Patient Safety In Primary Care
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EXECUTIVE SUMMARY

As part of the broader primary health care framework, primary care is a service at the entrance to the healthcare system. It addresses diagnosis, ongoing treatment and the management of health conditions as well as health promotion, disease and injury prevention. Primary care coordinates the care of patients and integrates their care with the rest of the health system by enabling access to other healthcare providers and services.

Healthcare is most frequently accessed by Canadians through and within the primary care setting. Due to the volume and diversity of services provided in primary care, patient safety is an essential and important aspect of this healthcare setting. The need for a systematic review of patient safety in primary care is identified as a priority to better understand what is known, as well as to identify gaps in this knowledge base.

This report builds upon what is known about patient safety in primary care. That knowledge emerges from three sources: 1) findings from published scientific studies and grey literature; 2) interviews with individuals who have expertise in patient safety in primary care; and 3) broad-based discussion among a relatively large group of individuals representing different interests in primary care. The report offers suggestions and outlines opportunities that, it is hoped, will provide momentum to those in both leadership and delivery roles to strengthen the infrastructures and supports necessary for a greater focus on patient safety in primary care.

BACKGROUND

Patient safety is an area of inquiry that emphasizes the identification of risk, reporting, analysis, and the prevention of unintended or potential harm associated with healthcare. Most of the current research on patient safety has focused on care provided in hospitals and has given limited attention to the identification and evaluation of the unique safety risks that patients may be exposed to in primary care. Likewise, little is known about the outcome of proposed strategies to enhance safety or about actions taken to prevent or ameliorate the impact of safety incidents in primary care.

To begin to explore the current state of knowledge, as well as the key issues, priorities, opportunities and strategies for advancing patient safety in primary care in Canada, the Canadian Patient Safety Institute (CPSI) partnered with the BC Patient Safety & Quality Council (BCPSQC) to fund new research. To assist with this initiative, a pan-Canadian Patient Safety in Primary Care Advisory Group was convened, consisting of clinicians, researchers, and decision-makers in the areas of patient safety and/or primary care.

Through a competitive process, a research team from the Institute of Health Economics (IHE), in Edmonton, Alberta, was commissioned to develop a background research paper on patient safety as it applies to primary care. This project had three phases: a comprehensive review of white and grey literature; qualitative interviews with several Canadian and international informants; and a roundtable event that brought together key stakeholders in the fields of patient safety and primary care from across Canada to discuss the research and opportunities for advancing a Canadian agenda for patient safety in primary care.

OBJECTIVES

The objectives of this study were to:

1. describe the concept of patient safety as it applies to primary care, including its unique issues and challenges;
2. provide an overview and synthesis of available findings from research on patient safety incidents relevant to primary care;
3. identify and evaluate current evidence in the scientific literature on actions taken or strategies proposed to enhance patient safety in primary care;
4. identify gaps in the current research literature on patient safety in primary care and discuss the relevance of findings from patient safety research in other healthcare sectors or settings;
5. identify key themes and priorities emerging from the literature and from the perspectives of stakeholders; and
6. identify potential opportunities and next steps for advancing patient safety in primary care in Canada.

METHODOLOGY

Literature searches

A prospectively designed protocol was used to map the evidence from the scientific literature on the topic of patient safety in primary care for the time period 1995 to January 2010. Comprehensive searches of biomedical electronic databases were conducted to identify English-language reports of original research on patient safety incidents that occurred in primary care and the actions
taken to address them. Only randomized controlled clinical trials, controlled clinical trials, and observational studies (cohort studies, case control studies, cross sectional studies) from countries with developed economies were considered for inclusion. These searches were supplemented by searches of grey literature, which included bibliographies of relevant studies, government websites, technical reports, and free searches over the Internet. The quality of the studies was assessed based on the strength of evidence they provided, which was evaluated using the SIGN grading system. Statistical pooling of studies was not feasible because of the heterogeneity among of the studies in terms of their study populations, types of incidents, and actions taken; therefore, study results were synthesized in a narrative way.

**Key informant interviews**

Individuals with expertise in patient safety in primary care are a source of information on current practices, impending initiatives, and concerns that may not have been documented in the published literature. Therefore, interviews were carried out with 16 Canadian and international leaders and stakeholders in the areas of patient safety and/or primary care.

**Roundtable event**

An invitational roundtable discussion was engaged as a means of highlighting the findings of the literature review and key informant interviews and to substantiate the findings of these two methodologies while also capturing additional information. The Patient Safety in Primary Care Roundtable was held in May 2010 in Toronto, Ontario. That roundtable event brought together approximately 50 stakeholders in the fields of patient safety, primary care and healthcare research from across Canada, including clinicians, patient representatives, researchers, policy makers, and other decision makers, as well as representatives of regulatory bodies and formal organizations. The event included presentations by IHE staff, based on an earlier draft of this report, and by Drs. Robert Varnam and Richard Jenkins of the UK National Health Service Institute for Innovation and Improvement.

**Findings**

Patient safety in primary care has emerged as a field of inquiry of increasing importance. Systems for understanding and managing patient safety have been developed, validated, and applied in the area of acute care; however, a reliable mechanism for documenting adverse events and managing patient safety in primary care has not yet been developed. Currently there is no system for the uniform collection of information about adverse events in primary care in Canada. As a result, the frequency and nature of patient safety incidents is difficult to discern. The different definitions and methods used in available studies, and the lack of a common terminology with which to classify safety incidents in primary care contributes to that difficulty.

A review of white and grey literature on patient safety in primary care identified two major themes in patient safety related to the provision of primary care:

- missed or delayed diagnosis; and
- medication management.

These themes were most often affected by three important aspects of primary care:

- communication;
- administrative processes; and
- the knowledge and skills of providers involved in treatment and/or counselling.

Clinicians experienced in primary care, as well as other key informants, emphasized improved communication as an important focus for enhancing patient safety. In particular, they noted the need for improving the transfer of information across the health service continuum (often called “handovers” or “handoffs”), and to patients who are elderly, or those experiencing communication challenges.

In interviews, key informants from Canada and other countries also agreed that the major issue in patient safety is communication, especially the management of patient information; from the provider to the patient, within the primary care delivery system, and between providers both within and external to primary care. More specifically, the key informants pointed to the:

- quality of the information that is available to providers;
- coordination of information between providers;
- ease of use and integration of new information in practice; and
- ability of patients to understand and use information provided to them.

The key informants also identified four features that are unique to primary care and that require consideration when discussing patient safety in these settings:

- the opportunity for providers to build long-term, open and significant relationships with patients over time;
• the physical infrastructure, such as clinical settings, and the virtual infrastructure of networks that support the provision of care among physicians and many other professionals;
• the care of patients when their diagnosis is not yet clear; and
• the necessity of integrating information from a wide variety of sources and providers.

Key informants generally agreed that some populations, such as the elderly, patients with co-morbidities or complex health issues, Aboriginal people, and people newly arrived in Canada, may be more vulnerable to safety concerns. However, the source of the vulnerability, rather than the populations, ought to be the focus of analysis and action.

Informants believe there are significant challenges in addressing patient safety in primary care but agree that by developing more effective means of communication with patients and using tools such as the electronic medical record in conjunction with systemic electronic health record linkages to collect and share patient information between providers, patient safety can be improved or enhanced in all primary care practices. It was emphasized that comprehensive and continuous care are important features of primary care, crucial to patient safety in primary care.

Participants at the roundtable event generally substantiated the findings from both the literature review and the interviews with key informants. They agreed that missed and delayed diagnoses and medication management are two of the main themes of patient safety in primary care. It was underlined that information does not necessarily flow freely and efficiently between and within primary care and other care settings, that primary care providers and consulting specialists too often work in isolation from each other, that the reimbursement systems do not generally support the cultivation of the provider-patient relationship, and that more research is needed to fully understand the causes of safety incidents and what actions may be taken to further enhance safety in primary care. The participants felt that there are gaps in the findings of the scientific literature, such as the role of non-clinicians or administrative staff in patient safety improvements. Further, it was recognized that aspects of safety in the diagnosis, treatment and care of children have not been reported in the literature.

SUMMARY

Incidents of unintended harm do occur in primary care and many are preventable. However, the scientific studies to date provide little information about the frequency and types of events that pose a safety risk for patients in primary care in Canada.

It should be noted that most findings from the literature have not emerged from the situation in Canada, but are based on results from studies of other healthcare systems in other countries. Considering our scarce knowledge of the current patient safety situation in Canada, it is important to launch further research on this subject to gather the facts needed for appropriate action. In order to thoroughly investigate patient safety issues in Canadian primary care, several key questions have been identified:

1. What is the frequency and what are the different types of patient safety incidents in primary care in Canada?
2. What is the role of diagnosis in patient safety in primary care and how can clinicians maximize patient safety in the absence or uncertainty of a final diagnosis?
3. Is there a discrepancy between prescribing practices and available criteria for appropriate prescribing in Canadian primary care?
4. What fraction of the work load and resources in emergency departments is due to safety incidents in primary care in Canada?
5. What is the total cost of safety incidents in primary care in Canada?
6. What are the overall economic, social and patient-related implications of patient safety in Canadian primary care?
7. What are the major opportunities for enhancing patient safety in Canadian primary care?
8. Can safety incidents be reduced by different funding or staffing models for primary care services in Canada?

From the perspectives of stakeholders, several system-level priorities and opportunities were identified as potential next steps for advancing patient safety in primary care in Canada:

1. Further research and data regarding the nature of patient safety incidents and adverse events in primary care in Canada, as well as the actions and strategies to enhance patient safety.
A pan-Canadian approach or framework for identifying and addressing patient safety in primary care, while respecting the uniqueness and responsibility of each jurisdiction in the delivery of primary care.

Continued efforts for national, provincial, territorial, regional and local organizations and associations to collaboratively highlight and communicate the key patient safety issues in primary care.

In addition to learning from acute and other care settings, continued awareness and investigation of the unique aspects of primary care to determine and develop targeted approaches to improving patient safety specific to primary care and its services.

Current practices, gaps and potential barriers for the disclosure and reporting of patient safety incidents in primary care should be identified and addressed.

Mechanisms for encouraging and supporting a focus on patient safety should be considered and evaluated for the various new and developing primary care delivery models, as well as the existing practices of family physicians and other providers across Canada.

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A greater focus on patient safety with relevance to primary care and other care settings in undergraduate, postgraduate and continuing medical and health professional education based upon the Safety Competencies framework (The Safety Competencies Steering Committee).

Experts in patient safety, primary care and healthcare research from across Canada – including clinicians, researchers, policy and decision-makers, regulatory bodies and professional organizations – have worked in partnership to provide a foundational piece for discussing and understanding the issues related to patient safety in primary care. By building on this foundation, the risks to patient safety can begin to be explored and identified, and the structures and models by which Canadian primary care is delivered can be modified to provide safer patient care.
INTRODUCTION

The findings presented in this report are based on several sources. This introduction includes a narrative review of the literature on the concept of patient safety in healthcare and the unique challenges of addressing patient safety issues in primary care. Chapter two presents a systematic review of the literature, and identifies some key themes and priorities that emerge from the analysis and the synthesis of finding. The third chapter presents the results of interviews with key informants, which are helpful in filling the gap between findings in scientific studies and experiences of patient safety issues in primary care. Chapter four is a summary of the outcomes from a roundtable discussion. Chapter five presents opportunities to improve patient safety in primary care. The structure of the report thus closely follows its objectives, which are as follows.

OBJECTIVES

The objectives of this study were to:

1. describe the concept of patient safety as it applies to primary care, including its unique issues and challenges;
2. provide an overview and synthesis of available findings from research on patient safety incidents relevant to primary care;
3. identify and evaluate current evidence in the scientific literature on actions taken or strategies proposed to enhance patient safety in primary care;
4. identify gaps in the current research literature on patient safety in primary care and discuss the relevance of findings from patient safety research in other healthcare sectors or settings;
5. identify key themes and priorities emerging from the literature and from the perspectives of stakeholders; and
6. identify potential opportunities and next steps for advancing patient safety in primary care in Canada.

DEFINITION AND SCOPE OF PATIENT SAFETY

The World Health Organization’s (WHO) International Classification for Patient Safety defines patient safety as the reduction of the risk of unnecessary harm associated with healthcare to an acceptable minimum (World Health Organization\textsuperscript{17}). An acceptable minimum refers to the collective notions of current knowledge, resources available and the context in which care is delivered weighed against the risk of non-treatment or other treatment.

The following illustration from the WHO World Alliance for Patient Safety shows a number of areas of potential safety incidents in healthcare.

Figure 1: Types of patient safety incidents in the International Classification for Patient Safety

Source: Adapted from the World Health Organization World Alliance for Patient Safety\textsuperscript{16}.

Figure 1 specifies 13 types of incidents that can influence patient outcomes. The literature search presented in this report captured many of these, however, for some types of incidents, the search failed to identify research focused on frequency effects, or strategies for their prevention that are specific to primary care. These incident types include infection and incidents related to blood products and oxygen and/or gas supply.

PRIMARY CARE

Primary care is a term that describes healthcare that is the first point of contact with the health system for most individuals seeking care. The providers of primary care serve patients of all ages, from children to seniors. Among other things, they diagnose illness; treat acute and episodic illnesses; monitor pregnancies; provide mental healthcare and psychosocial services; liaise with home care services; promote health and disease prevention through routine check-ups, screening for disease and nutrition counselling;
manage chronic conditions; make referrals to specialists; and provide end-of-life care (Health Canada4). Primary care is delivered by a variety of healthcare professionals, including physicians (general or family practitioners), nurses, nurse practitioners, pharmacists, dieticians, physiotherapists, social workers and others.

Primary care is an area of increasing interest to governments, regional health authorities and other decision makers who are trying to strengthen the Canadian health system by developing a firm foundation of first access services. Research has shown the benefits of a strong primary care system in improving health outcomes for patients, as well as in reducing the overall cost of the healthcare system (Starfield et al.35 and Delaune and Everett39). Compared to specialty care, the provision of primary care is shown, globally and within countries, to result in a more even distribution of health across populations (Starfield et al.3). The last 10 years have seen the development in Canada of various primary care models that take a patient-centred approach to the provision of primary care services by teams of health professionals. While there is a growing body of knowledge about ways to improve the quality of care offered within these models, there has been little attention given to patient safety in primary care.

The scope of primary care can be overwhelming, and this has significant implications in examining the issues of patient safety. In undertaking this review of patient safety in primary care, it was the advice of the advisory group overseeing the development of this paper to focus on primary care rather than the much wider and more challenging scope of primary health care. Several definitions were reviewed, including those from the important work of the well-known primary-care researcher Dr. Barbara Starfield, and from the Canadian Health Services Research Foundation, The College of Family Physicians of Canada and Accreditation Canada. After considerable discussion, a definition that incorporates elements from each of the above resources was agreed upon, as follows:

“As part of the broader primary healthcare framework, primary care is a service at the entrance to the healthcare system. It addresses diagnosis, ongoing treatment and the management of health conditions, as well as health promotion and disease and injury prevention. Primary care is responsible for coordinating the care of patients and integrating their care with the rest of the health system by enabling access to other healthcare providers and services.”

**Patient safety in primary care**

Patient safety is a fundamental principle of healthcare, along with access, timeliness, efficacy, efficiency, appropriateness and acceptability (WHO World Alliance for Patient Safety19). As an emerging focus, patient safety is an area of inquiry that emphasizes the identification of risk and the detection, analysis, reporting, prevention and alleviation of unnecessary harm or potential harm associated with the delivery of healthcare.

One of the first papers on patient safety focused on the primary care setting. Ely et al.27 explored the causes of self-disclosed errors by family physicians. The origins of the errors included being hurried, being distracted, concluding the diagnostic process too early, being misled by normal test results and lack of knowledge. Despite these significant and, perhaps, controversial findings, patient safety did not draw much research attention until the publication of the seminal work by Kohn et al.,49 which dealt with patient safety in U.S. hospitals. A few years later, the release of the pivotal Canadian Adverse Events Study4 drew attention to patient safety issues in acute care in this country. Research has only recently returned some attention to patient safety in primary care. Nevertheless, patient safety research, especially in primary care, is still in its infancy.

**Unique issues and challenges**

Primary care delivery is somewhat different from the delivery of healthcare in other settings. Primary care providers see essentially the whole spectrum of conditions and diseases. Patients appear with a wide variety of complaints and symptoms, which may or may not point to a certain diagnosis. The workload is often formidable and only limited time is available for each patient. The organizational structures vary from a solo practice physician to a large group of primary care providers organized into a primary care team, or may span a geographic area within a primary care network. The administrative and information support systems are different from those in many other healthcare settings. The key informants also identified the following four features that they felt are unique to patient safety in primary care:

**Building relationships:** The primary care setting that allows providers to build long-term, open, and significant relationships with patients.

**Infrastructure for care:** Both the physical infrastructure, such as clinical settings, and the virtual infrastructure of networks that support the provision of care among physicians and many other professionals are to a certain extent unique in primary care.
Understanding the diagnosis: Patients are frequently seen and treated in primary care settings when their diagnosis is not yet clear.

Integrating information transferred between multiple providers: Primary care providers are required to integrate information from a wide variety of sources and providers.

The risks that patients could encounter in primary care may differ substantially from those encountered in hospital care and may also differ between different settings within primary care. Risk profiles may vary depending on such factors as the human and technological resources available, the socioeconomic structure and disease panorama in catchment area, the healthcare delivery environment and patient expectations, as well as the type of health services provided.

Risks may be due more to the organization and management of primary care than to events caused by individual patients or providers. It is stressed here that the identification of risks is intended to identify aspects of healthcare service delivery and organization that may contribute to patient safety incidents, so that steps can be taken to reduce or eliminate these potential risks in the future. A well-designed healthcare system acknowledges that “to err is human” and, thus, should include systems to identify risks before they have an impact on patient outcomes.

Patients in primary care are increasingly encouraged to take a more active role in the management of their health. Many models of chronic disease management encourage providers to include patients in the active management of their conditions. Therefore, the participation of patients appropriately may be an important determinant of safety in primary care. Patients may not participate in their suggested treatments because of miscommunication, low health literacy, the financial cost and/or religious or lifestyle factors. For a number of reasons, including, as examples, financial costs to the patient and inadequate communication, patients may not adhere to their prescribed treatment or follow pre-diagnostic diet restrictions, leading to unclear test results. Both system features and patient compliance in its broad sense should be considered when examining patient safety in the primary care context.

These and other aspects of primary care are crucial in identifying its unique patient safety issues. In particular, a systems view, as is taken in this report, is more likely to be successful in identifying both risks and strategies to reduce the risks rather than an approach that focuses on individual providers or patients.

A MODEL FOR PREVENTING RISKS AND ADVERSE OUTCOMES

There are, in principle, two approaches to identifying the root cause of a risk as presented in the literature: the person approach and the system approach (Reason76 and Reason77). Each approach has an underlying model of error causation and a philosophy of error management (Reason77). The person approach takes a narrow view of risk causation by focusing on an individual (e.g. provider or patient) as the specific cause of error and manages the error by trying to correct the individual’s performance. The system approach takes a broader view of risk causation by looking at latent (hidden) factors within a system that contribute to errors (e.g. a non-culture of patient safety, a number of small problems that, when combined, lead to mistakes); and active (visible) factors by individuals within the system (e.g. incorrect identification of patients prior to administering medication). In this paper, we take a system approach to discussing risks to patient safety in primary care, as it is argued this will have a greater impact on improving patient safety (Gandhi et al.,36 Booth7 and Elder26).

One of the models in the literature for structuring patient risks in primary care presents four main levels from which strategies may be developed to reduce potential hazards and errors. To this model we have added a fifth level, namely, the patient level (Reason,10 Reason77 and Palmieri et al.72). These five levels, or defensive layers, are:

1. Organizational leadership;
2. Management;
3. Situations for safe practice;
4. Provider performance; and
5. Patient performance.

At the macro-level, organizational leadership is the defensive layer most distant from the patient. At the micro-level, patient performance is the defensive layer closest to the patient. Latent errors are more likely to occur at the macro end of the primary care delivery system, while active errors are more likely to occur at the micro end. For a further description of this model and an illustration of this structure, see Appendix A.

Organizational leadership

This level of primary care delivery can be defined as the decisions related to the composition of staff, policies and procedures, workplace culture and error reporting mechanisms (Palmieri et al.24).
One specific type of organizational leadership that may affect patient outcomes is the relationship between the primary care and the surrounding healthcare environment. An example of organization leadership is the referral relationship between a primary care physician and a consulting specialist, including the exchange of information regarding diagnosis and interventions or other actions taken by the specialist.

Another specific type of organizational leadership that may affect patient outcomes is the payment mechanism by which providers are remunerated. Different payment mechanisms, such as fee-for-service, capitation, pay for performance, and different types of alternate relationship plans (ARPs) may provide different incentives for specific types of services such as immunization and screening. For example, under a fee-for-service payment mechanism, a provider is paid for each insured service provided. Thus, there is an incentive to over-provide listed services and under-provide non-listed services. This, in turn, may affect patient outcomes.

Management
The second defensive layer of management is related to how providers are supervised within a primary care delivery system. Management is responsible to a system’s leadership team for system metrics and outcomes, correcting known gaps and actions of providers engaging in unsafe activities and managing workload pressures. It is believed that supervisors should foster a safe environment by actively identifying and addressing deficiencies among practitioners, equipment, processes and training (Palmieri et al.).

Situations for safe practice
The third defensive layer is situations for safe practices. This defensive layer comprises factors that provide reliable support, such as the information, equipment, or supplies needed for safe practice. If the situation is unsafe, adverse events can occur or permeate the layer. For example, a failure of an office’s computer system would prevent providers from verifying patient information and may create a situation of unsafe practice. Another example would be the ability of a primary care provider to refer patients to a specialist and the ability of the provider to follow up with the specialist about the patient.

Provider performance
The fourth defensive layer, provider performance, is at the micro-level of the primary care delivery system. Deficiencies in this layer can arise from active or latent factors on the part of providers. An example of a latent factor affecting provider performance is the location of a physician’s practice. Physicians are not randomly allocated across a geographic area and tend to choose to practice in urban rather than rural areas. Even within an urban area, physicians may choose to locate in areas with a preferred type of patient. Other broad categories of provider performance issues can include adverse medication events, errors in clinical judgment and decision making and/or administrative errors.

Patient performance
Even if the entire primary care delivery system is organized and managed to provide optimal healthcare, patient behaviour can determine the benefit, or harm, of the provided or offered care. Potential errors can derive from issues of attendance, assertion, adherence, memory and heedfulness, as well as poor judgment, lack of language literacy or health literacy, and having attitudes or lifestyles that are not beneficial to health (Buetow et al.).

Cross-cutting themes
There are a number of identified risks to patient safety in the literature that can be assigned to more than one defensive layer as a cross-cutting theme. An example of such a theme is patient-provider communication. Clearly, communication errors by the provider would be viewed as a hole in the fourth defensive layer (provider performance), while communication errors by the patient would be viewed as a hole in the fifth defensive layer (patient performance).

Another example of cross-cutting themes is electronic medical records. A delay in the training of physicians in the use of electronic medical records due to the type of physician payment scheme is an example of an issue in organizational leadership. At the same time, technical problems (such as a failure in the computer system) that prevent a trained physician from accessing a patient’s electronic medical records could be described as an issue in the safe practice defensive layer.

The WHO model
The issues raised above fit well with the views presented by the WHO World Alliance for Patient Safety. That initiative is dedicated to establishing evidence-based systems for improving the safety and quality of care in the member states (World Health Organization). One of the deliverables of this initiative will be the International Classification for Patient Safety (ICPS), which will use standardized concepts with agreed-upon definitions and terminology to facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information related to patient safety (World Health...
Comprehensive searches of biomedical electronic databases (the Cochrane Library, MEDLINE, EMBASE, CINAHL) were conducted for the period from 1995 to January, 2010. The search strategy was designed by an Information Specialist at the IHE and comprised both controlled vocabulary and keywords (see Appendix B). No filters by study design were used in the search strategy. In addition, Internet searches via Google and Google Scholar were carried out (see Appendix B) and the reference lists of relevant studies were perused to identify further studies. Government websites were searched for additional information.

The synthesis of the scientific evidence on patient safety in primary care followed the format of a rapid evidence review. A rapid evidence review is a summary of scientific research that is as comprehensive as possible given the constraints of a timetable in which it was produced. It uses systematic review methods, but is characterized by some limitations in the comprehensiveness of the search, the research scope or other stages of the review process (Hemingway). This rapid review did not include a formal assessment of the methodological quality of the included studies. The approach to quality focused mainly on summarizing/assessing the level of evidence, however some study characteristics that are related to the internal validity of studies such as the study design, method of sampling or allocation to interventions, and the methods for data collection were also described. The lack of a formal assessment of the methodological quality of the selected studies has an impact on the conclusions drawn from the findings reported in the individual studies.

IDENTIFICATION OF PATIENT SAFETY INCIDENTS IN PRIMARY CARE

The literature search resulted in the identification of 1323 citations. After screening titles and abstracts, 88 references potentially relevant to this question were selected for further examination. The full text of the 88 potentially relevant articles was retrieved and evaluated for inclusion in the review. Forty-six articles were included and 42 were excluded.

SYSTEMATIC REVIEW OF THE LITERATURE

This chapter includes a systematic review of the scientific literature, as well as a review of the grey literature in the field of patient safety in primary care. The systematic review was conducted with the aim of addressing the following questions:

- What types of patient safety incidents relevant to primary care have been identified in the literature?
- What research has been conducted on interventions or actions that address patient safety in primary care?
- Which are the key themes and priorities in patient safety in primary care that emerge from the literature?

To review the data abstraction tables of all included articles reviewed, please refer to the CPSI and BCPSQC websites.
Research on patient safety in primary care has focused mainly on specific aspects of the delivery of care, such as medication management, diagnosis, and communication between patients and practitioners. The reported incidences of patient safety issues differed substantially between different studies, depending on the specific research question addressed and the study approach used, and as a result of the lack of a common terminology for describing safety events.

Rates of patient safety incidents in primary care have been reported as low as 4 and as high as 240,000 per 1,000,000 primary care consultations (Makeham et al.\(^5\)). The following findings from the literature demonstrate the wide variation in the incidence of patient safety issues in primary care.

Rosser et al.\(^7\) described the issues anonymously reported by 15 family practitioners from Toronto, Canada, and compared those reported by 64 physicians in Australia, England, the Netherlands and the United States. The Toronto participants were not a representative sample of Canadian doctors, and those from other countries were convenience samples. Between June and December 2001, the Canadian physicians and other physicians reported an average of 6.3 incidents and 6.45 incidents each, respectively. Of the issues reported by Canadian doctors and other doctors, about 39% and 29%, respectively, resulted in harm to patients; and about 6% and 7%, respectively, resulted in “very serious” harm.

Makeham et al.\(^6\) estimated the incidence of anonymously reported patient safety incidents by 84 general practitioners over a 12-month period in 2003. The GPs were a random stratified sample of GPs in New South Wales, Australia. Based on their number of incidents reported, their Medicare encounters and individual patient contacts, the annual rate of incidences was about 2.4 per every 1000 patients seen and about 0.8 (95% CI: 0.076% to 0.080%) per 1000 Medicare patient encounters.

De Wet and Bowie\(^2\) developed and piloted a trigger tool to identify issues and adverse events in patient records. This retrospective study used a random selection of 100 patient electronic charts at five urban general practices in central Scotland. Five hundred charts, documenting 2251 patient visits between January 2007 and December 2007 and identified 730 triggers, formed the basis for the study. About 9% of patient charts revealed an event involving patient harm. An additional 4% of records had the potential for patient harm. About 42% of the actual or potential adverse events were considered preventable.

Other studies have estimated that, in developed nations, 5 to 80 adverse events per 100,000 consultations occur in primary care (Sandars and Esmail\(^8\)).\(^2\) Retrospective studies estimate that between 45% and 76% of patient safety incidents in primary care could have been avoided (Makeham et al.\(^5\)).\(^3\) The challenge to researchers and healthcare providers is to identify opportunities to avoid preventable patient safety incidents.

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2 The study included evidence from Australia, the Netherlands, Sweden, the United Kingdom, and the United States.

3 The systematic study used data drawn from scientific literature published between 1966 and December 2007, along with the evidence from 92 websites in Australia, Europe, and North America.

4 For example, a delayed diagnosis of colorectal cancer [because of an incorrect diagnosis of haemorrhoids] or oesophageal cancer (because of an incorrect diagnosis of Gastroesophageal Reflux Disease [GERD]).

5 Although Makeham et al.\(^5\) estimated 0.24% of the 166,569 patients studied over a 12 month period had an adverse event, de Wet et al.18 estimated that about 9 out of every 100 patients experience an adverse event based on a review of 300 patient records.

6 According to Rosser et al.\(^7\) and Wetzel et al.\(^11\), about 6% of adverse events cause serious harm to patients.
An adverse health outcome resulting from a safety incident in primary care may be hard to detect since it may not be realized immediately following the incident. But not all patient safety incidents lead to adverse outcomes. An incident can result in the patient’s being at high, medium, or low risk of a severe health outcome. Most incidents cause minor harm to patients or are detected prior to reaching the patient, resulting in no adverse outcome (Schiff et al., Franklin, Varkey et al., Kuo et al., and Makeham et al.).

However, a patient safety incident can result in serious complications that ultimately change a patient’s long-term pattern of healthcare use (such as increased hospitalizations, physician visits, and prescription drug use) (Makeham et al., Letrilliart et al., Farnan et al., Wong et al., Moore et al., Kripalani et al., Baker and Health Council of Canada). Some patient safety incidents may result in a patient’s death (Makeham et al., Baker and Baker et al.).

In conclusion, there is limited information about the incidence of adverse events in primary care. The international literature reviewed in this section estimates that as many as 24 of every 100 patients may experience an adverse event each year. Elder et al. and Hoffman et al. estimate that between 24 and 42 of every 100 patients who experience an adverse event are harmed and about 6 of every 100 patients who experience an adverse event may be seriously injured each year.

Since these estimates are not based on large samples, or nationally representative data, extrapolation to the Canadian context would not be appropriate. Further, the studies that are available do not consider all potential risks to patient safety, but only those that have been identified earlier. Therefore, the number of Canadians who experience, or are harmed by an adverse medical event each year cannot currently be estimated.

Table 1: Outcomes of adverse events

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<tr>
<td>Caused harm</td>
<td>9%</td>
<td>24%</td>
<td>42%</td>
<td>30%</td>
<td>25%</td>
<td>39%</td>
<td>52%</td>
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<tr>
<td>Potential for harm</td>
<td>27%</td>
<td>4%</td>
<td>70%</td>
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<td>Potential for serious harm</td>
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<td>76%</td>
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<tr>
<td>Caused serious harm</td>
<td>14%</td>
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<td>18%</td>
<td>9%</td>
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<td>Were preventable</td>
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<td>Actual and potential, were preventable</td>
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TYPES OF INCIDENTS IN PRIMARY CARE

Fourteen studies investigated the types of incidents that influence patient safety in primary care.\(^7\)

Bhasale et al.\(^6\) characterized patient safety incidents based on a non-random sample of 324 Australian physicians who made anonymous reports of potential or actual harm between October 1993 and June 1995. Of the 805 incidents reported, about 76% were deemed preventable while 27% had the potential for severe harm. Long-term harm was predicted in about 34% of cases.\(^8\) The main factors leading to these events were issues of medication management (about 50% of incidents), treatment (about 19%) and diagnostic (about 14%).\(^9\)

Elder et al.\(^15\) described the medical events in family practice based on a sample of family physicians of varying demographics in different areas of Cincinnati, Ohio. The prospective study included 351 reports on outpatient visits by 15 physicians in seven practices. About 24% of the visits identified incidents and preventable adverse events. GPs reported incidents in 3% to 60% of all patient visits. About 24% of incidents resulted in patient harm, while another 70% had the potential for harm. The main factors leading to the events were administration (about 49% of all events), physician actions (about 24%), patient communication (about 14%) and diagnostic and/or treatment issues (about 13%).

Fernald et al.\(^29\) undertook a prospective study of medical incident reports based on 475 clinician and staff from 33 practices in Colorado over a period of two years. Of the 608 relevant and codable reports, issues of communications (about 71%), diagnostic testing (about 47%) and medication management (35%) were the mostly commonly cited factors.\(^10\)

Fischer et al.\(^32\) conducted a cross-sectional study of incident reports filed by eight non randomly selected primary care clinics in the midwestern United States between January 1991 and June 1996. The purpose of the study was to estimate the prevalence of, and describe the factors contributing to, adverse patient events. Approximately 3.7 adverse events were estimated to occur in every 100,000 clinic visits. Of the 35 adverse events reported, 83% were considered preventable medical incidents\(^11\) related to diagnosis (about 26% of all incidents), treatment (about 31%) and other issues (about 26%). Approximately 14% of the events attributed to medical safety issues resulted in permanent and disabling outcomes, and one resulted in death.

Gandhi et al.\(^36\) assessed the degree of preventability of patient safety incidents in a study of 181 malpractice suits involving alleged harm due to missed or delayed diagnosis. About 59% of cases involved serious harm and about 30% of all cases resulted in death. About 59% of cases involved a miss diagnosis of cancer with breast cancer and colorectal cancer being missed in 24% and 7% of all cases, respectively. Most events were attributed to one of more of four breakdown points: 1) the decision of which test(s) to order (about 55% of all cases), 2) the follow-up of the patient (about 45%), 3) communications with the patient (about 42%), and 4) the interpretation of the test(s) (about 37%). The primary causes of the events were judgment (about 79% of cases), vigilance or memory (about 59%), knowledge (about 48%), patient (about 46%) and information transfer (about 20%).

Hoffman et al.\(^45\) studied 188 incident reports sent anonymously to a German web based reporting system between September 2004 and January 2006. Approximately 73% of the reports involved process issues, while 26% involved issues relating to the knowledge and/or skill of providers. The process issues included treatment (indicated in about 33% of all reports), communications (about 13%) and investigation (about 9%) issues. About 42% of all incidents resulted in patient harm.

Kostopoulou and Delaney\(^21\) classified the patient incident reports from an observational study of five general practices in one urban county in the United Kingdom, using a taxonomy of cognitive and system factors. A total of 78 reports were analyzed, of which 27% involved patient incidents and 64% involved near misses. Of all the reported incidents, one resulted in a death, about 17% involved serious patient outcomes and about 76% had the potential for a serious patient outcome. Administrative concerns were the most frequently identified issue, contributing to about 26% of all concerns. About 90% of reports identified work organization as a contributing factor, in particular excessive task demands (about 47%) and fragmentation of services (about 28%).

Makeham et al.\(^60\) undertook a pilot project to identify and analyze the types of incidents reported by 23 Australian general practitioners and compare them with those reported by practitioners in Canada, the United Kingdom and the United States. The GPs were not randomly selected. They were contacted by the researchers and invited to participate based on the number of hours they spent in clinical practice,\(^12\) their computer literacy, and their access to a computer with a

\(^7\) To review the data abstraction tables of all included articles reviewed, please refer to the CPSI and BCPSQC websites.
\(^8\) Long term harm included minor, moderate and major consequences as well as death.
\(^9\) Some incidents had more than one contributing factor.
\(^10\) The study found that confidential reports were more likely to be complete anonymous reports.
\(^11\) An event was determined to be a medical error if it involved a diagnostic, treatment, preventive or other medical issue.
\(^12\) They had to spend at least 20 hours per week in clinical practice and be absent no more than two weeks over the study period.
CD-ROM and an appropriate operating system\textsuperscript{13} and to the Internet. Over the study period of six months,\textsuperscript{14} 435 incidents were reported. From these, 171 incident types were identified and a five-level taxonomy was developed. The results showed that in all four countries about 80\% of incidents were process issues,\textsuperscript{15} while about 20\% involved knowledge and skill.\textsuperscript{16} Approximately 30\% of the incidents resulted in patient harm. About 9\% of all incidents in Australia were deemed “very serious” by the reporting GPs, while 3\% of the incidents in the other counties were so labelled.

Makeham et al.\textsuperscript{62} developed a taxonomy to classify patient safety events and determined the frequency of those events based on 415 reports to the Threats to Australian Patient Safety study over a 12-month period in 2003. These reports were made by 84 volunteer GPs who were a random stratified sample of the GPs in New South Wales, Australia. A three-level taxonomy was developed and verified by the three investigators. The levels included: 1) type (process of healthcare or knowledge and skill); 2) theme (healthcare analysis, medications, other treatments and communication); and 3) descriptors (35 possibilities including patient record and filing concerns, issues in patient physical examination, medication concerns, etc.). Healthcare processes were implicated in about 70\% of all incidents, while issues regarding the knowledge and skills of providers were attributed to the remainder. Medication issues was the theme in about 20\% of all reports while diagnosis and management were the theme in about 12\% and 19\%, respectively.

McKay et al.\textsuperscript{63} reviewed significant event analysis (SEA) reports that were submitted over an 18-month period between 2005 and 2007 for the purpose of identifying ways to improve healthcare safety and quality. The majority of the reports were judged to be satisfactory analyses of the events; however, a significant minority were deemed unsatisfactory. In addition, since the reports were voluntarily submitted for peer feedback, they cannot be considered representative of all patient safety events. In the 191 reports reviewed, about 25\% of events resulted in patient harm and about 57\% had the potential for harm. The main causes of the incidents were healthcare professionals’ issues (indicated in about 33\% of reports), communication issues (about 30\%), misdiagnosis and/or diagnostic delays (about 23\%), administrative factors (about 17\%) and medication management (about 12\%).

Phillips et al.\textsuperscript{73} retrospectively studied malpractice claims for the purpose of describing the specialties, settings, severities, health conditions and causes of the claims. Files from the Physician Insurers Association of America malpractice claims data from 1985 to 2000 were peer-reviewed, and, in 5921 cases (23\% of all reviewed files), negligence was found, of which 68\% occurred in the primary setting. The incidents were attributed mainly to missed and delayed diagnoses (indicated in about 34\% of claims), failure to supervise or monitor (about 16\%), improper performance (about 15\%) and medication management (about 8\%).

Phillips et al.\textsuperscript{73} explored whether physicians, staff and patients would anonymously report medical errors and whether there were systematic reporting differences among these groups. The 10-week study involved 401 staff and clinicians at 10 family medicine clinics in the United States. The individuals were asked to routinely report errors they observed over the study period and to report every incident they observed on five specified days. In total, 717 reports were made involving 935 errors. The results showed that there was no significant difference in reporting rates between the staff members and the clinicians, each group making an average of 0.98 reports. Approximately 37\% reports were made on the five specified days. About 96\% of the reports involved process incidents that were not related to the knowledge or skill of the providers. Clinician reports were more concerned with medication and laboratory issues, while staff reports were more concerned with the stream of patients and communication issues. In total, approximately 51\% of incidents were considered serious to very serious in nature. An analysis of the reports showed that patients with complex health problems were more vulnerable to serious outcomes than other patients. Consequences of the events included issues related to health (about 23\% of all events), patient care (about 46\%) and time and/or money (about 24\%).

Rubin et al.\textsuperscript{83} developed a taxonomy based on the results of a pilot of an anonymous incident-reporting system that ran in June of 2002 in 10 general practices in northeast England. A total of 940 incidents were reported over a two-week period, relating to communications (implicated in about 30\% of incidents), prescribing (about 42\%), appointments (about 7\%), infrastructure (about 16\%), patient care (about 3\%) and other issues (about 2\%). The incident-reporting system was deemed acceptable by the majority (68\%) of respondents and was found to be “threatening” by about 8\%.

Wetzel et al.\textsuperscript{81} assessed the real and potential injury caused by adverse incidents based on a prospective study of incident reports and a retrospective study of patient charts. Five GPs in two general practices participated in the five-month study in 2006. Thirty randomly selected medical charts per GP were reviewed. Of the 4095 patients who

\textsuperscript{14} The study period was June to October 2001 in Australia, and June to December 2001 elsewhere.
\textsuperscript{15} Process errors include office administration, investigation, treatment, communication, payment, and staff management issues.
\textsuperscript{16} Knowledge and skill issues include inappropriate completion of a clinical task, misdiagnosis, delayed diagnosis, and incorrect treatment.
were seen during the study period, 31 adverse events were identified. About 35% were identified through the chart review, and the remaining by the GPs. No patient harm was discernable in about 48% of cases, while in 39%, 6% and 6% of cases symptoms worsened or lengthened, mental burden was affected and hospitalization was required, respectively. The main causes of the events were issues related to administration (about 32% of all incidents), communication (about 26%), treatment (about 23%) and diagnosis (about 19%).

Wetzels et al. undertook a prospective study of incident reporting by five general practitioners in two practices in the Netherlands over a five-month period in 2006. Five different methods were used to capture adverse events: 1) physician-reported events; 2) pharmacist-reported events; 3) a survey of patients; 4) a random sample of medical charts; and 5) a review of deceased patients' charts. Of the 68 identified events, about 40% were reported by patients, about 29% were reported by physicians, about 9% were reported by pharmacists, 16% were discovered by randomly chart review and 6% were found through a review of deceased patients' records. The main areas in which these events occurred were treatment (about 32% of cases), communications (about 27%), office administration (about 24%) and diagnosis (about 17%) of cases.

It is difficult to discern an overall message from the studies reviewed, because their research foci, specific topics, study methodologies, taxonomies and sources of data vary greatly. Moreover, the results of the studies were based on fairly small numbers of adverse events, ranging from 31 (Wetzels et al.) to 805 (Bhasale et al.). In addition, the majority of the studies relied on reports filed by physicians and did not include the clinicians' or administrative staff's perspectives, or, more importantly, the perspectives of the patients. Physician-reported events tend to focus on human errors, while patients tend to focus on communication issues, interpersonal care and issues related to transition through the levels of care (National Health Service). The findings from these studies are therefore of questionable relevance to the Canadian healthcare system and cannot serve as the basis for an estimate of the incidence of patient safety issues in primary care in Canada.

**MISSED OR DELAYED DIAGNOSES**

Patients accessing primary care services may arrive with a host of symptoms of which some may be specific while others are non-specific. The physician must carefully examine all pieces of the sometimes extensive information, as well as discern their combined messages, before deciding on a probable or differential diagnosis, course of investigations, treatment or non-treatment, referral to specialists, and the interpretation of the consultants' findings. A missed or delayed diagnosis may be related to lack of clarity at any point in this stream of action: in the way the patient communicates symptoms or concerns; in test results and knowledge of their specificity and sensitivity; in outcomes of initial treatment; in the patient's adherence to suggested treatments and follow-up; and in the provider's knowledge, experience and ability to transfer information correctly to the patient. Studies estimate that over 15% (Hickner et al.) and up to 28% (Bhasale) of adverse events in primary care are related to the diagnostic process, with cancer being the condition most likely to have a delayed diagnosis (Gandhi et al.). As would be expected, delayed diagnosis is also more frequently associated with uncommon diseases characterized by co-morbidities and/or by symptoms that either mimic more banal illnesses or are non-specific (Kostopoulos and Delaney).

In a study of diagnostic delays across the healthcare system, about 28% of delays resulted in death, permanent disability or a life-risking incident. About 41% of delays resulted in a temporary injury, hospitalization, a high level of care and/or an invasive procedure (Schiff et al.). Within primary care, two studies have investigated the impact of diagnostic delay. One study found the potential for long-term harm in about 58% of all diagnostic delays, of which 43% result in minor harm (Bhasale). Another study found that patient harm occurred in at least 18% of all diagnostic incidents (Hickner et al.). Physical injury is not the only impact of these adverse events. Hickner et al. found that diagnostic delays may result in lost time and/or money (about 22%), delays in care (24%), pain and/or suffering (about 11%) and adverse clinical consequences (about 2%).

Several studies have estimated the rate of misdiagnosis and delayed diagnosis among all adverse medical events. Estimates range from 12% (Makeham et al.) to 34% (Phillips et al.). Since delayed diagnosis and misdiagnosis can have a dramatic impact on an individual's prognosis and well-being, it should not be surprising that they are implicated in the majority (about 59%) of malpractice suits (Gandhi et al.).

Three studies specifically explored the causes of diagnostic delays. The studies by Bhasale and Hickner et al. were based on voluntary reporting of adverse events in physicians' records, while the study by Gandhi et al. was based on a review of malpractice suits. All of the studies found that there was usually more than one factor that contributed to the occurrence of an adverse diagnostic event.
Bhasale1 analyzed reports of potentially harmful events by Australian general practitioners participating in a pilot incident-monitoring project. Of the first 500 anonymously reported incidents, about 28% included a diagnostic event. The judgment and skill of providers were the most common factors in diagnostic mishaps, accounting for about 44% and 40% of all incidents, respectively. A patient’s seeking another diagnostic opinion without informing the attending provider was a factor in 23% of all cases. Ineffective communication between the patient and the providers was implicated in about 21% incidents. The actions of others (for example, the collection of specimens by other providers) were implicated in 21% of all events. Inadequate follow-up and monitoring of the patient were implicated in about 13% of the cases.

Hickner et al.44 described the types and results of diagnostic process events anonymously reported by 243 family physicians and staff at eight practices in the American Academy of Family Physicians National Research Network. Four of the practices were rural, three were urban and one was in a suburban area. In total, 590 reports were filed relating to 966 processing concerns. The incidents occurred during test ordering (about 13% of all incidents), test implementation (about 18%), reporting to the physician (about 25%), physician response (about 7%), patient notification (about 7%), administration (about 18%), communication (about 6%) and other stages (about 8%). At least 18% of the events resulted in some patient harm, while 54% of incidents resulted in no harm. The impacts of the incidents included lost time and money (about 22% of cases), delays in care (about 24%), pain and/or suffering (about 11%) and adverse clinical consequences (about 2%). Adjusting for the provider type, the error type and the patient’s age, the study found that minority patients (black or Hispanic) were more likely to suffer harm or adverse impacts than white, non-Hispanic patients. The patients’ minority status could be an indicator of cultural and language misunderstanding between the clinician and the patient.

Gandhi et al.36 investigated the factors that contributed to missed and delayed diagnosis in 181 malpractice claims from four insurance companies. The most common breakdowns in the diagnostic pathway (and their prevalence) were the choice of diagnostic test (about 55% of occurrences), the follow up of the patient (about 42%), the examination of the patient (about 42%) and the interpretation of the results (about 37%). The judgment of the provider was implicated in about 79% of these breakdowns. The study found that, in the majority of cases, more than one breakdown and more than one provider contributed to a missed or delayed diagnosis. However, the generalization of these results should be cautioned against. Malpractice suits generally have an over-representation of incidents that have caused serious injury and an under-representation of near-misses.

**MEDICATION MANAGEMENT**

Medication incidents have been found to contribute to a large percentage of adverse events in primary care (Velo and Muniz19). Although a small percentage of medication errors actually reach the patient and result in clinically significant results, those that do can have considerable consequences both to patients’ health and in the cost to the healthcare system. Approximately one in every six patients hospitalized in Canada is admitted due to a preventable drug-related morbidity (Samoy et al.83). About 8%, 84%, 7% and 1% of these cases are rated as mild, moderate, severe and fatal, respectively (Samoy et al.86). Based on data from the Canadian Institute for Health Information (Canadian Institute for Health Information1418), the total cost of these preventable hospitalizations is about $2.6 billion per year.

Adverse medication events can occur due to errors in the diagnosis, the selection of the medication, the writing of the prescription, the interpretation of the prescription by the pharmacist, the dispensing of the medication, the labelling of the medication, the patient’s understanding of the timing, dosage, frequency and method of delivery, and the compliance of the patient (Garfield et al.9). As a result of these factors, Garfield et al.9 estimates that fewer than 23% of patients achieve the optimum benefit from their medication.

The three main medication management concerns are as follows:
1) general prescribing practices; 2) inappropriate prescribing to older patients; and 3) dispensing issues at pharmacies.

**General prescribing practices**

Approximately 14% (Phillips et al.73) to 50% (Bhasale6) of adverse events are related to medication management. In this section, the nine studies that specifically investigated the issues related to adverse events in prescribing are reviewed.

Gandhi et al.17 did a prospective study of adverse drug events involving patients of two hospital-based and two community-based adult primary care practices in Boston, Massachusetts. Between September 1999 and March 2000, 55% of the 1202 patients opted to participate and a total of 181 medical

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17 Some incidents had more than one contributing factor.
18 The provider was labeled as a staff member or a clinician.
19 The errors cited included test ordering, administration, test implementation, etc.
20 Kuo et al. (2008) studied 194 error reports from 52 practices in the United States. The authors found that about 5.5% of adverse drug events required hospitalization.
21 Garfield et al. (17) found that about 5% of hospital admissions in the UK were attributed to preventable medication-related morbidity. Extrapolating that finding, the estimated cost of such hospitalizations in Canada is about $3.53 billion per year. This calculation is based on the assumption that the rate of adverse drug events and the cost structure in Canada is the same as those in the United Kingdom. Costs have been converted to Canadian dollars on a per capita basis. The cost in Canadian dollars was estimated based on the rate of exchange between the British pound and the Canadian dollar on April 30, 2010 (1 CAD = 0.643 GBP).
events were reported, 162 of them involving medications. The authors estimated the rate of adverse drug events at 27 in every 100 patients. About 13% of the drug events were deemed to have serious consequences, including symptomatic heart slowness22, symptomatic low blood pressure23, and gastrointestinal bleeding. About 28% and 11% were deemed ameliorable and preventable, respectively. Of the ameliorable events, 63% were related to the physician response to drug-related symptoms and 37% were related to patient’s communication of their symptoms. Results showed that the patients’ age, sex, language and education level as well as the physician’s years in practice and whether computerized prescribing was used were not significantly associated with adverse events. Only the number of drugs taken was significantly related to the probability of an adverse event.

Kennedy et al.24 developed and implemented a system to capture prescribing concerns reported by pharmacists to 103 prescribers, nurses, managers and office staff working in seven primary care offices in Vermont. The voluntary reports were collected between June 2004 and July 2005 and then classified by severity and type of the issue24. Of the 216 errors reported, about 90% did not reach the patient. Of the cases that did reach the patient, about 83% resulted in no harm while about 17% caused temporary harm. About 55% of all incidents were commissions and about 30% concerned the strength of the medication. The drug classes most frequently involved in the reports were antidepressants, narcotics and antihypertensive medications. This may simply reflect the frequency with which these medications are prescribed and not the difficulty in prescribing them. Although almost 90% of those interviewed said they were willing to continue reporting after the study ended, none did.

Kuo et al.25 analyzed the results of two incident-reporting studies conducted by the American Academy of Family Physicians National Research Network in order to identify common types of medication concerns and estimate their frequency and preventability. One study included 42 family physicians in 42 practices reporting over a period of 20 weeks in 2000. The second study included 401 physicians and staff from 10 family medicine practices reporting over a period of 10 weeks in 2003. About 15% of the 1265 reported medical incidents included medication concerns related to prescribing (70%), administration (10%), documentation (10%), dispensing (7%) and monitoring (3%). About 41% of the medication issues were caught before they reached the patient. Of these, pharmacists caught 40%, physicians or nurses caught 24%, and 17% were caught by the patients themselves. The authors estimated that 57% of all medication issues could be prevented by using electronic prescribing and monitoring tools.

Nicholson et al.26 characterized adverse medication events based on a prospective sample of reports from four adult primary care practices in Boston, Massachusetts. Twenty-four internal medicine physicians and 661 patients agreed to participate in the seven-month study. Only two physicians reported no adverse events. A total of 2134 scripts were written — an average of about 89 per physician. The rate of adverse events ranged from 1% to 12% (mean 3%) across the 22 physicians who reported issues. About 34% of all events were attributed to three physicians with the highest incident rates. The severity of the incidents ranged from sleep disruptions to gastrointestinal bleeding. The authors concluded that system-wide initiatives are required to reduce the incidence of adverse drug events.

Sayers et al.27 documented and analyzed issues involving prescriptions written by 28 general practitioners and filled at 12 community pharmacies in the UK over a three-day period in November of 2003. A total of 3948 prescriptions were filled for 8686 drug items, of which 12.4% and 6.2%, respectively, were identified as involving at least one issue. About 72.9% of the issues were minor28, while 24.7% were considered major nuisances29 and 2.4% were considered potentially serious27. The most common problem was a lack of proper instructions.

Shah et al.30 described prescribing incidents involving scripts written by 23 GPs in three practices in the UK. The two-month prospective study identified concerns with approximately 7.5% of the 37,821 scripts presented to the three community pharmacies located near the practices. The main concerns were that the instructions for use were insufficient or illegible (about 36% of all incidents), the medication was not named (about 18%), the strength was not specified (about 9%), repeat prescriptions were on separate scripts (about 9%) and the recommended quantity was either not specified or not legible (about 8%).

Singh et al.31 performed a retrospective review of patient records at six primary care practices32 using a 39-item trigger tool. Only records of patients who had a cardiovascular condition and were over the age of 65 years were included. About 50% of the 1289 records reviewed had one or more triggers. Of those records, about 60% were randomly

22 Heart slowness is defined as an adult heart rate of less than 60 heart beat per minute. The medical term is bradycardia.
23 The medical term is hypertension.
24 Error type was multifaceted. It included: whether there was commission, omission, no error or if the error is unknown, and, if applicable, the type of prescription (medication, dosage, route, etc.) and the conditions that led to the error (ambiguous symbols, illegibility of handwriting, etc.).
25 Minor nuisances were those that required the pharmacist to make a professional decision prior to dispensing the prescription. No contact with the prescriber was required (Neville et al(59)).
26 Major nuisances were those that required the pharmacist to contact the prescriber in order for the prescription to be dispensed. An illegible prescription was considered a major nuisance (Neville et al (59)).
27 Potentially serious incidents were those in which dispensing the drug would have been dangerous to the patient. These included higher than recommended dosages of dangerous medications (Neville et al(59)).
28 One site was in a rural area and the other sites were in urban areas.
selected for further evaluation. Of the 908 triggers in the 383 charts, about 26% were adverse drug events, of which about 40% were considered preventable. About 30% of the preventable events were considered severe. The most frequent triggers were medication stops, hospitalizations and emergency room visits.

Steven et al.97 identified and described potentially harmful incidents reported anonymously by 623 Australian GPs between 1996 and 1998. A total of 1136 adverse medication events were detailed29. The main factors contributing to the events were drug contraindications (about 21% of all events), other inappropriate or premature use (about 39%), requisition and/or storage (about 20%) and patient adherence (about 20%).

These nine studies were based on reports by providers, patient and pharmacists and on reviews of medical records. They all appear to agree that adverse drug events due to prescribing is common (Gandhi et al.,37 Kuo et al.,53 Makeham et al.,60 Nicholson et al.,58 Sayers et al.,88 Shah et al.,91 Singh et al.90 and Steven et al.97). However, most incidents seem to be minor (Kennedy et al.47 and Sayers et al.88) or may not reach the patient (Kennedy et al.47 and Kuo et al.53) because they are caught by the prescriber, their support staff, the issuing pharmacist or the patient before causing any harm.

Two studies assessed the willingness of practitioners to respond to feedback suggestions related to their prescribing (Soendergaard et al.94 and Taylor et al.101). Soendergaard et al.94 assessed medication issues and other quality issues identified by a pharmacist who was employed 20 hours per week from June 2002 to November 2003 by three GPs at a general practice in Denmark. Of the 40 reviews completed, 103 medication-related concerns were identified. About 77% of the pharmacist’s recommendations were accepted and implemented by the physicians before the end of the study. Taylor et al.101 described medication alerts at an urban community of care centre involving 32 pharmacies and 28 physicians over the nine-month period from June 2003 to February 2004. Participating physicians used a personal digital assistant (PDA) that allowed pharmacies to receive the scripts electronically. The PDA triggered an alert if there was a potential problem with the script. Alerts were triggered in about 29% of the 22,419 scripts written and resulted in about 14% of those scripts being revised. The reasons for the alerts were medication-disease contraindications (41% of all alerts and 14% revised), medication interactions (24% and 14% revised), potential toxicity (16% and 13% revised), drug duplication (11% and 16% revised), contraindications for patient’s age (4% and 8% revised), potential dosage issues (3% and 23% revised) and other issues (1% and 21% revised).

29 In addition, there were 16 and 404 medication events that involved self-harm and issues during the therapeutic use (including side-effects and previously unknown allergies).

Table 2:
Outcomes of adverse medication events /medication incidents

<table>
<thead>
<tr>
<th>Percentage of adverse medication events /medication incidents</th>
<th>Gandhi et al.37</th>
<th>Kennedy et al.47</th>
<th>Kuo et al.53</th>
<th>Makeham et al.60</th>
<th>Sayers et al.88</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reached the patient</td>
<td>10%</td>
<td>59%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caused harm</td>
<td></td>
<td></td>
<td></td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td>Caused, or potentially caused, serious harm</td>
<td>13%</td>
<td>9%</td>
<td>2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ameliorable</td>
<td>28%</td>
<td></td>
<td></td>
<td></td>
<td>40%</td>
</tr>
<tr>
<td>Preventable</td>
<td>11%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Prescribing to older patients

Some patient groups appear to be more vulnerable to medication issues than others. Patients who have co-morbidities are more susceptible to adverse events due to a variety of factors, such as the frequency of their contact with the healthcare system, the number of medications they take and their frailty. These vulnerable populations include older patients, especially older female patients, and younger patients with complex health conditions.

Older patients are apt to take more medications and interact more frequently with the healthcare system than other cohorts because of their higher rate of disability. In 2006, about 43% of all individuals over the age of 65 had a disability, compared to 12% of those between 15 and 64 years of age (Statistics Canada). Long-term disability is significantly more prevalent among women (about 23%) than among men (about 20%). Women also have a higher prevalence of co-morbidities than men. Adjusting for age, chronic conditions, household income, education and smoking, women have a 7% higher probability of disability than men. Exacerbating these differences is that, among those with disabilities, women tend to have lower income levels and employment rates, are less likely to be married and have less social support than men. Each of these factors adds to the vulnerabilities of women with disabilities (DesMeules et al.).

Studies have shown that age increases the probability of medication misadventures. A Danish study of older patients taking five or more medications found that the majority of individuals had one or more inappropriate medications (Bregnhoj et al.). Eleven studies reviewed for this background paper analyzed the incidence of inappropriate prescribing to older patients. Bregnhoj et al. assessed the prevalence of potentially inappropriate prescribing (PIP) to patients 65 years of age and older by GPs in the county of Copenhagen, Denmark, over a three-month period. All GPs in the county were invited to participate and about 15% accepted, along with 212 of their patients. Of the 1621 medications prescribed, about 40% were deemed inappropriate, according to the Medication Appropriate Index. About 95% of the patients used one or more medications that were contraindicated (about 12%), ineffective (about 6%), of the wrong dosage (about 7%), included the wrong instructions (about 1%), had significant drug-drug interactions (about 1%), had clinically significant drug-disease interactions (about 9%), were duplications (about 3%), were prescribed for an inappropriate duration (17%) or were not the least expensive option (about 27%).

Brekke et al. estimated the prevalence of PIP to patients 70 years of age and older by GPs in Norway. The 2002 Beers Criteria, Swedish recommendations and a Delphi panel were each used to assess the appropriateness of prescriptions over a sample 12-month period. Prescription records were obtained from Norwegian Prescription Data, a database that links detailed information on drugs with information on prescribers. A total of 454 GPs with a combined older-patient population of 85,836 participated in the study. The mean age of the patients was about 79 years, and 66% were female. About 18% of the patients were prescribed at least one potentially inappropriate medication. Aging of the GP and practicing alone were factors significantly related to the probability of inappropriate prescribing. The sex of the patient was not significant.

Buck et al. undertook a cross-sectional analysis of the prevalence of PIP to patients 65 years of age and older at two primary care practices. The retrospective study included the electronic records of active patients as of April 1, 2006. According to the Beers 2002 and the Zhan 2001 criteria, about 23% and 17%, respectively, of the 61,251 patients were prescribed at least one potentially inappropriate medication. Eight medications accounted for the majority of the issues. Being female, taking more than five medications and seeing a provider frequently were significantly related to the PIP.

De Wilde et al. examined the trend in PIP to patients 65 years of age and older in the UK between 1994 and 2003 using the Beers 2002 criteria. The retrospective study included 131 general practices with about 162,000 registered patients of the appropriate age. The study suggested that the rate of PIP has changed little over time. About 33% and 32% of older patients were dispensed a drug that was potentially inappropriate in 1994 and 2004, respectively. In both 1994 and 2003, approximately 21% of older patients were issued a medication that was potentially “high risk.”

Goulding analyzed the trends in inappropriate medication use in patients aged 65 years and older between 1995 and 2000. The retrospective study used survey data from office-based physicians and outpatient departments and defined inappropriateness using the Beers 1997 and the Zhan criteria. According to the Beers criteria, one or more inappropriate medications were prescribed during about 8% of ambulatory patient visits in both 1995 and 2000. According to the Zhan criteria, one or more inappropriate medications were prescribed during 4% of the ambulatory patient visits in both 1995 and 2000. All else being equal, the probably of a PIP was higher for female patients and for patients taking multiple medications.
Howard et al. estimated the percentage and predictors of PIP. The 29-month study was based on data from 48 randomly selected practices in southern Ontario and included 777 randomly selected patients who were over the age of 65 years and took five or more medications. The study also included a cross-sectional analysis of patients’ prescription data from the provincial insurance data over a 12-month period. The determination of the appropriateness of the prescriptions was based on the Beers 1997 criteria. About 16% of the participants had at least one potentially inappropriate prescription. All else being equal, women were more likely than men to be provided a PIP.

Rigler et al. conducted a retrospective cohort analysis to characterize the patterns of inappropriate medication use and duration among ambulatory patients aged 60 years and older. These patients were a random sample of beneficiaries for whom data on prescription drug coverage was available for the period from May 2000 to April 2001 in the Kansas Medicaid database. The Beers 1997 criteria were used to identify the one-year prevalence of the prescription of unconditionally inappropriate medications. The results showed that inappropriate medication use occurred in 21% of the cohort. A small number of drugs (analgesics, antidepressants, antihistamines, muscle relaxants and oxybutynin) constituted the majority of the issues.

Ryan et al. undertook a prospective study of 500 patients from a single Irish town who were 65 years of age or older. The purposes of the study were to compare the rates of inappropriate prescribing as estimated by two validated screening tools (the Beers 1997 criteria and the Improved Prescribing in the Elderly Tool [IPET]) and to estimate the cost of inappropriate prescribing. With the Beers Criteria, about 13% of patients were deemed to be given an inappropriate prescription at a total cost of about $1,128.38 per month. With the IPET, about 10% of patients were deemed to have been provided with an inappropriate prescription at a total cost of about $521.85 per month.

Ryan et al. retrospectively reviewed the health records from three general practices in one region of Ireland to estimate the incidence of inappropriate prescribing using three different tools. The Beers 2002 criteria and two new processes (Screening Tool of Older Person’s Prescriptions [STOPP] and Screening Tool to Alert doctors to Right Treatment [START]) were used. The study included 1329 patients, all of whom were at least 65 years of age (mean age 74.9 ± 6.4 years), and about 61% of whom were women. A total of 6684 medicines were prescribed. The Beers’, STOPP and START tools estimated that about 18%, 21% and 23% of the patients were provided with potentially inappropriate prescriptions.

Sstraand et al. characterized inappropriate medication prescribing for patients 65 years of age and older by 156 GPs in Norway in November 1988 and November 1989. Inappropriateness was based on explicit measures that included the Beers 1997 criteria. About 72% of all scripts written were for repeat prescriptions. About 14% of all 16,774 scripts had at least one potentially inappropriate issue.

van der Hooft et al. described the frequency of, and change in, inappropriate prescribing to patients over the age of 65 years in the Netherlands between 1997 and 2001, based on the 1997 and 2002 versions of the Beers Criteria. Patient charts from 150 general practices were used for this study. The sample size ranged from 18,030 patients in 1997 to a high of 29,605 patients in 1999. The mean age of the patients was about 75 years, about 60% were women, and about 85% were prescribed one or more medications. The annual risk per patient of being prescribed one or more inappropriate prescriptions over the study period ranged from 17% to 19% using the 1997 Beers Criteria and from 19% to 20% using the 2002 Beers Criteria. The trend in inappropriate prescribing increased over the study period according to the 1997 version of the Beers Criteria, but no trend occurred according to the 2002 version. This difference was related to a change in the Beers Criteria in the medications to be avoided in the presence of co morbidities.

A summary of the evidence on PIP can be found in Table 3. All but one of the 11 studies used a version of the Beers Criteria as one of the methods to gauge the appropriateness of prescribing. Originally developed in 1991, the Beers Criteria include a list of potentially inappropriate medications for older adults created through the consensus of a panel of experts. It has been helpful in reducing the medication issues for older patients. The list was revised in 1997 and 2002 to incorporate new drugs and remove older drugs that have been taken off the market (Fick et al.). Among the studies that use a version of the Beers Criteria, the median prevalence of potentially inappropriate reported is about 18%, from a range of 8% to 32%. Further, Ryan et al. estimated the medication cost of inappropriate prescribing to patients who were 65 years of age or older to be at least $521.85 to $1128.38 per month.
Table 3:
Estimated percentage of the population affected by potentially inappropriate prescribing

<table>
<thead>
<tr>
<th>Authors</th>
<th>% of Affected Population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥60 years</td>
</tr>
<tr>
<td>Brekke et al.</td>
<td>18%</td>
</tr>
<tr>
<td>Bregnhoj et al.</td>
<td>40%</td>
</tr>
<tr>
<td>Buck et al.</td>
<td>23%</td>
</tr>
<tr>
<td>de Wilde et al.</td>
<td>32%</td>
</tr>
<tr>
<td>Goulding</td>
<td>8%</td>
</tr>
<tr>
<td>Howard et al.</td>
<td>16%</td>
</tr>
<tr>
<td>Rigler et al.</td>
<td>21%</td>
</tr>
<tr>
<td>Ryan et al.</td>
<td>13%</td>
</tr>
<tr>
<td>Ryan et al.</td>
<td>18%</td>
</tr>
<tr>
<td>Straand et al.</td>
<td>14%</td>
</tr>
<tr>
<td>Van der Hooft et al.</td>
<td>19%</td>
</tr>
</tbody>
</table>

Note: All studies use a version of the Beers Criteria except Bregnhoj et al.

One study, Bregnhoj et al., defined inappropriateness based on the Medication Appropriateness Index (MAI), which includes the relative expense of the medication. If the medication is not the least expensive alternative, it is deemed “inappropriate”. Bregnhoj et al. found that 27% of the drugs prescribed to patients 65 years of age and older were not the least expensive alternative. Since other studies did not include this parameter, the Bregnhoj et al. study found the highest incidence of PIP at 40% of all prescriptions.

Four studies considered socio-demographic factors that might be associated with the prevalence of PIP. Of these, three studies found that women were significantly more likely to be issued a potentially inappropriate prescription (Buck et al., Goulding, and Howard et al.). Polypharmacy was found to be positively related to inappropriate prescribing in two studies (Goulding and Buck et al.). The probability was also positively related to the age of the GP (Brekke et al.), the GP practicing alone (Brekke et al.), and number of visits the patient made to the GP (Buck et al.).

Inappropriate prescribing to older patients appears to be a significant issue. This vulnerable population may have more adverse events than are captured in these studies because they do not account for the potential outcomes of inappropriate medication use such as hospitalizations and falls that cause fractures. Women appear to be at an elevated risk, perhaps due to their higher incidence of disability and social exclusion.

**Dispensing issues at pharmacies**

Ashcroft et al. characterized medication incidents at 35 community pharmacies in the UK. The four-week prospective study documented concerns about 0.25% of the 125,395 presented scripts. About 85% of the incidents were caught prior to reaching the patient. The most common concerns were related to selection of the medication (60% of the incidents), labelling issues (about 33%) and bagging issues (about 7%). The causes of the incidents included misreading of the script (about 25%), selecting a medication with a similar name (about 17%) or similar packaging (about 8%), and dispensing a previously filled medication (about 11%). There were about four incidents that reached patients and 22 near misses for every 10,000 items dispensed. Franklin and O’Grady characterized dispensing incidents in 11 community pharmacies in the UK using the Delphi technique, and evaluated the probable impact of three different screening tools: 1) a pharmacy-based standalone system; 2) a linkage to patient medical records; and 3) the electronic transfer of prescriptions. Of
the 2859 issued items, about 2% contained content and/or labelling issues, and about 67% of these concerns were minor. A pharmacy-based system was expected to catch about one in every five content issues and few labelling issues. If the pharmacies had access to patients’ medical records, about 25% of the content and labelling issues could be prevented. If the prescribers sent prescriptions to the pharmacies electronically, about 50% of the content and labelling issues could be prevented. Overall, about 22% to 60% of the moderate incidents could have been avoided, depending on which system was implemented.

Knudsen et al. investigated the reasons for adverse drug events that reached patients in 40 randomly selected community pharmacies in Denmark. Of the 401 incidents that reached patients, about 59% were related to transcription issues. Of the 234 incidents for which severity could be assessed, about 5% resulted in serious harm to the patient. About 22% of the events included issues relating to the strength of the medications, while 20% related to dosage. The authors suggested strategies for reducing the number of incidents. These include eliminating handwritten scripts, implementing pharmacist-led medication reviews at hospitals, widening the use of electronic transfer of scripts from prescribers to pharmacists, displaying a list of common dispensing issues at every pharmacy, and double-checking all prescriptions prior to their issue to patients.

Warner and Gerrett classified medication management issues at 17 community pharmacies in southern Derbyshire, UK, based on a results of a piloted diary-based reporting study that lasted 104 months. Of the 485,940 prescribed medications, 0.2% raised concerns. Pharmacists reported the majority of issues (about 72%). About 23% of the events were recognized after the medications were dispensed. About 70% of the events involved dispensing issues, while about 24% were related to prescribing concerns, 25% to the strength and form of the medication, and 11% to an incorrect medication being either potentially or actually issued.

These four studies appear to suggest that dispensing issues at pharmacies are not rare. However, three studies reported a very low incident rate, from 0.2% (Warner and Gerrett) to 7.5% (Franklin and O’Grady) of all prescriptions.

Table 4: Estimated percentage of prescription concerns

<table>
<thead>
<tr>
<th>Percentage of issues</th>
<th>Warner and Gerrett</th>
<th>Franklin and O’Grady</th>
<th>Ashcroft et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.20%</td>
<td>≤ 4%</td>
<td>0.25%</td>
<td></td>
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</tbody>
</table>

**ACTIONS TAKEN TO ADDRESS PATIENT SAFETY RISKS IN PRIMARY CARE**

The literature search on actions taken to address patient safety risks in primary care resulted in the identification of 1323 citations. After titles and abstracts were screened, 87 references potentially relevant to the question were selected for further examination.

**Figure 3:** Flow diagram for the selection of studies on actions taken to address patient safety risks in primary care

- Total number of citations retrieved from literature searches (electronic and grey literature searches) N = 1323
- Articles retrieved and evaluated in full for inclusion N = 87
  - Articles included N = 16
  - Articles excluded N = 71
  - Multiple publications = 1
  - Unique studies included N = 15
- Reasons for exclusions
  - Did not meet study design criteria = 33
  - Unable to retrieve within time frame = 15
  - Not primary research = 13
  - Did not report on outcomes of interest = 5
  - Not primary care setting = 3
  - Not on actions taken = 1
  - Not conducted in a country from the list = 1

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35 A serious harm included outcomes for which hospitalization might be necessary.
36 Knudsen et al. did not report on incident rate, focusing only on errors that reached the patient.
Fifteen studies met the selection criteria for the question on the types of actions taken to address patient safety risks in primary care. The following sections summarize the findings from these studies. Fourteen of the 15 studies focus on strategies for improving medication management, such as medication reviews, interactive educational media and materials, and technology-assisted prescribing. Another study explored the use of SEAs to improve care in general practice.

Bergvist et al. conducted a non-concurrent prospective cohort study to evaluate the impact of improving the quality of the discharge summary on reducing medication issues in the transition from hospital to primary and community care. Patients discharged to community care from a hospital in Skane, Sweden, who were 65 years of age and older were eligible for inclusion. The 63 patients in the control group were enrolled from September to December 2005, while the 52 patients in the intervention group were enrolled from March to December 2006. The intervention consisted of having pharmacists review and provide feedback to physicians on the discharge summary prior to patient discharge, while the control group received no intervention. The main outcome was reduction of medication issues, which was determined by comparing the medication list from the discharge summary with the first medication list used in community care. The number of medication issues per patient was significantly lower in the intervention group. Similarly, the proportion of patients with any medication issue was lower in the intervention group; however, this result was not statistically significant. The authors concluded that review and feedback on issues in the discharge medication report reduced medication issues during the transition from hospital to primary and community care.

Bregnhoj et al. conducted a randomized controlled trial (RCT) to determine the effect of combined or single educational interventions on the prescribing behaviour of general practitioners. The study was conducted in primary care practices in the county of Copenhagen, Denmark. A total of 212 patients over the age of 65 who were exposed to polypharmacy participated in the study. Forty-one general practitioners were randomized to one of three intervention groups: 1) a combined intervention consisting of an interactive educational meeting regarding polypharmacy in the elderly, along with pharmacologist/pharmacist feedback on participating patients’ medication; 2) an educational meeting alone; or 3) no intervention. Data on prescriptions was collected over a three-month period and assessed using the Medication Appropriateness Index. There was significant improvement in medication appropriateness and a decrease in the number of medications in the combined-intervention group, but no change in the single-intervention and control groups. The authors concluded that a combined intervention consisting of an interactive educational meeting and a pharmacist’s recommendations for specific patients can improve the appropriateness of prescribing among elderly patients exposed to polypharmacy.

Fick et al. examined the impact of an integrated decision-support service on the frequency of prescribing potentially inappropriate medications (PIMs) for older adults in a randomized controlled trial. The study was conducted in primary care practices in the United States. A total of 355 primary care physicians were randomly assigned to either: 1) a decision-support service, in which physicians received an educational brochure listing PIMs, a list of alternative medications and a letter specifying which patients were currently receiving PIMs; or 2) no intervention. Physicians in the intervention group were invited to report any changes in PIM prescriptions or actions taken using a fax-back form. Approximately 71% of physicians in the intervention group who prescribed PIMs submitted at least one form reporting an inappropriate medication, of which 15% indicated that PIMs had been changed to more appropriate alternative medications. Outcomes for the no-intervention comparison group were not reported in the study. The authors concluded that this integrated decision-support service is a low-cost, replicable system for contacting and educating physicians on medication issues in older adults.

Ghandhi et al. conducted a prospective cohort study to investigate the effect of computer prescribing on the rate of medication prescription issues in four adult primary care practices in the United States. Twenty-four internists participated during the four-week period of the study. Two of the four practices used basic computerized prescribing, which consisted of printed prescriptions, required fields and non-mandatory default doses, while the remaining two practices used handwritten prescriptions. Outcomes of interest were the number of medication issues and potential adverse drug events. While the rates of prescription issues and of potential adverse drug events were both lower in the computerized prescribing group, the difference between groups was not statistically significant (4.3% versus 11.0%, p = 0.31; 2.6% versus 4.0%, p = 0.16). The authors concluded that basic computerized prescribing systems may not be sufficient for reducing prescription issues.

MacDonald et al. conducted a controlled clinical trial to examine the efficacy of a home delivery service for essential dietary products prescribed for patients with inherited

37 To review the data abstraction tables of all included articles reviewed, please refer to the CPSI and BCPSQC websites.
metabolic disorders. A total of 62 patients were recruited from the West Midlands region of the UK. Patients were allocated either to the home delivery service or to continuing in the traditional system for a period of 12 months. In the home delivery intervention, a coordinator contacted patients’ parents each month to determine their stock levels of essential dietary products and then acquired a prescription directly from the physician. Products were delivered according to a previously determined schedule. In the traditional system, patients or their parents requested prescriptions from their physician on an ad hoc basis, and prescriptions were either sent directly to the local pharmacist or taken to the pharmacist by patients. Outcomes of interest included the number of protein-substitute issues, delayed receipt of products and median change in blood phenylalanine concentrations. There were significant differences favouring the home delivery service group in the number of issues related to protein substitution and the flavour of the protein substitute (1 versus 12, p = 0.01; 1 versus 11, p = 0.03). One patient in the home delivery group experienced a delay in delivery of products, compared to 16 patients in the traditional group (p = 0.001) who experienced delays. There was no significant difference in the median change in blood phenylalanine concentration between the groups. The authors concluded that the long-term use of a home delivery system is effective and more safe and reliable than the traditional system.

Midlov et al. conducted a non-concurrent, retrospective cohort study to investigate the impact of a discharge medication report on the number of medication issues when elderly patients transfer from hospital to primary care. The study was conducted in seven wards at the Lund University Hospital in Sweden. Eligible patients were 65 years and older and received their medications from a nurse in their home or nursing home subsequent to hospital discharge. The 179 patients in the control group were discharged between September and November 2003 or February to March 2004, while the 248 patients in the intervention group were discharged between September and November 2004 or February to March 2005. A standard discharge summary was prepared for patients in the control group. In addition to the standard discharge summary, hospital physicians completed a medication report for patients in the intervention group, which described all medication changes during the hospital stay and the reasons for these changes. This medication report was sent to the general practitioner and the community or nursing home nurse and given to the patient. The primary outcome of interest was the number of medication issues that occurred in the transition from hospital to primary care. The proportion of patients with at least one medication issue was significantly different between the groups, favouring the intervention group. Similarly, the proportion of issues considered of moderate or high risk to the patient was significantly lower in the group with the medication report. Three months after discharge, the number of patients requiring medical treatment as a result of medication issues was significantly lower in the intervention group, as was the risk of medical consequences. The authors concluded that the medication report is effective in reducing medical issues as patient care transitions from hospital to primary care settings.

O’Connor et al. assessed the impact of a simulated physician learning intervention on the safety of diabetes care in an RCT. The study was conducted in 18 primary care practices in the United States. A total of 57 primary care physicians, including 25 family medicine and 32 internal medicine physicians, participated in the study. Physicians were randomly allocated to one of three study groups: 1) no intervention; 2) a simulated physician learning intervention, in which physicians were presented with three clinical scenarios and asked to conduct virtual patient-physician encounters for the management of each case; and 3) a simulated physician learning intervention combined with feedback from a physician opinion leader who observed the physicians as they completed the virtual patient management. Physicians receiving the simulated learning (groups 2 and 3) subsequently engaged in fewer risky prescribing behaviours compared to the no-intervention group (p = 0.03). In addition, physicians in group 2 achieved slightly better glycemic control in their patients, compared with groups 1 and 3. There was no difference between the groups in lipid management and intensification of glucose-lowering drugs. The study authors concluded that this educational intervention was effective in reducing risky prescribing behaviour and marginally improved diabetes patient outcomes. The addition of opinion leader feedback did not affect the outcomes.

Palen et al. conducted an RCT to evaluate the effect of laboratory monitoring alerts on prescription practices. A total of 207 internal medicine and family practice physicians from 16 clinical facilities in the United States participated in the trial. Physicians randomized to the intervention group received drug laboratory monitoring alerts through their computerized medication order system and were trained how to use these alerts to change medication dosing or order laboratory tests. The control group did not receive these monitoring alerts on their computerized order screens. The results showed no significant differences between the groups in the overall rate of compliance with
ordering the recommended laboratory monitoring for patients prescribed medications. However, for some specific medications, there was a statistically significant difference in the compliance with ordering tests, favouring the intervention group. The authors concluded that non-intrusive reminders may not improve adherence to guideline recommendations.

Pringle et al. conducted an RCT to evaluate the effectiveness of significant event analysis in improving patient safety in the primary care of diabetes. A total of 78 physicians from 20 multiple-partner practices in Lincolnshire and Manchester in the UK participated in the study. Practices were randomized to carry out a minimum of six event audits over a one-year period using either a conventional cohort-based approach or a significant event analysis. Conventional event auditing involved setting standards, measuring performance against the standards and making decisions on how to modify practices to bring them closer to the standards. In the significant event analysis group, each team was asked to draw up a list of significant events that would be monitored over time and discussed in a structured way at audit meetings. There was no significant difference between the two groups in the recording of variables. However, there were significantly fewer random blood sugar results, fewer HbA1 results and higher levels of random blood sugars in the conventional audit group. No significant difference in glycemic control or systolic blood pressure was found between groups. The authors concluded that significant-event analysis is beneficial in the auditing and improvement of care in general practice.

Rougehead et al. conducted a non-concurrent retrospective cohort study to investigate the influence of patient-specific feedback on the rate of home medication reviews in Australia. The intervention group was composed of veterans over 65 years of age who were currently prescribed five or more unique drugs. The 49,227 patients in the control group included veterans over age 65 who did not receive five unique medications, but did receive at least one prescription per month and a total of 20 prescriptions over a four-month period. The 40,270 patients in the intervention group received educational materials in the form of a letter informing them about their medication regimes, screened patients for any drug-related problems and reviewed drug information with the patient on the day of discharge. Several days after discharge, the pharmacist followed up with the patient by telephone and communicated any significant findings to the primary care physician. There was a significant difference between groups in the rate of preventable adverse drug events, favouring the pharmacist intervention group. However, no difference was found between the two groups in total adverse drug events or total healthcare utilization. Study authors concluded that pharmacist medication review, counselling and telephone follow-up were effective in lowering the rate of preventable adverse drug events after hospital discharge.

Tamblyn et al. conducted an RCT to investigate the effectiveness of computerized decision-making support in reducing the rate of inappropriate prescribing. A total of 107 primary care physicians in Québec, Canada, were randomly assigned to one of two groups: 1) a computerized decision-making support, in which alert messages identified prescribing problems and suggested alternative therapies; or 2) no intervention. The primary outcome measures were the rates of initiation and discontinuation of 159
prescription-related problems. There were significantly fewer inappropriate new prescriptions in the decision-making support group (RR = 0.82; 95% CI, 0.69 to 0.98). However, there was no difference between groups in the discontinuation of inappropriate medications prescribed previously, except in cases of therapeutic duplication and drug interaction. The authors concluded that computerized drug-decision support reduced the incidence of new PIPs, but had little effect on the discontinuation of previously prescribed drugs.

Tamblyn et al. conducted an RCT to compare on-demand versus computer-triggered decision supports in primary care. A total of 28 full-time general practitioners and family physicians in Québec, Canada, were randomized to either: 1) an on-demand drug decision support, which was activated only by physician request; or 2) a computer-triggered decision support, which assessed prescription problems and generated an automatic alert whenever a patient chart was opened or new/refill prescriptions were sent electronically or printed. The outcome of interest was the prevalence of prescribing problems at the end of the six-month follow-up period. There was no significant difference between groups in the prevalence of prescribing problems (OR = 1.03; 95% CI, 0.8 to 1.32). However, there was a significant reduction of medication duplications in the computer-triggered group (OR = 0.55; 95% CI, 0.33 to 0.90). The authors concluded that neither approach was effective in reducing prescribing problems.

Varkey et al. conducted a prospective, non-concurrent cohort study to evaluate whether a multifaceted intervention is effective in improving medication reconciliation. The study was conducted in an outpatient clinic in Minnesota in the United States. The study staff were a multidisciplinary team of 12 staff physicians, five nurse practitioners and three fellows. A total of 104 patients were enrolled in two phases. During the first phase, 54 patients received standard care. In the second phase, an additional 50 patients received a multifaceted intervention consisting of a letter to remind patients to bring their medication bottles to medical visits, verification and correction of medication lists, physician education on medication reconciliation, and weekly audits and feedback on physicians’ reconciliation performance. The study results showed a significant difference, favouring the intervention group, in the number of visits (p = 0.013) and in the number of medication lists (p = 0.005) with at least one discrepancy related to inadequate reconciliation of medications. The study authors concluded that multifaceted interventions directed to a multidisciplinary care team as well as to patients are effective in enhancing medication reconciliation.

Weingart et al. conducted a retrospective cohort study to determine whether electronic safety messages directed to patients can reduce the rates of adverse drug events. The study was conducted in three primary care practices in Boston, Massachusetts. A total of 267 patients were enrolled. All patients received and opened a MedCheck message, a drug safety application that automatically sent a query 10 days after patients received a prescription. The message listed patient’s medication and asked patients to respond regarding whether they have filled the prescription or have had any problems with the prescription. Patients’ responses were forwarded immediately to their primary care physician. The intervention group consisted of patients who responded to this electronic safety message, while the control group was patients who did not respond. The number of adverse drug events was compared between the two groups. Physicians were more frequently made aware of adverse drug events electronically than during medical visits (p = 0.01). The number of message exchanges between patients and physicians was significantly greater in the intervention group than in the control group (p = 0.001). The study authors concluded that electronic medication safety emails elicited patients’ medication problems and facilitated electronic dialogue between patients and their physicians.

Fourteen of the 15 studies above focus on ways to improve medication management. These studies proposed that medication management might be improved through: 1) medication reviews, recommendations and/or patient counselling by pharmacists (Bergvist et al., Bregnhøj et al., Schnipper et al., Varkey et al.), 2) interactive educational media and materials (Bregnhøj et al., Fick et al. and O’Connor et al.), 3) detailed medication reports on discharge from hospital that were also sent to the primary care provider (Midlov et al.), 4) educational material directed towards patients (Roughead et al., Varkey et al. and Weingart et al.), or 5) technology assisted prescribing (Tamblyn et al. and Tamblyn et al.). Another study found that significant event analyses should be used in conjunction with, but not as a substitute for, conventional audit methods.

The adequate transfer of information was highlighted in strategies to improve medication management. These strategies focussed on enhancing patient safety through a variety of means, such as patient and provider interactions, pharmacist and physician interactions, electronic reminders for allergic reactions and drug interactions, and communications about patients between providers in the hospital and in the community, an area of frequent concern in primary care.
A few strategies to enhance patient safety at the primary care level have been rigorously evaluated in the literature. Most of these strategies represent opportunities to improve patient safety in the area of medication management in primary care (Bergvist et al., Breghnhoj et al., Fick et al., Ghandhi et al., Midlov et al., Palen et al., Roughead et al., Schnipper et al., Tamblyn et al., Tamblyn et al., Varkey et al. and Weingart et al.). However, they also emphasize an important cross-cutting theme that emerged from the interviews with key informants: the transfer of patient information between providers or between providers and patients (i.e., “handovers”). Handovers occur many times each day in the average primary care practice. While handovers are assumed to be a common patient safety concern in primary care, the key informants emphasized the importance of these interactions much more than did the literature, except in reference to medication management.

The majority of these studies were based on a small number of patients and/or physicians, non-random samples and/or a short study period. Some studies did not include a control group (Fick et al.) or compared two different interventions (Tamblyn et al. and Pringle et al.). Further, one study (Weingart et al.) used the group of patients that did not respond to a message from the researchers as their control group in assessing an intervention to increase communication! In contrast to the other studies, the study by Roughead et al. was based on a large sample of patients; however, neither the intervention group nor the control group was randomly selected. The study found that interventions can increase the number of medication reviews performed. Although the study did not assess the effect on the incidence of adverse events, several studies found that medication errors are a major cause of adverse drug events (e.g., Buckley et al. and Kopp et al.). Overall, the quality of these studies is poor, or their implications for patient safety are unclear.

SUMMARY OF THE LITERATURE REVIEW

The international literature shows no agreement on the frequency of patient safety incidents in primary care. On the contrary, the number of events varies substantially among studies depending on such factors as the specific research question addressed, the study approach used, the patient group studied, and the terminology used to describe safety events. As examples, figures like the following are presented in the literature: 240 safety incidents per 100,000 patients (Makeham et al.), 3.7 incidents per 100,000 visits (Fischer et al.), 5 to 80 incidents per 100,000 consultations (Sandars and Esmail), and 3,000 to 6,000 per 100,000 visits (Elder et al.). With such variations in the mode of reporting, it is not even possible to state whether the frequency is high, moderate or low. Although one study reports on findings from Canadian settings, that information is greatly weakened by questionable methodology and a very small sample size. It must be concluded, therefore, that the number of safety incidents occurring in Canadian primary care is unknown.

The reasons given for the occurrence of safety incidents in primary care also vary substantially among studies. The most frequently cited factors are medication management errors, poor communications with the patient, poor information transfer within the healthcare system, inadequate administrative processes, and insufficient knowledge or poor judgment on the part of the provider. Other causes of safety events have been found in diagnostic processes, such as testing and the interpretation of test results, and in the organization of work, the infrastructure, the excessive work demand, the fragmentation of services, and the follow-up and monitoring of patients. None of these studies was carried out in Canada; therefore, not only is the frequency of adverse events in Canadian primary care unknown, but the potential sources of safety incidents are unknown as well.

In the literature, medication management is, by far, the most commonly cited issue in primary care safety incidents, although the majority of these incidents never reach the patient. The incidents that do reach the patient cause varying degrees of harm and healthcare interventions. One study estimated that up to 13% of medication-related events cause serious harm (Gandhi et al.). Another study (Brekke et al., Bregnhjoj et al., Buck et al., de Wilde et al., Ryan et al. and Van der Hooft et al.) demonstrated that one in six of all hospitalized patients in Canada are admitted due to medication-related morbidity (Samoy et al.). It is not known how many of those medication-related incidents are linked to primary care.

Adverse events from medication may occur for many reasons, such as interactions between medications, allergies to medications, and errors in diagnosis, in writing prescriptions, in pharmacists’ interpretation of scripts, in labelling medications, in dispensing drugs and in patients’ adherence to drug therapies. The events most frequently noted in the literature seem to be associated with drug contraindications, knowledge and skills of the provider, lack of proper instructions to the patient, strength of the medication, and non-adherence of the patient. An association has been found between inappropriate

38 Allergic reaction is considered a medical error only if the prescriber knew, or should have known, about the medication allergy.
prescribing and the age of the general practitioner, as well as with those practicing alone. The number of visits per patient is also linked to inappropriate prescribing. Of specific concern in the studies reviewed is prescribing to elderly patients, particularly women. Compared with those in other age groups, elderly people are more vulnerable to ill health and disease, and, therefore, more likely to visit healthcare facilities. Further, older patients often take many medications, some of which are inappropriate or contraindicated and can cause harm. Several studies have demonstrated that about 20% of the elderly in primary care have at least one medication that is inappropriate (ineffective or duplicative) (Brekke et al.,9 Bregnhoj et al.,9 Buck et al.,12 de Wilde et al.,27 Ryan et al.,85 and Van der Hooft et al.109).

Events that occur as a result of delayed or missed diagnoses, particularly in cases of cancer, are the cause of more serious harm than other safety events. Delayed or missed diagnoses often seem to be linked to the judgment and skills of the provider. That factor alone may be responsible for close to half of all safety incidents related to delayed or missed diagnoses. Other important factors are ineffective communication with, and from, the patient; inadequate follow-up and monitoring of the patient; mishaps in the diagnostic work-up, including misinterpretation of laboratory tests and findings from consultants; improper actions of other providers; and failures in administrative processes. Some studies found that often several factors contribute to missed or delayed diagnosis, especially when the diagnosis involves uncommon diseases, co-morbidities and conditions in which the symptoms are similar to those of more common diseases.

When it comes to proposed or implemented actions to improve patient safety in primary care, the literature focuses almost entirely on medication management. Suggestions include, for example, the development of control systems for drug interactions; more detailed medication reports to the primary care provider on discharge from hospital; comparisons of the medication list at discharge from hospital with the medication list used in community care; the inclusion of pharmacists in medication reviews, as well as in counselling and telephone follow-up after hospital discharge; the use of technology-assisted decision support for appropriate prescribing to different patient groups; and regular reviews of prescribed medications, in particular for the elderly, using criteria on appropriateness.

Some of the strategies proposed have been evaluated in scientifically rigorous studies. The following results are reported from single randomized controlled trials (RCTs):

- Educational meetings for general practitioners on appropriate prescribing for elderly can improve medication management (Bregnhoj et al.9).
- Educational brochures listing potentially inappropriate medications, including a list of alternative medications and a letter specifying which patients are currently receiving potentially inappropriate medication, can improve patient medication safety (Fick et al.31).
- Learning through case-study simulations can reduce risky prescribing for patients with diabetes (O’Connor et al.68).
- Pharmacists’ medication reviews, counselling and telephone follow-up are effective in lowering the rate of preventable adverse drug events after hospital discharge (Bergvist et al.4).
- An RCT performed in Québec (Canada) found that a computerized decision-making support, in which alert messages identify prescribing problems and possible consequences and provide alternative therapy suggestions, is effective in reducing the prescribing of potentially inappropriate medication, although it does not ensure the discontinuance of previously prescribed drugs (Tamblyn et al.96). However, another RCT from the same research team in Québec found that neither of the following approaches was more effective in reducing prescribing problems: 1) an on-demand drug-decision support, which was activated only by physician request; and 2) a computer-triggered decision support, that assessed prescription problems and generated an automatic alert whenever a patient chart was opened or new/refill prescriptions were sent electronically or printed (Tamblyn et al.97). These approaches were not compared to having no decision support tool.

CONCLUSIONS

Of the many conclusions that may be drawn from the findings in the literature review, the following seem to be most important in considering what needs to be done to enhance patient safety in Canadian primary care:

1. Few studies have been conducted on patient safety issues in primary care.
2. There have been only two reliable studies based on data from Canadian primary care. Both of these dealt with the effectiveness of decision support systems.
3. Research is needed on all aspects of patient safety in...
Canadian primary care, from the gathering of data on the frequency and type of events to the development of effective strategies for patient safety in primary care.

There are a few emerging themes that may deserve particular attention in future research on patient safety in primary care.

EMERGING THEMES

A synthesis of the literature shows that the emerging themes in the field of patient safety in primary care are medication management and missed or delayed diagnosis. The literature further indicates that safety concerns in primary care are rooted mainly in patient-provider communications, administrative processes and issues related to the provider’s level of knowledge and skill. It should be remembered, however, that the literature reviewed in this report is largely based on international experience with adverse events. Its relevance to the Canadian healthcare system is uncertain, since primary care delivery systems vary greatly across developed countries.

GAPS IN THE EVIDENCE BASE ON PATIENT SAFETY INCIDENT IDENTIFICATION AND ACTIONS TAKEN TO ADDRESS PATIENT SAFETY RISKS IN PRIMARY CARE

BACKGROUND

Individuals with expertise or interest in patient safety in primary care are a source of information on existing practices, impending initiatives and concerns that may not have been documented in the published literature. As a second research methodology, 16 interviews were carried out with Canadian and international leaders and stakeholders in the areas of patient safety and/or primary care.

METHODOLOGY

In consultation with the Advisory Group a list of 18 key informants for telephone interviews was developed. The informants were individuals in Canada, Australia and the UK with expertise relevant to the issues of patient safety and primary care (see Table 5).

<table>
<thead>
<tr>
<th>Location</th>
<th>Frequency</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>14</td>
<td>88%</td>
</tr>
<tr>
<td>BC</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Alberta</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Manitoba</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>Ontario</td>
<td>4</td>
<td>25%</td>
</tr>
<tr>
<td>Quebec</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>3</td>
<td>19%</td>
</tr>
<tr>
<td>Australia</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>16</td>
<td>100%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Workplace Setting</th>
<th>Frequency*</th>
<th>(%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academia</td>
<td>8</td>
<td>50%</td>
</tr>
<tr>
<td>Clinical</td>
<td>8</td>
<td>50%</td>
</tr>
<tr>
<td>Patient Safety</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Patient Advocacy</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Advisor/Consultant</td>
<td>4</td>
<td>25%</td>
</tr>
<tr>
<td>Management/Administration</td>
<td>1</td>
<td>6%</td>
</tr>
</tbody>
</table>

*Some key informants were active in more than one setting.
Eight questions and an interview guide were developed and used to guide the discussion and provide cues during the telephone interviews. The questions were provided to all informants prior to the interviews. The questions and guide are included in Appendix C.

Interviews were conducted between March 29 and April 23, 2010. Of the 18 key informants selected for interview, 16 individuals were contacted and confirmed for interview and two were unreachable for interviews in the time frame available. With one exception, interviews were completed in one 30- to 60-minute session. One interview was conducted in person, and all interviews were recorded with the informants' consent and subsequently transcribed.

INTERVIEW FINDINGS

The interviews generally followed the sequence of the questions in the guide; however, given the back-and-forth nature of the discussions and the informants' varying area of expertise, there was some degree of fluidity the order of questions and the way topics were covered. Reflecting the dynamic nature of the interviews these results are presented thematically, rather than in the strict sequence of the questions.

FUNDAMENTAL ISSUES IN PATIENT SAFETY IN PRIMARY CARE

The majority of the key informants believed that the fundamental issue in patient safety and primary care is patient care information. This was seen to include issues of the accuracy of the information available to practitioners on patients' charts, whether the charts record all of the care that the patients are receiving, and whether patients are providing all of the information that is needed for their care. For example, patients may not tell a physician about receiving care from another provider or about alternative or complementary treatments, and this information gap may have an impact on the safety of prescribing medications or other subsequent interventions.

“\textit{I am struck by how much emphasis we've put on communication with patients in our training for primary care and how little it finds emphasis in the research and the policy writing so far... Communication is central to great quality care and yet communication with a patient isn't very prominent (as a) safety issue.}”

Several informants indicated that the transfer of patient information is a significant concern within primary care. One informant delineated three dimensions of information transfer: transfer from the provider to the patient; transfer of diagnostic information fully and completely within the primary care delivery system; and transfer of information between providers. Many informants articulated concerns about information in these three dimensions in different contexts, indicating that a breakdown in information transfer in any of these dimensions will have a potential impact on patient safety.

“\textit{I think that the primary care team needs to be working along with and specialist and right now don't think that that is happening. There is a gap there.}”

Other issues related to information and patient safety that informants cited were the following:

- **Quality of the information that is available to providers:** Information that is not of high quality or completeness in reports of patient care is a potential safety issue as it decreases other providers’ certainty about their treatment decisions.
- **Coordination of information between providers:** In order for treatment to be effective and safe, providers must know what other providers are doing. This was cited as an issue in cases where different providers are treating the same condition (e.g., treatment of diabetes by a primary care physician and an endocrinologist) as well as in cases where different providers are treating different conditions.
- **Ease of use and integration of new information in practice:** This is an issue that especially relates to how information technology and the electronic health record (EHR) are introduced and used. If technology does not allow for new or modified information to be easily added to the patient record there are potential impacts on safety, as well as other questions about the utility of the technology.

“\textit{There really isn't a way to communicate information back (to the primary care provider) ... even when it is there, the ability to do it smoothly is lacking... I'll get a fax back that will have to be scanned to go on the electronic chart... and (that can consume) a large amount of time.}”

- **Ability of patients to understand and use information provided to them:** As one informant noted, the number of assumptions that providers make about how well information has been understood and will be used by a patient is significant. In many cases, if even one assumption is not true (for example, the patient does not do what a provider assumes he or she will do), the impact on care and the patient's safety can be serious.
“...there are things that will happen that are not necessarily classed as a medical error, but it definitely has an adverse effect on the outcomes. For example, there may not be adequate follow up, in terms of what a specialist recommended, what patients do between visits and then when they return back to their primary care provider.”

Finally, a number of key informants believe that the lack of definitive information on patient safety issues directly related to primary care means that identifying the leading issues is a significant challenge. These informants did not deny that some safety issues have been identified, such as incomplete or inaccurate information and medication issues; however, given the unique nature of primary care it was unclear to them whether these in fact are the crucial issues. For these informants, a definitive identification of the fundamental safety issues depends on further research specific to the primary care environment.

“...there is some kind of basic research that needs to be done to determine what are the most pressing patient safety issues that primary care providers need to focus on. My sense is that we don't really know that.”

THE PRIMARY CARE SETTING AND PATIENT SAFETY ISSUES

A majority of informants identified four major issues about the nature of primary care practice that make patient safety an issue. These are:

- **Building relationships:** Many informants believe that a unique aspect of the primary care setting is that it allows providers to build a long-term, open, and significant relationship with the patient, in contrast to acute care settings where the focus of care is on a specific problem or intervention. In primary care, it is essential that the caregiver builds a deeper and longer term relationship with the patient in order to provide effective and safe care.

  “...the primary provider has that integrator role that probably puts patient safety in a broader perspective than in an organization or institution based setting where the patient is there for a short period of time and the responsibility of the provider is limited in scope and time.”

  The importance of this relationship lies in the fact that patient care and safety are contingent on the primary care provider allowing patients to ‘tell their story’ so that the provider understands all of the elements of their situation and relates that to their ongoing care. This means that providers must be able to give patients time to do this (a challenge, as informants recognized that clinics are very busy places), as well as take the time to understand fully what it is their patients are telling them.

  “…the tendency in a busy practice is to deal with the immediate concerns of the patient and not necessarily step back and look at the person’s health broadly and some of the threats to it, including those that would be identified such as patient safety issues.” On the other hand, it is quite possible that this close relationship between the patient and his/her primary care provider may have a positive impact on the number of patient safety incidents in primary care.”

- **Infrastructure for care:** Most informants identified two aspects of infrastructure in primary care that are related to patient safety: the physical infrastructure, such as the clinical setting for primary care, and the virtual infrastructure of networks that support the provision of care in a variety of settings. In regard to physical infrastructure, informants felt that the structure and organization of a primary care clinic determine whether the provider has a complete understanding of a patient’s health and facilitate access to the kinds of care the patient requires to maintain his or her health. In regard to virtual infrastructure, many informants felt that there is an obvious risk to patient safety in not having such networks in place.

- **Understanding the diagnosis:** Many informants noted that because of the nature of primary care, patients are frequently seen and treated in primary care settings when their diagnosis is not clear. This is in distinct contrast to the acute care sector, where patients arrive with a well-established diagnosis or the diagnosis may be quickly established, and the required intervention is also clear. In primary care, the diagnosis frequently may not be clear or may not be determined for some time. As a result, decisions on care may result in necessary treatment delays. In other cases, where a diagnosis is indeterminate, tests and investigations may lead to confusion in the diagnosis and to delays in treatment or the wrong treatment being applied. Informants indicated that another critical issue for patients in primary care is that they may receive tests or treatment interventions that are not necessary until a definitive diagnosis and treatment is determined.

  “Primary care providers are more likely to see patients in the early stages of diseases when...the diagnosis is inherently uncertain. So I think that is one of the key things about primary care practice...the uncertainty of diagnosis.”
Integrating information transferred between multiple providers: Many informants felt that along with the issue of information infrastructure noted above, one specific aspect of information that impinges on patient safety in primary care is the requirement to integrate information from and for a wide variety of sources and providers. As with questions of diagnosis, this is seen to be an aspect of primary care that distinguishes it from acute care. Primary care providers receive information from a variety of sources, and in many cases the information received relates to a specific condition or intervention and must be integrated into the complete picture of the patient’s care. For example, a medical clinic may receive a follow-up report on a specialist visit or intervention that the primary care provider did not know had occurred (or be asked to provide follow-up to these interventions without follow-up instructions); or the clinic may receive information from pharmacists or other primary providers, such as physiotherapists or home care providers that the patient is seeing independently or without adequate inter-communication in the system. Integrating information from these divergent sources and ensuring that the patient’s care is safe is a challenge for primary care providers.

“... an endocrinologist was doing things quite differently than we were (to treat diabetes) and from a safety standpoint that is not a good thing. Not only does the patient get confused, but it means that you are going about things in two different directions and possibility at the same time, which can lead to negative results.”

POPULATIONS OF CONCERN OR AT RISK AND SAFETY IN PRIMARY CARE

The majority of informants identified populations that they felt are sources of specific concern in relation to patient safety in primary care. Frequently cited populations are identified in Table 6.

```
<table>
<thead>
<tr>
<th>Population</th>
<th>Number of Mentions by Key Informants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elderly/patients with complex conditions (usually the same group)</td>
<td>12</td>
</tr>
<tr>
<td>Patients with communication challenges</td>
<td>11</td>
</tr>
<tr>
<td>Poly-pharmacy patients</td>
<td>8</td>
</tr>
<tr>
<td>First Nations</td>
<td>5</td>
</tr>
<tr>
<td>Non-questioning patients</td>
<td>5</td>
</tr>
</tbody>
</table>
```
A consistent message from most informants was that, along with being alerted to the risks specific to a population, primary care providers need to be aware of the reasons why these are at-risk populations and of the measures they can take to compensate for the risks. That is, awareness of safety issues with these populations is not sufficient; providers must be aware of the full context of the patient’s situation to understand how to address those concerns. For example, patients who do not question a provider’s direction (especially that of physicians) may be refraining from doing so because of age (e.g., older patients) or culture (e.g., background of deference to authority or avoidance of conflict) or other factors. Providers must be aware of that specific context and account for it in the manner in which they address care and safety issues.

“I think there needs to be some kind of mechanism within a practice identifying those patients who are most at risk and targeting services or processes slightly different in terms of potentially increased monitoring of following up.”

As with the question of the fundamental issues in patient safety in primary care, a minority of informants felt that the populations of greatest concerns cannot yet be definitively identified, as the major issues in patient safety are not yet clear.

BARRIERS, CHALLENGES, OPPORTUNITIES AND RESEARCH GAPS FOR ADDRESSING PATIENT SAFETY IN PRIMARY CARE

Most informants saw the challenges, opportunities and research gaps in addressing patient safety in primary care as being related and in many cases corollaries to each other. A minority of the informants felt that the most immediate challenge is the identification of patient safety issues that are specific to primary care. These informants felt that until this is accomplished, action and research being undertaken on patient safety may be using incomplete and possibly inaccurate information.

“I think that if you asked the majority of family physicians... they would be able to identify many of the (patient safety) issues as things to be aware of. That doesn’t mean that they have the time or skills to address them.”

The majority of informants felt that the most significant challenge and opportunity is in the development of infrastructure in primary care.

Many felt that the primary care system is a system in name only, and that until infrastructure is created that allows providers to share information effectively, primary care will remain fragmented, with the attendant impacts on continuity of care and patient safety. The electronic medical record (EMR) was seen by most informants as a means of improving information infrastructure, as well as collecting information that will support ongoing research into safety issues. However, many informants noted that the EMR is only a technology; it is not a guarantee that the information collected will be complete or accurate, only that it will be in a digital format. The completeness, quality and utility of EMR information will be determined by providers. Some informants also indicated that the success of the EMR is contingent on the continued support for its introduction, and that, given the costs to date and the uncertainty of a ‘payoff’ of those costs in the near future, that support is not guaranteed.

A related issue identified by a large number of informants is the need for a culture shift in how patient safety is perceived in primary care.

“...and I think we have quite a way to go in primary care to establish the culture change needed to take the big leap forward.”

The majority of informants felt that the most significant challenge and opportunity is in the development of infrastructure in primary care. Many felt that the primary care system is a system in name only, and that until infrastructure is created that allows providers to share information effectively, primary care will remain fragmented, with the attendant impacts on continuity of care and patient safety. The electronic medical record (EMR) was seen by most informants as a means of improving information infrastructure, as well as collecting information that will support ongoing research into safety issues. However, many informants noted that the EMR is only a technology; it is not a guarantee that the information collected will be complete or accurate, only that it will be in a digital format. The completeness, quality and utility of EMR information will be determined by providers. Some informants also indicated that the success of the EMR is contingent on the continued support for its introduction, and that, given the costs to date and the uncertainty of a ‘payoff’ of those costs in the near future, that support is not guaranteed.

IN-PRACTICE PATIENT SAFETY INITIATIVES

Some informants who are in clinical practice identified specific patient safety initiatives that have been undertaken in their own or other practices. Most of these interventions relate to improved information flow, not only between
primary clinics and specialty care centres, but also within clinics and between providers within the same clinic. Some of the tools that informants identified are simple. For example, one primary care centre verifies a patient’s name at each visit to ensure that the correct patient is being seen and treated. Another has developed a tool that provides a printed version of all the health information from that clinic for each patient. Called a “Passport,” this document is reviewed by the patient in consultation with the provider to ensure both understand its contents. The Passport is also seen as a means of allowing patients to ‘own’ their healthcare information.

“...that’s when I give the patients the passport and spend some time thinking about the report and the people who otherwise would not understand their problems and I realize I haven’t had a grip on them either all these years.”

Among the more sophisticated initiatives described by informants is one in which diabetes care in the primary care setting is paid through capitation rather than fee-for-service. Some informants also identified the need to change remuneration incentives for all providers, not just physicians, to encourage the integration of patient safety in primary care.

“Fee for service (FFS) remuneration only pays for in-person clinical encounters, meaning that they do not always respond to patient concerns in a timely manner. It motivates clinical productivity, with little incentive to engage in activities such as coordination, reflection, medication reviews and case discussion.”

SYNTHESIS OF KEY INFORMANT INTERVIEWS

The 16 informants contacted for this paper represent a diverse group of health professionals who approach the question of patient safety in primary care from different perspectives. Not surprisingly, there was a significant degree of variability in their responses to many of the questions posed. There was also a high degree of unanimity on many topics. Their views on this issue are complex and diverse; they range from certainty about what problems need to be addressed (medication error is cited frequently), to certainty that there are issues to be addressed but the priority for doing so is not clear, to uncertainty that the most important issues have been identified.

Informants agreed that patient safety in primary care needs to be addressed, and many indicated that this is an issue that has not been well researched. Informants saw the question of patient safety as being separate from quality of care and quality improvement in primary care and thus believe it must be approached from a unique perspective. Another area of agreement among informants is that all aspects of patient information in primary care are essential to addressing the issue of patient safety. Even those informants who felt that the principal problems, and the extent of those problems, in patient safety are not clear, agreed that more complete and accessible patient information is needed. More broadly, informants agreed that information exchange is a significant concern in patient safety. This issue was seen to have many different facets: poor information exchange between providers, incomplete information about patients’ health and the treatments they are receiving, and poor exchange of information between providers and patients.

“The older adult..... tend not to question anything; you give them a script, they take it to the pharmacy, and they take it as directed. They have no idea what it’s for...they know that in the morning I take three white pills and one pink one and at noon I take my blue pill.”

The underlying concern, regardless of which facet of information exchange an informant was addressing, was that the information available to primary care providers is often insufficient and of inadequate quality. In general, informants agreed that the electronic medical record is essential to address this problem; however, it is only a tool. If the information on the EMR is incomplete, if providers do not use it, or if it is not integrated into all aspects of primary care delivery, its utility will be minimal.

“My own opinion is that (it is) critical to patient safety (that) patients have access to their own electronic medical records. They’re the ones that pick up whether there’s a drug missing in the list, they’re the ones who’ll pick up ‘hey, you know what, I had these laboratory tests and the results aren’t back’. Or, ‘I did get this lab test and it looks like normal but no one has called me’.”

From the perspective of most informants the nature of the primary care delivery system in relation to patient safety is a paradoxical one: along with offering some of the most complex challenges in addressing patient safety, it also offers the best opportunities to implement solutions to safety problems. Many informants felt that the nature of primary care makes it better suited to identifying and addressing problems in patient safety than the acute care sector, even though work on patient safety in that sector is recognized to be better developed conceptually and operationally. This paradox was seen to be manifest in many different aspects of the primary care environment. Informants generally recognized this within their own sphere of practice (i.e., nursing, medicine, pharmacy) but could also identify the challenges and opportunities across primary care.
Informants felt that the primary care setting is the best one for developing patient relationships that are deep, meaningful and long-lasting, and that these relationships help to address safety issues through better communications. This was seen to be in contrast to the acute care sector that is focused on single events or problems and rarely addresses patients on a long-term basis. The caveat to this is that patients and providers must allow time for these relationships to develop.

“Also over time (the primary care providers) tend to be the person who sees the patient over a number of years which puts them in a unique position to detect deterioration in the patient's health and wellbeing...”

Informants also felt that the primary care setting allows for a broader perspective on patients’ health; rather than focusing on one problem or procedure, as is the case in the acute care sector, the primary care setting allows providers to integrate all aspects of a patient’s health, including social factors, into a more complete understanding of the patient’s health and needs. Moreover, by its nature the primary care setting is where a patient’s diagnosis is usually established. This is recognized as being laden with potential safety issues (unnecessary tests or interventions, action taken on the basis of missed or delayed diagnoses, etc.); however, once the diagnosis is established the primary care setting is usually the best setting for ongoing treatment based on that diagnosis.

Informants also felt that the primary care setting offers the best opportunity for the integration of care, especially clinics that provide a range of services, and that this integration creates the best environment for managing care and minimizing the potential for adverse events arising because of fragmented care. Finally, informants felt that the primary care setting presents the best opportunity for the collection and management of patient information. It was recognized that this requires tools, such as the EMR; however, even with the caveats that surround the EMR, the primary care clinic is the best place for the centralization of health information. In fulfilling this role, the primary care clinic will play an essential role in integrating the delivery of care and minimizing the potential risks to patient safety overall.

Informants were equivocal on the question of specific populations being at risk. They generally agreed on which populations are most at risk: the elderly, those with complex conditions and those on multiple medications (usually the same patients, as noted by many informants), patients with mental health problems, First Nations populations and patients new to Canada. However, informants felt that rather than focusing on which populations are at risk, focus needs to be placed on why these populations are at risk. For example, seniors, patients with mental health problems and patients new to Canada may share a common risk factor of poor communication and misunderstanding of a provider’s direction. In viewing this from a safety perspective, providers need to be aware of that risk factor and how to ameliorate it with all patients, regardless of the population group. The essential message appears to be that many populations are at risk for an adverse incident, and the challenge for providers is to understand the nature of that risk and how to address it.

Finally, in regard to the barriers and challenges to addressing patient safety in primary care, informants’ responses reflected their responses to the questions on the fundamental safety issues and on the nature of primary care in relation to patient safety. Generally, where informants saw challenges, they also saw opportunities.

The first major challenge identified was that of providing support for the creation of infrastructure that would allow information sharing across different primary care settings. This reflects the emphasis placed on information and communication in addressing safety in primary care. Determining the safety issues of primary concern and ensuring that change and improvement take place will require a significant investment in infrastructures that support data collection and analysis. A related priority identified by informants is the need for a culture shift in primary care in order to ensure that patient safety is seen as an integral part of primary care. Specifically, shifts are required in how providers view primary care (all providers must have a system-wide perspective) and how patient safety is addressed (if adverse incidents are inevitable, they need to be seen as opportunities to learn and improve the processes of care, rather than opportunities to sanction providers).

Informants also felt that primary care must learn from the work done by others. They agreed that the acute care sector has much to teach the primary care sector about the underlying logic and processes of addressing patient safety in healthcare; how this logic is applied to primary care will require further research and ongoing evaluation and assessment. In addition, lessons from other countries should be adapted to the Canadian system, so that Canadian primary care can benefit from their experience and, more importantly, avoid repeating their mistakes. Several informants also pointed out that learning from and applying this work will require a significant investment in research, meaning that primary care will need to be a higher priority for future research on healthcare and health services.
ROUND TABLE EVENT

INTRODUCTION

An invitational roundtable discussion was engaged to: 1) highlight the findings of both the literature review and key informant interviews, and 2) substantiate the findings of these two methodologies while also capturing additional information. The Patient Safety in Primary Care Roundtable was held on the May 10, 2010, in Toronto, Ontario. The roundtable event brought together 50 stakeholders in the fields of patient safety, primary care and healthcare research from across Canada, including clinicians, patient representatives, researchers, policy and decision-makers, regulatory bodies and formal organizations. The event included presentations by IHE staff and, via WebEx from the UK, by Dr. Robert Varnam and Dr. Richard Jenkins of the National Health Service Institute for Innovation and Improvement.

Findings from the literature review and key informant interviews were presented to the participants, who were encouraged to read, analyse and discuss the results and to contribute their own views throughout the day’s discussions. The information extracted from the participant discussions was recorded on flipcharts and notes.

The following objectives for the roundtable event were identified by the pan-Canadian Advisory Group:

- to learn about and validate the findings from the literature review and key informant interviews;
- to hear from others who have improved patient safety in primary care;
- to identify priority issues and actions for patient safety in primary care in Canada;
- to identify possible barriers to and enablers of improved patient safety in primary care; and
- to identify next steps for improving patient safety in primary care including identification of champions, leaders and key organizations.

ROUND TABLE EVENT METHODOLOGY

The participants in the roundtable were selected by the pan-Canadian Advisory Group, the Canadian Patient Safety Institute (CPSI) and the BC Patient Safety & Quality Council (BCPSQC) because of their expertise in one or more of patient safety, primary care and healthcare research. The event was coordinated by a professional facilitator. A week prior to the event, each participant was provided with the preliminary findings of the literature review and the key informant interviews. The research team presented a summary of the preliminary findings at the commencement of the roundtable event. Following the presentation, the facilitator led a group discussion of the core themes and possible gaps in the findings.

From the literature, it became apparent that the UK is more advanced than most nations in adverse event reporting, practice audits, trigger tool development and patient safety research in primary care. Therefore, the CPSI and BCPSQC arranged a presentation by two of the most distinguished researchers in the field: Drs. Robert Varnam and Richard Jenkins from the National Health System in the UK. Drs. Varnam and Jenkins discussed the understanding of patient safety issues in primary care from a UK perspective and stressed that understanding the issues requires that adverse events be reported by internal staff, external staff and patients. The types of events reported by the three groups tend not to have much overlap; therefore, in combination, they provide a more complete description of the risks to patients than if fewer sources were relied upon. From this more complete picture, quantitative methods can be developed to measure the incidence of patient safety events – including adverse event rates, sentinel event rates and the analysis of routine data.

Drs. Varnam and Jenkins presented the Primary Care Trigger Tool (PCTT), which was developed by the NHS through the cooperation of 32 primary practices in England. The beneficial characteristics of the tool include the following: 1) it is objective, as the data come from chart audits and not self-reports; 2) it focuses on outcomes (not errors); 3) its triggers are related to common events; 4) it captures a large number of events; 5) it is reliable over time so that trends can be identified and the impact of safety initiatives can be assessed; and 6) it is available free on the NHS website.

After the NHS presentation, the participants broke into seven small groups. Each group was assigned two of the five core themes and asked to discuss the themes within the context of the opportunities for improvement, the probable impediments to progress and the factors that could enable progress. A Participant Guide was used to structure and guide the discussions (Appendix D). The composition of the small breakout groups was designed to incorporate a mix of expertise and geographic perspectives. Each small group chose an individual to guide the conversation and a scribe to document the important elements of the discussions. Thereafter, the facilitator guided the presentations as each small group reported on their discussions and welcomed further comments from all participants.

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40 Staff reports include event reporting surveys, walk-rounds and observations.
41 External staff reports include coroner, pharmacy, community, nurse and student reports.
42 The PCTT has a sensitivity rate of about 80% and takes it about two to four minutes to process an electronic patient record.
43 A large number of events are captured because the PCTT is based on common events, not staff reporting of, principally, memorable and rare events.
44 The PCTT can be accessed at http://www.institute.nhs.uk/option,com_trigger_tools_portal/ task,choose_tt/Itemid,2611.html (last accessed 12/10/2010)
Later, the same small groups discussed the potential next steps for advancing patient safety in primary care and the organizations that could be involved as partners, leaders and/or champions of the initiative(s). Thereafter, the facilitator again guided the presentations as each small group reported on their discussions and welcomed further comments from all participants.

THE PARTICIPANTS

Individuals were invited from across the country and the world to participate in the roundtable event. They were selected by the Advisory Group members, CPSI, and BCPSQC on the basis of their expertise in patient safety, primary care, and/or healthcare research. Over 100 people were invited to the roundtable, including clinicians from a variety of disciplines, patient representatives, policy makers, as well as researchers and decision makers. Attendees at the event represented seven Canadian provinces. Prince Edward Island, Newfoundland, New Brunswick, and the three territories were not represented – possibly due to travel restrictions in many healthcare and academic organizations at the time the event was held.

The participants provided information about their current roles: 33% represented an organization with an interest in patient safety and primary care, 26% were healthcare providers or were from health provider organizations, 19% were academics or were healthcare providers working in an academic setting, 12% were from health quality or health safety organizations, 5% were from government agencies or ministries, 4% were from patient safety advocacy organizations, one participant was a member of the general public, and one participant was a healthcare consultant.

ANALYSIS

The notes taken by the scribes and on the flip charts documenting the small and full group discussions were analyzed to identify the main themes and ideas.

GAPS IN THE KNOWLEDGE BASE

The participants agreed that there needs to be more research specific to the diagnosis of childhood conditions such as ADD/ADHD and asthma. These are conditions for which there is evidence of over-diagnosis (Cormier19, Forman and Ford31 and LindenSmith35); therefore, some children may be exposed to unnecessary medications and procedures. The over-diagnosis of conditions such as these may have long-term consequences for an individual’s health and employment opportunities. The literature search captured no studies that were focused specifically on children or on childhood diseases.

The participants also highlighted the lack of research regarding other allied health professionals, the use of multidisciplinary teams, the impact of guidelines (such as those to treat diabetes), and safety implications of cosmetic procedures. The absence of information on these issues is indicative of the nascent nature of patient safety research. These issues may be addressed as the literature develops.

THE ISSUES

A large group discussion focused on five core themes from the literature review and key informant interviews: 1) diagnosis; 2) medication management; 3) systems, structures and culture; 4) information on types and incidence of adverse events; and 5) communication. Each of the seven small groups was assigned two of these five issues to discuss. The groups were asked to identify the opportunities, the barriers and the possible mitigators, and/or ameliorators relevant to their assigned themes, many of which were commonly discussed across the groups and the themes, as well as in the literature and the during key informant interviews. An example is the potential of EMRs to promote patient safety by improving communication channels and the transfer of information.

Diagnosis

Participants focused on the diagnostic process as a unique feature that may lead to patient safety issues in primary care. They acknowledged that over- or under-diagnosis can lead to delays in diagnosis in some cases and missed diagnosis in others. The opportunities for improvement, therefore, include identifying the most common conditions at risk and providing guidance in the form of clinical practice guidelines and/or standards of practice. In addition, primary care could benefit from incorporating safety processes that have been found to be effective at other levels of care (e.g. acute care) and in other sectors (e.g. aviation), where safety research is more advanced.

The participants identified the lack of reporting systems, limited communication between providers in different levels of care, the lack of awareness that patient safety is an issue, premature closure of the diagnostic process, as well as the expectation that the patient will try alternative treatments as the most likely impediments to progress. With sufficient reporting, along with the analysis and dissemination of the findings, providers might be more aware of the likely pitfalls involved in diagnosing certain conditions. They may also become more cognizant of the value of sharing their experiences with others. The participants proposed that primary care examine its organization and structures to promote changes in the way care is delivered, so that patient safety receives a greater focus. Tracking adverse events in the diagnostic process may provide a clearer view of the
inherent hazards and, thereby, lead to stronger culture of safety that, in turn, transforms the system. Participants also emphasized that the safety culture could be strengthened by listening to the “patient’s voice” regarding their experiences in the provision of care.

**Medication management**

Medication management can be complicated by incomplete, or non-existent, communication between prescribers, incomplete medication lists, and patient adherence to a prescribed medication plan. The opportunities for improvement in medication management include making better use of the current IT systems and integrating a team approach to prescribing. IT systems can be used as a reason (or opportunity) to contact patients to update their medication lists, to retrospectively (or prospectively) search for possible adverse drug events, and as a method to reduce prescriptions errors by sending scripts electronically to community pharmacies. In addition, the inclusion of pharmacists on a primary care practice team could help providers become more knowledgeable and effective prescribers.

The barriers to progress include the current structure, philosophy and culture of primary care, the lack of evidence of medication effectiveness, and computer systems that are incompatible across practices, pharmacies, and levels of care. The current structure of primary care is dominated by independent practitioners operating in relative isolation from each other and the rest of the healthcare system. This structure has not been viewed as a patient safety concern in the past; however, better understanding and evidence has demonstrated that this compartmentalization may be a patient safety challenge. Without sufficient reporting, the true frequency of adverse drug events, and the opportunities to learn from them will be hidden from providers and the necessity of system change may go unnoticed. With respect to IT systems, even if scripts are unambiguous, legible, and complete, incompatible computer systems may lend themselves to adverse drug events solely because errors may occur during the transcribing of the medication orders.

The participants proposed that a centralized database on adverse medication events would provide a clearer picture of the importance of medication management. Prescribers might become more aware of the common medication incidents associated with some drugs and some patient populations. The participants suggested that the EMR data be used as a starting point for this database.

**Systems, structures and culture**

The systems, structure, and culture of primary care can lend themselves to providing a safer environment for patients. The opportunities for improvement include providing people with the proper tools for making the right decisions, engaging patient advocacy groups, developing primary care governance, and promoting enhanced communication between patients and providers. One of the fundamental tools for assessing, treating, counselling, and monitoring patients effectively is the timely access to appropriate information. A more efficient flow of patient information across the healthcare system could benefit patients and providers. The development of primary care governance could provide a systematic view of providing primary care in Canada. Such a view could lead to wider standardization across provinces and across the country, thereby, reducing the ambiguities of courses of care. The structure of primary care may also benefit from engaging patient advocacy groups in the change process. Adapting the system to address their views and perspectives may improve primary care delivery and patient safety through a greater understanding of patient information needs and treatment expectations. The participants suggested that the view that safety does not exist in isolation, but is a way of doing business, should be promoted so that the system can be transformed. The perspective that the goal is not to “fix the system,” but to improve the system should be espoused.

The barriers to progress include the significant structural variation across practices and across provinces/territories and the lack of time and money to investigate and address patient safety issues. Structural variation can impede progress because initiatives that may be effective in one context may be ineffective, or harmful, in another; therefore, policy design may need to be more ingenious (i.e., expensive) than when “one-size-fits-all” policies are possible. Without national standards, the probability of less than optimal information flow across the healthcare spectrum, due to non-compatible information systems, is also more likely.

The participants proposed that a national framework could be developed to provide a common vision and guidance. They stressed that the magnitude and breadth of patient safety in primary care needs to be quantified. Once the problem is gauged, decision makers and policy makers may see the need to reallocate resources to improve safety. Commitment to this plan is crucial.

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46 This is particularly relevant when patients are admitted or discharged from hospital or when they have more than one primary care provider.

47 Non-compliance may be the result of over or under use of medications whether it is deliberate or due to a lack of understanding.

48 Health Canada has a website for reporting adverse drug reactions (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/reaction-eng.php); however, drug reactions to new prescriptions are not considered medical errors since there would be no way for the physician, or the patient, to be able to predict the reaction. A medical error is made, however, when a patient is prescribed a medication for which they have a known and documented allergy.
Information on types and incidence of adverse events
The participants suggested that the EMR could be a good source of information for tracking and monitoring adverse events. The PCTT developed by the NHS was also suggested as a means to identify risks and to track adverse events. The details captured by the EMR or PCTT could be used as a starting point to build a national database that could be accessible to all providers and used to research and disseminate information on patient safety issues – including actions that might mitigate or ameliorate adverse outcomes.

The barriers to advancing the knowledge base in this area include the lack of time and funds to build a national database, the current culture that does not tend to value the reporting of adverse events and the lack of national acceptance and financial support for the development of an EMR.

The participants suggested that reporting adverse events may gain strength once the data are used and the lessons are shared and disseminated. Thereafter, administrators, health policy makers, healthcare professionals, office staff, and patients may become more aware of the potential harms involved in primary care and the culture of safety may mature and the system may be transformed.

Communication
Three communication nodes were identified by the participants as requiring greater attention: between patients and providers, providers and providers and providers and the system.

Patient and provider communication
The opportunities for improvement in the communication between patients and providers include creating a greater mutual understanding of providers’ and patients’ perspectives, expectations, and responsibilities. With greater understanding, the frequency of potentially harmful incorrect assumptions, due to a vacuum of information, is less likely.

The barriers to progress include the time required to understand the patient's lifestyle, clarify the provider's and the patient's roles in healthcare, and to assess, and, if necessary, ameliorate the patient's health literacy. The healthcare system tends not to promote or support these aspects of care. Providers are not generally reimbursed for taking the time to get to know and, if needed, to educate their patients. In fact, the fee-for-service mechanism for compensating physicians, which covers approximately 78% of all clinical payments in Canada (Canadian Institute for Health Information13), rewards providers for spending a minimal amount of time with their patients.

The participants proposed that the promotion and support of the concept of a primary care medical home would lead to a greater understanding between patients and providers. A primary care medical home is a patient-centered, individualized source of healthcare and service. It is based on a relationship between a patient and a provider, designed to improve the patient's health throughout the spectrum of referral and services. The promotion of such a concept in Canada would be supportive of enduring relationships between providers and patients. Given such support, patients, their family physicians and other primary care providers may come to understand each other better (The College of Family Physicians of Canada10).

Provider to provider communication
The opportunities for improvement in provider-to-provider communication include a greater mutual understanding of the need for effective communication to promote patient health and safety. For example, promoting communications between a nurse practitioner and a consulting specialist may lead to a more efficient referral system, reduced wait times for diagnosis, and more effective treatments. Through enhanced communication channels, specialists may be better able to prioritize referrals. Based on learning from previous communications, a nurse practitioner may be able to assess a patient and direct them to the appropriate specialist more efficiently. In turn, nurse practitioners may be able to better communicate treatment options to their patients.

The barriers to progress include the fact that many providers operate within the confines of single practices with little opportunity to communicate with providers outside the practice and even less opportunity to converse about particular cases. Using the above example, consulting specialists sometimes have little information on why a patient has been referred to them. Conversely, primary care providers may have scant information on the treatment of their patients once they have been transferred to the care of specialist.

The opportunities to advance progress in this area include strengthening the communication channels between providers, standardizing the referral process, continuing to establish EMRs, and interprofessional educational opportunities. Opening these communication channels may lead to a greater understanding of the information needs of primary care providers and consulting specialists. The time spent reacquiring information as the patient moves through the healthcare system might be reduced, thereby, making the system more efficient and/or reducing the risk of losing
information. More efficient information flow may increase the probability that a provider has the correct information to make the right decisions about a patient’s care.

Provider and system communication

The opportunities for improvement in provider and system communication include enhancing the flow of information between levels of care and between primary care providers, including pharmacists, laboratories, physiotherapists, psychologists, as well as other settings and service providers such as home care and hospitals.

The barriers to improvement include the fact that primary care is not an ordered and comprehensive assemblage of parts forming a unified system. The abounding variation in, and the independent nature of, primary care providers makes it difficult to develop a single communication tool that could be applied, valued, and functional across the primary care network.

The clustering of family health teams and/or primary care networks, the development and wider use of EMRs, and promotion of a primary medical home were suggested by the participants as ways to promote more efficient communication flow between the providers and the system.

THE OPPORTUNITIES

The participants concurred that the first step to improving patient safety in primary care is a better understanding of the issues, their incidence, and their outcomes. Without such knowledge, it would be difficult to build a clear case that patient safety in primary care deserves more attention from healthcare providers, decision makers, governments, and policy makers.

Some safety issues are known and are captured to a certain extent (such as adverse drug events) in the EMR within a practice; however, this information, and any steps taken to reduce their incidence or severity, is not shared. Setting up a data centre to receive aggregate, anonymized patient data from the EMR and coupling data and information management in the EMR with trigger tools (such as the PCTT) to identify possible adverse events, may provide greater insights into patient safety issues and their incidence. In addition, the lack of information on adverse events has not been conducive to scientific study. The data centre could provide a rich source of information for scientific research in the field, thereby further increasing the understanding of patient safety further.

Some patient safety issues have not yet registered with healthcare workers; therefore, the perspective of the users of the healthcare system is critical. A broader understanding of safety issues could be gained from engaging patients, their families, patient advocacy groups, and the general public. A deeper understanding of the issues could provide a more inclusive definition of patient safety in primary care. Thus, a wider range of issues could be documented and a more inclusive reporting and learning system built than currently exists.

Once the issues are better identified and understood, the severity and incidence of adverse events could be better estimated and published. Through the dissemination of this information, providers’, patients’ and decision makers’ attention may be drawn to the need for improved safety, and opportunities for improvement can be shared. For providers, the reporting and publication of the incidence of harm may draw attention to the need for a stronger safety culture and improved reporting of incidents. For patients, it may lead to greater engagement in their healthcare because they are more aware of their potential risks. Enhanced reporting and dissemination of the findings may provide an effective business case for decision makers to improve standardization, direct policies, and increase the resources allocated to primary health care quality and patient safety initiatives.

The participants suggested that policy analysis is needed. They agreed that a national policy forum should be held to discuss the current policy needs and how they can be achieved. From this forum, a national vision for safety in primary care could be built, which might provide guidance to the system.

In addition to documenting and reporting patient safety issues, the participants proposed that efforts should be made to catalogue best practices in primary care. The publication of these practices could aid primary care providers with diagnosis, treatment, counselling, and medication management options for their patients. Patients might also improve their health literacy and more effectively engage in their own care.

Enhancing the medical education of providers was seen as a priority for the participants. They suggested that the education of healthcare providers should be adapted to provide a greater focus on key patient safety issues and quality improvement processes. The education of providers could also include practice audits, thereby providing a greater understanding of the underlying causes of adverse events. This understanding is a crucial first step toward reducing the probability of reoccurrence.
Patient safety may be improved through the implementation of enhanced feedback opportunities for providers. These opportunities could include more intelligent trigger tools and the development of practice-based benchmarks. The participants agreed that efforts should be made to improve trigger tools so that they offer enhanced surveillance of patients. In their current state of development, trigger tools provide too many alerts that are of little significance. More intelligent trigger tools would take patient history into account and alert providers to possible adverse events that might otherwise go unnoticed. The participants proposed that research could be undertaken to develop benchmarks that could be disseminated to practices. These benchmarks would allow providers to compare the care they provide to that of other providers. Benchmarks could be developed based on the existing EMR data. Achievable benchmarks for primary care have been proposed and studied by the scientific literature. These include: the annual percentage of: older patients prescribed Beer’s list of medications, female patients over the age of 40 years with mammogram results and patients with diabetes mellitus having triglyceride measures (Wessell et al. 110).

The participants proposed that practitioners should be encouraged to take a team approach to care. Multidisciplinary teams could be strengthened through the exploration of the most effective roles for registered nurses (RNs), nurse practitioners (NPs), community pharmacists, social workers, psychologists, physical therapists, and other primary care providers, working within their full scope of practice. Such research could lead to greater job satisfaction for all healthcare providers.

SYNTHESIS OF ROUNDTABLE DISCUSSIONS

The participants generally substantiated the findings from the literature review and key informant discussions. They felt that missed and delayed diagnosis and medication management are two of the main patient safety issues in primary care. These issues maybe the outcomes of the structure of the primary care network. Information does not flow freely or efficiently, primary care providers and consulting specialists work in isolation from each other and reimbursement systems do not generally support the cultivation of the provider-patient relationship. The lack of incident reporting has left providers, patients, decision makers, and policy makers with no way to gauge how big the patient safety issue is. Without such knowledge there may be little impetus for change.

Across core themes and across the small groups, discussions often led back to similar opportunities, barriers, and ameliorators for progress. Interaction between the primary care ‘silos’ was an often cited opportunity for progress, and the lack of information was frequently discussed as a barrier to progress. The development of a national vision for primary care was often discussed as a possible vehicle for change.

The participants identified gaps in the literature. The participants highlighted the fact that evidence regarding the impact of non-clinicians, the impact of guidelines and the diagnosis, treatment, and care of children has largely been ignored by the literature. These gaps underscore the nascent state of patient safety research in the primary care setting and may begin to be better addressed with an increased awareness of patient safety in primary care. The participants also discussed the potential next steps to advance patient safety in primary care. These initiatives included building a business case for patient safety, the development of guidelines, adaptations to educational curriculum, and the encouragement of a team approach to care.

FUTURE STEPS

Incidents of unintended harm do occur in primary care and many are preventable. However, the scientific studies to date provide little about the frequency and types of events that pose a safety risk for patients receiving primary care in Canada.

Two themes emerged in relation to patient safety from the literature review: missed or delayed diagnoses and the management of medications. Both are, to a large extent, related to communications, administrative processes and the integration of new knowledge into clinical practice. Experts in both the key informant interviews and the roundtable discussion supported these areas as being important for patient safety in primary care.

However, it should be noted that these themes are based mainly on findings from studies of other healthcare systems in other countries. It should also be kept in mind that the evidence on frequency and type of incidents is limited and in many instances weak in scientific quality. Likewise, there is fairly limited evidence available about the outcome of actions proposed or initiated to improve safety in primary care.

Obtaining data about the actual situation in Canada is crucial for the development of effective and proactive systems for enhancing patient safety in primary care. Therefore, the findings from the literature review illustrate, first and foremost,
that research on patient safety, in particular from Canadian primary care systems, is needed.

A synthesis of proposals in the scientific literature and suggestions by key informants and participants at the roundtable discussion has resulted in the generation of a large number of suggestions for improving safety in primary care. For example:

- Effective communication could be improved by focusing on the effective transfer of information between care providers and their patients at all stages of primary care, from communicating test results to determining diagnoses, to prescribing and checking adherence to medication plans.

- Medication management could benefit by reviewing and reconciling the patient’s medication list from the discharge summary and the medication list used in community care, including pharmacists in such medication reviews, as well as in counselling and telephone follow-ups after hospital discharge.

- Technology-assisted prescribing and decision support tools could serve as aids for appropriate treatment and counselling, especially when caring for patients that may be more vulnerable to safety incidents.

All of these proposed actions may be of great importance in increasing patient safety in primary care. However, considering our scarce knowledge of the current safety situation in Canada, it is important to launch further research on this subject in order to gather the facts needed for appropriate action. In order to thoroughly investigate patient safety issues in Canadian primary care, several key questions have been identified:

1. What is the frequency and what are the different types of patient safety incidents in primary care in Canada?
2. What is the role of diagnosis in patient safety in primary care and how can clinicians maximize patient safety in the absence or uncertainty of a final diagnosis?
3. Is there a discrepancy between prescribing practices and available criteria for appropriate prescribing in Canadian primary care?
4. What fraction of the work load and resources in emergency departments is due to safety incidents in primary care in Canada?
5. What is the total cost of safety incidents in primary care in Canada?
6. What are the overall economic, social and patient-related implications of patient safety in Canadian primary care?
7. What are the major opportunities for enhancing patient safety in Canadian primary care?
8. Can safety incidents be reduced by different funding or staffing models for primary care services in Canada?

From the perspectives of stakeholders, several system-level priorities and opportunities were identified as potential next steps for advancing patient safety in primary care:

1. Further research and data regarding the nature of patient safety incidents and adverse events in primary care in Canada, as well as the actions and strategies to enhance patient safety.
2. A pan-Canadian approach or framework for identifying and addressing patient safety in primary care, while respecting the uniqueness and responsibility of each jurisdiction in the delivery of primary care.
3. Continued efforts for national, provincial, territorial, regional and local organizations and associations to collaboratively highlight and communicate the key patient safety issues in primary care.
4. In addition to learning from acute and other care settings, continued awareness and investigation of the unique aspects of primary care to determine and develop targeted approaches to improving patient safety specific to primary care and its services.
5. Current practices, gaps and potential barriers for the disclosure and reporting of patient safety incidents in primary care should be identified and addressed.
6. Mechanisms for encouraging and supporting a focus on patient safety should be considered and evaluated for the various new and developing primary care delivery models, as well as the existing practices of family physicians and other providers across Canada.
7. Consideration for building the capability and capacity for primary care providers and administrative staff to implement initiatives to improve the safety of care through participation in patient safety initiatives, accreditation programs and educational events and to implement practices aimed at improving patient safety.
CONCLUSION

This paper describes the concept of patient safety as it applies to primary care and the unique issues, challenges, key themes and priorities emerging from the literature and from the perspectives of stakeholders. The full delineation of patient safety is frustrated by the lack of research and, therefore, lack of data on the safety risks to patients who access primary care. The existing research on patient safety incidents relevant to primary care is reviewed and synthesized in this report, as well as the evidence currently available in the scientific literature on actions taken to address patient safety issues in primary care. There are currently no examples of established reporting systems for adverse events; therefore, the full scope of patient safety incidents in primary care has not been documented, nor have strategies for addressing these risks.

The relevance of findings from patient safety research in other healthcare sectors and settings is discussed in this report. Primary care could benefit from incorporating patient safety processes that have been found to be effective at other levels of care (e.g., acute care) and other sectors (e.g., aviation), where safety research is more advanced. An understanding of the logic and processes of addressing patient safety in acute health could be beneficial; however, determining the best method of applying that logic to primary care requires further research and ongoing evaluation and assessment. The Canadian system could incorporate the knowledge gained and safety measures implemented in other countries, such as requiring significant event analyses/audits and developing a reporting system for adverse events so that providers can become more aware of patient safety risks and their possible ameliorators.

The potential opportunities and next steps for advancing patient safety in primary care in Canada are also reviewed. Research into the aspects of patient safety in primary care should receive higher priority in healthcare and health services research in the future.
REFERENCES


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59 Makeham M, Dovey S, Runciman W, Larizgoitia I. Methods and Measures used in Primary Care Patient Safety Research: Results of a literature review. Methods & Measures Working Group of the WHO World Alliance for Patient Safety.


ABBREVIATIONS

AHRQ – Agency for Healthcare Research and Quality
ARP – alternative relationship plans
ASIPS – Applied Strategies for Improving Patient Safety
BCPSQC – British Columbia Patient Safety & Quality Council
CCT – controlled clinical trial
CI – confidence interval
CPSI – Canadian Patient Safety Institute
GP – general practitioner(s)
EHR – Electronic health records
ICPS – International Classification for Patient Safety
IPCI – Integrated Primary Care Information
IPET – improved prescribing in the elderly tool
IHE – Institute of Health Economics
METRIP – Medication Error Types, Reasons, and Informatics Preventability
mo – month(s)
NR – not reported
NS – not statistically significant
OR – odds ratio
PCTT – Primary Care Trigger Tool
PDA – personal digital assistant
PIAA – Physician Insurers Association of America
PIM – potentially inappropriate medication
RBS – random blood sugars
RCT – randomized controlled trial
RR – relative risk
RPSGB – Royal Pharmaceutical Society of Great Britain
SEA – significant events analysis
START – Screening Tool to Alert doctors to Right Treatment
STOPP – Screening Tool of Older Person’s Prescriptions
TAPS – Threats to Australian Patient Safety
UK – United Kingdom
USA – United States of America
yr – year(s)
**GLOSSARY**

*Actions taken to reduce risk:* actions taken to reduce, manage or control any future harm, or probability of harm, associated with an incident (Runciman et al.\(^8^3\)).

*Adverse reaction:* unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred (e.g., adverse drug reactions) (Runciman et al.\(^8^3\)).

*Alternative relationship plans (ARPs):* an alternative to the fee-for-service method of reimbursing physicians for their medical services. ARPs may provide compensation to physicians to care for underserviced socio-economic populations, such as northern, rural, intercity and elderly cohorts (Canadian Institute for Health Information\(^1^7\)).

*Ameliorating actions:* actions taken or circumstances altered to make better or compensate any harm after an incident. Ameliorating actions apply to the patient (clinical management of an injury, apologizing) and to the organization (staff debriefing, culture change and claims management) (Runciman et al.\(^8^3\)).

*Bias:* defined as a systematic deviation from the truth. In studies, it refers to systematic errors in measurement or assessment that cause either an overestimation or underestimation of the results (Rothman et al.\(^8^0\)).

*Control:* in clinical trials, a participant who is compared with an individual that received the intervention under study. The control participant may have received usual care, no intervention, or another active intervention (Rothman et al.\(^8^0\)).

*Cross-sectional study:* the observation of a defined population at a single point in time or time interval. Exposure and outcome are determined simultaneously (Rothman et al.\(^8^0\)).

*Controlled clinical trial:* a planned experiment in which participants are allocated to intervention or control group using a quasi-random or non-random methods and the outcomes are compared between the groups (Rothman et al.\(^8^0\)).

*Drug misadventure:* a wide-ranging label used to refer to adverse drug reactions, prescribing errors, and medication errors (World Alliance for Patient Safety\(^1^1^6\)).

*Error:* failure to carry out a planned action as intended or application of an incorrect plan (Runciman et al.\(^8^3\)).

*Event:* any deviation from usual medical care that causes an injury to the patient or poses a risk of harm (see also *Incident*) (World Alliance for Patient Safety\(^1^1^1\)).

*Event type:* the characteristics distinguishing a group or class of patient safety events (see also *Incident type*) (Runciman et al.\(^8^3\)).

*Harm:* impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability, and death (Runciman et al.\(^8^3\)).

*Harmful incident (adverse event):* an incident which resulted in harm to a patient (Runciman et al.\(^8^3\)).

*Hazard:* a circumstance, agent, or action with the potential to cause harm (Runciman et al.\(^8^3\)).

*Healthcare-associated harm:* harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury (Runciman et al.\(^8^3\)).

*Incident:* an event (usually unexpected and undesirable) that represents a negative deviation from the standard of care that occurs in a healthcare facility (see also *Event*) (Runciman et al.\(^8^3\)).

*Incident type:* a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features. A patient safety incident can be classified as more than one incident type (see also *Event type*) (Runciman et al.\(^8^3\)).

*Level of evidence:* a ranking system used to describe the strength of the results measured in a research study. The design of the study affects the strength of the evidence (Scottish Intercollegiate Guideline Network\(^9^2\)).
**Medication error:** any error occurring in the medication use process (World Alliance for Patient Safety\(^{116}\)).

**Methodological quality:** the extent to which the design and conduct of a study are likely to have prevented systematic errors (bias). Variation in quality can explain variation in the results of studies included in a systematic review. More rigorously designed ('better quality') studies are more likely to yield results that are closer to the “truth” (Rothman et al.\(^{80}\)).

**Mitigation actions:** actions or circumstances that prevent or moderate the progression of an incident toward harming the patient. Mitigating actions are designed to minimize the harm to the patient after the error has occurred and triggered damage control mechanisms (Runciman et al.\(^{83}\)).

**Near misses:** circumstances which had the potential to cause patient harm but were prevented or ran to completion without harm occurring (World Alliance for Patient Safety\(^{116}\)).

**Patient outcome:** the impact upon a patient which is wholly or partially attributable to an incident (World Alliance for Patient Safety\(^{116}\)).

**Patient safety incident:** a patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. A patient safety incident can be a reportable circumstance, a near miss, a no harm incident, or a harmful incident (adverse event) (Runciman et al.\(^{83}\)).

**Prevalence:** the proportion of individuals in a given population having a characteristic of interest (Last\(^{54}\)).

**Preventable:** accepted by the community as avoidable in the particular set of circumstances (Runciman et al.\(^{83}\)).

**Prevention:** actions taken to reduce the risk of reoccurrence of the same or similar patient safety incident and on improving system resilience. Prevention actions are those actions taken to reduce, manage, or control any future harm, or probability of harm, associated with an incident. These actions may be directed toward the patient (provision of adequate care, decision support), toward staff (training, availability of policies/protocols), toward the organization (improved leadership/guidance, proactive risk assessment), and toward therapeutic agents and equipment (regular audits, forcing functions) (Runciman et al.\(^{83}\)).

**Prospective cohort study:** a type of observational design in which a group of participants (a cohort) that have been exposed to a characteristic of interest (i.e., a preventive intervention) are followed over a period of time to assess outcomes. Comparisons are made with a group of individuals that are not exposed to the intervention of interest. They are longitudinal and go forward over time (Rothman et al.\(^{80}\)).

**Quality:** the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (World Alliance for Patient Safety\(^{116}\)).

**Randomized clinical trial:** a planned experiment in which participants are assigned to intervention or control groups using a random method. Comparisons between the groups are made for the outcomes of interest (Rothman et al.\(^{80}\)).

**Rapid evidence review:** a summary of research evidence that is produced as comprehensive as possible within the constraints of a given timetable. It is characterized by the use of systematic review methods, but with some limitations in the comprehensiveness of the search, the research scope or other stages of the review process (Hemingway\(^{44}\)).

**Retrospective cohort study:** a type of observational design in which a group of participants (a cohort) is assembled based on his previous exposure to a characteristic of interest (i.e., a preventive intervention). Comparisons are made with a group of individuals that were not exposed to the intervention of interest in the past. They are longitudinal and go backward over time (Rothman et al.\(^{80}\)).

**Risk:** the probability that an incident will occur (Runciman et al.\(^{83}\)).

**Safety:** the reduction of risk of unnecessary harm to an acceptable minimum (Runciman et al.\(^{83}\)).

**Statistical significance:** the likelihood that a finding or a result is caused by something other than just chance (Last\(^{54}\)).

**Systematic review:** summaries of research evidence that address a clearly formulated question using systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyze data from the studies that are included in the review (Cook et al.\(^{18}\)).

**Violation:** deliberate deviation from an operating procedure, standard or rule (Runciman et al.\(^{83}\)).
APPENDIX A - PRIMARY CARE HAZARD PERMEATION MODEL (PCHP MODEL)

Reason\textsuperscript{76} uses the system approach to construct the Swiss Cheese Model of human error within a complex adaptive system (CAS). Within any CAS there are inherent hazards present that can result in adverse outcomes. A CAS has a number of operational defences in place to minimize or prevent the transmission of a hazard through the CAS, resulting in an adverse outcome. Each operational defence represents a defensive layer, but errors within each defensive layer can result in a series of holes. The size and location of a defensive layer’s hole will vary across systems and time. Thus, a defensive layer is similar to a slice of Swiss cheese and a CAS is akin to multiple slices of Swiss cheese standing side by side. If the holes in each slice of Swiss cheese align, then a hazard can permeate a system’s defences and result in an adverse outcome.

The Swiss cheese model has recently been adapted to the provision of healthcare (i.e., the Health Care Error Proliferation Model in Palmieri\textsuperscript{72}. However, we felt the Health Care Error Proliferation Model did not account for the more active role patients play in primary care delivery.

Primary Care Hazard Permeation Model (PCHP Model)

In order to frame our discussion around patient safety in primary care, we felt it necessary to have a coherent framework to identify risks to patient safety in primary care. We have formulated the Primary Care Hazard Permeation (PCHP) model in order to provide structure to our discussion of the literature. The PCHP model focuses on the primary care delivery system within the healthcare environment and builds on the Health Care Error Proliferation Model by adding patient performance as a defensive layer. A graphical depiction of the PCHP model is given in Figure A.

Figure A:
Primary Care Hazard Permeation (PCHP) Model

The PCHP model frames the delivery of primary care as a CAS with a number of defensive layers that are intended to prevent a hazard from affecting patient outcomes. The PCHP model has five defensive layers: (i) organizational leadership; (ii) management; (iii) situations for safe practice; (iv) provider performance; and (v) patient performance. The five defensive layers are organized by proximity to the patient. At the macro-level, organizational leadership is the most distant defensive layer from the patient. At the micro-level, patient performance is the closest defensive layer to the patient. Latent errors are more likely to occur at the macro-end of the primary care delivery system, while active errors are more likely to occur at the micro-end.
APPENDIX B - SYSTEMATIC LITERATURE REVIEW

THE CONCEPTUAL FRAMEWORK

The conceptual framework for the International Classification for Patient Safety developed by the World Health Organization (WHO) World Alliance for Patient Safety Taxonomy was used to address the research questions of the review. This framework is presented in Figure B below.

Figure B: Conceptual framework for the International Classification for Patient Safety

## SEARCH STRATEGY

### Table A: Search strategy

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<th>Database</th>
<th>Edition or date searched</th>
<th>Search Terms ††</th>
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| The Cochrane Library  
http://www.thecochranelibrary.com | (Jan 26, 2010) | #1 MeSH descriptor Medical Errors explode all trees  
#2 MeSH descriptor Equipment Failure explode all trees  
#3 MeSH descriptor Iatrogenic Disease, this term only  
#4 MeSH descriptor Safety Management, this term only  
#5 (#1 OR #2 OR #3 OR #4)  
#6 (error or adverse or safe* or fail*):ti  
#7 (#5 OR #6)  
#8 (primary care or primary health care or family practice or general practice or general practitioner or family physician or community health care):ti,ab,kw  
#9 (#7 AND #8)  
| MEDLINE (includes in-process and other non-indexed citations)  
(Ovid Interface) | (Jan 26, 2010) | Primary Health Care/  
family practice/  
primary nursing care/  
family physic*:ti.  
physicians, family/  
gp.ti. or gps.ti.  
((primary adj2 care) or primary health care).ti.  
family doctor*:ti.  
((general or family) adj1 practi$).ti.  
community health services/  
(community health care or community health care).ti.  
or/1-11  
limit 12 to (english language and yr="1995 - 2010")  
error*:ti.  
(patient*: adj3 safe*).ti.  
(medica*: adj2 safe*).ti.  
(prescri*: adj2 safe*).ti.  
((inappropriat* or appropriate* or suboptimal) adj2 (prescri* or medic*)).ti.  
medication reconciliation.ti.  
(medication mismanagement or medication management).ti.  
primary care safety.ti.  
(safe* adj2 (climate or cultur*)).ti.  
unsafe.ti.  
(“quality and safety” or “safety and quality”).ti.  
misunderstandings.ti.  
iatrogen*:ti.  
adverse*:ti.  
sentinel event*:ti.  
significant event*:ti.  
critical incident*:ti.  
unanticipated outcome*:ti.  
near miss*:ti.  
(close call or close calls).ti.  
(incident*: adj2 report*).ti.  
(hand over* or handover* or hand off* or handoff*).ti.  
(communicat*: adj3 (insufficient or issue* or problem* or fail*)).ti.  
transfer of care.ti.  
safety management/  
iatrogenic disease/  
patient safety.jw. |
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<td>exp equipment failure/ Medical Errors/ medication errors/ or/14-43 (fail* adj2 (diagnos* or recogniz*)) not (heart failure or renal failure or liver failure or organ failure).ti. (lack* adj2 diagnos*).ti. misdiagnos*.ti. (miss* adj3 diagnos*).ti. under diagnos*.ti. underdiagnos*.ti. (over diagnos* or overdiagnos*).ti. or/45-51 13 and 44 13 and 52 55- 53 or 54</td>
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<tr>
<td>EMBASE (Ovid Interface)</td>
<td>(Jan 26, 2010)</td>
<td>Primary Health Care/ general practice/ primary medical care/ general practitioner/ family physic*.ti. (gp or gps).ti. ((primary adj2 care) or primary health care).ti. family doctor*.ti. ((private or general or family) adj practi$).ti. community care/ community health care.ti. or/1-11 limit 12 to (english language and yr=&quot;1995 - 2010&quot;) patient safety.jx. error*.ti. (patient* adj3 safety).ti. (medica* adj2 safety).ti. (prescri* adj2 safe*).ti. ((inappropriat* or appropriat* or suboptimal) adj2 (prescri* or medic*)).ti. medication reconciliation.ti. (medication mismanagement or medication management).ti. primary care safety.ti. (safe* adj2 (climate or cultur*)).ti. unsafe.ti. (&quot;quality and safety&quot; or “safety and quality”).ti. misunderstandings.ti. adverse*.ti. sentinel event*.ti. significant event*.ti. iatrogen*.ti. critical incident*.ti. unanticipated outcome*.ti. near miss*.ti. (close call or close calls).ti. (incident* adj2 report*).ti. (hand over* or handover* or hand off* or handoff*).ti. (communicat* adj3 (issue* or problem* or fail* or insufficient)).ti. transfer of care.ti. or/14-38</td>
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Note: †† “∗”, “#”, and “?” are truncation characters that retrieve all possible suffix variations of the root word e.g. surg* retrieves surgery, surgical, surgeon, etc. Searches separated by semicolons have been entered separately into the search interface.
Table B: 
Websites searched – grey literature

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### Australian Sites

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### United Kingdom Sites

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### United States Sites

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<tr>
<td>US Department of Health and Human Services</td>
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STUDY SELECTION

A set of broad screening criteria was developed to identify potentially relevant articles to the two topics of study (see Table C). Titles and abstracts retrieved in the search results were screened based on the relevance and applicability to the review questions:

- What types of patient safety incidents relevant to primary care have been identified in the literature?
- What research has been conducted on interventions or actions that address patient safety in primary care?
- Which are the key themes and priorities in patient safety in primary care that emerge from the literature?

When an article met the screening criteria for any of the questions or when there was not enough information to definitely exclude it, the full text was retrieved.

The full manuscripts that were deemed relevant were retrieved for a closer inspection. One reviewer appraised the full-text of potentially relevant studies using a standard form that outlined the eligibility criteria for the rapid review (examples of these forms may be requested from the lead author of this report).

Two reviewers selected the relevant studies to address each of the research questions outlined in the review protocol. Study selection was not completed in duplicate and only one reviewer completed the study selection per research question.

Table C:
Selection criteria

| Country: | Studies must have been conducted in countries deemed to have developed economics, as defined by the United Nations: Australia, Austria, Belgium/Luxembourg, Canada, Denmark, Finland, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Norway, Sweden, Switzerland, United Kingdom and the United States. |
| Type of studies: | Primary research studies were included. Systematic reviews, health technology assessment reports, narrative reviews, editorials, letters to the editor, commentaries and position papers were excluded. |
| Setting: | Primary care settings (e.g., outpatient clinics, medical offices [public and/or private], the community). Not included in this review are studies conducted in the following care settings: emergency rooms, acute care facilities, chronic care facilities and addiction treatment facilities. |
| Population: | Both children and adult populations. |
| Types of Patient Safety Incidents: | Studies in which the unit of analysis was the healthcare provider rather than the patient or the safety incidents were excluded unless they provide information about patient outcomes. |
| Patient Safety Interventions or Actions: | Studies focused on specific clinical groups or health problems were not included. Studies should target either a) patients, or b) primary care health professionals, including, but not limited to, doctors, nurses, pharmacists, allied health professionals and administrative staff. Studies targeting residents and students were not considered eligible. |
| Design: | Randomized controlled clinical trials, controlled clinical trials, observational studies (retrospective and prospective cohort studies). For the question related to types of patient safety incidents, case control studies, cross sectional studies). Case series, case reports and qualitative research were not considered eligible. |
| Types of safety incidents: | Studies that identify safety incidents defined as events resulting of actions or omissions that could have led to harm to a patient. They can be classified as incidents related to clinical administration, clinical process/procedures, documentation, health-care associated infections, medications, blood products, nutrition, oxygen supply, medical devices, provider or patient behaviour, accidents, infrastructures and organizational management. Studies must provide numeric data to describe the frequency of these events. Studies assessing quality improvement outcomes were not included. Patient safety incidents occurring outside the primary care were not considered. Studies documenting adverse drug reactions of specific medications were excluded. |
APPENDIX C - KEY INFORMANT INTERVIEW GUIDE

INTRODUCTION

In follow-up to the invitation letter that you received on March 22nd from the Canadian Patient Safety Institute and BC Patient Safety and Quality Council, we would like to thank you very much for agreeing to this interview. The Institute for Health Economics has been commissioned through a competitive process to prepare a research paper on Patient Safety in Primary Care in Canada. As part of the research process, we are conducting interviews with about 18 Key Informants from across Canada and internationally who were identified as expert stakeholders by the pan-Canadian Patient Safety in Primary Care Advisory Group. The purpose of these interviews is to assist us in the preparing a background paper that will be the foundation for discussion at a roundtable event in May of this year. Our research team has already completed a comprehensive literature review which will also make up much of the report.

I would like to tape this interview so that I can refer to it when I summarize our conversion. Please be assured that I will ask for your permission, of course, to quote and/or use your name in any written or oral form. Please feel free to stop me at any point if you have any questions or if you wish any clarifications.

I have a series of seven questions to guide our discussion and I expect that the interview to last approximately 45 minutes (no more than 60 minutes).

Would you please introduce yourself? Please describe your role, background, and interest and experience in primary care. Please describe your role, background, and interest and experience in patient safety.

Patient safety issues in primary care.
In your opinion, what are the Key issues related to patient safety in primary care today? (Cues: medication management, diagnostic errors, insufficient transfer of information between providers, patient’s level of understanding of information given by provider)

In your opinion, what is it about the primary care practice setting that makes patient safety an issue? (Cues: need to determine a diagnosis for patients seen in primary care, requirements for follow-up in managing continuity of care, variability of practices; absence of error reporting systems, often independent practice settings, communication with other healthcare providers)

Are there patient populations that you think we should be particularly concerned about when trying to maximize patient safety in primary care? (Cues: older adults/geriatrics, children, persons with chronic diseases/conditions, complex patients with multiple or high risk medications, mental health, aboriginal populations, newcomers to Canada, persons with disabilities).

In your opinion, what are some of the unique patient safety challenges for these patient populations?

What do you see as the most significant barriers to or challenges for addressing patient safety in primary care settings?

From your own experience, what do you see as the main opportunities for improving patient safety in primary care? (Cues: information systems, electronic alerts for chronic disease & medication management, inter-professional collaboration, general acceptance of patient safety taxonomy, adverse event reporting and learning systems, trigger tools, etc.). Have you initiated any innovative ways to improve patient safety in your practice?

Knowledge gaps and future research
Are there other gaps in knowledge relating to patient safety in primary care that we should be considering? What are the priorities for research to close these gaps?

Other
Are there other issues, other ‘lessons learned’ or words of advice you have to share with us as we prepare our report?
APPENDIX D - SMALL GROUP WORK PARTICIPANT GUIDE

The Patient Safety in Primary Care Roundtable will provide an opportunity to share unique perspectives and to guide the process of broadening the patient safety agenda in Canada. These discussions will complement the literature search and key informant interviews that have already taken place, under the guidance of the research team.

Table groups of 6-8 people have been assigned. Please check the back of your name tag to find your table number. Each Table has been assigned a Facilitator and a Scribe from the Advisory Group to support the discussion and capture the discussion input.

The key ideas from each of the breakout groups will be shared with the larger group after each topic. All of the Table input will be captured and shared with the researchers.

As your group begins each discussion topic, we invite you to keep these ideas in mind:

• Use the research findings and the context for Patient Safety described at the beginning of the meeting as the backdrop for the group’s discussion.
• Keep the primary focus of the discussions on Patient Safety. If other/related topics arise that don’t fit, but need to be captured, do so on a “Parking Lot” page.
• Consider your responses from a local, provincial and national lens.
• Keep the ideas flowing. There is no such thing as a dumb idea in brainstorming.
• Draw on evidence and Best Practices during the discussions versus anecdotes.

11:15 – 12:30: Opportunities, Barriers and Enablers: Small Group Discussion
Questions for consideration:

• What are the three opportunities for improvement in patient safety that should be seized/acted upon?
• What potential barriers have impeded progress to date?
• How might these barriers be overcome?
• What factors will enable/facilitate progress?
• How might we capitalize on these factors?

2:00 – 2:45: The Way Forward: Priorities and Next Steps
Looking at the list of opportunities, impediments and enablers:

• What are the potential next steps for advancing patient safety in primary care?
• Who (organizations, champions) needs to be involved? Who should lead? Be a partner?