SafetyNET-Rx: Insights and Lessons Learned From a Pilot Project

by

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DEDICATION PAGE

I would like to dedicate this thesis to my mother. Thank you for your unconditional love and support. Your optimism and determination to overcome life's challenges continues to inspire me and I thank God every day that you are in my life.

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ABSTRACT

Medication errors are under-reported in community pharmacies, thereby reducing the opportunities for creating solutions and jeopardizing patient safety. This research identified challenges and facilitators of medication error reporting, and lessons learned from using a continuous quality improvement program. In-depth interviews with pharmacists and technicians from 13 community pharmacies in Nova Scotia were analyzed using iterative thematic analysis.

The overall theme, From Secret to Shared, was comprised of: resistance; resolving resistance; and improved outlook. Suggestions for improvement included: increased ease of use, provision of feedback, and sharing of learnings among pharmacies. By understanding the context of medication errors, reporting and patient safety can be improved.

LIST OF ABBREVIATIONS USED

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
CFP	Canadian Foundation for Pharmacy
CIHR	Canadian Institutes for Health Research
CPhIR Program	Community Pharmacy Incident Reporting Program
CQI	Continuous Quality Improvement
IS	Information Systems
ISMP Canada	Institute for Safe Medication Practices Canada
MaPSAF	Manchester Patient Safety Assessment Framework
MSSA	Medication Safety Self-Assessment
NAPRA	National Association of Pharmacy Regulatory Authorities
NSHRF	Nova Scotia Health Research Foundation
NSCP	Nova Scotia College of Pharmacists
PDCA Cycle	Plan-Do-Check-Act Cycle
QRE	Quality Related Event
REB	Research Ethics Board
SSHRC	Social Sciences and Humanities Research Council of Canada
UK	United Kingdom
US	United States
WHO	World Health Organization

GLOSSARY

Adverse Event: An adverse event has been defined as "an unexpected and undesired incident directly associated with the care or services provided to the patient; an incident that occurs during the process of providing health care and results in patient injury or death; an adverse outcome for a patient, including an injury or complication" (Davies, Hebert, & Hoffman, 2003, p.40).

Adverse Drug Event: An adverse drug event is an injury caused by a medicine or lack of an intended medicine, and includes adverse drug reactions (ADRs) and harm resulting from a medication incident (Bates et al., 1997; Institute for Safe Medication Practices Canada, 2010). ADEs that occur despite the use of an appropriate medication are called ADRs and do not result from error (e.g., development of a severe rash as a result of an unknown allergy to the medication). However, adverse drug events that do result from the inappropriate use of medication or from error are medication errors.

Medication Error: Medication errors have been defined as "the failure to complete a planned action as it was intended, or when an incorrect plan is used, at any point on the process of providing medications to patients" (Davies et al., 2003, p. 31). Medication errors are preventable and can occur at any stage of the medication-use process, potentially leading to inappropriate medication use and patient harm.

Medication Incident: A medication incident is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer" (Institute for Safe Medication Practices Canada, 2008, p. 146). Medication incidents may be related not only to drug products, but include professional practice, and procedures and systems as well including: prescribing, order communication, product preparation, compounding, dispensing, distribution, administration, education, monitoring, and use (Institute for Safe Medication Practices Canada, 2008).

Near Miss: A near miss is "an event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient" (Institute for Safe Medication Practices Canada, 2010).

Quality Related Event (QRE): Quality related events (QREs) are "alleged or suspected medication errors that reach the patient, as well as medication errors that are intercepted prior to dispensing (i.e., near misses)" (Nova Scotia College of Pharmacists, 2010). Examples of common QREs include: incorrect drug, dose, quantity or patient.

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CHAPTER 1: INTRODUCTION

1.1 Introduction

Patient safety is an increasing area of concern throughout the entire Canadian healthcare system, however most of the research focusing on medication safety in Canada has been restricted to institutional settings such as hospitals and long-term care facilities. Only recently has there been a concerted effort to explore the safety of the medication-use system in community pharmacies in Canada (Boyle et al., 2011; Boyle, Scobie, MacKinnon, & Mahaffey, 2012; Scobie, MacKinnon, Deal, Boyle, & Mahaffey, 2010). This is concerning because medication incidents are one of the most frequently occurring and serious patient safety issues, and these events are highly under-reported in community pharmacies (Kelly, 2004). Between the years 2000 and 2012, ISMP's database held a total of 64,601 medication incident reports that had been voluntarily reported from Canadian hospital facilities and individual practitioners (R. Cheng, personal communication, June 12, 2012). Although voluntary reporting presents limitations in data interpretation, it does allow the opportunity to identify general trends in error reporting. Without a similar mechanism in community pharmacies, lack of detailed information about errors prevent organizations from learning the real underlying causes and as a result do not allow for adequate distribution of resources for the prevention of these errors. If there are contributing factors that inhibit pharmacy staff from reporting errors, they will be more likely to continue to occur, ultimately jeopardizing patient safety.

Within the last 60 years, continuous quality improvement (CQI) programs have been used in manufacturing and service industries all over the world as a general model for quality in organizational activities. CQI emphasizes a long term organizational commitment to quality improvement, employee empowerment, teamwork, and use of scientific methods to identify and address issues relating to poor quality, and plan and implement strategies for change (Shortell, Bennett, & Byck, 1998; Wakefield et al., 2001). In the last 20 years, CQI strategies have been implemented within the healthcare system, specifically ambulatory care and small practitioner settings, in addition to hospitals as part of the accreditation standards (Decker, 1992; Geboers et al., 2001). The implementation of CQI in community pharmacy in the literature was sparse prior to this research. This gap in the literature, in addition to the lack of information that exists around medication errors in community pharmacy, prompted the idea for this research and led to the inception of this study.

1.2 Research Objectives

The purpose of this research was to determine the factors influencing the extent that community pharmacy staff, including pharmacists and pharmacy technicians, using a standardized CQI program report medication errors. Specifically, the objectives of this research were:

1) To identify pharmacist and pharmacy technician perceptions of the challenges to reporting medication errors in community pharmacies;

2) To identify the perceived facilitators that encourage pharmacists and pharmacy technicians to report medication errors in community pharmacies; and

3) To identify insights and lessons learned of the pharmacists and pharmacy technicians involved in using a standardized CQI program designed to enhance medication error reporting and learning.

Insight, knowledge about, and the context surrounding the challenges and facilitators to reporting medication errors could help to identify and inform changes in the current systems of reporting and contribute to improved patient care and safety. Increased understanding about the context of medication error reporting and its relevance to patient safety is one of significant interest to various stakeholder groups which include, but are not limited to: pharmacy staff, pharmacy managers/owners, provincial regulatory authorities, and patients.

1.3 Practical Implications of Research

Upon entering professional practice in Canada, pharmacists abide by the Standards of Practice set by the National Association of Pharmacy Regulatory Authorities (NAPRA) and their provincial Code of Ethics. Even though it is expected that pharmacists will "hold the health and safety of each patient to be of primary concern" (Nova Scotia College of Pharmacists, 2007), it is inevitable that pharmacy staff will make errors given their human contribution to the workflow. These errors can be devastating for the pharmacy staff member involved in the error and can create self-doubt in his or her abilities to provide patient care. However, such errors present opportunities for pharmacists, pharmacy technicians, and management to learn and to take steps to proactively reduce their recurrence. This research will help community pharmacies learn from medication errors by examining the context in which errors occur, and the

characteristics that enhance or challenge error reporting through the use of a standardized CQI medication error reporting program. This will also create an opportunity for pharmacy staff to openly engage in dialogue about medication errors. Given the current "shame and blame" culture that exists in community pharmacy, this presents an opportunity for a culture shift toward recognizing errors as inevitable yet significant learning opportunities that can be shared between pharmacies to enhance overall patient safety across the healthcare system.

Aside from the potential for significant morbidity and even mortality resulting from a medication error, the effect of a major error can also negatively impact a community pharmacy through financial implications and years of rebuilding company reputation and customer loyalty. From the pharmacy manager/owner perspective, it is critical to have an effective CQI process in place to minimize the opportunity for medication errors to occur. At the time of this research, a CQI process was not a provincially legislated requirement in Nova Scotia, but this changed in January 2010 and is currently the responsibility of the community pharmacy manager. In addition to provincial legislation, pharmacy owners often have internal corporate policies and procedures for CQI, however these systems are mainly used for risk management and the reporting of errors is typically not anonymous, so pharmacy staff may be fearful to report incidents (Ho, Hung, Lee, & Kadija, 2010). These internal systems are also rarely designed to determine contributing and underlying factors of medication errors in this environment and much of the learning from these events is lost, allowing errors to potentially recur.

The mandate of the provincial pharmacy regulatory authorities is to govern the practice of pharmacy in the best interest of the public. There are differences across the country in medication error reporting practices in community pharmacies as standards are set by each individual provincial or territorial regulatory authority. The assessment of a CQI medication error reporting program in Nova Scotia will provide the regulator, Nova Scotia College of Pharmacists (NSCP), with valuable information about the facilitators and barriers to reporting medication errors in community pharmacy. This research also provides an opportunity to identify changes to enhance the safety not only within community pharmacies, but across the profession.

The community pharmacy environment is complex, i.e. some operate as independent stores; others as small chains; and yet others as regional/national chains integrated into a department store or grocery store. Insight and knowledge about reporting procedures through the use of a CQI medication error program in community pharmacies could help identify changes in the current systems of reporting as well as capture potential errors originating earlier in the supply chain (e.g., physician prescribing) that may result in improved patient care and safety. By reporting errors, pharmacy staff can learn from the mistakes in other pharmacies and avoid making the same mistakes in their practice. The findings of this study contribute to a safer healthcare system for Nova Scotians and promote a culture of support and sharing, instead of reproach, for the profession of pharmacy. This is especially important given the increasing number of high profile medication errors cases shown in the media (Patel, 2009; Perez Jr., 2010). The increased attention to these events is likely to evoke concern and possible distrust in the public regarding the quality and safety of the healthcare system. At a time when health

care professionals, pharmacists in particular, are lobbying for an expanded scope of practice, it is necessary to ensure an enhancement of the pharmacy's medication-use system that is routinely assessed and includes a process for learning from medication errors. The information gathered from this study will help gain insight into what systems are currently in place for reporting medication errors in community pharmacies, and how these systems can be improved for the future.

1.4 Thesis Outline

This thesis is divided into six chapters: introduction, literature review, methodology and study design, findings, discussion, and conclusions.

Chapter two, literature review, provides background information on patient safety in Canada including: patient safety in the community pharmacy setting; the use of CQI in healthcare; the organizational safety culture, in particular, in the community pharmacy setting; and health professional attitudes toward patient safety in pharmacy.

Chapter three, methodology and study design, outlines the background on the CQI program, SafetyNET-Rx, that was implemented in community pharmacies and the significance of this research including the study design, study participants, data collection and analysis. This chapter will also provide the rationale for using qualitative evaluation, in particular a case study approach and thematic analysis, and an evaluation plan for ensuring trustworthiness of the study.

Chapter four, findings, presents the findings from the study.

Chapter five, discussion, explores the findings using the original research objectives, discusses the limitations and implications of the study, and describes the techniques used to ensure trustworthiness of the study.

Chapter six, conclusions, provides a summary of the study and discusses future possibilities for research.

CHAPTER 2: LITERATURE REVIEW

2.1 Patient Safety in Canada

Patient safety is an increasing area of concern throughout the entire Canadian healthcare system and in recent years has become one of the leading healthcare and policy issues. There are various terms used in the literature to describe adverse outcomes associated with medication use (Ackroyd-Stolarz, Hartnell, & MacKinnon, 2006). Upon searching 160 websites related to medication safety, 25 terms with 119 definitions were found (Yu, Nation, & Dooley, 2005). To help clarify some of more commonly used terms in the medication safety literature, the following are defined in the glossary: adverse event, adverse drug event, medication error, medication incident, near miss, and quality related event. Throughout the remainder of this document, the terms medication error and near miss will be used except when citing literature that used a different, but related, term to describe an adverse consequence of medication use.

Several studies in the United States (US) have found that a significant number of adverse drug events occur in both hospital and long-term care environments (Budnitz, Lovegrove, Shehab, & Richards, 2011; Gurwitz et al., 2005; Nebeker, Hoffman, Weir, Bennett, & Hurdle, 2005). The Canadian Adverse Events Study was the first study in Canada to provide significant evidence of safety concerns in Canadian hospitals. This study revealed an adverse event rate of 7.5 per 100 hospitalizations where 2.8 adverse events per 100 admissions were considered to be preventable (Baker et al., 2004), roughly equivalent to those shown in similar studies in England, New Zealand, Australia, and the US (Baker, Jeffs, Law, & Norton, 2007). Approximately 24% of the adverse

events identified were due to the use of medications or fluids, and 15.9% of adverse events tragically resulted in death (Baker et al., 2004). Based on this information, it is not surprising that patients have been expressing concern about the safety of the healthcare system in recent years. In the 2007 Commonwealth Fund Survey, 17% of Canadians who participated believed that they had experienced a medical, medication, or lab error in the previous two years (Schoen et al., 2007). This translates to over 4.2 million adult Canadians (17% of 24.7 million adult Canadians in the 2006 census) who believe they have experienced an error within the past two years (MacKinnon, 2008). Experiencing a preventable mistake in healthcare has shown to result in mistrust of health care professionals by the public, and that behavior has the potential to negatively impact the provision of healthcare when needed (Elder, Jacobson, Zink, & Hasse, 2005).

A recent study looked at how Canada compared to seven other countries (Australia, France, Germany, Netherlands, New Zealand, United Kingdom (UK), and US) regarding patient safety and approximately one in four Canadians who were surveyed said they had experienced at least one medical error in the past two years (Scobie, 2011). This was higher than the overall rate (22.2%) in all eight countries, and second only to the highest rate (32.1%) in the US. This study also identified the patient risk factors for experiencing a medical error and those included: age 65 and younger, education level of some college or less, presence of at least two chronic conditions, use of four or more prescription medications, four or more physicians seen within two years, problems with care coordination, poor perceived communication with physicians, and at least one visit to an emergency department (Scobie, 2011). Given the documentation in the literature of the frequency of adverse events and increasing concern and distrust

among the public in the healthcare system, it is necessary to take action to improve patient safety through reducing risk and improving communication (CMA, 2007).

2.1.1. Prevalence of Medication Errors in the Community Pharmacy Setting

In the Canadian Adverse Events Study, adverse drug events were reported as the second most common type of adverse event, but that study was limited to the inpatient setting (Baker et al., 2004). Studies examining the safety of the medication-use system in community pharmacies have shown this healthcare setting is also not exempt from the potential to cause harm. One study conducted in the US, found the estimated error rate in community pharmacies was 0.017 errors per prescription (Flynn, Barker, & Carnahan, 2003). Another study conducted in the UK estimated a lower error rate in community pharmacies although it calculated near misses (0.0022 per prescription) and dispensing errors (0.0004 per prescription) separately (Ashcroft, Quinlan, & Blenkinsopp, 2005). If we extrapolate this data to Canada where, for example in 2011 approximately 525 million prescriptions were dispensed (Paquette, 2012), a range of 210,000 errors/year to 8,925,000 errors/year could result from community pharmacies alone. This would also result in an estimated 1,155,000 near misses/year. Even if the lower end of this range were to occur and result in serious harm and/or death, it would present a serious public health issue. Other European studies that have examined the frequency of medication errors in community pharmacies found varying results. In addition to the study in the UK mentioned previously, another UK study examining incidents in the dispensing process in community pharmacy found the rate of dispensing errors to be 0.0008/prescription and near misses 0.0048/prescription (Chua et al., 2003). In comparison, a Swedish study

found an average error rate of 0.00019 dispensing errors per prescription (Norden-Hagg, Sexton, Kalvemark-Sporrong, Ring, & Kettis-Lindblad, 2010) and another study in Danish community pharmacies found the error rate of dispensing errors to be 0.0001 per prescription and 0.0002 near misses per prescription (Knudsen, Herborg, Mortensen, Knudsen, & Hellebek, 2007). Knudsen et al. (2007) also noted most of the errors were found in the transcription stage, one of the five stages of medication delivery within the medication-use system: ordering, transcription and verification, dispensing, administration and consumption (Ackroyd-Stolarz, Hartnell, & MacKinnon, 2005). The rate of prescription corrections was found to be 0.0023 per prescription, evenly distributed between clinical (51.3%) and administrative (48.7%) causes (Knudsen et al., 2007). The value in pharmacists' ability to use their clinical knowledge to detect prescription related problems in community pharmacy was also demonstrated in another study where 54% of prescribing errors detected were able to be resolved by the pharmacist alone without any contact with the physician (Martinez-Sanchez & Campos, 2011). In conjunction with the application of pharmacist's clinical knowledge to detect drug related problems, the contribution of administrative causes to prescription corrections found by Knudsen et al. (2007) supports the need for CQI in community pharmacies to both prevent errors from reaching patients and to learn more about the types of errors occurring in this setting.

2.1.2 Sources of Medication Errors in the Pharmacy Setting

A review of the literature found that the most common medication errors related to dispensing, identified by both community and hospital pharmacies, involved: product

error (dispensing the wrong drug, strength, form or quantity); and labeling medication with incorrect instructions (James et al., 2009). Contributing factors to these errors included look-alike, sound-alike drugs, low staffing and computer software, however high workload, interruptions, distractions and inadequate lighting were also shown to increase the occurrence of errors.

The relationship between increased pharmacy workload and medication errors in community pharmacy continues to be one of significant interest. Recently, it was shown that community pharmacists perceive workloads have increased as compared to the previous year, regardless of pharmacy setting (chain or independent) (Jacobs, Ashcroft, & Hassell, 2011). Using a self-report survey of community pharmacists in the US, Szeinbach, Seoane-Vazquez, Parekh, and Herderick (2007) found there was a positive correlation between prescription volume and number of medication errors. Another study in the US found that the risk of dispensing drugs with potential drug-drug interactions was significantly related to: the pharmacists' workload, the overall workload of the pharmacy, and the automated systems used for prescription orders (Malone et al., 2007). Similarly, a study in Finland investigating community pharmacists' perceptions and opinions on the potential causes and preventative factors of dispensing errors found a heavy workload and the similarity of drug packaging to be the most important potential causes of medication errors (Teinila, Gronroos, & Airaksinen, 2008). Although these studies suggest workload is related to committing an error, a review conducted in 2011 indicated that more robust evidence is needed to determine the true relationship between pharmacy workload and patient safety (Hassell, Seston, Schafheutle, Wagner, & Eden, 2011). Given the increasingly high volumes of medications dispensed in community

pharmacies, the relationship between increased workload and making a medication error is of particular interest when researching patient safety in the community pharmacy setting. In addition to workload and the dispensing process in community pharmacy, the role of various social and organizational factors has been researched to determine their potential impact on medication safety. A US study exploring the perceptions of medication preparation errors made by certified pharmacy technicians working in hospital and community pharmacies reported that interruptions and inadequate staffing were perceived to be the largest contributors (Desselle, 2005). Interestingly, Szeinbach et al. (2007) found that community pharmacists perceived pharmacy design as a significant contributor to medication errors. In a recent study involving community pharmacists in the North West of England, several sociotechnical factors of community pharmacy work settings were shown to be potentially related to medication safety: relationships involving the pharmacist (interactions between the pharmacist and other people); demands on the pharmacist (including commercial, corporate and legal demands); and management and governance of pharmacists (including work design, governance processes and culture) (Phipps, Noyce, Parker, & Ashcroft, 2009). Teinila, Gronroos, and Airaksinen (2009) also found that pharmacy staff's discussion about medication errors and resultant changes in work routines, based on these errors, were considered to be the most important factors in error prevention. Examining continuous quality improvement programs, a key component of which is continuous feedback and discussion of ways to enhance performance, can provide a valuable opportunity for application in community pharmacy as well.

2.2. Continuous Quality Improvement (CQI)

The management philosophy of continuous quality improvement was developed and used successfully in the industrial sector for many years. The concept was first created in the 1930's by Dr. Walter A. Shewhart while working at Bell Laboratories and was based on the concepts of statistical process control (Decker, 1992). This model was further refined by Dr. W. Edwards Deming and Dr. Joseph M. Juran which resulted in revolutionary changes in the Japanese and American manufacturing industries, especially after World War II. Modern day CQI has evolved from a number of similar management philosophies (e.g., Plan-Do-Check-Act (PDCA) Cycle, Total Quality Management, Root Cause Analysis). For this research, CQI is operationalized as a management approach focused on the improvement of performance over the long term by continually and systematically examining the work processes within an organization to identify and address the root causes of issues in quality (e.g., errors and inefficiencies). CQI emphasizes an evolutionary approach to quality improvement, employee empowerment, teamwork, and the utilization of scientific methods to identify and address quality issues and subsequently plan and implement changes (Geboers et al., 1999; Shortell et al., 1998; Wakefield et al., 2001). Shewhart's PDCA cycle highlights continuous improvement, a key component of CQI where processes are continuously improved and revised to minimize the processes which are inefficient, wasteful and repetitive (Goldstone, 1998, p. 379). The planning stage involves the collection of relevant data to determine an understanding of how the process had been previously performed (Decker, 1992; Larson, 1998; Paliska, Pavletik, & Sokovic, 2007). Through identification of potential problems in the work process, strategies for corrective action can be created leading to the next

stage, whereby changes are made to improve the process. The results of the corrective actions taken are then analyzed and checked against the initial stages and, based on their performance, are adopted or removed. If successful, the processes become standardized and are applied to correct any further discrepancies that arise. The final stage feeds back into the cycle, working toward continuous improvement. Through the application of CQI, opportunities to improve are identified through the continuous process of evaluating performance with particular focus on the *process* of the CQI program, not the individuals involved (Wakefield et al., 2001), another key component of CQI. Focusing on the processes, and not the individuals, minimizes a culture of shame and blame and strives to improve quality by understanding the root cause and determining the appropriate solution and strategies for planning and implementation. The success of a CQI program is also reliant on another key component, the creation of an organizational culture that highlights employee empowerment and teamwork as essential to quality improvement. Team meetings that facilitate group discussions on existing trends enable staff to work together and feel empowered to develop solutions and strategies for improvement. Successful implementation of a CQI process also requires a commitment from management to the continuous improvement of quality, including built-in strategies to facilitate and reward the pursuit of quality (Decker, 1992).

After the embrace of CQI in the manufacturing and service industries, its introduction into the healthcare system occurred in the late 1980's. This occurred during the time of health care reform when the primary focus was minimizing costs, unfortunately in the absence of quality.

2.2.1 Continuous Quality Improvement (CQI) in Healthcare

Like other complex systems, healthcare institutions, too, are at risk of organizational accidents. The healthcare industry, however, involves numerous characteristics that make it unique including: the variation in activity and equipment, the high degree of uncertainty, the vulnerability of patients, and the differences in mode of delivery (Reason, 2004). In addition to the incorporation of CQI into the hospital setting, there have been examples of CQI within ambulatory care settings and within hospital pharmacy practice (Piccirillo, 1996; Zimmerman, Smolarek, & Stevenson, 1997). As opposed to examining medication errors, however, these have been primarily goal driven and focused on: patient satisfaction with visits; improving provider continuity of care and daily work processes; and increasing preventative services in clinical and pharmaceutical settings (Shortell et al., 1998). One study in the Netherlands that explored the adoption of CQI in small-scale physician practices found that a positive commitment from all individuals involved was the most important component for successful implementation of CQI in this setting (Geboers et al., 2001). Workload and lack of time were found to be important barriers to using the CQI model whereas the main advantages included: the ability to use a systematic approach, having a better understanding of the processes within practice, and creating plans for improvement.

Research detailing the use of CQI processes in reporting medication errors in the community pharmacy setting was sparse when the research proposal for this study was developed. Only recently have there been Canadian studies found that researched the use of a CQI process to report medication errors in community pharmacy. One Canadian study examining which key aspects of medication safety in community pharmacies

change as a result of implementing a standardized CQI program found significant improvements with quality processes and risk management, competence and education of staff, and communication of information, including drug orders (Boyle, Ho, MacKinnon, Mahaffey, & Taylor, 2012). Ease of use and learning capability were also considered by community pharmacy staff to be the most important characteristics of a reporting process (Boyle, Ho, et al., 2012). In Danish community pharmacies, Knudsen et al. (2007) measured the commitment to report prescription corrections, near misses, and medication errors related to prescribing using an ongoing CQI process. The errors and prescription interventions were documented, and the systematic analysis of the data resulted in the creation of improvements in quality. It was found that by evaluating aggregate data within pharmacies, not only can the frequency and severity of the errors be measured, but solutions to minimize or prevent future errors can be developed (Knudsen et al., 2007). Similarly, another study in England and the UK researching the development of a conceptual framework characterizing healthcare quality in community pharmacies found that in order to provide high-quality care, additional structures to learn from significant errors were needed (Halsall, Noyce, & Ashcroft, 2011). In Inland Australia, Madden and Ball (2011) found that although a culture of CQI exists among pharmacists, attitudes related to medication errors were diverse. In addition, it was found that the organizational safety culture and behavior modeled during the pharmacists' initial internship had the most profound impact on attitudes and behaviours related to medication errors.

The relationship between organizational culture and quality improvement is integral to CQI programs and requires investigating the organizational culture of

healthcare in more detail, in particular, the culture that exists in the community pharmacy setting.

2.3 Organizational Safety Culture

One of the key benefits of adopting a CQI program in healthcare is the enhancement of the safety culture. The term "safety culture" originated from disasters such as Chernobyl in 1986 and the Piper Alpha offshore oil explosion in 1988. The high-profile investigations into these events illustrated the systems breakdown due to, or lack of, the actions of those persons responsible for the systems creating significant interest and further research in the topic (Cox & Flin, 1998). Increased research in this area, has led to many definitions of safety culture in the literature, however Guldenmund (2000) used a definition that places safety culture within the broader text of organizational culture: "those aspects of organizational culture which will impact on attitudes and behavior related to increasing or reducing risk" (Fleming & Hartnell, 2007, p.45). Measuring the safety culture of an organization has become recognized as a valuable tool when trying to assess the quality of care provided (Norden-Hagg et al., 2010). The two fundamental beliefs that support most of the safety culture research are that: 1) a positive safety culture is related to improvements in safety performance; and 2) the culture of an organization can be improved (Clarke, 1999; Fleming & Wentzell, 2008; Guldenmund, 2000). Research has shown that the less supportive a culture is in an organization (i.e. a shame and blame culture), the less likely error reporting will occur. Ashcroft, Morecroft, Parker and Noyce (2005) assessed the feasibility of the Manchester Patient Safety Assessment Framework (MaPSAF) among community pharmacies in the UK. This tool

was designed to assess the current safety culture in community pharmacies and through this assessment five ascending levels of culture were developed: pathological, reactive, calculative, proactive, and generative. Ideally, UK pharmacies should strive for the generative culture where medication incidents are seen as inevitable, but also as learning opportunities and the knowledge that is gathered from these incidents is shared with other pharmacies to increase quality throughout the healthcare system. Risk management is considered an integral part of every business process in the generative culture and maximizes organizational learning. Through pharmacy staff interviews it was determined that, in reality, the majority of pharmacies are at the pathological stage, characterized by the avoidance of reporting medication incidents, if possible, and the lowest of the five stages of safety culture. The risk that medication incident reporting poses to the security of the individual's job and pharmacy's reputation have been suggested as potential reasons for the occurrence of the pathological culture in community pharmacies (Ashcroft, Morecroft, et al., 2005). More recently, another study found that community pharmacy staff in the UK felt a blame culture was evident in the workplace (Ashcroft & Parker, 2009). Some of the statements used to describe the perceptions of this environment included: "staff feel their mistakes are held against them"; "there is a blame culture, so staff are reluctant to report incidents"; "incidents and complaints are 'swept under the carpet' if possible"; and "staff in the pharmacy are seen as the cause of incidents, and the solution is retraining and punitive action" (Ashcroft & Parker, 2009, p.30). Another study analyzing a tool entitled the Pharmacy Safety Climate Questionnaire, found through exploratory and confirmatory factor analysis that a strong correlation existed between the following four factors when predicting a rating of

pharmacy safety in community pharmacies: organizational learning, blame culture, working conditions, and safety focus (Phipps et al., 2012). It was shown that pharmacy staff sensitivity to being blamed for errors was a barrier to organizational learning and that attempts made to improve safety were undermined by a work environment unsupportive of safe working. Phipps et al. (2012) also found a strong covariance existed between blame culture and work conditions which indicated that the tendency to blame others for errors increased as pressure on staff increased.

The culture of blame has been associated with chronic underreporting of incidents in community pharmacies for many years. In order to successfully move from the culture of blame toward one of sharing and learning, medication error reporting systems must be: confidential, non-punitive, independent, systems orientated, and responsive (Ashcroft, Morecroft, Parker, & Noyce, 2006).

2.3.1 Measuring Health Professional Attitudes Toward Patient Safety

Health professionals study and train to help patients and contribute to the eradication of disease, however, because we are human, infinite amounts of training or discipline cannot completely eliminate our propensity to cause error. "An important avenue for improving the safety of medication-use systems (and the overall healthcare system) lies in collecting information on incidents, examining the underlying factors, communicating the lessons learned, and implementing change" (Salsman, 2007, p. 437). Although error reporting systems can be voluntary or mandatory, the latter tend to have a greater focus on accountability and may be viewed as potentially punitive. Voluntary systems on the other hand are generally non-punitive, have a greater focus on learning,

and make available the opportunity for anonymous reporting (Chua et al., 2003). The World Health Organization (WHO) Draft Guidelines for Adverse Event Reporting and Learning Systems (2005) suggest that the characteristics of successful reporting systems include: 1) safe reporting for individuals who report; 2) constructive response as a result of reporting; 3) meaningful analysis of reports via available expertise and adequate financial resources; and 4) ability to disseminate information on hazards and recommendations for change.

Delivering safe and effective healthcare requires dedication and coordination by many health care professionals. The perceptions of medication errors and the likelihood of reporting medication errors among health care professionals have been shown to vary in both the hospital and community environments. One study in a hospital in the UK found that within and between health care professional groups, including doctors, nurses, pharmacists and pharmacy technicians, there was a wide variation in rating medication error severity (Williams & Ashcroft, 2009). Nurses and pharmacy technicians were found to rank medication errors as higher in severity than pharmacists or doctors, and pharmacists and nurses were found to be more likely than pharmacy technicians and doctors to report medication errors. Another study in the UK found that the likelihood of community pharmacists and support staff to report any medication incident was low, and the decision to report was primarily affected by the behaviour of the pharmacist, and less so the resultant patient outcome (Ashcroft et al., 2006).

Although there has been research identifying the types of medication errors in community pharmacy, more research is needed surrounding why pharmacy staff report errors and what, if any, organizational learning practices, including reporting and

feedback systems, exist in community pharmacies. To understand how health care professionals perceive medication errors and medication error reporting, further exploration of the safety culture, or climate, within the health care professionals' work environment is needed. Recently, Ashcroft and Parker (2009) developed and assessed a questionnaire used to determine safety climate in the community pharmacy setting. This tool can be used by community pharmacies to measure the attitudes of staff relating to seven safety climate domains: 1) investigating and learning from medication incidents; 2) staffing and management; 3) perceptions of the causes of medication incidents and reporting; 4) team work; 5) communication; 6) commitment to patient safety; and 7) education and training about safety.

Ashcroft, Morecroft, et al. (2005) have demonstrated that the blame culture exists in community pharmacies and pharmacists and pharmacy technicians do not report medication incidents due to the belief that the risk of being blamed outweighs the risk of learning from the incident. Similar barriers to reporting medication errors in hospitals have also been identified and categorized into five themes: reporter burden, professional identity, information gap, organizational factors, and fear (Hartnell, MacKinnon, Sketris, & Fleming, 2012).

The context surrounding medication error reporting and identification of root causes and processes that contribute to medication errors, and solutions to improve these processes, is necessary to provide optimal patient care and safety. CQI programs have the potential to improve safety, however there has been little uptake of CQI in the community pharmacy setting despite the prevalence of medication errors. This research study was developed as a result of this gap in the literature. Given the complexity of the

community pharmacy environment operating in a variety of settings, examining the commercial nature of services and influence on safety in this environment can provide necessary information to help improve the safety of this medication-use system. The establishment of an open culture involving discussions, learning and sharing about medication errors in community pharmacy is imperative if optimal quality and patient safety is ever to be achieved.

CHAPTER 3: METHODOLOGY AND STUDY DESIGN

3.1 Research Objectives

The objectives of this research were to: 1) identify pharmacist and pharmacy technician perceptions of the challenges to reporting medication errors in community pharmacies; 2) identify the perceived facilitators that encourage pharmacists and pharmacy technicians to report medication errors in community pharmacies; and 3) identify insights and lessons learned of the pharmacists and pharmacy technicians involved in a standardized CQI program designed to enhance medication error reporting and learning.

To achieve these objectives, a qualitative case study approach and in-depth interviews were conducted with pharmacists and pharmacy technicians from the participating pharmacies.

3.2 Study Design

3.2.1 The History of SafetyNET-Rx

The SafetyNET-Rx project was an innovative project funded by the Social Sciences and Humanities Research Council of Canada (SSHRC), Nova Scotia Health Research Foundation, (NSHRF), Canadian Foundation for Pharmacy (CFP), and Canadian Institutes for Health Research (CIHR). This project involved the implementation of a CQI program to enhance reporting and learning from medication errors in community pharmacies. The first phase, the pilot project, was developed in 2008

and involved 13 community pharmacies in Nova Scotia. The participating pharmacies represented: chain and independent pharmacies; urban and rural pharmacies; and low- and high-volume pharmacies. At the beginning of the pilot project, pharmacy staff, specifically one pharmacist (staff pharmacist or pharmacy manager) and one pharmacy technician, were invited as CQI facilitators to attend a one-day training session about quality management, quality related events (QREs), and the SafetyNET-Rx program including tools, forms and processes. This followed a train-the-trainers format and was a key component of the program. The SafetyNET-Rx program also included: a central anonymous reporting tool to an independent third party database as part of an integrative information system (IS) that was used to identify, report, analyze and learn from QREs; quarterly staff meetings to discuss and learn from reported QREs as well as suggest changes to prevent recurrence; and an annual self-assessment tool for evaluating performance on a continual basis (Figure 1.). The online reporting tool, originating as an edited version of the ISMP Canada reporting tool used in the hospital setting, was created incorporating feedback from the community pharmacy staff involved at the training session in conjunction with ISMP Canada. Paper forms, in addition to using the online tool, were available for the reporting of QREs. Once a QRE occurred, details of the QRE, including potential contributing factors, were entered into the online reporting tool that enabled anonymous reporting to a national database, hosted by ISMP Canada. Staff meetings were held quarterly, or immediately after a recorded QRE if deemed significant, to openly discuss the QREs since the last meeting, the root causes of the QREs, and suggestions for workflow changes to reduce recurrence. The suggested changes to workflow and processes, if approved by management, were implemented and staff

followed the new procedures until another QRE occurred that prompted the cycle again. The self-assessment tool used to identify improvements in the system, or lack thereof, on an ongoing basis was the Medication Safety Self-Assessment for Community/Ambulatory Pharmacy (MSSA) (Institute for Safe Medication Practices Canada, 2006). The MSSA includes components that focus attention on the organization's safety culture specifically concerning the reporting of medication errors and the pharmacy staff completed the MSSA at the beginning and end of the pilot phase. The pilot project covered a 12-month intervention period that ended in June 2009. The project was a partnership between St. Francis Xavier University, Dalhousie University, Nova Scotia College of Pharmacists (NSCP) and ISMP Canada.

The end of the pilot phase led to the enhancement of the SafetyNET-Rx program and the second phase of the project. The resultant changes comprised what is now the current program deployed in community pharmacies in Nova Scotia. During this phase, SafetyNET-Rx was further expanded to 68 community pharmacies across the province. The off-site training of CQI facilitators, the self-assessment tool, and the quarterly meetings remained key components of the CQI program, however, the main changes involved enhancement of the online reporting tool and the creation of the iPad application for the provincial pharmacy inspectors. There was considerable development of the online reporting tool with ISMP Canada to create the Community Pharmacy Incident Reporting (CPhIR) Program. Due to changes in provincial pharmacy legislation mandating a CQI process in community pharmacies at this time, an iPad-based application was created that captured detailed information on QRE reporting and learning in the individual pharmacies to help inspectors assess compliance to these standards. This

online application also provided convenience for the inspectors over traditional manual forms when having to conduct inspections every two years. This application captured the key aspects of the SafetyNET-Rx program pharmacies struggled with and helped determine areas needed for improvement prior to the next inspection, allowing pharmacies to trace their progression of performance over time.

Currently, SafetyNET-Rx is in its third phase of evolution. The program has been adopted by the Patient Safety Company Canada and is in the process of being converted to have a common look and feel as a complete online tool allowing better integration of the manual (e.g., root cause analysis) and online components (e.g., iPad application for inspectors). The integration is also designed to help streamline workflow for the CQI facilitator (e.g., if a significant QRE is recorded, it is automatically placed in the agenda for the next quarterly meeting for discussion).

It is important to note that phase one, the pilot project, was instrumental in the development and creation of SafetyNET-Rx as a CQI program in community pharmacies. This phase was critical for addressing initial challenges with the program for future enhancement as well as obtaining buy-in from other jurisdictions, and was the setting in which I based my research.

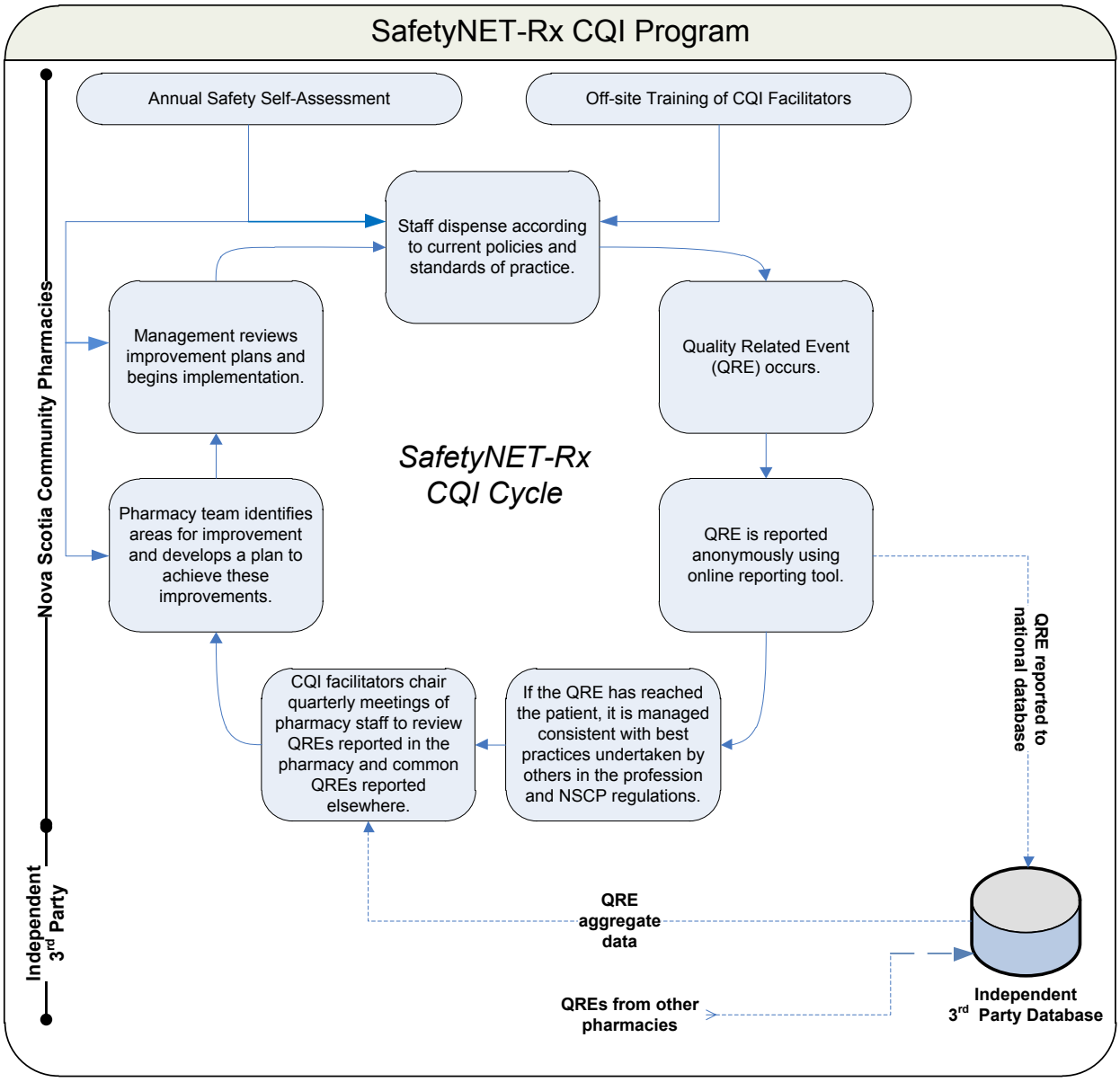

Figure 1: SafetyNET-Rx CQI Pilot Program

Adapted from: Boyle, Mackinnon, Mahaffey, Duggan, and Dow (2012).

3.3 Methodology

There are several frameworks one can apply when undertaking a research project. Prior to choosing a methodology for this project it was imperative that I identify my philosophical position as the researcher and how I believe we understand the world we

live in as well as my assumptions and beliefs. Locating my belief system helped me direct the different ways to approach this research, and the different types of methods best suited for this research. This process of self-awareness also elicited deeper insight throughout the inductive analysis process and contributed to my credibility as the researcher and the overall credibility of the study.

3.3.1 Choice of Methodology

Locating and discussing the nature of the paradigm that was guiding me, the researcher, in both ontological and epistemological ways was first and foremost when determining this study design. A paradigm can be described as the basic belief system or worldview that defines for an individual the nature of the world and their place in it (Guba & Lincoln, 1994). Paradigms differ on the nature of reality and depending on the paradigm: offer different reasons for doing research, view different types of data and methods as valuable, and differ in how meaning is derived from the data gathered (Willis, 2007). Identifying the paradigm in which I am located was important as it provided a way of focusing the method used, in a specific direction for a specific purpose (Richards & Morse, 2007). Ontology is concerned with issues of existence and the fundamental ontological question: what is the nature of reality and what can be known about it? Epistemology on the other hand examines the origin of human knowledge including the nature and limits of knowledge (Guba & Lincoln, 1994). It is my belief that the findings of a study are the creation of the interaction between the researcher and the participants in the research process and that the *context* in which any form of research is conducted is

fundamental to data interpretation. This belief system positions me within the interpretivist paradigm.

The ontological foundation of interpretivism is that reality is socially constructed (Willis, 2007). This differs significantly from the postpositivism paradigm guiding research in the traditional sciences where the purpose of research is to discover the true nature of reality and to determine ideals that can be generalized across varying contexts. Postpositivists believe that using the scientific method in research is the only way to objectively learn about the external world whereas interpretivists defend that research is inevitably influenced and shaped by preexisting views and beliefs of the researchers (Willis, 2007). Interpretivism supports both subjective and objective research methods, emphasizing that the appropriate methodology used to generate knowledge includes a hermeneutic approach, focusing on meaning and interpretation, and using the lived experience to better understand the social, cultural and political context in which those experiences occur (Polit & Beck, 2004). Interpretivism, unlike postpositivism where the goal is to remove as much subjectivity as possible from the research, requires interpretation where knowledge is socially constructed and the findings are relative to the individuals that produce and use the research. Interpretivists do not believe you can ever be certain that what you think to be true is true, only that the research will add to our understanding of different situations and that the application of this understanding is reflective, not technical as seen in postpositivist research. This approach allowed me the opportunity to discover meaning as the research progressed, as opposed to requiring the research begin with hypotheses and predictions at the outset. Interpretive research

produces practical knowledge by exploring how humans create meaning out of their interactions.

Qualitative methodologies enable researchers to investigate 'why' participants feel or think a certain way versus 'what' they feel or think. Given the complexity of the area under discussion (patient safety) and the multi-factoral influences surrounding medication error reporting, I chose a qualitative methodology to guide and explore this research. Giving considerable thought to how my influence as a community pharmacist could affect the collection, analysis and interpretation of findings in this study would prove to not only enhance the credibility of this study, but lead to a heightened self-awareness as well.

3.3.2 Strong Objectivity

Articulated initially by the feminist philosopher Sandra Harding, strong objectivity builds upon the insights of standpoint theory which argues more objective and relevant knowledge can be obtained by locating inquiry in the experiences of those 'others' who have been traditionally outside of the institutions from which social knowledge is generated (Harding, 1991). Strong objectivity acknowledges political influence in the production of power. Greater attention given to the social location and context of the producers of knowledge would contribute more transparent results. It is important not to confuse the concept of strong objectivity with that of the traditional postpositivist viewpoint of objectivity where all social and subjective values and interests are removed. Instead, strong objectivity supports the notion that research is socially situated and can be better conducted without claims of being value-free (Harding, 1991).

The standpoint theory approach helps to provide direction for: 1) maximizing strong objectivity by acknowledging and valuing the 'other's' perspective, and 2) understanding the researcher's power in the research process and position as a producer of knowledge, referred to as researcher reflexivity. By approaching the research process from the 'strong objectivity' point of view it was hoped that the production of knowledge would not only be useful, but would also address the relations of power that are so often hidden in the traditional research process. Reflecting on the 'other's' perspective for this research begs the question, where do pharmacists and pharmacy technicians rank in the hierarchy of health care professionals? Despite the intended collaborative nature of healthcare teams, the degree of influence on health policy and research relating to healthcare is not shared equally among the health care professions. The physician for many years has been considered the integral member of the healthcare team. How does this affect the perspective of pharmacists and pharmacy technicians on reporting medication errors? Is the pharmacist perspective seen as valuable as the physician perspective? The standpoint approach also elicits the acknowledgement of the hierarchy between pharmacy staff members (pharmacy manager, staff pharmacist and pharmacy technician) and that influence on the creation of knowledge for this study.

Researchers are encouraged to critically examine their historical location, values and interests, long shared by their scientific community and largely embedded and invested in their field of study, as a resource for obtaining greater objectivity. Harding refers to this difficult process as reflexivity. Ongoing examination of *what* and *how* the researcher knows, enables the researcher to be aware of the cultural, social, and political origins of their perspective, as well as the perspectives of those under inquiry (Harding,

1991). Applying this concept to my research required I reflect on and discuss my influence as a community pharmacist on the entire research process from conception of research objectives, through data collection, analysis, interpretation, and development of findings for this study. My inherent values and beliefs as a community pharmacist in this researcher role had me questioning throughout the research process if I have been inflicting my thoughts, values and beliefs on the participants. Has my power and politics as a pharmacist influenced the direction of questioning in interviews, the interpretation of data and analysis? Was there a difference in interviews with pharmacists and pharmacy technicians? How do I know my findings are truly representative of my participants? These questions plagued me throughout this entire process and forced me to examine, not only my own thoughts, behaviours and values, but where they are culturally, socially and historically located.

The acknowledgement of my position as a community pharmacist at the onset of this study enabled me to reflect on each component of the process and my influence on those components, all of which I documented in a reflective journal. I recorded my thoughts and behaviours that I was consciously aware of during the interview process and throughout data interpretation and analysis and writing this thesis. However, it would be remiss to assume I have not unconsciously influenced this research. It is my hope that by addressing these issues early on in the research process, I brought more credibility to this study and highlighted the concept of strong objectivity in research. By being aware of my inherent thoughts and beliefs and applying techniques to ensure trustworthiness, I have learned that I am inevitably part of this study, embedded in and throughout the research process.

3.4 Methods

3.4.1 Case Study Research

Case study research provides an opportunity to explore complex issues in detail and compare different situations in different settings (Yin, 2003). It also places more attention on the contextual aspects of an experience and is used extensively in social science research and practice-oriented fields (Heinz, 2007). I chose case study method for this research because it was appropriate to examine how various individual, cultural and/or organizational factors influence medication error reporting in community pharmacy. In case study research, there are two suggested ways to design a case study. A deductive approach involves the development of specific research questions at the beginning of the study then following an existing framework throughout data analysis to answer those questions (Patton, 2002). In contrast, an inductive, or more open approach, allows the evolution of research questions as the researcher discovers patterns, themes, and categories in the data and the findings emerge as a result of the analyst's interaction with the data. This study used an inductive approach to explore the context and the perceived challenges and facilitators to reporting medication errors in community pharmacies by pharmacists and pharmacy technicians.

Since a case is defined as "a bounded unit with an established identity" (Grbich, 1999), the 13 pharmacies that took part in the SafetyNET-Rx pilot project comprised the single case study. Case study research is useful for exploratory, descriptive, or explanatory purposes (Heinz, 2007). This was an explanatory case study where the goals

were to understand the context surrounding medication error reporting from community pharmacists and pharmacy technicians using a recently implemented CQI program, SafetyNET-Rx.

The case study approach to qualitative research constitutes a specific way of collecting, organizing, and analyzing data with the purpose of gathering comprehensive, in-depth information about each case of interest (Patton, 2002). The research design for this study was a within-case study. The initial study design for this research included a larger case (phenomenon of interest i.e., patient safety) divided into subcases (pharmacists and pharmacy technicians) where the similarities and differences would be compared both within and across the subcases to elicit insight into the larger phenomenon of interest (Gondo, Amis, & Vardaman, 2010). It was also hoped to gain further insight through comparison using pharmacy attributes: urban/rural, chain/independent, high/low volume pharmacies. However, to mitigate the chance of participant identification, a main concern of the Dalhousie University Research Ethics Board (REB), approval of ethics was granted on the provision that the groups would not be divided into subcases of any kind (pharmacists/pharmacy technicians; urban/rural, chain/independent, high/low volume pharmacies), and the pharmacists and pharmacy technicians would comprise a single case. In accordance with REB approval, a within-case analysis was done using thematic analysis to allow in-depth study of the complex phenomenon of interest. The participant groups were analyzed as one case and the findings that emerged were reported. Any differences found between participant groups were explored to deepen the analysis, and further my understanding for theme development. For example, any differences found in themes, or categories within themes, upon exploring pharmacy

technician responses, prompted a reanalysis of the entire case for refinement of category and theme development. These differences were reported as part of the findings, however, pharmacy technicians were not reported a separate group in accordance with the REB requirements. The constant comparative method of Glaser and Strauss (Burns, 2010) was used for comparison for this purpose within the case.

Individual participant in-person interviews were used as the method of data collection to maximize the opportunity for thick description. Thick description (i.e., rich detailed descriptions of people and places) forms the foundation of qualitative analysis and reporting and is instrumental is transporting the reader into the setting under investigation (Patton, 2002). The detailed descriptions from participants about the context of medication error reporting helped me extract my own interpretations of meanings and relevance, and understand the phenomenon being studied.

3.4.2 Participant Selection

Purposeful sampling was used in this study since the pharmacists and pharmacy technicians involved in the pilot project were those who knew the information required and were willing to participate, discuss and reflect on the research topic of interest. A pharmacist (represented in this case as a staff pharmacist or pharmacy manager) and pharmacy technician, who had worked full-time (35 hours/week or more) and been employed for a year or longer at one of the stores that had participated in the SafetyNET-Rx pilot project were considered to have the richest experience to draw upon and were contacted and invited to take part in the study (Appendix A). A total of 17 participants were interviewed, including 12 pharmacists (4 staff pharmacists and 8 pharmacy

managers) and 5 pharmacy technicians. Although 17 interviews were completed, data saturation was reached after 15 interviews. Data saturation is the point of sampling at which there is no new information retrieved and new data yield redundant information (Polit & Beck, 2004). Approximately 13 interviews have been suggested in a number of studies as an appropriate number of participants for a qualitative study of this nature.

3.4.3 Ethics Approval

Ethics approval for this project was received from the Dalhousie University Health Sciences Human Research Ethics Board in November 2009. Annual approval was received from Dalhousie University on October 27, 2010 and October 12, 2011.

3.4.3.1 Informed Consent

As part of obtaining ethics approval, an informed consent document was developed and distributed to each participant who agreed to take part in the study (Appendix B). In addition to the informed consent, this document also provided background information and the purpose of the study. The informed consent explained: what was expected of the participants; how participant confidentiality would be protected; any potential harm that could result as a consequence of participating in the study; and their ability to withdraw from the study at any time. The participants were given this document prior to confirming participation in the study in case the participants had any questions upon reading the document. The document was reviewed again just prior to the interview to provide the participant another opportunity to ask questions before signing the document. All consent forms were signed by the participant and

interviewer before the interview began. A consent form was also provided and signed by the pharmacy manager/owner of each pharmacy prior to the interview to ensure management was aware of their staff's enrollment in this study (Appendix C).

3.4.3.2 Compensation

As stated in the informed consent document, participants were not compensated for participating in this study, however any expenses incurred in relation to their participation (transportation, child care, meals, etc.) were reimbursed at a maximum limit of $40 Canadian.

3.4.4 Data Collection

Within the case study approach, I conducted in-depth interviews with the participants to help elicit insight into the experience of participating in the SafetyNET-Rx pilot project. In-depth interviews were chosen as the most appropriate method to collect data based on the research objectives and purpose of this study. The sensitive topic of discussion required confidentiality for participants to discuss personal experiences relating to the reporting of medication errors. The use of interchange through dialogue (i.e. face-to-face interviews) was used to build knowledge through the subjective experiences of the participants using an inductive approach (Patton, 2002). In-depth interviews provided a means for participants to share their personal stories freely and allowed me the opportunity to gain detailed in-depth information from each individual interview as opposed to using a survey which would not capture the same degree of richness and depth of information. In-depth interviews also provided the ability to capture

information from pharmacists and pharmacy technicians individually whereas choosing another method, i.e. a focus group, may have hindered some individuals from sharing their personal stories in front of the other group participants.

Pharmacists, including staff pharmacists and pharmacy managers, and pharmacy technicians were asked to discuss their perception of the SafetyNET-Rx program; any perceived improvements needed, and the context surrounding the challenges and facilitators to medication error reporting in the community pharmacy environment. Individual one-on-one interviews were conducted at a location and time chosen by the participant. The interview used a combination of informal conversational interviewing at the beginning of the interview followed by the delivery of semi-structured open-ended questions at the end, if necessary, to pursue specific aspects that may not have been raised in the conversation to that point (Appendix D). A conversational approach let the participant influence the direction of the interview and as a result questions were not asked in the same order or in the same way each time. The informal interview approach allowed flexibility in probing and posing of questions about new areas of inquiry that were not originally expected in the development of interview questions (Patton, 2002). To ensure consistency in data collection, I conducted all of the interviews and each interview was audio recorded, using a digital audio recorder and transcribed verbatim by a hired transcriptor. Prior to transcribing the interview, a pledge of confidentiality was signed by the transcriptor to protect the participants' identity and confidentiality of information provided (Appendix E). I listened to the audio recording after each interview was completed and again while reading the transcript to ensure accurate transcription and determine intonation for analysis.

3.4.5 Data Analysis

Due to the diversity of case study research there are a variety of approaches that can be used for data analysis (Heinz, 2007). When trying to explore in-depth understanding of a phenomenon, within-case analysis enables the researcher to deeply immerse themselves within the data of a single case (Paterson, 2010). The perceptions of the pharmacists and pharmacy technicians from the participating pharmacies were explored as one case. The findings from this case contributed information to the entire study, highlighting the findings that are shared across the participant groups as well as the unique differences found in the groups. This within-case analysis began with rich, descriptive data, which was particularly important to reveal the contextual nature of the case and the phenomenon under study.

The pharmacist and pharmacy technician interview data were thematically analyzed together using open coding, as described in Boyatzis (1998) in the within-case analysis. Codes were developed by applying a label or description to data that was discerned as a pattern among seemingly random information. Related codes were grouped together to form categories and the linking of related codes and categories led to eventual theme development. A theme was defined as "a pattern found in the information that at minimum describes and organizes the possible observations and at maximum interprets aspects of the phenomenon" (Boyatzis, 1998, p. 4). Upon discovery of any differences in categories or themes when exploring the pharmacist and pharmacy technician responses, constant comparative analysis was completed by reanalyzing the entire case for refining category and theme development using an iterative approach. The

constant comparative method by Glaser and Strauss was used which supports the use of comparisons both across and within cases (Burns, 2010). An iterative approach to research means upholding continuous flexibility and ongoing change throughout the study to meet the requirements of the research design, including data and analysis, as new information is collected (Bassett, 2010). This approach was chosen because it is valuable in preserving the richness and variability of the data and helps to ensure the data fulfill the research objectives.

The differences between pharmacist and pharmacy technician responses were not analyzed for the purpose of reporting the groups separately, but to deepen the development of themes. Recurrent patterns in participants' phrases were identified, and a code was applied. This process was repeated the same way multiple times. During this process, an iterative cycle occurred synergistically (Bassett, 2010). This involved the researcher moving back and forth between the inductive discovery of categories and codes to confirming them deductively while probing for new inductive insight, forcing the cycle to repeat. Through this process, the data was revisited with additional questions that emerged from the analysis, and interconnections between codes were identified to help strengthen theme development. Codes were sorted and compiled into categories and then overall themes were created. This process was revisited several times as I worked back and forth between the data, codes, and themes, ultimately leading to another iterative cycle, yielding additional insight. This approach continued throughout data analysis into writing the findings via continuous reflection and reexamination of the data.

After the themes had been identified in the data, a series of steps comprised the comparative process. First, the extent to which a theme (e.g., resistance) occurred within

the case was revisited and any differences found in the categories of that theme were compared within the case. Second, the categories and their characteristics were integrated including the relationships among, and differences within, the categories as well as the variations within the case. For example, under what conditions and when did the theme of resistance exist? Once the pattern of relationships within the categories were made apparent in the third step, the number of categories and characteristics were reduced which led to the final step of developing broader generalizations and theory.

The software program NVivo 8.0 was used for data entry and coding for the within-case analysis and generation of categories and themes. Data sources were coded to *free nodes* and represented codes and categories and included the particular reference in the data source. The assigned codes represented similar sections of text found in the data. The free nodes were then grouped into *tree nodes* which linked related codes and categories together. *Annotations*, or brief notes, were linked to the interview transcripts and were reviewed throughout analysis. *Memos*, larger annotations detailing emerging thoughts about themes and theories, were written and linked to the interview transcripts and revisited throughout the analysis and writing of the findings. Once concepts were identified, constant comparative analysis of the data was completed to determine if those categories and themes were present across both pharmacist and pharmacy technician groups. *Queries* were used within NVivo to compare data coded to multiple codes by different participant groups within the case. These characteristics of the NVivo software program allow for transparency of the completed research process and helped contribute to an audit trail of this case study.

The within-case analysis of this research used an iterative approach to thematic analysis to achieve thick description of the single case and to identify any thematic similarities and differences within the case representing the phenomenon of study. By using an iterative approach in this study, the subjective process of coding, interpretation, and analysis in qualitative research upholds a standard of reliability. To ensure further credibility, the criteria of rigour, or trustworthiness, were considered throughout the methodological plan for this study.

3.5 Rigour/Evaluation Plan

In qualitative research, the researcher's skills ensure the quality of data, the interpretation of results, and the creation of theory, thus the researcher must be prepared in qualitative methods prior to beginning the project to ensure trustworthiness, conventionally known as rigor, of the study (Richards & Morse, 2007). The terms internal validity, external validity, reliability, and objectivity are commonly used when discussing the standards for trustworthiness in quantitative research. For qualitative research, these terms are not perceived as relevant and have been reconceptualized to better align with the philosophy of qualitative research. The framework developed by Guba and Lincoln (1989) outlined the four key components that relate to trustworthiness of research findings using a qualitative approach: credibility (internal validity), dependability (reliability), transferability (external validity), and confirmability (objectivity).

3.5.1 Credibility

Credibility refers to the degree to which a research account is truthful, specifically the extent to which the researcher has articulated the match between the constructed realities of the participants and the appropriate representation of those realities by the researcher as supported by various stakeholders (Guba & Lincoln, 1989). The techniques used to enhance credibility of a study involve: prolonged engagement, persistent observation, peer debriefing, negative case analysis, progressive subjectivity, and member checks (Guba & Lincoln, 1989). Participating in prolonged engagement and persistent observation was an essential component of building trust with the participants and increased the likelihood they would be more open and honest and accept my interpretations as the researcher. I also worked closely with the qualitative research expert on my thesis committee to uncover any differences in data interpretations. This is referred to as peer debriefing and involved working with her to review and explore the various themes of the study (Guba & Lincoln, 1989). I also searched for rival themes during the analysis to ensure my explanations of the findings included all cases, a process termed negative case analysis. By disclosing and revisiting my belief system and biases at the outset of the study and throughout the progression of the research process I was able to apply progressive subjectivity. Both negative case analysis and progressive subjectivity contributed to the credibility of this study and were documented using memos in NVivo throughout the entire process to keep track of coding decisions, changes in category/theme development, and the relabeling of themes as often as needed. Reflective notes were also included in the memos, including methodologic and theoretical notes, to help attach meaning to what was observed throughout the interviews. A reflexive paper journal was maintained throughout the process to provide reflection on

how my experiences as a pharmacist helped to probe further in the interview as well as gain insight throughout each of the interviews, reinforcing the strong objectivity approach. Part of this journal included a research diary detailing the history and development of the project to maintain a dated and documented history of how the project and analysis progressed. The memos, reflexive journal and research diary were all essential components of the audit trail that was maintained detailing all events and decisions made throughout the project. Member checks were not used in this study because it was a challenge to find a time to conduct the interviews with the participants due to their busy schedules. Asking them to review their interview transcript required additional time and would likely, due to the time lag, be a challenge to accurately remember what was said in the interview.

Data saturation, defined for the purposes of this study as the point where there are no new codes identified despite the generation of additional data, also contributed to the credibility by ensuring thick description to bring the case study report to life.

3.5.2 Dependability

Dependability refers to the degree to which the findings would be similar if repeated over time (Guba & Lincoln, 1989). Because methodological changes are expected in inductive qualitative designs, such as this study, it was important to track any changes so that reviewers could follow the process, judge the decisions that were made by the researcher, and obtain an understanding of how interpretations unfolded. A dependability audit provided a means for documenting the process and any methodologic changes. Throughout this study, I documented memos and reflective notes in NVivo that

included methodologic and theoretical notes to help attach meaning to what was observed throughout the interviews. I kept a written research diary detailing the history and development of the project to maintain a dated and documented history of how the project and analysis progressed.

3.5.3 Transferability

Transferability refers to the generalizability of the findings and whether the findings can be transferred to another setting (Guba & Lincoln, 1989). The term transferability refers to the ability of another researcher to transfer the findings of this study to another situation or setting. The best way to achieve this was to use thick description to create the most complete database possible and provide others with enough information to make transferability judgments when applying the study to their own situation of interest. The detailed data analysis plan provided thick description of the case in this study.

3.5.4 Confirmability

Confirmability refers to the notion of neutrality, or the degree to which the data, interpretations and findings are rooted in contexts and persons apart from the researcher (Guba & Lincoln, 1989). In the postpositivist paradigm, objectivity is rooted in the method, however, in the interpretivist paradigm, the integrity of the findings is rooted in the data. A confirmability audit was completed that included documentation tracking the data to the source and illustrating the processes used to collect interpretations so that outside reviewers can confirm the data and interpretations of the study. This audit is

usually done in conjunction with a dependability audit as discussed previously in the sections discussing credibility and dependability.

Finally, identifying my philosophical position as a community pharmacist conducting this research helped focus the development of the methodology and study design. Applying the methods chosen enabled participants best suited to inform this study's research objectives and provide thick description of data for analysis and interpretation.

CHAPTER 4: FINDINGS

4.1 Participants

The purpose of this study was to explore the experiences of the pharmacists and pharmacy technicians who participated in the SafetyNET-Rx pilot project. The participants were purposively selected and a total of 17 individuals were interviewed, including 12 pharmacists (4 staff pharmacists and 8 pharmacy managers) and 5 pharmacy technicians. The majority of the participants were female (76%) and years of experience ranged from less than 10 years to greater than 20 years (≤ 10 years: 6 participants; 11 to 20 years: 6 participants; > 20 years: 5 participants). The interviews took place from January 2010 to August 2010 and the average length of interview was 41.29 (min:sec).

4.2 Background

For anyone working in a community pharmacy, the thought of making a medication error has often evoked feelings of fear and shame. Thinking about the potential harm that could come to their patient and how they have contributed to it causes a dramatic decrease in self esteem and self confidence. This in turn results in the feeling of isolation and the need to keep such events quiet, only revealing the secret to those who need to know. This secrecy has perpetuated a 'shame and blame' culture where finger pointing and lack of sharing have resulted in the repetition of mistakes due to the missed opportunities for learning. The SafetyNET-Rx program provided a mechanism to enhance and learn from the reporting and discussion of medication errors in community pharmacies. Initially, there was resistance to elements of the program, the reporting tool,

scheduling quarterly meetings, and training staff, and due to the predominant safety environment of fear and secrecy that existed in community pharmacies, the increased workload of the tasks involved, and the lack of time available to complete these tasks. As the participants worked through resolving the resistance to these elements of the program, a seemingly positive change in the safety environment of these community pharmacies became apparent. Participants shared how the creation of a safe and open environment to discuss medication errors resulted in an improved outlook and gathered support for the program and a means for pharmacy staff to see things, in particular the making and reporting of medication errors, in a different way.

4.2.1 Resistance

Upon initial implementation of the SafetyNET-Rx program, participants acknowledged there was resistance to the different components of the program. The resistance was due largely to the additional workload (i.e., training staff, using the reporting tool, and scheduling quarterly meetings) and also the fear that existed around medication errors. Completing the additional workload while maintaining daily dispensary function, in a timely manner, led participants to resist using the program. In addition to the workload, the participants described the fear of making a medication error and how that led to additional feelings of shame and lack of self-worth. The fear of causing a patient harm, the embarrassment of their co-workers thinking they were inept, and the judgment that ensued resulted in their opposition to the program.

4.2.1.1 Additional Workload

The implementation of the various elements of the program was one of considerable burden for participants, involving an increased workload. The individual components of the SafetyNET-Rx program were all tasks that required pharmacy staff to spend time away from the daily dispensary functions including: assessing, processing, and filling prescriptions; counseling patients on prescription and non-prescription medications and therapies; contacting other health care providers and third party plans regarding problems with prescriptions; and receiving and putting away the drug order. As a result, the requirements of the program (i.e., training staff about the program; filling out the reporting form for each medication error and near miss; holding quarterly meetings for discussion of reported events; and completing an annual self-assessment for monitoring system improvements on a continual basis) interfered with the time needed to complete the daily pharmacy functioning. The increased workload was said by the participants to be challenging, especially the lack of time to complete these tasks, while maintaining the priority of regular dispensary functions.

> Well, it was a bit of a challenge, I will say that. Just because we are busy. So at first... Before it went on-line, it was the issue of doing paperwork which was very time-consuming, and then where do you put the paperwork, and then all that kind of stuff. So when it went on-line, it was much easier. However, we only have 3 computers. You're rattling for a computer as it is. And then if you have to actually write up a near hit, and then it takes time to go through that. Not that it took all that much time, it just took time waiting for a computer and doing it at the computer.[E105, Pharmacist]

While the online reporting tool was described as easier and faster to use than the paper forms, it still required time that was often perceived as time that could be spent fulfilling the daily dispensary tasks of the pharmacy, the participants said.

> I know there was resistance, especially here at the beginning, saying it takes too much time. By the time you did this, that and the other, you could have checked 3 more prescriptions by that time.[B002, Pharmacy Technician]

Although initially all medication errors and near misses were reported by each of the pharmacies, participants found this became too difficult to maintain as it was too time-consuming and interfered with completing regular dispensing in a timely manner. Thus, as the project progressed, the pharmacies began to report only those medication errors and near misses deemed significant by their respective pharmacy staff. The significance of which errors would be reported and who would be responsible for reporting the errors were determined differently depending on the pharmacy. Some of the participants stated they encouraged the person who *found* the medication error, while others encouraged the person who *made* the medication error, to report the error. For either choice, participants felt it made the staff more accountable for their actions.

> If you just have one person being the form filler then everyone doesn't learn what they can learn or what the opportunity is there to learn. If you are filling out your own then you see what you do. If you pass it off to someone else, you can forget about it like that. [snaps fingers] So it doesn't stay with you as long.[D004, Pharmacy Technician]

While some participants felt a sense of reassurance that the responsibility of this task was carried by all the members of the dispensary team, others stated that they preferred to have one person designated with the reporting responsibility because that worked best in their pharmacy to maintain the workflow and served as a guarantee that all forms were filled out appropriately. The person designated with this role in those pharmacies ranged from pharmacy managers and pharmacists to pharmacy technicians.

Another requirement of the SafetyNET-Rx program was the scheduling of quarterly meetings to discuss reported medication errors. It was a significant challenge scheduling annual staff meetings let alone a meeting for all pharmacy staff to attend every 3 to 4 months, participants said. Some of the pharmacies consisted of large pharmacy staff (more than 20 individuals) and considered it unrealistic to schedule quarterly meetings for all to attend. A particular concern shared by the pharmacy managers was the lack of compensation from head office for time spent during quarterly staff meetings, hindering staff willingness and attendance. It was aptly put by the following participant.

> The cost of that and paying for all them to be working for 2 hours while I have 3 people that are available to cover. And they can't just cover the 2 hours, they have to cover that whole night shift. And so that's what it means to have a meeting.[H108, Pharmacy Manager]

Suggestions of ways to communicate and discuss reported medication errors without meeting quarterly were expressed by the participants. Some said they had to make time during work hours to meet with the staff members, a few people at a time, several times throughout the week to discuss the reported medication errors and near misses. Other participants developed a communication logbook for their pharmacy to share the findings from the reported errors and near misses as a means to disseminate the information to all of their pharmacy staff.

The importance of training the staff in the success of implementing the program and bringing people to understand the reasons why the SafetyNET-Rx program is important was noted, too, by participants. Time and scheduling constraints however posed a challenge to participants. Because of the inability to schedule a time for all

pharmacy staff to meet, and lack of compensation to meet outside work hours, some pharmacies were unable to provide the intended group training session. Some participants mentioned informal discussions held with pharmacy staff in the dispensary about the SafetyNET-Rx program to tell them about the key elements of the program and provision of additional information for reference if needed.

4.2.1.2 Fear

> Every pharmacist remembers their first medication error.
>
> It was horrible. And I remember afterwards thinking why hasn't...why don't we talk? Like you just feel so secluded and alone. And you feel stupid. Like oh my gosh, maybe I shouldn't do this job. Maybe I am not smart enough to do this.[J110, Pharmacist]

Fear on many levels led to participants' resistance to using SafetyNET-Rx. Despite the difference in responsibilities and roles of the pharmacy staff, fear was expressed by all participant groups. Fear of having to face potentially hurting a patient as a result of making an error. Fear of being singled out in front of their co-workers because they made an error; fear of embarrassment and shame felt from making that error; and fear of their co-workers knowing they made an error and feeling judged as incompetent or unable to do their job. Given that medication errors were traditionally kept hidden and not discussed, this cascade of fear was described by the participants as ultimately 'digging away at your confidence'. Feelings of isolation were created.

> Just feeling stupid and just feeling like you don't know anything. Like how could you have missed that? ... I had to leave work that day crying. I was going to quit my job. I was so upset. I mean nobody could have been madder than I was at

> myself… I mean the patient hadn't taken any. They noticed it right away. But just the fact that I had done that just made me sick.[D004, Pharmacy Technician]

Participants shared that the fear of making a mistake and potentially hurting a patient was a heavy burden and often times one that they carried alone.

> Because everybody is scared to death to say they ever did anything wrong. You know, scared to death, really. And I think liability is probably at the least of a pharmacist's... We are always afraid of hurting somebody. It's hard to talk about.[A101, Pharmacist]

The use of the SafetyNET-Rx program forced error reporting to become more open in community pharmacies and heightened the fear amongst participants knowing that co-workers would know when and how many times they had made a mistake, the participants said. Participants said that when an error occurred, they felt afraid to be written up on one of the reporting forms as they felt there was a perception that it meant they lacked ability to do their job. This resulted in staff wanting to hide mistakes to avoid feeling disgraced, ultimately perpetuating an environment of shame and blame. Because of the fear of being singled out, participants said that they even felt relieved when an error that had occurred was attributed to someone else or another pharmacy.

> And you know what it's like when you read something in the newspaper, like that little girl with the methadone… Like you read it and really go, "God!" And all anybody would say is thank god that wasn't our pharmacy. That is all they say.[B002, Pharmacy Technician]

The fear of being singled-out in front of co-workers for making a medication error and the subsequent embarrassment and shame felt from this led to resistance toward the

reporting and discussion elements of the program and posed a unique challenge for the participants to overcome.

4.2.2 Resolving Resistance

Incorporating the different elements of the SafetyNET-Rx program into their dispensary posed seemingly insurmountable challenges for many participants. Perseverance on the part of some participants to what they saw as a potentially worthwhile approach for dealing with medication errors led to the development of strategies to 'make it friendly' in each of their pharmacies. Some felt the best way to accomplish this was by increasing the convenience of use of the reporting tool and decreasing the time needed away from the daily dispensary functions. While being able to better incorporate the reporting tool into day-to-day functioning of the pharmacy, each step of the dispensing process that had become taken-for-granted by participants given their experience in community pharmacy was now made explicit in order to ensure diligence and safety through the processing of prescriptions. The steps in the dispensing process that had become second nature for the pharmacy staff due to years of experience were now being consciously thought about and articulated.

After some of the learnings from the near misses and medication errors were discussed openly and an environment of sharing began to develop, the program began to be perceived as having value. The development of a more open environment also helped to resolve the resistance by justifying and assigning merit to the time taken to complete the program tasks (i.e., reporting errors and near misses using the reporting tool). The emergence of sharing helped allow the value of the program to come to light and as a

result, the reporting tool component began to be included as one of the daily dispensary functions with which it had previously competed.

4.2.2.1 Making It Friendly

Resistance was resolved in part by determining ways to make the SafetyNET-Rx program friendly so staff would use the program with minimal interference in the daily functioning of the pharmacy. Increasing ease of access to the SafetyNET-Rx program was important. Participants proposed several ways they did this including: placing the reporting forms close to the dispensary area; assigning a designated basket for completion of reporting forms; providing a communication scribbler for writing down learnings from near misses and errors if unable to attend quarterly meetings; and using the online reporting form on a separate computer away from the dispensary as not to impede dispensing functions. Brightly coloured paper reporting forms were placed at each computer terminal to make them more easily noticeable and stand out from the piles of paper in the dispensary and the online reporting form was bookmarked and open on each computer so it was ready to use. Another tactic some participants noted as helpful was to have a folder or basket specific for any errors or near misses that needed to be entered into the online program at a later time. This folder or basket was placed in a specific spot known to all staff and the forms were entered online and then filed in a binder when the opportunity arose.

Having someone responsible for ensuring use of the program was also a suggestion mentioned by participants of how to make the program friendly. A designated leader, or SafetyNET-Rx ‘coach’, who would encourage reporting and maintain staff

enthusiasm was important for successful implementation of the program. The leader also trained new staff members about the program and enforced meetings and discussion of errors and near misses to ensure continual learning throughout the group.

> There needs to be someone to be excited, to tell everyone else the benefits, to kind of make everyone come together as a team, to say its okay to not feel bad, it's okay to not beat yourself up about it. And in some stores, you are going to have some resistance. So you really do need to have at least one person that kind of gets excited about it and makes it so that it is not a bad thing to point out when there's near misses.[D004, Pharmacy Technician]

Some participants stated that making the reporting process mandatory would create a more willing environment to participate and staff members would be less likely to forego reporting. The suggestions for mandatory reporting was thought to make it easier to ensure everyone in the dispensary participated and would result in less 'nagging' of those who were resistant.

Another way to make it friendly was to slow the dispensary process down, to help enable the staff to avoid making mistakes as more time was being spent on each step of the dispensary process. Participants across all groups expressed that spending more time on each step of the dispensing process, a process that had become implicit to many of the participants given their experience in community pharmacy, was now made explicit in order to ensure diligence and safety through the processing of prescriptions.

> We are just more conscious. Well, I mean they were conscious before but it just makes you think about it more because you know you have to report something. So the checks, everybody just seems to be checking more stuff between the two – the original and the hard copy. We may be too quick in doing this. You know, you have to maybe slow down just a little bit.[A001, Pharmacy Technician]

A proposed suggestion from participants for ease of use of the program and to minimize time would be to have the program tied seamlessly to the pharmacy software so that most of the data needed for the reporting form could be seamlessly transferred. Given the variety of pharmacy software programs currently in use, this may be something to look for in the future provided the technology is developed to support its use.

4.2.2.2 Sharing Emerges

As part of the SafetyNET-Rx program, quarterly meetings, or alternative communication strategies, were employed to allow the pharmacy staff to discuss any errors or near-hits that had occurred and ways to prevent them from recurring. Initially, having to discuss errors openly with others caused resistance from the staff due to the current culture of secrecy that existed around medication errors. As some participants pointed out, the open discussion at quarterly staff meetings about the medication errors and near misses were presumed by staff initially to consist of finger pointing, but once staff could see that their co-workers at one time or another made mistakes as well, the climate of shame and isolation began to diminish. The discussion about medication errors and sharing of learnings facilitated easier communication amongst staff and helped to create an environment where errors were no longer hidden, but discussed openly. This communication was considered to be valuable to pharmacy staff as it enabled staff members to no longer fear the isolation of making a mistake and subsequently being judged as incompetent.

> Because I see the other sheets. They are not just all mine. So other people do have mishaps. It's not just me. And the fact that I can actually write it down and talk

about it to [other team members]. And it's like I don't need to feel bad.[D004, Pharmacy Technician]

The creation of a safe supportive environment to discuss errors openly allowed participants to begin sharing how they felt when they had made an error. Through the open discussions about errors with their co-workers, participants across all groups felt a shared sense of responsibility and these discussions enabled the pharmacy staff to see themselves more collectively as a team, sharing the responsibility of patient safety in the dispensary.

> From our point of view, it's almost like... It's not individual accountability, it's like you want your pharmacy itself to put its best foot forward. It's a team. Like I said, in the beginning, there were a few misgivings about finger pointing. But it just never materialized. And everyone got much more comfortable with it, seeing how it was done.[E005, Pharmacy Technician]

Participants stated that being able to talk openly about the mistakes made and the supportive environment from sharing led to a valuing of the program, even by those who were most resistant initially.

> ... the people that were maybe the most resistance in the beginning are the ones that say, “Okay, make sure you write that up in the SafetyNET book.” And so I think everyone has kind of grasped onto that and seen the value in it.[C103, Pharmacist]

4.2.3 Improved Outlook

Working through the resistance to the program by making it friendly and seeing the emergence of sharing led to an improved outlook for participants about medication

error reporting. In the interviews, discussions ensued about how errors came to be seen and addressed differently. Errors were no longer made but were reported as well. The sharing and learning about errors led pharmacy staff to make proactive changes in their pharmacies to prevent errors from recurring. The open discussion about errors helped transition the dispensary environment from one of fear and isolation to encouragement and support. The veil of secrecy was lifted.

4.2.3.1 See Errors in a Different Way

Participants described how they worked though resolving the resistance to the program by finding ways to make the program 'friendly'. Having regular discussions about medication errors allowed pharmacy staff to begin to look at errors in a different way. Proactive thinking was engaged by participants about how they could prevent potential errors in the pharmacy instead of what to do after the error has already occurred.

> ... I think we're all on the same page is probably a better term for it. You know, it focuses... Your line of thinking is how can I reduce this or stop it from happening the next time? As opposed to before, it was like what a pain in the rear end this is.[E005, Pharmacy Technician]

Focusing on each step of the dispensing process and slowing everything down enabled participants across all groups to be consciously aware in that moment, leading to increased diligence and the evasion of potential mistakes.

> Well, I could just see us making less mistakes and being a little more aware of the things that we were messing up before. Like little things. It's like taking things for granted. Okay, so I grabbed the wrong bottle from the shelf. No big deal. Put it back. It isn't necessarily a big deal because the patient didn't get it but in the same breath, why did I grab the wrong bottle in the first place? Maybe I should have

> been checking this more. Maybe I should take... Like now, I'll take the prescription with me to the bay to make sure I'm grabbing the right drug.[B002, Pharmacy Technician]

> Like I was always so fast and not really paying enough attention probably when I was billing them through. So I think this has really caused me to slow down a little bit and take those extra couple of seconds to actually make sure it's right.[C103, Pharmacist]

In their interviews, participants stated that the SafetyNET-Rx program was perceived as valuable due to its positive impact on pharmacy function and the development of accountability, and development of empowerment among pharmacy staff. The positive impact on pharmacy function was attributed mainly to the ability to learn from previous medication errors. Learning about errors not only enabled changes to be made by the staff to prevent errors from recurring but these changes were also perceived to result in increased awareness, and safety of the pharmacy. In particular, the pharmacists noted an increased organization in the dispensary as a result.

> It certainly did overall improve our outlook on trying to prevent and find errors where things could possibly come up, situations. And as far as organization and workflow in our dispensary... I think we have improved an awful lot since then. So that's a good thing that has come out of it.[F106, Pharmacist]

The program had seemed to foster the development of accountability and empowerment throughout the pharmacy staff which was perceived to be as a result of embracing more responsibility. As they learned to proactively prevent medication errors in their pharmacy, participants found they had more control over being able to stop errors from occurring and there was a sense of power with this control.

> I think it's wonderful because it keeps you accountable and it gets that conversation started. Because at staff meetings now, we can say, well, this is what has happened this particular month. Now, what can we do to prevent that from happening in the future. So I think it's wonderful in that respect.[C103, Pharmacist]

The SafetyNET-Rx program helped foster a sense of team accountability as opposed to individual accountability that was expressed to exist prior to using the program. A feeling of relief was expressed by participants that they could tell their patients that a CQI program existed in their pharmacy and that this program helps them to examine the current processes in their dispensary to proactively avoid medication errors from taking place. This provided a means of support, especially when encountering the unfortunate event of a medication error.

> A totally different attitude… I love being able to say to the customer, 'We have a system. We can look at this. We will look at this. And we'll take steps to ensure it doesn't happen again.' I think that has been a big change.[B102, Pharmacist]

Participants also said they felt a sense of pride and responsibility because of being involved with the SafetyNET-Rx program.

4.2.3.2 The Veil Has Lifted

The resistance and fear surrounding medication error reporting that existed prior to, and initially upon using, the SafetyNET-Rx program faded as discussion about medication errors became more acceptable and part of everyday life in the pharmacy. A supportive environment was created where staff was encouraged to report errors in the hopes of learning additional ways to prevent these events from occurring again.

> … You just feel devastated that you've made… that anything has gone wrong. But I think the veil has lifted. Like there's no problems talking about it. They're not trying to hide anything anymore.[J110, Pharmacist]

Being able to talk about medication errors openly, created the opportunity for positivity to emerge from negativity for participants, and an opportunity for a topic traditionally so secretive to be unveiled and examined.

> The SafetyNET has been good. And everyone is aware of it and aware of the benefit of it because we talk about it more now. So I mean like I said before, it's like let's not talk about it, kind of push it aside and hide it, and it didn't happen. But it's a totally different situation now. Look what I did! I don't know what I was thinking.[D004, Pharmacy Technician]

Making a medication error will always remain an unwanted event for pharmacy staff, however recognizing the opportunity to learn and discuss ways to prevent the same event from occurring has allowed something positive to come from what was once thought to be only a negative event.

4.2.4 From Secret to Shared

The fear of making a medication error is a familiar feeling among pharmacists and pharmacy technicians in community pharmacy. There is the fear of potentially harming a patient, based on an error you have made, which alone can be paralyzing. But there is also the fear of being outed to your co-workers for having made the error, feeling judged as incompetent, and the fear of embarrassment and shame felt from making this error. The existence of this fear had traditionally allowed secrecy surrounding medication errors to be the norm. Given the secrecy and condemnation that existed around

medication errors, individuals felt isolated when they made an error as they had no way of knowing that other co-workers may have made similar, or different, errors as well. Implementing the SafetyNET-Rx program meant reporting all errors and openly discussing these errors with pharmacy staff resulting in resistance due to fear. The reporting of errors would inevitably single out pharmacy staff who had made mistakes and the fear of that made many unwilling to use the program. Fear and additional workload were the main contributors of the resistance to using the SafetyNET-Rx program. Attempting to complete the required elements of the SafetyNET-Rx program while maintaining daily functioning was considered a challenge and if time spent using the reporting tool or discussing medication errors and near misses interfered or impeded the processes of daily functioning, resistance to the program surfaced. Overcoming the resistance of fear and additional workload the program presented would prove to be a challenging endeavor until the program provided a perceived benefit to the pharmacy staff such as allowing open discussion of errors in a safe environment instead of secrecy and blame.

In order to persevere, participants met the challenge with creative ways to improve the elements of the program, or 'make it friendly' in each of their community pharmacies. By increasing the convenience of use of the reporting tool and trying to incorporate the tool into daily dispensary functions it was hoped it would be easier for staff to participate. Trying to resolve the fear would present the biggest challenge in resolving the resistance. However, when the program began to create an environment of sharing and open discussion about errors, despite the challenge of meeting quarterly, the program began to be perceived as more valuable. The ability to openly discuss mistakes

with one another in a safe environment allowed individuals to see one another as a team, sharing the burden of mistakes made. The feelings of isolation and embarrassment were lessened as it was made clear others made mistakes as well. Being able to talk openly about the mistakes made and the supportive environment that evolved from sharing led to a greater valuing of the program. Simultaneously with sharing, the intense fear felt by participants diminished and the value of the SafetyNET-RX program was amplified.

Prior to SafetyNET-Rx, the reporting of an error was largely associated with corporate liability, a formal secretive process only completed when there had been potential harm brought to a patient as a result of a medication error. These reportings were not shared or discussed among staff. SafetyNET-Rx had created a reason to discuss errors openly and, in addition, provided a means to learn from these errors. Once the participants began to openly discuss errors, and an environment of sharing began to emerge, the opportunity to learn from these events became the focus. Pharmacy staff could make proactive changes. Shared learning about medication errors allowed each individual to feel supported as a team player and led to empowerment for positive change in their work environment. The veil of secrecy had lifted and the revelation of sharing had begun.

CHAPTER 5: DISCUSSION

The purpose of this research was to explore the insights and lessons learned of the participants in the SafetyNET-Rx project and to gain a better understanding of the context of the facilitators and barriers to medication error reporting in community pharmacy through the use of a CQI medication error reporting program. This study presents a unique addition to this field of literature. Pharmacists and pharmacy technicians from community pharmacies in Nova Scotia were interviewed for their views, providing a unique Nova Scotian perspective with potential application to the rest of Canada. A qualitative approach was used, valuable when researching a sensitive topic such as medication error reporting, and when the goal is to identify the perspectives of those experiencing a certain situation or phenomenon (Dey, 1993). In-depth interviews encouraged participants to express themselves more freely than if focus groups or surveys had been used to elicit in-depth information and thick description of data. The complexities and context surrounding the reporting of medication errors by pharmacists and pharmacy technicians were elicited in unstructured interviews. Key themes were inductively identified in the interview data (Bates et al., 1997; Boyatzis, 1998) and will provide valuable contributions to the future improvement of the SafetyNET-Rx program and education of community pharmacy staff and regulators on the facilitators and barriers to medication error reporting.

The research objectives were: 1) To identify pharmacist and pharmacy technician perceptions of the challenges to reporting medication errors in community pharmacies; 2) To identify the perceived facilitators that encourage pharmacists and pharmacy

technicians to report medication errors in community pharmacies; and 3) To identify insights and lessons learned of the pharmacists and pharmacy technicians involved in a standardized continuous quality improvement program designed to enhance medication error reporting and learning.

5.1 Perceived Challenges to Medication Error Reporting Using SafetyNET-Rx

Incorporating the elements of the SafetyNET-Rx program into everyday dispensary functions added considerable burden to the current pharmacy workload. 'Shame and blame' has been widely reported in health care, and especially in community pharmacy (Ashcroft, Morecroft, et al., 2005; Ashcroft et al., 2006; Phipps et al., 2012) and was the culture within which SafetyNET-Rx was introduced. The required additional tasks of reporting and then having to openly discuss those reports was accompanied by participants' fears of being shamed and blamed by their colleagues. Together, workload and fears resulted in resistance to the implementation of the SafetyNET-Rx program.

5.1.1 Increased Demands

The demands on the pharmacy staff range from business to legal to patient care related needs. Maintaining daily functioning of the pharmacy dispensary (processing and filling prescriptions, counseling patients, calling other health care providers and third party plans to resolve problems with prescriptions, and receiving and putting away the order) requires constant focus and organization. The inevitable distractions in this environment (telephone ringing, staff and patient questions, patients waiting at the counter) make daily functioning challenging and likely opportunities for errors to occur.

The additional workload of reporting errors using SafetyNET-Rx required staff to complete more tasks in this already demanding environment. Trying to complete reporting and maintain daily dispensing in an existing minefield of distractions demanded extra time of staff and contributed to resistance in using the program. Similar challenges were still found to exist in Phase II of SafetyNET-Rx, in particular, finding time to report, reporting apprehensiveness, having all pharmacy staff involved in reporting, meeting to discuss reported errors, and accepting online reporting technology (Boyle, MacKinnon, et al, 2012). Ironically, the increased workload led to resistance in using the program, a program designed to help prevent errors - errors which are more likely to occur in an environment of increased workload. High workload, interruptions and distractions have been shown to be contributors to the occurrence of dispensing errors (Ashcroft, Quinlan, et al., 2005; James et al., 2009; Malone et al., 2007). High workload, in particular, has been perceived by pharmacists to be one of the most important causes of dispensing errors (Teinila et al., 2008). Although there is no clear definition of high or heavy workload, and the perception may vary among pharmacy staff, the responsibilities of using the program were perceived by pharmacy staff to contribute to a high workload and ultimately impeded use of the program. It became apparent that to successfully implement a CQI program for medication error reporting into the current dispensing workflow, an easy-to-use program that required minimal time to complete the necessary tasks was essential.

Maintaining pharmacy staff momentum and enthusiasm about the use of the program was a challenge. Training the staff to bring everyone to an understanding about the SafetyNET-Rx program was carried out in various ways due to budgetary and time

constraints. This was considered an important part in the success of the implementation of the program, especially the designation of a staff member as the SafetyNET-Rx leader or 'coach', referred to as 'champion' in the CQI literature. Having someone believe in the ability of the program and be the 'coach' to help support staff and maintain motivation was important. The pharmacy staff perceptions of the significance between staff training and understanding and a positive attitude toward medication error reporting mirrors previous literature. A study in the UK researching the feasibility of a self-reporting system for dispensing errors and near misses in four community pharmacies found that attitudes of staff members became more positive with training and understanding of the study, in conjunction with experience (Chua et al., 2003). Even in other areas of healthcare, for example small-scale physician practices, a positive commitment from all individuals involved were noted to be imperative for successfully implementing CQI programs (Geboers et al., 2001). Having a pharmacy team 'coach', in addition to staff training, can facilitate the development of relationships and the creation of a group norm supportive of safe behavior. This has been documented as an important factor in promoting medication safety in the community pharmacy setting (Phipps et al., 2009).

5.1.2 Aversion

Being the subject of blame, or being seen to blame others, has been proposed as a probable barrier to discussing and learning from adverse events in pharmacy practice (Ashcroft et al., 2006; Phipps et al., 2009). To pharmacy staff, using SafetyNET-Rx meant having to report near misses and errors that would bring more light to these errors and the persons involved in making them. In addition to the fear of being singled out for

making an error, the thought of co-workers knowing about the error evoked feelings of shame and embarrassment and resulted in resistance to using the program. Phipps et al. (2012) uncovered similar behaviour in that sensitivity to being blamed for errors among staff was a barrier to organizational learning. Interestingly, as the pressure within the work organization increased, the tendency to blame others increased as well (Phipps et al., 2012). This is similar to the contributors of resistance found in this study whereby the additional workload of using the SafetyNET-Rx program and fear of being blamed as a result of others knowing who committed what error, impeded use of the program. The fear that contributed to resistance in using the program illustrated the safety culture at play within those organizations. Interestingly, the same fears of medication error reporting in this study involving shame and blame from other colleagues and punishment from management have been uncovered in the hospital environment in this province as well (Hartnell et al., 2012). Work design, layout of the workspace, and equipment, have also been reported to influence pharmacists' work (Phipps et al., 2009), but these findings did not emerge from this study.

5.2 Perceived Facilitators to Medication Error Reporting using SafetyNET-Rx

Increasing ease of use of the elements of SafetyNET-Rx was attempted to reduce the additional workload and make the process easier for staff. Increasing ease of use has been noted in the literature to be an important component of an effective error reporting process (Hartnell et al., 2012; Salsman, 2007). However, knowing the tangible ways to increase a program's ease of use is crucial in achieving success. In this study, 'Making It Friendly' involved creative strategies pharmacists and pharmacy technicians employed to

achieve increased ease of use of the program. 'Making It Friendly' was an innovative finding and the term was developed by the participants themselves. The qualitative nature of this study allowed the context for 'Making It Friendly' to be found. Without an understanding of the context of 'Making It Friendly', strategies to improve the ease of use of the program components will not be successful. Once pharmacy staff found the components of the program (i.e., reporting tool, quarterly meetings, staff training) 'more friendly' and began using the program, the incorporation of error reporting resulted in a heightened awareness among staff to slow the dispensing process down. Dispensing tasks that had once been implicit, and that might contribute to errors, were now becoming explicit. As tasks became explicit, potential errors were more easily caught as they happened. As the emergence of sharing began, the perceived value of the program increased and the participants began to feel safe discussing medication errors. Through the creation of an open and safe environment to discuss medication errors pharmacy staff began learning about errors and near misses in their pharmacy and started to see their working environment, and in particular medication errors, in a different way.

5.2.1 Ease of Use

Making the program 'friendly' included incorporating various tangible ways to mitigate the additional workload and increase the likelihood pharmacy staff would use the program. It was hoped increasing ease of use would create a positive attitude about reporting. According to Salsman (2007), it is essential that reporting systems be user friendly and easily accessible to users. Adapting the cumbersome tasks of the program was important to obtain pharmacy staff buy-in and to help outweigh the influence of the

shame and blame culture within which the program was introduced. The relationship demonstrated between ease of use of reporting and safety culture is relevant because the safety culture of an organization can act as either a barrier or enabler to reporting, for example a cumbersome error reporting process may negatively affect an individual's behaviour about reporting (Fleming & Hartnell, 2007). It is important however from the regulatory authority or pharmacy administrator perspective that the extent to which pharmacy staff increase ease of use of the program through 'making it friendly' does not sacrifice the standardization of CQI, which in the long term could undermine the intent of implementing a quality improvement process.

By slowing the dispensary process down pharmacy staff were spending more time on each step of the dispensing process, hence steps that had become implicit over the years were now made explicit in order to ensure diligence and safety through the processing of prescriptions. This concept has been highlighted in other research. Public health care workers have been shown to use both tacit knowledge and explicit knowledge in their regular everyday work environment (Kothari, Bickford, Edwards, Dobbins, & Meyer, 2011). Explicit knowledge is that with which one can teach and explain. Although there is no agreed upon definition of tacit knowledge in the literature, it can be described as "knowledge-in-practice developed from direct experience and action; highly pragmatic and situation specific; subconsciously understood and applied; difficult to articulate; usually shared through interactive conversation and shared experience" (McAdam, Mason & McCrory, 2007 cited in Kothari et al., 2011, p.3). The transformation of tacit knowledge into explicit knowledge by pharmacy staff while using the SafetyNET-Rx program highlighted the importance of reflecting on each step involved in the

prescription dispensing process to prevent medication errors. The use of tacit knowledge in the pharmacy setting has also been documented using terms such as *reflective practice*. Including this concept at the inception of pharmacists' learning through more problem-based curricula has been suggested to help teach reflective practice and better prepare pharmacists for their role in patient-centered care (Droege, 2003; Waterfield, 2010). By focusing on each step of dispensing and slowing it down, pharmacy staff were able to discuss ways in which each step could be improved to prevent the recurrence of errors.

5.2.2 A Different View

To successfully increase medication error reporting, the development of a culture without fear of retribution is necessary (Ashcroft et al., 2006). Once the participants began to see the value in openly discussing medication errors and the safe and supportive environment that began to emerge, there was an increased willingness to use the SafetyNET-Rx program. Through open discussion with one another of errors made, pharmacy staff began seeing errors in a different way. Staff began creating proactive changes to prevent the recurrence of errors including: separating look-alike drugs; posting notes beside medications on the shelf to alert staff about look-alike or sound-alike medications; and removing sources of noise or distractions from the dispensary environment. Similarly in other studies learning to become more aware of contributors to dispensing errors such as look-alike and sound-alike drugs and interruptions and distractions in the dispensary, led to staff making proactive changes to their dispensary organization and workflow (Ashcroft, Quinlan, et al., 2005; James et al., 2009; Malone et al., 2007). Once actions were taken and staff could see the resultant positive changes, the

momentum and value of using the program increased. These findings mirror what has been stated in the literature, “reporters will also develop a better understanding of the value of a reporting system if they perceive visible actions and responses as a result of the reporting and analysis of error” (Salsman, 2007, p.443).

5.2.3 Revelation of Sharing

Revealing a safe and open environment to discuss medication errors from predominantly one of secrecy became a powerful facilitator to using the SafetyNET-Rx program. The opportunity for individuals to talk openly with other staff about medications errors in a non-punitive environment encouraged use of the program and cultivated a safe and open environment in these community pharmacies. In a generative organizational culture, pharmacies learn and share information about incidents with staff and incidents are seen as learning opportunities versus the previous dominant pathological culture where incidents are hidden and no attempts are made to learn from incidents (Ashcroft, Morecroft, et al., 2005). The move from our current pathological culture to one that is generative has been stated to be the “key to success” in developing a reporting culture, but also considered the biggest challenge to moving toward a safer healthcare system (Ashcroft, Morecroft, et al., 2005; Ashcroft et al., 2006). The findings from this study illustrated how the SafetyNET-Rx program in its infancy helped participants take the first steps in moving the safety culture in community pharmacies. The full scope of the CQI philosophy involves planning and implementing changes to core processes for overall systems improvement. From an administrator perspective, the results from this study may appear as though the pharmacies have not yet transitioned

from the “low hanging fruit” and structured elements of CQI to the more challenging unstructured elements of CQI involving planning, implementing, and monitoring of changes to core dispensing processes. The timeframe of this study may not have been long enough to achieve these more challenging unstructured changes, thus understanding the full breadth of outcomes when using a CQI process over time in this environment requires more research. Although the changes that were made as a result of SafetyNET-Rx were short-term, the beginning of a more generative culture in these community pharmacies sparks hope that expanded use of the program will lead to more pharmacies embracing this change toward a more open culture around medication error reporting. To be able to work in a demanding healthcare environment where working together and preventing errors through staff discussion and collaboration are a priority, is certainly one step in the right direction.

5.3 Suggestions for Improvement of Medication Error Reporting Using SafetyNET-Rx

Participants identified suggestions for improvement through the process of ‘Making It Friendly’. Although the suggestions are reflective of those in the literature, the context provided from the participants regarding these suggestions is essential and fundamentally important to obtaining success. The main suggestion for improvement of the program was making the reporting form easier and faster to use. Suggestions to decrease time needed to report included incorporating the software into existing pharmacy software and adding functional ability within the report to have sections pre-populated, or eliminated, based on what was entered.

Improved communication and education through the sharing of learnings were also suggested by the participants. The provision of feedback to each pharmacy based on reports that had been submitted was requested so pharmacy staff could better understand the reports provided by the reporting program. Participants suggested that the provision of information including individualized reports and statistical analysis for each pharmacy detailing areas for improvement would be beneficial for discussion at quarterly meetings. The importance of feedback after reporting has been found to enhance the perception of the effectiveness and value of reporting, and is of considerable importance not just in pharmacy, but in healthcare in general (Bradley, Power, Hesselgreaves, McMillan, & Bowie, 2009; Hartnell et al., 2012; Wilkens & London, 2006). In addition, the provision of learnings shared across all pharmacies was suggested so that common themes or trends in error reporting could be known and shared across the community pharmacy community. Receiving additional education and training about the medication error reporting process was also considered important for success of the SafetyNET-Rx program, a finding that was identified as important when reporting in the hospital environment as well (Hartnell et al., 2012).

5.4 Rigour and Trustworthiness

Qualitative research involves examining processes and meanings that cannot always be determined using traditional quantitative methods. Providing the reader with enough information to audit the actions and decisions of the researcher helps to establish the rigour, or trustworthiness, of a study (Guba & Lincoln, 1989). The most common

criteria used to evaluate the rigour, or trustworthiness, of qualitative research are credibility, dependability, transferability and confirmability.

5.4.1 Credibility, Dependability, Transferability and Confirmability

The credibility of a study refers to the legitimacy of the collected data and how well the data corresponds to all participants (Guba & Lincoln, 1989). Dependability refers to the reliability of the research and takes into account if sufficient information was provided to reproduce the same result (Guba & Lincoln, 1989). The transferability of the research refers to the extent to which the findings can be generalized to other settings or groups outside the context of the study situation. This transfer is done by another researcher through the application of these findings to another situation or setting. To determine how my interpretations and conclusions were reached and derived from the data, confirmability was established by achieving credibility, dependability and transferability (Guba & Lincoln).

Purposive sampling, used in this study, ensured participants with the types of experiences related to the research objectives would be able to provide 'the widest possible range of information for inclusion in thick description' (credibility and dependability) (Guba & Lincoln). Thick description is also necessary for findings to be transferable (transferability). The characteristics of the participants (staff pharmacists, pharmacy managers, and pharmacy technicians with various years of experience) also helped enhance the transferability to ensure the results would be meaningful to other community pharmacy staff in the province.

Throughout the research process, I kept memos, a reflexive journal and a research diary of both immediate and later perceptions and thoughts about research participants and interviews (credibility, dependability, confirmability). The use of memos and a reflexive journal also offered a means for reflection about the research process and my role, as a researcher and pharmacist, and potential influence on data collection and analysis, maintaining reflexivity as part of the strong objectivity approach. These notes were an essential part of maintaining an audit trail so that all events that occurred and decisions made were transparent. The research diary served as a record of writing, coding, and theorizing and another component of the audit trail contributing to the authenticity and reliability of the research. The following is an excerpt from my research diary:

> Nov. 20, 2010 - There appears to be a change is the way participants are seeing medication error reporting. Is it the reporting that looks different to them, or the error itself? Or both? Slowing things down has enabled them to see each step of dispensing more clearly. What does this mean? Making proactive changes based on what they've learned about their errors is helping them see a positive side to when errors occur. Revisit data and reflect on this - codes: workflow changes, prevention, diligence, being more cautious, empowerment, impact on pharmacy.

As part of the memos, I kept a thematic log when summarizing an interview that identified any themes that mirrored the participants' responses and ideas (credibility, dependability). Transcript auditing was also done to ensure accuracy and to maintain familiarity with the data to have confidence in its trustworthiness (credibility, dependability) (Boyatzis, 1998). The audit trail consisting of memos, transcripts, a reflexive journal and research diary served as a road map to determine how themes and

conclusions were reached and how the findings were derived from the data (confirmability).

5.5 Limitations and Implications for Research

Like any research study, this study has limitations that should be considered when interpreting the findings as well as implications for future research.

5.5.1 Limitations

In accordance with REB approval, the inability to report on subcases (pharmacist/pharmacy technician; urban/rural, chain/independent, high/low volume pharmacies) within this study, due to potential identification of participants, was a limitation. The pharmacists and pharmacy technicians involved in the SafetyNET-Rx pilot study volunteered and were eager to implement a medication error reporting program in their community pharmacies. Because these volunteers were willing to try this new endeavor of medication error reporting, they may not be representative of pharmacy staff in a typical community pharmacy and may have been more likely to persevere and continue to use the program given their initial willingness to be part of the study. A time lag of approximately one year lapsed between when the data was collected and when the data analysis was completed. While the findings are considered representative of the data collected it is possible that the circumstances and environments at the community pharmacies changed during this time. The findings presented may also not reflect current medication error reporting practices at each of those community pharmacies as this study was based on an earlier version of SafetyNET-Rx .

5.5.2 Implications

Despite such limitations, this research has a number of important implications to researchers, pharmacy managers and staff, pharmacy owners/corporate head offices and pharmacy regulatory authorities.

There has been very little research exploring medication error reporting and patient safety through the use of a CQI program in a community pharmacy setting. At the time this study was designed, no publications of similar research were found. The qualitative approach used in this research study encouraged participants to express their opinions and thoughts openly which added a richness not likely achieved using a quantitative approach. Interviewing pharmacists and pharmacy technicians allowed the different perspectives of medication error reporting, including similarities and differences, to be elicited, but it also allowed the context for success to be unraveled, something only found from a qualitative study of this nature. The implementation of strategies to improve ease of use of the SafetyNET-Rx program without knowing the context for success is but a waste of time. This study brought this important finding to the field of research involving medication error reporting and can help others implement strategies in a context of 'making it friendly' and make sharing less daunting for pharmacy staff.

With increasing pressure for pharmacies to adopt a CQI process, this research provides pharmacy managers with several issues to be aware of, as well as ways to address those issues, upon implementing such a program. Since currently a CQI process is mandatory in community pharmacies in Nova Scotia, this research can help pharmacy

managers in the province address potential issues they may be experiencing using the CQI program in their pharmacy. This research can also help pharmacy staff see the value in talking about medication errors and that the creation of an open, safe environment to have these discussions can result in significant changes in their work environment to improve the safety of patients and pharmacy practice. Pharmacy owners and corporate head offices can also use this research to identify the key challenges and how those challenges can be addressed upon implementation of a CQI process in their pharmacies.

Having the mandate of protecting the public, the pharmacy regulatory authorities can use this research to highlight the value of using a CQI program in community pharmacies. Although pharmacy provincial legislation may vary across the country, the interest in upholding patient safety is one of primary importance to all regulatory authorities and this research provides a case for using a CQI program in community pharmacies and offers guidelines for initial implementation should other groups choose to implement this process.

CHAPTER 6: CONCLUSIONS

6.1 Summary

The growing area of concern surrounding patient safety in Canada has led to a more recent examination of the safety of the medication-use system in community pharmacies (Boyle, Ho, et al., 2012; Boyle, MacKinnon, et al., 2012; Boyle et al., 2011; Scobie et al., 2010). Medication errors can result in devastating, if not life-threatening, effects to patients and are of significant concern to pharmacy staff, pharmacy business owners, regulatory authorities, policy makers, healthcare administrators, and the general public. Through medication error reporting the causes behind these errors can be identified and measures taken to prevent the recurrence of these errors. However, the reality is, despite legislation, medication errors are significantly under-reported.

This study explored the context surrounding the facilitators and challenges to medication error reporting using a CQI process in thirteen community pharmacies from the perspectives of pharmacists and pharmacy technicians. A qualitative approach was used to elicit perceptions and beliefs about medication error reporting in these pharmacies. Through in-depth interviews with the participants, positive facilitators and challenges to reporting were identified as well as ways to improve the CQI program, SafetyNET-Rx for future use. Insight into the safety culture within these organizations and its relationship to medication error reporting was also uncovered. The iterative process used throughout data collection and analysis led to the discovery of several themes: resistance, resolving resistance, and improved outlook. Overall the suggestions for improvement of the program included: increasing ease of use for better incorporation

within daily functioning of the pharmacy; improved feedback and communication on learnings from reported errors and near misses; and receiving additional education and training about the medication error reporting process, all within the context of 'making it friendly'. Without the context provided from the participants' description of the ways in which pharmacy staff implemented strategies for success, increased ease-of-use, improved feedback, communication, and education will not work. This highlights the significance of knowing and understanding the context for success and the importance of this innovative finding within this study.

The theme of *resistance* related to the barriers to using the CQI program in community pharmacy and the participants' resistance to reporting medication errors. This theme consisted of two main categories: *additional workload* and *fear*. In addition to every day dispensary functioning, the additional workload of using the components of the program - filling out the reporting form for errors and near misses, scheduling quarterly meetings to discuss reported events and recommendations for change, and completing an annual self-assessment survey to monitor system improvements on an ongoing basis - led to a perceived lack of time and ultimately an unwillingness for participants to use the program. In addition, the fear of having to openly discuss the details surrounding who made which errors with other colleagues created more resistance to using the SafetyNET-Rx program.

The themes of *resolving the resistance* and *improved outlook* consisted of facilitators to using the program for medication error reporting. Resolving the resistance described ways in which the participants tried to incorporate the elements of the program into daily functioning to increase its utilization. Resolving the resistance encompassed the

themes: *making it friendly* and *sharing emerges*. Making it friendly focused on ways to increase ease of use of the program within regular daily dispensary functions. The importance of a program coach, or leader, was also noted by the participants for successful implementation. Incorporating medication error reporting into the community pharmacy environment led to participants slowing the dispensing process down and making those steps that had once been implicit, due to years of experience of working in the pharmacy, now explicit. Participants had become consciously aware of actions taken during dispensing, actions that had once been routine. The opportunity for discussion of errors at quarterly meetings moved participants' perception of finger pointing to one of acceptance and support. Through the emergence of sharing, a safe environment was created from one of secrecy and the perceived value of using the program by participants was enhanced.

The theme of *improved outlook* illustrated the transformation of how the participants viewed medication errors and reporting of these errors. This theme consisted of: *see errors in a different way* and *the veil has lifted*. Participants were more consciously aware in each moment of dispensing process which led to increased diligence and the evasion of potential mistakes. The creation of open discussion about medication errors allowed participants to start thinking proactively about possible recommendations for change within their dispensary. These changes were perceived to result in increased organization, awareness, and safety of the pharmacy which helped foster a sense of accountability and empowerment in participants. The veil has lifted symbolized the emergence of positivity from negativity - the creation of an open safe arena to discuss and learn about medication errors from one of secrecy and blame.

From secret to shared depicts the story told of the participants in the SafetyNET-Rx pilot project. The existence of fear of making a medication error had traditionally allowed secrecy surrounding medication errors to be the norm in community pharmacy and across the healthcare system. This contributed to feelings of 'shame and blame' for all pharmacy staff. Implementing a CQI medication error reporting program, SafetyNET-Rx, forced pharmacy staff to report errors and near misses and openly discussing these errors with one another. The additional workload of the program and the participants' feelings of fear created resistance to using the program. Participants met the challenge with creative ways to try and work through the resistance. By making it friendly and increasing ease of use of the program, it was hoped participants would be more willing to use the program. When the program began to create an environment of enabling sharing and open discussion about errors, the perception of the value of the program was enhanced.

Moving from reporting errors to protect corporate liability to a venue for learning about errors created an environment of sharing where pharmacy staff began to think proactively, not reactively about errors. Shared learning about medication also led to a sense of empowerment and pride for pharmacy staff. The veil of secrecy had lifted.

6.2 Future Research

The results of this study can be used to improve SafetyNET-Rx and maximize the programs' ability to be easy to use, safe and effective throughout the healthcare system. This research contributes a valuable addition to the existing literature in the area of medication error reporting. Although there are limitations to this study, as mentioned

previously, those limitations present opportunities for future research. This study focused on the pilot phase of SafetyNET-Rx and the pharmacists and pharmacy technicians from the 13 community pharmacies that participated were explored a single case, thus differences between these groups were not investigated. Additional research involving the second phase of SafetyNET-Rx would expand on these findings and provide additional information on the current perceptions of using a CQI program in community pharmacies.

This study focused on a CQI program that was a top down approach, initiated by the regulatory authority in the province, and thus the challenges identified should be generalizable to that approach only. CQI programs developed as a grassroots approach, initiated by the pharmacy staff, can present different challenges, for example, not having the formal support of regulators for development and marketing of tools. Future research examining the implementation of a grassroots approach to a CQI program in community pharmacies without these formal support mechanisms may provide insight into these various challenges. Since this research focused on the initial adoption of SafetyNET-Rx and reflected the short-term safety changes, future research is needed to determine the long-term safety changes that occur, or do not occur, as a result of using this CQI program for medication error reporting.

A mixed-methods design using secondary data from pharmacies and/or pharmacy inspection reports and participant interviews with pharmacy staff, owners, and inspectors could also add to our understanding of the challenges involved in implementing changes to safety, and the impact of those changes on the individual's job satisfaction and relationships among pharmacy staff. A qualitative approach exploring physician and

patient perceptions of medication error reporting and patient safety in the community pharmacy environment would also add a significant piece of research to this body of literature.

Currently, the SafetyNET-Rx program is being used in community pharmacies throughout Nova Scotia and opportunities for implementation across Canada and in the United States are being investigated.

REFERENCES

Ackroyd-Stolarz, S., Hartnell, N., & MacKinnon, N. J. (2005). Approaches to improving the safety of the medication use system. *Healthcare Quarterly, 8*(Special Issue), 59-64.

Ackroyd-Stolarz, S., Hartnell, N., & MacKinnon, N. J. (2006). Demystifying medication safety: Making sense of the terminology. *Research in Social and Administrative Pharmacy, 2*(2), 280-289. doi:10.1016/j.sapharm.2006.01.001

Ashcroft, D. M., Morecroft, C., Parker, D., & Noyce, P. R. (2005). Safety culture assessment in community pharmacy: Development, face validity, and feasibility of the Manchester Patient Safety Assessment Framework. *Quality and Safety in Health Care, 14*(6), 417.

Ashcroft, D. M., Morecroft, C., Parker, D., & Noyce, P. R. (2006). Likelihood of reporting adverse events in community pharmacy: An experimental study. *Quality and Safety in Health Care, 15*(1), 48.

Ashcroft, D. M., & Parker, D. (2009). Development of the pharmacy safety climate questionnaire: A principal components analysis. *Quality Safety in Health Care, 18*(1), 28-31.

Ashcroft, D. M., Quinlan, P., & Blenkinsopp, A. (2005). Prospective study of the incidence, nature and causes of dispensing errors in community pharmacies. *Pharmacoepidemiology and Drug Safety, 14*(5), 327-332. doi:10.1002/pds.1012

Baker, G. R., Jeffs, L., Law, M., & Norton, P. G. (2007). Improving the safety and quality of health care in Canada. In N. J. MacKinnon (Ed.), *Safe and effective: The eight essential elements of an optimal medication-use system* (pp. 1-18). Ottawa, ON, Canada: Canadian Pharmacists Association.

Baker, G. R., Norton, P. G., Flintoft, V., Blais, R., Brown, A., Cox, J., . . . Tamblyn, R. (2004). The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. *CMAJ: Canadian Medical Association Journal, 170*(11), 1678-1686. doi:10.1053/cmaj.1040498

Bassett, B. R. (2010). Iterative. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 503-505). Thousand Oaks, California: Sage Publications.

Bates, D. W., Spell, N., Cullen, D. J., Burdick, E., Laird, N., Petersen, L. A., . . . Leape, L. L. (1997). The costs of adverse drug events in hospitalized patients. *JAMA: The Journal of the American Medical Association, 277*(4), 307-311. doi:10.1001/jama.1997.03540280045032

Boyatzis, R. E. (1998). *Transforming qualitative information: Thematic analysis and code development*. Thousand Oaks, California: Sage Publications.

Boyle, T. A., Ho, C., MacKinnon, N. J., Mahaffey, T., & Taylor, J. M. (2012). Safety implications of standardized continuous quality improvement programs in community pharmacy. *Journal of Pharmacy Practice.* Advance online publication. doi:10.1177/0897190012452312

Boyle, T. A., MacKinnon, N. J., Mahaffey, T., Duggan, K., & Dow, N. (2012). Challenges of standardized continuous quality improvement programs in community pharmacies: The case of SafetyNET-Rx. *Research in Social and Administrative Pharmacy.* Advance online publication.doi:10.1016/j.sapharm.2012.01.005

Boyle, T. A., Mahaffey, T., MacKinnon, N. J., Deal, H., Hallstrom, L., & Morgan, H. (2011). Determinants of medication incident reporting, recovery, and learning in community pharmacies: A conceptual model. *Research in Social and Administrative Pharmacy, 7*(1), 93-107. doi:10.1016/j.sapharm.2009.12.001

Boyle, T. A., Scobie, A., MacKinnon, N., & Mahaffey, T. (2012). Implications of process characteristics on quality-related event reporting in community pharmacy. *Research in Social and Administrative Pharmacy, 8*(1), 76-86. doi:10.1016/j.sapharm.2010.11.004

Bradley, N. A., Power, A., Hesselgreaves, H., McMillan, F., & Bowie, P. (2009). Safer pharmacy practice: A preliminary study of significant event analysis and peer feedback. *International Journal of Pharmacy Practice, 17*(5), 283-291.

Budnitz, D., Lovegrove, M., Shehab, N., & Richards, C. (2011). Emergency hospitalizations for adverse drug events in older Americans. *The New England Journal of Medicine, 365*(21), 2002-2012. doi:10.1056/NEJMsa1103053

Burns, J. M. C. (2010). Cross-case synthesis and analysis. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 264). Thousand Oaks, California: Sage Publications.

Chua, S., Wong, I. C. K., Edmonson, H., Allen, C., Chow, J., Peacham, J., . . . Grantham, J. (2003). A feasibility study for recording of dispensing errors and 'near misses' in four UK primary care pharmacies *Drug Safety, 26*(11), 803-813.

Clarke, S. (1999). Perceptions of organizational safety: Implications for the development of safety culture. *Journal of Organizational Behavior, 20*(2), 185-198.

CMA. (2007). *7th annual national report card on health care.* Retrieved January 10, 2009, from www.cma.ca

Cox, S., & Flin, R. (1998). Safety culture: Philosopher's stone or man of straw? *Work and Stress, 12*(3), March 12, 2011-189-201.

Davies, J. M., Hebert, P. C., & Hoffman, C. (2003). *The Canadian Patient Safety Dictionary*. Ottawa, ON, Canada: College of Physicians and Surgeons of Canada.

Decker, M. D. (1992). The application of continuous quality improvement to healthcare. *Infection Control and Hospital Epidemiology, 13*(4), 226-229. doi:10.1086/646514

Desselle, S. (2005). Certified pharmacy technicians' views on their medication preparation errors and educational needs. *American Journal of Health-System Pharmacy, 62*(19), 1992-1997. doi:10.2146/ajhp040549

Dey, I. (1993). *Qualitative data analysis: A user-friendly guide for social scientists*. London : New York, NY: Routledge.

Droege, M. (2003). The role of reflective practice in pharmacy. *Education for Health: Change in Learning & Practice (Taylor & Francis Ltd), 16*(1), 68.

Elder, N. C., Jacobson, C. J., Zink, T., & Hasse, L. (2005). How experiencing preventable medical problems changed patients' interactions with primary health care. *Annals of Family Medicine, 3*(6), 537-544. doi:10.1370/afm.346

Fleming, M., & Hartnell, N. (2007). Measurement and improvement of safety culture. In N. J. MacKinnon (Ed.), *Safe and effective: The eight essential elements of an optimal medication-use system* (pp. 41-58). Ottawa, ON, Canada: Canadian Pharmacists Association.

Fleming, M., & Wentzell, N. (2008). Patient safety culture tool: Development and guidelines for use. *Healthcare Quarterly, 11*(Special Issue), 10-15.

Flynn, E. A., Barker, K. N., & Carnahan, B. J. (2003). National observational study of prescription dispensing accuracy and safety in 50 pharmacies. *Journal of the American Pharmaceutical Association, 43*(2), 191-200.

Geboers, H., Grol, R., van den Bosch, W., van den Hoogen, H., Mokkink, H., van Montfort, P., & Oltheten, H. (1999). A model for continuous quality improvement in small scale practices. *Quality in Health Care, 8*(1), 43-48.

Geboers, H., Mokkink, H., van Montfort, P., van den Hoogen, H., van den Bosch, W., & Grol, R. (2001). Continuous quality improvement in small general medical practices: The attitudes of general practitioners and other practice staff. *International Journal for Quality in Health Care, 13*(5), 391-397. doi:10.1093/intqhc/13.5.391

Goldstone, J. (1998). The role of quality assurance versus continuous quality improvement. *Journal of Vascular Surgery, 28*(2), 378-380. doi:10.1016/S0741-5214(98)70180-6

Gondo, M., Amis, J., & Vardaman, J. (2010). Case within a case. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 134-136). Thousand Oaks, California: Sage Publications.

Grbich, C. (1999). *Qualitative research in health: An introduction*. Thousand Oaks, California: Sage Publications.

Guba, E., & Lincoln, Y. (1994). Competing paradigms in qualitative research. In N. Denzin, & Y. Lincoln (Eds.), *Handbook of qualitative research* (pp. 105-117). Thousand Oaks, California: Sage Publications.

Guba, E. G., & Lincoln, Y. S. (1989). *Fourth generation evaluation*. Newbury Park, California: Sage Publications.

Guldenmund, F. W. (2000). The nature of safety culture: A review of theory and research. *Safety Science, 34*(1-3), 215-257. doi:DOI: 10.1016/S0925-7535(00)00014-X

Gurwitz, J. H., Field, T. S., Judge, J., Rochon, P., Harrold, L. R., Cadoret, C., . . . Bates, D. W. (2005). The incidence of adverse drug events in two large academic long-term care facilities. *The American Journal of Medicine, 118*(3), January 5, 2011-251-258. doi:10.1016/j.amjmed.2004.09.018;

Halsall, D., Noyce, P. R., & Ashcroft, D. M. (2011). Characterizing healthcare quality in the community pharmacy setting: Insights from a focus group study. *Research in Social and Administrative Pharmacy, In Press*, May 20, 2012-1-11. doi:10.1016/j.sapharm.2011.09.001

Harding, S. G. (1991). "Strong objectivity" and socially situated knowledge. *Whose science? Whose knowledge? Thinking from women's lives* (pp. 138-163). Ithaca, NY: Cornell University Press.

Hartnell, N. R., MacKinnon, N. J., Sketris, I., & Fleming, M. (2012). Identifying, understanding and overcoming barriers to medication error reporting in hospitals: A focus group study. *BMJ Quality Safety, 21*, 361-368. doi:10.1136/bmjqs-2011-000299

Hassell, K., Seston, E., Schafheutle, E., Wagner, A., & Eden, M. (2011). Workload in community pharmacies in the UK and its impact on patient safety and pharmacists' well-being: A review of the evidence. *Health and Social Care in the Community, 19*(6), 561-575. doi:10.1111/j.1365-2524.2011.00997.x

Heinz, P. B. (2007). Case study: The method. In P. Munhall (Ed.), *Nursing research: A qualitative perspective* (pp. 344-358). Sudbury, MA: Jones & Bartlett.

Ho, C., Hung, P., Lee, G., & Kadija, M. (2010). Community pharmacy incident reporting: A new tool for community pharmacies in Canada. *Healthcare Quarterly, 13*(Spec), 16-24.

Institute for Safe Medication Practices Canada. (2006). *Medication safety self-assessment for community/ambulatory pharmacy.* Toronto, ON, Canada:

Institute for Safe Medication Practices Canada. (2008). Demystifying medication incident reporting. *Canadian Journal of Hospital Pharmacists, 61*(2), p. 146-148.

Institute for Safe Medication Practices Canada. (2010). *Definition of terms.* Retrieved November 12, 2010, from http://www.ismp-canada.org/definitions.html

Jacobs, S., Ashcroft, D. M., & Hassell, K. (2011). Culture in community pharmacy organisations: What can we glean from the literature? *Journal of Health Organization and Management, 25*(4), 420-454.

James, K. L., Barlow, D., McArtney, R., Hiom, S., Roberts, D., & Whittlesea, C. (2009). Incidence, type and causes of dispensing errors: A review of the literature. *The International Journal of Pharmacy Practice, 17*(1), 9-30.

Kelly, W. N. (2004). Medication errors: Lessons learned and actions needed. *Professional Safety, 49*(7), 35-41.

Knudsen, P., Herborg, H., Mortensen, A. R., Knudsen, M., & Hellebek, A. (2007). Preventing medication errors in community pharmacy: Frequency and seriousness of medication errors. *Quality Safety in Health Care, 16*(4), 291-296. doi:10.1136/qshc.2006.018770

Kothari, A., Bickford, J., Edwards, N., Dobbins, M., & Meyer, M. (2011). Uncovering tacit knowledge: A pilot study to broaden the concept of knowledge in knowledge translation. *BMC Health Services Research, 11*, 198. doi:10.1186/1472-6963-11-198

Larson, C. A. (1998). Customers first: Using process improvement to improve service quality and efficiency. *Reference Services Review, 26*(1), 51-60. doi:10.1108/00907329810307443

MacKinnon, N. J. (2008). Could 7 million Australians and Canadians be wrong? A status report on medication-use safety in Australia and Canada. *Journal of Pharmacy Practice and Research, 38*(1), 6.

Madden, M. E., & Ball, P. A. (2011). The decision-making processes of pharmacists in inland Australia - a pilot study. *Rural and Remote Health, 11*(Article No. 1573), 1-13.

Malone, D. C., Abarca, J., Skrepnek, G. H., Murphy, J. E., Armstrong, E. P., Grizzle, A. J., . . . Woosley, R. L. (2007). Pharmacist workload and pharmacy characteristics associated with the dispensing of potentially clinically important drug-drug interactions. *Medical Care, 45*(5), 456-462.

Martinez-Sanchez, A., & Campos, R. M. (2011). Detection of prescribing related problems at the community pharmacy. *International Journal of Clinical Pharmacy, 33*(1), 66-69. doi:10.1007/s11096-010-9459-9

Nebeker, J., Hoffman, J., Weir, C., Bennett, C., & Hurdle, J. (2005). High rates of adverse drug events in a highly computerized hospital. *Archives of Internal Medicine, 165*(10), 1111-1116. doi:10.1001/archinte.165.10.1111

Norden-Hagg, A., Sexton, J. B., Kalvemark-Sporrong, S., Ring, L., & Kettis-Lindblad, A. (2010). Assessing safety culture in pharmacies: The psychometric validation of the Safety Attitudes Questionnaire (SAQ) in a national sample of community pharmacies in Sweden. *BMC Clinical Pharmacology, 10*, 8.

Nova Scotia College of Pharmacists. (2007). *Code of ethics.* Retrieved November 3, 2011, from http://www.nspharmacists.ca/ethics/index.html

Nova Scotia College of Pharmacists. (2010). S*tandards of practice for quality assurance programs in community pharmacies*. Retrieved June 15, 2011, from http://www.nspharmacists.ca/standards/documents/QualityAssurance.pdf

Paliska, G., Pavletik, D., & Sokovic, M. (2007). Quality tools-systematic use in process industry. *Journal of Achievements in Materials and Manufacturing Engineering, 25*(1), 79-82.

Paquette, A. (2012). Top Rx drugs of 2011. *Pharmacy Practice, 28*(1), 45-47.

Patel, A. (2009). *Tragic medication errors result in accidental abortions and premature birth.* Retrieved August 9, 2012, from http://abcnews.go.com/Blotter/story?id=8383062#.UCkRPqC9tBk

Paterson, B. L. (2010). Within-case analysis. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 970-972). Thousand Oaks, California: Sage Publications.

Patton, M. Q. (Ed.). (2002). *Qualitative research and evaluation methods* (3rd ed.). Thousand Oaks, California: Sage Publications.

Perez Jr., J. (2010). *Girl dies after medication error.* Retrieved July 24, 2012, from http://www.omaha.com/article/20100530/NEWS01/705319943/1003#girl-dies-after-medication-error

Phipps, D. L., De Bie, J., Herborg, H., Guerreiro, M., Eickhoff, C., Fernandez-Llimos, F., . . . Ashcroft, D. M. (2012). Evaluation of the pharmacy safety climate questionnaire in European community pharmacies. *International Journal for Quality in Health Care, 24*(1), 16-22. doi:10.1093/intqhc/mzr070

Phipps, D. L., Noyce, P. R., Parker, D., & Ashcroft, D. M. (2009). Medication safety in community pharmacy: A qualitative study of the sociotechnical context. *BMC Health Services Research, 9*, 158.

Piccirillo, J. F. (1996). The use of patient satisfaction data to assess the impact of continuous quality improvement efforts. *Archives of Otolaryngology--Head Neck Surgery, 122*(10), 1045-1048. doi:10.1001/archotol.1996.01890220015003

Polit, D. F., & Beck, C. T. (2004). *Nursing research: Principles and methods* (8th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

Reason, J. (2004). Beyond the organisational accident: The need for "error wisdom" on the frontline. *Quality Safety in Health Care, 13 Suppl 2*, ii28-ii33. doi:10.1136/qhc.13.suppl_2.ii28

Richards, L., & Morse, J. M. (2007). *Readme first for a user's guide to qualitative methods* (2nd ed.). Thousand Oaks, California: Sage Publications.

Salsman, B. (2007). Medication incident reporting systems. In N. J. MacKinnon (Ed.), *Safe and effective: The eight essential elements of an optimal medication-use system* (pp. 435-453). Ottawa, ON, Canada: Canadian Pharmacists Association.

Schoen, C., Osborn, R., Doty, M. M., Bishop, M., Peugh, J., & Murukutla, N. (2007). Toward higher-performance health systems: Adults' health care experiences in seven countries, 2007. *Health Affairs, 26*(6), w717-w734.

Scobie, A. C. (2011). Self-reported medical, medication and laboratory error in eight countries: Risk factors for chronically ill adults. *International Journal for Quality in Health Care, 23*(2), 182-186. doi:10.1093/intqhc/mzq082

Scobie, A. C., MacKinnon, N. J., Deal, H., Boyle, T. A., & Mahaffey, T. (2010). Perceptions of community pharmacy staff regarding strategies to reduce and to improve the reporting of medication incidents. *Canadian Pharmacists Journal, 143*(6), 296-301.

Shortell, S. M., Bennett, C. L., & Byck, G. R. (1998). Assessing the impact of continuous quality improvement on clinical practice: What it will take to accelerate progress. *The Milbank Quarterly, 76*(4), 593-624. doi:10.1111/1468-0009.00107

Szeinbach, S., Seoane-Vazquez, E., Parekh, A., & Herderick, M. (2007). Dispensing errors in community pharmacy: Perceived influence of sociotechnical factors. *International Journal for Quality in Health Care, 19*(4), 203-209. doi:10.1093/intqhc/mzm018

Teinila, T., Gronroos, V., & Airaksinen, M. (2008). A system approach to dispensing errors: A national study on perceptions of the Finnish community pharmacists. *Pharmacy World Science, 30*(6), 823-833. doi:10.1007/s11096-008-9233-4

Teinila, T., Gronroos, V., & Airaksinen, M. (2009). Survey of dispensing error practices in community pharmacies in Finland: A nationwide study. *Journal of the American Pharmacists Association, 49*(5), 604-610. doi:10.1331/JAPhA.2009.08075

Wakefield, B. J., Blegen, M. A., Uden-Holman, T., Vaughn, T., Chrischilles, E., & Wakefield, D. S. (2001). Organizational culture, continuous quality improvement, and medication administration error reporting. *American Journal of Medical Quality, 16*(4), 128-134. doi:10.1177/106286060101600404

Waterfield, J. (2010). Is pharmacy a knowledge-based profession? *American Journal of Pharmaceutical Education, 74*(3), Article 50. doi:10.5688/aj740350

Wilkens, R., & London, M. (2006). Relationships between climate, process, and performance in continuous quality improvement groups. *Journal of Vocational Behavior, 69*(3), 510-523. doi:10.1016/j.jvb.2006.05.005

Williams, S. D., & Ashcroft, D. M. (2009). Medication errors: How reliable are the severity ratings reported to the national reporting and learning system? *International Journal for Quality in Health Care, 21*(5), 316-320. doi:10.1093/intqhc/mzp034

Willis, J. W. (2007). *Foundations of qualitative research: Interpretive and critical approaches*. Thousand Oaks, California: Sage Publications.

World Health Organization. (2005). *WHO draft guidelines for adverse event reporting and learning systems: From information to action.* Unpublished manuscript.

Yin, R. K. (Ed.). (2003). *Case study research: Design and methods* (3rd ed.). Thousand Oaks, California: Sage Publications.

Yu, K. H., Nation, R. L., & Dooley, M. J. (2005). Multiplicity of medication safety terms, definitions and functional meanings: When is enough enough? *Quality and Safety in Health Care, 14*(5), 358-363. doi:10.1136/qshc.2005.014159

Zimmerman, C. R., Smolarek, R. T., & Stevenson, J. G. (1997). Peer review and continuous quality improvement of pharmacists' clinical interventions. *American Journal of Health-System Pharmacy, 54*(15), 1722-1727.

APPENDIX A: Recruitment Script for Contact with Participants

RECRUITMENT SCRIPT via telephone

Hello <Pharmacist name OR Pharmacy Technician name>. My name is Heidi Deal; I am a Graduate Student from the Department of Applied Health Services Research at Dalhousie University. I would like to invite a pharmacist and pharmacy technician from your store to participate in my research study to discuss the SafetyNET Pilot Project, the insights and lessons learned based on participant interviews. You have been chosen because you are a participant in the SafetyNET Pilot Project and are thus a subject matter expert on the program.

As a participant, you will be asked to answer a series of questions via an in-person conversation with myself. The conversation could last between 1-2 hours, and will be held at a time of your convenience. I assure you that your identifying information will be kept confidential. If you think you might be interested in participating I will send you a brief information package outlining the purpose of the study and your role in it. Included will be a consent letter that I ask you to return to me via mail or fax.

If you would like to receive the information package, you may tell me now or email me at heidi.deal@dal.ca and I will send you the information package.

Do you have any questions now? Should you have any questions at a later time, please contact me at 902-494-2034 or you may contact my supervisor, Dr. Neil J MacKinnon, at 902-494-6379.

Thank You.

APPENDIX B: Consent Form for Participants

Heidi Deal
Applied Health Services Research
Dalhousie University
902-494-2034
heidi.deal@dal.ca

Information Letter and Consent Form
For the research study:
SafetyNET: Insights and Lessons Learned From a Pilot Project
By Heidi Deal (Principal Investigator)
Dalhousie University
Email: heidi.deal@dal.ca
Phone: 902-494-2034
Supervisor: Dr. Neil J MacKinnon
Associate Director of Research & Associate Professor
College of Pharmacy
902-494-6379
neil.mackinnon@dal.ca

Dear (name of participant)

We invite you to take part in a research study being conducted by Heidi Deal, a graduate student at Dalhousie University, as part of her Applied Health Services Research Masters Program. Your participation in this study is voluntary and you may withdraw from the study at any time. The study is described below. This description tells you about the risks, inconvenience, or discomfort that you might experience. Participating in this study might not benefit you directly, but we may learn things that will benefit others. You should discuss any questions you have about this study with Heidi Deal by contacting her by email or phone.

Purpose of Study:
This study will serve as a qualitative evaluation of the SafetyNET pilot program to gain insight into how SafetyNET can be strengthened and improved in preparation for the roll out of SafetyNET across Nova Scotia in 2010. Since SafetyNET is the first continuous quality improvement program for community pharmacies in Canada that is specifically targeted to improving the safety of the medication-use system, perspectives from program experts, such as you, are needed to determine what can be done to improve the program, and medication error reporting in community pharmacies. It is the purpose of this study to explore these perspectives and determine the challenges and processes that encourage medication error and QRE reporting in community pharmacies. Your responses may help to design a better system for error reporting in the future. We will only be asking questions about using SafetyNET as a reporting system, not what types of QREs were reported.

Procedure of Study:
In-person interviews with agreeing participants will provide novel information about medication error and QRE reporting in each respective community pharmacy. Each interview is expected to last between 1-2 hours and will take place at a location and time chosen by the participant. Your responses will be analyzed for common ideas and themes that may emerge among participants.

Risk/ Benefit
There is little risk for you in this study. I ask for your participation for only as long as you feel comfortable and you are free and able to withdraw at any time during the study. Please notify Heidi Deal by email should you choose to do this. Your confidentiality will be upheld throughout the research process, including in any subsequent report. Your participant status (being a pharmacist or pharmacy technician) will be linked to themes and ideas revealed in the interviews. Your interview responses will be grouped together with the other participants into codes and themes and will not be used to identify you by your name or your community pharmacy name. All the responses, regardless of the source, will be grouped together based on their meaning. Individual quotations may be used in the presentation of results only to represent themes identified. You will not be identified individually by your name or the pharmacy you work in as all quotations used in the report will be linked to participant status (pharmacist group or pharmacy technician group). Your name and your community pharmacy name will not be used or be connected to your responses in any way. Also, the data will not be reported based on store volume, urban/rural location or store type (independent vs. corporate). It is not foreseen that this study will benefit you directly; however the results of the study will provide information regarding medication error reporting in community pharmacies that could help identify changes in the current systems of reporting that may result in improved patient care and safety.

Your Role in Study:
If you choose to participate you will be asked about your experience in the SafetyNET project during a recorded in-person interview with Heidi Deal, which will take approximately 1-2 hours to complete.
If there are any expenses incurred in relation to your participation (transportation, child care, meals, etc.) please retain a receipt and give it to Heidi Deal only. Reimbursement of expenses incurred has a maximum limit of $40 Canadian.
Heidi Deal will be aware of your name and affiliation and she will be the only one who can connect your responses with your name. However she has signed a pledge of confidentiality, and will not release any identifying information. Your responses will be kept in confidence with Heidi Deal only. All information will be coded and no identifying indicators will be associated with the data. Safeguards to ensure your confidentiality are in place including: using a novel ID number to identify you as a participant; keeping all IDs and data password protected and under lock and key (Heidi Deal is the only one with password and key to access the data); and the Pledge of Confidentiality signed by Heidi Deal. Any questions you may have you can direct to Heidi Deal.

Interviews will be recorded with an audio digital recorder for transcription purposes.

If you have any difficulties with, or wish to voice concern about, any aspect of your participation in this study, you may contact Patricia Lindley, Director of Dalhousie University's Office of Human Research Ethics Administration, for assistance (902) 494-1462, patricia.lindley@dal.ca

SafetyNET: Insights and Lessons Learned From a Pilot Project Using Participant Interviews

If you are willing to participate in an in-person interview, for approximately one to two hours regarding your experiences, perspectives and opinions of the SafetyNET Pilot Project, please read the following paragraph and sign at the bottom of this page.

****

I have read the explanation about this study. I have been given the opportunity to contact the researchers to ask questions and discuss the study. I hereby consent to take part in this study. I realize my participation in this study is voluntary and that I am free to withdraw from this study at any time.

Name: _____

Signature: _____

Date: _____

I understand the interview will be audio taped by the researchers, and consent to this process.

Signature: _____

I understand that direct quotations, which will be anonymous, may be connected with participant status (pharmacist or pharmacy technician) information and may be used in the presentation of the results of this study and I consent to these being used.

Consent ( ) Do not consent ( )

Signature: _____

I would like to obtain a copy of the final report of this study.

Yes ( ) No ( )

My preferred method of receiving the report is via:

Email ( ) Residential mail ( )

Please send to this address:

_____

Signature: _____

Signature of Researcher_____ Date_____

APPENDIX C: Consent Form for Pharmacy Owner/Manager

Heidi Deal
Applied Health Services Research
Dalhousie University
902-494-2034
heidi.deal@dal.ca

Information Letter and Consent Form
For the research study:
SafetyNET: Insights and Lessons Learned From a Pilot Project
By Heidi Deal (Principal Investigator)
Dalhousie University
Email: heidi.deal@dal.ca
Phone: 902-494-2034
Supervisor: Dr. Neil J MacKinnon
Associate Director of Research & Associate Professor
College of Pharmacy
902-494-6379
neil.mackinnon@dal.ca

Dear (name of owner/pharmacy manager)

Since your pharmacy was one of the 13 stores involved in the SafetyNET Pilot Project for the past year, we invite one of your pharmacists and pharmacy technicians to take part in a research study being conducted by Heidi Deal, a graduate student at Dalhousie University, as part of her Applied Health Services Research Masters Program. Your participation in this study is voluntary and the study is described below. This description tells you about the risks, inconvenience, or discomfort that the participants may experience. Participating in this study might not benefit you directly, but we may learn things that will benefit others. You should discuss any questions you have about this study with Heidi Deal by contacting her by email or phone.

Purpose of Study:
This study will evaluate the SafetyNET program, as well as gain insight into how SafetyNET can be strengthened and improved in preparation for the roll out of SafetyNET across Nova Scotia. It is the purpose of this study to perform a qualitative evaluation of the SafetyNET pilot project and determine the challenges and processes that encourage medication error and QRE reporting in community pharmacies. We will only be asking questions about using SafetyNET as a reporting system, not what types of QREs were reported. Your pharmacy staff's responses may help to design a better system for error reporting in the future.

Procedure of Study:
In-person interviews with agreeing participants will provide novel information about medication error and QRE reporting in each respective community pharmacy. Their

responses will be analyzed for common ideas and themes that may emerge among participants.

Risk/ Benefit

You and your staff's confidentiality will be upheld throughout the research process, including in any subsequent report. There will be 2 staff members interviewed from each of the 13 participating pharmacies. Your staff's interview responses will be grouped together with the other participants into codes and themes and will not be used to identify you, your store or your staff by name or community pharmacy name. Your staff's status (being a pharmacist or pharmacy technician) will be linked to themes and ideas revealed in the interviews and all the responses will be grouped together based on their meaning. Individual quotations may be used in the presentation of results only to represent themes identified. Your name and your community pharmacy name will not be used or be connected to your staff's responses in any way. Also, the data will not be reported based on store volume, urban/rural location or store type (independent vs. corporate). It is not foreseen that this study will benefit you directly; however the results of the study will provide information regarding medication error reporting in community pharmacies that could help identify changes in the current systems of reporting that may result in improved patient care and safety.

Heidi Deal will be aware of your staff's name and affiliation and she will be the only one who can connect their responses with their name. However, she has signed a pledge of confidentiality, and will not release any identifying information. Your staff's responses will be kept in confidence with Heidi Deal only. All information will be coded and no identifying indicators will be associated with the data.

If you have any difficulties with, or wish to voice concern about, any aspect of your participation in this study, you may contact Patricia Lindley, Director of Dalhousie University's Office of Human Research Ethics Administration, for assistance (902) 494-1462, patricia.lindley@dal.ca

SafetyNET: Insights and Lessons Learned From a Pilot Project Using Participant Interviews

If you are willing to provide your pharmacy staff with permission to participate in this study please read the following paragraph and sign at the bottom of this page.

****

I have read the explanation about this study. I have been given the opportunity to contact the researchers to ask questions and discuss the study. I hereby consent for my pharmacy staff to take part in this study. I realize their participation in this study is voluntary, without any obligation to so do so, and that should they agree to participate, or not participate, in the study, there will be no negative consequences.

Name: _____

Name of Pharmacy: _____

Signature: _____

Date: _____

APPENDIX D: Questions for Participants

The following are potential questions to be used in face-to-face interviews with pharmacists and pharmacy technicians. It is anticipated that many of the responses to the questions below will be addressed spontaneously by participants in a conversation about their experiences with the SafetyNET project. The questions that follow will be used as a guide and asked only where the information has not arisen spontaneously during conversation.

Could you tell me about your experience of the SafetyNET project?

How has the SafetyNET project changed reporting practices in this pharmacy?

How has the SafetyNET project changed individual staff actions in the pharmacy? How would you describe this change?

How has the SafetyNET project changed reporting processes (workflow/dispensing procedures) in this pharmacy? How would you describe this change?

How has the SafetyNET project changed enabling technology, such as the online reporting form and feedback tools, in the pharmacy? How would you describe this change?

Has there been any resistance to the SafetyNET project? If yes, could you elaborate on what that resistance is, and why?

What changes would you suggest to the SafetyNET project?

How has the SafetyNET project changed in-store and corporate management support mechanisms in the pharmacy? How would you describe this change?

How has the SafetyNET project changed the link to national improvement initiatives (i.e. ISMP, reporting to a national database) in the pharmacy? How would you describe this change?

Overall, how do you think the project has changed the level of safety in your pharmacy?

APPENDIX E: Pledge of Confidentiality for Principal Investigator, Research Assistant and Transcriptor

This is to certify that I, _____, the principal investigator, a research assistant or transcriber for Heidi Deal's graduate thesis entitled "SafetyNET: Insights and Lessons Learned From a Pilot Project" at Dalhousie University, understand that any information (written, verbal or other form) obtained during the performance of my duties must remain confidential. This includes all information about members, clients, families, employees and other associate organizations, as well as any other information otherwise marked or known to be confidential.

I understand that any unauthorized release or carelessness in the handling of this confidential information is considered a breach of the duty to maintain confidentiality.

I further understand that any breach of the duty to maintain confidentiality could be grounds for immediate dismissal and/or possible liability in any legal action arising from such breach.

_____
Signature of Student/Transcriptor

_____
Date

_____
Signature of Witness

For any questions contact
Heidi Deal
Dalhousie University
902-494-2034
heidi.deal@dal.ca