

Evaluation of a Screening Questionnaire to Identify Patients at Risk of Drug Therapy Problems in Community Pharmacies

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ABSTRACT

Context: Suboptimal drug use is a major contributor to adverse patient outcomes in primary care. Considering their accessibility and frequent interactions with patients, community pharmacists may be well suited to identifying patients who are at high risk of drug therapy problems (DTPs) and who may benefit from a comprehensive medication assessment.

Objective: To determine if a short screening tool can identify patients at risk for DTPs in a community pharmacy setting.

Design: A five question self-administered screening tool was identified in the literature and adapted to reflect current practice in community pharmacy. Adults requesting a refill prescription from three different community pharmacies over 12 weeks completed the screening tool, and had a comprehensive medication assessment with a pharmacist. Information from the assessment was used to: a) determine the ability of patients to correctly answer the screening tool questions and to classify themselves into the appropriate risk category (High or Low Risk); b) compare the number of DTPs identified in each risk category (High vs Low); and c) determine the number of High Risk and Low Risk patients who would qualify for any of the existing provincial medication review programs in Canada.

Results: 49 patients completed the study. Most patients were able to answer the questions on the screening tool correctly. The strength of agreement was very good (Kappa 0.91, $p < 0.01$) between the overall patient determined risk category and pharmacist determined risk category. Patients identified as High Risk ($n=18$) had a mean of 3.72 ($p < 0.01$) more DTPs than Low Risk patients ($n=31$). All but one (94.4%) of the High Risk patients had at least one Moderate or Severe DTP, while less than half (48.4%) of Low Risk patients had at least one Moderate or Severe DTP. The majority of High Risk patients were eligible for medication reviews in all programs except for Newfoundland and Labrador, New Brunswick and Saskatchewan. Close to a third of

Low Risk patients were eligible for medication reviews in Prince Edward Island, Nova Scotia and Ontario.

Conclusions: This screening tool is a trustworthy method for identifying patients in community pharmacies who have a large number of DTPs. Patients identified as High Risk using this screening tool may be good targets for community pharmacy based comprehensive medication assessments.

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LIST OF ABBREVIATIONS

AB.....	Alberta
ADRs.....	Adverse Drug Reactions
BC.....	British Columbia
BPMH.....	Best Possible Medication History
CDM.....	Chronic disease management
DRR.....	Drug Regimen Review
DTPs.....	Drug therapy problems
HIPA.....	Health Information Protection Act
ISMP.....	Institute for Safe Medication Practice
NB.....	New Brunswick
NL.....	Newfoundland and Labrador
NS.....	Nova Scotia
NSAID.....	Non-steroidal anti-inflammatory drug
ON.....	Ontario
PC.....	Pharmaceutical Care
PEI.....	Prince Edward Island
PIPEDA.....	Personal Information Protection and Electronic Documents Act
SK.....	Saskatchewan
USD.....	United States Dollars

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Chapter One – Introduction

1.1 Overview of the Problem

Many patients in the ambulatory setting suffer from sub-optimal health in part due to preventable adverse drug events and poor chronic disease management (CDM). Drug related causes account for a significant number of emergency room visits and hospitalizations in Canada, a large proportion of which are thought to be preventable.(1–3)

Community pharmacists are in a prime position to address medication mismanagement due to frequent contact with patients and specialized training regarding medications. Previous research supports the ability of community pharmacists to improve medication management. For example, significantly improved hypertension(4) and dyslipidemia(5)(6) control has been demonstrated when pharmacists performed a comprehensive medication assessment within community pharmacies. Community pharmacist-led comprehensive medication assessments have also been shown to decrease medication related hospital admission rates in patients with five or more medical conditions.(7) Unfortunately the majority of evidence based interventions described in the literature have not been integrated into mainstream community pharmacy practice, likely because these studies tested complex and multi-faceted interventions that took large amounts of pharmacist time(8), and community pharmacists currently spend a limited amount of their time providing such clinical services.(9)

Considering their accessibility and frequent, yet brief, interactions with large numbers of patients, community pharmacists may be well suited to screen for patients who are at high risk of drug therapy problems (DTPs). A drug therapy problem is defined as any drug related issue that contributes to sub-optimal patient health outcomes. Examples of DTPs include a drug causing an adverse reaction, a drug at a dose too low to achieve the desired therapeutic benefit, and the drug being taken incorrectly by the patient. Many community pharmacists work under very tight time constraints and struggle to spend large amounts of time with individual patients,

especially on short notice, making a brief screening intervention potentially quite feasible. After identifying patients who are at high risk for DTPs, community pharmacists could have the option to manage the high risk patients themselves (if they had time and if they were engaging in one of the provincially sponsored medication reviews programs) or they could refer the high risk patients to other professionals who may be in a better position to provide a comprehensive medication assessment (i.e. pharmacists working in primary care teams or outpatient clinics).

While comprehensive medication assessments have been shown to be valuable, it is unclear which patients are best served by this intervention. This is due to a lack of evidence in the literature regarding which patients will benefit the most from a pharmacist led comprehensive medication assessment. The lack of evidence may help to explain why the eligibility criteria utilized by all of the provincially funded Canadian medication review programs are highly variable and inconsistent.(10) The identification or development of evidence based screening criteria to identify patients at high risk of experiencing DTPs would likely assist these provincial programs in creating more consistent and effective eligibility criteria, and presumably help pharmacists target the most appropriate patients.

As part of a systematic literature review of Medline, Embase, International Pharmaceutical Abstracts and Google Scholar, as well as a review of the grey literature, a screening tool was identified that appeared to have good potential to detect patients needing a comprehensive medication assessment and that was thought to be reasonable for use in community pharmacies. The tool was previously tested in an outpatient family medicine clinic setting and found to effectively identify patients with multiple DTPs (who may benefit from a comprehensive medication assessment)(11); however, this screening tool has not been similarly tested in a community pharmacy setting. The tool is comprised of a patient self-administered screening questionnaire that includes five short dichotomous questions and it was found to be simple and quick to complete by patients who were waiting to see their family physician.(11) Due to the ease of use and the apparent utility of this screening questionnaire within a family medicine clinic setting, it was also thought to be potentially useful in community

pharmacies for identifying high risk patients with multiple DTPs (who may benefit from a comprehensive medication assessment).

The purpose of this research study was to evaluate the effectiveness of a modified version of this screening questionnaire to identify patients at risk for DTPs in a community pharmacy setting who may benefit from a medication review.

Chapter Two - Literature Review

2.1 Drug Therapy Problems

The concept of Pharmaceutical Care (PC) was introduced in 1990 by Hepler and Strand. The goal of PC is “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient’s quality of life”.(12) These definite outcomes are: to cure a disease, eliminate or reduce symptoms of a disease, stop or slow the disease, or prevent disease development or symptoms of a disease. PC may only be achieved by the pharmacist interacting and collaborating with other health care professionals who are involved in the patient’s care. Within the therapeutic plan, three main goals must be held paramount for the pharmacist: identifying potential or actual drug therapy problems, resolving actual drug therapy problems, and preventing drug therapy problems. A drug therapy problem is defined as any drug related issue that contributes to sub-optimal patient health outcomes.

There are seven generally accepted categories of drug therapy problems: adverse drug reaction(s) (ADRs), suprathereapeutic dose (dose too high), subtherapeutic dose (dose too low), inappropriate drug (wrong drug), drug not indicated (taking a drug for an unknown reason), drug therapy required (not taking a drug that is necessary for optimal treatment) and noncompliance (taking a drug incorrectly).(13) Management of DTPs often requires collaboration between different health care providers; however, pharmacists can independently resolve some DTPs. It is part of the professional responsibility of all pharmacists to actively search for and attempt to resolve DTPs.

2.2 Patient Morbidity as the Result of Medication Mismanagement

Medication mismanagement and drug therapy problems account for a significant proportion of hospital admissions and the majority of these may be preventable.(1–3) A Canadian study found that 24.1% of hospitalizations in a large Canadian hospital were the result of a drug related issue.(2) Furthermore, 72.1% of these issues were deemed to be preventable. The vast majority of the identified DTPs that caused hospital

admission were serious; 83.8% being of moderate severity, 7.4% being high severity, and 0.7% being fatal. The types of DTPs identified in this study most commonly were adverse drug reaction (35.3%), inappropriate drug (17.6%), and noncompliance (16.2%).

In another study, of 1017 patients who visited a Canadian emergency department, 122 (12.0%) were deemed to be there due to a medication issue. Of those patients, 68.0% of the issues were likely preventable.(1) Most commonly, the drug related visit was due to an adverse drug reaction or non-compliance. The authors also found that the probability of hospital admission was greater in patients who were visiting the emergency department due to a drug related cause, compared to patients visiting for any other cause. Similar research in the United Kingdom found that 6.5% of hospital admissions were due to drug related causes, of which 67.2% were deemed preventable.(3)

Clearly this is a major global issue that requires action. The prevention of drug therapy problems is a large role for pharmacists, and comprehensive medication assessments may identify DTPs, which may avoid some of these emergency department visits and hospitalizations.

2.3 Comprehensive Medication Assessments

A comprehensive medication assessment is a clinical intervention in which a health provider (usually a pharmacist) spends dedicated time with a patient, generally in a private setting, to review his/her medications and medical conditions, ensuring that the patient is receiving optimal treatment for their conditions. Through comprehensive medication assessments (sometimes referred to as Medication Therapy Management, or Comprehensive Medication Assessments, or simply Medication Assessments or Medication Reviews), the health provider is able to determine if the patient's drug therapy goals are being met and to identify any actual or potential DTPs. Actively searching for DTPs is an important aspect of providing pharmaceutical care.(13)

In the IMPACT trial(14), pharmacists were able to identify at least one DTP in 93.8% of patients who received comprehensive medication assessments. On average, pharmacists in this study identified 4.4 DTPs per patient and the most common

problems fell into the following categories: additional medication required (27.0%), non-compliance (16.5%), sub-therapeutic dose of a drug (16.2%) and adverse drug reactions (7.9%).

In a large study in the United States, pharmacists were able to identify and resolve 5780 DTPs for 2524 patients who received a comprehensive medication assessment.(15) Eighty-nine percent of patient's therapeutic goals were achieved at the final encounter with the pharmacist, an increase of 15% from baseline.

Similarly, Roth and colleagues(16) were able to identify a mean of 4.2 DTPs per patient in a study where elderly patients in the United Kingdom who were on five or more medications received a pharmacist led comprehensive medication assessment. Six month follow up found that the majority of the DTPs had been addressed and resolved during the study period. The authors were also able to demonstrate that the patients included in the study had a significant reduction in the use of acute health care services during the study, potentially due to the resolution of DTPs.

Pharmacist led comprehensive medication assessments can clearly identify a multitude of potential and actual DTPs in patients, making a potentially significant impact on the alarming rates of medication mismanagement in the primary care system. However, identifying, resolving and preventing DTPs (by performing comprehensive medication assessments) is not currently routine in community pharmacy practice, despite the large amount of evidence supporting the benefits of this type of pharmaceutical care intervention.

2.4 DTP Identification by Community Pharmacists

In the community pharmacy setting, the rate of pharmacists identifying DTPs is relatively low. Observational studies indicate that between 0.74% and 2.5% of patients visiting community pharmacies are identified as having at least one DTP during routine practice.(17–20) This is much lower than the rates of DTPs found when pharmacists practicing in other settings interact with similar patient populations. In the IMPACT Trial, pharmacists practising as co-located members of a family medicine team identified at least one DTP in 93.8% of patients.(14) Pharmacists who systematically reviewed repeat prescriptions in a general practice in the United Kingdom were able to identify

DTPs in 157 of 285 patients (55.1%).(21) Another study involving pharmacists performing a brief medication review prior to the patient being seen by a physician for repeat prescription found that 16.8% of patients had at least one DTP identified, and 76.8% of these DTPs were then actively managed by the physician. When no medication review was performed, only 8% of patients were identified as suffering from at least one DTP, and only 37.5% of the identified DTPs were actively managed by the physician during the visit.(22) Yet another study investigated a short screening questionnaire used in community pharmacies, meant to determine if patients familiar to the pharmacy were at risk for DTPs. The results of the questionnaire highlighted that even patients well known to the pharmacy had some medication related issues that could impact their drug therapy outcomes that the pharmacists were not aware of.(23) Based on the literature, it appears that pharmacists practicing in a typical community pharmacy setting may be missing large numbers of high-risk patients with DTPs and may not be capitalizing on an important opportunity to resolve these DTPs and improve patient health.

Explanations for why community pharmacists may not be identifying as many DTPs as they likely could include: a) There are no evidence based, standardized screening procedures in the literature that could be implemented in this setting to assist community pharmacists in identifying patients at high risk for DTPs, who may benefit from a comprehensive medication assessment.(24) b) Most community pharmacists work under very tight time constraints and do not spend large amounts of time with individual patients(9), especially on short notice, making it extremely difficult to perform the comprehensive medication assessments that are generally required to effectively and thoroughly identify DTPs in individual patients.

Considering their accessibility and frequent, yet brief, interactions with large numbers of patients, many community pharmacists may be well suited to screen for patients who are at high risk of drug therapy problems (DTPs). After identifying patients who are at high risk for DTPs, community pharmacists could have the option to manage the high risk patients themselves at a later date (if they had time and if they were participating in one of the provincially sponsored medication reviews programs) or they could refer the high risk patients to other pharmacists who may be in a better position to

provide a comprehensive medication assessment (i.e. pharmacists working in primary care teams or outpatient clinics). The identification or development of evidence based screening criteria to identify patients at high risk of experiencing DTPs would assist community pharmacists who want to test the feasibility and benefits of taking on this screening role.

2.5 Refill Encounter as an Opportunity for a Screening Intervention

A prescription refill encounter at a community pharmacy may be an effective and appropriate opportunity for community pharmacists to screen for patients who are at high risk of DTPs (if evidence based screening criteria existed). Processing a new prescription usually entails more work for the community pharmacy staff as compared to a refill prescription. In addition to properly dispensing the medication, a new prescription must be correctly entered into the pharmacy software and the pharmacist must carefully consider the safety and efficacy of the prescribed medication for that individual patient, often with more scrutiny than during a prescription refill encounter. The initial prescription dispensation is also commonly the time when the pharmacist provides the most education to the patient on their new medication, requiring a significant amount of the pharmacist's time.(25,26) Consequently, it may be most feasible and practical for community pharmacists to screen for patients at high risk of DTPs during the refill prescription encounter as there may be more time to spend with the patient.(27,28)

Screening for DTPs during the refill prescription encounter may offer additional advantages compared with screening during a new prescription. The patient may be more cognisant regarding their medication(s) and medical condition(s) at a refill, after having experienced living with the medical condition(s) and having experience taking their medication(s). In addition, lack of efficacy or the presence of adverse effects can only be determined after the patient has been taking the medication. Likewise, adherence problems may only become apparent after a patient experiences the medication on a chronic basis. For these reasons, a prescription refill encounter may be an excellent opportunity to screen to DTPs.

2.6 Medication Review Programs in Canada

Most provinces in Canada have implemented government sponsored programs to compensate community pharmacies for providing variations of a clinical pharmacist service that is commonly referred to as a medication review. Ontario was the first province to remunerate community pharmacies for a standardized medication review program in 2007 called MedsCheck. Since 2007, similar programs have appeared in several other provinces.

Each program has unique expectations regarding the details of the intervention and the breadth and depth to which pharmacists are mandated to review and assess each patient's medications. However, all of these programs share the common goal of having a pharmacist meet with a patient to provide education about the medications they are taking; to provide the patient (and pharmacy) with a current best possible medication history; to identify, and address DTPs; and to elucidate and monitor patients' progress towards the goals of their drug therapy.

The provincial funding available for these programs is limited and pharmacist time continues to be at a premium. Consequently, each province has limited patient access to these services by developing strict eligibility criteria. The presumed goal of the eligibility criteria is to ensure that these programs improve patient outcomes and utilize public resources responsibly, by providing the service to the highest risk patients who will likely benefit the most.

Eight of the ten provinces in Canada have a provincially funded program that could be considered a medication review for individuals who are members of the respective provincial drug plans, although not all use the term 'medication review' to describe the service being provided. Table 1 contains an overview of the eligibility requirements of these provincial programs. Manitoba, Quebec and the territories did not offer provincially funded medication review program similar to the other provinces, and are therefore not included in the table. Some provinces offered more than one variation of the service, which is reflected in Table 1.(10)

Table 1: Overview of Eligibility Requirements for Community Pharmacy Medication Review Programs in Canada(10)

Province	Name of Program	Eligibility Requirements
Newfoundland and Labrador (NL)	Medication Review(29)	Individuals with diabetes taking an oral hypoglycemic agent and/or insulin.
Prince Edward Island (PEI)	PEI Basic Medication Review(30)(31)	Individuals taking 3 or more chronic medications covered by PEI Pharmacare programs, and are participants in one of the following PEI provincial programs: Seniors' Drug Cost Assistance, Financial Assistance, or Private Nursing Home.
Prince Edward Island (PEI)	PEI Diabetes Medication Review(30)(31)	Individuals enrolled with the PEI Pharmacare Diabetes program and on at least 1 medication covered by PEI Pharmacare programs used in the treatment of diabetes.
Nova Scotia (NS)	Basic Medication Review Service(32)	Beneficiaries of any NS Pharmacare program (except the Under 65 – Long Term Care Program) who do not reside in a nursing home, home for special care, and do not receive medication in compliance packaging. Individuals must be taking 3 or more prescription medications that are used for the treatment of chronic conditions, and are covered by the NS Pharmacare program.
Nova Scotia (NS)	Advanced Medication Review Service(32)	Beneficiaries of the Seniors' Pharmacare Program who do not reside in a nursing home, home for special care and do not receive medication in compliance packaging. Individuals must be taking 4 or more prescription medications, or be taking one of the designated medications ^a . Individuals must have at least one of the designated diseases ^b .
New Brunswick (NB)	PharmaCheck(33)	NB Prescription Drug Program plan A (Seniors) beneficiary taking 3 or more chronic prescription medications.
Ontario (ON)	MedsCheck(34)	Individuals must be on a minimum of 3 prescription medications for chronic condition(s).
Ontario (ON)	MedsCheck for Ontarians living with Diabetes(35)	Individuals must be diagnosed with Type 1 or Type 2 diabetes, and be taking one or more medications for treating diabetes.
Ontario (ON)	MedsCheck at Home(36)	Individuals must be on a minimum of 3 prescription medications for chronic condition(s) and are not able to attend to the community pharmacy.

Ontario (ON)	MedsCheck for Long Term Home Care Residents(37)	Individuals must reside in a licensed Long-Term Care Home.
Saskatchewan (SK)	Compliance Packaging with Medication Assessment(38)	Individuals must be eligible Home Care patients or Mental Health patients, with a minimum of one medication covered by the SK Drug Plan in the compliance package.
Saskatchewan (SK)	Saskatchewan Medication Assessment Program(39)	Individuals age 65 and over, living in the community, and: (1) be taking 5 or more chronic medications, of which 3 must appear on PIP (the provincial database of dispensed medication); or, (2) be taking an anticoagulant medication; or, (3) be taking a medication on the <i>Beers List</i> .
Alberta (AB)	Comprehensive Annual Care Plans for Albertans(40)	Individuals with “complex needs” ^c .
Alberta (AB)	Standard Medication Management Assessment for Albertans(40)	Individuals must have at least 1 “chronic condition” ^c , and be taking at least 3 different prescription medications or 2 prescription medications and insulin.
British Columbia (BC)	Medication Review Services (41)	Individuals must have at least 5 qualifying medications (discreet DINs) active within the last 6 months on the provincial PharmaNet system, and there must be a clinical need ^d .

a) Designated medications include methyl dopa, indomethacin, cyclobenzaprine, diazepam, chlordiazepoxide, clorazepate or amitriptyline.

b) Designated diseases include asthma, diabetes, hypertension, hyperlipidemia, congestive heart failure, chronic obstructive pulmonary disease or arthritis.

c) “Complex needs” defined as the presence of both chronic condition(s) and risk factors. There are two categories of patients with “complex needs”; those with at least two chronic conditions and those with one chronic condition and one or more risk factor. Chronic conditions include: hypertensive disease, diabetes mellitus, chronic obstructive pulmonary disease, asthma, heart failure, ischaemic heart disease, and mental health disorder. Risk factors include: tobacco use, obesity, and addictions.

d) Clinical need is obtained when a prescriber requests a medication review, when the patient has multiple diseases, the patient has chronic diseases, the patient’s medication regimen includes one or more non-prescription medications, the patient’s medication regimen includes one or more natural health products, then patient has a drug therapy problem(s), the patient was recently discharged from hospital, the patient has multiple prescribers, and the patient is receiving medication(s) that require laboratory monitoring

The most striking aspect of these medication review programs is the lack of consistency with respect to the eligibility criteria utilized by each provincial program. Despite providing similar clinical pharmacist interventions, there appears to be little congruence amongst programs regarding the patients who are eligible to receive the services. Some programs require patients to be taking a minimum number of chronic medications to be eligible (but no consistent number of medications is used), while other programs are available to patients taking certain high-risk medications (e.g., anticoagulants) or with specific chronic diseases (e.g., diabetes), regardless of the number of medications taken. Some use a combination of these approaches, where eligible patients must suffer from a specific chronic disease and be taking a minimum number or type of medications.

The prevailing similarity amongst these programs' eligibility criteria is that most appear to be based on known risk factors for preventable medication related ADRs or the presence of DTPs. There are many agreed upon risk factors for ADRs and DTPs including, but not limited to; advanced age, certain medical conditions, high number of medications or medication doses per day, narrow therapeutic index drugs and large number of comorbidities.(42–44) Unfortunately the evidence supporting these risk factors does not provide clear thresholds for people who are “High Risk” or “Low Risk”, making it very difficult to use these risk factors to create appropriate eligibility criteria for medication review programs.

The eligibility criteria utilized by these provincially funded medication review programs in Canada are inconsistent and highly variable, raising doubt that all programs are targeting the most appropriate patients for these new services. The development of an evidence based tool or screening protocol that is capable of identifying patients who will benefit from a community pharmacist medication review would allow provincially funded medication review programs to adopt consistent eligibility criteria that would ensure health care resources are used responsibly and patient outcomes are improved optimally.

2.7 Lack of an Evidence-based Screening Protocol for Patients at High Risk for DTPs in the Community Pharmacy

Very little research has been published describing systematic screening for patients at high risk for DTPs in the community pharmacy setting, and the majority of the screening methods in the literature are in the form of time-intensive structured interviews, which may be difficult to implement in a typical community pharmacy.

Hugtenburg and colleagues employed a pharmacist-led interview asking patients to describe their experience with their medications when they received their first refill of a new prescription (i.e. the second prescription), to screen patients who might be experiencing DTPs in The Netherlands.(45) In this study, 22.3% of patients who were screened using the interview tool were identified as experiencing at least one DTP. The control pharmacy did not engage patients in the interview, and identified zero patients at risk of DTPs. However, the pharmacist-led interviews had poor uptake, and staff required multiple re-education sessions to ensure proper handling of the second prescriptions.

A computer generated process to screen for patients at risk for DTPs based on patient's overall drug costs was evaluated in Switzerland.(19) The program selected patients whose six month drug cost exceeded \$1440 United States Dollars (USD). These patient's records were then evaluated by community pharmacists, who found that the screened patients experienced an average of 2.6 DTPs per patient. Unfortunately, the authors of this uncontrolled study did not validate the screening process by confirming the presence of the DTPs with each patient; they simply identified potential DTPs by reviewing the patient's medication lists. This type of screening would not be effective for patients who were patrons of multiple pharmacies, and would also not include patients' over the counter medications and natural health products.

Gordon and colleagues used a semi-structured pharmacist-led interview to screen for patients at risk for DTPs. A series of open and closed ended questions were asked in a community pharmacy and clinic setting to adult patients on cardiovascular medication for a cardiovascular condition.(46) The patient participation rate in the pharmacy was high, as 69.7% of those who were approached agreed to the screening interview. Greater than one third of the individuals screened using this process were

identified as having at least one DTP. While the interview was effective at screening patients who ultimately experienced DTPs, each screening interview took a median time of 12 minutes, which may be too great of a time burden on the majority of community pharmacies to simply screen for patients who may benefit from a subsequent medication assessment.

In a European study, a standardized questionnaire was used by pharmacists to screen for patients at risk for DTPs in people who presented at the community pharmacy with hospital discharge prescriptions.(47) The study concluded that patients who were determined to be at risk of DTPs using the questionnaire had an average of 1.6 DTPs each. This questionnaire targeted patients post hospital discharge, and it is not known if this questionnaire would be effective at screening for DTPs in the general population.

In another study, researchers asked patients who were over 65 years of age and on at least two chronic medications to complete a ten question self-assessment questionnaire to screen for people at high risk of DTPs.(48) This study was performed in the United States, at three community pharmacies in one large city. The author assessed patient acceptability of the questionnaire, the reliability and validity of the 10 individual questions, and how the questions correlated with subsequent Drug Regimen Review (DRR) severity scores, which is an indication of DTP risk. However, they did not perform comprehensive medication assessments on the individual patients who completed the questionnaire to confirm the presence of DTPs. All patients were able to complete the questionnaire without assistance, patient acceptability was high, and patients had high levels of confidence in their ability to remember their prescription and non-prescription medications. Patients were able to correctly answer the questions the majority of the time, and five of the ten questions were significantly correlated with an increased DRR score.(11)

A 59 item questionnaire (named "The DTP Risk Assessment Tool") was recently developed for use by home care nurses who care for elderly patients.(49) The questionnaire includes sections about medication use, home life as well as current or recent symptomology. The questionnaire is intended to be used as a referral guide, and includes a section where a nurse can recommend one of many action plans. The "DTP

Risk Assessment Tool” has not yet been validated with patients, and therefore its effectiveness has not been determined. The length of the questionnaire may also not be conducive to being used in community pharmacies.

The previously described interventions and screening tools have varying levels of usefulness in identifying patients who are at high risk for or who are suffering from DTPs; however, none of the interventions have been integrated into mainstream community pharmacy practice. There are several barriers to the uptake of these screening protocols. Screening pharmacy records based on medication cost(19) to identify patients at high risk of DTPs is unreliable as it misses non-prescription products and does not allow for patient interaction. Pharmacist-patient interviews that were utilized in the reviewed studies were very time consuming and required a private space to complete, which can make them difficult to implement within a typical community pharmacy.(46) The key to a feasible screening process that has the potential to be useful for community pharmacists and their patients may lie in the process being simple and requiring a minimal time commitment from the pharmacy staff.

2.8 The Langford Screening Questionnaire

Only one screening tool was identified in the literature that had potential for mainstream use in a community pharmacy setting (which was not previously discussed in Chapter 2.7). The Langford Screening questionnaire is composed of five questions with dichotomous “Yes” or “No” answers (See Appendix 4).(11) The questions are based on known risk factors for the presence of DTPs and have previously been determined to have high patient acceptability and patient/investigator reliability.(44,48) The risk factors included in the questionnaire are: taking five or more medications, taking 12 or more doses of medication daily, taking medication that requires frequent therapeutic drug monitoring, and being treated for three or more different medical conditions.

In the Langford study, patients taking two or more medications were approached in the waiting room of a large family physician’s clinic and asked to self-administer the five item questionnaire. The 194 patients who completed the questionnaire were

randomized to either a control group (89 patients; standard screening process in which the questionnaire responses were ignored and patients were referred to a pharmacist for a comprehensive medication assessment only if the physician felt a referral was necessary) or the intervention group (105 patients; patients referred to a pharmacist for a comprehensive medication assessment if they responded “Yes” to three or more questions on the questionnaire). All patients referred to the pharmacist in both groups received a comprehensive medication assessment. The study found that pharmacists identified a similar number of DTPs in both patient groups, regardless of the source of the referral (intervention group 3.1 DTPs per patient, standard screening process 2.4 DTPs per patient). However, the screening questionnaire identified a much larger number of high risk patients. A total of 20.0% (n=21) of the patients from the intervention group were screened as being high risk and were referred to a pharmacist, compared with 5.6% (n=5) of the patients in the control group ($p=0.003$). This suggests that although standard physician screening is effective at identifying high risk patients, the screening questionnaire was able to identify more high risk patients. The authors concluded that the screening questionnaire was a useful method to identify patients at high risk of DTPs when compared to physician referrals, and could be used, in addition to standard physician referrals within a family medicine clinic setting, to increase the number of patients at high risk of DTPs being referred to pharmacists for a comprehensive medication assessment.(11)

Although the screening questionnaire was tested in a family physician office setting, it is possible that it may also be effective in a community pharmacy setting. The screening questionnaire is self-administered, which requires very little time from the pharmacist, and patients have previously demonstrated that no assistance is typically required to answer the questions.(48) Scoring the responses and segregating patients into High Risk and Low Risk groups is quick and simple due to the dichotomous nature of the questionnaire. For these reasons, the Langford screening questionnaire may be an excellent tool for screening for patients at high risk for DTPs in the community pharmacy setting.

Chapter Three - Study Purpose

The purpose of this research study was to evaluate the effectiveness of using a modified Langford screening questionnaire (renamed the Medication Risk Assessment Questionnaire) to identify patients at risk for drug therapy problems in a community pharmacy setting who may benefit from a comprehensive medication assessment.

Chapter Four – Research Objectives

1. To determine if the Medication Risk Assessment Questionnaire identifies patients within a community pharmacy setting who have a significant number of DTPs.
 - a. To determine if patients who screen High Risk by the Medication Risk Assessment Questionnaire have more drug therapy problems than those who screen Low Risk.
 - i. Hypothesis: Patients who screen High Risk will have on average 2 more drug therapy problems than patients who screen Low Risk.
 - b. To determine if patients who screen High Risk with the Medication Risk Assessment Questionnaire have proportionally more serious or potentially more dangerous drug therapy problems than those who screen Low Risk.

2. To establish the level of agreement between the patient self-administered responses to the Medication Risk Assessment Questionnaire, and the subsequent risk categorization with the correct responses and categorization as determined after completion of a comprehensive medication assessment with a pharmacist.
 - i. Hypothesis: The strength of the agreement will be “Very Good” or “Excellent” ($k = 0.81 - 1.0$)

3. To compare the Medication Risk Assessment Questionnaire with the eligibility requirements of provincial medication review programs in Canada.
 - a. To determine the proportion of patients who screen High Risk with the Medication Risk Assessment Questionnaire who would be eligible for a medication review under each of the provincial medication review programs in Canada.
 - b. To determine the proportion of patients who screen Low Risk with the Medication Risk Assessment Questionnaire who would be eligible for a medication review under each of the provincial medication review programs in Canada.

Chapter Five –Methods and Procedures

All protocols were approved by the University of Saskatchewan’s Behavioural Research Ethics Board (Certificate of Approval: BEH 13-293) prior to the commencement of this study. All personal data, including medical and health information, which was collected during this research has been managed in accordance with all HIPA and PIPEDA guidelines.

5.1 Modification of the Langford Screening Questionnaire

The chosen screening questionnaire was identified from a previous publication by Langford et al. (2006), in which the questionnaire was tested in a family medicine clinic setting (see Chapter 2.8). The questionnaire was pilot tested on five individuals (three pharmacists and two laypersons) prior to use in the study to ensure the questions were clear and understandable. Two of the five individuals felt that the term “non-prescription products” from Question #1 (Do you take 5 or more medications?), was unclear, and did not include vitamins, minerals or herbal products. Based on the pilot test, it was decided that the question should be changed to explicitly include vitamins and herbals by adding the phrase “including prescription and non-prescription products, vitamins and herbals). No other issues were identified during pilot testing.

The medications in Question #5 (Do you take any of the following medications?) were updated to reflect modern prescribing practices and recent evidence regarding medications that are implicated in high numbers of adverse drug reactions. Drugs that were no longer commonly prescribed in ambulatory settings (quinidine, phenobarbital, procainamide and theophylline)(50) were removed from the list. Drugs added to the list included non-steroidal anti-inflammatory drugs (NSAIDs), opioids, insulin, rivaroxaban, dabigatran and apixaban. NSAIDs and opioids are classified as analgesics by Health Canada, and were among the top 10 drug groups of most common suspects for adverse drug reactions reported to the Canada Vigilance Program, which monitors adverse drug reporting.(51) Similarly, rivaroxaban, dabigatran and apixaban are classified as antithrombotic agents, which were number seven in these top 10 drug

groups. The Institute for Safe Medication Practice (ISMP) define insulin and opioids as “high alert” medications because they have an increased risk of causing significant harm when used inappropriately, and may require supplemental action to reduce the risk of inappropriate use.

Each drug, or class of drugs, that is now listed in the updated Question #5, with the exception of phenytoin, appears on at least one of the three following lists: ISMP’s List of High-Alert Medications in Community/Ambulatory Healthcare(52), Canada Vigilance Program’s top 10 groups of suspect health products most commonly reported in 2012(53), and the Beers criteria for Potentially Inappropriate Medication Use in Older Adults.(54) See Table 2. For the purposes of this document, the modified version of the Langford Questionnaire is referred to as the “Medication Risk Assessment Questionnaire”.

Table 2. Drugs included in Question #5 of the Medication Risk Assessment Questionnaire and presence of each drug (or class of drugs) on three medication alert lists.

Drug/Class of Drugs	ISMP High Alert	Canada Vigilance Top 10	Beers Criteria
Carbamazepine	Yes	No	No
Lithium	No	Yes	No
Phenytoin	No	No	No
Digoxin	No	No	Yes
Insulin	Yes	No	No
Drugs for pain (opioids and NSAIDs)	Yes	Yes	Yes
Drugs for preventing blood clots (warfarin, dabigatran, rivaroxaban, apixaban, ASA)	Yes	Yes	Yes (Dabigatran and ASA)
Sulfonylureas (drugs to lower blood sugar)	Yes	No	Yes
Methotrexate	Yes	Yes	No

5.2 Research Setting

Three different community pharmacies in Saskatoon were approached to act as the setting for patient recruitment for this research project. Three pharmacies were recruited to increase the generalizability of the results (compared to recruiting just a single pharmacy). Pharmacies that were recruited were: (a) those that did not have a focus on specialty practice, such as compounding pharmacies, or methadone pharmacies; (b) those with the availability of a private consultation area for comprehensive medication assessments to be performed and; (c) those with daily average prescription volumes between 75 and 400. This prescription volume was chosen to ensure that the pharmacies would have adequate patient populations to increase the probability of recruiting an appropriate number of patients.

Pharmacies were invited to participate by phone and the researcher discussed the project and protocol with invited dispensary staff in person to ensure they had a thorough understanding of what was required of them before they were accepted as a study site. Random selection of pharmacies was considered, however; due to the somewhat restrictive pharmacy inclusion criteria, and requiring the community pharmacy staff to collaborate with the researcher during the comprehensive medication assessment recommendations and accept responsibility for the patient once the researcher's time was complete at the site, it was decided to approach specific pharmacies that (based on the research team's previous experiences) may have a high likelihood of successfully participating. Community pharmacy staff was also required to occasionally aid in patient information gathering by requesting lab results from physicians, as well as provide therapeutic recommendations to the prescriber.

5.3 Experiment One: To establish the level of agreement between the patient self-administered responses to the Medication Risk Assessment Questionnaire, and the subsequent risk categorization with the correct responses and categorization as determined after completion of a comprehensive medication assessment with a pharmacist

5.3.1 Study Procedure – Data Collection

- 1) Patients who met the inclusion criteria (see below) were flagged by the regular community pharmacy dispensary staff during normal prescription processing. Potentially eligible patients were then approached in consecutive order (the order in which they requested their refill prescription) by the researcher at the pharmacy counter, who explained the purpose of the research project and attempted to obtain informed consent from the patient. The number of people approached and the number of people who consented was recorded.
 - a. Inclusion criteria:
 - i. Adult patients (equal to or greater than 18 years old) who were physically present in the pharmacy and requesting a refill prescription (as defined below) for themselves.
 - ii. Patients who could speak and read English and who were capable of completing the Medication Risk Assessment Questionnaire themselves (agents of the patient were not permitted to complete the Medication Risk Assessment Questionnaire on behalf of the patient).
 - iii. Patients must be picking up at least one refill prescription, which was defined as: a prescription medication that is the same drug at the same dose and regimen (i.e. directions for administration) as the previous dispensation. The previous dispensation must have occurred within the previous 6 months.
 - b. Exclusion criteria

- i. Patients who were unable to read and write in English.
 - ii. Patients with a lack of competence to self-administer the Medication Risk Assessment Questionnaire (e.g., severe dementia) were excluded from the study.
 - iii. Patients known to the dispensary staff that may be unfit for the study due to a variety of factors such as potential for patient agitation or patient time constraints. Patients not deemed appropriate for the study by the dispensary staff were not approached to participate in the study.
- 2) Patients were offered a token of appreciation for participating in the research if they consented and completed participation in the study (\$10 gift card).
- 3) Patients who provided informed consent were asked to complete the Medication Risk Assessment Questionnaire (See Appendix 1), as well as a patient demographics form (See Appendix 2) and handed the forms back to the researcher in a sealed envelope. The patient's name was written on the Medication Risk Assessment Questionnaire so that the responses could be analyzed later. The sealed envelopes were not opened until all assessments and patient data collection were complete.
- 4) All patients who completed the Medication Risk Assessment Questionnaire and demographics form were asked to participate in a comprehensive medication assessment with the researcher. The comprehensive medication assessments were all performed by the researcher (RP) and they were scheduled to take place in the community pharmacy's private counseling room at a date that was mutually convenient to the participant and the researcher.
- 5) The process for the performing the comprehensive medication assessments was:
 - a. Gather patient medical history.
 - b. Gather information to complete a Best Possible Medication History (BPMH), including all medications (prescription and non-prescription products), doses and regimens using a standardized form (Appendix 3).
 - c. Assess patient for presence of DTPs.
 - d. Request lab work from the patient's physician(s) if required.

- e. Compose consultation letter to the patient's most responsible physician based on the comprehensive medication assessment, including detailed recommendations for management of any identified DTPs.
 - f. Forward a copy of the consultation letter to the patient's community pharmacy for completeness of the patient's record.
- 6) Patients who completed the Medication Risk Assessment Questionnaire were categorized into two groups at the completion of the study, after the comprehensive medication assessment was completed. These thresholds for defining risk groups are the same thresholds used in the original evaluation of the Medication Risk Assessment Questionnaire.(11,48)
- a. Those that responded "Yes" to less than three questions were categorized to the Low Risk group.
 - b. Those that responded "Yes" to three or more questions were categorized to the High Risk group.

5.3.2 Study Procedure – Data Analysis

After the comprehensive medication assessment was complete, the researcher used the data collected during the assessment process to determine if the patient self-administered Medication Risk Assessment Questionnaire was completed accurately by determining the level of agreement between the self-administered Medication Risk Assessment Questionnaire responses (and subsequent risk categorization) and the correct responses (and risk categorization) based on information collected during the comprehensive medication assessment, to determine if patients were able to correctly answer each question (and be assigned to the correct risk categorization). All data was entered and analyzed in IBM SPSS version 22.0.

Demographic and clinical characteristics of the patients were presented descriptively. The Kappa value describes the statistical level of agreement for categorical variables(55). Table 3 shows common Kappa Values and the corresponding levels of agreement.

Table 3. Level of agreement as described by Kappa value(55)

Kappa Value	Level of Agreement
<0	None
0.01-0.20	Poor
0.21-0.40	Slight
0.41-0.60	Fair
0.61-0.80	Good
0.81-0.92	Very Good
0.93-1.00	Excellent

- 1) The Kappa coefficient of agreement was calculated separately for each of the five questions in the Medication Risk Assessment Questionnaire. The number of observed agreements, Kappa coefficient as well as the level of agreement is reported.
- 2) The number of patients who screened High Risk based on the self-administered Medication Risk Assessment Questionnaire results was compared to the number of patients who screened High Risk based on the responses (and risk categorization) from information collected during the comprehensive medication assessment to determine the ability of the Medication Risk Assessment Questionnaire to accurately place patients into the High Risk category when it is self-administered by patients.
 - a. The Kappa coefficient of agreement was calculated and reported, along with the number of observed agreements and the level of agreement.

5.4 Experiment Two: To determine if the Medication Risk Assessment Questionnaire identifies patients within a community pharmacy setting who have a significant number of DTPs

5.4.1 Study Procedure – Data Collection

Data for Experiment Two was collected during the data collection procedure of Experiment One.

- 1) DTPs identified during the comprehensive medication assessments with the patients were documented as part of the standard patient care process.
 - a. By reviewing the information and records from the comprehensive medication assessment (including pertinent lab values, when required), DTPs were identified, counted and recorded for each patient.
 - b. Each DTP was classified into one of the following eight DTP categories based on the characteristics of the DTP.
 - i. Adverse drug reaction
 - ii. Supratherapeutic dose
 - iii. Subtherapeutic dose
 - iv. Inappropriate drug
 - v. Drug not indicated
 - vi. Drug therapy required
 - vii. Noncompliance
 - viii. Unsure or Other DTP

5.4.2 Study Procedure – Data Analysis

All data was entered and analyzed in IBM SPSS version 22.0.

- 1) The number of DTPs identified in the High Risk group and the Low Risk group were compared.
 - a. The mean number of DTPs per patient was calculated for the High Risk and Low Risk groups.
 - b. A Mann-Whitney U-test was used to compare the mean number of DTPs per patient between the High Risk and the Low Risk groups and

to determine if the difference was statistically significant. The Mann-Whitney U test was selected as the data was non-parametric.

- 2) Descriptive statistics were used to report the number of DTPs which belong to each DTP category for both High Risk and Low Risk groups.
- 3) The severity of all DTPs was determined and analyzed.
 - a. DTP severity was determined by the researcher based on the adapted Schneider criteria(56) as described in Appendix 5. DTPs were stratified into Mild, Moderate or Severe categories based on the criteria. This severity index was chosen, as it was the best objective measure for assigning severity scores to DTPs for community dwelling patients that was identified in the literature. The researcher had access to all patient related documents that were available to the pharmacist during the comprehensive medication assessments (and the documentation created by the pharmacist) to assist in the risk stratification process (including description of identified DTPs, pharmacist consult letters, medication lists, medical history, laboratory values, etc.)
 - b. DTP severity scores initially assigned by the researcher were agreed upon with two external auditors (one pharmacist and one physician).
 - i. Each of the external auditors were given all patient related documents that were available to the pharmacist during the medication reviews (and the documentation created by the pharmacist) to assist in the risk stratification process (including description of identified DTPs, pharmacist consult letters, medication lists, medical history, laboratory values, etc.). Each auditor independently assigned a risk category to each identified DTP (using the adapted Schneider criteria), without knowing the risk score that was initially assigned by the researcher. The researcher then compared the two auditor's risk scores with his own previously assigned risk score. In each case where all

three did not agree on the risk score, the DTP was flagged for subsequent discussion and review.

- ii. Each flagged DTP in which all three reviewers did not agree regarding the risk score was discussed with the two auditors and the researcher, and a severity score was agreed upon by all three individuals. The unanimously agreed upon severity was recorded as the approved final severity score for that DTP.
- c. Pearson Chi squared analysis was performed to compare the number of patients in each group who had at least one Moderate or Severe DTP.
- d. A Mann-Whitney U was used to compare the mean number of Moderate or Severe DTPs in the High Risk and the Low Risk groups.

5.5 Experiment Three: To compare the Medication Risk Assessment Questionnaire with the eligibility requirements of provincial medication review programs in Canada

5.5.1 Study Procedure – Data collection

Data for Experiment Three was collected during the data collection procedure of Experiment One.

- 1) Individuals who identified as High Risk based on their self-administered Medication Risk Assessment Questionnaire answers had information from the comprehensive medication assessment reviewed to determine if they would qualify for any of the following provincially funded medication review programs (see Table1 for a full description of the eligibility criteria of each program).
 - a. Newfoundland and Labrador Medication Review
 - b. Prince Edward Island Basic Medication Review or Prince Edward Island Diabetes Medication Review
 - c. Nova Scotia Basic Medication Review Service or Nova Scotia Advanced Medication Review Service

- d. New Brunswick PharmaCheck
 - e. Ontario MedsCheck, MedsCheck for Ontarians living with Diabetes, Ontario MedsCheck at Home or Ontario MedsCheck for Long Term Care Home Residents
 - f. Saskatchewan Compliance Packaging with Medication Assessment or Saskatchewan Medication Assessment Program
 - g. Comprehensive Annual Care Plans for Albertans or Standard Medication Management Assessment for Albertans
 - h. British Columbia Medication Review Services
- 2) Individuals who identified as Low Risk based on their self-administered Medication Risk Assessment Questionnaire answers had information from the comprehensive medication assessment reviewed to determine if they would qualify for any of the following provincially funded medication review programs
- a. Newfoundland and Labrador Medication Review
 - b. Prince Edward Island Basic Medication Review or Prince Edward Island Diabetes Medication Review
 - c. Nova Scotia Basic Medication Review Service or Nova Scotia Advanced Medication Review Service
 - d. New Brunswick PharmaCheck
 - e. Ontario MedsCheck, MedsCheck for Ontarians living with Diabetes, Ontario MedsCheck at Home or Ontario MedsCheck for Long Term Care Home Residents
 - f. Saskatchewan Compliance Packaging with Medication Assessment or Saskatchewan Medication Assessment Program
 - g. Comprehensive Annual Care Plans for Albertans or Standard Medication Management Assessment for Albertans
 - h. British Columbia Medication Review Services

5.5.2 Study Procedure – Data Analysis

All data was entered and analyzed in IBM SPSS version 22.0.

- 1) Patients who screened High Risk with the Medication Risk Assessment Questionnaire who qualified for each program were analyzed using descriptive statistics.
- 2) Patients who screened Low Risk with the Medication Risk Assessment Questionnaire who qualified for each program were analyzed using descriptive statistics.

5.6 Sample Size Calculation

The sample size calculation was performed presuming that both the High Risk and Low Risk groups would be similar in size. A difference of two or more in the mean number of DTPs between High and Low Risk groups was hypothesized to be a clinically significant difference. Clinical significance is a subjective measure, based on the judgement of the professional. For this study, clinical significance is related to the amount of harm reduced (such as reduction in the potential rate or severity of adverse drug reactions, and decreased number of negative health events such as myocardial infarction), the potential for years of life saved and the quality of life years gained. With a mean difference of two DTPs between the High Risk and Low Risk groups, the likelihood of identifying at least one clinically important DTP (i.e. one that when resolved, would amount to a reduction in harm) was thought to be high.

Based on that hypothesis, the power calculation was computed as follows:

$$n = \frac{2}{d^2} \times c_{0.05,80\%}$$

Where n is equal to the number of participants required in each group, d is equal to the standardized difference, and c is a constant for 0.05 α , 80% β .(57)

The standardized difference is equal to the target difference divided by the standard deviation. Due to a lack of existing research data in the literature review regarding this population and these endpoints, the standard deviation of the number of drug therapy problems in this population was an estimate based on previous experience

and clinical judgement. Varying the estimates of the standard deviation resulted in a variety of sample sizes. See Table 4.

Table 4. Estimates of sample size required for study

Standard Deviation estimate	Standardized difference (d)	Sample size per group (n)
0.8	2.5	3
1.2	1.666	6
1.8	1.111	13
2.2	0.9091	19
3	0.6666	36

This table demonstrates that even with an expected large standard deviation in the number of DTPs in the population, a sample size of less than 100 total patients was needed to be recruited for this study. This number was thought to be attainable during the 12 week data collection period that was thought to be manageable for a Master of Science project.

5.7 Researcher's Role

In this study, the researcher had many roles. The researcher was a licensed pharmacist, and was the pharmacist that was directly involved in patient care (i.e., performing all of the comprehensive medication assessments with patients who consented to participate in the study). The researcher was also responsible for approaching potential participants in the pharmacies, as well as obtaining consent from patients and providing the Medication Risk Assessment Questionnaire to patients. The researcher also performed all data analyses.

Chapter Six – Results

6.1 Patient Recruitment

Three pharmacies were recruited to participate as study sites for this project. Each pharmacy was located in a different neighbourhood on the east side of the City of Saskatoon: Shoppers Drug Mart at Broadway and Taylor, Pharmacy First on 8th Street and Safeway Pharmacy in University Heights. Population statistics from the neighbourhoods surrounding each pharmacy was obtained from the 2011 City of Saskatoon Neighbourhood Profile to provide additional information (beyond what was collected from each individual participant during the study) about the population in which this study was performed.(58)

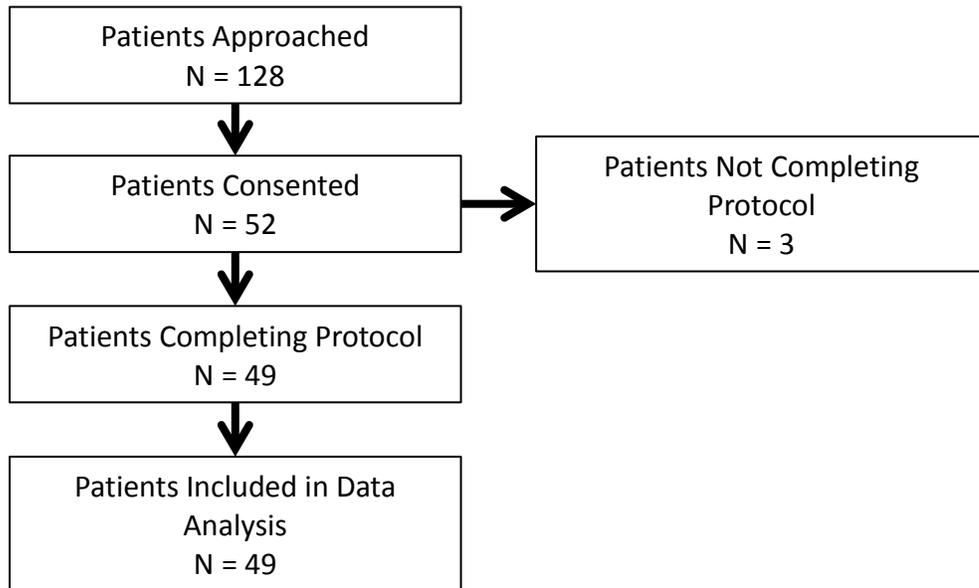
Shoppers Drug Mart at Broadway and Taylor in Saskatoon is surrounded by the Adelaide-Churchill, Avalon, Buena Vista, Haultain and Queen Elizabeth neighbourhoods. Pharmacy First on 8th Street borders Greystone, Brevoort Park, College Park, College Park East and Wildwood . Safeway Pharmacy in University Heights serves the areas of University Heights, Forest Grove, Arbor Creek, Willowgrove and Erindale. Information regarding the communities that surround the three pharmacies is presented in Table 5. While many patients frequent pharmacies that are in their neighbourhoods, patients also choose pharmacies based on other factors such as convenience, loyalty programs and price(59); therefore, not all patients recruited in each pharmacy necessarily lived in the surrounding neighbourhoods.

Table 5. Pharmacy neighbourhood demographics

	Shoppers Drug Mart Broadway and Taylor Neighbourhood	Pharmacy First on 8th Street Neighbourhood	Safeway Pharmacy University Heights Neighbourhood
Population	15387	23779	21149
Average Annual Household Income	\$69 996	\$71 994	\$106 267
English as First Language (%)	87.9	76.2	85.9
No Education Certificate/Diploma/Degree (%)	12.0	11.5	10.4
Highschool Certificate or Equivalent (%)	21.7	23.7	20.5
Apprenticeship/Trades Certificate/Diploma (%)	8.1	7.4	7.6
University Diploma or Degree (%)	42.5	39.1	42.2

Recruitment took place for four consecutive weeks at each pharmacy, starting on November 18th 2013, and finishing February 28th 2014. A total of 128 patients were approached to participate in the study, 52 provided informed consent and were recruited for the study, and 49 patients completed the entire study protocol. Two patients consented to the study and performed the Medication Risk Assessment Questionnaire; however, they did not participate in a comprehensive medication assessment. One patient withdrew shortly before the scheduled comprehensive medication assessment due to a perceived lack of benefit. Figure 1 displays the recruitment summary.

Figure 1. Patient recruitment



6.2 Baseline Patient Characteristics

The average age of patients who completed the study protocol was 53.9 years. The majority of patients were female (83.9%), highly educated and spoke English as their first language. The average number of medications (prescription and non-prescription) per patient was 7.2. High Risk patients had an average of 11.7 medications per patient compared with 4.6 in the Low Risk patients. See Table 6 for a summary of the baseline patient characteristics. Characteristics are also shown for patients in each risk category (as determined by researcher completed Medication Risk Assessment Questionnaires).

Table 6. Baseline patient characteristics

	Low Risk Patients	High Risk Patients	All Patients
Number	31	18	49
Mean Age	48.7	62.7	53.9
Std. Error for Age	3.4	2.4	2.5
Female Gender (%)	26 (83.9%)	11 (61.1%)	37 (75.5%)
English as First Language (%)	29 (93.5%)	18 (100%)	47 (95.9%)
Grade School as Highest Level of Education (%)	0 (0%)	1 (5.6%)	1 (2.0%)
High School as Highest Level of Education (%)	5 (16.1%)	5 (27.8%)	10 (20.4%)
Any Post-Secondary as Highest Level of Education (%)	26 (83.9%)	12 (66.7%)	38 (77.6%)
Mean number of medications	4.6	11.7	7.2

6.3 Level of Inter-rater Agreement of the Medication Risk Assessment Questionnaire

6.3.1 Level of Agreement for Each Question and for the Medication Risk Assessment Questionnaire Overall

The level of agreement between the self-administered patient responses on the Medication Risk Assessment Questionnaire and the “correct” responses (as determined by the researcher after the comprehensive medication assessment) was calculated separately for each of the five questions in the Medication Risk Assessment Questionnaire. The inter-rater agreement was also calculated for the Medication Risk

Assessment Questionnaire as a whole (i.e., placement of patients into the proper overall risk category). See Table 7.

Table 7. Kappa values and the level of agreement for the Medication Risk Assessment Questionnaire.

	Kappa value	P value	Level of Agreement(55)
Question 1	0.877	<0.01	Very Good
Question 2	0.422	<0.01	Fair
Question 3	0.836	<0.01	Very Good
Question 4	0.489	<0.01	Fair
Question 5	0.912	<0.01	Very Good
Medication Risk Assessment Questionnaire Overall	0.910	<0.01	Very Good

Questions 1, 3 and 5 had “Very Good” levels of agreement. Questions 2 and 4 had “Fair” levels of agreement. Questions 2 and 4 (“Do you take 12 or more doses of medication each day?” and “Have your medications or the instructions on how to take them changed 4 or more times in the past year?”) appear to be more complex for patients to answer. Similar levels of agreement have previously been reported for all five questions.(48)

The level of agreement for the Medication Risk Assessment Questionnaire overall was “Very Good”, despite the fact that agreement was “Fair” on two of the five individual questions. This indicates that patients have a very high likelihood to be categorized into the appropriate risk category (High Risk or Low Risk) based on their responses to the Medication Risk Assessment Questionnaire questions. All calculated kappa values were statistically significant ($P < 0.01$).

Only two patients (4.1%) were incorrectly categorized by the patient self-administered Medication Risk Assessment Questionnaire. Both patients answered “Yes” to less than three questions, making them Low Risk, while the researcher answered “Yes” to three or more questions, making the correct categorization as High Risk.

6.4 Identified Drug Therapy Problems (DTPs)

6.4.1 Number of Identified Drug Therapy Problems

A total of 165 DTPs were identified in the 49 patients who completed the study protocol. Patients who were categorized (using the researcher responses) as High Risk had, on average, 3.72 more DTPs per patient compared with those who were categorized as Low Risk ($P < 0.01$). See Table 8.

Table 8. Mean number of identified DTPs in Low Risk and High Risk groups

	Number	Mean Number of DTPs	95% CI
Low Risk	31	2.00	1.46-2.54
High Risk	18	5.72	4.29-7.16

6.4.2 Categorization of Identified Drug Therapy Problems

The 165 identified DTPs were categorized into 8 different categories. These categories consist of the 7 standard DTP categories as described by Cipolle and colleagues(13) as well as one supplementary category: “Other or Unsure”. Those DTPs that were categorized into “Other or Unsure” were actual or suspected DTPs that could not be confirmed, largely due to a lack of information provided from the most responsible physician, or due to a lack of pertinent lab results. For example, one patient had not had any laboratory tests for over 12 months, and as such it was unable to be determined if the warfarin dose was correct for this patient. Another patient was taking metoprolol for no clear indication, and the pharmacist was unable to determine if the medication was still required for this patient. See Table 9.

Table 9. Drug therapy problem categories

DTP Category	Number (%)
Requires a Drug	62 (37.6%)
No Indication for Drug	20 (12.1%)
Inappropriate Drug	19 (11.5%)
Other or Unsure DTP	18 (10.9%)
Noncompliance	16 (9.7%)
Adverse Drug Reactions	11 (6.7%)
Subtherapeutic Drug	11 (6.7%)
Supratherapeutic Drug	8 (4.8%)
Total Number of DTPs	165 (100%)

6.4.3 Severity of Drug Therapy Problems

Each identified DTP was placed into one of six severity categories using the Adapted Schneider Criteria for DTP Severity (See Appendix 5 for a detailed description of each risk category).(56) The majority of the DTPs were “Moderate” in severity (53.9%), while the remainder were “Mild” in severity (46.1%). There were no “Severe” DTPs identified. See Table 10.

Table 10. Severity of identified DTPs

	Number of DTPs in Low Risk Patients (%)	Number of DTPs in High Risk Patients (%)	Total DTPs (%)
Mild 1	15 (24.2%)	6 (5.83%)	21 (12.7%)
Mild 2	23 (37.1%)	32 (31.1%)	55 (33.3%)
Moderate 1	24 (38.7%)	61 (59.2%)	85 (51.5%)
Moderate 2	0 (0%)	4 (3.9%)	4 (2.4%)
Severe 1	0 (0%)	0 (0%)	0 (0%)
Severe 2	0 (0%)	0 (0%)	0 (0%)
Total	62 (100%)	103 (100%)	165 (100%)

All DTPs that were identified as Mild 1 were recommendations for patients who did not receive an influenza vaccination during the current flu season to receive seasonal influenza vaccines before the subsequent flu season. Due to a shortage of influenza vaccine during the study period, many people were unable to receive influenza immunizations that season. One example of a Mild 2 DTP that was identified in a study participant was a compliance issue. The patient was frequently forgetting to take her prescribed oral contraception (as many as five times per month) and was

sexually active. Because of this situation, there was the potential for pregnancy (which, for that patient, was a negative health outcome). The pharmacist recommended a few compliance aids (such as placing the medication in an area where it would be clearly visible as part of a daily routine, and for the patient to set an medication reminder alarm), and discussed alternative birth control options (barrier methods, intra uterine devices, etc).

An example of a Moderate 1 DTP was a patient taking meloxicam 15mg once daily for which they had no indication, placing them at risk for complications from this fairly high risk drug, with no therapeutic benefit. The pharmacist communicated with the primary care physician on this matter, and recommended the medication be stopped. Because the patient had been taking the medication for over 10 years (seemingly without a reasonable indication), there was no urgency for the physician to meet with the patient promptly, which would have moved the severity to a Moderate 2 DTP.

6.4.3.1 Comparison between groups of patients with at least one Moderate or Severe DTP

In order to determine if one group experienced a higher number of clinically significant DTPs, the percentage of patients who were identified as having at least one Moderate or Severe DTP in each group were compared. Forty-eight percent of Low Risk patients had at least one Moderate or Severe DTP, whereas 94.4% of High Risk patients had at least one Moderate or Severe DTP (P < 0.01). See Table 11.

Table 11. Patients who have at least one Moderate or Severe DTP

	Patients that have ≥1 Moderate or Severe DTP (%)	Patients that have <1 Moderate or Severe DTP (%)	Total
Low Risk	15 (48.4%)	16 (51.6%)	31
High Risk	17 (94.4%)	1 (5.5%)	18

6.4.3.2 Overall comparison of DTP severity between groups

The mean number of mild DTPs in Low Risk patients was 1.23 per patient compared with 2.11 in High Risk patients (P=0.03). The mean number of Moderate

DTPs in Low Risk patients was 0.77 per patient compared with 3.61 in High Risk patients, a difference of 2.84 DTPs per patient ($P<0.01$). See Table 12.

Table 12. Overall DTP severity comparison

	Number of patients	Mean number of DTPs per patient	Mean number of Mild DTPs per patient	Mean number of Moderate DTPs per patient	Mean number of Severe DTPs per patient
Low Risk	31	2.00	1.23	0.77	0.00
High Risk	18	5.72	2.11	3.61	0.00
		P<0.01	P=0.03	P<0.01	

6.5 Comparison of the Medication Risk Assessment Questionnaire with the Eligibility Requirements of Provincial Medication Assessment Programs in Canada

All patient information was analyzed to determine which patients would be eligible for a medication review service in each of the provinces that has such a program. Table 14 reports the proportion of Low Risk and High Risk patients who would have been eligible for a medication review in each province.

Table 13. Eligibility for provincial medication review programs in Canada

	% Low Risk Patients Eligible (n)	% High Risk Patients Eligible (n)
Newfoundland and Labrador	3.2% (1)	38.9% (7)
PEI	32.3% (10)	100% (18)
Nova Scotia	32.3% (10)	100% (18)
New Brunswick	3.2% (1)	32.3% (10)
Ontario	32.3% (10)	100% (18)
Saskatchewan	0% (0)	32.3% (10)
Alberta	25.8% (8)	94.4% (17)
British Columbia	3.2% (1)	94.4% (17)

Prince Edward Island, Nova Scotia, Ontario and Alberta have relatively high rates of Low Risk patients who would be eligible for medication reviews while New Brunswick and Saskatchewan have relatively low proportions of High Risk patients who are eligible for provincial medication review services. Newfoundland and Labrador, New Brunswick, Saskatchewan and British Columbia have low proportions of Low Risk patients who are eligible for provincial medication review services. Prince Edward Island, Nova Scotia, Ontario, Alberta and British Columbia have relatively high proportions of High Risk patients who are eligible for medication reviews.

The common factor for programs in Prince Edward Island, Nova Scotia and Ontario is that any patient taking at least three chronic medications qualifies for a medication review. This threshold of three or more chronic medications makes nearly one third of the patients identified as Low Risk eligible for medication reviews. In Alberta the eligibility criteria is similar; as patients taking three or more prescription medications (or two prescription medications and insulin) qualify for a Standard Medication Management Assessment provided they also have one of the accepted chronic conditions, such as hypertension, diabetes, COPD or a mental health disorder; which are commonly treated with prescription medications.

In Newfoundland and Labrador, only patients taking oral hypoglycemic medication and/or insulin qualify for a medication review, which limits the amount of High Risk patients who qualify to 38.9%. New Brunswick and Saskatchewan medication review programs are only available to individuals over the age of 65 (amongst other criteria), which limits the number of High Risk patients who would have qualified.

British Columbia's Medication Review Services eligibility criteria exclude the majority of Low Risk patients (96.8% excluded), and accept the majority of High Risk patients (94.4%) due to excluding patients taking less than 5 prescription medications.

Chapter Seven - Discussion

7.1 Research Objective 1: To determine if the Medication Risk Assessment Questionnaire identifies patients within a community pharmacy setting who have a significant number of DTPs.

The findings of this study suggest that the Medication Risk Assessment Questionnaire is effective at identifying patients at high risk of DTPs, who may benefit from a comprehensive medication assessment. Patients who were determined to be High Risk by the Medication Risk Assessment Questionnaire had significantly more DTPs than those who were Low Risk (5.72 vs. 2.00, $P < 0.01$) and their DTPs were also, on average, more serious (63.1% of DTPs in High Risk patients were of Moderate severity vs. 38.7% in Low Risk patients).

Unfortunately there are limited published studies available for comparison with the results of the Medication Risk Assessment Questionnaire in this study. Hugtenburg and colleagues(45)(see Chapter 2.7) found that 22.3% of patients were categorized as “high risk” when an in-depth community pharmacist-led interview was used as the screening tool, while the Medication Risk Assessment Questionnaire, categorized 36.7% (18/49) of community pharmacy based patients as High Risk. While it is impossible to draw definitive conclusions from these apparent differences in rates of high-risk patients in each study, because no direct comparison of the two screening processes has ever been performed; it suggests that the Medication Risk Assessment Questionnaire might be capable of identifying more high risk patients in a community pharmacy setting than the time intensive patient interviews used in the Hugtenburg study.

The original evaluation of the Langford screening tool(11), was performed in a family physician clinic setting. That study found proportionally fewer high risk patients compared with this study (20.0% vs. 36.7%). This could suggest that patients who present to a community pharmacy to refill a prescription might, on average, be at greater risk of experiencing DTPs compared with patients waiting for an appointment in

a family physician office. However, more research is required to confirm this hypothesis.

The number of DTPs identified in this study can also be compared to other studies in an effort to further interpret the results. A Swiss study(19) that used overall drug costs to screen for high-risk patients found an average of 2.6 DTPs per high-risk patient and the original evaluation of the Langford questionnaire found 3.1 DTPs per patient. Other studies investigating the impact of pharmacist-led comprehensive medication assessment programs indicate that the average number of DTPs identified (and/or resolved) per patient ranges from 2.3 to 4.4.(14–16) The average number of DTPs in this Medication Risk Assessment Questionnaire study was 3.4 per patient, which is within the range previously reported in the literature. This suggests that the complexity of the patients in our study was likely similar to those in other studies and that the pharmacist who performed the comprehensive medication assessments likely did a thorough job of the assessments.

7.2 Research Objective 2: To establish the level of agreement between the patient self-administered responses to the Medication Risk Assessment Questionnaire, and the subsequent risk categorization with the correct responses and categorization as determined after completion of a comprehensive medication assessment with a pharmacist.

This project had three specific research objectives which each to some degree relied on the ability of the patient participants to correctly answer the Medication Risk Assessment Questionnaire, without the aid of the researcher or pharmacy staff. The high level of agreement ($k = 0.910$) which was found between the patient self-administered responses to the Medication Risk Assessment Questionnaire and the correct responses to each question (as determined from their medication records after completion of a comprehensive medication assessment) suggest that participants were able to accurately complete the Medication Risk Assessment Questionnaire without assistance.

Questions 1 and 3 (see Appendix 1) may be easier to answer because they ask patients to determine if they meet relatively simple to calculate thresholds for numbers

of medications (five) and medical conditions (three). This may partially explain the high Kappa values that were found for these two questions. Question 5 asks patients to recognize if they are taking one or more of the 12 listed high alert/high risk medications or class of medications. This question had the highest level of agreement of any question, with a Kappa value of 0.912. This high Kappa value is likely due to most patients being able to recognize the name of the drugs they are taking when they see them in a list. The high Kappa values indicate that these three questions work well and should not be modified in future versions of the Medication Risk Assessment Questionnaire.

Questions 2 and 4 had “Fair” levels of agreement (Kappa value 0.42 and 0.489 respectively). Question 2 is complex as it requires patients to calculate a high threshold of doses of medication taken per day (12 doses), and some patients may have difficulty mapping out their daily dosing schedule in a short amount of time, especially without their medications present. What constitutes “dose” may also be difficult to interpret for some patients. For example, a patient inhaling two puffs of a metered dose inhaler may think of that as two doses (one dose in each puff), while others may interpret that to be only one dose. Dimitrow and colleagues(49) have a similar question in their “Drug Related Problem (DRP) Risk Assessment Tool”, and have chosen to include a detailed example in the tool. It reads “Example of counting the doses: Drug 1: 1 tablet 3 times a day = 3 doses, Drug 2: 1 dose 2 times a day = 2 doses, i.e., in total 5 doses a day”. Future versions of the Medication Risk Assessment Questionnaire could be modified to include similar examples to clarify what constitutes a dose, which may be helpful in increasing the inter-rater agreement of this question.

Question 4 may be difficult for patients to answer accurately because it requires patients to think about their medication history in a comprehensive manner, and they may not be able to recall all the recent changes or modifications that have been made to their regimen. It should also be noted that it was difficult for the researcher to answer this question on behalf of patients with complete certainty as this response was generated based solely on the medication record, which may not have complete

information on all of the patient's medication changes. It is unclear how this question could be modified in the future to improve its reliability.

Despite the fact that two of the five questions had a "Fair" level of agreement, the Medication Risk Assessment Questionnaire assigned almost all participants to the correct risk group ("Very Good" level of agreement for the overall Medication Risk Assessment Questionnaire, Kappa value = 0.910). These findings are consistent with previous evaluations of similar screening tool questions(48), confirming that the Medication Risk Assessment Questionnaire can be effectively self-administered by patients in a community pharmacy setting, with little or no assistance from pharmacy staff. The high Kappa values give a large degree of confidence that the results of this study are trustworthy, in that the Medication Risk Assessment Questionnaire can assign patients to the correct risk groups based on their self-administered responses.

7.3 Research Objective 3: To compare the Medication Risk Assessment Questionnaire with the eligibility requirements of provincial medication review programs in Canada.

This project was not designed nor intended to be an evaluation of the current medication review program eligibility criteria across Canada. However, previously published research identified that the highly variable eligibility criteria of these programs are not evidence based and have not been formally evaluated to determine their effectiveness in identifying high risk patients who might benefit the most from a comprehensive medication assessment.(10) Although some of the provincially funded medication review programs in Canada would have included the majority of the High Risk patients identified by the Medication Risk Assessment Questionnaire (and consequently not included most of the Low Risk patients), many others would have excluded large numbers of High Risk patients, while at the same time including many Low Risk patients (see Table 14). This large discordance could indicate that not all provincial medication review programs are optimized to accept and reject the most appropriate patients. The results of this study provide additional evidence that a formal evaluation of the eligibility criteria used by medication review programs in Canada is warranted.

7.4: Limitations

There are a number of limitations to this study, including the possibility of researcher bias. The researcher (RP; who recruited all patients, performed all comprehensive medication assessments and collected and analysed all research data), is a practicing pharmacist with experience working in a community pharmacy setting and who consequently may have had pre-conceived notions about the usefulness of this intervention. In an attempt to reduce the potential impact of researcher bias on the results, the Medication Risk Assessment Questionnaire was completed independently by the patient out of sight of the researcher, and placed into a sealed envelope prior to returning it to the researcher. This envelope was only opened after all comprehensive medication assessments were complete, and the researcher had completed Medication Risk Assessment Questionnaires on behalf of each patient using the information from the comprehensive medication assessments. This procedure was followed to minimize potential researcher bias during the comprehensive medication assessment with the patient so that the researchers' assessment of the number and severity of DTPs would not be influenced by the patient's assigned risk category. In addition, external auditors confirmed the DTP severity assessments of the primary investigator, in a further effort to mitigate potential researcher bias.

One positive aspect of having the primary investigator complete all of the comprehensive medication assessments and identify all of the DTPs was that it was easier to ensure the process was as consistent as possible across all patients. To further ensure that consistently high quality medication assessments were performed, a standard comprehensive medication assessment form was used during all assessments. In addition, team therapeutic discussions were held on a regular basis to allow the primary investigator to discuss particularly difficult or uncertain cases with a group of experienced colleagues.

Using DTPs as an endpoint in this study is also a limitation. In previous studies, the identification of DTPs has not been definitively linked with an improvement in patient health outcomes, such as hospitalizations or emergency department visits. However, this is a commonly used endpoint in pharmacy practice research studies that do not

have the resources or scope to measure long-term patient health outcomes. In order to add greater clinical meaning to the number of DTPs identified in this study, the severity of the DTPs was also assessed. Unfortunately, there is no standard method for assessing the severity of DTPs and the Adapted Schneider Criteria for DTP Severity (which was used in this research) has not been previously studied in community pharmacy patients, and has therefore not been validated in this setting.

It would have been ideal to follow up on the outcomes of the DTPs identified during the study to determine the extent to which they were addressed by physicians and ultimately resolved, and the impact the identification of DTPs ultimately had on patient health outcomes. However, due to the scope of this project, there was not adequate time or resources available to perform long-term follow-up of the identified DTPs.

Participating pharmacies were not selected randomly, which is another limitation of this study. Pharmacies were selectively chosen for participation in this project based on their expected interest in, and acceptability of the intervention. Random selection of pharmacies may have made the results more generalizable by having a potentially more representative patient sample and a pharmacy staff that was not pre-selected to be accepting of the intervention. However, since the purpose of this study was to test the effectiveness of the Medication Risk Assessment Questionnaire (and not its acceptability to pharmacy staff nor the feasibility of implementation), it was decided to forgo random selection in an effort to ensure an adequate number of patients and in the interest of timely completion of the project.

An additional limitation is that pharmacy staff were able to exclude patients for study participation who they thought would not be appropriate for any reason. This was included in the methodology to reassure pharmacy staff that the intervention would not be bothersome to their emotionally or physically unstable patients. Although this created the potential for large numbers of patients to be excluded and a misrepresentative sample recruited, patient exclusion by pharmacy staff occurred only once to the researchers knowledge (0.8% of approached patients) during the entire study, across all three sites (in the case of an intoxicated patient).

The relatively homogenous characteristics of the recruited patients also reduces the generalizability of the results. Participants in this study were mostly English speaking (95.9% spoke English as first language), highly educated (77.6% had some post-secondary education) and were recruited from pharmacies surrounded by communities with a high average household income (\$66,996 - \$106,267), which is not representative of many areas of Saskatoon or Canada. This may affect the generalizability of the results related to the ability of the patients to correctly answer the questions on the Medication Risk Assessment Questionnaire, because it is possible that less educated patients who do not speak English as their first language may have more difficulty answering the questionnaire independently. It has also been shown that Non-English speaking patients suffer from more adherence related DTPs than English speaking patients(60); likely due to language barrier induced comprehension issues.

Due to the study design there is also the potential of volunteer bias. Previous research suggests that people who volunteer for research studies tend to be more educated and of higher social class and they may also be healthier, and may follow treatment plans more closely than non-volunteers.(61) While volunteer bias may be unavoidable, this project made it clear to participants during the consent process, and during the comprehensive medication assessment that all information would remain confidential and anonymous, which is a cited barrier to volunteering.(61) It is possible that patients who perceived the comprehensive medication assessment as valuable enough to participate in the study would do so because of existing concerns surrounding their medications or medical conditions, however this view was never conveyed to the researcher. Due to the steps taken to ensure that all patient recruitment activities highlighted the confidential nature of the study procedure and the lack of expressed patient concerns regarding their medications prior to the comprehensive medication assessment, the potential for volunteer bias was minimized.

7.5 Future research

Although the findings of this study suggest that the Medication Risk Assessment Questionnaire is effective at identifying patients at high risk of DTPs (and those whose DTPs are of greater severity) who may benefit the most from a comprehensive

medication assessment, the optimal threshold of “Yes” responses for identifying high risk patients remains unknown. This study used a threshold of three “Yes” responses to categorize High Risk patients based on the threshold used in previous research.(11,48) This threshold was arbitrarily selected in previous studies and it is possible that an alternative threshold may be more effective at differentiating patients at highest risk for serious DTPs. A subsequent study that could recruit a sufficient number of patients would help to answer this research question.

Further research is also required to determine if the Medication Risk Assessment Questionnaire would be feasible to integrate into typical community pharmacy practice. Considering that the Medication Risk Assessment Questionnaire is quick for patients to complete (under 2 minutes(11)), it requires little or no help from pharmacy staff, and the results can be interpreted (and patient’s assigned to risk categories) quickly and easily by non-pharmacists, it is certainly possible that it could be successfully implemented in this setting. However, community pharmacy workflow is complex and implementing even small changes such as implementing a short interview upon patient refill request(45) can be a challenge.

This research project was able to determine that in some provinces High Risk patients would not qualify for a medication review. Conversely, many of the Low Risk patients would qualify for a medication review in some provinces. A future evaluation of the current provincial medication review programs could help to determine the number and types of DTPs that are being identified, as well as the clinical significance of those DTPs. These results could then be compared to the results of this study, and the analysis may be used to better inform the provinces on which eligibility criteria might be best to identify patients that community pharmacists should target to optimize efficiency of these services.

Chapter Eight – Conclusions

The five question Medication Risk Assessment Questionnaire tested in this research study has been proven to have a Very Good level of agreement ($k = 0.910$) between patient self-administered responses and researcher responses after a comprehensive medication assessment. This strong level of agreement indicates that patients are able to complete the Medication Risk Assessment Questionnaire correctly, and that the results of the self-assessment can be trusted for most patients.

The Medication Risk Assessment Questionnaire is effective at identifying patients at high risk of DTPs, who may benefit from a comprehensive medication assessment in a community pharmacy setting. Patients identified as High Risk by the Medication Risk Assessment Questionnaire had significantly more DTPs (mean of 5.72 DTPs vs. 2.00 in Low Risk patients ($P < 0.01$)), and significantly more Moderate or Severe DTPs (3.61 Moderate or Severe DTPs per patient vs. 0.77 Moderate or Severe DTPs in Low Risk patients ($P < 0.01$)). Consequently, patients identified as High Risk using the Medication Risk Assessment Questionnaire would be ideal targets for community pharmacists who are performing comprehensive medication assessments.

Overall, the Medication Risk Assessment Questionnaire tested in this research study can be answered correctly by patients and it identifies High Risk patients who have numerous DTPs. It may be a useful tool for community pharmacies looking to expand their practice to include comprehensive medication assessments.

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Appendix 1 – Medication Risk Assessment Questionnaire

Medication Risk Assessment Questionnaire

Please complete all of the questions below to the best of your ability.

- 1) Do you take 5 or more different medications on a regular basis?
(including prescription and non-prescription products, vitamins and herbals) Yes No
- 2) Do you take 12 or more doses of medication each day? Yes No
- 3) Are you currently taking medications for 3 or more medical conditions? Yes No
- 4) Have your medications or the instructions on how to take them changed 4 or more times in the past year? Yes No
- 5) Do you take any of the following medications? Yes No
- | | |
|---------------------------|----------------------------|
| Carbamazepine (Tegretol®) | Any drug for chronic pain |
| Phenytoin (Dilantin®) | Insulin (any type) |
| Warfarin (Coumadin®) | Drugs to lower blood sugar |
| Rivaroxaban (Xarelto®) | Methotrexate |
| Dabigatran (Pradax®) | Lithium (Carbolith®) |
| Apixaban (Eliquis®) | Digoxin (Lanoxin®) |

When you have completed the questionnaire, please return it to the researcher.

Thank You

Appendix 2 – Patient Characteristics Questionnaire

Patient Characteristics

Please complete all of the questions below to the best of your ability.

What is your age? _____

Gender: Male Female

Is English your first language? Yes No

What is the highest level of education you have completed?

Grade School High School Any Post-Secondary education

When you have completed the questionnaire, please return it to the researcher.

Thank You

Appendix 3: Medication Review Form

Medication Review Form

Patient information

Date: ____, 2013__

Location: _____

Demographics	Wt	Ht	Age
	Occupation		Living arrangement
	Health insurance (coverage issues and affordability of meds)		
Allergies and Alerts	Medication allergies (<i>describe reaction and when experienced</i>)		
	Past adverse reactions (<i>describe reaction and when experienced</i>)		
Social drugs	What is the pts' primary concern about their medications?		
	To what extent does the pt understand their medications?		
Social drugs	Smoking / tobacco?		
	Caffeine?		
	Alcohol / Recreational drug use?		
PMH	Relevant past medical history		

Meds Taken in past (include why and when stopped)

Current Medications (Rx, OTC, Herbals)

Drug Therapy Problems to investigate

Remind pt that you need to ask a series of 'yes/no' questions to make sure you didn't miss anything in your assessment and to screen for side effects to their medications

Review of Systems	EENT (vision, hearing, or nasal problems; coughing)
	Cardio (chest pain, heart problems, HTN, lipids)
	Pulmonary (breathing problems)
	GI (stomach problems or pain, nausea, constipation, trouble swallowing)
	Skin (any skin troubles)
	Endocrine (diabetes, thyroid history)
	Hepatic (any history of liver problems)
	Diet (general diet, weight changes)
	Reproductive (incontinence, impotence, hot flashes)
	Renal / urinary (urinary frequency, renal dysfunction)
	Hematology (bruising, bleeding)
	MSK (pain)
	Neuro (numbness, tingling, balance or falls, memory)
Psych (mood)	

ID (any infectious diseases like HIV, Hep C, TB, etc)

Immunizations

Influenza () Pneumovax

Other _____

Any additional diagnoses not discussed?

Appendix 4: Langford Screening Questionnaire

Medication Risk Assessment Questionnaire

Patient ID: _____

Please complete all of the 13 questions below to the best of your ability. When you have completed the questionnaire, inform the researcher.

Thank you for participating.

- 1) Do you take 5 or more medications? No Yes
- 2) Do you take 12 or more medication doses each day? No Yes
- 3) Do you take any of the following medications?
- | | | |
|---------------------------|-----------------------------|------------------------------|
| Carbamazepine (Tegretol®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Lithium (Carbolith®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Phenytoin (Dilantin®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Quinidine (Biquin®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Warfarin (Coumadin®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Digoxin (Lanoxin®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Phenobarbital (Nembutal®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Procainamide (Procan®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| Theophylline (Theo-Dur®) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
- 4) Are you currently taking medications for 3 or more medical problems? No Yes
- 5) Have your medications or the instructions on how to take them been changed 4 or more times in the past year? No Yes

What is your age? _____

Gender Male Female

Postal code? _____

Language spoken at home? _____

In which country were you born? _____

What is your yearly income level before taxes?

- \$0–20,000/yr \$20,001–40,000/yr \$40,001–60,000/yr \$60,001+/yr

What is the highest level of education you have completed?

- Grade school High school College University

Please check which medical conditions you have. Please check "other" and add condition(s) if necessary.

- | | |
|--|--|
| <input type="checkbox"/> Asthma or lung disease | <input type="checkbox"/> Parkinson's disease |
| <input type="checkbox"/> Diabetes | <input type="checkbox"/> Alzheimer's disease |
| <input type="checkbox"/> Arthritis | <input type="checkbox"/> Previous stroke |
| <input type="checkbox"/> Previous heart attack | <input type="checkbox"/> Epilepsy |
| <input type="checkbox"/> Stomach ulcer/heartburn | <input type="checkbox"/> Kidney disease |
| <input type="checkbox"/> Angina | <input type="checkbox"/> Cancer |
| <input type="checkbox"/> Irregular heart beat | <input type="checkbox"/> Thyroid problems |
| <input type="checkbox"/> High blood pressure | <input type="checkbox"/> Crohn's disease/colitis |
| <input type="checkbox"/> High cholesterol | <input type="checkbox"/> Other (please specify): |
| <input type="checkbox"/> Vision/eye problems | _____ |
| <input type="checkbox"/> HIV positive | _____ |
| <input type="checkbox"/> Depression | _____ |
| <input type="checkbox"/> Anxiety | _____ |

End of questionnaire. Thank you for your participation.

Please return the questionnaire to the researcher. Have a nice day.

Appendix 5 – Adapted Schneider Criteria for DTP Severity

Severity Evaluation		Pharmaceutical Intervention in Primary Care		
Category	DTP Status	With patient	and/or	With health care professionals
Mild 1	A DTP occurred in the past.	Pharmacist provides advice to prevent the subsequent occurrence of the DTP.		Pharmacist may provide information on patient's medications and other relevant information to the patient's circle of care.
Mild 2	A DTP is present.	Pharmacist provides specific advice to resolve the DTP.		Pharmacist communicates with the patient's health care team and/or issues a pharmaceutical opinion to recommend a change in pharmacotherapy.
Moderate 1	A DTP is present.	Pharmacist provides specific advice to resolve the DTP and carries out a monitoring plan of specific symptoms.		Pharmacist communicates with the patient's health care team and/or issues a pharmaceutical opinion to recommend a change in pharmacotherapy. Pharmacist suggests a monitoring plan, specific to vital signs or laboratory tests.
Moderate 2	A DTP is present.	Pharmacist provides specific advice to resolve the DTP and carries out a monitoring plan of specific symptoms. Pharmacist recommends to patient to visit his/her physician quickly		Pharmacist communicates with the patient's health care team and/or issues a pharmaceutical opinion to recommend a change in pharmacotherapy quickly. If needed, pharmacist can suggest the physician to meet the patient promptly or communicate with the health care team in order to follow up vital signs and/or ask for laboratory tests.
Severe 1	A DTP is present.	Pharmacist recommends to patient to go to the Emergency Room immediately		
Severe 2	A DTP is present.	Pharmacist calls 911 for the patient to be conducted to the Emergency Room immediately.		