik van de gegevens over therapietrouw rondom het innemen van bloeddrukverlagende medicijnen uit de feedbackstudie om te kunnen beoordelen of gekoppelde administratieve gezondheidsgegevens gebruikt konden worden voor het achterhalen van medicijnverstrekking-, patiënt- en apotheekspecifieke kenmerken die verband houden met een betere kwaliteit van door apothekers verleende zorg over

apotheken in Quebec. De resultaten valideerden het gebruik van de gegevens voor het distilleren van kenmerken waarvan bekend is dat ze samenhangen met therapieontrouw, zoals mannelijk geslacht, steeds jongere leeftijd, pas gestart met behandeling, meerdere voorschrijvers en meerdere apotheken die het medicijn verstrekken. Apotheken die in totaal meer professionele diensten hadden verleend en apotheken met een betere interne continuïteit van de zorg hadden een kwalitatief betere zorgverlening. Noch het aantal farmaceutische adviezen gericht op therapieontrouw ten aanzien van bloeddrukverlagende medicijnen, noch een grotere overlap tussen apothekers was van invloed op de kwaliteit van de door apotheekteams verleende zorg. De invloed van het totaal aan professionele diensten leidde tot de hypothese dat de zorgverlening van betere kwaliteit is in apotheken waar apothekers voorrang geven aan hun professionele dienstverlening ten opzichte van hun betrokkenheid bij technische distributietaken. De relatie tussen een verbeterde continuïteit van de zorg binnen de apotheek en een kleinere kans op therapieontrouw staaft een dergelijke hypothese, aangezien patiënten eerder een vertrouwensrelatie opbouwen met hun apotheker wanneer de continuïteit van de zorg beter is. Een van de slotconclusies was dat administratieve farmaciedeclaratiegegevens gebruikt kunnen worden om medicijnverstrekking-, patiënt- en apotheekkenmerken direct te meten en daarmee het aantal en de juistheid van beoordeelde apotheekspecifieke kenmerken vergroten.

Hoofdstuk 7 besprak de resultaten van de vier onderzoeksprojecten, waarmee het wetenschappelijk beproefde model voor geïntegreerde bij- en nascholing voor openbaar apothekers werd herzien. Het model omvat een prestatiescreening van de kwaliteit van door openbaar apothekers verleende zorg waarbij administratieve farmaciedeclaratiegegevens gebruikt worden om de prestaties op apotheekniveau ten aanzien van voorgestelde zorgkwaliteitsindicatoren te meten. Hoewel de prestaties van de afzonderlijke apotheekteams ten aanzien van de voorgestelde indicatoren eenvoudig te berekenen waren, leidde feedback op de desbetreffende prestaties bij vervolgmeting niet tot een verbetering van scores voor de indicatoren. De feedback leidde er wel toe dat apothekers meer diensten verleenden met het doel het medicatiebeleid van astmapatiënten te verbeteren, maar deze diensten waren niet in staat verandering aan te brengen in misbruik van medicijnen. Met behulp van nieuwe methoden die gebruik maakten van gekoppelde administratieve gezondheidsgegevens werden factoren gedistilleerd die bepalend zijn voor een betere kwaliteit van zorg door apotheekteams. De resultaten hiervan duidden op een betere zorg in apotheken met een betere continuïteit van de zorg en met hogere facturen voor een verscheidenheid aan apothekersdiensten. Hoewel de resultaten nog gevalideerd moeten worden met aanvullende zorgkwaliteitsindicatoren, geven ze aan dat de cultuur en mate waarin eigenaren vrij zijn om zich op professionele diensten toe te leggen van invloed zijn op de kwaliteit van de in openbare apotheken verleende zorg.

Bij het doornemen van de resultaten van deze studies kwam naar voren dat de ontwikkeling van systemen voor het beoordelen van de kwaliteit van zorg door openbaar apothekers hoofdzakelijk bemoeilijkt wordt door de afwezigheid van een duidelijke en algemeen aanvaarde definitie van “kwaliteit van zorg door openbaar apothekers”. Voor Canada geldt dat wanneer de definitie van kwaliteit van zorg door apothekers gebaseerd wordt op de definities van kwaliteit van gezondheidszorg die door Canadese gezondheidsorganisaties worden gehanteerd, toekomstige initiatieven met betrekking tot de kwaliteit van openbaar apothekers bij bestaande Canadese regelingen zouden aansluiten en daarin zouden worden ingebed. Zodra een dergelijke definitie is geformuleerd kunnen bestaande zorgkwaliteitsindicatoren onder de loep genomen worden om te kijken of daaruit mogelijk bruikbare zorgkwaliteitsindicatoren voor openbaar apothekers afgeleid kunnen worden. De selectie van geschikte apothekersindicatoren wordt echter verder bemoeilijkt doordat er te weinig literatuur voorhanden is over de invloed van apothekersdiensten op gezondheidsuitkomsten die voor patiënten en zorgstelsels van belang zijn. De bestaande literatuur laat tegenstrijdige bevindingen zien en wordt vaak beperkt door de selectie van alternatieve uitkomstmaten die niet door zorgstelsels worden geprioriteerd. Dat deze uitdagingen worden erkend blijkt uit het feit dat standaard uitkomstmaten in ontwikkeling zijn voor gebruik in effectenstudies waarin de beoordeling van de dienstverlening door openbaar apothekers centraal staat. Uitkomstindicatoren die het gebruik van mogelijk verkeerd voorgeschreven medicatie door patiënten meten, zoals onze indicator die het gebruik van Flurazepam door ouderen mat, sluiten aan bij prioritaire gezondheidsdoelstellingen. De relevantie zou verder toenemen als er bewijs voorhanden is dat een verband aantoont tussen apothekersdiensten en een verminderd gebruik van dergelijke, mogelijk verkeerd uitgeschreven recepten en dientengevolge een afname van bijvoorbeeld het aantal SEH-bezoekjes, vallen of ziekenhuisopnames. Samenwerking met bestaande zorgkwaliteitorganisaties is noodzakelijk om te kunnen garanderen dat indicatoren van de kwaliteit van zorg door openbaar apothekers relevant zijn en om de rol van openbaar apothekers als zorgverleners binnen kwalitatief hoogwaardige zorgstelsels te benadrukken.

Addendum
Valorization paragraphs

1. What is the social (and/or economic) relevance of your research results (i.e. in addition to the scientific relevance)?

The research questions in this dissertation focused on evaluating community pharmacists' provision of care that aims to improve patients' use of medications. The research questions were grounded in the long-standing awareness of the social and economic costs of preventable medication-related morbidity and mortality, and the potential for community pharmacists to minimize these costs through provision of quality care and services (1). Although there has been a general awareness of the extent and impact of inappropriate medication use, the World Health Organization (WHO) catapulted this awareness to a new level in 2017 when they identified 'Medications Without Harm' as their third global patient safety challenge (2). WHO's goal is to reduce the global level of severe, avoidable harm related to medications by 50% over five years, identifying that medications can cause serious harm if taken incorrectly or monitored insufficiently, or as the result of a medication-related error, accident or communication problem (3). WHO highlights that the global cost of medication errors alone has been estimated at US$ 42 billion annually and that unsafe medication practices are a leading cause of preventable harm around the world. Three target areas have been identified by WHO: high-risk situations where inappropriate medication use can cause greater harm; polypharmacy where patients take four or more medications, and; transitions of care where the risk of communication errors regarding appropriate medication use is higher.

The alignment of these target areas with pharmacists' traditional, acknowledged responsibilities for safe and effective dispensing of medications is clear. In addition, in many countries pharmacists are increasingly being authorized to provide, and in some cases reimbursed to provide, new services that take advantage of pharmacists' potential to contribute more directly to achieving Medication Without Harm. These services target each of the prescribing, dispensing, administering, monitoring and medication use stages of WHO's medication process. Medication reviews, pharmaceutical opinions, refusals to dispense, refill-extensions, independent prescribing, new-medicines services, medication reconciliation and minor ailments management are examples of services pharmacists have been authorized to provide to manage preventable medication-related harms. However, challenging and unanswered questions exist as to what pharmacists' care and which of these services (if any) effectively and consistently improve medication use. Answers to these questions require methodologies that accurately measure both if the service was provided and the quality of service provided, and that evaluate the impact on outcomes important to patients and health care systems. Only when such methodologies have been developed can an understanding be gained of pharmacists' services that consistently decrease medication-related harms and of the strategies that improve the quality and impact of these services. Development and evaluation of these methodologies are the core questions addressed in this dissertation.

2. To whom, in addition to the academic community, are your research results of interest and why?

Pharmacy regulatory authorities are the stakeholders most directly interested in the results of our research as they are responsible for ensuring the safe and effective practice of licensed pharmacists with focus on protection of the public. In many countries, a component of this responsibility is the mandatory requirement for assurance of pharmacists' continuing competence to practice. The framework developed and evaluated for this dissertation stemmed directly from earlier work with the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA) and was designed specifically for use by regulatory authorities for quality assurance of community pharmacists' practice.

Health quality assurance organizations, that have been developed on a national and provincial level, represent a second group of organizations interested in the results of this research. Most of these organizations have developed indicators that are used to evaluate the quality and impact of care provided by a range of health care professionals. As evidence and awareness grew of both the costs associated with preventable medication-related harms and the potential for management of these costs by pharmacists, interest in community pharmacy quality-of-care metrics and systems increased. In Ontario, the pharmacy regulatory authority (the Ontario College of Pharmacists, OCP) has partnered with the provincial health quality assurance organization (Health Quality Ontario, HQO) with the goal of developing four to five indicators that measure pharmacy practice quality and system-level impact (4). Results of our research were relied upon in the preparatory discussion for development of these indicators and, as described below, in the round-table discussion held in 2018.

Public and private payers of medications are a third group interested in the results of this research, particularly related to the methodologies developed to evaluate the impact of new pharmacists' services. The need for such evaluation systems has been identified by these stakeholders across Canada with interest expressed in our methodologies at both the provincial and federal level. Provincial payers have acknowledged making a leap of faith when agreeing to authorize and fund pharmacists' provision of professional services targeted at improving use of medications (5). In the absence of an accepted, evidence-based pharmacist-service evaluation framework, there is only limited and inconsistent evidence available documenting the impact of pharmacists' services. Private and public payers are responding to this lack of evidence by limiting and, in some cases, reversing decisions to fund pharmacists' provision of these services (6, 7).

Pharmacy advocacy organizations and pharmacy owners are the final interested group, the former of which represent practicing pharmacists on a national (i.e. Canadian Pharmacists' Association (CPhA)) or provincial (e.g. Ontario Pharmacists' Association) level. Chapter 3 presented a targeted effort to translate our research findings into

pharmacy practice. We used the barriers and facilitators identified via our continuing professional development framework to analyze the development and implementation of a well-recognized, quality pharmacists' travel health service. Published in CPhA's journal, this article was identified as a benchmark process to be used by pharmacists interested in implementing new services.

In addition to use of the framework for introducing new services, our methodologies for evaluating the impact of pharmacists' services are of particular relevance to these organizations and to pharmacy owners. To counter the actions of public and private payers to limit /reverse payment authorizations for pharmacists' services, pharmacy advocacy organizations and owners require robust evidence of the impact of these services.

3. Into which concrete products, services, processes, activities or commercial activities will your results be translated and shaped?

The preliminary nature of the research conducted for this dissertation limits the translation of results into concrete products or commercial activities, especially given that results highlight the shortage of evidence confirming the consistent impact of pharmacists' services on patient outcomes. However, our research results are influencing and being translated into the processes and activities of the four stakeholder groups as follows:

Pharmacy regulatory authorities: Results of our research were highlighted in 2018 at a national invitational meeting hosted by the pharmacy regulatory authority of Nova Scotia. This conference addressed the use of complexity theory to address the problem of how community pharmacists' practice could consistently and efficiently be transitioned to focus on improving patient's use of medications (8). Among presentations on pharmacists' attitudes, professional identity and reviews of evidence, our research results highlighted the need for measurement systems and indicators that are consistent with health systems' priorities and that measure what matters most to patients.

In follow-up to the April 2018 meeting, the Nova Scotia College of Pharmacists identified a number of undertakings related to community pharmacy quality metrics as part of their 2019 strategic plan. These include identifying how patients expect the status quo of their health to be impacted by the care they receive from a pharmacist, a summary of potential pharmacy quality-of-care indicators and a review of the evidence to support these indicators. As per the strategic plan, these undertakings aim to contribute to the development of policies that improve the Nova Scotia health care system by ensuring that the practice of pharmacy aligns with evolving patient care needs. Negotiations are presently underway for collaboration with the Nova Scotia College of Pharmacists to complete these undertakings including use of the results of this dissertation and the expertise gained via completion of the associated research projects and analysis.

Health quality assurance organizations: The introduction, analysis and research results from this dissertation served as the basis for the backgrounder written for the invitation-only roundtable hosted by OCP and HQO in May of 2018. This event built upon lessons learned to achieve consensus on a set of principles to guide the identification of pharmacy quality indicators for public reporting (9). Ideally this work will lead to the incorporation of measurement and reporting of pharmacists' care into HQO's existing suite of quality reports and resources (10). These include confidential and customized reports provided to family physicians that could potentially be modified to provide similar reports to community pharmacists. In addition, yearly public reports on the performance of Ontario's health system are created that could potentially incorporate indicators measuring quality of pharmacists' care (11).

Discussions are ongoing with these organizations to determine the next steps in incorporating the results of our research into the processes for both identifying appropriate community pharmacists' quality of care indicators and developing methodologies for using performance on these indicators to improve pharmacists' quality of care.

Public and private payers of medications: The Ontario Pharmacy Research Collaboration (OPEN) received $5.7 million (Canadian dollars) in 2013 from the Ontario Ministry of Health and Long-Term Care Health System Research Fund to study the quality, outcomes and value of pharmacists' services (12). Results of our research projects informed the funding proposal for the project related to development of a pharmacists' services evaluation framework. Initial results of this work identified that development of this evaluation framework is a key priority across Canada, confirmed that no comprehensive, functioning pharmacy evaluation frameworks were available, and determined that priorities for evaluating methodologies were inconsistent across stakeholders (13, 14).

Results of our research continued to inform the work of OPEN via the 2014 invitational meeting where the use of quality indicators in community pharmacy was introduced as a methodology to both measure community pharmacists' quality of care and evaluate the impact of new pharmacists' services (15). This lead to a Canadian Institute of Health Research grant to OPEN for a symposium entitled "Incorporating Quality Improvement into Community Pharmacy to Improve Drug Prescribing, Use and Health Outcomes for Older Adults" (16). Results of our research projects were presented as the keynote address at this conference (17). Learnings from this dissertation continue to serve as background to guide ongoing OPEN research projects, including those recently funded via an additional $2 million (Canadian dollars) from the Ontario Ministry of Health and Long-Term Care Health System Research Fund (18).

In addition to interest from public payers, a key Canadian private insurer attended the 2014 presentation of our research results at the OPEN provincial meeting and subsequently expressed interest in developing a pharmacy quality measurement system for use within their insurance group. Follow-up led to Green Shield Canada insurance

group's introduction to the Pharmacy Quality Alliance (PQA) and subsequent partnership with PQA's Pharmacy Quality Solutions (PQS) to introduce Green Shield's Value Based Pharmacy program in Canada (19, 20). This program provides audit and feedback of pharmacy-level performance on selected quality indicators. Green Shield Canada has recently published their plans for performance improvement which include: Phase 1 provision of comparative feedback alone, Phase 2 pharmacy-level performance results available publicly via the internet for pharmacy selection, and Phase 3 variable dispensing fee reimbursements dependent on indicator performance (21).

As discussed in this dissertation, methodological questions remain regarding the appropriateness of the measures used within Green Shield Canada's program, the validity of assessment results for comparison purposes, and the evidence supporting pharmacists' capacity to improve their performance and to impact on patient outcomes. However, introduction of Green Shield Canada's commercial activity has piqued regulatory and professional interest in the appropriate selection of pharmacy quality metrics and methodologies for robust measurement and improvement in community pharmacists' performance. As no other research is ongoing in this area in Canada, our methodologies / indicators / recommendations are being considered by at least two provinces for use in development of more robust quality assurance programs.

Pharmacy advocacy organizations: The Canadian Pharmacists Association (CPhA) recently embarked upon a process to develop a forward-thinking, uniform national scope of practice for the profession of pharmacy across Canada (22). In follow-up to presentation of our research results and recommendations at the Nova Scotia College of Pharmacists' meeting, CPhA requested discussion regarding the definition and measurement of pharmacists' quality of care. Advocacy organizations are aware that in the absence of a nationally agreed upon, pragmatic, evidence-based definition of quality pharmacists' care, disparate and potentially self-serving definitions and metrics could be developed and applied across Canada.

4. To what degree can your results be called innovative in respect to the existing range of products, services, processes, activities and commercial activities?

Availability of detailed and linked administrative health data that included billing records for dispensings of medications and community pharmacists' services, access to a population-based sample of pharmacies and robust data analysis methodologies make this research unique in the world. Although the PQA has developed commercial systems for measuring and reporting pharmacy level performance across selected metrics in the USA, the primary stakeholder for this US-based work was the insurance industry (i.e. private payers). Green Shield Canada has recently introduced a PQA-based reporting system, adopting the PQA-insurance focus with less emphasis on evaluating the methodologies used by PQA / PQS or the theories underlying the measurement and improvement of pharmacists' quality of care. By contrast, these have been the focus of

the research completed for this dissertation, with emphasis on determining the requirements for appropriate selection and use of pharmacy quality metrics to improve both pharmacists' performance and patients' use of medications.

A number of countries have developed indicators aiming to measure the quality of pharmacists' care, with the Netherlands leading work including evaluation of the validity of their proposed indicators. However, despite ongoing work in the Netherlands, the USA, UK, the Organization for Economic Co-operation and Development (OECD) and the Pharmaceutical Care Network of Europe, recent reviews document a continuing lack of well-developed, validated indicators for measurement of the processes and outcomes of pharmacists' quality of care. The results of our analysis that indicated the need to re-evaluate the indicators most frequently selected as measures of pharmacists' quality of care have been adopted as best practice by the two pharmacy regulatory authorities working in this area in Canada. Our recommendations to both select indicators important to patients and health care systems, and to carefully evaluate the literature reporting on the impact of pharmacists' services on these indicators, formed the basis for ongoing strategic initiatives by the NSCP.

The detailed, coded data in our administrative health databases of pharmacists' service provision addressed the challenge faced by many countries of lack of documentation of service provision. Early work such as that in the Netherlands relied on self-report by pharmacists of services provided while the research in this dissertation capitalized upon the province of Quebec's long history of both reimbursing pharmacists for professional services and requiring service details for reimbursement. As pharmacists are increasingly being reimbursed to provide services, the methodologies developed via our research can be used to evaluate the impact of these services. Further, the methodologies developed for direct measurement of pharmacy characteristics from administrative health data and multi-level analysis of determinants of quality of care represent first published results. Our research results are, therefore, innovative and standard-setting for ongoing pharmacy-services' evaluation research and policy-initiatives at both provincial and federal levels.

5. How will this/these plan(s) for valorization be shaped? What is the schedule, are there risks involved, what market opportunities are there and what are the costs involved?

The primary factor shaping plans for valorization of our research results is market realization. The need for stakeholders to embark upon strategic initiatives related to defining and measuring pharmacists' quality and impact of care has been described. The more challenging question is whether pharmacy stakeholders acknowledge the breadth of these needs and/or the need for expertise and ongoing research to adequately address these strategic initiatives. Creation of policy is the focus of many of the relevant stakeholders, and policy development can be strongly influenced by political process and

administrative requirements. Consensus building can take priority with a tendency to focus on inclusivity rather than expertise. Therefore, risks include that work to identify evidence-based definitions of quality pharmacists' practice and community pharmacy quality-of-care metrics could be caught up in political processes and consensus building that is not necessarily evidence-based. This risk is exacerbated by the tendency of the profession to rely on pharmacy-only working groups and pharmacy-centric evidence for development of core policies (23). Core evidence and expertise may not be not considered (24), such as Mossialos et al's article on the lack of policy-relevant evidence to support the expanding role of the community pharmacist (25) or relevant, robust systematic reviews from the Cochrane Database (26, 27).

Increasing recognition of the potential for pharmacists to improve medication use is, however, creating new opportunities for both implementation of results of this dissertation and ongoing research. Funds such as those for medication optimization projects via the Frailty Network provide opportunities for further research (28). Ongoing collaboration with regulatory authorities offers more direct opportunities for knowledge translation and development of policies based on and further expanding the results of this dissertation.

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Curriculum vitae

Throughout her career, Nancy Winslade has been deeply involved with policy, practice, education and research endeavors that focus on improving medication use. She is a pharmacist by education, completing her Bachelor of Science in Pharmacy at the University of Toronto in Ontario, Canada, her residency at Sunnybrook Medical Centre in Toronto and her PharmD at the Statue University of New York at Buffalo in the USA. She began her career at the University of Toronto Faculty of Pharmacy and Sunnybrook Medical Centre as an intensive care pharmacist in 1985. She shifted her practice setting to family medicine when she was seconded by the University of Toronto, ultimately developing a community health centre-based pharmacist clinic. As an Associate Professor at the University of Toronto Nancy focused on developing and evaluating new pharmacist practice models and novel methodologies for teaching pharmacy students. Her academic administrative responsibilities included developing and implementing the Faculty's post-baccalaureate PharmD program. She was the inaugural Director of this program from 1992 until 1994, at which time she relocated to Europe.

While residing in Europe from 1994-2003, Nancy began consulting with focus on development and evaluation of health profession's education and assessment programs. In pharmacy, contracts included development of the Canadian National Association of Pharmacy Regulatory Authorities' (NAPRA) competencies for pharmacists at entry-to-practice, evaluation and revision of NAPRA's National Continuing Competence Assurance Program, evaluation of the Alberta College of Pharmacists' external review program and development of the Association of Faculties of Pharmacy of Canada's (AFPC) Educational Outcomes. The latter form the basis of the Canadian Council on Accreditation of Pharmacy Program's (CCAPP) accreditation criteria for student outcomes.

While in Europe Nancy completed her Masters in Health Professions Education at the University of Maastricht, focusing on program evaluation and assessment systems for health profession's faculties and for practising health care professionals. Her thesis developed and validated an assessment of prescribing competence for physician assistants and medical technicians in the Canadian Military and Nancy continued this military work as a consultant both in Europe and upon her return to Canada. In recognition of her expertise in assessment, in 2000 she became associated with the American Association of Colleges of Pharmacy's (AACP) Educational Institute. AACP also commissioned her to prepare recommendations for an ideal, evidence-based student assessment program following her work at the 2000 Institute.

Upon her return to Canada Nancy continued her consulting work in program evaluation and assessment with primarily national organizations including the Canadian Patient Safety Institute (CPSI), the Canadian Association of Physician Assistants, the Canadian Examiners in Optometry, the Canadian National Drug Safety and Effectiveness Network and the National Organization of Nurse Practitioner Faculties (USA). Nancy also joined McGill University's Faculty of Medicine to continue her work on assessment in the health care professions through completion of her PhD at the University of Maastricht's School of Health Education.

Nancy has recently relocated from Montreal, Quebec to Ottawa, Ontario. While completing her dissertation on community pharmacists' quality of care metrics, she has continued her consulting work focusing on regulatory, educational and practice policy supporting safe and effective medication use.

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