Tighter regulations needed for over-the-counter codeine in Canada

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SINCE I STARTED PRACTISING PHARMACY IN ONTARIO 5 YEARS ago, I have felt uneasy about over-the-counter (OTC) codeine. The national Narcotic Control Regulations suggests that every pharmacist should counsel on these drugs,¹ but in my experience, this rarely happens. Most patients can easily buy 200 pills of these OTC narcotics as long as they simply tell the pharmacy cashier that they have “had it before.” A change is needed to ensure safer and more effective use of OTC codeine products in Canada.

When analyzing Canada’s opioid epidemic, OTC codeine should not be ignored. Several studies have shown misuse of these products. A 1997 Canadian survey of regular codeine users found that 37% were dependent on codeine, 4% abused it, and one-half of all regular users obtained codeine over the counter.² In a retrospective chart review of patients attending a methadone maintenance treatment clinic from 1997 to 1999 in Toronto, Ontario, 46% of opioid users were using codeine and 35% of opioid users were using OTC codeine.³ In another chart review of patients attending an opioid detoxification program in Toronto, Ontario, from 2000 to 2004, 35% reported using codeine and 5% were using OTC codeine.⁴ Between 2011 and 2014, 514 Ontarians began methadone treatment for addiction to OTC codeine.⁵

International research provides insight into the problems with OTC codeine. In France, a study of 53 purchasers of codeine at a community pharmacy found that 15% were using codeine for nonmedical reasons, 7.5% reported dependence and 7.5% reported abuse.⁶ New Zealand and Australia have published many case reports highlighting the harms of OTC codeine in their jurisdictions.⁷⁻¹⁰ In these reports, many patients addicted to OTC codeine had gastrointestinal-related morbidities (hemorrhage, anemia, hematemesis) secondary to the nonsteroidal anti-inflammatory drugs (NSAIDs) in codeine combination pills. OTC codeine is commonly sold in combination with acetylsalicylic acid (ASA) and acetaminophen in Canada, and both of these noncodeine drugs could cause similar collateral harms as a result of codeine misuse.

Another study showed that of all codeine deaths recorded in Australia between 2000 and 2009, OTC codeine products were the primary codeine product consumed in 40% of cases.¹¹ These data highlight some of the problems with OTC codeine and the need for stricter regulation of these products.

Despite requirements for counselling on OTC codeine purchases, there are considerable barriers in community pharmacy practice that prevent this from happening effectively. Patients who misuse codeine often have predetermined agendas and are unwilling to accept the advice of community pharmacists. These patients know how to “work the system” to get OTC codeine. Patients tell me that they have tried all other analgesics such as acetaminophen and NSAIDs and that their family physician knows they take OTC codeine. Many people are purchasing codeine for a patient not present in the pharmacy, such as a family member. It is difficult to decide if the person purchasing codeine—whom I have likely never met before—is telling the truth. Most community pharmacists have limited access to a patient’s medical history or even a list of current medications. This makes for a difficult and frustrating clinical encounter in which pharmacists are trying to decipher legitimate versus illegitimate use of codeine based on counselling alone.

Pharmacists would benefit from tools to help them counsel on OTC codeine and to help separate those who misuse versus those who do not. One such tool would be a prescription monitoring program (PMP). A PMP would give pharmacists real-time alerts of potential misuse at the time of purchase.

Research exists on PMPs that monitor prescription drugs in Canada and the United States, showing that after these programs are implemented, double-doctoring and polypharmacy use decrease.¹²⁻¹⁴ This suggests that these programs can help to reduce inappropriate prescribing and dispensing of opioids and other controlled drugs. Whether this ultimately leads to a reduction in abuse and addiction is not clear, and further research is needed.¹⁴ If concepts (e.g., practitioner license number recording, flags for double-doctoring and polypharmacy)

associated with these prescription-only PMPs were applied to an OTC codeine-monitoring program, then inappropriate OTC codeine use might be reduced as well.

Most provinces have systems in which OTC codeine sales can be uploaded to a central database as part of the patient's provincial drug record.¹⁵⁻¹⁹ However, these centralized records are imperfect, sometimes recording OTC codeine only as an "FYI" on the side of the provincial record (Saskatchewan College of Pharmacists, personal communication, December 5, 2015). There is not yet any research available on the success or impact of these centralized systems in Canada.

Implementing a PMP is not the ultimate solution and may not be sufficient in curbing OTC codeine misuse. A PMP could tell pharmacists that, for example, a patient had purchased 200 pills of OTC codeine 60 days ago. But under what clinical circumstances, if any, would it be appropriate for a pharmacist to sell this patient another bottle? Even with a PMP, pharmacists in many provinces would still not have access to medical and medication histories. Pharmacists are still left making clinical decisions about these narcotics with an incomplete clinical picture.

There is a convincing argument that all codeine products should be available only by prescription. In my personal practice experience, people tell me they are purchasing OTC codeine for 1) chronic pain, 2) anticipatory acute pain (e.g., to keep on hand in case of migraine), 3) cough and 4) acute pain. Patients with chronic pain requiring narcotics should have their pain assessed by a physician and should be getting these medications with a prescription. In other scenarios, it is debatable whether OTC purchases should be allowed. The risks of keeping codeine available without a prescription need to be weighed against the benefits. Risks include easier public access to a drug associated with dependence, addiction, overdose-related deaths and potential collateral toxicity from acetaminophen and ASA. The *Food and Drug Regulations* in Canada state that if a drug

has abuse or dependence potential, then that factor alone is enough to consider moving a drug to prescription-only status.²⁰ Keeping OTC codeine on hand in home medicine cabinets can be risky, exacerbated by the fact that in many provinces, these products are commonly sold in bottles of 200 pills. In a recent Ontario survey, 1 in 8 youth reported using an opioid pain reliever recreationally in the past year, and the majority got it from home.²¹

The benefits seem negligible: OTC analgesics with no codeine (e.g., ibuprofen, naproxen, acetaminophen) are likely just as effective, possibly even more, than OTC products with codeine for acute pain.²²⁻²⁷ For acute cough, there is a paucity of data, but the available evidence shows that codeine is not effective.²⁸ It could be argued that Canadians should have access to OTC codeine for acute pain relief or acute cough when no other health facilities (e.g., family physician or dentist) are easily accessible and when the patient has tried all other noncodeine products. This, in my opinion, is the only scenario in which pharmacists might be allowed to sell OTC codeine. But this is a rare scenario in community pharmacy and keeping codeine available for this very small group of patients should be questioned.

In the midst of Canada's fight against opioid abuse, the case for tighter OTC codeine regulations should be considered. There is little benefit to Canadians in having a minimally effective yet addictive product available without prescription, especially when there are other less risky options available. Manitoba has recently announced that all codeine products will be available only by prescription, with pharmacists being able to prescribe in certain circumstances using a strict protocol.²⁹ This is a step toward a safer way to dispense codeine and has great potential to prevent harm and misuse of this drug. It is hoped that all provinces across Canada follow suit and eventually implement stricter policies. ■

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