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Guidelines for Pharmacists Selling Naloxone as a Schedule II Drug

Introduction

Naloxone is an injectable solution indicated for the treatment of natural and synthetic opioid induced respiratory depression¹. As of June 24, 2016, naloxone will become a Schedule II drug when indicated for emergency use for opioid overdose outside hospital settings. Prior to this, naloxone was a prescription only medication in Canada.

Background

Overdose occurs when opioids bind to receptor sites on the brain stem, desensitizing the brain stem to carbon dioxide levels in the blood to the degree that breathing mechanisms are not normally triggered. This leads to depressed respiration and hypoxia. Death related to accidental opioid overdose in Manitoba has significantly increased in recent years. These deaths have primarily involved pharmaceutical opioids, polysubstance use, oral or intravenous routes of consumption and, in some cases, the victim was prescribed the drug that caused the overdose. A study of 302 accidental deaths due to opioid overdoses in Manitoba found that prescription opioids were highly implicated in the unintentional deaths. Manitoba experiences approximately 100 overdose deaths per year, which is approximately equivalent to the mortality rate for motor vehicle collisions in Manitoba². The availability of injectable naloxone from community pharmacies and other distribution programs will help to address the rising number of opioid (including fentanyl) overdoses and deaths by increasing access to take-home-naloxone (THN) kits to at-risk Manitobans³.

Guidelines

In addition to the requirements outlined in the [Practice Direction Sale of NAPRA Schedule II Drugs](#) and the [NAPRA Supplemental Standards of Practice for Schedule II and III Drugs](#), the following items apply when pharmacists are selling naloxone as a Schedule II drug:

- 1. Pharmacists must be knowledgeable in all aspects of naloxone when involved in patient care with naloxone for emergency use for opioid overdose outside hospital settings.**

Section 18 of the Pharmaceutical Regulation states that a member may only engage in aspects of pharmacy practice that he or she has the requisite knowledge, skill and judgement to provide or perform and that are appropriate for his or her area of practice. The expectation is that pharmacists will be knowledgeable in the use of naloxone for opioid overdose treatment prior to dispensing or selling the medication. All pharmacists *must* complete the following before selling naloxone:

- i. Review the Overdose Prevention and Response Training Manual

- http://towardtheheart.com/assets/uploads/Training%20Manual%20and%20Documents_2016.05.10.pdf
- N.B.: Please note that when reading the manual, naloxone is no longer a prescription only medication and does not require a prescription in Manitoba.
- ii. Watch the educational video below:
 - Naloxone Saves Lives, Hello Cool World: <https://vimeo.com/164669763>
- iii. Read the Practice Direction Sale of NAPRA Schedule II Drugs (non-prescription, pharmacy only sale), available at:
 - <http://cphm.ca/uploaded/web/Legislation/Sale%20of%20Schedule%20%20Drugs.pdf>
- iv. Thoroughly review this guideline document
- v. Engage in additional ongoing professional development as deemed necessary

2. A pharmacist must consider appropriate information to assess whether it is appropriate to dispense or sell naloxone⁴.

As per the Practice Direction Sale of NAPRA Schedule II Drugs, all Schedule II drugs (including naloxone and take-home naloxone (THN) kits) must only be available from a licensed pharmacist and kept in an area of the dispensary with no public access and no opportunity for patient selection⁵.

The pharmacist must enter into a dialogue with the client seeking a THN kit. This dialogue and training must take place in a confidential area in the pharmacy. When engaging in this dialogue, the pharmacist should gather relevant information such as⁴:

- History of opioid use
- History of past naloxone use and response
- Allergies and type of reaction

Individuals who may benefit from a THN kit include²:

- All individuals who use opioids, both prescription and non-prescription, for legitimate medical purposes and for recreational purposes;
- Individuals identified by the above group as the person most likely to be present if they were to overdose (e.g. partners, family, friends, roommates); and
- Any person who knows an opioid user and would like to be prepared in the event of an accidental overdose.

Given the safe and effective nature of naloxone, it is very unlikely that it would not be appropriate to provide a THN kit to someone who requests it for emergency use for opioid overdose².

3. A pharmacist must provide sufficient equipment and information to enable the patient to receive the intended benefit of the drug therapy⁴.

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To protect the health and well being of the public by ensuring and promoting safe, patient-centred and progressive pharmacy practice.*

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As outlined in the Overdose Prevention and Response Training Manual mentioned above, important information when providing naloxone to an individual includes, but is not limited to:

- How to identify an opioid overdose
- The contents of each THN kit
- The importance of rescue breathing
- When to administer naloxone
- How to prepare the dose for administration by withdrawing the dose of naloxone from the ampoule/vial into the syringe
- How to landmark on the thigh and administer an intramuscular injection
- How to avoid and manage needle-stick injuries
- When to use the second dose of naloxone
- The importance of calling 911 immediately for medical assistance due to the short half-life of the drug
- After care and the importance of staying with the person until emergency first responders arrive
- Any other information the pharmacist deems relevant

Pharmacists are reminded to emphasize the importance of contacting emergency services (911) in the event of an opioid overdose. Pharmacists should counsel their patients on the risk of rebound toxicity following administration of naloxone and the importance of follow-up monitoring after an overdose. The current labels for naloxone do not adequately cover this information, thus reinforcing the importance of the pharmacist's role in dispensing naloxone.

The minimum required items for each initial take-home-naloxone kit include:

- 2 x 1 mL ampoules/vials of injectable naloxone 0.4 mg/mL
- 2 x 3cc syringes with auto-retractable needles (1" length recommended)
- 2 alcohol swabs
- 1 rescue breathing shield with one-way valve
- 1 printed card with overdose signs and symptoms, and overdose response steps
- 2 vinyl gloves
- 1 patient information leaflet on naloxone (supplied by the manufacturer and photocopied if need be)

Pharmacies are encouraged to provide all the above items for subsequent THN kits, but pharmacists can use professional judgement to provide only some of the items if and when appropriate to do so.

Unlike some prescription medications where a complete dialogue on refills is only required at the pharmacist's professional judgement, complete counselling should occur every time a customer purchases naloxone. This counselling will review the important training and education points for a drug that is not regularly used, as well as an opportunity for the pharmacists to act as a resource for opioid dependency.

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Additional Resources

Street Connections: Overdose

http://www.streetconnections.ca/content.php?navigation_id=2294

College of Pharmacists of British Columbia Naloxone Ampoule Brochure

http://library.bcpharmacists.org/6_Resources/6-5_Pharmacy_Resources/5188-Naloxone_Brochure_Ampoule_BW.pdf

College of Pharmacists of British Columbia Naloxone Vial Brochure

http://library.bcpharmacists.org//6_Resources/6-5_Pharmacy_Resources/5189-Naloxone_Brochure_Vial_BW.pdf

College of Pharmacists of British Columbia Checklist for Naloxone Training

http://library.bcpharmacists.org/6_Resources/6-5_Pharmacy_Resources/5184-Naloxone_Checklist_For_Training.pdf

References

1. Lexicomp Online®, Lexi Drugs®, June 6, 2016.
2. Winnipeg Regional Health Authority. Clinical Practice Guideline: Overdose Lay Responder Preparation by Public Health Nurses (2016).
3. Pharmacy Benefact, Alberta Blue Cross. Update on the Naloxone Program (2016). Accessible at: <https://www.ab.bluecross.ca/pdfs/pharmacy-benefacts/pharmacy-benefact-575.pdf>
4. Alberta College of Pharmacists. Guidance for Pharmacists and Pharmacy Technicians Dispensing or Selling Naloxone as a Schedule 2 Drug (2016). Accessible at: https://pharmacists.ab.ca/sites/default/files/THN%20kit%20Guidelines_May%2011%20final%20circulation.pdf
5. College of Pharmacists of Manitoba. Practice Direction: Sale of NAPRA Schedule II Drugs (non-prescription, pharmacy only sale) (2014). Accessible at: <http://mpa.in1touch.org/uploaded/web/Legislation/Sale%20of%20Schedule%202%20Drugs.pdf>

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