



Legal Interventions to Reduce Opioid-Related Mortality: Access to Naloxone

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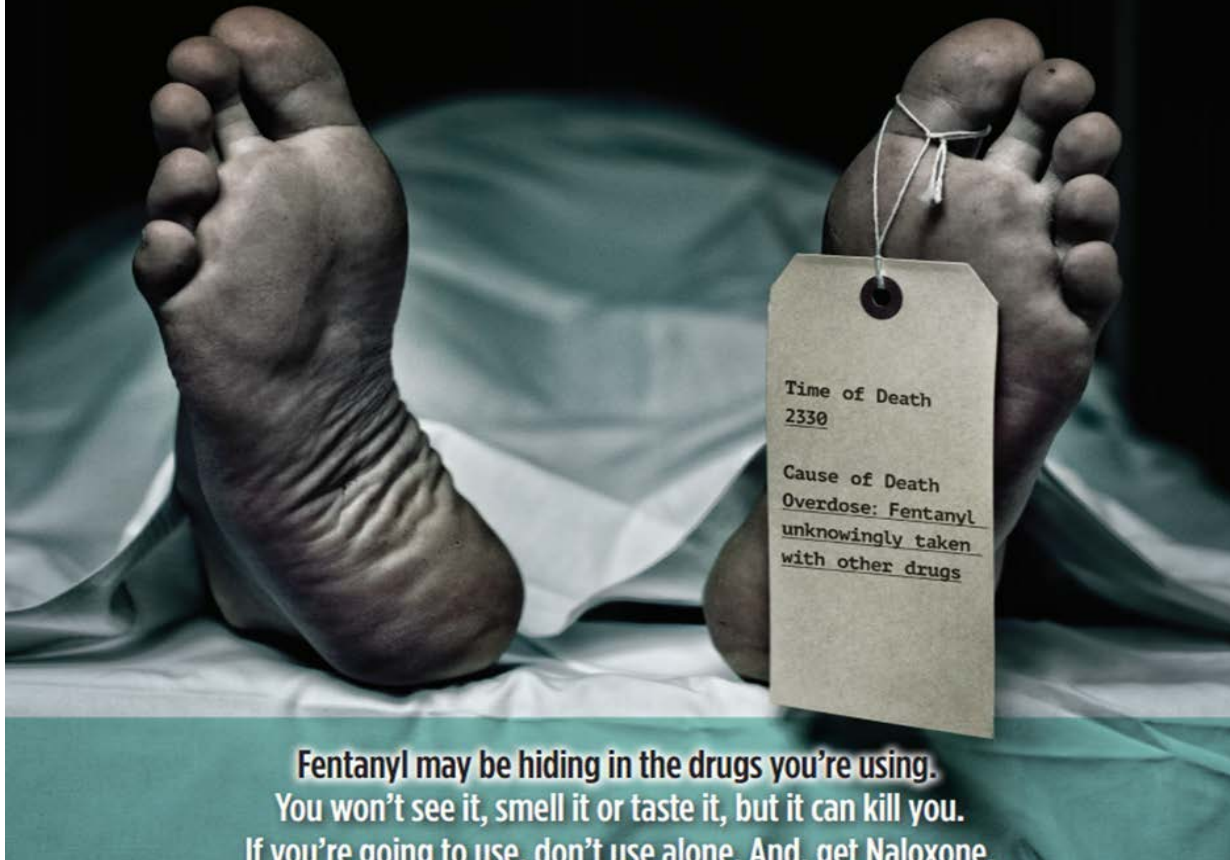
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Health Ethics Seminar

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IT'S NEVER GOING TO BE YOU...
UNTIL IT IS.



Tools to address an issue

- ▶ Non-legal
 - ▶ We all use these most of the time
 - ▶ This includes government and other organizations
- ▶ Legal
 - Legislation (federal and/or provincial) (Acts)
 - Regulations
 - Orders (e.g. Ministerial orders)
 - Directions
 - Standards of practice
 - Conditions of funding or provision or resources
 - Etc.

How do we choose which tool to use?

- ▶ Depends on the situation
- ▶ Depends on the tools available at the time
- ▶ Depends on what is seen as most effective – or good enough if competing issues to address
- ▶ And many other factors

Access to naloxone

- ▶ Aim to increase access
- ▶ First step – identify the barriers
 - ▶ E.g. Prescription drug – so prescription only available through a health care professional with competency and authority to prescribe
 - ▶ E.g. only able to dispense from controlled locations (e.g. licensed pharmacy) – who else can dispense?
 - ▶ E.g. only authorized persons may administer injectable naloxone
- ▶ Other factors to consider?
 - E.g. Still want interaction with health care professional? To educate, train, provide other advice?
 - E.g. Want ability to monitor dispensing to assess effectiveness of change?

Some legal options

- ▶ Increase authority of certain health care professionals to do certain restricted activities (Schedule 7.1 *Government Organization Act*)
 - E.g. prescribe a Schedule 1 drug (within the meaning of the *Pharmacy and Drug Act*)
 - E.g. dispense a Schedule 1 or 2 drug (within the meaning of the *Pharmacy and Drug Act*)

Expanding scopes of practice

- ▶ Usual process for changing scopes of practice for regulated health care professionals
- ▶ Another possible option: If certain criteria met, M.O.s issued by Minister of Health
 - Schedule 7.1 of *Government Organization Act*
 - Section 3.1
- ▶ Such M.O.s may be issued to prevent, combat or alleviate a “public health emergency” as defined in Alberta’s *Public Health Act*

M.O.s under GOA

- ▶ “public health emergency” an occurrence or threat of an illness, health condition, epidemic or pandemic disease, a novel or highly infectious agent or biological toxin, or the presence of a chemical agent or radioactive material that poses a significant risk to the public health”
- ▶ No declaration of a public health emergency is required

Steps taken...

- ▶ Ministerial Orders issued to authorize RNs and RPNs to prescribe naloxone
 - December 2015
 - February and May 2016
- ▶ Ministerial Orders issued to authorize paramedics, EMTs and EMRs to dispense naloxone on same basis
 - December 2015 and May 2016
- ▶ Paramedics, EMTs and EMRs moved under *Health Professions Act* and new regulation made
 - Fall 2016 – so no need to reissue last M.O.s

Drug on federal Prescription Drug List

- ▶ 1st step: federal government recognition of issue and action
- ▶ Prescription Drug List established by the federal Minister of Health (*Food and Drugs Act*)
- ▶ Alberta could not reschedule while drug on PDL



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Notice: Prescription Drug List (PDL): Naloxone

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January 14, 2016
Our file number: 16-100479-342

The purpose of this Notice of Consultation is to provide an opportunity to comment on the proposal to revise the listing for Naloxone on the Prescription Drug List (PDL) to allow the non-prescription use of Naloxone for the conditions listed below.

The proposed wording of the new listing is:

Drugs containing the following: Naloxone or its salts

Including (but not limited to): Naloxone hydrochloride

Qualifier: Except when indicated for emergency use for opioid overdose outside hospital settings

Effective Date: to be determined

Rationale

Naloxone, an opioid antagonist, is indicated for the complete or partial reversal of opioid depression, including respiratory depression induced by an overdose of an opioid (natural and synthetic). It is also indicated for the diagnosis of suspected acute opioid overdose. Both the 0.4 milligram/millilitre and the 1 milligram/millilitre strengths are proposed to switch.

Opioid overdose is a very serious and often life-threatening condition. Loss of life due to opioid overdoses - both accidental and voluntary - constitutes a serious public health concern. The large increase in opioid overdose episodes has prompted the provinces to design programs to provide greater access to naloxone at the site of the overdose, either through first responders or "take-home programs". These programs are hindered by the prescription status of naloxone. The provinces and territories have collectively asked Health Canada to re-evaluate the status of naloxone.

In response to the request, Health Canada undertook a Benefit-Harm-Uncertainty (BHU)

Qualified removal from PDL

- ▶ When indicated for emergency use for opioid overdose outside hospital settings
- ▶ Many thought this meant it could now be dispensed without a prescription for this purpose

That wasn't the whole solution...

- ▶ Alberta's *Pharmacy and Drug Act*
- ▶ Alberta's *Schedules Drugs Regulation*
 - Alberta's drug schedules
 - reference to National Association of Pharmacy Regulatory Authorities Drug Schedules
- ▶ Application to NAPRA?
- ▶ OR amend Alberta's Regulation?

Naloxone rescheduled by AB ahead of NAPRA

- ▶ Naloxone rescheduled from Alberta's Schedule 1 to Schedule 2 for emergency use
- ▶ Could be dispensed without a prescription from dispensary area of pharmacy
- ▶ Could be dispensed by authorized health care professionals in other settings
- ▶ No prescription required (though could still be prescribed) but ensured interaction with health care professional who could provide appropriate advice, training, etc.

Grants for take home naloxone kits

- ▶ AH initial grant to community agencies \$300,000
- ▶ AHS/AH funded kits
- ▶ Plans developed/implemented to support dispensing of kits through emergency rooms, other clinical settings, community pharmacies, community agencies

Greatly increased access

- ▶ And – still barriers
- ▶ Reassessment and decision to expand access further

Naloxone de-scheduled in AB

- ▶ Removed from all Alberta drug schedules
- ▶ Provides potential ability to access without interaction with a health care professional
- ▶ If sold or dispensed without an interaction with a regulated health care professional, no need to address other duties of HCPs

Another e.g. of legal measures

- ▶ Further M.O.s issued under GOA
 - Authorize police officers, peace officers and firefighters to administer injectable naloxone
 - January 2017

Public health emergency

- ▶ Alberta's *Public Health Act* provides authority to declare a public health emergency if certain criteria are met
 - CMOH advises that a PHE exists or may exist, AND prompt co-ordination of action or special regulation of persons or property is required in order to protect the public health
 - LGiC is satisfied criteria met based on CMOH advice

If criteria met, does that mean declaration should be made?

- ▶ Extraordinary powers
- ▶ Powers not in keeping with law/normal processes in a democratic society
- ▶ To be used only when necessary
- ▶ Actions of government and public health officials are to be *Charter* compliant
 - i.e. in keeping with our Constitution which supercedes other legislation

What are the powers available?

- ▶ If LGiC declared, Minister responsible for Act may, by order, without consultation, suspend or modify the application or operation of all or part of an enactment (and if Minister responsible is not available, Minister of Health)

What powers are available?

- ▶ Minister of Health or AHS may:
 - Acquire or use real or personal property
 - Authorize or require any qualified person to render aid
 - Authorize the conscription of persons
 - Authorize entry into any building or on any land, without warrant, by any person
 - Provide for distribution of essential health and medical supplies and provide, maintain and coordinate the delivery of health services

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