Racing for accessibility of a life-saving drug

A timeline of naloxone's changing status in the midst of the opioid crisis

Sandra Botros

Faculty Reviewer: Amardeep Thind MD, PhD (Epidemiology and Biostatistics)

INTRODUCTION

In recent years, the problem of addiction and misuse of opioid drugs has been on the rapid rise in Canada. Overdose deaths have increased dramatically, due partly to increasing availability of prescription opioids on the illicit drug market, and in particular a surge in the availability of the potent opioid fentanyl. In British Columbia, the hardest hit province, overdose deaths have doubled since 2012, and the involvement of fentanyl in these deaths has risen from 5% to 60%.^{1,2} Naloxone hydrochloride (sold in the U.S. under the trade name Narcan®) is an opioid antidote used to reverse the effects of opioid overdose in emergency situations. In a short time, Canada has seen rapid changes in regulation and availability of naloxone in a desperate attempt to reduce overdose deaths in what is being called a “public health crisis”.¹ A key change that has happened recently was the removal of naloxone from the Prescription Drug List (PDL), making it available over-the-counter in pharmacies. This article outlines the steps taken to increase availability and remove prescription status of naloxone in response to Canada's ongoing opioid epidemic.

TAKE HOME PROGRAMS

While naloxone has been around for many years, its use has historically been confined to hospitals and emergency rooms. As overdose rates continued rising, there were increasing efforts to increase public availability of the life-saving drug. In 2005, the Edmonton needle-exchange program Streetworks implemented Canada's first take-home naloxone program. In 2011, Toronto similarly launched their POINT program (Preventing Overdose in Toronto), followed by a province-wide program through the Ontario Harm Reduction Distribution Program.³ British Columbia began a province-wide take-home naloxone program in 2012, operated by the BC Centre for Disease Control Harm Reduction Program.⁴ These programs typically provide opioid users with naloxone prescriptions and kits, overdose prevention education, and training on use of naloxone kits. Often, training sessions were also provided to family and friends of users, who may be present during an overdose.

THE ROAD TO PRESCRIPTION FREE STATUS

Prior to the lifting of naloxone's prescription status, several provinces took steps to increase accessibility of the drug in overdose situations. Since 2015, for example, Manitoba and Nova Scotia made changes that allowed physicians to prescribe naloxone without having to see the patient; Saskatchewan began allowing physicians to prescribe naloxone directly to family and friends of opioid users; and BC and Alberta made it possible for registered nurses to

prescribe naloxone.⁵

Naloxone's removal from Health Canada's PDL was achieved in March 2016. This was the first step to allowing access in pharmacies without prescription. Health Canada proposed the amendment to the PDL on January 14, 2016 and shortened the normal 75-day public consultation period to 65 days to expedite the process. The amendment received overwhelming public support, and it was approved on March 22. Due to the urgent nature of the situation, Health Canada opted to bypass the usual six-month delay in implementation, making the amendment effective immediately.^{5,6}

After a change to the federal PDL, a drug's status must be changed on the provincial drug schedules, which describe the legal conditions for its sale in the respective provinces. When a change is made in the PDL, The National Association of Pharmacy Regulatory Authorities (NAPRA) usually provides a common final recommendation to all provinces regarding drug scheduling, and the provinces generally follow NAPRA's recommendations. Most provinces have a system of “scheduling by reference”, meaning they automatically implement all NAPRA recommendations, while some (BC, Alberta, Newfoundland) have additional approval processes in place, but still generally end up following the same recommendations. The urgency for naloxone access led to the BC government and BC College of Pharmacists bypassing this process completely and classifying naloxone as a Schedule II drug in BC on March 24, 2016.⁵ NAPRA made their final recommendation on June 24, 2016 to classify naloxone as a Schedule II drug,⁷ making pharmacies in most provinces, including Ontario, immediately eligible to dispense it.

REMAINING BARRIERS AND FUTURE DIRECTIONS

Removing naloxone from the PDL has been an important step in improving its availability. There are still several barriers, however, in ensuring adequate availability in practice. One concern is the difficulty of administering an injection drug. Currently, pharmacies provide training sessions on use of naloxone kits, but training isn't standardized, and the skill can be difficult to master and recall during high-stress emergency situations.^{8,9} A nasal spray form of naloxone exists (Narcan® nasal spray in the U.S.), but until recently was not approved in Canada. The nasal spray form is far easier to administer and would likely prevent more overdoses. In an interim order termed “an emergency public health measure”, Health Canada authorized the nasal spray for import and sale from the U.S. in July 2016, pending an expedited review for its approval in Canada.⁸ This allowed it to be sold in Canada before being approved for manufacture in Canada. Following the review, the nasal spray

was approved for non-prescription use in October 2016, allowing the manufacturer to begin steps to bring it to the Canadian market.¹⁰ In June 2017, Health Canada authorized a Canadian version of the nasal spray, to be transitioned into the market when the interim order expired in July 2017. It is being carried by RCMP, police officers, and first responders, but its availability in pharmacies is not well-documented and is likely still in transition.¹¹ Unfortunately, a major concern with naloxone nasal spray is the high cost – at approximately \$125 for two doses, it is much more costly than the cheaper injectable kits (\$5-\$20 per dose), which are free at most pharmacies.⁹

Another important consideration is that although naloxone is an important harm reduction tool, it will not solve the opioid problem. The Canadian government recognizes that overdose prevention, although important, is just one part of the strategy to combat opioid abuse. Continuous improvement is also critically needed in curbing opioid prescription, educating the public, and treating addiction.¹

At this point, there has not yet been any formal evaluation of the effect that removing naloxone from the PDL has made on curbing overdose deaths. Further research is needed moving forward to determine if this much-publicized public health measure has succeeded and had its intended effect.

REFERENCES

1. Parliament of Canada [Internet]. Ottawa (ON): Report and Recommendations on the Opioid Crisis in Canada 2016. [cited 2017 Feb 27]. Available from: <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=e&Mode=1&Parl=42&Ses=1&DocId=8685723&File=18>.
2. White P, Howlett K. Ontario, Ottawa expand free access to antidote for opioid overdoses [Internet]. The Globe and Mail; 2013 May 18. [cited 2017 Feb 28]. Available from: <http://www.theglobeandmail.com/news/national/ontario-to-make-free-antidote-to-opioid-overdose-available/article30076911/>
3. Eggerston L. Take-home naloxone kits preventing overdose deaths. CMAJ. 2014 Jan; 186(1): 17.
4. Banjo O, Tzemis D, Al-Qutub D, Amlani A, Kesselring S, Buxton J. A Quantitative and qualitative evaluation of the British Columbia Take Home Naloxone program. CMAJ Open. 2014 Jul; 2(3): 153-161.
5. Canadian Centre on Substance Abuse [Internet]. Ottawa (ON); c2017. CCENDU Bulletin: The Availability of Take Home Naloxone in Canada. c2016. [cited 2017 Feb 28]. Available from <http://www.ccsa.ca/Resource%20Library/CCSA-CCENDU-Take-Home-Naloxone-Canada-2016-en.pdf>.
6. Health Canada [Internet]. Ottawa (ON); c2017. Notice: Prescription Drug List (PDL): Naloxone; c2016 [cited 2017 Feb 27]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl-ldo-noa-ad-naloxone-eng.php>.
7. National Association of Pharmacy Regulatory Authorities (NAPRA) [Internet]. Ottawa (ON): NAPRA: c2009. National Drug Schedules: Final Recommendation on naloxone hydrochloride; c2016. [cited 2017 Feb 28]. Available from: <http://napra.ca/pages/home/default.aspx?id=3758>.
8. Health Canada [Internet]. Ottawa (ON); c2017. Notice - Availability of Naloxone Hydrochloride Nasal Spray (NARCAN®) in Canada; c2016. [cited 2017 Feb 28]. Available from: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/notice-avis-nasal-eng.php>.
9. Dimoff A. High price of naloxone nasal spray makes distribution of vital drug difficult [Internet]. CBC News; 2016 July 12. [cited 2017 Feb 28]. Available from: <http://www.cbc.ca/news/canada/british-columbia/costly-naloxone-nasal-spray-1.3675243>.
10. Health Canada OK's non-prescription nasal spray overdose antidote [Internet]. CBC News; 2016 Oct 3. [cited 2017 Feb 28]. Available from: <http://www.cbc.ca/news/health/naloxone-nasal-spray-1.3789643>.
11. Canadian Pharmacists Association [Internet]. Ottawa (ON); c2017. Environmental Scan: Access to Naloxone across Canada. c2017. [cited 2017 Nov 15]. Available from: https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Environmental%20Scan%20-%20Access%20to%20Naloxone%20Across%20Canada_Final.pdf.