

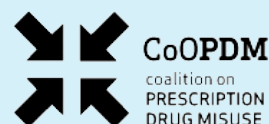
First Do No Harm: Responding to Canada's Prescription Drug Crisis

March 2013

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Executive Summary

Certain prescription drugs, like opioids, sedative-hypnotics and stimulants, are associated with serious harms like addiction, overdose and death. These drugs can have a devastating impact on individuals and their families, as well as place a significant burden on our health, social services and public safety systems. In countries like Canada, where these prescription drugs are readily available, the associated harms have become a leading public health and safety concern. Canada is the world's second largest per capita consumer of one type of these drugs, opioids (International Narcotics Control Board, 2013). Some First Nations in Canada have declared a community crisis owing to the prevalence of the harms associated with prescription drugs (Dell et al., 2012). While Canadian cost data is lacking, recent research from the United States estimates the annual cost of the non-medical use of prescription opioids to be more than \$50 billion, with lost productivity and crime accounting for 94% of this amount (Hansen, Oster, Edelsberg, Woody, & Sullivan, 2011).

The Response

The National Advisory Council on Prescription Drug Misuse was formed in response to the growing problem in Canada. Led by the Canadian Centre on Substance Abuse (CCSA), 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 (PDACC), the Council developed *First Do No Harm: Responding to Canada's Prescription Drug Crisis* (the *Strategy*). The *Strategy* represents a broad collective effort by contributors who are active participants in this work and stewards of its realization.

Council members were invited to participate because of their expertise, involvement and commitment to the issue, and their ability to take on responsibility in addressing it or in implementing solutions. Members represent governments, healthcare professionals (physicians, pharmacists, coroners, dentists and nurses), patients and families, First Nations, enforcement officials, regulators, industry leaders and researchers. This membership reflects a commitment to coordinated action across multiple sectors and jurisdictions.

The Council developed a strategy that addresses the harms associated with prescription drugs, while giving important consideration to their therapeutic uses. Council members were actively involved in developing the recommendations, sought input from their networks of organizations and across sectors, and focused on communication and coordination within and across jurisdictions, disciplines and communities.

First Do No Harm: Responding to Canada's Prescription Drug Crisis addresses prescription drugs that are legal and have therapeutic uses, but also have a high potential for harm. This Strategy defines the scope of the prescription drug crisis Canada faces and provides a roadmap for reducing the harms associated with these drugs. It presents 58 achievable short- and longer-term recommendations that Council members believe will address these harms and have a collective impact. The members share in the issue and will now share in addressing it through implementing the recommendations.



The Recommendations

The *Strategy* was developed around five streams of action: Prevention, Education, Treatment, Monitoring and Surveillance, and Enforcement. In addition to the five streams, three other areas cut across all streams and are important to this work: legislation and regulations, research, and evaluation and performance measurement. The strategy demonstrates the linkages among the recommendations and across sectors. The recommendations aim to:

- Prevent prescription drug-related harms to individuals, families and communities;
- Educate and empower the public and promote healthy and safe communities;
- Promote appropriate prescribing and dispensing practices among healthcare practitioners;
- Increase timely, equitable access to a range of effective treatment options throughout the continuum of pain and addictions treatment;
- Identify effective, evidence-informed practices and policies and build upon them;
- Develop a standardized pan-Canadian surveillance system to improve our understanding of the nature and extent of the harms associated with prescription drugs in Canada;
- Establish prescription monitoring programs in each province and territory to share information about prescribing and dispensing practices across disciplines and jurisdictions on a timely basis and take timely action;
- Ensure that law enforcement has adequate tools, training and resources to address the diversion of prescription drugs;
- Engage industry, governments, regulatory bodies and others with a stake in this issue to join forces, commit to specific recommendations, leverage existing resources and strengthen system capacity to address this issue;
- Develop or clarify legislation and regulations to reduce barriers to effective treatment and prevent harms;
- Conduct research to address knowledge gaps and promote effective strategies to deal with this important issue;
- Engage industry in concrete, responsible actions that promote patient safety, improved patient outcomes and risk mitigation; and
- Provide a contextual lens to First Nations, geographically remote, isolated and rural populations.

The *Strategy* pays specific attention to First Nations and geographically remote, rural and isolated communities to highlight their unique needs. Unless otherwise noted, the *Strategy* applies within this context and care will be taken to ensure the recommendations are accurately interpreted for application within the culture of First Nations, and for remote, rural and isolated communities. The diversity of First Nations communities in geography, culture, language and governance must be reflected in whatever action is taken on the recommendations of the *Strategy*.



Next Steps

The launch of the *Strategy* marks the end of the first phase of a long process. The next phase will be implementing the recommendations and evaluating the *Strategy* and its impact as we move ahead. An annual report on progress towards achieving expected outcomes will ensure that stakeholders are informed on developments.

The Council will continue to lead the work of the *Strategy* and oversee implementation of its recommendations. The initial emphasis will be on those recommendations that can be implemented in the next 24 months. This work will inform implementation of the remaining, longer-term recommendations.

A Call to Action

Key stakeholders from across Canada have identified the prescription drug crisis as a priority for action and have committed to addressing it. Many have invested their knowledge, expertise, experience, analysis, creativity and energy to developing the *Strategy*.

The *Strategy* will continue to evolve as more information and research becomes available and as activities are implemented. However, the vision is set and the roadmap for action outlined. Collectively, we are working towards a Canada that allows for the benefits of prescription drugs, such as opioids, sedative-hypnotics and stimulants, while minimizing the harms associated with them.

This is an ambitious challenge. It requires a sustained and serious commitment to coordinated actions that support the common, long-term vision of addressing this complex public health and safety issue. It will succeed through a respectful sharing of knowledge, expertise, enquiry, promising practices, analysis and lived experience, and the collective will and momentum of all who have a role in responding to the prescription drug crisis in Canada.



Living with the Harms of Prescription Drugs

The harms associated with prescription drugs are

- a community issue
- a family issue
- a healthcare issue
- a public safety issue
- an industry issue

We all have a responsibility in addressing them.



On June 10, 2004, my only child died suddenly and unexpectedly. Michael went to bed and never woke up. The coroner who investigated Michael's death determined that he died as a result of "hydromorphone intoxication." His death was ruled an accident, and no street drugs or alcohol were in his system. His death was preventable.

My son and I shared a beautiful, close, loving relationship. He lived at home and was the focus of my life. Michael was a thoughtful, generous, warm and caring soul with a smile that would light up a room. He loved children and children loved him; he was extremely close to his family, had many friends and had a successful business partnership.

However, things changed during Michael's last year.

In the summer of 2003, Michael seemed easily agitated and upset over the slightest things. Even though he tried to hide this from me, I sensed something was wrong, but made the mistake of thinking this was due to the ups and downs of a new relationship. When I talked to him about it he said "Mum, don't worry I'm seeing a doctor." It wasn't until after Michael's death that I learned that his doctor prescribed him more than 13,000 pills in a period of 14½ months. The day before his death Michael was prescribed a drug he had never taken before — Dilaudid®. The active ingredient in Dilaudid is hydromorphone, one of the most powerful opioids ever synthesized.

The next morning Michael never woke up.

Unfortunately, this kind of indiscriminate prescribing is all too common. It breaks my heart when I think back and imagine the anguish, both physical and mental, that he must have experienced from the excessive amounts of highly addictive medication.

After Michael's death, I began searching for answers. I realize now that two visits to the emergency department in Toronto may have started Michael on a slippery slope. Twice in 2002, my son was diagnosed with kidney stones. Both times he was treated and discharged with a prescription for Percocet™, which is oxycodone. Neither the doctor nor the pharmacist warned us that Percocet could be addictive. The use of opioids "as prescribed" is not sufficient to prevent patient harm. My son died within two years of his first Percocet prescription.

The system failed Michael and it continues to fail others. It is my hope that *First Do No Harm* will lead to a system that doesn't fail others as it did Michael. We must bring about the necessary changes to end the epidemic of death and addiction caused by prescription drugs by ensuring that they are regulated, marketed, prescribed and used in an evidence-based manner.

This vignette also represents the many untold stories and is written for all the loved ones lost to a system that failed them. We can and must do better.

— Ada, mother



Webequie is an isolated Ojibway community of about 800 people in Northern Ontario. It is 540 kilometres northwest of Thunder Bay, on an island in a lake. It is only accessible by air or a seasonal winter road. The closest year-round road access is at Pickle Lake, 250 kilometres to the southwest.

The people of Webequie are standing together with the support of the community and regional leadership to recover from the devastating impacts of widespread abuse of Oxycontin® (oxy). Many lives were deteriorating because of the misuse of these prescription pills. Finding a way forward wasn't easy. The challenges were a profound lack of funding and very little knowledge of what could be done to help. So Webequie, along with other Matawa First Nations and the tribal council, set about using shoestring budgets to provide direct community support.

Oxy pills were selling for \$600 to 700 for an 80 milligram pill. These drugs led to robberies, break and enters, and violence. There were some individuals who were so desperate for money that they sold their appliances, furniture and TVs to feed their habit. Many children went hungry. Those on drugs did anything for the money. Family violence was common.

As a community we suffered greatly, but were committed to finding a way forward. What we recognize in our Ojibway worldview and way of life is that we should be asking ourselves what was the way our ancestors saw; only then can we clearly see our way forward. First Nations substance abuse is intertwined with the historical erosion of culture, intergenerational impacts of residential schooling and other forms of emotional abuse, which caused deep trauma.

We realized we needed a customized approach to the prescription drug problem. We found about 70% of our population was involved with misuse of prescription drugs. As an isolated community, the reality was that 100% of residents were impacted in some way by prescription drug harms.

The drugs resulted in deterioration of the kinship and values that define us as a people. The rise in community safety issues was apparent. Kids were neglected and acted out at school. Bullying and truancy became more evident. These drugs resulted in dysfunctional families, and mental and emotional abuse. People would inject drugs and drop the needles where children could find them.

From 2011 to 2012, a Suboxone® trial was initiated by the Webequie First Nation. In total, 101 people participated in the program, which was initially paid for by the community. The intent was to get people off Oxycontin. Participants did an initial induction for four to five days, and then were closely supervised for a month. They then "maintained" after to prevent a relapse. At that time the doses were tapered off.

We had counselling that included traditional and western approaches. People were able to access traditional knowledge and medicine. Most were able to stay off oxy for a year after. We have one doctor and community nurses living in Webequie year-round who are trusted. Addiction doctors fly in as needed. People had the choice whether to combine traditional Anishinabe cleansing with medical and non-medical detoxification. We are now on a journey towards a place of hope and healing. The drug treatment program brought together Elders, and western and traditional medicine. Those affected are healing. Parents are now playing with kids. Our community is much healthier than a year ago and we have renewed hope. As indigenous people, our culture and spirituality offers resilience. Our journey is not complete, but we are in a much better place and will continue to move forward.

— Levi, a First Nation prescription drug awareness coordinator



I was a regular kid with a normal life in a good family. My parents were very supportive. No one else in my family did drugs: I was the black sheep. I started experimenting when I was just 15 and started smoking pot with my best friend who was 14. My friend's dad used to take us to places we'd never get in and buy us beer. I thought he was super cool.

One day his dad came home and dumped three piles of cocaine out of a baggie and took his line and told us to take a line. I was scared, obviously. I didn't want him to think I was scared so I did it. Cocaine took my anxiety issues away. I tried opioids and they were even better than cocaine. I tried oxycodone and Dilaudid®. I kept hanging out with my friend and his dad. We started looking for drugs everywhere and using friends to get them. Drugs made me feel less shy and nervous around girls. In high school, drugs are very prevalent.

Drugs became the focus of my life. I found a cheap supply pretty easily at first. My friend stole Dilaudid eight milligram pills from his dad, who had a prescription, and he'd sell them to me for a dollar. He only stole 20 at a time so his dad wouldn't notice. Kids sold prescription drugs at school and it seemed safe as the pills are prescribed by a doctor. The problem is they aren't safe. They are all addictive; I found opioids to be the worst.

Eventually my cheap sources ran out and I started buying them from the street. I stole about \$700 from my grandmother by "helping her" with groceries. I was 18 when I was charged with seven counts of theft for stealing cartons of cigarettes. I stole stuff from my cousin's house. I was in detox more than 10 times. I just wasn't ready to quit. The drugs had too much of a hold on me.

I stole and sold necklaces and a camcorder for drug money. I stole my uncle's handgun and was caught by the police while trying to sell it. I went to jail that night and then to court. I still had drugs hidden in my winter coat. I asked for a magazine and a pencil and used that to crush them up. I snorted them off the magazine in the courthouse holding cell.

The only thing I wanted was that drug. Nothing else mattered to me. My parents were extremely angry and upset. I lied about how much I owed the dealers so my dad gave me \$500. I paid what I owed and snuck back into the house with drugs. While my mom was still in bed, I crushed up and snorted pills.

At 20 years old things changed drastically. After a night of drinking while on a mix of Dilaudid and other drugs, I robbed a late night motel. This time when I went to court I broke down and cried for everything I'd put my family and other people through. I was sentenced to four years in prison and was terrified. The withdrawal was horrific and lasted over a week.

When I started feeling better, I was allowed outside. I was surrounded by concrete, but could look up at the sky. I remember breathing fresh air and vowing I'd never use drugs again. I believe everything happens for a reason. I worked out and graduated high school from prison. I got on a methadone program at prison and have stayed clean for four years. Today, I work with lots of young people so they don't live through what I did. I'm involved with addiction services and tell my story at doctor's conferences. I also have a blog to help kids and families: www.pastaddiction.blogspot.com. My life is so much better now without drugs. I wish I'd quit sooner.

— Neil, young man recovered from prescription drug misuse



I signed up with the Toronto Police as a cadet when I was 17 years old. I was sworn in on my 21st birthday at the rank of police constable. I was young, fit, loved hockey. I loved my life and had a promising career ahead. Some injuries caused a shift in my back vertebrae, but I continued playing hockey. I had a small bit of pain when I skated, but no pain on the job.

In 1989, after seven years in busy Toronto divisions, I moved to a smaller town to advance my career as a police detective. A few years later I left the station for home and my car was T-boned. The impact pinned my knees under the dash. I was x-rayed from head to toe at the hospital. Doctors said there was “nothing significant.” I was told to take two weeks off and given a prescription for Percocet® for the pain.

I had my eye on an upcoming promotion exam and after two weeks I went back to my full duties. The pain in my lower back worsened and a rheumatologist determined that there had been a spinal shift. The doctor gave me a prescription for 100 Percocet® while waiting for surgery to fuse my vertebrae. The surgery that should have taken away the pain was a complete failure. I was forced to withdraw abruptly from Percocet seven days after surgery. The withdrawal was horrific and pain was still there. Doctors scheduled a second back surgery six months later. Meanwhile, I went back to work.

I never looked for Percocet or took pills improperly until doctors flatly refused to give me any more. As a cop, I knew certain people around town who had Percocet. I found medication where I could from friends and even from criminal acquaintances. I was in chronic pain. My tolerance kept building, so I had to keep increasing the number of pills I took. I went from 2 to 4 to 6 pills a day. Unfortunately, the second surgery was also a failure. I was prescribed Percocet again. This time I tapered down with the help of the doctor despite the pain. Eventually, I went to Tylenol 3® and diazepam. I was off all narcotic pain meds for four to six months.

Then, my doctor prescribed Oxycontin®. I was told it was a better drug and the “addictive component was less.” I was at square one and taking more pills than ever. My doctor’s solution was for me to claim to be an addict just to get access to the methadone clinic to taper off Percocet.

People in chronic pain shouldn’t be victimized. I was a respected officer. Now, I had to hide from my own guys just to sneak into the meth clinic and sit for hours waiting for my “carry.” I would cover my head and worry I’d be sitting with someone I’d arrested as a plain clothes detective. I wasn’t asked to act like an addict, but told I was one since methadone in the clinic was not for pain management, but for drug treatment. I was horrified. Methadone was very effective for pain management.

My supervisors found out and I was justifiably disciplined for some of my actions, but not dismissed. I was labeled a “druggie” by administration and my colleagues. It was the loneliest time of my life. Unable to do the job without pain medication, I felt I had no choice and walked away from my career. The next 10 years I was in and out of boring jobs. The pain clinic saved my life. I now combine prescription and non-prescription treatments to manage pain. I use Percocet and methadone in very low doses. I’ll be trying an experimental electrical implant device this spring. Because my pain is well managed, I’ve been able to build a successful private investigation business and teach part-time as a college professor. I’m also involved in overseas humanitarian missions in Haiti. I have my life back.

— Peter, former police officer, pain patient



Introduction

The harms associated with controlled psychoactive prescription drugs such as opioids analgesics, sedative-hypnotics and stimulants (hereafter referred to as prescription drugs) are emerging as a significant public health and safety concern. This is a concern especially in countries where there is ready access to these types of drugs. Canada has become the world's second largest per capita consumer of prescription opioids. Some First Nations in Canada have declared a community crisis owing to the prevalence of the harms associated with prescription drugs (Dell et al., 2012). The current situation needs prompt and coordinated intervention on many fronts and across political jurisdictions, professions and sectors. Silos of excellence are simply not an option in dealing with this public health and safety crisis.

The management of acute and chronic pain and the use of prescription opioids are often linked, as are the treatment of anxiety and sleep disorders and the use of benzodiazepines. However, the use of these medications is associated with risk of harm such as addiction and death from overdose. A key challenge is when and how to use these medications effectively and safely, first doing no harm. To meet this challenge, consideration must be given to evidence-informed approaches to prevention and treatment of broader issues such as addiction, mental health disorders, co-morbidities, concurrent disorders, pain, and chronic disease. Attention must also be given to the social determinants of health across the country and among First Nations people in Canada. There is a growing population of First Nations people who link their psychological pain and trauma, and associated prescription drug use to their experience in residential schools and child welfare (Health Canada, 2011).

First Do No Harm: Responding to Canada's Prescription Drug Crisis (the Strategy) is a 10-year strategy that identifies immediate, short-term measures to deal with the existing problem and sets a foundation for longer-term collaborative action.

Focus of the Strategy

The *Strategy* addresses prescription drugs that have legal status and therapeutic uses, together with a high potential for harm. These medications include:

- Opioid pain relievers such as those containing oxycodone, hydromorphone, fentanyl, morphine and codeine;
- Stimulants such as those containing dextroamphetamine, methylphenidate, and amphetamines;
- Sedative-hypnotics such as those containing diazepam, and alprazolam; and
- Those medications that are used to treat addiction, but that can also result in harm, such as methadone and buprenorphine.

This *Strategy* focuses on the harms associated with these prescription drugs, and recognizes that those harms need to be considered along with the benefits these drugs can deliver. These harms include addiction, illness requiring hospitalization, overdose and death that can be associated with misuse, over-consumption, poly-drug use, and non-medical use, as well as with therapeutic use, when medications are taken as prescribed. The associated impacts and costs—physical, emotional, psychological and public safety—are borne by individuals, families, communities and society at large.



Environmental and social conditions that increase risk for women, youth, seniors, First Nations and Inuit, and newborns require particular attention. Effective treatment and prevention approaches need to specifically attend to the diversity of different populations, including their geographical and cultural contexts, and the many other factors that contribute to risk and the impacts of prescription drugs across the system.

To reduce these harms, the *Strategy* also addresses:

- Diversion away from the authorized supply chain from manufacturer to patient;
- Inappropriate prescribing or dispensing behaviour; and
- Addiction, mental health, co-morbidities, concurrent disorders and pain, all of which are affected by these prescription drugs.

The *Strategy* takes these factors into account and puts forward achievable recommendations for action with a particular focus on short-term strategies that can be accomplished within the first two years of implementation.



Part A: Why a Pan-Canadian Strategy?

Canada is the second-largest per capita consumer of prescription opioids (International Narcotics Control Board, 2013). The harms associated with prescription drugs, whether acquired legally or illegally, include addiction, overdose, and death. These harms can place a burden on healthcare, social services and public safety systems. The resulting impact on individuals, families and communities can be devastating.

There has also been a surge of criminal activity for diverting prescription drugs from legal, regulated supply routes to illegal markets (Royal Canadian Mounted Police, 2010). This situation increases the pressures on Canada's enforcement measures and potentially compromises their effectiveness.

Addressing the non-medical use of prescription drugs and related harms was identified as a priority for action during Canada-wide consultations undertaken in 2003-2004 by Health Canada and the CCSA to inform the *National Framework for Action to Reduce the Harms Associated with Alcohol and other Drugs and Substances in Canada* (CCSA, 2005). First Nations also identified this priority during their national initiative to develop *Honouring Our Strengths: A Renewed Framework to Address Substance Use Issues Among First Nations in Canada* (Health Canada, 2011), led by the Assembly of First Nations (AFN), the National Native Addictions Partnership Foundation and Health Canada. First Nations leadership has also continued to push the issue of prescription drugs through resolutions passed at both AFN Annual General Assemblies and Special Chiefs Assemblies and continue to advocate for additional resources to better meet the needs of First Nations (AFN, 2011, 2012).

During the 2006 National Thematic Workshop on Preventing the Problematic Use of Psychotropic Pharmaceuticals (Health Canada, 2007), participants identified six priority areas that essentially correspond to the streams addressed in this *Strategy*. The AFN recognized at its 2010 and 2011 AFN Special Chiefs Assembly that opiate addictions and related harms are emerging substance misuse challenges (AFN, 2010, 2011) and they will continue to be a priority for First Nations leadership. Participants at the Public Safety Workshop on Emerging Issues in Enforcement in 2010 (Public Safety Canada, 2011a) and the Illicit Use of Pharmaceuticals Workshop in 2011 (Public Safety Canada, 2011b) discussed emerging enforcement issues and subsequently met with health sector representatives. In 2012, the Canadian Association of Chiefs of Police adopted a resolution endorsing the need for a strategy to address the harms associated with prescription drugs.

The recent formation of the Federal/Provincial/Territorial (FPT) Working Group on Prescription Drug Abuse (PDA) in early 2013 is intended to enhance collaboration and coordination of inter-governmental leadership to address prescription drug issues. It will review recent and relevant PDA reports and strategies; identify areas of potential FPT collaboration and report to FPT Deputy Ministers in May 2013. In addition, the other coordinated inter-governmental response related to the responsibility over these issues for First Nations and Inuit communities is the Prescription Drug Abuse Coordinating Committee (PDACC), which brings together Health Canada's First Nations and Inuit Health Branch (FNIHB), Health Products and Food Branch (HPFB) and Healthy Environments and Consumer Safety Branch (HECSB), the Assembly of First Nations (AFN), the National Native Addictions Partnership Foundation (NNAPF) and CCSA to address the harms associated with prescriptions drugs among First Nations in Canada.



To address this need and the many calls to action that have been issued over the past decade, CCSA hosted a National Dialogue on Prescription Drug Misuse in February 2012 in Ottawa (CCSA, 2012). More than 70 participants attended the Dialogue and decided upon two broad courses of action:

- CCSA would continue to lead the development of a pan-Canadian strategy that would be comprehensive, actionable and evidence-informed; and
- A National Advisory Council on Prescription Drug Misuse (NAC) would be formalized to oversee its development (Phase 1), implementation (Phase 2) and evaluation (Phase 3).



Part B: National Advisory Council on Prescription Drug Misuse

Mandate of the National Advisory Council on Prescription Drug Misuse

The National Advisory Council on Prescription Drug Misuse (NAC), convened in June 2012 by CCSA, includes experts from federal and provincial governments; pain and addiction specialists, and other health professionals, including pharmacists, nurses, public health practitioners, dentists and physicians; researchers; First Nations; regulators; enforcement officials; industry leaders; and patient and community advocacy agencies. The multi-sectoral membership reflects the commitment to coordinated action among governments, the healthcare professions, the criminal justice system, provincial licensing authorities, industry and other stakeholders. (See the Acknowledgements for the members of the NAC.)

The NAC's primary objective is to develop an evidence-informed pan-Canadian *Strategy* to reduce the harms associated with prescription drugs. The aim of the strategy is to provide a roadmap for multiple stakeholders to collectively address this complex public health and safety issue.

While the focus of the *Strategy* was finalized in 2013 and the tentative strategy title revised from a focus on misuse to one addressing harms, the name of the NAC was not changed at that time. Moving into the implementation phase, however, the name will be revised to better reflect the *Strategy* focus and the new phase.

Phases for the Work of the NAC

As decided in June 2012 at the inaugural meeting of the NAC in Halifax, the work of the NAC will proceed through three phases.

Phase 1: Develop *First Do No Harm: Responding to Canada's Prescription Drug Crisis* (the *Strategy*)

The *Strategy* takes an evidence-informed approach to addressing addiction, mental health, co-morbidities, concurrent disorders, pain management and the therapeutic uses of these prescription drugs. The *Strategy* includes 58 recommendations for action, along with timelines and stakeholder roles and responsibilities.

Phase 2: Implement the recommendations

The recommendations strive to reduce the harms associated with prescription drugs and ensure access to appropriate medications. Recommendations are tailored to stakeholders and are adaptable to local and regional situations. In Phase 2, further partnership development will take place along with the promotion of the *Strategy* and its uptake.

Phase 3: Complete an impact evaluation of the *Strategy*'s implementation

This phase includes activities to evaluate the impact of initiatives implemented in Phase 2 and is woven throughout the implementation phase.



Guiding Principles for Strategy Development

The work of the NAC is supported by the *National Framework for Action to Reduce the Harms Associated with Alcohol and Other Drugs and Substances in Canada* (CCSA, 2005). The NAC adopted the following principles for the *Strategy*.

1. Addressing the harms associated with prescription drugs is a complex public health and safety issue.
2. Successfully addressing this complex issue requires:
 - A coordinated, comprehensive approach;
 - Multi-sectoral, interdisciplinary collaboration;
 - Meaningful contribution from key stakeholders;
 - Adequate representation from those most affected and accountable;
 - Integrated knowledge exchange;
 - Evidence-informed, relevant and accessible interventions;
 - Continuous evaluation and process improvement;
 - Inclusion of First Nations culture, cultural practices, and interventions and Indigenous Knowledge;
 - A broad approach that recognizes the impact of the determinants of health;
 - Consideration of Canada's diversity, including geographic differences; urban, rural and remote communities; the multicultural nature of our society; and other issues related to health equity; and
 - Responsible industry involvement that puts a premium on patient and public safety.
3. Investments in strong partnerships provide the platform for success.
4. Inclusion, transparency, shared leadership and shared accountability are fundamental elements to working together.

Process for Developing the Strategy

The NAC was co-chaired by the Director, Addiction Services, Nova Scotia Department of Health and Wellness; the Senior Medical Advisor, College of Physicians and Surgeons of Alberta; and the Chief Executive Officer of CCSA. At the February 2012 Dialogue, participants identified five complementary, interrelated streams of action that would make up the *Strategy*:

- Prevention
- Education
- Treatment
- Monitoring and Surveillance
- Enforcement



In June 2012 in Halifax, Expert Advisory Committees (EACs) were formed for each stream. NAC members self-selected their membership in the EACs, which are led by a chair or co-chairs. (the chairs and co-chairs are identified in the Acknowledgements.) Each EAC identified its over-arching goal, developed recommendations supported by a rationale, proposed leaders and partners for each recommendation, and set out key milestones.

In September 2012, the NAC re-convened in Calgary to review, refine and validate the draft recommendations developed with the EACs over the summer months, seek support for the final report and work towards developing and implementing the *Strategy*.

In December 2012, a revised draft report was sent to members of the NAC to share within their organizations and networks for further input and organizational support. Themes emerging from the feedback were identified for further discussion at an NAC meeting in February 2013 in Edmonton, where the NAC revised and reached agreement on the recommendations. The NAC also reached agreement on the title, *First Do No Harm: Responding to Canada's Prescription Drug Crisis*. Further, members agreed to a proposed structure for moving forward to the Implementation Phase (Appendix D). The NAC agreed that CCSA draft Terms of Reference for Phase 2 for review.

CCSA was tasked with finalizing the *Strategy* as agreed to by the NAC, incorporating the revised recommendations, ensuring that the context for each stream reflected the changes in the recommendations; and incorporating suggestions for revision into the rest of the document. Additional revisions to the language of the document were made to better reflect the new title. The final document was sent to NAC members for review to identify any factual errors and areas of discussion and agreement that were not captured in the document. A teleconference was held in February 2013 to discuss the final *Strategy* and to obtain NAC advice on its release.

The NAC has benefitted from advice and input from the Prescription Drug Abuse Coordinating Committee (PDACC), which brings together Health Canada's First Nations and Inuit Health Branch (FNIHB), Health Products and Food Branch (HPFB) and Healthy Environments and Consumer Safety Branch (HECSB), the Assembly of First Nations (AFN), the National Native Addictions Partnership Foundation (NNAPF) and CCSA to address the harms associated with prescriptions drugs among First Nations in Canada.

See Figure 1 for the Input Process for Developing the *Strategy*.

Strategy Linkages with First Nations Issues and Activities

In Canada, there are 50 distinct First Nations languages across 630 First Nations communities, ranging from larger reserves located near major urban centres to small and remote reserves. These communities exist within various layers of governance, from the community Chief and Council, to tribal, regional and national councils. Some First Nations communities are self-governing and exercise control over their health programs; are economically stable; generally enjoy good health and well-being and continue to pass on their cultural knowledge, language and traditions. However, many communities face major challenges, such as high unemployment, poor housing, low levels of education and inadequate health care services. First Nations communities participating in a national survey between 2008 and 2010 reported that alcohol and drug use and abuse were considered to be the number one challenge for community well-ness faced by on-reserve communities (82.6% of respondents), followed by housing (70.7%) and employment (65.9%) (Health Canada, 2011).



Significant barriers to appropriate health care to address the harms associated with prescription drugs for First Nations located in remote areas, such as the Cree, Ojibway, Dene and Innu peoples, include:

- Poor or no access to health care and services (Chiefs of Ontario, 2010; Health Canada, 2011; FNIHB, 2012; Reading 2007);
- Lack of clear communication by rotating staff of non-indigenous physicians and nurses from urban centres who deliver care that can conflict with those given by another set of care providers; and
- Frustrating efforts to provide clear information to community members about the best course of behaviour to follow to prevent or treat health issues and illness (Reading, 2007).

First Nations community health directors report that First Nations people are reluctant to ask questions and share a partnership role in their own health care because of the effects of colonization, the perception of physician and health care providers as “authority” and the challenges in translation across First Nations and English or French. For these reasons, First Nations are reported to be less likely to have seen a physician even when controlled for the needs of a younger population (Reading, 2007).

In 2012, the Mental Health Commission of Canada (MHCC) released *Changing Directions, Changing Lives: The Mental Health Strategy for Canada*. Within the strategy, the MHCC states that “[T]ackling the complex issues that affect mental health in northern and remote regions will require different governments and organizations to work together to implement cross-sector solutions. It will also require funding that reflects the higher cost of providing services and the unique contexts in northern and remote areas. Programs developed in cities in the south cannot simply be transferred to northern and remote places and be expected to work. Communities should have access to funding and support to develop, implement, and evaluate their own solutions to addressing the mental health needs of their communities” (Mental Health Commission of Canada, 2012, p.86).

First Nations have based their way of life upon their values, spirituality, culture and relationship with the land. This way of life included well-functioning societies that valued the role played by each person within the community at each stage of life, including women, men and two-spirited people (Chansonneuve, 2005). First Nations have a holistic vision of health and well-being based on a balance of spiritual, mental, emotional and physical health, as well as social and economic well-being.

Colonization has taken a drastic toll on this way of life through measures such as the Indian Residential School system and “the ‘60s scoop” — the forced adoption of Aboriginal children starting in the 1960s — the undermining of systems of governance and banning of spiritual, cultural and economic practices, and societal racism and forced dislocation from the land, to name a few. Many First Nations have been struggling to relearn and reconstitute a way of life and worldview that pre-dates colonization. However, it is also important to understand that there are many First Nations people who have no connection to culture or their cultural identity and prefer it that way. Also, some First Nations communities do not allow cultural spiritual practices within the community which is often dominated by the church.

Given the legacy of colonization, a process of decolonization has emerged as a priority for First Nations. Decolonization is a process where First Nations people and communities critically engage their traditional cultures, redefine themselves as people and reassert their distinct identities. It involves processes such as grieving and healing over the losses suffered through colonization, the



renewal of cultural, spiritual and land use practices, and improved access to mental wellness resources. The increasing importance of decolonization has led First Nations leaders and communities to call for healing, family restoration and strengthened communities of care (Health Canada, 2011).

First Nations health is widely understood to also be affected by a range of historical and culturally-specific factors. These additional factors are sometimes referred to as First Nations or Aboriginal-specific determinants of health and include loss of language and connection to the land; colonization; residential school abuses; systemic racism; environmental destruction; and cultural, spiritual, emotional and mental disconnectedness (Health Canada, 2011).

Many First Nations communities aim to achieve wellness, which is distinct from the often-medicalized model of “health” in that it is holistic and promotes an equal balance of mental, physical, emotional and spiritual aspects of life. There is some agreement that the *Diagnostic and Statistical Manual*, version IV and V does not, and perhaps cannot, attend accurately to the reality of trauma and post-traumatic stress for First Nations. The differences in culture and histories that are associated with the effects of trauma and ways of healing go beyond the individual and family to include community and beyond the personal past to include historical past. Treatment for pain management must consider the biopsychosocial model of pain, as well as distinct cultural approaches to pain management. This refocus means systematically considering the biological, psychological and social, and distinct cultural factors and their complex interactions in understanding health, illness and healthcare delivery. Although pain might be observed as physical, there can be psychological and social factors that impact or intensify the physical pain. Therefore, pharmacological treatments might not be the best or only option for pain management.

Culturally specific interventions are holistic, meaning that they do not attend separately to the mind or brain, and the physical or emotional parts of an individual. Instead they attend to mind, body, spirit and emotions all at once. Although the specific intervention can be more targeted, cultural interventions and practices to address the harms of prescription drugs include:

- Reconnecting to cultural identity through reunification with a First Nations community;
- Obtaining a spirit name;
- Identifying a clan family;
- Using natural medicines for prayer, cleansing and detoxification;
- Using traditional foods, especially berries;
- Holding ceremonies such as sweat lodge or the ghost feast (also known as a memorial feast or feast for the dead) that attends to grief and loss; and
- Intervening to facilitate reconnection to the land and environment (Hopkins, 2010).

All of these practices and interventions are based on cultural evidence that stems from the teachings of the people and have been passed on in written form or through oral tradition, but have not been changed by people or circumstances; instead, they remain true to spiritual law.

How culture is attended to in addressing the harms of prescription drugs should be guided by the concepts of cultural competency and cultural safety, which are defined as follows:

- **Culturally Competent:** Cultural competence requires that service providers, both on- and off reserve, are aware of their own worldviews and attitudes towards cultural differences; and include both knowledge of, and openness to, the cultural realities and environments of the



clients they serve. It is also necessary for indigenous knowledge to be translated into current realities to meaningfully inform and guide direction and delivery of health services and supports on an ongoing basis.

- **Culturally Safe:** Cultural safety extends beyond cultural awareness and sensitivity within services and includes reflecting upon cultural, historical and structural differences and power relationships within the care that is provided. It involves a process of ongoing self-reflection and organizational growth for service providers and the system as a whole to respond effectively to First Nations people (Health Canada, 2011).

Cultural relevancy requires acting in a culturally competent manner to ensure that any action based on culture respects the diversity of culture and is specific to the individual, family or community. There can be challenges for healthcare professionals working with “unregulated professions,” such as cultural practitioners and Elders. Other divisions can be raised by differing world views, lack of appreciation or understanding for indigenous knowledge and western knowledge, and jurisdictional differences specific to governance, funding and policy. These challenges and barriers must be worked through with mutually agreeable roles, responsibilities, goals and expected outcomes.

Challenges to addressing prescription drug misuse among First Nations in Canada are compounded most significantly by the absence of primary healthcare systems. When First Nations language is a primary or only language, there are significant language barriers to communication for healthcare professionals. Unresolved trauma and intergenerational trauma presents difficulty in distinguishing psychological and physical pain.

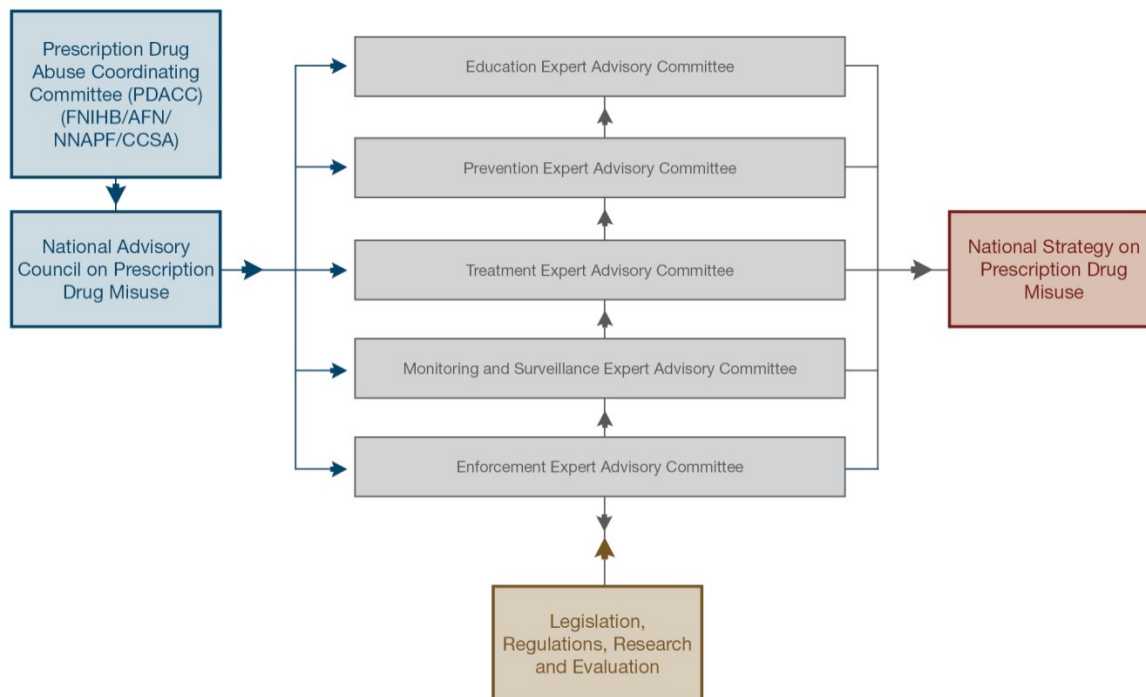
One example specific to First Nations in Canada is from a 2007 Saskatchewan study that found that “differences in prescription drug abuse ... between northern and southern Saskatchewan First Nations reserve communities ... are related to factors such as prescriptive practices and delivery of medications; geographical location (remote versus non-remote locations, proximity to urban centres); ... the accessibility and availability of illicit and licit substances,” and physician payment structures (Dell et.al, 2012).

Chronic health diseases, often associated with pain, abound among First Nations in Canada, such as arthritis and rheumatism, high blood pressure, diabetes, asthma, heart disease, cataracts, chronic bronchitis and cancer (First Nations Information Governance Centre [FNIGC], 2005). The presence of these diseases helps in understanding the pathway to prescription drug use and misuse, as they result in making these drugs available in First Nations communities.

In the context of the issues that need to be addressed specific to First Nations populations, it must also be recognized that First Nations people and communities have many strengths. Most important, are their culture and indigenous knowledge, which is not included in the evidence put forward to address the harms of prescription drug use and related issues (Dell et al., 2012).



Figure 1: Input Process for Developing the Strategy





Part C: International Context

Different countries and surveys use varying terminology and report on different measures with respect to the harms associated with prescription drugs such as opioids, sedative-hypnotics and stimulants. These differences sometimes mean that comparison is not possible. This part of the report maintains the specific language used by the individual countries and survey instruments.

The United Nations Office on Drugs and Crime (UNODC) emphasizes that the harms associated with prescription drugs are a “major and growing health problem” (UNODC, 2011). According to the 2012 World Drug Report, the estimated annual use of opioids, including the non-medical use of prescription opioids, morphine and heroin, ranges from 0.6% to 0.8% of the population aged 15 to 64 (UNODC, 2012). Although global figures are not available specifically for the non-medical use of prescription opioids, tranquilizers and sedatives, the use of such drugs is a growing health problem.

The United States

In the United States, the Office of National Drug Control Policy (ONDCP) describes opiate abuse as “the nation’s fastest-growing drug problem” and an “epidemic” (ONDCP, 2011). According to recent data produced by the Substance Abuse and Mental Health Services Administration (SAMHSA) from the National Survey on Drug Use and Health (SAMHSA, 2011), an estimated 14.7 million Americans aged 12 and over reported using prescription drugs for non-medical reasons in 2011.

Prescription drugs are second only to cannabis as the most prevalent type of drug used in the country, excluding alcohol and tobacco. The number of non-medical prescription drug users peaked at 16.5 million in 2006 and recently declined for the first time since 2008, to 14.7 million in 2011 mainly because of a decrease in the non-medical use of prescription pain relievers. In 2011, 11.1 million Americans reported the non-medical use of pain relievers, down from 12.7 million in 2006. Non-medical past-year use of sedatives was the only other prescription drug to decrease, in this case from 906,000 Americans in 2010 to 526,000 in 2011. Although the overall rate of treatment admissions for substance misuse among people aged 12 and older was stable from 1999 to 2009, there was a 430% increase in admissions for the misuse of prescription opioid drugs in the same period (Holmes, 2012).

Data from the U.S. highlight the harms associated with prescription drug use, misuse or abuse. The estimated number of drug-related emergency department visits involving the misuse or abuse of prescription drugs increased by 115% between 2004 and 2010 (SAMHSA, 2012). In 2010, approximately 49% of these visits involved pain relievers (opioid and non-opioid) and about 35% involved drugs used to treat insomnia and anxiety. Overdoses of prescription pain relievers have more than tripled in the past 20 years (Centers for Disease Control and Prevention, 2011). A California study showed that from 1990 to 2005 hospital patients with opioid-related disorders had the highest risk of death compared with people with diagnoses related to other drugs, and their risk of death was 5.71 times higher than for healthy individuals (Callaghan et al., 2012).

Europe

In Europe, the prevalence of prescription drug misuse is difficult to assess from the available data. However, according to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (2011), the use of opioid treatment drugs that have been diverted from a treatment setting appears



to be an issue of concern. Direct comparisons between North America and Europe are difficult given the differences in the regulatory framework and prescribing practices. However, the potential for misuse is an issue within the European pharmaceutical monitoring system (EMCDDA, 2010).

Australia

In Australia, past-year use of prescription drugs for non-medical purposes, including pain relievers, tranquilizers, steroids, methadone, buprenorphine and opiates with the exception of heroin, by people aged 14 and older increased from 3.7% in 2007 to 4.2% in 2010. The most commonly used prescription drugs were pain relievers (3%) followed by tranquilizers and sleeping pills (1.4%) (Australian Institute of Health and Welfare, 2011).

Developing Countries

In contrast with the attention paid to prescription drug misuse in North America and Australia, developing countries in regions including Africa, Central America, the Caribbean and South Asia are more concerned with improving access to prescription drugs. In February 2012, the Morphine Manifesto (Pallium India, the International Association for Hospice and Palliative Care, and the Pain and Policy Studies Group/WHO Collaborating Center at the University of Wisconsin, 2012) was released. Signed by leading foundations and organizations worldwide, the Manifesto calls for an “end to the unethical practice of promoting access to expensive opioid analgesics without also making available low cost immediate release oral morphine” (Pallium India, 2012). It also calls upon governments, healthcare institutions and the pharmaceutical industry to ensure the accessibility of immediate release morphine to patients in need, at a cost that the individual and community can afford. Africa is the region with the largest number of countries recording little or no available pain medications.



Part D: Prescription Drugs and Associated Harms in Canada

This part of the report reviews the best available data related to the harms associated with prescription drugs with the potential for abuse in Canada and identifies gaps in our understanding of the issue. Surveys report using varying terminology and measures with respect to estimates and indicators of the harms associated with prescription drugs, and can often not be directly compared. This part of the report maintains the specific language used by the survey instruments.

Canada has the second-highest level of prescription opioid use globally, with a total of 26,380 Standardized Defined Daily Doses (S-DDD) of prescription opioids consumed in 2008–2010 (International Narcotics Control Board, 2011). This consumption represents a 203% increase from the 8,713 S-DDD consumed during 2000–2002, which is an increase steeper than that observed in the United States (Fischer & Argento, 2012). As reviewed below, there are harms associated with prescription drugs, including opioids, sedative-hypnotics and stimulants. Although these drugs have therapeutic purposes, they have a high tendency for misuse because of their psychoactive properties and associated risk for psychological and physical dependence. Other factors that can influence the potential for misuse and harm include their accessibility, perceptions of relative safety, opportunities for diversion along the supply chain, economic incentives, promotion by the pharmaceutical industry, enormous demand, proximity to markets and low risk of arrest and prosecution.

Acquisition of Prescription Drugs

There are various routes for the acquisition of prescription drugs that can subsequently be misused or result in harm. The routes include legitimate prescribing for therapeutic purposes, “double doctoring” and diversion techniques such as prescription fraud and forgery, thefts and robberies, street drug markets and Internet purchases. An Ontario study showed that, of 1,095 overdose deaths between 1991 and 2004, 56.1% of patients had been given an opioid prescription within four weeks before death (Dhalla, Mamdani, Sivilotti, Kopp, Qureshi, & Juurlink, 2009). In a study of opioid-dependent patients admitted to the Centre for Addiction and Mental Health in Toronto, 37% reported receiving opioids from physician prescriptions, 26% from both a prescription and “the street,” and 21% from the street (Sproule, Brands, Li, & Catz-Biro, 2009).

The misuse or non-medical use of prescription drugs can involve borrowing medications from a friend or relative, deliberately using higher-than-recommended doses, hoarding medications and using medications together with alcohol or medication that has a sedating effect. Identity fraud can also be employed to unlawfully obtain prescription drugs. In jurisdictions where health cards do not contain picture identification, cards are sold on the black market. Out-of-province cards also have black market value as prescriptions filled using them are not captured in provincial/territorial prescription monitoring programs.

Therapeutic Uses of Prescription Drugs

Sedative-hypnotics can provide effective treatment for anxiety, sleep induction and alcohol and drug withdrawal. Stimulants are used to treat conditions such as Attention Deficit and Hyperactivity Disorder (ADHD) and narcolepsy. Opioids are used for pain management – the most common reason



for seeking health care (Todd et al., 2007). A large prospective, multi-centre study of emergency departments in Canada and the United States noted that although pain accounts for up to 78% of visits to emergency departments, analgesics are under used and delays for treatment are common (Todd et al., 2007). Research suggests that between 15% and 29% of the Canadian population experiences chronic pain, with limited access to appropriate and timely treatment: 50% have had to wait six or more months and many areas of Canada do not have any specialist pain treatment services (Fischer & Argento, 2012).

Primary care providers likely write the bulk of opioid, sedative and stimulant drug prescriptions in Canada. They manage the majority of chronic pain patients in Canada. But primary care physicians are poorly trained in both chronic pain and addiction management (Dubin et al., 2011; Watt-Watson et al., 2009).

Population Data

According to the 2011 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS), 22.9% of Canadians aged 15 and older reported using a psychoactive prescription drug in the last 12 months, a drop from the 26% reported in 2010 (Health Canada, 2012a). The decline in the use of prescription drugs derives from the decrease in the reported past-year use of opioid pain relievers by Canadians, from 20.6% in 2010 to 16.7% in 2011. Rates of past-year use of stimulants (0.9%) and sedatives or tranquilizers (9.1%) by Canadians in 2011 were not significantly different from rates reported in 2010 (Health Canada, 2012a).

Certain populations in Canada have been identified as having rates of prescription drug use or misuse, or experience related harms that stand out as higher than rates in the general population. These include women, youth, seniors, First Nations and Inuit, and newborns. Available data related to these populations is reviewed below.

Although not specifically reviewed in this report, there are other groups that might be at risk for prescription drug misuse, including active military personnel and veterans, incarcerated offenders, homeless people, individuals with psychiatric conditions or concurrent disorders and healthcare professionals. Further research is needed to examine the prevalence of prescription drug misuse and related harms among these populations to determine the extent and nature of the problem.

Women

According to data from the 2011 CADUMS, past-year use of any psychoactive prescription drug was found to be significantly higher among females (25.5%) than males (20.2%), as was past-year use of sedatives or tranquilizers (12% for females vs. 5.9% for males) (Health Canada, 2012a). In contrast, the past-year prevalence of stimulants was found to be significantly higher among males compared to females (1.2% vs. 0.5%) (Health Canada, 2012a). The higher prevalence of sedative medication use in women might be the result of their longer life expectancies, more frequent use of healthcare professionals and direct-to-consumer marketing strategies that target them (British Columbia Ministry of Health, 2008). It has also been suggested that women are more likely than men to be prescribed benzodiazepines for non-medical reasons, such as coping with stress and grief, or for adjusting to childbirth and menopause (British Columbia Ministry of Health, 2008).



Approximately 22% of Canadian women of childbearing age (15-44 years) reported the past-year use of a psychoactive prescription drug during 2011 (Health Canada, 2012b). The past-year prevalence of use of pain relievers among this population was 16.8% in 2011; the prevalence of past-year use of sedatives or tranquilizers was 8.2%.

Newborns

The use of psychoactive drugs during pregnancy can result in drug withdrawal in babies, known as Neonatal Abstinence Syndrome (NAS). Research has shown that NAS occurs in 55% to 94% of neonates exposed to opiates *in utero* (American Academy of Pediatrics Committee on Drugs, 1998). According to the Canadian Institute for Health Information (CIHI), there were 1,057 reported cases of NAS in Canada in 2009–2010 (CIHI, 2012). In Ontario, rates of NAS have risen from 171 cases reported in 2003 to 564 cases in 2010 (CIHI, 2012). While this number is higher than the national average, it might be a conservative estimate, as many cases of NAS are believed to go undetected. Non-opioid drugs, such as benzodiazepines, barbiturates and alcohol, have been associated with short-term effects on newborns, causing withdrawal that manifests with tremors, irritability and seizures (Lall, 2008).

Youth

Youth are more likely than adults to experience harm from substance use in general, which is why youth represent a high-risk group for prescription drug misuse and associated harms. Research shows that youth view prescription drugs as “safer” than illegal drugs (Twombly & Holtz, 2008). Among Ontario grade 7-12 students who reported using opioid analgesics non-medically in 2007, 72% reported obtaining them from home and 6% reported obtaining them from friends (Brands, Paglia-Boak, Sproule, Leslie, & Adlaf, 2010). Adolescents’ brains are undergoing rapid and extensive development, and this can be affected by substance use, particularly early-onset use (CCSA, 2007). Early-onset drug use is also associated with increased risk of later drug dependence, poly-drug use and possibly the use of riskier drugs (CCSA, 2007; Chen, Storr, & Anthony, 2009).

Recent data from CADUMS show that youth aged 15 to 24 reported significantly lower rates of past-year psychoactive prescription drug use (17.6%) compared to adults aged 25 and older (23.9%). The past-year use of pain relievers (14.3%) was found to be higher than that of sedatives and tranquilizers (4.0%) and stimulants (2.4%) among this age group (Health Canada, 2012a). A similar trend in past-year use has been reported by the 2010–2011 Youth Smoking Survey, which involves students in grades 6 to 12. The survey noted that past-year use of pain relievers to get high and not for medical purposes (3.9%) was relatively higher than that of sleeping medicine (2.5%), stimulants (2.2%) and tranquilizers (1.5%) (Health Canada, 2012c).

Several provincial surveys highlight the extent of harms associated with prescription drugs among youth. For instance, a survey of Ontario students in grades 7 to 12 revealed that 14.0% reported the non-medical use of prescription opioid pain relievers during 2011 (Paglia-Boak, Adlaf, & Mann, 2011). Findings from the 2008 *Alberta Youth Experiences Survey* showed that almost one in five (17.2%) grades 7 to 12 students reported using prescription drugs without a prescription in the 12 months prior to being surveyed. Codeine was found to be the most frequently used prescription drug, with 15.5% of students having used it in the past year (Alberta Health Services, 2009).



Seniors

Prescription drugs are used widely by adults aged 65 and older, a growing demographic. Owing to the prevalence of chronic pain and insomnia, seniors are more likely than the general population to receive prescriptions for psychoactive medications that have the potential for harms, including opioids and benzodiazepines (Simoni-Wastila & Yang, 2006). One study showed that 38% of institutionalized seniors experienced pain on a regular basis, compared with 27% of seniors living in households (Ramage-Morin, Shields, & Martel, 2010). In both populations, rates were higher for women than men. The use of benzodiazepines by seniors is also a concern, as these drugs can cause confusion, drowsiness or lack of coordination, which increases the risk of falls, even when they are taken as prescribed. There is also higher risk of drug interaction with prescription medications because of higher use of other medications among seniors (CIHI, 2011).

Accurate, reliable data on the prevalence of prescription drug misuse among seniors in Canada is lacking. However, as the population ages, the number of seniors needing treatment for prescription drug-related harms will likely increase. This prediction is based on a study that estimated that the number of older adults in need of substance misuse treatment in the U.S. could increase from 1.7 million in 2000 to 4.4 million in 2020 (Gfroerer, Penne, Pemberton, & Folsom, 2003). As the baby boomers enter the “golden” years, the rates of recreational drug abuse have increased in the U.S. reflecting the outlook of this generation whose mantra was “turn on, tune in, drop out.” A similar pattern is likely in Canada.

First Nations

Data suggest that the harms associated with prescription drugs, particularly opioids, occurs at disproportionately high levels in First Nations communities in Canada. Recent data from Health Canada's First Nations and Inuit Health Branch (FNIHB), Non-Insured Health Benefits (NIHB) program show that 898 opioid prescriptions were dispensed per 1,000 First Nations individuals aged 15 and older in Ontario in 2007, with 119 prescriptions for oxycodone formulations alone (Health Canada, 2010). In 2006–2007, eligible First Nations and Inuit people accounted for 56% of Percocet® and 49% of OxyContin® claims made to the NIHB program in Ontario (FNIHB Health Canada, 2010, as cited in Expert Working Group on Narcotic Addiction, 2012).

Changes made under the NIHB program have led to a 50% reduction in the amount of long-acting oxycodone provided since 2010 without a significant shift to other long-acting opioids (Health Canada, 2012d). These changes include:

- Monitoring prescriptions to identify potential misuse and prevent double-doctoring;
- Establishing maximum monthly and daily drug limits;
- Changing the listing status of extended release oxycodone to exception status;
- Real-time warning and claims rejection messaging to pharmacists at the point of sale; and
- Establishing an external, expert drug and therapeutics advisory committee.

The 2008–2010 First Nations Regional Health Survey revealed that among First Nations people aged 18 and older living on-reserve or in northern First Nations communities, 4.7% reported past-year use of illegal (heroin) or prescription opioids (including morphine, methadone and codeine) without a prescription, and 5.7% reported non-prescribed use of sedatives or sleeping pills, including diazepam and oxaxepam (First Nations Information Governance Centre [FNIGC], 2012). Among First



Nations youth aged 12 to 17, 1.3% reported using illegal or prescription opioids without a prescription during the previous 12 months and 2.2% reported non-prescribed use of sedatives or sleeping pills (FNIGC, 2012).

First Nations reports indicate higher rates of emotional and physical abuse of family members, especially of children and elders. Communities with higher than average percentages of drug addiction and chemical dependency have higher incidences of suicide, violent crimes, illegal activity and other forms of abuse (Assembly of First Nations, 2011). Other First Nations communities have reported epidemics of from 43% (Chiefs of Ontario, 2010) to as high as 85% (Health Canada, 2011) of the communities' population addicted to opiates. In these instances there are also external problems, involving child and family services, conflicts with law enforcement, and absenteeism from places of work, education and volunteerism (Chiefs of Ontario, 2010).

Epidemiological data tend to portray First Nations peoples as generally unhealthy and implicitly unable to manage their own affairs. This portrayal has a disempowering effect for some communities and individual members. In direct contrast to the negative portrait, First Nations communities are striving to realize their legitimate aspirations for self-determination and governance. Self-governance can have a powerful effect on cultural continuity, postulated to be linked as a determinant of mental health status and suicide (Chandler & Lalonde, 2003).

Harms and Costs Associated with Prescription Drugs

The use and misuse of prescription drugs can result in various harms to health, including addiction, withdrawal, injury and death related, for example, to road crashes, accidental overdoses and suicide. There are societal harms as well, including crime and victimization, loss of human potential and pressures on community and institutional resources available for treatment and prevention. The human and dollar costs associated with these harms are significant (Hansen, Oster, Edelsberg, Woody, & Sullivan, 2011).

An analysis of visits to emergency departments sheds light on other health harms associated with prescription drugs. In Ontario between 2005–2006 and 2010–2011, there was an almost 250% increase in the number of emergency room visits related to narcotics withdrawal, overdose, intoxication, psychosis, harmful use and other related diagnoses (Expert Working Group on Narcotic Addiction, 2012). In Alberta, disorders caused by stimulants other than cocaine were the most prevalent reason for emergency department visits related to prescription drugs between 2003 and 2006 (16.6 visits per 100,000) (Wilde, Wolfe, Newton-Taylor, & Kang, 2008).

Prescription opioid-related deaths doubled in just over 10 years in Ontario, from 13.7 deaths per million in 1991 to 27.2 per million in 2004, more than double the mortality rate from HIV (12 per million) (Fischer & Argento, 2012). Depressants (e.g., benzodiazepines or alcohol) were factors in 92% of the opioid-related deaths (Fischer & Argento, 2012). The Office of the Chief Coroner of Ontario reports that opioid-related deaths nearly tripled over an eight-year period, from 168 in 2002 to 494 in 2010. Of the total 3,222 opioid-related deaths reported during this period, deaths related to oxycodone ($n=970$) were found to be the most prevalent, followed by morphine ($n=722$) and methadone ($n=595$) (B. Lauwers, personal communication, October 27, 2012).

A recent review of opioid-related deaths in Ontario showed an increase in deaths related to pain medication. The study noted that most (66.4%) of the people who died had been seen by a physician at least once in the month prior to death, with the median number of days between the visit and death being nine for those who went to the emergency room and 11 for those who made an office visit. The final encounter with the physician usually involved a mental health or pain-related



diagnosis. In most cases, the coroner determined that the death was an accident (Dhalla et al., 2009).

In Alberta, deaths attributable to poisoning from narcotics or psychodysleptics (with undetermined intent) accounted for the second-highest prescription drug-related death rate (3.79 per 100,000) between 2003 and 2006 (Wild et al., 2008).¹ The rate of prescription opioid overdose deaths of persons in one region of British Columbia (2.7 per 100,000 persons) is similar to that of the number of residents killed in any given year in motor vehicle accidents involving alcohol (2-3 per 100,000 persons) (Corneil, Elefante, May-Hadford, Goodison, & Harris, 2012), with poly-prescription drug use being identified as an important contributing factor.

Demand for prescription opioid-related treatment is increasing. From 2004 to 2009 in Ontario, admissions to substance use treatment programs for prescription opioids doubled (Fischer, Nakamura, Rush, Rhem, & Urbanoski, 2010). In 2005–2006, 10.6% of individuals seeking addiction treatment in Ontario did so for prescription opioids; by 2010–2011, this percentage had increased to 18.6% (Expert Working Group on Narcotic Addiction, 2012).

The number of individuals enrolled in methadone maintenance treatment in Ontario has risen substantially over 10 years, from approximately 7,800 in 2001 to 35,228 in 2011, with these increases considered to be largely driven by individuals with problematic prescription opioid use (Fischer & Argento, 2012).

¹ This report combined narcotics with psychodysleptics in the reporting of mortality.



Part E: Strategic Streams of Action and Recommendations

This section presents the five strategic streams for action: **prevention, education, treatment, monitoring and surveillance**, and **enforcement**. The aim of each stream is summarized, the context for the stream is discussed and the recommendations presented. In addition, proposed leads for each recommendation, links with recommendations from other streams, and short-term recommendations are identified. The evidence supporting the recommendations is in a separate document that accompanies this *Strategy* document.

Prevention

Aim: Promote the appropriate use of prescription drugs and prevent harms and adverse health and social consequences associated with prescription drugs to individuals, families and communities.

Context

The *Ottawa Charter for Health Promotion*, which defines health promotion as the process of enabling people to increase control over and improve their health (World Health Organization [WHO], 1986), is the foundation for this stream. A key theme of this document is “coordinated action by all concerned” (WHO, 1986). The Public Health Planning and Policy Framework developed by the Assembly of First Nations (Reading, Kmetz, & Gideon, 2007) sets out a holistic framework of principles to ensure that the social determinants of health specific to the First Nations context are adequately addressed.

Improvement in a person's health requires a secure foundation in nine fundamental conditions: peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice and equity. The Ottawa Charter highlights the importance of advocacy, enabling and mediation, and defines the five components of health promotion upon which the *Strategy's* prevention recommendations are based:

- Building healthy public policy;
- Creating supportive environments for health;
- Strengthening community action;
- Developing personal skills; and
- Reorienting health services.

Health promotion focuses on promoting overall population health, preventing injuries and harm, and achieving health equity through both universal and tailored strategies. Universal strategies cover structural resources and social supports for health (e.g., adequate housing and income, social cohesion, inclusion, supportive environments, access to information and life skills) and focuses on creating opportunities and conditions that support resilience and health-enhancing behaviours. First Nations perspectives of health promotion must attend to protective factors, for example, pride in cultural identity, speaking a traditional language, culturally relevant education, literacy skills, access to high school, recreational activities and ties to a supportive adult or Elder.



One of the key differences between prescription drugs, such as opioids, sedative-hypnotics and stimulants, and other psychoactive substances, such as alcohol, tobacco, cocaine and heroin, is that the former are medicinal compounds approved by Health Canada and available for therapeutic use only with a prescription. Although prescription drugs are occasionally obtained via breaks in the supply chain, it is widely acknowledged that most of the psychoactive prescription drugs are obtained directly via prescription or via diversion from a prescription (Sproule et al., 2009). As an example, opioids are extraordinarily useful in the management of pain near the end of life and acute pain (e.g., after surgery). In the last 25 years, they have also been prescribed with increasing frequency for chronic non-cancer pain. Despite their increasing use in this setting, the evidence supporting the use of opioids in this setting is weak (Juurlink & Dhalla, 2012).

The harms associated with prescription drugs affect people across different demographic profiles owing to the therapeutic nature of these drugs and the ease of accessibility through diversion. Thus, universal prevention approaches can be effective for the general population. Moreover, people in some environments have an increased vulnerability to, and risk of, drug-related harms (e.g., correctional facilities, military service, communities with high rates of poverty and unemployment, and rural and remote areas). In these settings, strategies that address such issues as mental illness, psychological trauma and stress, cultural safety and community development are vital, and can empower communities to play an active role in prevention initiatives. These initiatives can include multi-sectoral and multi-disciplinary drug strategies and programs.

Tailored approaches identify the conditions that create risk, incorporate cultural awareness and focus on people who are at higher risk for harms associated with prescription drugs. Such approaches reflect the interplay between the determinants of health and actual living conditions. Efforts to prevent the adverse consequences of prescription drugs, therefore, need to be adapted to local needs and take into account differing social, cultural and economic situations.

Unlike most other health issues, substance use problems, including those related to prescription drugs, are often attributed to a person's moral and personal failure, resulting in stigmatization of and discrimination against those who are affected. Stigma (negative attitudes) and discrimination (associated negative behaviour) are serious impediments to the well-being of people with substance use problems – particularly for women and those with chronic problems – and their impact often persists far beyond the resolution of the immediate problem (National Treatment Strategy Working Group, 2008).

Health promotion is a shared responsibility of the health sector and other sectors. Working together, all sectors must be aware of, take responsibility for and collaborate on prevention and health promotion activities. Individuals, their families and community leaders all have a role to play in managing the use of prescription drugs and preventing the harms that can result. Communities have the ability to draw upon local capacity and become knowledgeable about substance harm prevention and relevant cultural competencies, and can advocate for or take direct action on conditions that foster community health and safety.

Much can be learned from successful tobacco- and alcohol-related prevention initiatives that have attempted to limit consumption in the general population, in high-risk populations (e.g., youth) and in risky circumstances (e.g., drinking and driving). Lessons can be derived from understanding whether and how strategies from those initiatives can be transferred to preventing harms and adverse health and social consequences related to prescription drugs. A comprehensive approach would focus on all levels of the production and consumption chain – pharmaceutical production, drug distribution, healthcare practitioner prescription and patient health monitoring, pharmacy dispensing, individual consumption, and family and community supports.



Several points of intervention with the pharmaceutical industry might improve medication safety and prevent harms. The key clinical sections of product monographs can be reviewed to ensure that they are evidence-based and promote safe use, particularly the indications, precautions and dose titration sections. For example, Health Canada has already negotiated with Purdue to remove one statement from its previous OxyContin® monograph and other product monographs should be reviewed. Drug advertising directed at healthcare practitioners should also be reviewed.

Provincial or territorial governments, through their drug formularies, determine which drugs will be covered under their drug benefits plan and are therefore in a position to influence drug prescription and consumption. Saskatchewan, Ontario and the Atlantic provinces have de-listed certain forms of oxycodone from their formularies. Other prescription drugs that these and other jurisdictions might consider in future reviews include high-dose, non-tamper-resistant oxycodone and the 30-milligram hydromorphone tablet.

Prevention policies that have been directed at prescribers to reduce the harms associated with prescription drugs such as addiction, overdose or death, encourage prescribers to:

- Use caution and try other alternatives before prescribing medications to high-risk patients and patients with conditions for which there is uncertain evidence of effectiveness;
- Titrate cautiously, with close monitoring and short dispensing intervals, when prescribing to high risk patients;
- Prescribe tamper-resistant medications whenever possible; and
- Taper the dosages for patients who have not responded to therapy; and attempt to limit the mean daily dose per patient.

Typically, patients at high risk for addiction are younger, have a personal history of addiction or an active psychiatric disorder (Becker, Sullivan, Tetrault, Desai, & Fiellin, 2008; Edlund, Martin, Fan, Devries, Braden, & Sullivan, 2010; Fishbain, Cole, Lewis, Rosomoff, & Rosomoff, 2008; Manchikanti, Giordano, Boswell, Fellows, Manchukonda, & Pampati, 2007; Sullivan, Edlund, Zhang, Unützer, & Wells, 2006; Wilsey, Fishman, et al., 2008).

To illustrate in the case of opioids, fibromyalgia and low back pain are two common pain conditions for which opioid therapy is not routinely indicated (Chou & Hoyt Huffman, 2007; Deshpande, Furlan, Mailis-Gagnon, Atlas, & Turk, 2007; Martell et al., 2007; Volinn, Fargo, & Fine, 2009). The serious risks of opioids are dose-related, including addiction, overdose, falls and accidents (Saunders et al., 2010). The Canadian guideline's "watchful dose" is 200 milligrams of morphine equivalent per day (National Opioid Use Guideline Group, 2010), although the risk climbs substantially at doses well below this threshold (Dunn et al., 2010; Gomes, Mamdani, Dhalla, Paterson, & Juurlink, 2011). Opioid addiction and overdose deaths have increased in parallel with opioid prescribing. In addition to the clear temporal correlation, researchers have also demonstrated that:

- Opioid overdose deaths are more common in areas where opioids are more frequently prescribed (Brownstein, Green, Cassidy, & Butler, 2010; Dhalla et al., 2009; Fischer et al., 2013);
- The risk of overdose death is higher in individuals prescribed higher doses (Bohnert et al., 2011; Dunn et al., 2010; Franklin et al., 2012; Gomes et al., 2011); and
- Physicians who prescribe more opioids are also more likely to prescribe the last opioid before an individual's overdose death (Dhalla et al., 2009).



Researchers have also shown that addiction to prescription opioids is not rare, and as many as one-third of patients being treated for chronic non-cancer pain with opioids could meet criteria for an opioid use disorder (Boscarino et al., 2011).

Improvements in prescribing practices can be achieved through education, regulation and funding limits. Education is considered in the next section. Regulation — setting standards for prescribing practices — is within the purview of provincial medical colleges and governments. There is evidence that medical regulation is effective in changing prescribing practices. For example, the Washington State medical regulatory authority requires physicians to obtain a consultation before prescribing opioids in doses greater than 120 milligrams morphine equivalent per day. A survey of Washington primary care physicians showed strong support for the policy requiring consultation at high doses (Morse, Stockbridge, Egan, Mai, Wickizer, & Franklin, 2011). However, in Canada, pain clinics are already flooded with consultation requests and a Royal College of Physicians and Surgeons pain specialty program is years from graduating less than 20 specialists each year.

Funding policies of third-party payers (Ministries of Health, Health Canada's Non-Insured Health Benefits [NIHB] program, provincial and territorial workers compensation boards and private insurers) can also be used to improve prescription practices. For example, the Workplace Safety and Insurance Board in Ontario does not reimburse prescriptions for long-acting opioids for the first twelve weeks after an injury and does not fund doses above 200 milligrams morphine equivalent dosage. However, these policies must not prevent prescribers from prescribing high doses when clinically indicated (e.g., for severe neuropathic pain syndromes unresponsive to non-opioid treatments).

Finally, preventive policies are needed to reduce harm in individuals who continue to misuse prescription opioids. The distribution of take-home naloxone through venues regularly accessed by people who use opioids, such as methadone programs, emergency departments and needle exchange programs, is one prevention initiative that has been associated with reductions in overdose mortality in the United States (Coffin & Sullivan, 2013).

Together, this evidence suggests that a national strategy designed to reduce the harms associated with prescription drugs such as opioids, sedative-hypnotics and stimulants should include a clear focus on prevention. Such interventions must be evidence-informed and tailored, and their outcomes evaluated to ensure the effective and efficient use of available fiscal resources. Monitoring and surveillance, combined with research and evidence on effective prevention and implementation strategies, are critical for understanding emerging trends and good practice. Guidelines, legislation, regulation and education aimed at improving the effectiveness and safety of prescribing and dispensing practices are also needed and addressed elsewhere in the *Strategy*.

Prevention Recommendations

Recommendations	Proposed Leads	Links*	ST**
1. Establish a pan-Canadian task force of healthcare providers (e.g., physicians, nurse practitioners, pharmacists and allied health workers), policy planners, researchers, industry representatives and members of the public to:	Health Canada	M&S	
a. Encourage provincial regulatory colleges to develop and implement policies that promote appropriate prescribing practices.	First Nations, Inuit and Métis leaders	L&R	
	Patient and family support associations	T	
	Regulatory colleges	Ed	



Recommendations	Proposed Leads	Links*	ST**
<p>b. Review and strengthen product monographs and labels:</p> <ul style="list-style-type: none"> i. Review the international evidence and existing programs (e.g., Risk Evaluation and Mitigation Strategies) to identify, develop and implement effective risk mitigation strategy standards and models for pharmaceutical companies. ii. Require Health Canada-approved evidence-informed risk mitigation strategies for both branded and unbranded products prior to approval for market. iii. Require adjustments to both branded and unbranded product monographs, labels and risk mitigation if post-marketing surveillance identifies additional risks or harms. <p>c. Encourage third-party payers (provincial health ministries, Non-Insured Health Benefits, provincial insurance boards, private insurers) to implement policies that require prior authorization for high-potency and high-dose formulations.</p>	Industry		
2. Develop and promote risk-reduction programs for individuals who use prescription drugs in a manner that places them at increased risk of adverse consequences.	<p>Health Canada</p> <p>Public Health Agency of Canada</p> <p>Provincial/territorial health ministries</p>		
3. Identify, develop, promote and evaluate evidence-informed, culturally-safe practices, resources and policies to build community and individual capacity to address conditions that increase or protect against harms associated with prescription drugs for:	<p>Provincial/territorial health ministries</p> <p>Canadian Federation of Municipalities</p> <p>First Nations, Inuit and Métis leaders</p> <p>Patient and family support associations</p>		
4. Develop, implement and evaluate evidence-informed prescription drug-related social marketing campaigns and related resources directed to specific populations or communities, including information about:	<p>Health Canada</p> <p>Public Health</p> <p>First Nations, Inuit and Métis leaders</p> <p>Patient and family associations</p> <p>Provincial/territorial colleges</p> <p>Industry</p>	En	
<ul style="list-style-type: none"> a. The benefits, harms and limitations of use as prescribed and of non-medical use; b. Appropriate use; c. Signs and symptoms of misuse, addiction and overdose (and actions to be taken); d. Safe storage and disposal; e. Other strategies to prevent harms (e.g., related to drug-impaired driving); and f. Wellness promotion and alternatives to pain medications (e.g., self-care strategies). 			



Recommendations	Proposed Leads	Links*	ST**
5. Review existing evidence and/or conduct objective and independent research on the effectiveness of tamper-resistant and abuse-deterrent technology and packaging and make recommendations as needed to reduce the harms associated with prescription drugs and pediatric exposure.	Health Canada ISMP Canada Research organizations	L&R	
6. Develop and promote guidelines for individuals and families related to the use, safe storage and disposal of prescription medications. Guidelines should include family assessment, community medication disposal resources and strategies to address barriers to safe storage (e.g., locked boxes) and disposal.	ISMP Canada Patient and family associations First Nations, Inuit and Métis leaders Regulatory bodies, especially pharmacy Provincial/territorial health ministries		
7. Review existing patient brochures, product labels and inserts (including prescriber indications), auxiliary labels, and recommendations for specialist consultation and patient education. Revisions as needed should seek to standardize language, promote comprehension and prevent or reduce the harms associated with prescription drugs (e.g., operating a motor vehicle while using prescription medications, caution when combined with other medications or alcohol).	ISMP Canada Patient and family associations Industry Health Canada	L&R	
8. Review existing evidence and/or conduct objective and independent research and make recommendations on the effectiveness, including cost-effectiveness, of community-based prevention initiatives designed to reduce overdose and related deaths (e.g., take home naloxone programs).	Health Canada Research organizations		
9. Conduct an independent review of the evidence and make recommendations as appropriate on the link between promotion (e.g., advertising, marketing to clinicians) and the harms associated with prescription drugs.	Health Canada Research organizations CAMH CCSA Public Health Agency of Canada		
10. Develop and evaluate accessible evidence-informed resources for practitioners and educators working with youth to help incorporate prescription drug-related harm prevention into programs and policies, while ensuring that unintended consequences are avoided. This should include:	Provincial and territorial health ministries of health or public health Public Health Agency of Canada		
a. Population health promotion initiatives that focus on asset building and the promotion of resilience; and	National youth addiction and mental health associations		
b. Building prescription drug-related content into existing prevention initiatives by leveraging what already exists in communities	Recognized national youth		



Recommendations	Proposed Leads	Links*	ST**
	organizations First Nations, Inuit and Métis leaders		
11. Develop and promote the effective implementation of guidelines and processes for practitioners (e.g., probation, parole and NGO staff, and peer support workers) working in and with corrections facilities and their clients to ensure discharge planning includes:	Correctional Service of Canada Corrections and criminal justice advocacy organizations Provincial/Territorial corrections programs First Nations, Inuit and Métis leaders		
a. Referral and seamless linkage to accessible treatment (e.g., addiction, mental health and pain management) services within their local communities;			
b. Education on harms associated with prescription drugs and risks related to use following release, including			
i. Risks of inadvertent death related to loss of tolerance should use of prescription drugs be resumed at pre-incarceration doses; and			
ii. Strategies to mitigate these risks.			
12. Improve access and provide budgetary allocation to services and supports in all communities and settings (including rural and remote) along the full continuum of addiction, mental health and pain management services.	Federal/provincial/territorial governments	T	

Legend:

* Links refer to linkages between recommendations across action streams: P=prevention; T=treatment; Ed=Education; M&S=Monitoring and Surveillance; En=Enforcement; L&R=Legislation and Regulations; E&PM=Evaluation and Performance Measurement

** ST refers to short term recommendations intended to be implemented within 24 months

Education

Aim: Identify and address the educational needs and support mechanisms required by healthcare practitioners, primarily prescribers and dispensers (in collaboration with other members of the healthcare team, including social workers, addiction counsellors and community workers, as well as other practitioners) in various communities and practitioner settings, using a biopsychosocial approach, in the areas of addiction, mental wellness, co-morbidities, concurrent disorders, pain management, trauma-informed-care, and primary and secondary prevention, as well as populations at risk of harms associated with prescription drugs.



Context

The education stream focuses primarily on the impact of prescribing and dispensing practices on the harms associated with prescription drugs such as opioids, sedative-hypnotics and stimulants, and seeks to influence those practices. It recognizes the importance of involving other members of the healthcare team and patients, as well as social services, law enforcement, corrections officers, addictions counsellors, community workers, and lay practitioners in clinical decision making in remote and First Nations communities.

The education of healthcare practitioners (including medical, nursing, pharmaceutical and dental) must address the complexities related to addiction, mental health, co-morbidities, concurrent disorders and pain, conditions for which these prescription drugs can be prescribed. Practitioners and patients must consider both the therapeutic uses and the harms associated with these drugs and that these harms might outweigh the benefits. With First Nations populations, attention must be given to historical trauma and the understanding of the role that culture plays in one's healing journey. As well, appropriate dosing, duration of therapy and evidence of effectiveness for specific conditions are important aspects of clinical decisions related to prescription drugs. Evidence-informed alternatives to medication should also be considered prior to or instead of prescribing these drugs.

Previous reports have identified gaps in the education of healthcare practitioners in the areas of addiction, co-morbidities, concurrent disorders, pain management and trauma-informed care. (See Canadian Pain Society, 2011; Isaacson, Fleming, Kraus, Kahn, & Mundt, 2000; Lippe, Brock, David, Crossno, & Gitlow, 2010; Newfoundland & Labrador OxyContin Task Force, 2004; Polydorou, Gunderson, & Levin, 2008; Watt-Watson et al., 2009.) For example, a national survey of U.S. medical residency programs in 2000 found that, of the programs studied, only 56% required substance use disorder training (ranging from 31.8% in pediatrics to 95% in psychiatry). The number of curricular hours in the required programs ranged from three (emergency medicine and obstetrics-gynaecology) to 12 (family medicine) (Isaacson et al., 2000). Similar gaps have been noted in curricula related to pain studies. A recent study (Watt-Watson et al., 2009) examined the time that major Canadian universities spend on teaching mandatory pain-related content to health science, dentistry and veterinary students. In this study, only one-third of the health sciences programs were able to identify the time dedicated to teaching mandatory pain-related content and the average total time per discipline per certificate varied from 13 hours to 41 hours. In contrast, all respondents from the veterinary sciences were able to identify the time spent on mandatory pain-related content, with a mean of 87 hours per certificate.

Education is also needed on providing healthcare with populations at increased risk: seniors, youth, newborns, First Nations and Inuit, and individuals involved in the corrections system. Another potentially at-risk group includes military personnel and veterans. A recent study found that, of military veterans who sought help for chronic pain, those with post-traumatic stress disorder were more than twice as likely to receive opioid pain relievers as those without mental health problems (Seal et al., 2012). More information is needed on the nature and incidence of prescription drug misuse by healthcare practitioners themselves.

Also of note is the gap in health science curricula related to the risks and benefits of various medications, including opioids, and the prevention and management of overdose (Lank, 2012). Using pain management as an example, the Illicit Use of Pharmaceuticals Workshop (Public Safety Canada, 2011b) concluded that "over-prescribing often occurs as a result of a lack of education, training and awareness on how to effectively prescribe for acute or chronic pain." This lack of education also creates significant misunderstanding of the various treatment modalities for chronic



non-cancer pain. In fact, the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* was developed in part because physicians and other stakeholders were seeking guidance regarding safe and effective use of opioids (National Opioid Use Guideline Group, 2010).

Gaps can also be found in continuing education programs offered to healthcare professionals. To address these curriculum gaps, education could include content related to interdisciplinary assessments and the use of and access to non-pharmacological interventions. There is also benefit in educating other sectors, such as law enforcement, corrections officers, addictions counsellors and community workers, on the risk for addictions and potential harms associated with prescription drugs.

Thus, the central goal in developing curricula at the undergraduate, post-graduate, and continuing professional development levels for healthcare practitioners must be to address these gaps and educate prescribers and dispensers about the harms associated with and therapeutic uses of these medications. Healthcare practitioners and others need to work with patients and the general public to help them become better informed about these drugs and to participate in shared decision making with their healthcare providers.

To that end, there is a need to identify core competencies for prescribers, dispensers and other members of the care team. Core competencies should encompass those prescribing and dispensing practices that affect the prevalence and severity of addiction, including patient selection, dose titration, monitoring, management of high-risk patients and tapering. Widespread use of these competencies will limit the exposure of vulnerable patients to high doses of medications, thus reducing complications such as addiction and overdose. It will also reduce the supply of these drugs available for diversion. Evidence suggests that the healthcare practitioners' weakness in these competencies has contributed to the current prescription drug crisis. For example, opioid dose is strongly associated with the risk of overdose (Dunn et al., 2010; Gomes et al., 2011). The majority of overdose deaths in Ontario occurred among patients of family physicians who were high opioid prescribers (Dhalla, Mamdani, Gomes, & Juurlink, 2011). Experimental studies have shown that measures related to opioid abuse liability (e.g., feeling high, drug liking) are dose-related (Walsh, Nuzzo, Lofwall, & Holtman, 2008).

Research points to effective strategies for changing clinical behavior. To be effective, education must be sustained, multi-faceted, evidence-informed and easily accessible to practitioners. Isolated educational events by themselves appear to be only minimally effective in changing physician prescribing patterns (Kahan, Gomes et al., in press). Effective educational strategies include criteria, academic detailing, local and long-distance clinical support networks, and clinical tools such as pocket cards and clinical summaries. Although further research is needed, there is some evidence that these interventions are effective in changing physician prescribing patterns.

Clinical support networks for addiction and pain management in Ontario and the Atlantic region have reported good success and high levels of practitioner satisfaction. The Ontario College of Family Physician, in partnership with the College of Physicians and Surgeons of Ontario, created the Medical Mentoring for Addictions and Pain (MMAP) program that currently serves some 180 providers in Ontario and their patient populations. An Atlantic Mentoring Network – Pain and Addiction (building on the Chronic Pain Collaborative Care Network) is currently under development based on MMAP. These programs include the ongoing provision of pain management and addiction treatment support, education and advice (in person as well as via email, webinars, teleconferencing and phone consultations) by specialist mentors to family physician mentees. It is interactive, evidence-informed and uses case-based interactive study. Mentees can consult with mentors through email and telephone consultation.



Evidence-informed practice guidelines can have positive impacts on clinical practice, including prescribing practice, and on patient outcomes. (See Grimshaw, Eccles, & Tetroe, 2004; Grimshaw, Eccles, Thomas, MacLennan, Ramsay, Fraser, & Vale, 2006; Grimshaw, Thomas, MacLennan, Fraser, Ramsay, Vale, Whitty, Eccles, Matowe, Shirran, Wensing, Dijkstra, & Donaldson, 2004.) Several guidelines currently exist regarding prescription drugs: for example, the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* (National Opioid Use Guideline Group, 2010) and the *Buprenorphine Guideline for Treatment of Opioid Dependence* (Handford et al., 2012). As the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* addresses one modality for managing chronic non-cancer pain, additional guidance should be sought related to other treatment options for this type of pain before deciding on the use of prescription drugs (National Opioid Use Guideline Group, 2010).

Guidelines, academic detailing and other educational interventions achieve small to moderate impacts in isolation, but they might be more effective when combined (Boaz, Baeza, Fraser, & the European Implementation Score Collaborative Group, 2011). Two state-wide comprehensive educational programs involving academic detailing in the United States were associated with reductions in opioid overdose mortality and in the percentage of cases who received an opioid prescription prior to death. In addition to academic detailing, these programs used a prescription database and wide distribution of patient materials and clinical guidelines (Albert, Brason, Sanford, Dasgupta, Graham, & Lovette, 2011; Cochella & Bateman, 2011; Johnson, Porucznik, Anderson, & Rolf, 2011).

Apart from specific guidelines or links to guidelines, the National Pain Centre website has several tools to assist in the promotion of evidence-informed pain management. One of these is the Opioid Manager, a chart tool that supports clinical application of the principles of the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain*. This tool can be downloaded and printed, and is also available for a small fee as an iPhone app. It has been downloaded approximately 4,000 times. It has also been incorporated into a number of electronic medical records that are listed on the website. Although research is underway, the Opioid Manager has not been formally evaluated as to its impact on prescriber behaviour or patient outcomes.

Continuing education for healthcare practitioners relies to a great extent on healthcare-related industry (including pharmaceutical industry) sponsorship. Industry also uses the educational process to ensure that its products are used, but also used appropriately. The direct involvement of the pharmaceutical industry in continuing professional education and clinical practice guidelines has been criticized in the literature and media with calls by some for a total ban on industry involvement in the development of educational initiatives and the standards for such (Steinman, Landefeld, & Baron, 2012; Van Zee, 2009). However, continuing health science education accreditation bodies (professional associations and universities) have been dealing with these issues for many years and have developed operating principles (Accreditation Council for Continuing Medical Education, n.d.; American Medical Association, 2011; Canada's Research-Based Pharmaceutical Companies, 2012; Canadian Medical Association, 2007). Typically, the requirement is that educational content must be developed independent of any support and that support is given as an unrestricted grant for delivery of the educational material. Many independent bodies (professional associations and universities) exist across Canada for review and accreditation of the process and content of educational material. While some call for an independent body to receive and manage a general fund created from industry contributions to support necessary continuing educational activity, others believe strongly that healthcare providers could educate themselves without relying on industry funding.



Education Recommendations

Recommendations	Proposed Leads	Links	ST
<p>1. Establish and implement core competencies for all types of healthcare practitioners in the assessment and management of addictions, mental health, co-morbidities, concurrent disorders and pain:</p> <p>a. Identify existing competencies and standards of care to determine the extent to which they address the harms associated with prescription drugs;</p> <p>b. Develop competencies with involvement from practitioners, individuals, families, industry and the community;</p> <p>c. Work with educators to embed these competencies into the core curricula for each healthcare practitioner;</p> <p>d. Ensure that cultural considerations are reflected in these competencies;</p> <p>e. Include competencies related to the provision of trauma-informed services;</p> <p>f. Include competencies regarding understanding and influencing the determinants of health and their impact on patients' prescription drug harms;</p> <p>g. Gather knowledge of local resources for individuals and families.</p>	<p>Regulatory authorities</p> <p>Professional colleges and associations</p> <p>First Nations, Inuit and Métis leaders</p> <p>Educational institutions</p>		ST
<p>2. Develop accredited healthcare practitioner continuing education programming specific to the appropriate use of these prescription drugs:</p> <p>a. Encourage regulatory and educational authorities for prescribing and dispensing healthcare practitioners to adopt core competencies that affect the prevalence and severity of addiction and overdose, which includes patient selection, dose titration, monitoring and tapering.</p>	<p>Professional associations</p> <p>Educational institutions</p> <p>First Nations, Inuit and Métis leaders</p>		ST
<p>3. Implement accessible academic-detailing programs (e.g., RxFiles Program in Saskatchewan) that provide evidence-informed education on prescribing and dispensing practices in all provinces and territories and evaluate the effectiveness and impact of these programs:</p> <p>a. Link these programs to prescription monitoring programs, where possible, to determine change in practice.</p>	<p>Educational institutions</p>		
<p>4. Design and develop clinical decision-support tools to be used at the point of care to support effective, evidence-informed practice in the areas of addiction, mental health, co-morbidities, concurrent disorders and pain management:</p> <p>a. Conduct an evaluation to determine effectiveness and impact on practice and patient outcomes.</p>	<p>CE providers</p> <p>Electronic health records providers</p>		ST
<p>5. Develop appropriate local and long-distance clinical networks that provide healthcare practitioners with prompt and easily-accessible</p>	<p>Educational institutions</p>	T	ST



Recommendations	Proposed Leads	Links	ST
clinical advice and information (e.g., Medical Mentoring for Addictions and Pain (MMAP) in Ontario, Atlantic Mentorship Network – Pain and Addiction and the Pre-Health Professional Club in Saskatchewan). Standardize these networks across all provinces and territories.	Regulatory bodies Professional associations and societies		
6. Revise healthcare practitioner curricula to ensure that addiction, mental health, co-morbidities, concurrent disorders and pain management are addressed in undergraduate, graduate and post-graduate programs for all healthcare practitioners. These curricula should reflect identified core competencies and include: <ul style="list-style-type: none"> a. Interdisciplinary assessment; b. Both non-pharmacological and pharmacological interventions; c. Risk for addictions and potential harms associated with medications that have the potential for harms; d. Use of effective, evidence-informed practices; e. Appropriate use of prescription medications; f. Trauma-informed care; g. Culturally safe practices; h. Use of non-medical approaches to care and treatment. 	Educational institutions Regulatory bodies Professional associations and societies		ST
7. Identify, develop where needed, promote and evaluate evidence-informed guidelines and policies related to effective and appropriate prescribing practices in various settings (e.g., urgent care and hospital emergency departments).	Associations of emergency healthcare practitioners		ST
8. Train and equip multidisciplinary practitioners (e.g., healthcare practitioners, emergency medical services, law enforcement, corrections and addiction counsellors) to recognize and manage prescription drug overdoses.	EMS associations		

Treatment

Aim: Enhance system capacity to increase functionality (or decrease disability) of affected individuals, families and communities by increasing timely and equitable access to a range of effective treatment options throughout the continuum of addictions treatment including comorbidities such as pain, anxiety disorders, insomnia, and ADHD.

Context

The attention paid to problematic substance use in general is inadequate owing to a lack of addiction treatment services, the barriers to access for services and system navigation, the limited related education of healthcare practitioners and others, and a lack of coordination among the existing services (College of Physicians and Surgeons of Ontario, 2010; Manitoba OxyContin Working Group, 2009). The gap must be closed between the availability of treatment options and Canadians' treatment needs. Services and support offered to Canadians with substance-related problems need



to be strengthened and coordinated into a more seamless system. More funding and resources need to be invested in services to shorten wait times and increase access to a range of treatment options. The *Guiding Concepts of the National Treatment Strategy* (National Treatment Strategy Working Group, 2008) outline the core components that should inform treatment system improvement in Canada. The report also identifies barriers to access. While there is insufficient evidence to state that there is a lack of treatment services, it is safe to say that the system is not optimal in terms of accessibility, quality and range of service intensity.

Although, the misuse of sedative-hypnotics (i.e., benzodiazepines, barbiturates) and stimulants (i.e., amphetamines and their related compounds) have been reported, the misuse of opioids has grown exponentially with devastating consequences.

Healthcare practitioners are confronted with an increasing number of patients experiencing both acute and chronic non-cancer pain. Acute pain is a universal phenomenon. Appropriate treatment is humane and hastens recovery from a variety of underlying conditions, such as fractures and dental procedures. However, chronic pain, which serves no functional purpose, can be disabling and persists beyond the time expected for healing. No other condition in Canada incurs more healthcare costs and lost income than chronic pain (Lynch 2011; Phillips & Schopflocher, 2008).

One in five Canadian adults suffers from chronic pain (Moulin, Clark, Speechley, & Morley-Forster, 2002). It is associated with the worst quality of life, even compared with other chronic diseases such as chronic lung or heart disease (Choiniere et al., 2010). People living with chronic pain have double the risk of suicide compared with people without (Tang & Crane, 2006). Chronic pain, while hard to cure, can be managed effectively by focusing on the goal of improved functioning using medication, nerve blocks, physiotherapy, rehabilitation and cognitive behavioural therapy, self-management, and other methods.

Treatment to address the harms associated with prescription drugs occurs along a continuum, beginning with diagnosis and assessment of addiction, mental illness, co-morbidities, concurrent disorders and pain. It includes provision of medication-assisted treatment (e.g., methadone and buprenorphine/naloxone maintenance where appropriate), withdrawal management and non-pharmacological approaches. Treatment requires a coordinated intervention strategy focusing on appropriate prescribing practices and thereby also reducing the volume of available prescription drugs accessible through diversion and addressing prescription drug harms, without undermining the availability and quality of care for conditions where prescription drugs are indicated (e.g., ADHD, chronic or cancer pain).

Within an enhanced, needs-based, coordinated, accessible, responsive and well-functioning system of care, therapies and support services must be seen as viable and be funded and supported appropriately. In most provinces, buprenorphine/naloxone can only be prescribed by physicians with a methadone exemption, and/or for patients in whom methadone is contraindicated (as in the case of QT syndrome). The availability of methadone is not keeping pace with the need; access to this treatment is often inconsistent and, in some areas, non-existent (Luce & Strike, April 2011). Advocacy is needed to improve access to methadone, a treatment approach shown through research to be effective, and other opioid treatment options, and to the number of physicians who can prescribe it. All opioid treatment programs should include a comprehensive care model wherever feasible, while taking into account evidence that maintenance programs are effective when compared to no treatment. Opioid Medication Assisted Treatment (e.g., methadone or buprenorphine/naloxone) serving First Nations populations can be more effective when they are linked to and collaborated with First Nations community health programs (Health Canada, 2011).



The importance of the role of primary care in the management of addictions, mental health, co-morbidities, concurrent disorders and pain cannot be overstated. Primary care practitioners need access to appropriate unbiased education and support to assess and manage these conditions, as well as access to referral pathways when the problem is severe. Shared-care and collaborative-care models that involve local networks of pain, addictions, mental health, primary care and other sectors should be developed. Recognition of the role and usefulness of team-based approaches, including Elders and cultural supports as part of a multidisciplinary team, would allow knowledge exchange between healthcare practitioners and other service providers to ensure coordinated care plans, and also promote information sharing, dialogue and teamwork to address the stigma and fears linked to the use of medication (Health Canada, 2011).

In Ontario, there are good examples of treatment approaches that have been inclusive of First Nations community values so that tapering in opiate substitution therapy is seen as possible and is inclusive of alternative therapies and culture-based treatment practices. The strict disease model that promotes lifelong dependency does not align with First Nations values, culture and spiritual beliefs. Developing the relevant and culturally safe approach to address the harms of prescription drugs in First Nations must include their voice and in this regard, there must be clearly defined and culturally respectful ways to exchange ideas and strategies.

A network of experts, available through the use of communications technologies such as webinars and telemedicine, could provide supervision, mentorship and peer consultation to primary care practitioners and enhance access to expertise in underserved areas of Canada. One example of such a network is the Atlantic Mentorship Network – Pain and Addiction referred to in the Education context.

There is a lack of research into the development and evaluation of effective, evidence-informed screening, brief intervention and referral to treatment for prescription drug-related harms, as there are few approaches currently available and they only demonstrate short-term effectiveness (i.e., 3-6 months) (Bashir, King, & Ashworth, 1994; Otto et al., 2009; Zahradnik et al., 2009).

Manufacturers of medications, funders of drug formularies and the healthcare community all have a significant role to play in diminishing the harms from prescription drug misuse. This effect can be achieved by implementing policies and practices in healthcare settings to promote the judicious use of prescription drugs. Universally adopting the practice of prescribing and dispensing just enough medication, with the least chance for harm, will contribute to a reduction in the amount of medications that are prescribed and subsequently misused.

Timely and equitable access to treatment that is holistic, effective and appropriate can be achieved through changes to policy and regulation, funding mechanisms, evidence-informed practice and exchange of new and emerging practices. Individual patients and others with lived experience should be included in decision making or on advisory bodies to ensure that system changes are accessible, relevant and responsive.

Treatment Recommendations

Recommendations	Proposed Leads	Links	ST
1. Identify and develop, as needed, and evaluate policies, regulations and formulary reforms that reduce barriers to evidence-informed care and promote safe, evidence-informed treatment options:	Regulatory authorities	L&R	
a. Review and promote equitable access to optimal evidence-	Professional associations	E	
	Health Canada	M&S	



Recommendations	Proposed Leads	Links	ST
<p>informed pharmacological and non-pharmacological treatment options for addiction, mental health, co-morbidities, concurrent disorders and pain (e.g., shared care models);</p> <p>b. Identify existing prior authorization strategies for prescription drugs (with a particular focus on high-potency opioids and extended-release formulations) and work with funders to implement effective strategies:</p> <p>i. Engage potential funders including public and private insurers and regulatory bodies;</p> <p>ii. Evaluate for effectiveness, cost-effectiveness and unintended consequences;</p> <p>iii. Interlink with evidence-informed guidelines and as part of a comprehensive integrated approach;</p> <p>iv. Review and promote equitable access to evidence-informed treatment options to identify and address legislative and other barriers (e.g., standardize treatment reimbursement).</p>	<p>Insurers</p> <p>Research organizations</p> <p>Healthcare institutions</p>	<p>P</p> <p>P</p> <p>Ed</p>	
<p>2. Provide evidence-informed, tailored and culturally-appropriate risk-reducing strategies (e.g., short-course dispensing in public insurance plans):</p> <p>a. Reduce the availability of high-risk drugs, including over-the-counter products, with poor evidence of effectiveness;</p> <p>b. Implement systems to mitigate unintended consequences of formulary reform.</p>	<p>Funders</p> <p>Regulatory bodies</p>		
<p>3. Identify; develop, as needed; promote and evaluate funding mechanisms and incentives that:</p> <p>a. Improve and promote access to treatment, which should include:</p> <p>i. Pharmacological interventions;</p> <p>ii. Psychosocial support and counselling; and</p> <p>iii. Withdrawal management programs.</p> <p>b. Improve and promote access to withdrawal management programs, including in rural and remote areas and for those on opioid treatment or other medications;</p> <p>c. Create multidisciplinary teams (e.g., family care clinics and primary care networks) that have the expertise and can provide the full range of treatment options related to pain, mental illness, concurrent disorders, co-morbidities and addiction, including cultural practices and interventions;</p> <p>d. Improve and promote the use of and access to non-pharmacological approaches for the effective treatment of:</p> <p>i. Prescription drug misuse;</p> <p>ii. Mental illness;</p>	<p>Funders</p> <p>Regulatory bodies</p> <p>Healthcare institutions</p>		



Recommendations	Proposed Leads	Links	ST
<ul style="list-style-type: none"> iii. Co-morbidities and concurrent disorders; and iv. Acute and chronic pain. e. Ensure treatment system capacity for an adequate number of accessible, trained and skilled health practitioners and family and community agencies; f. Develop mechanisms to optimize the use of prescription drugs to maximize the benefit and reduce harms through practices, policies and choices of treatment options. 			
<p>4. Promote the use of evidence-informed guidelines for treatment of addiction, mental illness, co-morbidities, concurrent disorders, and acute and chronic pain (including effective non-pharmacological approaches):</p> <ul style="list-style-type: none"> a. Review and critically appraise existing international guidelines (e.g., Institute of Medicine standards) to identify best practices internationally and existing gaps in Canadian guidelines; b. Develop new or update existing guidelines as needed with input from specialty societies (e.g., emergency physicians, nurse practitioners, family practitioners) representing various healthcare settings: <ul style="list-style-type: none"> i. Search for and appraise existing guidelines; ii. Assess the adaptability of existing guidelines to various settings and/or the need for new guidelines; iii. Adapt guidelines as indicated; iv. Develop new guidelines as indicated; and v. Update existing guidelines as needed; c. Promote (through training and the provision of resources) the value and use of evidence-informed guidelines; d. Ensure that healthcare practitioners have access to evidence-informed practice guidelines; e. Identify effective non-pharmacological approaches for use with specific conditions (addiction, mental health, co-morbidities, concurrent disorders and pain); f. Revise the opioid guidelines to ensure they are culturally-appropriate and can be implemented in rural and remote settings; g. Expand the implementation of evidence-informed clinical practice guidelines (e.g., buprenorphine/naloxone, opioid use and Neonatal Abstinence Syndrome). 	<p>CAMH</p> <p>Professional associations</p> <p>First Nations, Inuit and Métis leaders</p> <p>CADTH</p>	<p>Ed</p>	<p>ST</p>



Recommendations	Proposed Leads	Links	ST
5. Develop and promote the use of evidence-informed culturally appropriate individual, family and community resources to assess, prevent, reduce the harms associated with, and provide access to appropriate treatment for prescription drug problems, as well as adjunct therapies.	ISMP Canada Community agencies Patient and family associations First Nations, Inuit and Métis leaders		
6. Identify, develop, evaluate and implement effective, evidence-informed screening, brief intervention and referral to treatment for prescription drug harms that: <ul style="list-style-type: none"> a. Are tailored to healthcare (e.g., physicians, nurses, pharmacists, dentists) and social service practitioners; b. Can be used with/adapted for a variety of patient groups (e.g., those with addiction, dependence, mental health, co-morbidities, concurrent disorders, chronic pain, etc.); c. Are culturally relevant; d. Can be used for self-screening by individuals and families; e. Are linked to community-based treatment and other relevant services. 	CAMH Professional associations First Nations, Inuit and Métis leaders		ST
7. Healthcare practitioners should use validated risk-assessment tools to help determine a patient's risks associated with prescription drugs: <ul style="list-style-type: none"> a. Review the evidence related to existing risk assessment tools (e.g., Screener and Opioid Assessment for Patients with Pain; Opioid Risk Tool) to ensure validity of tools being promoted; b. Include this activity in any relevant guidelines, as appropriate. 	Professional associations Regulatory bodies	Ed	
8. Ensure healthcare practitioners have timely access to expertise to support evidence-informed clinical decision making: <ul style="list-style-type: none"> a. Establish communities of practice and networks of networks to increase competencies to manage the complexities of prescription drug misuse; b. Develop shared-care and collaborative-care models to address prescription drug harms and related co-morbidities that involve local networks of key health fields (e.g., pain, addictions, primary care, etc.); c. Identify, promote, expand, establish and evaluate networks of experts to provide supervision, mentorship and peer support to primary care practitioners in the areas of addiction, mental health, co-morbidities, concurrent disorders and pain management: <ul style="list-style-type: none"> i. Connect with and review existing models: <ol style="list-style-type: none"> 1. Medical Mentoring in Addiction and Pain (MMAP) (Ontario); 2. Pharmacist Mentoring in Addiction and Pain (PMAP) 	Provincial and territorial governments Health Canada Canadian Executive Council on Addictions First Nations, Inuit and Métis leaders	Ed	



Recommendations	Proposed Leads	Links	ST
<p>(Ontario);</p> <p>3. Atlantic Mentorship Network – Pain and Addiction;</p> <p>4. Elder models working with healthcare practitioners;</p> <p>ii. Establish targets and determine how measurement will be executed;</p> <p>iii. Conduct evaluation for effectiveness and cost-effectiveness;</p> <p>d. Develop and promote individual and community self-management tools for addiction, mental health, co-morbidities, concurrent disorders, and pain, across the full continuum of care.</p> <p>9. Align current investments in the treatment sector that are working towards common aims.</p>	<p>Federal government</p> <p>Industry</p> <p>Provincial/territorial governments</p> <p>Research institutions</p> <p>Health care organizations</p> <p>Patient and family groups</p>		

Monitoring and Surveillance

Aim: Develop a coordinated national surveillance system related to prescription drugs, leveraging existing opportunities, including linkages to prescription monitoring programs, and monitoring overall key outcomes related to misuse, abuse and harms.

Context

A pan-Canadian surveillance system would be responsible for the ongoing collection, analysis and dissemination of information to those who need to know in order to inform policy and practice. It is an essential component of any strategy designed to address the harms related to prescription drugs such as opioids, sedative-hypnotics and stimulants.

The goals of a national surveillance system related to prescription drugs are to:

- Track, on an ongoing basis, patterns of prescription drug misuse and harms at national, provincial, territorial and regional levels;
- Identify priority issues, trends and areas that require additional focus, intervention or research;
- Evaluate the impact of interventions; and
- Develop an annual status report on the state of the Canadian surveillance 'system' and the issue in Canada.



Existing activities to monitor the harms associated with prescription drugs in Canada are fragmented. Discrete information is tracked by different federal and provincial agencies within their respective jurisdictions, as well as by organizations such as the Institute for Safe Medication Practices (ISMP) Canada. While some data are available, among existing surveys there is no consistency in terminology, the prescription drugs that are evaluated or the target populations. The data sources that do exist in Canada, such as coroner reports, poison centre records, IMS Health data, losses and thefts data, post-market surveillance related to adverse events data, medication incidents and law enforcement records, are not part of any comprehensive national initiative. There is no single group dedicated to addressing these issues. Effective action will require multi-stakeholder collaboration.

A Canadian prescription drug surveillance system would incorporate a repository for pan-Canadian data. It would provide access to data in a timely manner and support informed decision making on matters of policy and practice. A surveillance system would generate baseline indicators regarding the harms associated with prescription drugs, and be linked with a pan-Canadian response to the issue. Such data would help evaluate intervention strategies and lead to more effective support and care.

Prescription monitoring programs (PMPs) are a core part of a broader surveillance system. They monitor the prescription and disbursement of prescription drugs designated as controlled substances. They support interventions to reduce or prevent the harms associated with these drugs. PMPs can provide evidence of suspected misuse and produce timely and critical information to a prescriber or pharmacist about a patient's controlled substance prescription history. This information helps to identify high-risk patients who can benefit from early interventions. Current programs are not comprehensive, vary by province and are at different stages of development.

Evidence suggests PMPs can be effective in improving the prescribing practices related to controlled substances and addressing the prescription drug problem. For example, some research has shown that PMPs are associated with reductions in the rate of increase of opioid abuse and opioid treatment admissions in the United States and reductions in high-risk prescribing practices for opioids and benzodiazepines in Canada (Dormuth, Miller, Huang, Mamdani, & Juurlink, 2012; Reifler et al., 2012). There is a lack of understanding related to the significance of evidence arising from aggregated PMP data. This research will increase knowledge on prescribing patterns and provide insight into the harms associated with prescription drugs.

Expert opinion (Ohio Prescription Drug Abuse Task Force, 2010) suggests that regulatory bodies for healthcare practitioners should regularly monitor prescribing practices to reduce high-risk prescribing behaviour. Several approaches have been identified as potentially effective in addressing prescribing practices. These approaches include educational or warning letters, audit and feedback, and mandatory prescribing limits (Gonzales & Kolbasovsky, 2012; Vik, Ulan, Wright, Mah, & Virani, 2012). Research is lacking, however, on the possible unintended consequences of these types of interventions, such as potential negative impacts of broadly applying restrictions in clinical care.

Federal, provincial and territorial privacy law, which is not harmonized across jurisdictions, is a significant challenge not unique to the monitoring and surveillance stream. Legislation limits how and why personal data are collected and stored. Limited understanding of this legislation impacts how these data are used and shared.



Monitoring and Surveillance Recommendations

Recommendations	Proposed Leads	Links	ST
<p>1. Standardize the key elements of a Canadian prescription drug surveillance system, such as:</p> <ul style="list-style-type: none"> a. Data holders; b. Data streams (e.g., coroner reports, poison centre records, IMS Health data, losses and thefts data, post-market surveillance related to adverse events data, medication incidents); c. Definitions and common terminology; d. Indicators (explore potential linkages with other projects such as the National Treatment Indicators, Drug and Alcohol Network of Surveillance Experts [DANSE], Canadian Tobacco, Alcohol and Drugs Survey [CTADS], existing provincial surveillance systems); e. Collection methods; f. Reporting; g. Links with data systems for alcohol and other drugs, as well as risk factors and sentinel surveillance for local planning. 	<p>Federal government</p> <p>Professional associations</p> <p>ISMP Canada</p>		ST
<p>2. Convene a Canadian Prescription Drug Surveillance Task Force to operationalize a national surveillance system based on the standardized elements established in recommendation number 1.</p>	CCSA		ST
<p>3. Create a Canadian community of practice for Prescription Monitoring Programs (PMPs):</p> <ul style="list-style-type: none"> a. Identify and share effective and evidence-informed practices; b. Establish standardized components of Canadian PMPs; c. Leverage resources; d. Benefit from and share with international programs; e. Collaborate on research; f. Engage in knowledge exchange; g. Provide knowledge and expertise to jurisdictions interested in developing PMPs; and h. Determine the effectiveness of specific promising practices, such as real-time access by prescribers and dispensers. 	<p>Health Canada</p> <p>CCSA</p> <p>Provincial and territorial prescription monitoring programs</p>	T	ST
<p>4. Encourage and assist regulatory bodies to actively monitor and intervene, as needed, with members to reduce high-risk prescribing or dispensing practices, as supported by data and evidence. This can be achieved in collaboration with existing PMPs, where available.</p>	<p>Health Canada</p> <p>Regulatory authorities</p> <p>Federation of Medical Regulatory Authorities of Canada</p> <p>Provincial and territorial prescription monitoring programs</p>		



Recommendations	Proposed Leads	Links	ST
5. Assist all provinces and territories to have PMPs implemented by 2015 and standardization in place by 2017.	Provincial and territorial governments Canadian PMP Network		
6. Ensure that there is appropriate provincial and territorial PMP legislation to:	Provincial and territorial governments Canadian PMP Network		
a. Assess when information sharing is appropriate;			
b. Provide a framework for governance and operations of PMPs, where appropriate; and			
c. Facilitate information sharing within and across jurisdictions. To this end, conduct a legislative review of provincial and territorial privacy legislation relevant to PMPs that will allow for information-sharing, where appropriate, among healthcare professionals, licensing authorities, law enforcement, researchers, provinces and territories, and governments.		L&R	
7. Establish an ongoing formal program of research on the effectiveness of PMPs, core components and impact, including unintended consequences.	Canadian PMP Network Research organization		
8. Align current investments in the monitoring and surveillance that are working towards common aims.	Federal government Professional associations Research bodies and health organizations Industry Patient groups Data sources		ST

Enforcement

Aim: To advocate for the tools and resources required by law enforcement to effectively prevent diversion and to intervene, suppress and address criminal actions to prevent or reduce the illicit use, including diversion and trafficking, of prescription drugs.

Context

Law enforcement agencies across Canada are beginning to recognize that the illegal use of prescription drugs is a major and growing problem. However, these agencies are encountering significant operational and systemic challenges that hinder their ability to play their part and intervene successfully in the reduction of prescription drug diversion (Public Safety Canada, 2011b).

The challenges posed when addressing the illegal use, including the diversion and trafficking of prescription drugs, differ from other law enforcement interdictions because the targets — prescription drugs — are legal, are readily available and have a legitimate role in the treatment of various health conditions. When prescribed and used appropriately, opioids, sedative-hypnotics and



stimulants have therapeutic benefits for people experiencing pain or those with certain illnesses. However, law enforcement has to deal with the harms associated with prescription drugs, especially their diversion from the legal supply chain and the resulting harms to the health and safety of individuals, families and communities.

Diversion of prescription drugs to the illegal market occurs at breaks in the manufacturing and supply chain management processes, as well as through thefts and robberies from delivery vehicles, storage facilities, pharmacies, dental offices, hospitals, private dwellings and through improper disposal. Diversion to the illegal market also results from healthcare fraud (e.g., “double doctoring” and “doctor shopping”), prescription theft and forgery, and Internet purchases from unregulated sources.

Individuals who obtain these drugs legally contribute to diversion when they use them in ways other than as they were prescribed, share them with others or sell them for profit. Prescription drugs are lucrative to sell, owing to their high profit margin and the ease with which they can be carried compared to illegal drugs. Diversion can be committed both by individuals and by organized crime groups involved in drug trafficking.

According to the RCMP's 2009 *Drug Situation Report* (RCMP, 2010), opiate derivative medications, particularly oxycodone, as well as benzodiazepines, were among the top diverted controlled prescription drugs across Canada that year. The report indicated that prescription drugs were also being illegally manufactured to respond to the growing demand by foreign sources. However, the report also indicated that most prescription drugs are still obtained through legitimate domestic sources. The Criminal Intelligence Service of Canada's 2010 *Report on Organized Crime* indicated that the prescription drugs commonly trafficked in Canada include sedatives, stimulants, opioid pain relievers and steroids.

Over 5,000 new litigation files handled by the Public Prosecution Service of Canada involving charges laid under the *Controlled Drugs and Substances Act* in 2011–2012 pertained to prescription drugs. These were in addition to more than 3,000 files carried over from previous fiscal years. The highest numbers of such files pertained to opioid pain relievers.

In addition to being diverted through the illegal market, prescription drugs are commonly passed on by, taken from or shared among friends and family members. Results of the 2011 *Ontario Student Drug Use and Health Survey* show that 67% of Ontario youth who reported using an opioid pain reliever non-medically in the past year indicated they obtained the drugs from someone at home (Paglia-Boak et al., 2011). Most people do not understand the risks of sharing these medications with or “helping out” their friends or family members who have acute or chronic pain or anxiety, for example.

Because many prescription drugs that are harmful and misused come from the medicine cabinets of friends and families, the proper medical storage and disposal of prescription drugs can effectively reduce diversion (Florida Office of the Attorney General, 2012; Public Safety Canada, 2011b; Wisconsin State Council on Alcohol and Other Drug Abuse, 2012). Various prescription drug take-back initiatives are underway in Canada. These initiatives aim to reduce the volume of prescription drugs available for diversion and inform the public of the harms associated with prescription drugs and actions they can take to reduce the risks.

A number of issues impede law enforcement efforts to reduce diversion. When investigating criminal distribution, the legal status of prescription drugs poses a major challenge. Unlike illegal drugs, investigations for illegal prescription drug use must prove that the prescription drugs were illegally



obtained or are being used illegally. Additional police resources are required when building and proving a case.

Given the complexity and increasing reach of the problem, there is a need to raise awareness among law enforcement and justice officials, not only about the impact of the problem on public safety, but also about the costs and the tools and resources needed to conduct effective investigations and make referrals to appropriate community supports and services.

There is a need to review training resources on prescription drug issues available to police officers, which should include strategies to identify and intervene with people who are misusing and make referrals to appropriate community resources. A review of privacy legislation could potentially enable the sharing of information among law enforcement, prescribing and regulatory authorities, and healthcare professionals.

Research is needed to assess the cost and impact of illegal prescription drug use, including diversion and trafficking, on law enforcement budgets and public safety, and on other parts of the criminal justice system. The standardization of death investigations across the country will contribute to our understanding of the impact of the prescription drug crisis in Canada. Law enforcement and healthcare professionals should continue to explore cross-jurisdictional and interdisciplinary communication and collaboration opportunities, while respecting privacy legislation. Because large volumes of prescription drugs come from legitimate sources, the problem will not be solved with enforcement measures alone.

Enforcement Recommendations

Recommendations	Proposed Leads	Links	ST
1. Determine the impact of addressing illicit use, including the diversion and trafficking of prescription drugs, on law enforcement resources for policing and related activities, such as prosecution and corrections, and identify specific recommendations for action to prevent diversion for criminal purposes: a. Conduct a cost-impact assessment related to prescription drugs on law enforcement resources and public safety.	Public Safety Canadian Bar Association Canadian Civil Liberties Association Advocacy groups		ST
2. In order to prioritize the issue, raise awareness among key law enforcement and justice bodies (e.g., Canadian Bar Association, the Canadian Judges Forum, Canadian Judicial Council) regarding the impacts related to the illicit use of prescription drugs	Canadian Association of Chiefs of Police, Drug Abuse Committee FPT Governments (public safety, health)		ST
3. Promote the safe storage and disposal of prescription drugs: a. Review or develop protocols for police, regional public health organizations, local pharmacies and others to implement and evaluate take-back initiatives that aim to encourage the safe storage, distribution, and disposal of narcotics and other controlled drugs, including the risks of sharing or lending prescription drugs; b. Collaborate with regional public health organizations and local pharmacies to develop guidelines for the storage and disposal of prescription drugs;	Public Safety Canadian Association of Chiefs of Police Public Health Health Canada CCSA Industry	M&S	ST



Recommendations	Proposed Leads	Links	ST
<ul style="list-style-type: none"> c. Review the evidence related to and evaluate the impact of take-back initiatives (e.g., awareness, amount of drugs no longer available for diversion, public security outcomes, reduced harms and unintended consequences, if any) d. Identify, review or develop regulations related to the measurement and disposal of medications returned to pharmacies or other locations. 		<p>P</p> <p>P</p>	
4. Identify gaps in tools or training for criminal justice professionals to better address the illicit use of prescription drugs, including the need to make appropriate and timely referrals to community services to reduce the harms related to prescription drug use			
5. Ensure that death investigations across Canada are conducted in an evidence-informed and consistent manner:	Office of the Chief Coroner Provincial and territorial governments	M&S	
<ul style="list-style-type: none"> a. Review protocols, policies and practices related to drug intoxication (overdose) deaths; b. Develop and promote the implementation of a death investigation guideline for coroners and medical examiners that includes information on prescription drugs, as well as the impact of these drugs on cause of death or factors associated with cause of death, and that clarifies morphine equivalents. c. Require that all provincial death investigations systems in Canada adopt practices that seek to document with care the names and dosages of drugs suspected to have contributed to the deaths. In particular, prescription drugs should be converted to dosage reporting (e.g., "morphine equivalents," in the case of opioid use) to allow death investigators, researchers and police to understand the contribution of drug dosages to the death, particularly where they exceed established national guidelines. d. Identify and address barriers to immediate access to and sharing of relevant information related to the death investigation by death investigators, prescribers and dispensers, and across jurisdictions 		<p>L&R</p> <p>M&S</p>	ST
6. Identify and address barriers to immediate access to and sharing of relevant information of arrests and convictions of possible diverters between law enforcement and regulatory colleges, prescribers and dispensers:	Federal, provincial and territorial governments Regulatory bodies	M&S	
<ul style="list-style-type: none"> a. Compliance inspection from federal, provincial and territorial governments; b. Compliance by governments and regulatory bodies also part of the enforcement process; 			



Part F: Legislation and Regulations

Countries have been tackling the health, social and economic harms associated with prescription drugs for decades. No fewer than 13 treaties and protocols have been adopted over the past 100 years under the auspices of the United Nations and its predecessor, the League of Nations. The three U.N. conventions that today govern the import and export, production, distribution and possession of psychoactive substances are the U.N.'s most universally implemented treaties (United Nations, 1961, 1971, 1988). In Canada, prescription drugs are governed by legislative and regulatory requirements enacted and monitored by federal, provincial and territorial governments, and professional governing bodies.

Controlled Drugs and Substances Act

The *Controlled Drugs and Substances Act* (CDSA) provides for the control of substances that can alter mental processes and can produce harm to health and to society when diverted or misused. Except as authorized under its related regulations, possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of most controlled substances, are prohibited under the CDSA. Through the administration of the CDSA and its regulations, Health Canada implements programs that are designed to control the movement of prescription drugs containing controlled substances into, out of, and within Canada so as to minimize the risk of diversion to an illegal market, while ensuring that controlled substances remain in legal distribution channels for legitimate medical, scientific and commercial use.

Controlled substances are listed in six schedules to the CDSA and for each schedule there is a set of penalties for offences involving substances in that schedule. For example, there are offences and penalties associated with the possession of opioids (generally listed in Schedule I) and stimulants, such as methylphenidate (generally listed in schedule III), but not for simple possession of benzodiazepines, such as lorazepam (generally listed in schedule IV). However, “multiple doctoring” for any of these three categories of drugs constitutes a punishable offence (see Appendix III).

Enforcement of the CDSA for Prescription Drugs Containing Controlled Substances

Several factors can hamper the attempts by law enforcement to mitigate the diversion of prescription drugs, including:

- The absence of a prescription drug monitoring system in many jurisdictions;
- Legal limitations on the disclosure of personal information;
- A lack of training for complex investigations of activities associated with legal products;
- A lack of allocated resources; and
- The complexity of investigating health professionals who might be involved in diversion.



For example, without strong intelligence from reliable sources, a police officer wanting to investigate suspected “multiple doctoring” violations must first obtain search warrants based on probable cause. The officer must then examine and extract records from all unknown pharmacies and visit each prescribing physician to gather evidence.

Regulations Governing Prescription Drugs Containing Controlled Substances

There are several regulations under the CDSA that authorize activities regarding prescription drugs containing controlled substances. For example, the *Narcotic Control Regulations* govern activities involving opioids. *Benzodiazepines and Other Targeted Substances Regulations* govern activities with any sedatives and Part G of the *Food and Drug Regulations* governs activities with stimulants such as methylphenidate.

All three sets of regulations cover activities performed by manufacturers, wholesalers, hospitals, pharmacists and practitioners. In all cases, regulated parties must have security measures in place to protect against loss and theft.

Licensed dealers intending to import, export, produce, sell or distribute prescription drugs containing controlled substances must meet specific criteria, such as criminal record checks, to obtain a licence from the Minister. Import and export can be conducted only by licensed dealers using permits issued for each transaction. The Minister can refuse to issue, revoke or suspend a license or permit.

The regulations do not cover the licensing of hospitals, but do govern the distribution and use of prescription drugs containing controlled substances within hospitals. The regulations limit purchasing to authorized persons. Distribution of prescription drugs containing controlled substances to patients must be authorized by practitioners and adequate internal controls must be kept by the person in charge of the hospital and his or her delegates.

Pharmacists are also responsible for the destruction of unused or expired prescription drugs containing controlled substances when they are returned to pharmacies. While technically these returned controlled substances should be recorded as part of the pharmacy's inventory of controlled substances, this is rarely done in practice because returns from individuals often contain unmarked or unpackaged medications that are thus not identifiable as controlled substances.

An important provision governing practitioners states that a practitioner can only prescribe a controlled substance when the recipient is a patient under his or her care and the drug is required as part of treatment. Despite the requirement that practitioners can only prescribe for someone under their care, they do not always have the tools they need to know if someone has already received a prescription for the same drug or a different drug indicated for treatment of the same symptoms. Although covered by professional and ethical standards of practice, prescribers are also expected to educate themselves and their patients on the appropriate use and potential side effects of the drugs prescribed. This is key to detecting accidental misuse, overdose and the signs of misuse.

The Minister must, upon request, share certain information related to pharmacists and practitioners with their respective provincial or territorial licensing authority, if certain conditions are met. Where a practitioner or a pharmacist violates certain provisions in the regulations, the Minister can issue a notice that prohibits the practitioner or pharmacist from conducting certain activities, such as prescribing or ordering controlled substances. This notice would be distributed to certain persons and organizations, including licensed dealers across Canada and pharmacists in the province where



the practitioner or pharmacist practices. Ministerial discretion is subject to specific conditions, including prior consultation with the appropriate provincial licensing authority.

Part of the rationale for developing the CDSA in early 1990s was to consolidate Canada's drug control legislation into a single comprehensive instrument. The federal government had to take into account Canada's commitments under the United Nations Drug Control Conventions to include precursor chemicals used in the illicit production of controlled substances, and recommendations from the Dublin Commission to further control anabolic steroids and address trends in drug abuse such as "designer drugs". There are now numerous sets of regulations under the CDSA, and while they each have their own purpose, there are inconsistencies and gaps that, if addressed, could make the framework more transparent and could make it easier for regulated parties to comply.

Health Canada also recently created new regulations that allow nurse practitioners, midwives and podiatrists to prescribe and administer certain controlled substances when treating patients, if they are authorized to do so under provincial or territorial legislation.

Compliance Monitoring

The CDSA and its regulations provide a framework governing the production and movement of controlled substances, including prescription drugs containing controlled substances. The department's ability to maximize compliance and enforcement activities is dependent on its ability to review and analyze comprehensive supply chain data, assess areas of highest risk and target compliance activities accordingly. Health Canada's ability to detect and prevent the diversion of prescription drugs needs to be strengthened.

In the past, Health Canada had programs for national prescription monitoring and compliance monitoring, down to the retail level. These programs were based on the submission of monthly reports of sales for select psychoactive prescription drugs by licensed dealers and the bi-monthly submission of similar reports from pharmacists. Monitoring activities and reporting requirements were dismantled in the mid-1990s, marking a shift from monitoring controlled substances in the supply chain toward a focus on safety and efficacy under the *Food and Drug Regulations*. From this time until 2007, the only compliance activities being performed by Health Canada related to controlled substances were security inspections of licensed dealers, issuance of authorizations for the disposal of unused, expired or unserviceable controlled substances by hospitals and pharmacies, and a small number of investigations.

In 2007, using funds made available under the Enforcement Action Plan of the National Anti-Drug Strategy, an inspection program for controlled substances was re-introduced with a focus on inspecting licensed dealers under the *Precursor Control Regulations*. Precursor chemicals are substances essential to the illegal production of substances such as methamphetamine and MDMA (ecstasy), but that are also used for a wide array of legitimate purposes (e.g., substances to produce fragrances, flavouring agents, petroleum products, fertilizers and paints).

In late 2010, the inspection program was extended to controlled substances with the establishment of a new risk-based compliance and enforcement plan that links the level of oversight and frequency of inspection with a licensed dealer's history, the substances the dealer handles and the activities for which he or she is licensed. Health Canada also collaborates with provincial and territorial licensing authorities for pharmacy and medicine, and law enforcement partners on various compliance promotion and education activities.



The Food and Drugs Act and Regulations

Part of the purpose of the *Food and Drugs Act* (1953) is to prevent deceptive or unsafe practices in the production, sale, advertisement, packaging, labelling and storage of drugs as defined in Part C of the *Food and Drug Regulations*. These regulations set out a series of pre-market approval requirements for new drugs, including the requirement to obtain a Notice of Compliance (NOC), specific labelling and packaging requirements depending on the type of drug being sold, and the requirement for labels to include a drug identification number prior to sale. Manufacturers are also required to adhere to specific production standards and good manufacturing practices, and manufacturers and importers must hold an establishment licence indicating compliance with these requirements. There is no basis in the *Food and Drugs Act* for the Minister of Health to withhold approval of a drug where the drug is otherwise considered safe and effective for its recommended use. The law does not permit approval to be withheld on the basis of misuse.

Other Federal Legislation that Require Consideration in Addressing Prescription Drug Misuse

The *Criminal Code of Canada* contains general provisions dealing with theft, robbery, fraud and conspiracy to commit such crimes, all of which can be committed with respect to prescription drugs. In addition, its provisions governing organized crime, seizure and forfeiture of the proceeds of crime can apply to large-scale cases of prescription drug diversion.

The *Personal Information Protection and Electronic Documents Act* (2000) governs the collection, protection, use and disclosure of personal information associated with “any work, undertaking or business that is under the legislative authority of Parliament.” The Act covers personal health information.

The *Privacy Act* (1985) protects personal information collected by the federal government. It applies strictly to federal departments, whereas PIPEDA applies to the private sector. The Privacy Commissioner oversees both PIPEDA and the *Privacy Act*. Privacy legislation can present a barrier to information sharing among members of the healthcare team and across sectors such as with social services and enforcement, at least in part because of misinterpretation of the legislation.

The *Canadian Charter of Rights and Freedoms* (1982) has had an impact on the legal regime governing prescription drugs, including enforcement and compliance activities.

First Nations in Canada under self-government can also develop their own legislation to deal with substances, enforcement and health care. For example, some First Nations communities have legislation banning alcohol and others who have established their own First Nations Health Authority provide buprenorphine outside of the Non-Insured Health Benefits program.

Recent Announcements

As of November 2012, Health Canada imposed new conditions to licences held by dealers authorized to perform activities with products containing controlled release formulations of oxycodone. In addition to requirements for loss and theft reporting to both Health Canada and law enforcement, companies will now be required to report suspicious or unusual activities. Health Canada inspectors will investigate anything that seems suspicious and appropriate action will be taken, including suspending or revoking a licence to produce, distribute or sell these drugs. If illegal



activity is suspected, inspectors will refer the case to law enforcement. The goal of these new conditions is to facilitate closer communication between Health Canada and the companies involved in supplying these risky types of products.

Legislation and Regulations Recommendations

Recommendations	Proposed Leads	Links	ST
1. Review Health Canada's regulatory and related information requirements throughout the supply chain, from manufacturers and distributors to the healthcare practitioners who prescribe and dispense, including the drug approval process, to examine vulnerabilities in supply chain, identify information required to exercise levers, work with provinces and territories to access necessary information and strengthen regulations as indicated.	Health Canada		
2. Review the federal and provincial/territorial regulatory requirements for medication-assisted treatment (e.g., methadone or buprenorphine/naloxone) to determine the extent to which they act as barriers or facilitators of access to treatment; consider the safety features that are addressed by these regulations and recommend revisions as indicated: a. Recognize the role that First Nations governments have with regard to medication-assisted treatment (e.g., methadone or buprenorphine/naloxone) in their communities.	Health Canada Provincial and territorial governments		
3. Determine whether regulations are required to reduce the risk of diversion associated with the handling of unused prescription drugs when they are returned directly to pharmacies for destruction.	Health Canada	M&S En P	
4. Consider implementation of complete lifecycle surveillance as a condition of approval of new and existing branded or unbranded opioids, sedatives and hypnotics, and stimulants to enhance understanding of their potential risks and therapeutic effectiveness.	Health Canada Provincial and territorial governments		
5. Review and, if necessary, recommend amendments to existing privacy legislation to help facilitate information sharing related to prescription monitoring programs among prescribers, dispensers and other health practitioners, as well as with law enforcement and industry, where appropriate and considered, and with a view not to criminalize addiction and to differentiate this from criminal diversion. Recommend amendments as necessary. a. Where existing legislation allows the sharing of information, provincial and territorial governments, working with their information privacy commissioners, should develop plain language guidance to practitioners so that they fully understand and can implement the scope of the legislation.	Provincial and territorial governments Regulatory authorities Provincial and territorial privacy commissioners		



Part G: Research and Knowledge Exchange

According to 2002 estimates, substance misuse and harms costs Canadians close to \$40 billion, most of which is associated with alcohol and tobacco (Rehm et al., 2006). There is currently no information on the costs of prescription drug misuse and harms in Canada. Recent research from the United States estimates the annual cost of the non-medical use of prescription opioids to be more than \$50 billion, with lost productivity and crime accounting for 94% of this amount (Hansen et al., 2011). To effectively address the issue, the direct and indirect costs of prescription drug misuse and harms must be quantified, both across the Canadian healthcare system and within society.

Social and environmental conditions of certain populations in Canada have been identified as possibly contributing to rates of prescription drug misuse and related harms higher than the general population (e.g., women, youth, seniors, First Nations and Inuit, and newborns). While data do exist for some of these groups, there are also serious gaps in understanding the nature and extent of the problem. For example, the CADUMS survey reports on the use of prescription drugs, but the data includes appropriate therapeutic use as well as misuse. Accurate, reliable data on the prevalence of prescription drug misuse among Canadian seniors is lacking, as is data on First Nations and Métis. Other groups at risk for prescription drug misuse and for which data is lacking, include military personnel and veterans (Born, Bogaert, Payne, & Wiens, 2009), incarcerated offenders (Johnson, MacDonald, Cheverie, Myrick, & Fischer, 2012) and healthcare practitioners. Further, data might exist but not be publically available or easily accessed by researchers.

More research is needed to identify the determinants, extent and nature of prescription drug misuse and harms among these populations. This research will also contribute to the development of universal and tailored prevention, screening and treatment for these populations. Early detection and treatment can significantly improve health outcomes, which will help reduce the burden on public healthcare systems. To add to the body of research knowledge and determine the progress and impact of the *Strategy*, it should be evaluated on an ongoing basis.

Research Recommendations

Recommendations	Proposed Leads	Links	ST
1. Conduct a study to estimate the health, social and economic costs of prescription drug misuse and harms in Canada.	Health Canada CCSA	M&S	ST
2. Facilitate and support data holders sharing relevant data with researchers to enable a better understanding of the nature, extent and impact of prescription drug misuse among various populations.		M&S	ST
3. Develop a research funding strategy related to prescription drug misuse and harms (e.g., addiction, concurrent disorders, chronic pain, overdose and death):	CIHR Federal, provincial and territorial governments	M&S	ST
a. Convene a meeting of researchers in the area of prescription drug misuse and harms to set a national research agenda and funding strategy.	National and provincial regulatory colleges		



Recommendations	Proposed Leads	Links	ST
4. Explore and better understand the variations in prescribing patterns between provinces and territories, and the impacts on morbidity and mortality.		M&S	
5. Ensure the incorporation and balance of Indigenous knowledge along with Western knowledge to inform decision making among First Nations communities in practice, policy and program decisions: a. Capture and include indigenous knowledge as one evidence source to inform decision making; b. Tailor evidence to specific community settings (e.g., rural, remote and northern communities).		M&S	
6. Conduct an independent review of the evidence and make recommendations as appropriate on the link between patient outcomes (addictions, pain and related harms) and: a. The adequacy — or lack thereof — of screening tools; b. The existing training requirements of healthcare practitioners; c. Mandatory vs. voluntary training of healthcare practitioners to prescribe medications for pain.	Health Canada Research organizations CAMH CCSA Professional associations and colleges		



Part H: Evaluation and Performance Measurement

The *Strategy*'s implementation activities will be guided by a logic model and their impact assessed within a performance measurement and evaluation framework. Key performance indicators will drive data collected over the 10-year period of the *Strategy* to measure relevance, effectiveness, cost effectiveness, and unintended harms and benefits. As an initial step in the evaluation process, appropriate and relevant baseline data will need to be collected for the identified performance indicators. Based on this baseline data and research, it will then be possible to establish goals or targets for the *Strategy*.

As part of the evaluation process, an annual progress report will be developed and distributed to the National Advisory Council and other relevant stakeholders on progress towards achieving expected immediate, intermediate and long-term outcomes.

Evaluation and Performance Measurement Recommendations

Recommendations	Proposed Leads	Links	ST
1. Develop an evaluation framework and logic model to guide the evaluation of the Strategy's activities.	Evaluation Implementation M&S Team		ST
2. Establish targets for each stream's recommendation based on the baseline data and other evidence.	Evaluation Implementation M&S Team		ST
3. In collaboration with a Canadian surveillance system (as recommended in the Monitoring and Surveillance section of this Strategy), gather and analyze relevant baseline data on which to measure the impact of the Strategy moving forward. Include populations of special interest.	Evaluation Implementation M&S Team		ST
4. Produce and publish an annual progress report on Strategy activities and impact for wide dissemination, including to both Houses of Parliament, the Council of Ministers and Deputy Ministers of Health, Justice and Public Safety, Aboriginal Affairs and Northern Development, the Council of the Federation, the Health Council of Canada, federal-provincial-territorial chief public health officers, and provincial and territorial legislatures.	Evaluation Implementation M&S Team		ST



Part I: Call to Action

Stakeholders from across Canada have identified and made a commitment to address the prescription drug crisis. Many have invested their knowledge, expertise, experience, analysis, creativity and energy to developing this ten-year, pan-Canadian strategy to reduce the harms associated with prescription drugs such as opioids, sedative-hypnotics, and stimulants.

Addressing the harms associated with these prescription drugs ranks high in the priorities and operations of many organizations and sectors. Despite numerous competing priorities, organizations are allocating valuable resources to this issue, directly and indirectly. The status quo simply cannot continue. People are becoming addicted and many are dying. Their families and communities are suffering. Action must be taken — NOW.

The launch of *First Do No Harm: Responding to Canada's Prescription Drug Crisis* marks the end of the development phase (Phase 1) on which the Coalition on Prescription Drug Misuse (Alberta), the Nova Scotia Department of Health and Wellness and the Canadian Centre on Substance Abuse provided leadership and invited others to become involved. The document is designed to guide those who lead Phase 2, the implementation of the *Strategy* recommendations, and Phase 3, the evaluation of the *Strategy*. There is still much work to be done.

This document sets out 58 achievable recommendations within the short term and sets a path to which many organizations and sectors can collectively commit over the long term to minimize the harms of prescription drugs, while allowing for the benefits. The *Strategy* is comprehensive, multidisciplinary, multi-sectoral and integrated. It supports the strategic use of available resources to address the harms associated with prescription drugs in the most effective ways possible to:

- Prevent harms to individuals, families and communities;
- Empower the public and promote healthy and safe communities;
- Promote appropriate prescribing and dispensing practices among healthcare practitioners;
- Increase timely, equitable access to a range of effective treatment options;
- Identify effective, evidence-informed practices and policies and build upon them;
- Share information across disciplines and jurisdictions on a timely basis;
- Increase knowledge and understanding of the nature and extent of the harms associated with prescription drugs in Canada;
- Ensure that law enforcement has adequate tools and resources to address the diversion of prescription drugs; and
- Apply critical thinking and cultural awareness to the issue and proposed responses.

This *Strategy* will undergo refinements to keep it relevant and responsive, planned time lines might change, and priorities might shift, but the vision is set. Collectively we are working towards a Canada that allows for the benefits while minimizing the harms associated with prescription drugs.

This is an ambitious challenge. It requires a sustained and serious commitment to coordinated actions that support the common, long-term vision of addressing this complex public health and safety issue. It will succeed through a respectful sharing of knowledge, expertise, enquiry, promising



practices, analysis and lived experience, and the collective will and momentum of all who have a role in responding to the prescription drug crisis.

It is achievable if we share the vision and work together. Let's get started.

Next Steps

The important next steps include:

- Convening the First Do No Harm Implementation Council and Implementation Teams;
- Identifying or confirming the leaders and resources to take the plan forward;
- Developing an evaluation plan and performance measurement strategy;
- Collecting baseline data from which to move forward and gauge our success;
- Continuing and promoting the good work that is already in progress; and
- Focusing our attention on what can be achieved in the short-term, while keeping our long-term vision in mind.



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Appendix A: Acronyms

ADHD: Attention Deficit Hyperactivity Disorder
AFN: Assembly of First Nations
CACP: Canadian Association of Chiefs of Police
CADTH: Canadian Agency for Drugs and Technology in Health
CADUMS: Canadian Alcohol and Drug Use Monitoring Survey
CAEP: Canadian Association of Emergency Physicians
CAMH: Centre for Addictions and Mental Health
CAPB: Canadian Association of Police Boards
CCSA: Canadian Centre on Substance Abuse
CDPC: Canadian Drug Policy Coalition
CDSA: Controlled Drugs and Substances Act
CECA: Canadian Executive Council on Addictions
CFPC: College of Family Physicians of Canada
CMA: Canadian Medical Association
CNA: Canadian Nurses Association
CoOPDM: Coalition on Prescription Drug Misuse
CPA: Canadian Police Association
CPHA: Canadian Public Health Association
CPhA: Canadian Pharmacists Association
CIHI: Canadian Institute for Health Information
CIHR: Canadian Institute for Health Research
COO: Chiefs of Ontario
EAC: Expert Advisory Committee
EHS: Emergency Health Services
EMCDDA: European Monitoring Centre for Drugs and Drug Addiction
FCM: Federation of Canadian Municipalities
FNIGC: First Nations Information Governance Centre
FNIHB: First Nations Inuit Health Branch
FNIM: First Nations, Inuit and Métis
HEAL: Health Action Lobby
HC: Health Canada



ISMP: Institute for Safe Medical Practices
LHIN: Local Health Integration Network
NAC: National Advisory Council on Prescription Drug Misuse
NAS: Neonatal Abstinence Syndrome
NIHB: Non-Insured Health Benefits
NNAPF: National Native Addictions Partnership Foundation
NOUGG: National Opioid Use Guideline Group
PDACC: Prescription Drug Abuse Coordinating Committee
PHAC: Public Health Agency of Canada
RCMP: Royal Canadian Mounted Police
RCMP-DOCAS: RCMP, Drugs and Organized Crime Awareness Service
RCPSC: Royal College of Physicians and Surgeons of Canada
SAMHSA: Substance Abuse and Mental Health Services Administration
UNODC: United Nations Office on Drugs and Crime
WHO: World Health Organization
WSIB: Workplace Safety and Insurance Board



Appendix B: CDSA Offences and Maximum Penalties

CDSA Schedule	Possession, Multiple Doctoring	Trafficking, Possession for the purpose thereof	Importing, Exporting, Possession for the purpose thereof	Production
I Opioids Cocaine PCP Methamphetamine Amphetamine Flunitrazepam	indictable offence: 7 years summary conviction: first offence: \$1,000 or 6 months or both subsequent offence: \$2,000 or 1 year or both Part I 4.(3) Part I 4.(7)(a)(i) and (b)	indictable offence: life — 1 or 2 years minimum if conditions apply no summary conviction Part I 5.(3)(a)(i) and (ii)	indictable offence: life — 1 or 2 years minimum if conditions apply no summary conviction Part I 6.(3)(a) and (a.1)	indictable offence: life — 2 years minimum or 3 years minimum if conditions apply no summary conviction Part I 7.(2)(a)
II Cannabis Cannabinoids	indictable offence: 5 years less 1 day summary conviction: same as first offence under I exclusively summary conviction: 30 grams or less of marihuana, 1 gram or less of hashish — \$1,000 or 6 months or both Part I 4.(4) and (5) Part I 4.(7)(a)(ii) and (b)	indictable offence: life Exception for marihuana and hashish in quantities of 3 kg or less — 5 years less 1 day no summary conviction Part I 5.(3)(a) and 5.(4)	indictable offence: life — 1 year if conditions apply no summary conviction Part I 6.(3)(a)	indictable offence: non-cannabis: life- 1 year or 18 months minimum if conditions apply cannabis: 14 years — 6 months to 3 years minimum depending on number of plants no summary conviction Part I 7.(2)(a)(1)(d)
III Methylphenidate Hallucinogens Others	indictable offence: 3 years summary conviction: same as under I Part I 4.(6) Part I 4.(7)(a)(iii) and (b)	indictable offence: 10 years summary conviction: 18 months Part I 5.(3)(b)	indictable offence: 10 years summary conviction: 18 months Part I 6.(3)(b)	indictable offence: 10 years summary conviction: 18 months Part I 7.(2)
IV Benzodiazepines Barbiturates ATS with therapeutic applications Anabolic steroids Others	no CDSA offences for possession double doctoring: indictable offence: 18 months summary conviction: same as under I Part I 4.(7)(a)(iv) and (b)	indictable offence: 3 years summary conviction: 1 year Part I 5.(3)(c)	indictable offence: 3 years summary conviction: 1 year Part I 6.(3)(c)	indictable offence: 3 years summary conviction: 1 year Part I 7.(2)(d)



Appendix C: Glossary of Terms Related to Prescription Drugs

Abuse

Abuse is the “use of pharmaceutical drugs with centrally acting reinforcing properties that is associated with increased risk for harm, as characterized by obtaining drugs from illegitimate sources, or risky patterns of use (excluding under-use), that deviate from accepted medical practice and/or scientific knowledge, or taking the drugs for purposes which are not therapeutic.”

Health Canada. (2007). Draft consensus statement. Workshop to build consensus on concepts and indicators for research on psychotropic pharmaceutical abuse. September 2006. Ottawa: Author.

Abuse liability (or abuse potential)

“The propensity of a particular psychoactive substance to be susceptible to abuse, defined in terms of the relative probability that use of the substance will result in social, psychological, or physical problems for an individual or for society. Under international drug control treaties (see conventions, international drug) WHO is responsible for determining the abuse liability and dependence potential, as distinct from therapeutic usefulness, of controlled substances.”

http://www.who.int/substance_abuse/terminology/who_lexicon/en/

Academic detailing or educational outreach

This is a method of educational outreach that aims to influence practitioner behaviour, often prescribing behaviour, in which a trained person meets (generally for less than 10 minutes) with providers in their practice setting to provide information. Strategies employed are based on research in the fields of marketing, adult learning, diffusion of innovations, persuasive communication and behaviour modification techniques.

Davies, P., Walker, A.E., & Grimshaw, J.M. (2010). A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. *Implementation Science*, 5 (14).

Grimshaw, J.M., Shirran, L., Thomas, R., Mowatt, G., Fraser, C., Bero, L., Grilli, R., Harvey, E., Oxman, A., & O'Brien, M.A. (2001). Changing Provider Behaviour: An Overview of Systematic Reviews of Interventions; *Medical Care*, 39(8 Supplement 2), 112-45.

Addiction

“Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

“Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal



relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.”

Definition from the American Society of Addiction Medicine. Adopted temporarily by the Canadian Society of Addiction Medicine on 2011-Oct 5 through a motion by the CSAM Board of Directors http://www.csam.org/non_member/definition

Auxiliary Labels

These are medication labels that contain important information for patients, including warnings; potential serious side effects; dietary information; instructions for storing, preparing or administering the drug; or cautionary details.

Biopsychosocial approach

This approach involves systematically considering the biological, psychological, and social factors and their complex interactions in understanding health, illness, and health care delivery. Although pain may be observed as physical, there can be psychological and social factors that impact or intensify that physical pain. Therefore, pharmacological treatments may not be the best or only option for pain management.

Controlled drugs or controlled substance

“A controlled substance is any type of drug that the federal government of Canada has categorized as having a higher-than-average potential for abuse or addiction. Such drugs are divided into categories based on their potential for abuse or addiction. Controlled substances range from illegal street drugs to prescription medications.”

Health Canada, <http://www.hc-sc.gc.ca/hc-ps/substancontrol/index-eng.php>

Concurrent disorders

The co-occurrence of mental health and substance abuse problems

Canadian Centre on Substance abuse. (2009). *Substance abuse in Canada: concurrent disorders*. Ottawa, ON: Author. <http://www.ccsa.ca/2010%20CCSA%20Documents/ccsa-011811-2010.pdf>

Co-morbidities

The simultaneous presence of two or more health conditions or diseases in the same patient

Cultural awareness

Cultural awareness is the first step towards achieving cultural safety. It can be built by observing activities and how people participate in them, and involves being able and willing to recognize or acknowledge and accept difference within a population.

National Collaborating Centre for Aboriginal Health. (2013). *Towards Cultural Safety for Métis: An Introduction for Health Care Providers*. Prince George: University of Northern British Columbia.



http://www.nccah-ccnsa.ca/Publications/Lists/Publications/Attachments/76/Cultural%20Safety%20Fact%20Sheet_EN.pdf

Cultural awareness addresses the diversity between clients and between healthcare provider and each client.

Papps, E. (2005). Cultural safety: Daring to be different. In D. Wepa (Ed.), *Cultural Safety in Aotearoa New Zealand* (pp. 20-28). Auckland, New Zealand: Pearson Prentice Hall.

Cultural competence

Cultural competence is a process that involves the health care provider actively developing their knowledge and skills specific to clients' and client population's culture and world view while demonstrating a clear definition of the limits and boundaries in knowledge, skills, cultural specific practice. Cultural competence is exhibited when the healthcare provider works within a client's physical, spiritual and cultural needs by respecting and understanding the client's culture and historical trauma. Cultural competency develops a strong foundation to promoting a culturally safe environment for the client

Indigenous Physicians Association of Canada and the Royal College of Physicians and Surgeons of Canada, Family Medicine Curriculum Development Working Group. (2009). *Cultural Safety in Practice: A Curriculum for Family Medicine Residents and Physicians*. Ottawa: Author.

Cultural safety

Cultural safety extends beyond cultural awareness and sensitivity within services and includes a reflection of cultural, historical, and structural differences and power relationships within the care that is provided. Cultural safety

- Aims to re-dress inequities in power structures by transferring the power from the healthcare practitioner to the person.
- Goes beyond the relationship between the healthcare practitioner and the client to ensure the healthcare environment is also culturally responsive by actively and continuously assessing and working to facilitate change through building cultural competency in healthcare structures and process such as: service design, policy, human resources, service delivery and in achieving health outcomes that are culturally-relevant and meaningful.
- Is achieved when programs, instruments and procedures, methods and actions are implemented in ways that do not harm people with different cultural values. is to assist mental health and addiction workers to effectively and safely communicate, verbally and non-verbally, with First Nations clients.

National Native Addictions Partnership Foundation. (2011). *Working with First Nation's People: Culturally Safe Toolkit for Mental Health and Addiction Workers Literature Review*. Muskoday, Saskatchewan: Author. Retrieved on February 22, 2013 from <http://nnapf.com/wp-content/uploads/2012/03/DRAFT-LIT-REV-Working-with-First-Nation-Cultural-Safety-Toolkit.docx>

National Native Addictions Partnership Foundation. (2011). *Working with First Nation's People: Culturally Safe Toolkit for Mental Health and Addiction Workers*. Muskoday, Saskatchewan: Author. Retrieved on February 22, 2013 from



<http://nnapf.com/wp-content/uploads/2012/03/DRAFT-Working-with-First-Nations-People-Culturally-Safe-Toolkit-for-Mental-Health-and-Addiction-Workers.docx>

Cultural sensitivity

Cultural sensitivity is recognition of the differences between cultures and world views. It goes beyond recognizing differences to include appreciation for and comfort with differences.

Diversion

Prescription drug diversion involves the unlawful redirecting of regulated pharmaceuticals from legal sources to the illegal marketplace and can occur at all points along the drug supply chain.

Misuse

Misuse can be broadly defined as the use of medications for purposes other than the indication for which the drug was prescribed.

Vik, S., Ozegovic, D., & Samanani, S. (2011). *Literature Review to Support Conceptualization of a Prescription Drug Misuse Surveillance System in Alberta*. Edmonton, AB: OKAKI Health Intelligence. Retrieved on February 22, 2013 from <http://www.prescriptiondrugmisuse.ca/wp-content/uploads/2010/01/111018-Okaki-CoOPDM-literature-review-final.pdf>

Non-medical use

This type of drug use involves the taking of prescription drugs, whether obtained by prescription or otherwise, other than in the manner or for the reasons or time period prescribed, or by a person for whom the drug was not prescribed.

United Nations Office on Drugs and Crime. (2011). *The non-medical use of prescription drugs*. Policy direction issues. Discussion paper. New York: United Nations. Retrieved on February 22, 2013 from http://www.unodc.org/docs/youthnet/Final_Prescription_Drugs_Paper.pdf

Post-market surveillance

Post-market surveillance is the evaluation and monitoring of drugs, health products and medical devices following authorization by Health Canada of these products for sale in Canada.

Health Canada. (2007). *Planning for Our Future: Federal Regulatory Post-Market Surveillance Strategy 2007-2012*. Ottawa: Author. Retrieved on February 22, 2013 from http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/strategy_strategie_surveillance-eng.php

Primary prevention

Primary prevention involves interventions or approaches focused on protecting healthy people from getting a disease or experiencing an injury and reduces both the incidence and prevalence of a disease or injury.



Product monographs

A product monograph for a prescription drug is a document that provides the necessary information for the safe and effective use of a drug. This information includes the structure, function, proper uses, dosing, mechanism of action, side effects and adverse effects associated with that drug.

Psychoactive

A psychoactive substance affects the mind, mood or other mental state or processes through changes to the way the brain and nervous system work.

Secondary prevention

Secondary prevention involves interventions or approaches that are implemented after an illness or serious risk factors have already been diagnosed and that aim to stop or slow the progress of the disease (if possible) or prevent or reduce the harms associated with it.

Supply chain (the pharmaceutical drug supply chain in Canada)

This is the means through which prescription medicines are delivered to patients. Pharmaceuticals are produced in manufacturing sites; transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price; dispensed by pharmacies; and ultimately delivered to and taken by patients. There are many variations on this basic structure, as the players in the supply chain are constantly evolving, and commercial relationships vary considerably by geography, type of medication, and other factors.

Trauma-informed services

“Trauma-informed services are knowledgeable of and sensitive to trauma-related issues present in survivors. A trauma-informed system is one in which all components of a given service system have been reconsidered and evaluated in the light of a basic understanding of the role that violence plays in the lives of people seeking health and addiction services. A trauma-informed system uses that information to design service systems that accommodate the vulnerabilities of trauma survivors, and allows services to be delivered in a way that will avoid inadvertent re-traumatization and facilitate consumer participation in treatment (Harris & Fallot, 2001).”

Klinik Community Health Centre. (2008). *Trauma-informed: The trauma toolkit. A resource for service organizations and provider to deliver services that are trauma-informed.*

Winnipeg, MB: Author. Retrieved on February 22, 2013 from http://www.trauma-informed.ca/traumafiles/Trauma-informed_Toolkit.pdf

Trauma-informed services take into account knowledge of the impact of trauma and integrate this knowledge into all aspects of service delivery. From a trauma-informed perspective, “problem behaviours” are understood as attempts to cope with abusive experiences. Disorders become responses, and symptoms become *adaptations*. The question shifts from “What is wrong with this woman?” to “*What happened to this woman?*” Working in a trauma-informed way does not require disclosure of trauma nor treatment of trauma, it is about working in ways that accept where the woman is at and do not retraumatize.

BC Centre for Excellence on Women's Health. (2009). *Trauma-informed approaches in addictions treatment.* Vancouver, BC: Author. Retrieved on February 22, 2013 from



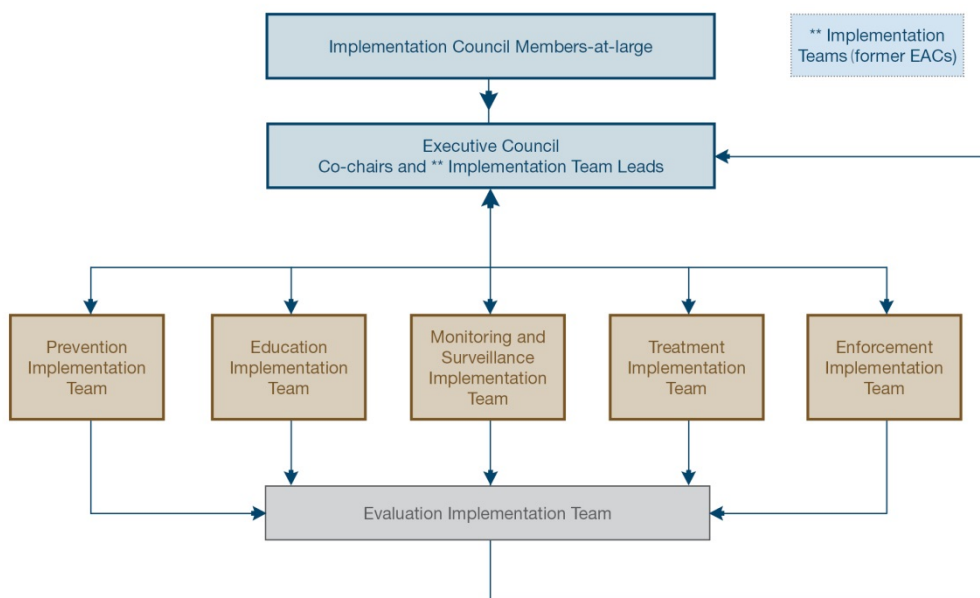
<http://www.bccewh.bc.ca/publications-resources/documents/GenderingNatFrameworkTraumaInformed.pdf>

Trauma-informed services take into account an understanding of trauma in all aspects of service delivery and place priority on the person's safety, choice and control. Such services create a treatment culture of nonviolence, learning, and collaboration. Whereas, trauma-specific services more directly address the need for healing from traumatic life experiences and facilitate trauma recovery through specialized counselling and other clinical interventions.

Poole, N., Urquhart, C., Jasiura, F. & Smylie, D. (2013). *Trauma-informed Practice Guide*. Vancouver, BC: British Columbia Centre of Excellence for Women's Health, Government of British Columbia, Ministry of Health (in press).



Appendix D: Proposed Governance Structure for Implementation and Evaluation





Canadian Centre
on Substance Abuse
Centre canadien **de lutte**
contre les toxicomanies

Partnership. Knowledge. Change.
Collaboration. Connaissance. Changement.

The Canadian Centre on Substance Abuse changes lives by bringing people and knowledge together to reduce the harm of alcohol and other drugs on society. We partner with public, private and non-governmental organizations to improve the health and safety of Canadians.