



HARMS ASSOCIATED WITH OPIOIDS AND OTHER PSYCHOACTIVE PRESCRIPTION DRUGS

Background

The harms associated with psychoactive prescription medicinesⁱ including sedatives and tranquilizers¹, stimulants², and analgesics, particularly opioids³, such as oxycodone, hydromorphone and fentanyl, are a significant public health and patient safety issue.

Canada has one of the highest per capita consumption of prescription opioids in the world.⁴ Dispensing of medications has substantially increased in Canada, although patterns vary considerably between provinces.⁵ In 2011, while opioid consumption for medical purposes in morphine equivalence (ME)ⁱⁱ was 62mg per person globally, Canada's ME was 812mg per person.⁶ When comparing to other developed countries, Australia's ME was 427 and Denmark's 483. In North America, about 5% of the adult population, and substantially higher rates for teens and young adults, reported non-medical opioid use in the previous year. This rate is higher than all other illegal drugs, with the exception of marijuana.⁷

Psychoactive medications pose significant health and safety risks. The harms include overdoses, suicides, motor vehicle accidents, relationship and employment problems, workplace accidents and exposure to blood borne pathogens and other infections when used by injection, besides addiction.

Data are not collected systematically in Canada, making it difficult to assess the harms and track the trends and impact of the introduction of policy changes. However, practitioners have seen the significant impact of these prescription drugs on their patients and to public

i Psychoactive drugs are substances that, when taken, have the ability to change an individual's consciousness, mood or thinking processes (WHO, 2004). Psychoactive prescription drugs include sedatives (such as benzodiazepines and barbiturates), stimulants (such as amphetamines), and opioids (such as oxycodone, hydromorphone, morphine and fentanyl). [World Health Organization (2004) *Neuroscience of psychoactive substance use and dependence*. Available at: http://www.who.int/substance_abuse/publications/en/Neuroscience.pdf]

ii Comprises six main opioids: fentanyl, hydromorphone, methadone, morphine, oxycodone and pethidine.

health. Studies in Ontario show that the number of people enrolled in methadone maintenance treatment rose from about 7,800 in 2001 to over 35,000 in 2011, where opioids have surpassed heroin as the drug used.⁸ Opioid-related deaths nearly tripled from 2002 to 2010, according to the Office of the Chief Coroner of Ontario.⁹ Another study showed that other non-opioid depressants (sedatives), such as benzodiazepines, were involved in 92% of the opioid-related deaths.¹⁰

The impact is felt particularly among vulnerable populations, such as youth, seniors, First Nations and those living in poverty. In 2013, opioids were reported as the third most common drug used by students in Ontario (after alcohol and marijuana).¹¹ Opioid addiction rates anywhere from 43% to 85% have been reported in some Indigenous communities.^{12 13} While accurate data on the harms of prescription medication among seniors is lacking, it is well known that the prevalence of pain is higher among older adults and that they account for a significant proportion of prescriptions.

The “high” they produce also leads to these medications being sought after for recreational purposes and, as they are legal products, they are often more easily accessible than street drugs. Surveys with youth have shown that as much as 70% of opioids have been obtained from legitimate prescriptions to family and friends (55% were shared at no cost).¹⁴ As well, because opioids have high abuse liability and addiction potential, people have resorted to illegal behaviour to obtain them, such as doctor-shopping, forging prescribers’ signatures, or buying from street dealers.

Of great concern, opioid dispensing levels are strongly correlated with increased mortality, morbidity and treatment admissions for substance use.^{15 16} Studies in Ontario and British Columbia have replicated similar findings in the US. Many patients were prescribed these medications and developed dependence.¹⁷

Psychoactive medications are important therapeutic tools and serve legitimate purposes, when prescribed in an appropriate manner with proper assessment, and as part of a comprehensive therapeutic strategy and monitoring. Medications, such as opioids, have been essential in areas such as palliative and cancer care and have contributed to the alleviation of suffering.

Since the 1990s, opioids have been recommended for longer-term treatment of chronic non-cancer pain, and have become widely used due in part to aggressive promotion and marketing for this indication.^{18 19} However, there is evidence for significant pain relief in the short term but a need for more evidence regarding maintenance of pain relief over longer periods of time, or for improved physical function.^{20 21 22}

Important contributing factors for the increase in prescriptions are also the lack of supports and incentives for the treatment of complex cases, including availability and funding for treatment options for pain and addictions. Alternate approaches to pain management require

more time with the patient. In addition, there are new highly potent opioid drugs available.²³
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Canada's physicians are deeply concerned about the harms of opioids and other psychoactive prescription medications. As prescribers, they have a fundamental role in helping to ensure safe and effective use of these drugs, and the deterrence of abuse.^{25 26 27} Physicians assess patients and consider whether a prescription is clinically indicated according to best practices, as well as consider whether the benefits outweigh the risks, while screening for risk factors for substance dependence and diversion. This area can be a source of tension with patients who might seek to obtain drugs through fraudulent means.²⁸ It is also an area which causes concern to many physicians, and this could be affecting access to adequate pain management where it is needed.²⁹

The challenge for physicians and public policymakers is how to mitigate the harms of psychoactive prescription drug use, while ensuring that patients have access to the appropriate treatment for their clinical conditions.

Comprehensive National Strategy

Canada's physicians believe that this challenge requires a complex and multifaceted solution; and to further such a solution, the CMA recommends that Canada have a comprehensive national strategy to address the harms associated with psychoactive drugs in Canada, whether illegal or prescription-based, complementing existing strategies to address the harms associated with the two legal drugs – alcohol and tobacco. This comprehensive approach is necessary, as isolated measures can have unintended consequences, such as under-medicating people that require a medical treatment or constraining people to seek illegal drugs as an option when medications are made tamper-resistant.

The federal government has created the National Advisory Council on Prescription Drug Misuse, co-chaired by the Canadian Centre on Substance Abuse, the Coalition on Prescription Drug Misuse (Alberta) and the Nova Scotia Department of Health and Wellness, in partnership with Health Canada's First Nations and Inuit Health Branch's Prescription Drug Abuse Coordinating Committee. In its 2013 report *First Do No Harm: Responding to Canada's Prescription Drug Crisis*³⁰, there are nearly 60 recommendations toward the development of a strategy to combat the harms associated with psychoactive prescription medications. However, there is much still to be done.

The CMA supports collaborative efforts by the federal and provincial/territorial governments, and by health professionals and other stakeholders, to develop and implement a comprehensive national strategy. Such a strategy should include the following:

1. Improvement of Drug Safety

Health Canada, as the agency that approves prescription drugs for use and monitors their

safety once on the market, has several levers by which it can control Canadians' access to drugs. One of these is the *Controlled Drugs and Substances Act (CDSA)* and its regulations, which govern access to illegal products and recently has included psychoactive prescription drugs.

Because of their health and safety risks, it is important that Health Canada ensures that the *CDSA* subjects psychoactive substances to high levels of regulatory scrutiny during both the approval process and post-approval surveillance. The *Act* should require manufacturers to:

- Meet stringent pre-approval requirements. For example, Health Canada could require intensive review of pre-approval clinical trial results and of product monographs by an expert impartial review committee (including addiction, pain and public health expertise); or require that the manufacturer fulfill special conditions, such as formal post-market studies, as a condition of the drugs' approval; or even require larger sample sizes or longer study periods to assess harms;
- Adhere to restrictions on the marketing of controlled medications to health professionals and the general public. The adequacy of regulations needs to be assessed in this regard.
- Develop and cover tamper-resistant formulations of psychoactive drugs of concern. Although not a standalone solution, tamper-resistant formulations can reduce the potential for manipulation to be able to use through snorting, chewing or intravenously.

2. Enhancement of Optimal Prescribing through Evidence-Based Guidance, Education and Support for Prescribers

CMA recommends that appropriate prescribing of psychoactive medications should be addressed through evidence-based guidance and education. A strategy to support optimal therapy might include:

- Support for models of care that allow a physician to spend time with complex patients.
- Ongoing development and dissemination of clinical guidance. The *Canadian Guideline for Use of Opioids to Treat Chronic Non-Cancer Pain* was published in the *CMAJ* in 2010. CMA has co-sponsored an online CME module based on this guideline. There is interest in similar guidelines for sedatives and stimulants.
- Evaluative research to support the critical review of guidelines periodically. It is essential to review data on chronic conditions for which risks might outweigh benefits.
- Relevant, unbiased and easily accessible information for prescribers, which can readily be incorporated into everyday practice. This should include clinical decision-support tools for use at the point of care, inclusive of dosing guidelines and guidance on when to seek consultation with experts. Physicians also require tools, including those that facilitate: monitoring of effectiveness and tolerance by tracking pain and physical function; screening for past and current substance use; screening for depression; tapering of problematic or ineffective doses; among others.

- Educational programs in optimal prescribing, pain management and in the management of addictions, as part of the curriculum in medical school, and residency training as well as in continuing education. Particular support is needed for those in primary care.
- Guidance for prescribers about how to deal with conflict in their practice. This would include guidance for patient-centred educational discussions on safe opiate prescribing and use and management of addictions.
- Access to expert advice if required through such means as:
 - Policies or standards of practice developed by provincial regulatory colleges of physicians, which can include limitations on prescription volume, treatment period and indications.
 - Communities of practice, knowledge hubs and clinical support networks that link practitioners with experts in the field, facilitating triage and supporting front line generalists. Experts can not only provide clinical information, but can provide mentorship and personal advice about best practices.
 - Feedback to practitioners about their prescribing practices, particularly if potentially concerning patterns are identified. This initiative should be facilitated by collaborative work between health care professionals and their respective provincial regulatory colleges.
 - Academic detailing programs, which use personalized, one-on-one techniques to deliver impartial prescribing information to practitioners.

3. Enhancement of Optimal Prescribing through Physician Regulation and Prescription Monitoring Programs

Medicine is a regulated profession, and the provincial colleges of physicians have ultimate authority and responsibility for the oversight of physician practice. The colleges have taken a leading role in educating their members about appropriate prescribing, in monitoring prescribing practices to ensure their appropriateness and taking disciplinary action when required, and through collaborating with law enforcement agencies to detect and halt criminal diversion.

The CMA recommends that federal and provincial regulations regarding controlled substances recognize the established authority of physician regulatory colleges for the oversight of the medical profession.

While prescription monitoring programs (PMPs) exist in most provinces, they vary considerably in terms of quality, the nature of the information they require, whether health care practitioners have real-time access, and the purpose for which the data are collected. Standardization of monitoring systems across Canada according to best practices can contribute to addressing the harms associated with psychoactive prescription medication by:

- Allowing health care practitioners to identify previous or concomitant prescriptions of controlled medications with more than one practitioner at the time the prescription is requested or filled;
- Deterring interprovincial or jurisdictional fraud, by allowing health care practitioners to identify other prescriptions at the time the prescription is requested or filled; and
- Improving professional regulatory bodies' capacity for oversight and intervention by establishing a mechanism for real-time monitoring.

The CMA recommends that all levels of government work with one another and with health professional regulatory agencies to develop a pan-Canadian system of real-time prescription monitoring. As a first step, the CMA recommends the establishment of consistent national standards for prescription monitoring.

PMPs should be compatible with existing electronic medical and pharmacy record systems and with provincial pharmaceutical databases. Participation in prescription monitoring programs should not impose an onerous administrative burden on health care providers. PMPs should not deter physicians from using controlled medications when necessary.

CMA also recommends that Health Canada ensure that its legislative framework be used to facilitate and support the advancement of e-health, specifically e-prescribing. Electronic health records can help individual physicians or pharmacists identify potential diversion and double prescriptions, at the point where a prescription is written or filled. The electronic health record also facilitates the sharing of information among health professionals, and could minimize the potential administrative burden.

PMPs should conform to privacy laws, protecting patient confidentiality while enabling the sharing of necessary information. The CMA strongly recommends that Health Canada undertake a privacy impact assessment of the regulatory framework for controlled prescription drugs, and share the results with stakeholders.

4. Increase in Access to Treatment for Pain

Chronic pain affects many aspects of a person's life including their ability to work, their emotional, mental and physical health, and their quality of life. Pain costs Canada an estimated \$60 Billion dollars per year; more than the cost of heart disease, cancer and diabetes.³¹ CMA has endorsed a national strategy for pain, developed and proposed by the Canadian Pain Coalition and Canadian Pain Society,³² which addresses four target areas: awareness and education; access; research; and ongoing monitoring.

Experts believe that improved access to specialized pain treatment could reduce inappropriate use of pain medications. Current best practices in pain management include:

- Care by an interprofessional team that could include physiotherapists, occupational therapists, psychologists and other health professionals;

- Recommendation of non-pharmaceutical interventions such as therapy for trauma and social pain, social supports and coping strategies;
- Appropriate pharmaceutical prescription options, covered by provincial formularies; and
- A focus on patient participation and empowerment.

However, specialized pain treatment programs are in short supply. Wait times are greater than one year at more than one third of publicly funded inter-professional treatment programs.³³ In many parts of Canada, particularly rural and remote areas, such programs are not available. In addition, while physician visits are covered by the public health care system, services provided by other health professionals are more likely to be either covered by private health benefits or paid out of pocket, and are therefore beyond the means of many Canadians. These factors may result in heavier reliance on prescription medication as treatment for chronic pain.

The CMA recommends that all partners work to improve and promote access to specialized treatment programs for pain management, and that investments be made in research about options for treatment.

5. Increase in Access to Treatment for Addiction

Access to addiction treatment is very limited and, when available, is primarily comprised of detox or the substitution treatments with methadone or Suboxone® (buprenorphine and naloxone). As addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry by definition, which manifests along biological, psychological, social and spiritual dimensions, treatment must address all those areas rather than just one or another.³⁴

The CMA supports the enhancement of access to options for addiction treatment that address different needs. Treatment programs must be coordinated and patient-centred, and address physical, psychological, social and spiritual circumstances. For example, it is important that addiction programs be culturally relevant for Indigenous communities.

Treatment programs must also be integrated within the health care system and be adequately funded to meet evidence based, best-practice guidelines.

CMA also supports the development and dissemination of practice tools and guidelines to help physicians assess the addiction potential of a patient receiving psychoactive medications, and to assist in managing patients who have addiction and related problems and complications.

6. Increase in Information through Epidemiological Surveillance

One of the challenges in dealing with prescription drug abuse, which can reflect hazardous (episodic) use, harmful (regular) use or addiction, is the incompleteness of our knowledge of

the extent of the problem. Countries, such as the US and France, are able to monitor psychoactive drug use, while in Canada we still rely on unsystematically collected or locally limited data. The creation of a national surveillance system that supports the collection of systematic, standardized information would:

- Permit the thorough assessment of the problem, with the development and monitoring of indicators;
- Support the early detection of diversion or inappropriate prescribing behaviour;
- Support the establishment of best practices to address crucial issues;
- Identify research priorities; and
- Evaluate the impact of the implementation of strategies.

Sources of information should include PMPs, coroner's investigations, emergency room admissions, and poison control data, among others.

7. Prevention of Deaths due to Overdose

Overdose deaths have increased dramatically over the past ten years. The risk of harm from overdose may be compounded if recreational users are afraid to call for emergency assistance for fear of facing criminal charges. Opioid death and complications overdoses can be prevented with appropriate medication and prompt emergency response. The CMA recommends the:

- Creation and scaling up of community-based programs that offer access to naloxone and other opioid overdose prevention tools and services. Training should be made available to health workers, first responders, as well as opioid users, families and peers about the prevention of overdose fatalities.³⁵
- Improvement of access to naloxone to reverse opioid overdoses. This should include the prescription of naloxone to high risk individuals and third parties who can assist a victim experiencing an opiate-related overdose.
- Enactment of *Good Samaritan* laws by all levels of government in order to protect callers from criminal charges if they call emergency services to report an overdose.³⁶

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8. Provision of Information for Patients and the Public

Awareness programs that provide accurate information to patients and the general public are important, and could include:

- Information on the benefits and harms of psychoactive prescription medication use, and signs of dependence and overdose. This should include the risk of dependence and addiction associated with the use of opiates for the treatment of acute and chronic pain.

- Messages aimed at the prevention of problematic drug use among young people and other populations at risk.
- Information regarding safe medication storage and disposal, and reducing access to medications from family and friends. CMA supports national prescription drug “drop off” days, and recommends that patients be educated about the importance of routinely returning unused prescription drugs to the pharmacy.

Recommendations

The CMA recommends that Canada have a comprehensive national strategy to address the harms associated with psychoactive drugs in Canada, whether illegal or prescription-based. This strategy should include:

- That Health Canada require that manufacturers meet stringent pre-approval requirements, adhere to restrictions on the marketing of controlled medications to health professionals and the general public, and develop formulations of psychoactive drugs of concern that are tamper-resistant.
- Support for optimal prescribing through evidence-based guidance, education and supports, such as clinical guidance, clinical decision-support tools, educational programs, expert advice, and supportive models of care.
- The enhancement of optimal prescribing through physician regulation and the development of a pan-Canadian system of real-time prescription monitoring programs, compatible with electronic medical and pharmacy record systems, based on national standards.
- Increased access to specialized pain management and treatment, according to best practices, with investments in research.
- The enhancement of access to options for addiction treatment that address different needs, and the support for the development and dissemination of practice tools and guidelines.
- The creation of a national surveillance system that supports the collection of systematic, standardized information to better inform and track policy changes.
- The creation and scaling up of community-based programs that
- Offer access to opioid overdose prevention tools and services, including the improvement of access to medication to reverse opioid overdoses (naloxone) and the enactment of *Good Samaritan* laws by all levels of government.
- The provision of accurate information to patients and the general public, including safe medication storage and disposal.

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