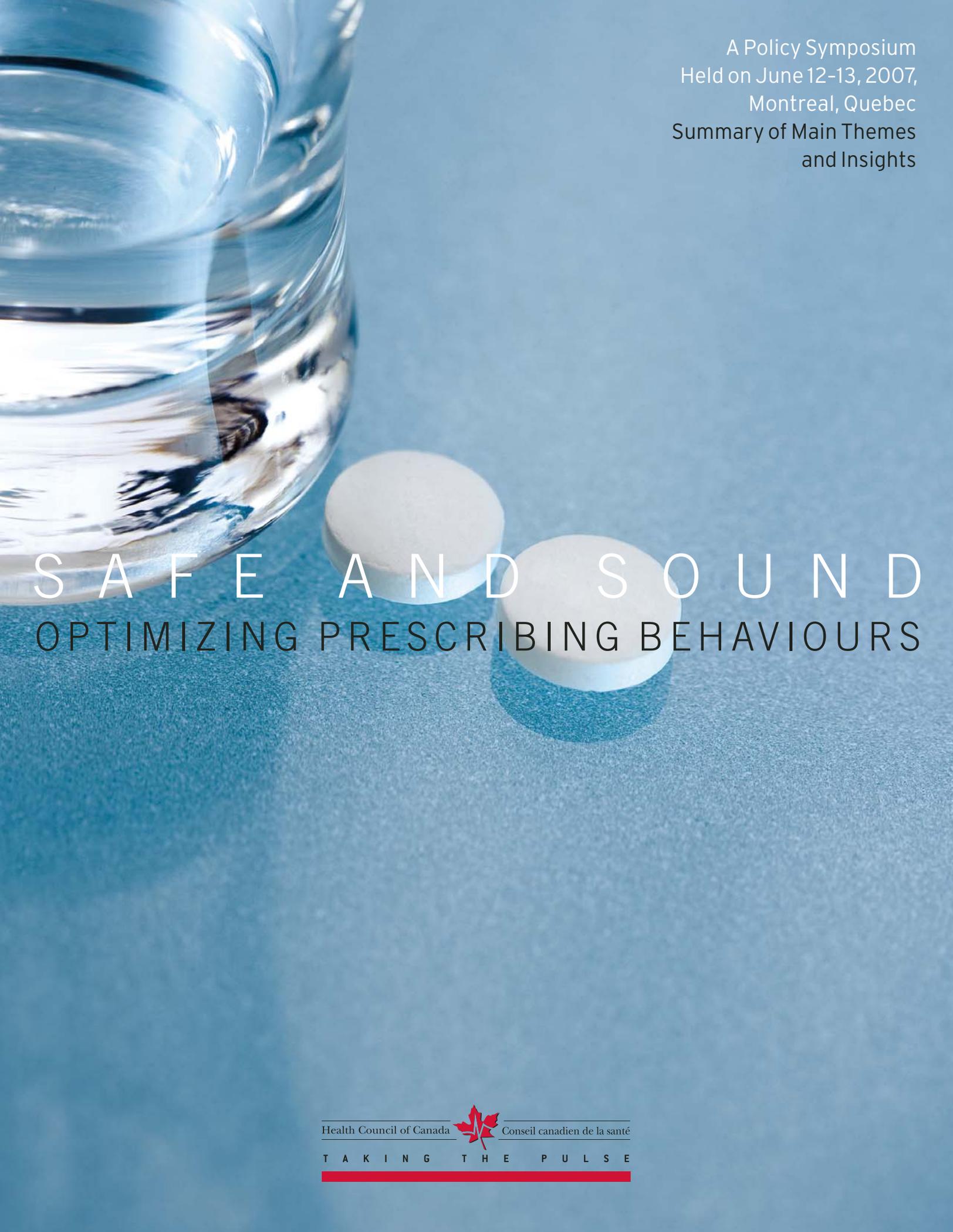


A Policy Symposium
Held on June 12-13, 2007,
Montreal, Quebec
Summary of Main Themes
and Insights

A glass of water is on the left side of the image, partially filled. Two white, round pills are on the blue surface in front of the glass. The background is a solid blue color.

S A F E A N D S O U N D
OPTIMIZING PRESCRIBING BEHAVIOURS

Health Council of Canada



Conseil canadien de la santé

T A K I N G T H E P U L S E

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HEALTH COUNCIL OF CANADA

**SAFE AND SOUND:
OPTIMIZING PRESCRIBING BEHAVIOURS**

A Policy Symposium Held on June 12-13, 2007
Montreal, Quebec

Summary of Main Themes and Insights

Executive summary

This report summarizes the central themes and advice from the Health Council of Canada emerging from a symposium, “Safe and Sound: Optimizing Prescribing Behaviours,” hosted by the Health Council on June 12-13 in Montreal. The purpose of the symposium was to support the continued development of Canada’s National Pharmaceuticals Strategy, in particular to “enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem.”

A number of studies have documented the problems of overuse, underuse, and inappropriate use of prescription drugs in Canada, problems which result in missed health benefits, harm to individual Canadians, and unnecessary costs to the health care system.

There are two major fronts on which to act in order to optimize prescribing:

- 1) supporting safe and sound decision-making by physicians and patients, so that the patient is more likely to receive the most appropriate prescription; and
- 2) changing the policy and regulatory landscape that influences prescribing and medication use in Canada.

Critical to success on both of these fronts is:

- 3) the electronic health record, an essential transformative tool.

Safe and sound decisions by prescribers and patients require targeted education and easier access to the right information. Prescribers, pharmacists, patients, and the general public could all benefit from expanded, more coordinated, and more comprehensive use of academic detailing across Canada and education campaigns on appropriate drug use. The costs of running academic detailing programs – one of the few strategies shown to be effective in making prescribing more

appropriate – should be weighed against the costs of not running them. The lack of consistent and mandatory training in quality use of medicines in Canada’s medical schools is concerning and points to the urgent need to correct this problem.

Australia’s National Prescribing Service has shown that academic detailing (in which publicly funded professionals, not pharmaceutical industry representatives, visit health care providers with up-to-date information on appropriate prescribing) can save money for the health care system. Among other strategies, Australia has also recently employed large-scale, targeted consumer-education campaigns to promote the optimal use of drugs. There is much that Canada can learn from Australia’s leadership.

Changing the landscape requires new regulatory and funding policies to improve access to beneficial medicines and to monitor and respond to unexpected health effects after medications are on the market. High drug prices, as well as gaps and inequities in insurance coverage for prescription drugs, continue to affect the accessibility of beneficial medicines. Efforts to optimize prescribing practices may be wasted if Canadians cannot access necessary drugs because they cannot afford them.

Public policy affecting the licensing, marketing, and ongoing surveillance of the health outcomes of drugs must also be part of a national strategy to make the use of prescription drugs more effective – for the health of Canadians and the future of our health care system.

The electronic health record has the potential to transform the patient-prescriber relationship by providing information to guide safe and effective prescribing decisions at every health care encounter. This tool also has great potential to support evidence-based public policy on pharmaceuticals and ongoing quality improvement in health care by generating real-world data on drug use and clinical outcomes after medicines are on the market. There is no systematic and ongoing effort in Canada today to measure how prescription drugs are used and with what effect. The electronic health record is an expensive undertaking but vital to health care renewal, and the Health Council of Canada continues to strongly support the rapid adoption of this transformative tool.

WHAT WE HEARD

Participants at the symposium recommend that health care policy makers, educators, managers and providers focus on the following actions:

Education and information for prescribers and patients: supporting safe and sound decisions

1. Expand existing provincial academic detailing efforts and develop programs in provinces where they do not exist. Otherwise the ongoing educational needs of health care professionals who prescribe medications will continue to be addressed mainly by detailers funded by the pharmaceutical industry to deliver their messages.

2. Create trusted and accessible sources of drug information for patients. Patients feel left out of the prescribing process. Patients with more education about their condition are more likely to take their medications as prescribed.

3. Enhance the capacity of – and collaboration among – current initiatives to optimize prescribing and medication use across Canada. For example, as a pan-Canadian program, the role of the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) could be expanded to deliver more products and services.

Regulation and policy: changing the landscape

4. Continue to develop processes that support evidence-based decision-making about prescribing and drug coverage, and educate Canadians about drug cost, safety, and effectiveness. This could help Canadians understand that not all funding decisions are based strictly on cost. To manage costs, it is more equitable

and more supportive of population health to base prescribing and coverage decisions on science, rather than arbitrarily restricting access to public funding for prescription drugs.

5. Accelerate efforts to improve access to prescription drugs for Canadians with no or inadequate insurance coverage.

6. Strengthen legislation to ban all forms of direct-to-consumer advertising of prescription drugs. Legislation should clearly prohibit help-seeking and reminder ads.

7. Ensure that medical training programs devote an appropriate amount of curriculum time to the quality use of medicines.

8. Create a systematic pan-Canadian surveillance strategy to monitor and respond to unanticipated and unintended health effects of medication use after drugs are on the market. For example, a system of regional surveillance centres could monitor drug use and clinical outcomes throughout Canada, help inform policy, and initiate quality improvement projects on a large scale.

9. Consider the merits of adding a graduated-licensing provision to all new drugs released in Canada to build on the knowledge gained through the surveillance strategy.

The electronic health record: a transformative tool

10. Accelerate the development of population-based drug information systems linked to other patient health information. Electronic health records are the only way to create fully integrated patient information and the only way to assess the impact of prescription medications on patient outcomes and the cost to the health care system.

The Health Council of Canada continues to support the development of all elements of the National Pharmaceuticals Strategy and urges all parties to make this vision a reality in the shortest possible time.

Foreword

Prescription drugs play an essential and growing role in Canada's health care system and the health of Canadians. Canadians spend more than \$20 billion each year on medications, the second-largest cost category in health care. But some drugs are over-prescribed, some are under-prescribed, and some prescriptions are not the best or safest choice for the patients who receive them. All Canadians should expect to get the right medicines at the right time for the right problem; yet, for a variety of reasons, many do not.

First Ministers recognized these issues when they committed to develop a National Pharmaceuticals Strategy (NPS) as part of the 2004 *10-Year Plan to Strengthen Health Care*. We recognize that this strategy is ambitious and broad in scope, having nine key elements, and the NPS task force decided last year to concentrate its short- to medium-term efforts on five of these elements. To complement these activities, the Health Council organized a two-day symposium to support the continuing development and implementation of another of the NPS goals: to "enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem."

What needs to be done to ensure that Canadians get the right drugs for the right problems? How can we make prescribing in Canada safer and more soundly based on the best available science? This symposium, "Safe and Sound: Optimizing Prescribing Behaviours," was designed to focus attention on initiatives that can optimize the prescribing practices of health care professionals, so that Canadians receive drugs that are appropriate and effective when needed.

We hope that this symposium will help to stimulate action to ensure that more Canadians can benefit from appropriate medicines and fewer experience unintended harm. We encourage policy-makers, funders and practitioners to facilitate and support the adoption of the practices highlighted in this report and in the background paper we commissioned to support the symposium.

Canada needs to develop better access to trusted information for prescribers and patients. Proven strategies such as academic detailing – in which publicly funded professionals (rather than pharmaceutical industry representatives) visit health care practitioners to keep them up-to-date on the best evidence on appropriate prescribing – clearly deserve more attention. We also need to ensure that gains made in educating prescribers and patients are not lost through patients' inability to afford necessary drugs or undermined by direct-to-consumer advertising. And we need to speed up the implementation of electronic health records and electronic drug information systems in every jurisdiction. These are essential tools to support the development of post-market surveillance of prescription drugs, to monitor whether medicines are having their intended benefits or are leading to unintended harm. Electronic systems also have the potential to transform the way prescribers and patients interact, guiding safe and effective prescribing decisions at every health care encounter.

We thank everyone who participated in this meeting and in particular the members of the symposium steering committee who worked for many months to bring this event together: Ms. Barb Shea, Dr. Stephen Graham, Dr. Craig Campbell, Dr. Jeff Poston, Mr. Phil Hassen, Mr. Wayne Lepine, Dr. Bernard Marlow, Mr. Paul Gudaitis, and our fellow Councillors Mr. Jean-Guy Finn and Dr. Alex Gillis. We also thank the Health Council secretariat for their work in organizing the symposium and its associated materials, available at www.healthcouncilcanada.ca. While we gratefully acknowledge the contributions of our external committee members, this report reflects the analysis and conclusions solely of the Health Council of Canada.

Canadians spend a great deal on prescription medicines to relieve pain, improve quality of life, and extend our years, but suboptimal prescribing costs us dearly as well. There is no simple prescription to fix these problems, yet we should not accept the status quo. The Health Council looks forward to continued dialogue and action to support health care professionals and patients so that drugs are used only when needed and the right drug is used for the right problem.

JEANNE BESNER, RN PhD
Chair, Health Council of Canada

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Chair, Symposium Steering Committee

Introduction

In all three of our reports to Canadians on the progress of health care renewal, the Health Council of Canada has strongly supported the development of a National Pharmaceuticals Strategy (NPS) as outlined in the First Ministers' 2004 *10-Year Plan to Strengthen Health Care*. The strategy was to contain nine elements, including one to "enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem."

In June 2007, the Health Council of Canada hosted the "Safe and Sound: Optimizing Prescribing Behaviours" symposium to assist in the continued development of the NPS. We recognized that moving forward on a national strategy to influence prescribing behaviour depends on persuading top-level decision-makers of its continued importance and providing them with options regarding what is possible and what it will take to put such a strategy in place. In order to accelerate progress in this area, decision-makers need answers to two questions: What impact will actions to optimize prescribing behaviors have on Canadians' health and on the sustainability of the health care system? And what can be done to improve the situation?

"The national pharmaceuticals strategy will... enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem."

First Ministers' 2004 *10-Year Plan to Strengthen Health Care*

As a first step, we saw a need for a conference that would assemble champions of change who have implemented tried-and-true practices known to optimize prescribing and who, together with patients, physicians, pharmacists, academics, regulators, and private insurers, could discuss the barriers and facilitators to better prescribing.

This report summarizes the central themes identified throughout the symposium, supported by key information from presentations by Canadian and international experts and additional evidence from other sources. We begin by providing some background on the importance of optimizing prescribing practices and on the current situation in Canada. The report closes with the participants' advice on how to advance optimal prescribing in concert with other elements of the National Pharmaceuticals Strategy.

MORE AVAILABLE AT
WWW.HEALTHCOUNCILCANADA.CA:

- Symposium agenda and speaker biographies
- Audio presentations with accompanying slides
- Background paper commissioned for the symposium, *Optimal Prescribing and Medication Use in Canada: Challenges and Opportunities*

Background

Prescription medications are the foundation of many medical therapies. Canadians receive 400 million prescription medications every year¹ at a cost of approximately \$24 billion. This represents 17% of total health care expenditures, second only to spending on hospitals, and spending on drugs is one of the fastest growing sectors in the Canadian health care system. Between 1997 and 2004, public and private sector drug expenditures rose annually by 12.8% and 10%, respectively. In 2004, the public sector paid for just under half (47%) of all prescription drug costs.²

Prescription medicines have produced substantial gains in quality and years of life for Canadians. Yet, too many Canadians are being harmed by suboptimal prescribing and many are not receiving the potential benefits of medications. Underuse, overuse and inappropriate use of medications are ongoing concerns, and prescribing practices can vary widely across the country. In addition, because of the country's patchwork of public insurance policies with respect to prescription drugs, many Canadians are unable to afford medications that they could benefit from. Among the evidence from Canada are the following examples:

Underuse:

- Modest increases in prescribing and use of a cholesterol-lowering drug could decrease mortality rates for Canadians who have already had a heart attack.³
- Modest increases in prescribing and use of prescription medications among people with diabetes can help prevent avoidable complications such as heart attacks, strokes, and blindness.⁴
- A study of four Canadian provinces found that use of recommended drugs after a heart attack was too low and varied widely between regions. For example, the percentage of elderly patients who had not been prescribed any of three recommended drugs ranged from 20% in British Columbia to 8% in Nova Scotia.⁵

Underuse refers to health benefits forgone when a drug could be used but is not. **Overuse** occurs when a drug is used unnecessarily. **Inappropriate use** occurs when patients use the wrong drug or dose.

CANADA'S NATIONAL PHARMACEUTICALS STRATEGY

The 2004 *10-Year Plan to Strengthen Health Care* directed health ministers to develop and implement a national strategy including the following nine actions:

- Develop, assess and cost options for catastrophic pharmaceutical coverage;
- Establish a common national drug formulary for participating jurisdictions based on safety and cost effectiveness;
- Accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process;
- Strengthen evaluation of real-world drug safety and effectiveness;
- Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
- Enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem;
- Broaden the practice of e-prescribing through accelerated development and deployment of the electronic health record;
- Accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and
- Enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies.

Overuse:

- Within one year of admission to nursing homes, nearly one-quarter of residents who have dementia are prescribed an antipsychotic to control behaviour,⁶ although this class of medication has limited evidence of benefit and increases the risk of death by up to 60%.^{7,8}
- Nearly half of elderly patients prescribed benzodiazepines to help them sleep after discharge from hospital are still taking the drugs six months later, despite warnings that these drugs are associated with cognitive impairment and injuries from falls and motor vehicle collisions.⁹

Inappropriate use:

- Drug interactions among seniors result in excess hospitalizations and it is estimated that 2-8% of the hospitalizations among seniors could be prevented.¹⁰
- An estimated 28% of seniors living in nursing homes are given prescription medications considered inappropriate.¹¹
- Drug interaction among patients being treated for heart disease and heart failure have resulted in excessive hospitalizations and death.¹²

In the 2004 *10-Year Plan to Strengthen Health Care*, the First Ministers directed the Health Ministers to establish a Ministerial Task Force to develop and implement the National Pharmaceuticals Strategy. In September 2006, participating governments released a progress report that said: “While recognizing that substantive, long-term improvement in pharmaceuticals management is contingent on advancing all elements of the NPS, in order to facilitate timely and concrete results for Canadians, the Ministerial Task Force identified five areas for short- to medium-term focus i) catastrophic drug coverage; ii) expensive drugs for rare diseases; iii) common national formulary; iv) pricing and purchasing strategies; and v) real world drug safety and effectiveness.¹³

Optimizing prescribing behaviors was one of the remaining four elements of the NPS not identified as an area for immediate intergovernmental action. The Health Council’s symposium was designed to assist in the continued development of Canada’s NPS. While optimal prescribing was the focus of the symposium, discussion at the meeting showed that many of the NPS elements are interrelated.

TO LEARN MORE...

To help inform discussion at the symposium, the Health Council of Canada commissioned a report synthesizing what is known about how to optimize prescribing. The comprehensive paper by Dr. Ingrid Sketris and team, *Optimal Prescribing and Medication Use in Canada: Challenges and Opportunities* (available at www.healthcouncilcanada.ca), contains extensive information on interventions that are generally effective, sometimes effective, and generally ineffective, with examples of initiatives underway in Canada and internationally. The report also provides background information on Canada’s medication-use system and the factors affecting prescribing. It should be useful reading for anyone planning an intervention to improve prescribing or who wishes to understand the complexities of optimizing prescribing behaviours.

Central symposium themes

Dr. Robyn Tamblyn, professor in the Department of Medicine at McGill University and an internationally recognized expert in pharmacoepidemiology and electronic health records, served as chair of the symposium. In setting the stage for the meeting, Dr. Tamblyn said that optimizing prescribing behaviour “will be the salvation of the health care system.”

Three central themes arose throughout the day-and-a-half meeting as to how to make optimal prescribing a reality in Canada. There are opportunities to effect positive change in optimal prescribing through:

- 1) education and information for patients and prescribers, so that prescribing decisions are more likely to be safe and sound and patients are more likely to receive the most appropriate prescription; and
- 2) the policies and legislation that govern the Canadian medication-use system.

And critical to success in both of these avenues is:

- 3) the electronic health record.

1) EDUCATION AND INFORMATION FOR PRESCRIBERS AND PATIENTS: SUPPORTING SAFE AND SOUND DECISIONS

Prescribers and patients need the right information to ensure that the right drug is used for the right patient at the right time. Panelist and family physician Dr. Marilyn Caughlin, who practices in Saskatchewan, summarized the challenges for prescribers by explaining that busy doctors need simple tools to help them translate the evidence from research on drugs into that “pen-and-paper decision in their five-to-10-minute encounter” with a patient. Often, the most recent information a frontline physician receives is through a visit from the pharmaceutical industry, she said, and “if nothing has intercepted that,” prescribing decisions can be heavily influenced by the industry perspective. For such interception, she noted, she has come to rely on academic detailing (described below) as an unbiased source of useful information on prescribing.

One plenary speaker – Dr. Jeremy Grimshaw, director of the Canadian Cochrane Centre and of the Clinical Epidemiology Program at the Ottawa Health Research Institute – cautioned that there is no “magic bullet.” No single intervention will dramatically improve prescribing patterns. Interventions with the best design and implementation can expect to improve prescribing on average by around 5-10%. However, these small, incremental changes can have large benefits when implemented across an entire population. The following methods are designed to maximize the likelihood of prescribers and patients choosing the best drug and using it correctly.

Academic detailing: getting the right information to prescribers

Academic detailing is the practice of commercially independent health care professionals visiting health care practitioners in their offices to provide objective information on medications and disease management. Drs. Ingrid Sketris and Jeremy Grimshaw both presented research evidence demonstrating that this is one of the more effective methods to promote evidence-based prescribing. Typically, an academic detailer is a pharmacist who spends 10-30 minutes with a prescriber and presents two to three key messages on optimal prescribing. This intervention relies on “pushing” the information towards health care professionals. Dr. Anne Nguyen, coordinator of the BC Community Drug Utilization Program, described this practice as an attempt to put into perspective the marketing messages of detailers employed by pharmaceutical companies.

9 However, academic detailing is expensive, labour-intensive, and not widely used across Canada. As a result, the limited activity that does occur is overwhelmed by detailing efforts of the pharmaceutical industry. As of February 2007, only five provinces had academic detailing programs (British Columbia, Nova Scotia, Saskatchewan, Alberta, and Manitoba) but Alberta's provincial-level program had been discontinued.¹⁴ The total academic detailing workforce in Canada is small – approximately 10 people in all, or about one publicly funded detailer for every 3,100 general practitioners (GP). In contrast, the pharmaceutical industry employs 5,500-6,000 detailers in Canada, or about one for every five to six GPs. Dr. Michael Allen, a symposium participant and director of the Dalhousie Academic Detailing Service, has compared academic detailing to the story of David and Goliath.¹⁴ Whether real life will follow the Biblical story, if academic detailing programs are not expanded in Canada, remains to be seen.

Dr. Lynn Weekes, CEO of Australia's National Prescribing Service, spoke about the extensive academic detailing efforts in her country. The National Prescribing Service employs 110 academic detailers or facilitators for the 22,000 general practitioners across Australia (about one detailer for every 200 GPs). Tackling two major topics per year, the program is expected to save \$40 million in drug expenditures – although this may not represent net savings because optimal prescribing will frequently increase costs where drugs have been under-prescribed. Their current campaign “Common colds need common sense, not antibiotics” is designed to reduce the inappropriate use of antibiotics and, in addition to academic detailing, includes social marketing and educational strategies directed at the general public as well as health care providers.

COMPUS: generating information for health care professionals

Getting the right information about drugs to health care providers and consumers is a key role of the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), as outlined by vice-president Barb Shea and Dr. Lisa Dolovich, chair of the COMPUS Expert Review Committee (CERC), an advisory body on optimal prescribing. Funded by Health Canada, COMPUS is one of three core divisions of the Canadian Agency for Drugs and Technology in Health (CADTH) and its mandate is to identify and close gaps between optimal prescribing and actual practice by developing information tools for providers and consumers.

An example of COMPUS's work is with proton pump inhibitors (PPI), a class of drugs used to treat common gastrointestinal conditions such as peptic ulcer and acid reflux disease. These drugs are widely prescribed in Canada, with over 12 million prescriptions in 2004 and evidence of both under- and over-prescribing.¹⁵ To help prescribers use these drugs appropriately, COMPUS has developed a range of tools that promote evidence-based messages on PPIs, including an academic detailing newsletter, a quick-reference guide for evidence-based prescribing, and interactive presentations for pharmacists and physicians. CERC is currently tackling the issue of drug use for diabetes, including a review of gaps between recommended therapies and current patterns of prescribing.

Discussion at the symposium indicated substantial support for the continuing growth of COMPUS so that it becomes the trusted source of timely and accessible information on optimal prescribing for health care providers, as well as patients and policy-makers. Moving expert advice into everyday health care practice presents an ongoing challenge. As Barb Shea noted, “We can only be successful if our tools are implemented.”

Patient adherence: taking the right drug the right way

Appropriate prescribing is useless if patients do not take the drug as prescribed. Dr. Jean-Pierre Grégoire, dean of the Faculty of Pharmacy at Laval University, presented more than three decades of research on patient adherence to better understand why patients may not take appropriate drugs after receiving a prescription. The World Health Organization estimates that only about 50% of patients take their medications as directed. Increased adherence is associated with better health outcomes, and poorer adherence is associated with higher hospitalization rates and higher health care costs. The burden of non-compliance, in terms of individual health and system costs, is likely to increase as the prevalence of chronic disease rises among Canada’s population.¹⁶

There are different types of interventions that can increase medication adherence in chronic medical conditions. Unfortunately, they are generally complex and most do not significantly affect clinical outcomes.^{17,18} Dr. Grégoire stressed the need to recognize the three separate steps that are involved when patients take medications: the patient must agree with the need for the drug (acceptance); the patient must take the drug correctly (compliance); and, if needed, the patient

must continue to take the drug over time (persistence). Interventions that involve community pharmacists (who can influence acceptance, compliance, and persistence) in conjunction with physicians (who primarily influence acceptance) are promising. There might also be a role for public marketing campaigns to help foster improved adherence. As patient advocate Linda Wilhelm noted, patients should be involved in decision-making at all stages and should be an integral part of developing programs that aim to influence their decision-making on the use of medication.

Public education: connecting patients to essential information

Patient advocates spoke about their information needs related to prescription drugs. People often turn to the Internet when they are considering their options for recommended medications, when they receive a new prescription, or during medication use, but the amount of information online can be overwhelming and finding trusted and useful sources can be frustrating. Participants suggested a possible role for government-sanctioned websites to fill this gap.

Some participants also called for more patient-oriented information and better communication strategies between patients, pharmacists, and physicians. Certainly, the electronic health record could prove useful in enhancing communications between these three groups. Electronic information systems can, for example, link physicians (who prescribe drugs) with pharmacists (who dispense them) to improve communication between them. Electronic information systems can also be used by patients, for example, to order medication or refills from pharmacies and to learn more about a prescribed medication and its side effects.

The need to help the public understand funding decisions on new drugs was another important theme throughout the symposium. Many participants shared the view that the Canadian public generally sees government decisions on drug funding as attempts to limit access to effective medications in order to cut costs. The complexity of decision-making – which must weigh effectiveness, safety, costs and other factors – is not well understood, and this reality presents an opportunity for governments and health care providers to improve public information through marketing campaigns or other methods.

2) REGULATION AND POLICY: CHANGING THE LANDSCAPE

There are powerful system-level changes available to policy-makers to influence prescribing patterns. Participants identified a number of potential changes to current funding mechanisms, regulations, legislation, and medical education that could be part of a strategy to optimize prescribing.

Approvals to market medicines: could a “graduated licensing” system enhance post-market surveillance?

Health Canada is responsible for granting approval for new prescription medicines to be marketed in Canada. This decision is based on safety and efficacy as demonstrated through clinical trials using carefully selected patient participants. Although the federal government has a clear mandate to ensure the safety of medications, after approval is granted there are essentially no restrictions on how a prescriber can use a drug. Nor does Canada have a system in place to ensure that the risks and benefits of medications as used in practice match the expected results based on research prior to approval.

UNINTENDED CONSEQUENCES

The real-world example of Vioxx serves as a powerful reminder that drugs can have unanticipated consequences and that these adverse events are sometimes difficult to detect in a clinical trial setting but possible to assess in larger population studies. Vioxx was approved for use in 1999 for treatment of arthritis pain. Its major advantage over other existing pain medications was that it caused fewer cases of serious gastrointestinal side-effects such as bleeding. Merck & Co., Inc., the drug’s manufacturer, withdrew Vioxx in 2004 after the interim results of a large post-market study demonstrated a marked increase in cardiovascular events such as strokes and heart attacks.^{19,20}

The lack of systematic post-market surveillance can lead to undetected problems after a drug is approved for use. Suppose, for example, that a large clinical trial has 3,000 participants – 1,500 receiving an established treatment and 1,500 receiving an experimental new drug. Unbeknownst to researchers, the experimental drug causes liver disease in 0.4% of the people who take it. This means that approximately six people in the experimental group might develop liver disease, but this signal of a potential risk from the drug might be too small to be picked up during the study. Detecting this problem might also be further masked because some people in the control group might develop liver disease as well. If, after regulatory approval, two million Canadians were prescribed this drug, there could be as many as 8,000 additional cases of liver disease (0.4% of two million). Without a comprehensive system in place, these additional cases might go undetected because nobody was expecting this adverse event. (See sidebar “Unintended consequences.”)

Dr. Geoff Anderson, a specialist in drug policy and professor in the Department of Health Policy, Management and Evaluation at the University of Toronto, raised the idea of a graduated licensing system to help monitor and respond to unintended health effects after medicines have been approved for use in Canada. Health Canada regulations could dictate that, upon approval, new drugs must be shown to be effective and safe through larger pragmatic (real-world) studies. If these conditions are not met over the course of a specified time period, the drug would be removed from the market or have restrictions placed on its use.

None of this will be possible without a robust surveillance system that links information about individual Canadians’ use of medicines to information about their subsequent clinical outcomes. While ensuring individual privacy, such a system is essential to help us confirm that prescribed medications are having their intended benefits and detect unintended harm. This type of information could be derived from a comprehensive electronic health record (which most people in Canada do not yet have), as well as from population-based information systems (which currently exist in Canada). At present, there are several research institutions or groups across Canada with the capability and expertise to perform these population-level analyses in British Columbia, Manitoba, Ontario, Quebec and Nova Scotia.²¹ Two federal agencies – the Canadian Institute for Health Information and the

Patented Medicine Prices Review Board – are working together to develop the National Prescription Drug Utilization Information System (NPDUIS).²² NPDUIS provides comparative information on medication use in Canada. However, this database does not link information on drug use to information on the use of other health services, which weakens its ability to reach its potential as a useful surveillance tool to track the health effects of medication use.

Direct-to-consumer advertising: does it contribute to inappropriate prescribing?

Symposium participants frequently spoke about the negative influence of direct-to-consumer advertising (DTCA) of prescription drugs in Canada. Pharmacist and physician panelists remarked that they had felt pressure from patients who, in their opinion, had been influenced by DTCA to ask for advertised medicines that were not appropriate for them. A patient advocate proposed an innovative idea – if DTCA is allowed to continue, pharmaceutical companies could be compelled to donate a percentage of their advertising budgets to academic detailing programs.

In a background paper commissioned by the Health Council of Canada, *Direct-to-Consumer Advertising of Prescription Drugs in Canada: What are the Public Health Implications?*, Dr. Barbara Mintzes of the University of British Columbia found no evidence that direct-to-consumer advertising results in improved health or better compliance, increased detection of disease, or prevented hospitalizations.²³ The only types of pharmaceutical advertising allowed in Canada are reminder ads (only the drug brand name is used and no claims are made) and help-seeking ads (no brand is mentioned but the ad can suggest that patients talk to their physician about a particular condition). Despite regulations in this country, many Canadians have exposure to drug advertising from US television and other media. The power of media to influence treatment decisions has been demonstrated by a study of the impact of a CBC documentary on a controversial acne medication. (In this case, the effect was positive – to bring practice more in line with research evidence).²⁴ Based on Dr. Mintzes’s comprehensive report, the Health Council has called for strengthened federal legislation to ban all forms (including help-seeking ads and reminder ads) of direct-to-consumer advertising of prescription drugs in Canada.²⁵

Inadequate drug insurance: does it affect patients’ health?

Many Canadians do not have adequate insurance to cover the cost of prescription medications, and many have no drug coverage at all. Participants spoke about the inconsistency of the *Canada Health Act* in providing for patients in hospitals to receive necessary drugs through provincial insurance plans but leaving patients to pay for those same drugs when they are back at home. This may lead patients to forgo necessary but costly medications when they don’t have adequate insurance. There is evidence that patients’ health can suffer if they have no drug coverage or coverage with restrictions such as cost-sharing. Previous research by the symposium chair, Dr. Robyn Tamblyn, found that elderly patients and welfare recipients in Quebec who had to pay part of the cost of their prescriptions were less likely to use essential drugs and more likely to experience a serious adverse event or emergency department visit.²⁶

The role of medical education: do physicians learn enough about prescribing?

Dr. Jean Gray, professor emeritus of Medical Education, Medicine and Pharmacology at Dalhousie University, identified a disturbing trend of declining attention to education on pharmaceuticals in medical schools, although, as she noted, physicians are the ones who usually hold the prescription pad. A survey of Canada’s 16 medical schools in 2004 found that three of the schools had no defined program in basic pharmacology, and training in clinical pharmacology was mandatory in only 10 of the schools.²⁷ Medical education in Canada is guided by frameworks and licensing standards set by a number of organizations, such as the Royal College of Physicians and Surgeons, Medical Council of Canada, and Canadian College of Family Physicians. These professional bodies could lead changes to correct this problem by ensuring that competency in appropriate prescribing is a core part of medical education.

Enhancing collaboration: is there a need for a facilitating agency?

“The problems in drug use are not created by any one group and won’t be solved by any one group,” a participant said, summing up the need expressed by a number of people for a central organization that – building on the work of COMPUS – could serve the information needs of prescribers, patients, and the public. Patient advocates frequently spoke about their frustrations in trying to locate trusted information on the Internet. Participants suggested that a single organization be responsible for producing information (or sanctioning and standardizing existing information) for both patients and prescribers. Australia’s National Prescribing Service is one example of this type of organization.

The federal and provincial governments both have critical roles as guardians of public safety and as funders in the Canadian medication-use system. Dr. Sketris highlighted the need for a process for different levels of government, stakeholder organizations, providers, and patients to work effectively together.

3) THE ELECTRONIC HEALTH RECORD: A TRANSFORMATIVE TOOL

An electronic health record (EHR) is a secure and private lifetime record of an individual’s health care history including lab test results, diagnostic imaging, records of physician and hospital visits, and prescription drug lists.²⁸ This tool has the potential to transform the patient-prescriber relationship and the policies governing prescribing in Canada. Yet too few Canadians have a comprehensive electronic health record that is accessible to them and their health care providers.

The EHR can help prescribers and patients

Electronic health records help provide the right information to providers at the point of care through the use of decision-support tools (such as prescription drug information, guidelines on appropriate therapeutic choices, alerts about possible drug-to-drug and drug-to-disease interactions). With the introduction of the EHR, providers will be better equipped to select the most appropriate medication therapy for their patients. The EHR is also a platform to introduce e-prescribing – the process of electronically transmitting a prescription to the pharmacy. This reduces one source of medication-use errors because it eliminates the problem of pharmacists misinterpreting poor handwriting.

The benefits of the EHR were highlighted during a policy conference co-hosted by the Health Council of Canada and Canada Health Infoway in 2006:²⁹

- In Denmark, the use of e-prescribing has reduced the rate of medication problems from 33% to 14%.³⁰
- The Vanguard Group in Boston was delivering guideline-recommended care 60% of the time before any interventions. This figure rose to 90% when they introduced an EHR combined with team-based care.³¹

Many hospitals in Canada have established an institutional EHR, but international research indicates that only about 23% of Canadian family physicians use computers to help them deliver care, and very few of the systems in use are a true EHR. This is much lower than other similar industrialized countries such as Australia (79%), Netherlands (98%), and the United Kingdom (89%).³²

The EHR can improve prescription drug surveillance and support policy change

There is no systematic and ongoing effort to measure the clinical outcomes of drug use after approval by Health Canada. With current systems, we may know how many patients are taking what drugs, but we can’t easily learn why (for what conditions) they received the prescription and how their health improves or worsens after taking the medication. The EHR has the potential to begin filling this gap by enabling ongoing surveillance of drug use after medications are on the market. An EHR could become a powerful quality improvement tool and provide real-world data on drug safety and effectiveness. These data could be the basis of a system that routinely monitors prescription drug use in Canada, while protecting individual privacy, and that supports the continual measurement and improvement of quality of care in the Canadian health care system.

Conclusion

The problem of suboptimal prescribing in Canada is well documented and illustrates why health care renewal matters to the health of Canadians. There are two major fronts on which to act in order to optimize prescribing: supporting safe and sound decision-making in the provider-patient relationship, and changing the landscape that influences prescribing and medication use. An essential, transformative tool – the electronic health record – spans both avenues of change.

Safe and sound decisions on prescribing require targeted education and easier access to the right information. Prescribers, pharmacists, patients, and the general public could all benefit from expanded, more coordinated, and more comprehensive use of academic detailing across Canada and education campaigns on appropriate drug use. The costs of running academic detailing programs – one of the few strategies shown to be effective in making prescribing more appropriate – should be weighed against the costs of not running them. The same is true for education campaigns designed to optimize prescribing. Australia’s National Prescribing Service has shown that academic detailing can save money, and they have also adopted the strategy of large-scale education campaigns. There is much that Canada can learn from Australia’s leadership. The lack of consistent and mandatory training in quality use of medicines in Canada’s medical schools is concerning and points to the urgent need to correct this problem.

Changing the landscape requires new regulatory and funding policies to improve access to beneficial medicines and to monitor and respond to unexpected health effects after medications are on the market. High drug prices make drugs unaffordable for those without insurance; gaps and inequities in that insurance coverage continue to affect the accessibility of beneficial medicines. Efforts to optimize prescribing practices will be wasted in part if Canadians cannot take advantage of necessary drugs because they can’t afford them.

Public policy affecting the licensing, marketing, and ongoing surveillance of the health outcomes of drugs must also be part of a national strategy to make the use of prescription drugs more effective – for the health of Canadians and the future of our health care system.

On the electronic health record, Dr. Robyn Tamblyn underscored its importance through her final thoughts at the symposium’s conclusion. Canada Health Infoway is building the road for e-health, but it is up to the future users of the EHR to design cars for that road, she said. The EHR will not drive the kind of change envisioned in the symposium discussion without that essential collaboration. The only way the EHR will have all the features we desire, is if health care providers, patients, researchers, and policy-makers collaborate with Canada Health Infoway and software developers and ask for those features. It will serve us well “if you tell it what to do.”

WHAT WE HEARD

This symposium was helpful in identifying key activities that should be part of a national strategy to optimize prescribing, so that drugs are used only when needed and the right drug is used for the right problem.

Participants at the symposium recommend that health care policy makers, educators, managers and providers focus on the following actions:

Education and information for prescribers and patients: supporting safe and sound decisions

1. Expand existing provincial academic detailing efforts and develop programs in provinces where they do not exist. Otherwise the ongoing educational needs of health care professionals who prescribe medications will continue to be addressed mainly by detailers funded by the pharmaceutical industry to deliver their promotional messages.
2. Create trusted and accessible sources of drug information for patients. Patients feel left out of the prescribing process. Patients with more education about their condition are more likely to take their medications as prescribed. Similarly, educational campaigns can improve understanding about appropriate use of medicines for common conditions such as Australia’s “Common Colds Need Common Sense” campaign.

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3. Enhance the capacity of – and collaboration among – current initiatives to optimize prescribing and medication use across Canada. For example, as a pan-Canadian program, COMPUS' role could be expanded to deliver more products and services. As a trusted information source, COMPUS would provide broader information and support to the range of stakeholders involved in optimal drug therapy. Adequate support is important to augment the implementation efforts of those involved in behaviour change initiatives, such as continuing medical educators and academic detailing groups. At the same time, governments and others need to adequately fund initiatives such as academic detailing, to facilitate the uptake and implementation of evidence-based information and to ensure that the investment of public funds results in positive health outcomes for Canadians.

Regulation and policy: changing the landscape

4. Continue to develop processes that support evidence-based decision-making about prescribing and drug coverage, and educate Canadians about drug cost, safety, and effectiveness. This could help Canadians understand that not all funding decisions are based strictly on cost. To manage costs, it is more equitable and more supportive of population health to base prescribing and coverage decisions on science, rather than arbitrarily reducing the number of beneficiaries or increasing deductibles and co-payments. Governments can save money through tighter management of their drug plans, cross-jurisdictional cooperation and optimized prescribing behaviours. Such improvements will also enhance governments' ability to provide coverage for high-cost medications with a proven health benefit.

5. Accelerate efforts to improve access to prescription drugs for Canadians with no or inadequate insurance coverage. Inequities and gaps in insurance coverage across Canada are obstacles in the path to more effective use of medications. If an inability to pay for medications leads patients not to fill prescriptions, any gains we make in optimizing prescribing will be lost.

6. Strengthen legislation to ban all forms of direct-to-consumer advertising of prescription drugs. Legislation should clearly prohibit help-seeking and reminder ads.

7. Ensure that medical training programs devote an appropriate amount of curriculum time to the quality use of medicines.

8. Create a systematic pan-Canadian surveillance strategy to monitor and respond to unanticipated and unintended health effects of medication use after drugs are on the market. For example, a system of regional surveillance centres could monitor drug use and clinical outcomes throughout Canada and help inform policy and initiate quality improvement projects on a large scale.

9. Consider the merits of adding a graduated-licensing provision to all new drugs released in Canada to build on the knowledge gained through the surveillance strategy.

The electronic health record: a transformative tool

10. Accelerate the development of population-based drug information systems linked to other patient health information. Electronic health records are the only way to create fully integrated patient information and the only way to assess the impact of prescription medications on patient outcomes and the cost to the health care system. This information should be made readily available to support national initiatives that inform governments and support the monitoring of the safety and effectiveness of prescription drugs.

The Health Council of Canada continues to support the development of all elements of the National Pharmaceuticals Strategy and urges all parties to make this vision a reality in the shortest possible time.

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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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