OPTIMAL PRESCRIBING AND MEDICATION USE IN CANADA
CHALLENGES AND OPPORTUNITIES

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Ingrid Sketris, PharmD, MPA(HSA)
Ethel Langille Ingram, MA
Heather Lummis, BSc Pharm, MSc

Faculty of Medicine and College of Pharmacy, Dalhousie University
Capital District Health Authority, Halifax, Nova Scotia
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Acknowledgements

The Health Council of Canada commissioned this paper to provide a foundation for discussion at the June 2007 symposium, Safe and Sound – Optimizing Prescribing Behaviours, an initiative designed to assist in the continued development of Canada’s National Pharmaceuticals Strategy. The Health Council gratefully acknowledges the authors, as well as the Councillors on the steering committee for the symposium: John Abbott, Alex Gillis, Jean-Guy Finn, and Bob Nakagawa (chair).

From the authors:
This paper was completed with the guidance and assistance of many individuals.

The volume of material related to optimal prescribing is extensive, the health professionals involved numerous, and the domains diverse. Thus the supportive role played by the following expert advisors was invaluable. We are thankful for the time that they spent reviewing numerous drafts and providing valuable feedback, and also for their constant encouragement.

Dr. Jean Gray, Professor Emeritus, Medical Education, Medicine and Pharmacology, Dalhousie University

Dr. Wayne Putnam, Associate Professor, Department of Family Medicine, Dalhousie University

Dr. Neil MacKinnon, Associate Professor, Pharmacy Administration, and Associate Director of Research, Dalhousie University College of Pharmacy

The material developed on best practices was reviewed and augmented by organizations noted in the document. We wish to recognize the valuable input provided by Judith Mackson, National Prescribing Service Ltd.; Alain D. Mayhew, Effective Practice and Organization of Care Group, University of Ottawa; Jim Wright, University of British Columbia; Janet Cooper, Canadian Pharmacists Association; Lisa Dolovich and Connie Sellors, Centre for Evaluation Medicines, McMaster University; and Dawn Frail, Nova Scotia Department of Health.

The “Prescribers in Canada” was reviewed by the registrars of provincial regulatory authorities. We would like to thank Karen Wolfe, Director of Pharmacy Practice Support, National Association of Pharmacy Regulatory Authorities, for facilitating this review. Michele Arthur, Program Lead, Pharmaceuticals, Canadian Institute for Health Information, provided us with confirmation on drug expenditures.

We thank Jocelyn LeClerc of the Initiative for Medication Management, Policy Analysis, Research & Training for her overarching support on this project; Elizabeth Foy and Pamela Edmunds for their valuable assistance with literature retrieval; Shelley McKibbon for assistance with RefWorks; Denise Sprague for reviewing the documents; and Chris Cameron for his technical guidance. We also want to acknowledge the invaluable support provided by the staff at the Health Council secretariat.

Finally, we would like to thank the Health Council of Canada for supporting this work. The Canadian Health Services Research Foundation, Canadian Institutes for Health Research, and Nova Scotia Health Research Foundation provide a Chair in Drug Use Management and Policy Research to Ingrid Sketris, which enabled her to take on this project.
Executive Summary

Both suboptimal prescribing and variation in prescribing practices exist in Canada, leading to underuse, overuse and inappropriate use of drugs. To assist in the continued development of Canada’s National Pharmaceuticals Strategy, the Health Council of Canada commissioned this background paper as a foundation for discussion at a symposium on appropriate prescribing, June 12-13, 2007, in Montréal. Presentations and a report from the symposium, Safe and Sound – Optimizing Prescribing Behaviours, will be available on the Health Council’s website, www.healthcouncilcanada.ca/safeandsound.html.

This paper reviews the challenges for Canada’s health care system in ensuring that drug prescriptions are appropriate, safe and effective. And it summarizes what is known about the effectiveness of various approaches to improve prescribing practices.

With this evidence in mind, the authors present the following advice for action by health care system managers, health care providers, patients and their caregivers, regulators and the private sector.

Recognize the issues
- Both suboptimal prescribing and variation in prescribing practices exist in Canada leading to underuse, overuse or inappropriate use of drugs.
- Provinces and territories vary in the health care providers allowed to prescribe, the drugs they can prescribe, and the drugs that will be reimbursed.
- Canada does not have a comprehensive drug utilization system that can link drug use by patients to outcomes (such as improved patient health and reduced hospitalizations) and link drug use and outcomes across payers (public and private) and across sectors (primary care, acute care and continuing care, including long-term care).

Be strategic and targeted
- Involve patients and caregivers. They have a role to play in safe, appropriate, cost-effective medication use by taking drug therapy as negotiated with the prescriber and monitoring their responses to the drug.
- Consider the barriers and facilitators. In selecting interventions to improve prescribing practices, consider not only the context for prescribing but also the barriers and facilitators to change.
- Use strategies known to be effective. Multi-faceted interventions, academic detailing and reminders are among the most effective strategies for changing prescribing behaviour.
- Integrate and coordinate systems. Integrated and coordinated systems are needed to provide educational and other interventions that may improve the prescribing practices of health care providers who work in primary care, acute care, and continuing care, including long-term care.
- Examine the system and the resource base. Organizational systems, human resources and other resources are needed to assist prescribers and other health care professionals through their full range of responsibilities within the medication-use system.

Evaluate
- Improved methods are needed for prescribers to remain current and to determine if drug information is valid, reliable and relevant to their patient setting.
- Strategies and policies used to improve prescribing and medication use should be regularly evaluated to determine their impact on patient health outcomes, health services utilization and broader societal goals.
Introduction

Canadians receive approximately 400 million prescriptions each year¹ and spend $24.8 billion annually on drugs, about $770 per person.² Yet, we do not systematically capture information that can tell us whether the right drugs are reaching the right people with the intended benefits, while avoiding unintended harm.

In their 10-Year Plan to Strengthen Health Care in 2004, the First Ministers identified nine elements of a proposed National Pharmaceuticals Strategy (NPS),³ which were reaffirmed in the National Pharmaceuticals Strategy Progress Report of June 2006.⁴ That report highlighted key challenges to appropriate prescribing and identified them as threats to the health of Canadians and cost drivers to the system. These challenges include:
- improper drug selection;
- inappropriate dosage;
- adverse drug reactions;
- drug interactions;
- therapeutic duplication; and
- patient non-compliance.

This paper summarizes the opportunities to address these challenges, focusing from a system perspective on interventions to improve prescribing practices. We review the evidence on effectiveness for various strategies and describe the complex landscape in which prescribing currently functions in Canada, including our medication-use system and a range of issues that affect prescribing practices. Behavioural and system change theory, although important to the topic of optimal prescribing, was beyond the scope of this paper.

This paper explores the sixth element of the NPS: “enhance action to influence prescribing behaviour of health professionals so that drugs are used only when needed and the right drug is used for the right problem.” It also relates to two other elements: “strengthen evaluation of real-world drug safety and effectiveness” and “broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record.”⁵

Canada’s medication-use system

From research to patient, prescription drugs travel a long journey. The drug development, regulation, financing, prescribing and use system in Canada is very broad and includes both pre-marketing and post-marketing activities (Figure 1). This paper focuses on specific aspects of the post-marketing phase: prescribing, medication use, and monitoring in community settings.

Ideally, the prescribing of drugs by professionals, the provision of care by pharmacists, the use of drugs by patients, and other elements of the medication-use system would all work together to provide patients with good health outcomes at an affordable cost to society.⁵

Prescribing

Physicians and other licensed practitioners prescribe medications in order to promote health and prevent, ameliorate, or cure disease. In 2005, there were nearly 70,000 physicians⁶ in Canada making prescribing decisions for their patients. The role of prescriber is evolving—with the goal of enhancing collaboration between physicians and other health care providers to potentially increase accessibility, choice, and quality of care for patients—⁷ and the ranks of prescribers now also include dentists, nurse practitioners, pharmacists, midwives, optometrists, podiatrists, registered nurses and clinical assistants.

Federal and provincial legislation governs which licensed practitioners have the authority to prescribe drugs. Who can prescribe and what they can prescribe varies across the country, with the exception of physicians and dentists (Table 1).⁸,⁹ Currently all provinces and two territories allow nurse practitioners to prescribe under specific guidelines. One approach is for pharmacists and nurse practitioners to develop...
collaborative agreements with physicians, which determine the services provided, accountability and documentation responsibilities. In Alberta, regulations came into effect on April 1, 2007, to allow pharmacists to prescribe specific drugs and blood products, and to administer intramuscular and subcutaneous injections. In Manitoba and in Québec, nurses will be able to prescribe a six-month supply of contraceptives (although women require a doctor’s examination to get a refill).

**Pharmacy services**

Prescription drugs are provided to ambulatory patients primarily through pharmacies located in their communities or accessed via the Internet or by mail order. Canada has approximately 7,500 community pharmacies. Prescription drug purchases by Canadian hospitals and pharmacies (wholesale spending for prescription and over-the-counter products available only in pharmacies) reached $16.57 billion in 2005.

Pharmacists may provide other professional services (also called cognitive services) such as referring patients to physicians or other health care providers, in-store screening or risk assessments for chronic diseases, trial prescriptions, refill reminders, educational seminars, and disease management. Cognitive services have demonstrated positive patient outcomes in some studies but no measured effect in others.

**The patient’s role in medication use**

Patients and their caregivers are becoming increasingly involved in their care decisions. They have a role to play in safe, cost-effective use of medication by taking and monitoring drug therapy as negotiated with and prescribed by their prescriber.

**WHAT IS GOOD PRESCRIBING?**

Good prescribing is essential to avoid unsafe and ineffective drug therapy. The World Health Organization has defined the steps for rational (good) prescribing as listed below:

- Diagnose the problem using information provided by the patient and/or the caregiver, the history and physical, and laboratory tests and other investigations.

- Define the therapeutic objectives based on the pathophysiology of the patient’s condition.

- Select the non-pharmacologic or pharmacologic treatment(s) with which the patient also agrees. If a medication is necessary, the correct one is chosen based on the diagnosis, the drug’s benefits, risks and costs, and its suitability for the patient.

- Write the prescription.

- Provide information to the patient/caregiver to promote adherence.

- Monitor (physician and pharmacist) the patient’s response to therapy.
Methodology

Many sources of evidence are used in decision-making by providers, patients, managers and other decision-makers. For this paper, a broad review of the literature was conducted with a primary focus on material in the public domain, including peer-reviewed journals, textbooks, the Cochrane Library databases, selected Internet sites, newsletters, proposals, and presentations and reports published by foundations and government organizations. Some information concerning specific interventions was accessed through information requests. The result is a narrative approach with highlighted themes relevant to optimal prescribing and medication use in Canada. Additional details of the literature search can be found in Web Appendix A on the Health Council’s website at www.healthcouncilcanada.ca/safeandsound.html.

Canadian literature has been integral to the discussion in this paper, and where possible, Canadian prescribing interventions have been included as examples. An index of Cochrane Reviews that address the areas of prescribing is provided in Web Appendix D.

Behavioural and system change theory, although important to the topic of optimal prescribing, was beyond the scope of this paper.

Challenges to optimal prescribing

A key challenge for individual prescribers: keeping current on information from research and other sources

It is a daunting task for prescribers to remain current with the medical literature, and medication is only one of many areas in which health care providers need to keep pace with new research evidence. Consider this snapshot of the complex world of prescribing for Canadian physicians in 2005:

- 322 million office-based patient visits, of which 94% resulted in handwritten paper records;
- approximately 400 million prescriptions dispensed in pharmacies, 81% of them prescribed by general practitioners;
- 22,000 human drug products on the market in Canada;
- 24 active substances received market authorization and 16 new active substances were reported by the Patented Medicine Prices Review Board (PMPRB); and
- 1.8 million new medical papers published (in 2004) in 20,000 journals from 300,000 clinical trials.

To further complicate matters, there are a myriad of information sources available to prescribers—sources they must assess to determine if the information is valid, reliable and relevant to their patient setting. Prescribers receive information provided to them (sometimes referred to as “push”) and they retrieve information when they need it (“pull”). Information varies by delivery method (e.g. print, e-mail, website, personal visit), source (e.g. government, industry, professional society), quality, relevance and timeliness. (See Web Appendix B for a list of information sources.) Improved methods are needed to help prescribers remain current on relevant literature and to ensure they have the skills to appraise and apply the literature in an increasingly complex health care environment.

A key challenge for the health care system: evaluating the quality of prescribing and the appropriateness of drug use

Scales and measures have been developed to assess the effectiveness and efficiency of specific parts of the medication-use system. Suboptimal prescribing has been found worldwide, and many quality improvement systems that include drug-related quality indicators exist in other countries. While various research projects have documented suboptimal prescribing in this country (see p. 9, “Examples of Canadian Drug-Use Studies”), Canada has limited capacity for the measurement of prescribing and its outcomes. Suboptimal prescribing has led to regional variations in drug use, unnecessary and inappropriate drug use,
Examples of Canadian Drug-use Studies

This sample of studies illustrates the problem of inappropriate and potentially harmful prescribing that exists in Canada.

- A Canada-wide study in 1996 reported that the total number of individual medications taken every day by seniors varied significantly, from 7.1 per person in British Columbia to 5.2 in Québec and the Atlantic Region. Benzodiazepine use by seniors was the highest in Québec (36%) and the lowest in the Prairie Region (18%). Benzodiazepines are used for a number of conditions, including trouble in sleeping, anxiety, panic attacks, and muscle spasms. Patients using benzodiazepines are at risk of daytime drowsiness, confusion, memory loss, depression, falls and fractures, and motor vehicle accidents. These risks are higher in seniors; therefore seniors’ use of benzodiazepines should be extremely limited.

- A Newfoundland study of community-based patients with infections found that only 61% of antibiotic prescriptions complied with prescribing guidelines, 10% of the prescriptions were not necessary, 20% were for the wrong drug, and 10% could have used a narrower spectrum drug. Family physicians overestimated the number of infections with a bacterial cause. The majority of needless prescriptions (58/60) were for infections normally caused by viruses, e.g. upper respiratory tract infections (colds) and bronchitis in children.

- A Québec study of community-dwelling residents examined the appropriateness of their drug use by using predefined criteria. The study found that 6.5% of these patients were prescribed at least one inappropriate drug and that nearly two-thirds of inappropriate prescriptions (4.2% of the patients) were for a long-acting benzodiazepine. Drug duplications or interactions were experienced by 5.1% of residents in this study.

- A Saskatchewan report of long-term care residents found that 28% received high-risk medications and 21% received benzodiazepines in 2001, putting them at risk of potentially avoidable adverse effects. Almost 25% of benzodiazepine users exceeded the maximum recommended dose.

- An Ontario study of the population over the age of 65 linked excess hospitalizations to drug-to-drug interactions. This study examined three different combinations of drug-to-drug interactions and found that 2–8% of the hospitalizations studied could have been prevented if the patients had not been receiving both of the medications that lead to the adverse interactions.

- A Nova Scotia study identified over 5,000 Pharmacare beneficiaries who received respiratory medications using nebulization. The nebulizer, a device used to deliver liquid medications in the form of a fine mist, is no longer recommended in most patients because portable inhalers are just as effective, safer and less expensive for most of these patients.
dangerous drug combinations, missed opportunities for beneficial therapy, and unintended harm. However, the extent of suboptimal prescribing in Canada and its effects on patient outcomes and on health care system costs, including the affordability of prescription drugs, are not systematically captured.

A systematic approach is required to evaluate the appropriateness of prescribing in Canada and to monitor quality improvement as changes in practice occur. Avorn suggests “assessing prescribing quality should be woven into the fabric of the delivery system, performed on an ongoing basis, and tightly linked to educational strategies to improve care.”

Factors affecting prescribing

In order to promote safe, effective and efficient drug use, it is important to recognize the many interacting factors that influence decision-making in the medication-use system. Improving the medication-use system may require influencing several factors, including the professional, organizational and social contexts and settings. Figure 2 illustrates the complexity of influences on prescribing during a clinical encounter, and several factors are explored below.

Patient and societal-related factors

The patient’s family and medical history, lifestyle, use of medication and natural health products, and the physician’s knowledge of, and feelings towards, a patient may influence prescribing. An increasing number of patients present with undifferentiated diseases or multiple illnesses that are being treated with numerous therapeutic interventions. Many physicians embrace shared decision-making models with patients that incorporate the patient’s values, preferences, and attitudes towards benefits and risks, experience of illness, socio-economic factors and support systems. Some research suggests that general practitioners are concerned that if patients do not get the drug they want, they will switch doctors. For antibiotics, however, doctors may overestimate the pressure by patients to prescribe.

The dominant responsibility for physicians is to their individual patients. Societal demand for medicines also has a role to play, as do societal values. For example, when prescribing antibiotics, physicians may need to weigh the treatment success for individual patients against the loss of effectiveness for future patients due to antimicrobial resistance.

Medication-related factors

The inherent properties of drugs—factors such as pharmacology, pharmacokinetics, pharmacodynamics, dosage, formulation, taste, and ease of administration—are important in prescribing decisions. Prescribers and patients also examine the scientific evidence about a drug’s safety and effectiveness; price plays a role as well.

Prescriber-related factors

Physicians’ knowledge, attitude and skills related to prescribing are important influences on their prescribing practices. Their underlying beliefs and values, as well as their perceptions of innovation and the benefits and risks of drugs, matter as well. Also important are physicians’ information-seeking behaviour, their own experiences and those of their peers. Habit plays a role—with some authors suggesting that physicians have an “evoked set” of drugs with which they are familiar.

The effect of physician demographics on prescribing has been studied with varied results. Some studies suggest that age, gender, urban versus rural location of practice, experiences at medical school, and specialty versus generalist care may all play a role, but findings have not been consistent.
A 2005 Cochrane Review of tailored interventions to overcome identified barriers to change in professional health care practice\(^{29}\) used the Cochrane Effective Practice and Organisation of Care Group (EPOC)\(^{40}\) classification of barriers: (1) information management, clinical uncertainty; (2) sense of competence; (3) perceptions of liability; (4) patient expectations; (5) standards of practice; (6) financial disincentives; (7) administrative constraints; and (8) others.

**Practice environment and organization-related factors**

Physicians are influenced by their peers, specialists, opinion leaders, and group norms. Jacoby et al. suggest that “low prescribers” (physicians who prescribed three or fewer of eight index drugs during the study period, compared to five or more for “high prescribers”) conform more strongly to group norms, have a shared view of prescribing, and are cost-conscious.\(^{81}\) Their practice environments may have technical support (e.g. electronic health records, electronic drug information resources) and human resource supports (e.g. nurses, pharmacists, educators, dietitians, psychologists, health informatics experts), and there may be organizational factors (e.g. type of group practice, the length and frequency of patient visits, access to specialists and diagnostic procedures) that also affect prescribers’ behaviours.\(^{82}\)

**Information and other external factors**

Prescribers receive information from the pharmaceutical industry and many other sources.\(^{69,83-93}\) The most significant industry source is detailing (office visits and “cyber detailing,” also called e-detailing and web-based detailing) to physicians and the provision of drug samples.\(^{94,95}\) Direct-to-consumer advertising also has an influence.\(^{96-101}\) While Canada does not permit direct-to-consumer advertising of prescription drugs, Canadians do have access to American television, as well as to the Internet and US print media. Mintzes et al. reported that in a study of 748 individuals surveyed in primary care in Vancouver, 87.4% had seen a prescription drug advertisement\(^{97}\) and 3.3% requested the advertised drug. Annual spending on this type of promotion in the US was $2.5 billion US in 2000, a small proportion of total marketing efforts by the pharmaceutical industry.\(^{95}\) Drug companies also use targeted mailings, websites, call centres and sponsored conferences to present their message to prescribers.

The myriad of sources of drug information for prescribers in Canada is captured in Web Appendix B.

Other external factors that can affect prescribing include: media stories, drug reimbursement policies of government and private drug plans and the associated workload for prescribers, government policies on physician remuneration, standards of practice from professional organizations, prescribers’ concerns about legal liability, regulatory and control measures, and political considerations.\(^{61,102-106}\)

**Interventions to improve prescribing practices and the medication-use system**

Various interventions have been used to influence physician prescribing. These include health professional, patient, financial, organizational, and regulatory and control interventions. The Effective Practice and Organisation of Care Group (EPOC) of The Cochrane Collaboration reviews interventions to improve professional practice primarily from randomized controlled trials (RCTs).\(^ {105}\) These interventions have been described and critiqued in the Cochrane Reviews, other narrative reviews and individual studies.\(^ {48,79,86,107-118}\) (See Web Appendix D for a description of The Cochrane Collaboration, EPOC and relevant Cochrane Reviews.) The Canadian Agency for Drugs and Technologies in Health (CADTH) also highlights interventions (see www.cadth.ca).
The effect size of interventions is often small (a 10% improvement in prescribing is typical), and limited evidence is available to determine which intervention to choose in which context. Although educational interventions are delivered by specific organizations, physicians are exposed to many other sources of knowledge.

Initiatives to improve prescribing and medication use can focus on interventions to modify the behaviour of physicians; on financial incentives for physicians, patients or the system; and on interventions affecting the health care system.

A. Interventions targeting prescribers and other health care providers

The educational and behavioural change interventions, as shown in Table 2, can be categorized as generally effective, mixed effect and generally ineffective. A selection of Canadian and international examples of “smart” practices to influence prescribing is provided in Table 3.

1. Generally effective

a) Multi-faceted interventions

What is it?
Multi-faceted interventions are defined as those that include two or more interventions, for example, education programs for patients combined with changes to criteria for the reimbursement of drug costs.45,120

Does it work?
Multi-faceted interventions in some settings produce improvements in the quality of physician interventions.121-123 Combining two or more interventions may sometimes be appropriate. These models often focus on enlisting a “trusted source” (such as a respected colleague or a university’s continuing medical education department) to help distill evidence and provide tools. For example, the Drug Evaluation Alliance of Nova Scotia targeted physicians, pharmacists and patients in their intervention to promote the switch from wet nebulization respiratory medications to portable inhalers.45 However, one review found that single interventions often worked as well.120,122 Documenting barriers and needs prior to intervention implementation has been found to be useful to tailor interventions.123

b) Academic detailing

What is it?
Academic detailing (also called counter detailing) is an educational approach, funded by government or the health care organization, in which a trained educator (often a health professional) visits a physician or a group of physicians in their practice setting. In Canada, academic detailing programs are delivered by continuing health professional education departments in five provinces: Alberta, British Columbia, Manitoba, Nova Scotia and Saskatchewan. The Canadian Academic Detailing Collaboration, a coalition of these groups, works together to improve effectiveness and efficiency of therapies.124,125 There is a vast difference between budgets and staffing for publicly funded academic detailing programs compared to the detailing efforts of the pharmaceutical industry.126

Does it work?
Based on the limited information available, academic detailing programs have been found to be mainly, but not always, effective, with some studies showing small improvements (1–2%) in physicians’ practices and other studies demonstrating larger improvements (24–45%).118,127-133 Academic detailing shows promise, but it is expensive and its effectiveness and cost-effectiveness need to be further studied. Not all physicians embrace this model.134 For example, in Nova Scotia, approximately 50% of physicians see an academic detailer.133 This is similar to the Australian experience.130,135-137
c) REMINDERS

WHAT IS IT?
Electronically generated (e.g. linked to an electronic health record) or paper-based reminders (e.g. a note in the chart) alert health care providers to recommended prescribing practices or cautions related to a patient’s history. Standing orders, often used in hospitals, are a method of reminding physicians about appropriate care for specific diseases. They are usually given before or during patient contact.

DOES IT WORK?
Automatic reminders, or computerized decision support systems, may work if physicians believe in the prescribing behaviour, if they have “forgotten” a concept or rule, if they are busy multi-tasking, or if their practice setting lacks coordination. However, many clinical situations are complex and the alerts may be ignored if they are not sophisticated enough to fit physicians’ practices and patients’ needs. Effectiveness may depend on physician characteristics (e.g. their experience) and characteristics of the clinical environment.

2. MIXED EFFECTS: SOMETIMES EFFECTIVE AND SOMETIMES NOT

a) AUDIT AND FEEDBACK/PHYSICIAN PROFILING

WHAT IS IT?
In an audit and feedback process, physicians examine their own practice with the help of experts (through, for example, observations and chart reviews) to inform their future prescribing decisions. Physicians can also compare their prescribing patterns with those of their peers, or against a standard to inform their future prescribing decisions. Such audits can be carried out at the individual patient, physician, practice and health care organization levels. Audit and feedback studies have attempted to increase the rate of generic drug prescribing, to move prescribing towards a specific drug or to increase conformance with clinical practice guidelines. Audits can be conducted using medical charts, electronic data or visual observation. A group of physicians in Québec implemented an interesting audit system for family practitioners to improve patients’ outcomes and physicians’ practices by using morbidity and mortality audits. Some authors have observed that “active feedback or reminders contain an implicit or explicit judgment of the practice observed and sometimes also advice about the preferred clinical practice.”

One approach is to use physician profiling, a feedback method that focuses on patterns of care, not on individual clinical decisions. Profiling can be used alone or in combination with other written educational materials or continuing professional development. Issues related to the profile produced include: the type of patients and criteria used; the source, messenger and method of profile delivery; the availability and nature of data; and the frequency and type of profiles. Profiling of primary care physicians is a particular concern because of the diverse mix of patients they treat and the small numbers of patients sharing similar diagnoses. There are also issues related to privacy, confidentiality and data security.

DOES IT WORK?
The effectiveness of audit and feedback is variable. A study in Ontario suggested that confidential feedback to prescribers, along with educational materials, improved physician prescribing of antibacterials. However, other Canadian studies did not show effectiveness. A study in Nova Scotia that evaluated the use of mailed unsolicited profiles from government on prescribing of topical corticosteroids found that this strategy was not effective in decreasing potency or expenditures. Similarly, a study in Ontario demonstrated that the provision of educational materials and
confidential feedback to Ontario primary care physicians related to their benzodiazepine prescribing for elderly patients was not effective.\textsuperscript{146} In general, audit and feedback has had limited effectiveness in changing physician behaviour, and the conditions that lead to its effectiveness are uncertain.\textsuperscript{145, 149-152} One reason for the uncertainty is that it is hard to match the individual complexities of a patient practice with the simplicity of a rating scale.\textsuperscript{153} The Australian audit and feedback model is interesting. It allows physicians to self audit, provide information to the National Prescribing Service (NPS) and then be critiqued on their practice. This process is done in confidence, and physicians are reimbursed for a specific set of activities.\textsuperscript{130, 135, 136}

The UK Audit Commission\textsuperscript{154} suggests that general practitioners should have access to support staff to provide data analysis related to prescribing.

b) LOCAL OPINION LEADERS

WHAT IS IT?
One of the preferred methods of learning by physicians is communication with peers.\textsuperscript{155, 156} Local opinion leaders (also known as educational influencers, gatekeepers, informal leaders, or informal educators) are respected peers of prescribers, deemed to understand the local context. Their roles may include endorsing written educational material, providing lectures, chairing meetings and visiting physicians.\textsuperscript{118} Opinion leaders can be engaged in this work by drug companies, government, hospitals, universities and others.

DOES IT WORK?
Local opinion leaders may influence clinical practice.\textsuperscript{107, 155} Some studies conclude that local opinion leaders have a small positive effect, while other studies find they have no effect at all.\textsuperscript{118} They can influence prescribing and assist with guideline implementation, although not all studies show their effectiveness.\textsuperscript{155-160} A concern is that approaches used by local opinion leaders to synthesize evidence are not always consistent.\textsuperscript{161}

c) DRUG UTILIZATION REVIEW PROGRAMS

WHAT IS IT?
Drug utilization reviews (DUR) evaluate the use of drugs in patient populations or in individuals using a structured process and approved evaluation criteria. The reviews can be performed by institutions, health insurance companies and other organizations. DUR programs attempt to improve our understanding of prescribing patterns so that changes can be made to enhance patient outcomes and control costs.\textsuperscript{162} Drug utilization reviews have been conducted retrospectively and concurrently (i.e. at the time of clinical encounter, when the prescribing decision is made).

DOES IT WORK?
Retrospective drug utilization review programs generally do not work well.\textsuperscript{163, 164} In a study of three hospitals in Québec, Gregoire et al. examined the quality of prescribing cisapride, a gastrointestinal prokinetic agent, by comparing the effect of retrospective DUR, concurrent DUR, and a control hospital with no DUR. The study showed that the concurrent DUR program significantly improved the appropriateness of prescriptions whereas the retrospective DUR did not. Cisapride was withdrawn from the market in 2000, after the study was completed.\textsuperscript{164}

d) LOCAL CONSENSUS PROCESS, CARE PATHWAYS, AND GUIDELINES

WHAT IS IT?
Evidence generated from clinical trials must take into account the local context. In a local consensus process, health care providers respond to expert recommendations on appropriate management of a clinical problem. Consensus processes have been used to generate care pathways and local guidelines, with the goal of promoting the local uptake of specific health care practices. Care pathways, also referred to as critical paths, clinical pathways and care paths,\textsuperscript{165} are multidisciplinary management tools that are patient-focused and based on current evidence. Local guidelines are developed by local teams, including physicians, other health care professions, managers and others to manage patients with specific health conditions based on the local context.
DOES IT WORK?
The effectiveness of these strategies is unclear, particularly in identifying the levers required to change processes within the health care system or to reallocate funding or human resources. An example of a consensus process is found in the UK. There, four Bradford Primary Care Trusts (PCTs) jointly funded the Promoting Action on Clinical Effectiveness (PACE) program, which develops evidence-informed guidelines on a select number of topics each year (e.g., improving prescribing practice in diabetes, psychosis and heart failure). Participants in the consensus group include general practitioners, pharmacists, hospital consultants, nurses, social service workers, and patient representatives. Some PACE goals include: building teamwork within practices; developing experience in action planning; reaching agreement to share audit data, action plans and ideas with other practices and with the PCTs and enhancing knowledge of best clinical practice based on the latest medical evidence. The availability of funding to assist general practitioners and other practice staff to attend education events based on the guidelines developed builds capacity at the practice level; and the evaluation of PACE through re-audit of the guidelines, amongst other techniques, provides a measure of effectiveness.

3. GENERALLY INEFFECTIVE
a) DISSEMINATION OF PASSIVE (PRINT AND ELECTRONIC) EDUCATIONAL MATERIALS
WHAT IS IT?
Educational materials include clinical practice guidelines, drug cost comparisons, and overviews of key clinical trials, among others. Clinical practice guidelines are systematically developed statements (often with the level of evidence assigned to each statement) designed to assist both physicians and patients in making appropriate health care decisions. Such guidelines combine scientific knowledge with professional consensus, and can be developed by governments, professional societies, voluntary health organizations, industry and others. Guidelines vary in quality, are difficult to keep up to date, and do not always examine the cost-effectiveness of the interventions or their impact on expenditures if implemented.

DOES IT WORK?
Distributing educational materials not requested by physicians has been shown to produce either small changes in prescribing or none, but this intervention can be cost-effective if changes result. The source of the information, the method of providing the information and the nature of the drug affect the usefulness of the intervention.

While single mailings do not work well, a study on the impact of a series (12) of regular, printed educational Therapeutics Letters (an initiative of British Columbia’s Therapeutics Initiative) to 499 physicians in British Columbia found that physicians who received the letters prescribed the recommended drug more often than physicians who did not receive the letters. The authors’ interpretation was that “the combined effect of an ongoing series of printed letters distributed from a credible and trusted source can have a clinically significant effect on prescribing to newly treated patients.”
Many reasons are proposed for the failure of guidelines to promote change in prescribing. These include lack of awareness of guidelines, lack of knowledge of guideline recommendations, disagreement with the content of the guidelines, personal characteristics of providers (e.g. concern about autonomy), lack of self-efficacy, logistic and financial barriers to implementation, and inertia. Guidelines do not exist for all patients’ conditions and they often address only single diseases whereas many patients have multiple diseases; or patients may not want the therapy recommended by the guidelines. In addition, drugs recommended in the guidelines may not be affordable to the patient or the system. Both reporting systems and communities of practice (groups of people with a common concern who interact regularly to improve their work) assist this process.

b) EDUCATIONAL MEETINGS

WHAT IS IT?
Educational meetings for health professionals have been used by academia, government, the voluntary health sector and the pharmaceutical industry. Educational meetings can take the form of large didactic lectures or small group participatory seminars. These often involve experts providing their knowledge of the field, including literature and experience. Sometimes they involve small groups of physicians or multidisciplinary teams during which barriers and facilitators to prescribing are addressed. Videoconferencing and the Internet can also be used as a forum for meetings. Videoconferencing and the Internet can also be used as a forum for meetings.

DOES IT WORK?
The effectiveness of large didactic lectures is variable, with many studies showing no effect. Small group participatory educational meetings have been shown to be effective in some studies and appear promising, but further research is needed. Educational meetings do help confirm knowledge and reinforce current norms of practice to physicians.

B. Financial interventions for prescribers, patients and others

WHAT IS IT?
Financial interventions can be used by government or private health care organizations to achieve their goals, including: improving the quality of prescribing, transforming clinical practice, and achieving value for money. Financial interventions can act as either direct or indirect incentives. They can operate through methods used to reimburse prescribers, manage budgets, encourage cost sharing by patients, and change prescribers’ practices (for example, by increasing physicians’ access to multidisciplinary teams including nurse practitioners, pharmacists, and other health care professionals).

Direct incentives target prescribers’ (e.g. physicians’) incomes. They can have a positive effect on income (for example, bonuses for meeting an objective or payments in exchange for preferential drug prescriptions) or a negative effect (for example, withholdings or fines for not meeting stated objectives).

Indirect incentives target non-prescribers (e.g. patients, pharmacists) who, in turn, influence prescribers and their prescribing decisions (e.g. funding of a pharmacist to work with prescribers to improve the overall management of medicines).

DOES IT WORK?
The evidence from research on various types of financial strategies is summarized below. Overall, the impact of a financial incentive depends on its characteristics and contextual factors. Characteristics of incentives include: recipient of the incentive (e.g. individual provider, group, others); size of the potential income effect, which is dependent on the monetary value of the incentive and the number of encounters or patients to which it will apply; and cost of implementing and monitoring the incentive. Contextual factors include: motivation for the incentive; presence of other incentives; the provider’s understanding of the purpose for the incentive; and presence of enabling factors at both the organization and patient levels.
One recommendation on how to move toward achieving effectiveness, productivity, accessibility, continuity, quality and responsiveness in health care—suggested in Choices for Change: The Path for Restructuring Primary Healthcare Services in Canada—was to address funding mechanisms, including the promotion of a mix of reimbursement methods for physicians, such as salary, capitation and/or fee-for-service.

1. REIMBURSEMENT SCHEMES FOR PRESCRIBERS

WHAT IS IT?
Reimbursement methods or payment schemes for prescribers include fixed payment (e.g. capitation, salary) and variable payment (e.g. fee-for-service, pay-for-performance, bonuses, withholdings). The latter depends upon the quantity of services provided or targets met.

Capitation is a fixed amount of money per person enrolled in a practice per time period. The financial incentive is to spend less (i.e. provide fewer services per person or to change the mix of services provided to increase efficiency). Benefits may include a focus on prevention, which could lower future demand for health services. Concerns include the possibility that practices might not be receptive to elderly clients or to those with chronic conditions (both groups are perceived to be frequent service users) unless capitation formulas are carefully adjusted.

A salary is a fixed payment per time period regardless of the number of services provided. Salary is generally considered incentive neutral with respect to income and prescribing practice, but there may be an impact on productivity and the type of services provided.

Fee-for-service reimbursement is a variable payment based on the number of services provided. This type of payment scheme can include strong financial incentives (increased income) to provide additional services or specific high-value services (e.g. visits required for prescription refills).

Pay-for-performance reimbursement uses explicit financial incentives to reward physicians for achieving desired outcomes or to penalize them when objectives are not met. Current activities focus on linking pay-for-performance incentives to quality and performance. There is considerable variation among definitions and methods of implementation and there are concerns related to performance measurement. In Canada, there are several physician pay-for-performance initiatives that target preventative aspects of a practice.

Bonuses are lump sums paid when a target is met; withholdings are monies withheld when a target is not met.

Mixed or blended methods often combine capitation with fee-for-service components.

DOES IT WORK?
There is limited understanding of the theoretical application of financial incentives to prescribers of drugs, as well as limited empirical evidence of their effectiveness and the impact of contextual factors. Concerns are related to the following issues: conflict between internal motivation (professionalism) and external motivation (money), which leads to ethical considerations; the unknown impact of external factors (e.g. market, and regulatory, organization, and patient variables) to the incentive; and unintended effects from the use of financial incentives. Another factor to be considered is that physicians appreciate the power to use resources innovatively to benefit their patients. Clearly, internal drivers of health professionals play a key role when considering financial incentives.
Many reviews discuss the effects of financial incentives (or disincentives) on physician prescribing, but most studies focus on physicians’ ordering of tests, making referrals or admitting patients to hospitals, not specifically prescribing. Reviews that focus on financial incentives used by health maintenance organizations in the US and managed care financial incentives in European national health care systems concur on the lack of specific research directed to prescribing.

*Fixed payment* reimbursement schemes (capitation and salary) are considered the most effective methods of containing costs because they reduce the incentive for physicians to increase the quantity of their services. The fee-for-service reimbursement method, which is based on the number of services provided, was associated with higher rates of prescribing than those associated with salary in one study conducted in Newfoundland. As a rule, positive financial incentives are more effective than penalties in changing physician behaviour. It is important to consider that at issue is not just the quantity of services but the type of services provided and the methods of monitoring them.

Potential benefits can accrue from *pay-for-performance* initiatives. For example, the uptake of bundled evidence-based practice guidelines approved by expert panels, in conjunction with pay-for-performance initiatives based on these practice guidelines, can lead to more standardized care and can improve health outcomes. However, the practice guidelines need careful vetting of the evidence and independence from the pharmaceutical industry. Benefits will depend upon the underlying characteristics of the incentives used (e.g. size, magnitude), as well as contextual factors (e.g. provider characteristics, type and size of practice, experience with financial incentives). In recent years, government and other health care funders have been focusing increasing attention on the potential benefits of pay-for-performance; Australia, the United Kingdom and the United States have initiated programs without having substantial evidence of their effectiveness. Pay-for-performance is beginning to be used in Canada, but effectiveness is not conclusive. Halprin and Davis suggest that the following practical steps are necessary prior to implementation of pay-for-performance in Canada:

- Don’t take steps in isolation.
- Choose the tools wisely.
- Go slowly. Figure out what works and what doesn’t.
- Reward achievement, not improvement.
- Focus on the physician–patient encounter.

**WHAT IS THE CANADIAN SITUATION AND WHAT QUESTIONS CAN BE ASKED?**

In Canada, the primary reimbursement mechanism for physicians is fee-for-service, although the number of physicians receiving alternative forms of payment (salary) is increasing. The Canadian Institute for Health Information reported that the total amount of alternative payments to physicians increased by 22.4% in one year, from $1.95 billion in 2002/2003 to $2.38 billion in 2003/2004. Nova Scotia and Newfoundland had the highest physician full-time equivalents (FTEs) for alternative payment modes (25.7% and 26.4% respectively) compared to the national average (11.5%).

**2. DRUG BUDGETS**

**WHAT IS IT?**

Drug budgets can be used at different levels (i.e. individual provider level, practice level, and health care organizational level) to contain or reduce the use of pharmaceuticals or to promote the use of less expensive drugs. Drug budgets can be fixed or targeted. They have been used in several European countries within a framework of the overall funding and organization of public health expenditures. A fixed or hard budget covers prescribing over a given time period. It can encourage prescribing of less expensive alternatives, such as generic drugs. There can be rewards (e.g. retain all or a portion of a surplus) and penalties (e.g. repay overspending). Mossialos et al. reported on the United Kingdom experience of fundholding, which employed both: rewards for a budget surplus and penalties for overspending.
A targeted, indicative or shadow budget is a suggested budget amount that tracks and reports drug expenditures to each physician, practice and health care organization to inform them of compliance with their budget target. Rewards and penalties are not usually imposed.

**DOES IT WORK?**
A study of the UK prescribing incentive scheme, where practices were rewarded for both cost containment and achievement of locally determined quality targets, concluded that the size of the reward payments may have contributed to prescribing cost control, but effectiveness on prescribing quality remained uncertain. Without rewards or penalties and without a cap on drug spending or clear objectives, a budget will not be effective in achieving its goals. In addition, the implementation of drug budgets can lead to a “drug budget silo mentality,” where the focus is pharmaceuticals rather than overall resource use, and such important issues as a conflict between goals of cost-containment and efficiency can be missed.

There is limited Canadian experience with the use of drug budgets as a tool to improve prescribing. In Ontario, a joint program was proposed between the provincial medical association and the government whereby an additional $50 million would be available for physician services if spending under the Ontario Drug Benefits Program was reduced by $200 million over four years. There was controversy surrounding the proposed program, which was not implemented.

### 3. PRACTICE LEVEL FINANCIAL INCENTIVES
**WHAT IS IT?**
Financial incentives that encourage change to a physician’s practice environment can influence prescribing practices. For example, the provision of pharmacist, nurse practitioner or other provider support, funded by a third party (e.g. government) to improve the management of medicines within physicians’ practices, may indirectly impact physicians’ prescribing in terms of quality, volume or cost. Grants or subsidies can be used to encourage prescribers to adopt health information technology.

**DOES IT WORK?**
There is a direct and positive income effect for the pharmacist or other health professional involved in a multidisciplinary team, as well as a benefit to the prescriber in the decision-making process. However, this incentive does not always work, and cost-effectiveness is unknown.

### 4. PATIENT COST-SHARING
**WHAT IS IT?**
Patient cost-sharing is an additional charge to patients when (1) drugs are not covered by the formulary, (2) the doctor prescribes and the patient chooses a brand name drug (i.e. the drug plan reimburses the cost of a generic only) or a specific chemical compound (i.e. the drug plan reimburses a different, less expensive drug) and (3) there are specific premiums or co-payments for drugs reimbursed. Prescribers may adapt their prescribing, taking into account the financial costs to patients.

**DOES IT WORK?**
Some Canadian studies have found that use of medications considered effective and essential decreased after implementation of cost-sharing in drug insurance plans. In addition, implementation of cost-sharing for drugs in a publicly funded health care system such as Canada’s can lead to increased use of health care services: visits to physicians and hospitals, which do not require out-of-pocket payments, may be used as economic substitutes for prescription drugs.
C. Interventions targeting patients, caregivers and the public

WHAT IS IT?
Interventions that target patients, caregivers and the public can be directed at various contact points, including the decision to seek professional care, but the best approaches continue to be explored. Putnam poses the question, “Do patients find the discussion of evidence helpful, meaningful and empowering or do they find such discussion esoteric and obfuscating?”

The EPOC framework offers a classification system for methods to improve patient health care. Information can be provided directly to patients by health professionals, family members and friends, peers, libraries, the Internet and the media. Information tools for consumers are produced by many sources, including Health Canada (the Canadian Health Network, www.canadian-health-network.ca) and provincial health ministries. Three provinces (New Brunswick, Nova Scotia and Saskatchewan) and three territories (Northwest Territories, Nunavut and Yukon) fund public access to The Cochrane Library reviews. An evaluation conducted on the use of The Cochrane Library by Saskatchewan residents between January and March 2005 found over a 50% increase in the number of hits (from 2,595 to 6,148).

DOES IT WORK?
Patient decision aids, self-management tools, drug information services and evidence-based information can be used to help patients prepare for contact with professionals to understand the potential benefits and risks of medications and to communicate their preferences.

The UK Audit Commission suggests that general practitioners need specific strategies on dealing with the pressure from patients to prescribe. Arroll et al. concluded from a systematic review that the use of delayed prescriptions was an effective means of reducing antibiotic use for acute respiratory infections. With a delayed prescription, the patient is given prescriptions to be used later if symptoms persist.

Social marketing campaigns have been used to improve drug use in Canada and elsewhere. In Australia, social marketing campaigns have demonstrated an influence on both non-steroidal anti-inflammatory drugs and antimicrobial use. The use of non-steroidal anti-inflammatory drugs decreased in Australia after the country made improvements in the areas of education for professionals, public information and regulatory measures.

Direct-to-consumer advertising provides patients with information, but the risks and benefits need further study. In Australia, the National Prescribing Service created a website to educate the public about the common cold. This site includes information and educational tools such as interactive online books and screensavers.

D. Interventions targeting the health system and clinical practice environment

1. SYSTEMS APPROACHES

WHAT IS IT?
Interventions to change prescribing behaviour can also take place at the system level (e.g. national, provincial / territorial, district health authority, institutional, primary care team levels). Initiatives appropriate at these levels include those targeting leadership and management, disease management, integrated care, and organizational structures or cultures. Financial incentives can also be applied at the system level.

Continuous quality improvement (CQI) is an approach that can be implemented to effect change at the system level. It can be defined as a structured organizational process for planning and executing a continuous stream of improvements in systems in order to provide quality health care that meets or exceeds patients’ and practitioners’ expectations. CQI has been heralded as providing health care with a scientifically valid method of attaining its goal of providing affordable, accessible, efficient and high-quality patient care. The CQI philosophy is based on the principle that it is far more efficient and cost-effective to treat patients right the first time, rather than repeatedly re-treating them.
Complex adaptive systems and systems re-engineering approaches, including use of total quality management principles and knowledge translation, can be applied to increase the use of evidence in the prescribing process. Total quality management, a systematic approach to management, requires that changes be made to organizational processes, priorities, individual beliefs and attitudes. As defined by the Canadian Institutes of Health Research (CIHR), knowledge translation "refers to the process of supporting the uptake of health research in a manner that improves the health and health care of Canadians through improved understandings, processes, services, products or systems."

Disease management has been defined as "any intervention involving coordination of diagnosis, treatment or other aspects of ongoing management by a person or multidisciplinary team in collaboration with or supplementary to the primary care provider." Studies have been carried out on disease management interventions involving diabetes, hypertension, cardiovascular disease and other areas.

Pharmacovigilance involves detection, evaluation, understanding and prevention of adverse drug reactions at the individual or population level. Alberta has implemented a pharmacovigilance model that is based on collaborative partnerships between community and academic rheumatologists, industry and government.

An example of a systems approach using a consensus process to develop evidence-based guidelines is the Promoting Action on Clinical Effectiveness (PACE) program. The consensus group is practice-based, team-based and multidisciplinary, with required evaluation to determine effectiveness. (PACE is also discussed with respect to local consensus processes, on page 15.) Further work is needed to determine the efficacy of multidisciplinary teams in improving patient outcomes.

DOES IT WORK?
To generalize the success of a quality improvement initiative from one setting to others, it is important to consider the setting, message, and method of the successful initiative, as well as the "facilitators, barriers and motivations both of those receiving the intervention and those designing it." There is a need to integrate prescribing across hospitals, home care, nursing homes, and primary care, such as approaches to develop joint formularies and treatment guidelines between primary and secondary care.

Disease management programs may be effective in the short term, but further long-term study is needed. New approaches to service delivery (e.g. telehealth) have also been shown to be effective. While results are promising, the optimal components and methods of delivering disease management remain unclear.

Continuing post-marketing pharmacovigilance requires that "regulators, sponsors, health insurers, health care providers, and independent researchers actively pursue and manage emerging knowledge about risk-benefit relationships and uncertainty and they communicate that knowledge to patients, health care providers, and health care organizations in a timely manner."

2. CLINICAL DECISION SUPPORT SYSTEMS, ELECTRONIC HEALTH RECORDS, AND KNOWLEDGE MANAGEMENT

WHAT IS IT?
Clinical decision support is "information and knowledge offered to the clinician to facilitate the best decision and thereby reduce medication errors;" e-prescribing is "clinicians’ computerized ordering of specific medication regimes for individual patients." The implementation of electronic clinical decision supports holds great promise for the health care system. According to Richard Alvarez, CEO of Canada Health Infoway, "Research estimates that once fully implemented, eHealth will save about $7 billion a year across the system." Canada lags behind other countries in the routine use of electronic prescribing systems by primary care physicians (11%), compared to the Netherlands (85%), New Zealand (78%), UK (55%),
and Australia (81%). However, some progress has been made and most jurisdictions are in the process of implementing drug information systems. These systems provide a platform for e-prescribing and are a critical building block for the patient electronic medical record. In addition, British Columbia's Pharmanet, a secure computer network linking community pharmacies, allows pharmacists and authorized medical practitioners in the community and hospitals controlled access to their clients' medication profiles; and Ontario now uses an Emergency Department Drug Viewer, which allows physicians in some hospitals to view prescriptions provided to people eligible for the Ontario Drug Benefit Program (e.g. seniors, residents of long-term care facilities, home care and social assistance recipients, and others who qualify for provincial drug-cost support).

In the absence of electronic health records, physicians usually are not able to see their patients' full drug histories because patients often receive prescriptions from more than one physician (e.g. on-call physicians; specialist physicians; walk-in or ambulatory clinics, emergency departments) and from more than one pharmacy. Physicians may also be unable to access laboratory and other test results if they have been ordered by other physicians. This lack of access to key information on patients may impact health care providers' ability to provide optimal diagnosis, treatment and monitoring.

**DOES IT WORK?**

Electronic health records and integrated health systems can improve the quality of prescribing and reduce medication errors, duplications of therapy, inappropriate drug interactions and preventable adverse drug events. A systematic review by Garg et al. reported that computerized clinical decision support systems improved practitioner performance in 62 out of 97 studies.

Tamblyn et al. provide a list of elements needed to improve safety and quality of drug management:

- "integration and display of patient demographic information from office management systems; retrieval and display of all currently active drugs from community pharmacy systems; automated alerts for relevant prescribing problems (therapeutic duplication, excess dose, dose adjustment for weight and renal impairment, drug-disease, drug-drug, drug-age, and drug-allergy contraindications) prioritized by importance; integration of electronic prescriptions into pharmacy software to avoid transcription errors; transmission of orders to discontinue medication to dispensing pharmacies; and monitoring of patient adherence and treatment outcomes."

A 2002 electronic prescribing study involving 100 physicians working for the Tufts Health Plan (www.tuftshealthplan.com) measured the impact of e-prescribing as follows:

- up to two hours less spent on the prescription process per day per prescriber;
- 30% fewer calls between physicians and pharmacists;
- savings of nearly one hour per pharmacist in a typical day;
- increased quality of care reported by 35% of prescribers due to the ability to check drug interactions and prescription accuracy; and
- increased adherence to Tufts Health Plan preferred drugs reported by 50% of the prescribers.

There are many challenges to integration of patient information. A 2006 Quebec study suggests that adoption of electronic health records has been slow because of issues related to the governance structure in ambulatory care, lack of funding, lack of clarity regarding privacy, and unclear regulatory frameworks. In addition, legal concerns abound, as do those about ensuring the quality of the system. Finally, technology poses a challenge insofar as integration of drug reference and formulary tools into both desktop and personal digital assistant (PDA) applications.
3. FORMULARIES

WHAT IS IT?
A formulary is a list of medications that are provided or reimbursed through public and private insurance plans, which undergoes regular review in order that physicians can provide the most appropriate, safe and cost-effective therapy to their patients. The Institute of Medicine suggests that evaluation of formularies focus on the following categories: the number of drugs covered, the placement of drugs within a therapeutic class, policies on prior authorization and exceptions to formulary rules, and methods of reviewing and appraising policies. The decisions for formulary inclusion usually rest with an expert committee of physicians, pharmacists and others. A sound formulary system increases the value of health care delivered and promotes evidence-based medicine through the rigorous process of formulary review. Formularies can be employed in health care facilities and drug plans. Specific criteria can be set to direct prescribers to prescribe first-line therapy only for those patients who will benefit the most.

Drug benefit formularies usually have three reimbursement levels: general benefit (no restrictions to prescribing), limited use (physicians must first provide information that shows the patient meets the criteria for use), and non-benefit (not covered).

DOES IT WORK?
Formularies in Canada vary in what drugs they cover and the methods they use to cover them. Naturally, formularies will affect prescribing, but the magnitude of effect and impact on patient outcomes has not been well researched. One study compared the medication use under the limited use policy of the Ontario Drug Benefit Program with use in other provinces that list the drugs for general benefit. The study found that there was lower use of the drugs in Ontario; however, prescribing quality and patient outcomes were not addressed. Pearson et al. refer to a decrease in prescribing expenditures when managed care organizations moved from fixed co-payments to three-tier pharmacy benefit designs, whereby members/patients incur the lowest out-of-pocket costs for generic drugs, higher costs for preferred brand names and the highest costs for non-preferred brand names.

Difficulties in producing a safe, appropriate drug formulary include finding committee members with sufficient expertise and establishing methods to determine the appropriate group of drugs to fund, taking into account individual patient needs, public values and budget impacts. As well, safety and effectiveness and economic data are often limited in scope or are of poor quality.

E. Regulatory and control approaches

WHAT IS IT?
Regulatory and control approaches consider laws, rules, administrative orders and policies and programs. They can be implemented by federal, provincial, territorial governments or institutions and can affect many areas of concern in appropriate prescribing—such as monitoring of prescriptions for patterns of abuse or overuse, clinical performance review by professional regulatory bodies, and the regulation, packaging and marketing of prescription drugs.
For example, to more effectively deal with drug abuse, Nova Scotia passed the Prescription Monitoring Act, which established a system to monitor the prescribing, dispensing and use of specific drugs. An appointed prescription-monitoring board and a computerized information system support the electronic Prescription Monitoring Program that links with pharmacies across Nova Scotia.
Requirements exist for licensing of prescribers, and various innovations have occurred in the continuing competency requirements for prescribers, pharmacists, nurses and other professionals.\textsuperscript{113} In Québec, for example, clinical performance assessments were carried out and a peer review of medical records was conducted by the Professional Inspection Committee of the Collèges des Médecins du Québec.\textsuperscript{288} Other regulatory tools include the allocation of drugs to specific categories (e.g. restricting methadone to authorized prescribers)\textsuperscript{290} and triplicate prescription programs, which require pharmacists to send to the regulatory body a copy of prescriptions filled for certain regulated drugs. Many health care organizations have policies related to working with the pharmaceutical industry, control of drug samples and access to manufacturers’ detailers.\textsuperscript{93, 154, 289}

DOES IT WORK?
Regulation encompasses: the processes involved in allowing a drug to be marketed; the approval of labels, product monographs and patient instructions; the regulation of advertising; and the classification (scheduling) of drug products to control their use and set conditions for withdrawal from market.\textsuperscript{286} Some studies examining the impact of packaging drugs in fixed combinations and in unit doses have found small effects in adherence.\textsuperscript{291, 292}

Because clinical trials involve relatively small numbers of patients in highly controlled settings, it is important to also collect safety and effectiveness data in routine clinical settings from health care providers, patients and the pharmaceutical industry.\textsuperscript{253, 291, 294} One tool that the government can use more often is conditional licensing. It allows products to come to market faster than they would otherwise, and conditional licensing requires pharmaceutical manufacturers to follow up with patients rigorously. If Health Canada doesn’t like what it sees, it has many options: it can request changes to the product monograph (including dose and duration) and to the schedule in which the drug is assigned, it can regulate advertising, and even withdraw the drug from the market. Post-marketing, Health Canada is limited in its ability to ask for additional information from pharmaceutical companies. Various challenges have been noted and proposals for reforms in drug regulation have been suggested.\textsuperscript{281, 295-299}

Liability issues are critical as well.\textsuperscript{300-302} For example, to avoid lawsuits, physicians may request additional tests for their patients to monitor for rare drug-related adverse events.

F. Interventions targeting other stakeholders

Beyond health care professionals, other stakeholders who have an interest in safe, appropriate and effective drug use include the pharmaceutical manufacturers, drug wholesalers, software vendors, employers and those who administer their drug benefits, voluntary health organizations, and seniors’ organizations. The outcomes guarantee approach is one example of an intervention involving these stakeholders. It is piloted by Keele University in England in partnership with a local health authority and a pharmaceutical manufacturer, where the health service can receive a refund from the drug manufacturer if its drug does not meet agreed performance targets.\textsuperscript{303, 304}
Canadian interventions: some examples

Many organizations in Canada are working to improve prescribing. Among them are: Health Canada; CADTH (Canadian Agency for Drugs and Technologies in Health) and its programs COMPUS (Canadian Optimal Medication Prescribing and Utilization Service) and CDR (Canadian Drug Review); Canada Health Infoway; CIHI (Canadian Institute for Health Information); PMPRB (Patented Medicine Prices Review Board); and NPDUIS (National Prescription Drug Utilization Information System), a collaboration of CIHI and PMPRB. Because regulatory authority related to drugs in Canada is spread across federal, provincial and territorial agencies, it is challenging to coordinate national initiatives.

Four examples of Canadian interventions are described in Table 3 and Web Appendix C: e-Therapeutics, a program of the Canadian Pharmacists Association and multiple partners; the Therapeutics Initiative of British Columbia; IMPACT (Integrating family Medicine and Pharmacy to Advance primary Care Therapy), a provincial–university project in Ontario; and DEANS (Drug Evaluation Alliance of Nova Scotia).

International interventions: some examples

Other countries have established various structures to improve prescribing. Several interesting examples include:

- Australia’s National Prescribing Service (NPS), www.nps.org.au;
- The Scottish Medicines Consortium, www.scottishmedicines.org;
- The Centers for Education & Research on Therapeutics in the US, www.certs.hhs.gov/index.html;
- The UK’s National Institute for Health and Clinical Excellence (NICE), www.nice.org.uk;
- National service frameworks of the UK Department of Health, www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/HealthAndSocialCareArticle/fs/en?CONTENT_ID=4070951&chk=W3arW; and

Keep in mind that the practices described on these websites may not be applicable to Canada because of differences in the way drugs are licensed and used. See Table 3 and Web Appendix D for descriptions of the National Prescribing Service in Australia and The Cochrane Collaboration and its Canadian Network and Centre.

Conclusion

Health professionals and the systems in which they work can use numerous approaches to improve prescribing and medication use. These include interventions at the system level (e.g. changes in government policy), health professional or practice level (e.g. academic detailing, audit and feedback, clinical practice guidelines, care pathways, opinion leaders, and financial interventions) and at the patient level (e.g. education programs, including peer education). Programs and policies can be guided by an understanding of theoretical frameworks, evidence from published research and from experience in other jurisdictions, and knowledge of the local context.

No single approach is appropriate for every prescribing problem, prescriber practice or health care setting. The safety, effectiveness, cost-effectiveness, acceptability, and social and ethical aspects of interventions to improve prescribing and medication use need real-world evaluation. This is especially critical for broad national or province-wide approaches. Implementation of targeted strategies to improve prescribing and medication use for a wide range of stakeholders will help achieve desired patient health outcomes and broader societal goals for public health and the health care system.
Figure 1 provides an overview of the drug development, regulation and use system in Canada, beginning with drug research and concluding with patient consumption and monitoring. The shaded area is the focus of the paper.

* Activities may occur concurrently. For example, some health technology assessments on emerging technologies occur before the drug is marketed. In addition, functions ensuring safety, effectiveness and efficiency are not constrained to one component of the system; for example, drug labelling can be amended from information gained post-marketing.

** Non-Insured Health Benefits, Veterans Affairs Canada, Royal Canadian Mounted Police, Corrections Canada, Department of National Defence, federal government employees and provincial/territorial pharmacare programs.

Acronyms: PMPRB: Patented Medicine Prices Review Board; CADTH: Canadian Agency for Drugs and Technologies in Health; RCT: randomized controlled trial.
FIGURE 2
FACTORs AFFECTING PRESCRIBING DURING THE CLINICAL ENCOUNTER

Prescriber factors
- Demographics
- Education
- Professional role/societal motivations
- Professional ethics code
- Knowledge, skills, attitude, beliefs
- Competency/self-efficacy
- Experience with drugs
- Assumptions about patient
- etc.

Practice organization factors
- Organization structure
- Organization culture
- Access to electronic health records
- Access to multidisciplinary services
  (e.g. specialists, pharmacists, nurse practitioners)
- etc.

Professional societies
- Guidelines, etc.

Regulatory bodies
- Regulation
- Licensing
- Accreditation
- etc.

Private sector goods and services
- DRUG INDUSTRY
  - Research, production
  - Marketing
- INSURERS
  - Drug reimbursement policies
- EMPLOYERS
  - Funding health insurance
- OTHERS

Government (elected officials and civil service)
- Legislation
- Regulatory and control policies
- Financing (e.g. pharmacare, health professionals, practice level incentives)
- Education

Patient factors
- Health needs
- Experience of illness
- Concomitant diseases and drugs
- Socio-economic status
- Health knowledge
- Family history
- Preferences
- Values, beliefs
- Trust in doctor
- etc.

Patient support
- Caregivers
- Support systems
- others

Other health service delivery organizations
- Hospitals
- Drug dependence services
- etc.

Media
- Internet
- Print
- Radio
- Television
- etc.

Society
- Values
- Preferences
- etc.

Volunteer health sector
- Advocacy
- Guidelines
- Patient education
- Research funding
- etc.

University
- Education
- Research
- Community service
- etc.


Note: Communication channels between the organizations indicated in this figure are not captured. International factors are not represented. Patients often see multiple prescribers.
# TABLE 1
**PRESCRIBERS IN CANADA (AS OF MARCH 2007)**

<table>
<thead>
<tr>
<th>Prescribers</th>
<th>Number of provinces / territories where privileged</th>
<th>Provinces / territories where privileged</th>
<th>Prescribing privileges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>13</td>
<td>All provinces/territories</td>
<td>Most drugs; specific authority required for some drugs (e.g. methadone)</td>
</tr>
<tr>
<td>Dentists</td>
<td>13</td>
<td>All provinces/territories</td>
<td>Specific guidelines (e.g. oral antibiotics)</td>
</tr>
<tr>
<td>Clinical assistants</td>
<td>1</td>
<td>Manitoba</td>
<td>Specific guidelines, defined as a “physician extender”</td>
</tr>
<tr>
<td>Nurse practitioners / Extended practice nurses</td>
<td>12</td>
<td>All provinces, Northwest Territories, Nunavut</td>
<td>Specific guidelines (e.g. non-steroidal anti-inflammatory drugs in MB)</td>
</tr>
<tr>
<td>Nurses</td>
<td>2</td>
<td>Quèbec, Yukon</td>
<td>Specific guidelines (e.g. contraceptives, renewal may be restricted to physician)</td>
</tr>
<tr>
<td>Midwives</td>
<td>4</td>
<td>British Columbia, Manitoba, Ontario, Quèbec; Saskatchewan (pending)</td>
<td>Specific guidelines (e.g. antibiotics, anti-fungal agents, contraceptives in MB)</td>
</tr>
<tr>
<td>Optometrists</td>
<td>6</td>
<td>British Columbia, Saskatchewan, Quèbec, New Brunswick, Nova Scotia, Newfoundland and Labrador</td>
<td>Specific guidelines (e.g. ophthalmic drugs in NS)</td>
</tr>
<tr>
<td>Podiatrists</td>
<td>4</td>
<td>British Columbia, Alberta, Ontario, Quèbec</td>
<td>Specific guidelines (e.g. antibiotics and anti-fungal agents in AB)</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>6</td>
<td>British Columbia, Alberta, Manitoba, Saskatchewan, Quèbec, Nova Scotia</td>
<td>Specific guidelines (e.g. emergency contraception in BC, SK, MB, QC; continuing care in NS, MB; broader privileges in QC, AB)</td>
</tr>
</tbody>
</table>

Sources: Alberta College of Pharmacists; Canadian Pharmacy Law 1995-2006; Soon et al.; National Association of Pharmacy Regulatory Authorities.
## Table 2
The Effectiveness of Strategies to Change Prescribing Behavior and Medication Use

<table>
<thead>
<tr>
<th>Levels of effectiveness*</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generally effective</td>
<td>Multi-faceted interventions</td>
</tr>
<tr>
<td></td>
<td>Academic detailing</td>
</tr>
<tr>
<td></td>
<td>Reminders, decision supports</td>
</tr>
<tr>
<td>Mixed effect</td>
<td>Audit and feedback</td>
</tr>
<tr>
<td>(sometimes effective</td>
<td>Local opinion leaders</td>
</tr>
<tr>
<td>and sometimes not)</td>
<td>Drug utilization review</td>
</tr>
<tr>
<td></td>
<td>Local consensus groups</td>
</tr>
<tr>
<td></td>
<td>Interventions targeting patients, caregivers, and the public**</td>
</tr>
<tr>
<td>Generally ineffective</td>
<td>Education†</td>
</tr>
<tr>
<td></td>
<td>(e.g. dissemination of printed educational materials; didactic education sessions such as courses and conferences)</td>
</tr>
<tr>
<td>Effectiveness unknown</td>
<td>Financial interventions††</td>
</tr>
<tr>
<td></td>
<td>Administrative or organizational interventions§</td>
</tr>
</tbody>
</table>

Adapted from:


Both sources analyze strategies to change prescribing, in addition to other aspects of clinical practice. We have integrated our synthesis of the literature with the aspects of their tables that are relevant to prescribing.

Notes:

* Context, design of strategy and method of implementation are key to determine effectiveness.

** Time spent in one-on-one interventions with patients/caregivers is probably the most effective, but public interventions involving mass media can also be effective.

† Interactive education appears promising.

†† While there are limited data on the effect of financial incentives and penalties to physicians on prescribing, reimbursement criteria in pharmacare programs affect prescribing. Effectiveness depends on the characteristics of the incentive and on contextual factors.

§ Systematic reviews, while mixed, show that electronic health records generally improve prescribing.
### TABLE 3
SMART PRACTICES THAT INFLUENCE PRESCRIBING: SELECTED CANADIAN AND INTERNATIONAL EXAMPLES

(See Web Appendices C and D for more information on these programs)

<table>
<thead>
<tr>
<th>Organizations</th>
<th>Category</th>
<th>Type of intervention</th>
<th>Scope/Focus</th>
<th>Clientele</th>
<th>Description</th>
</tr>
</thead>
</table>
| e-therapeutics                                   | Pharmacy professional organization (Canadian Pharmacists Association) | Education: Web-based clinical decision support tools (e.g., e-CPS, drug monographs, treatment protocols, drug interaction alerts) | National / Primary care, acute care, community care | Health providers, health care institutions, pharmacies, patients and caregivers | - A subscribed service; developed and managed with partners  
- Provides “just in time” access to Canadian drug and therapeutic information  
- Hosts educational events on the products |
| Therapeutics Initiative (TI)                     | University-based initiative | Educational programs; drug benefit assessments; evaluations of drug use               | Provincial (British Columbia)/ Primary care and hospital/acute care | Physicians and pharmacists | - Source of therapeutics information for physicians and pharmacists independent from pharmaceutical industry  
- Produces bi-monthly newsletter targeting problematic therapeutic issues for physicians and pharmacists |
| Integrating family Medicine and Pharmacy to Advance primary Care Therapeutics (IMPACT) | University – demonstration project | Educational and multi-faceted interventions, including patient assessments, drug information, patient education, medication-focused practice system enhancements | Provincial (Ontario)/ Primary care | Patients and physicians | - Developed IMPACT Toolkit for family physicians, managers and pharmacists with a comprehensive set of tools and strategies to integrate a pharmacist into family practice following experience with 8 sites  
- Family Health Teams can request a pharmacist program; if approved, funded by Ontario Ministry of Health and Long-Term Care |
| Drug Evaluation Alliance of Nova Scotia (DEANS) | Provincial Department of Health coordinated initiative with university and other participants | Drug evaluation, multi-faceted educational interventions and evaluation | Provincial (Nova Scotia)/ Primary care, acute care, continuing care | Health care providers and patients | - A single structure under which all of the provincially funded drug program management components can be considered in the context of addressing drug care issues  
- Utilizes multi-faceted, multidisciplinary interventions |
| National Prescribing Service (NPS)               | Independent, non-profit, public corporation | Information, education, support and resources, social marketing                      | National (Australia)/ Primary care, acute care, community, and consumers | Health care providers and the Australian community/ consumers | - Partnership with GPs, pharmacists, specialists, other health professionals, government, pharmaceutical industry, consumer organisations and the community  
- Implemented in local areas by NPS facilitators (n=140) who operate out of divisions of general practice located around Australia (n=199) |
| The Cochrane Collaboration                       | International non-profit, independent organization with Canadian Network and Centre | Drug use evaluations (syntheses of high-quality, timely research evidence, usually based on randomized controlled trials, across all areas of health care) | International / Primary care, acute care and community care | Policy makers, health care providers and consumers | - The Cochrane Library is available by subscription, on the Internet and CD-ROM.  
- Internationally there are 51 Cochrane Review Groups, 26 Cochrane Centres, 11 Methods Groups plus Networks and Fields.  
- In Canada there is a Cochrane Centre with 18 Network sites (located in 9 provinces and 1 territory), 5 Cochrane Review Groups, 2 Fields and 1 Methods Group. The Effective Practice and Organisation of Care Review Group (EPOC) is based at the University of Ottawa. |
References


2. Canadian Institute of Health Information. (2006). Drug Expenditure in Canada 1985 to 2005. Ottawa: CIHI. Note: Total spending on drugs in Canada was estimated at $24.8 billion in 2005. This represents final costs on prescribed and non-prescribed drugs (over-the-counter drugs and personal health supplies) and includes dispensing fees, mark-ups and taxes. It does not include these drug expenditures: hospital/institutional, samples, premiums, clinical trials, emergency releases, drugs sponsored by pharmaceutical companies, special access drugs in some provinces, or drugs from non-Canadian sources, e.g. Internet pharmacy.


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Institute of Medicine recommendations on drug safety.

Gano A et al. (2002). Interventions used in disease management programs for patients with chronic illness—which ones work? Meta-analysis of published reports.


282. Laupacis A. (2002). Inclusion of drugs in provincial drug benefit programs: who is making these decisions, and are they the right ones? CMAJ / JAMC; 166(1):44-47.


Acronyms Glossary

CADTH Canadian Agency for Drugs and Technology in Health
CDR Common Drug Review
CIHI Canadian Institute for Health Information
CIHR Canadian Institutes of Health Research
COMPUS Canadian Optimal Medication and Prescribing Utilization Service
CQI continuous quality improvement
DEANS Drug Evaluation Alliance of Nova Scotia
DUR drug utilization reviews
EHR electronic health record
EPOC Effective Practice and Organisation of Care Review Group of The Cochrane Collaboration
IMPACT Integrating family Medicine and Pharmacy to Advance primary Care Therapy
IMPART Initiative on Medication Management, Policy Analysis, Research & Training (at Dalhousie University)

NPDUIS National Prescription Drug Utilization Information System
NICE National Institute for Health and Clinical Excellence (in the UK)
NPS National Pharmaceuticals Strategy (in Canada); the National Prescribing Service (in Australia)
PACE Promoting Action on Clinical Effectiveness (a UK program)
PCT Primary Care Trusts (in the UK)
PMPRB Patented Medicine Prices Review Board
TI Therapeutics Initiative (at the University of British Columbia)
ABOUT THE HEALTH COUNCIL OF CANADA

Canada’s First Ministers established the Health Council of Canada in the 2003 Accord on Health Care Renewal and enhanced our role in the 2004 10-Year Plan to Strengthen Health Care. We report on the progress of health care renewal, on the health status of Canadians, and on the health outcomes of our system. Our goal is to provide a system-wide perspective on health care reform for the Canadian public, with particular attention to accountability and transparency.

The participating jurisdictions have named Councillors representing each of their governments and also Councillors with expertise and broad experience in areas such as community care, Aboriginal health, nursing, health education and administration, finance, medicine and pharmacy. Participating jurisdictions include British Columbia, Saskatchewan, Manitoba, Ontario, Prince Edward Island, Nova Scotia, New Brunswick, Newfoundland and Labrador, Yukon, the Northwest Territories, Nunavut and the federal government. Funded by Health Canada, the Health Council operates as an independent non-profit agency, with members of the corporation being the ministers of health of the participating jurisdictions.

The Council’s vision
An informed and healthy Canadian public, confident in the effectiveness, sustainability and capacity of the Canadian health care system to promote their health and meet their health care needs.

The Council’s mission
The Health Council of Canada fosters accountability and transparency by assessing progress in improving the quality, effectiveness and sustainability of the health care system. Through insightful monitoring, public reporting and facilitating informed discussion, the Council shines a light on what helps or hinders health care renewal and the well-being of Canadians.

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<tr>
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<td>Mr. Jean-Guy Finn</td>
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<td>Dr. Stanley Vollant</td>
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