Professional Practice Webinar

Current Issue – Buprenorphine-Naloxone (Suboxone®) for the Treatment of Opioid Dependence

August 8, 2017

Presentation Overview

- This webinar will include:
  - An overview of the principles of harm reduction
  - A discussion on the critical shortage of pharmacies participating in opioid dependence treatment (ODT) and the need to increase access to ODT
  - Consideration of pharmacists' professional obligations, the Code of Ethics, and the patient's right to receive care
  - An overview of relevant sections of the NLPB *Standards for the Safe and Effective Provision of Medication for the Treatment of Opioid Dependence*
  - References for new evidence supporting opioid agonist maintenance treatment

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What is Harm Reduction?

- CAMH defines harm reduction as

  "any program or policy designed to reduce drug-related harm without requiring cessation of drug use. Interventions may be targeted at the individual, the family community or society"

  -Ericksone et al., 2002 as cited in Isaac, Janecek, Kalvik, Zhang, 2015

- Opioid agonist maintenance treatment (OAMT), e.g. methadone or buprenorphine-naloxone, is an example of a harm reduction approach

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What is Harm Reduction?

- Other examples strategies to reduce harm of drug use: (Isaac, Janecek, Kalvik, & Zhang, 2015):
  - Supplying clean needles for drug administration
  - Promoting less hazardous routes of administration (e.g. switching from I.V. use to oral)
  - Providing safer environments for substance-use (e.g. safe injection sites)
  - Reducing harms associated with overdose (e.g. providing naloxone kits)

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Joint Statement of Action to Address the Opioid Crisis (November 19, 2016): Pharmacy related highlights

- Implementing the **Federal Action on Opioids** includes:
  - **Supporting better prescribing practices:** this includes continuing to promote best practices and national approaches through the Federal/Provincial/Territorial Prescription Monitoring Program Network; and sharing prescribing practice information obtained from pharmacy inspections with selected Provincial/Territorial regulatory authorities, as appropriate.
  - **Reducing easy access to unnecessary opioids:** this includes adding new contraindications for approved opioids; requiring a prescription for low-dose codeine products; requiring manufacturers to develop and implement risk management plans for high-risk opioids; and providing updated guidance to pharmacies on the handling and destruction of consumer-returned prescription drugs.
  - **Supporting better treatment options for patients: …*"promoting increased access to buprenorphine/naloxone as a first line treatment choice…"***
  - **Reducing the availability and harms of street drugs:** Includes continuing to facilitate increased access to naloxone
- Continuing to implement the **Health Portfolio's Prescription Drug Abuse Strategy** (2014-2019):
  - Increased pharmacy inspections to help reduce the diversion of prescription drugs

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Provincial Commitments for the Opioid Action Plan

- **By December 31, 2017:** Implementing a **Provincial Prescription Monitoring Program** focused on prescription drugs with high potential for abuse. Specific actions include:
  - **By December 2016:** Establishing the governance structure for the program;
  - **By January 2017:** Implementing of Safe Prescribing Course for Physicians;
  - **By May 2017:** Establishing wide-scale access to patient drug profiles for physicians;
  - **By May 2017:** Implementing a Provincial Pharmacy Network;
  - **By December 2017:** Operationalizing Prescription Monitoring Program database and analytics capacity; and
  - Exploring the legislation required to enable the Prescription Monitoring Program.

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Provincial Commitments for the Opioid Action Plan

- Implementing a **provincial Take Home Naloxone Kit program** to increase capacity for Opioid Overdose response. Specific actions include:
  - **By December 2016:** Collaborating with community partners, regional health authorities, and other government departments in the development of a provincial Take Home Naloxone Kit program;
  - **By December 2016:** Establishing target populations and provincial distribution sites;
  - **By January 2017:** Developing and implementing related training, education and program awareness materials;
  - **By October 2017:** Developing and implementing a program evaluation framework to strengthen the effectiveness of the provincial Take Home Naloxone program; and
  - **By January 2017:** Developing and implementing a multi-faceted opioid overdose awareness and education campaign

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Provincial Commitments for the Opioid Action Plan

- **By March 2017:** Initiating **coverage of Suboxone under special authorization**, until an Atlantic Common Drug Review can be completed. Specific actions include:
  - **By December 2016:** Determining updated physician licensure requirements to prescribe Suboxone;
  - **By December 2016:** Identifying training/operational requirements for physicians/pharmacists/others working with clients on Suboxone;
  - **By January 2017:** Communicating and consulting on the plan with Newfoundland and Labrador Medical Association, Association of Registered Nurses of Newfoundland and Labrador, Prescribers, Pharmacy Association of Newfoundland and Labrador and others as required;
  - **By February 2017:** Finalizing and implementing training and any operational requirements, e.g. revised billing codes; and
  - **By March 2017:** Communicating publicly.
- Early December 2016, the Minister of Health and Community Services announced that buprenorphine-naloxone (Suboxone) no longer requires special authorization

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Towards Recovery: The Mental Health and Addictions Action Plan for NL

- Released June 27, 2017
- Vision
  - A province that promotes positive mental well-being and resilience and supports individuals and families with lived experience of mental illness and addiction to live full and rewarding lives
- Values
  - Respectful, person-centred, *accessible*, recovery-focused, *collaborative*, effective and efficient, *responsive*, and inclusive
    - Service delivery must be inclusive, sensitive, compassionate and free from stigma and discrimination
    - Directed toward meeting the person's needs
    - Appropriate services available and close to home, and accessible at the first sign of a mental health or addictions issue
    - Shared responsibility for improving service delivery among government, community agencies, care providers, individuals, and families

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Gaps Analysis for ODT

- Highlighted that access to methadone and buprenorphine-naloxone are critical ODT services
- Lack of access to MMT due to few pharmacies participating in ODT services, and/or caps on the number of patients serviced
  - Has become magnified with increasing numbers of patients initiating treatment
  - Disparity of services between rural and urban
- Suggestion that pharmacists and physicians have personal biases toward treating people with addictions
  - Refusal to prescribe or dispense ODT, but will prescribe and dispense opiates
  - Do not embrace harm reduction
  - Many patients report that they face stigma when accessing care

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Gaps Analysis for ODT

- Reasons provided for resistance to participation:
  - May create negative care environment due to the physical appearance of some patrons receiving methadone treatment, and their coexisting mental health or behaviour issues
  - Concern that it may increase shoplifting
  - Concern that involvement would jeopardize other clientele
  - Inability to separate ODT from their general practice (as physicians would do by providing clinics on alternate days to different patient populations)
  - Insufficient staff to support extended hours and/or days of operation, or for buprenorphine-naloxone specifically, the amount of time it takes to administer tablets

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Gaps Analysis for ODT

- Pharmacists commonly cited that there is a low percentage or number of patients successful in the program
- Need to reevaluate the concept of “success” and to define the goals of the program
- Success is not limited to being weaned off treatment, abstinence, or full recovery
- Need to set realistic expectations and measure success in relation to improvements in individual functionality and public safety
- 97% of informants with lived experience reported that methadone will help them stay off drugs
- 82% provided a high rating for the helpfulness of methadone
  - Reasons provided for score were achieving a sense of normalcy, support provided by the program, the ability to be free from their addictions, and that the program “saved” their life

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Pharmacy ODT Services

- Lack of access to ODT services from pharmacies is a growing concern
  - Increasing access to services is part of the federal and provincial Opioid Action Plan to address the opioid crisis
- Currently there are 56 community pharmacies offering ODT services
  - Many pharmacies have capped numbers
  - There are still many communities where ODT cannot be accessed from the pharmacy
    - Resources are concentrated on the Northeast Avalon
- NLPB continues to receive phone calls from physicians, patients, and patient advocates voicing concern about this issue

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The Code of Ethics

1. ***Registrants hold the health and safety of each patient to be of primary consideration.***
2. Registrants maintain a professional relationship with each patient.
3. ***Registrants respect the autonomy, values and dignity of each patient.***
4. Registrants respect and protect the patient's right to confidentiality.
5. ***Registrants respect the patient's right to receive care.***
6. Registrants observe the law, preserve high professional standards and uphold the dignity and honour of the profession.
7. Registrants continuously improve their professional knowledge and skills.
8. ***Registrants cooperate with colleagues and other health care professionals to ensure optimal patient-centred care.***
9. ***Registrants contribute to the health care system and to societal health needs.***
10. Registrants act to enhance and nurture the profession of pharmacy.

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Standards for the Safe and Effective Provision of Medication for Opioid Dependence Treatment

- **Pharmacist Requirements for Participation in ODT**
  - Apply to the NLPB for authorization; and
  - Provide proof of successful completion of an education program on the use of medication in the treatment of opioid dependence approved by the Board;
    - NOTE: Applications for authorization must be made within one year of successful completion of the required education program.
  - Once authorized, the pharmacist must:
    - Maintain competence in ODT
      - Continuing professional development should be undertaken, as necessary, to maintain knowledge and skills.
    - Agree to provide medication for the treatment of opioid dependence only in accordance with the standards and within the limits of their own competence

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Standards for the Safe and Effective Provision of Medication for Opioid Dependence Treatment

- **Pharmacy Requirements for Participation in ODT**
  - Pharmacist-in-charge must apply to NLPB to register the pharmacy as a site for opioid dependence
  - Pharmacy Layout and Design
    - Doses must be administered in patient consultation room that ensures visual and acoustical privacy and confidentiality and that is clean, safe, and comfortably furnished for the patient.
  - Hours of Operation
    - The pharmacy should be prepared to accommodate witnessed daily dosing when necessary, where possible.
    - Pharmacies that do not operate 7 days a week must facilitate the patient acquiring their doses on the days the pharmacy is closed (e.g. pre-scheduled patients dosing times, collaboration with physicians for authorization of take-home doses (if deemed safe for the patient), or collaboration with physicians and another pharmacy to arrange dosing at an alternate site.

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Pharmacy Requirements for Participation in ODT
(cont'd)

- Staff Education
  - All pharmacist and non-pharmacist staff need to be appropriately educated, trained, and understand the scope of their role in ODT
- Security
  - Theft prevention
    - Preparations containing methadone and buprenorphine should be stored in a locked and secure location at all times (i.e., during hours of operation and when the premises are closed for business)
- Policy and Procedure Manual
  - The pharmacy must develop, maintain and regularly review a policy and procedure manual related to ODT
- Required References
  - CPSNL Methadone Maintenance Treatment Standards and Guidelines
  - Health Canada Best Practices: Methadone Maintenance
  - Opioid Agonist Maintenance Treatment, 3rd edition
  - Centre for Addictions and Mental Health (CAMH) Buprenorphine-Naloxone for Opioid Dependence: Clinical Practice Guideline

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Standards for the Safe and Effective Provision of Medication for Opioid Dependence Treatment - Buprenorphine/Naloxone

- **Section 6 of the Standards**
  - 6.1 Collaboration Between the Pharmacist and the Prescriber
  - 6.2 Establishing the Pharmacist-Patient Relationship
    - Verbal discussion and written agreement
  - 6.3 Assessing the Prescription
    - TRPP program and prescription requirements
    - Buprenorphine-naloxone dosing
    - Information about initiation and suspension of take-home doses
  - 6.4 Dispensing the Prescription
    - Formulations
    - Preparing witnessed doses
    - Preparing take-home doses
  - 6.5 Releasing the Prescription
    - Witnessed doses and take-home doses
  - 6.6 Responding to Special Circumstances
    - Intoxication or sedation
    - Missed doses

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Key Points related to Buprenorphine-Naloxone

- Physician eligibility
  - Do not have to have a special exemption from Health Canada to prescribe buprenorphine-naloxone
  - From Suboxone product monograph:
    - Patients prescribed Suboxone should be carefully monitored within a framework of medical, social, and psychological support as part of a comprehensive opioid dependence treatment program
    - Suboxone should only be prescribed by physicians who meet the following requirements:
      - Experience in substitution treatment in opioid drug dependence, and
      - Completion of a recognized SUBOXONE® Education Program
  - CPSNL echo these requirements
    - Complete the Centre for Addiction and Mental Health (CAMH) Opioid Dependence Core Course (or equivalent program acceptable to the College)
    - Complete a recognized educational program on prescribing Suboxone (such as the CAMH Buprenorphine-Assisted Opioid Dependence Treatment course or www.suboxonecme.ca)
    - Practice Guideline: Suboxone for Opioid Dependence available on the CPSNL website
- NLPB and CPSNL have jointly communication the necessity for physician-pharmacist collaboration with regard to ODT

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Key Points related to Buprenorphine-Naloxone

- Dosing
  - Based on buprenorphine-naloxone component
  - Induction dose given when patient is in moderate withdrawal
  - Increased according to patient needs over a few days
  - Dosing chart in Standards was based on CAMH clinical practice guideline and states a max dose of 8 mg on day 1
  - From the product monograph,
    - “The recommended starting dose is 8 mg Suboxone on Day 1, initiating with 4 mg and then an additional 4 mg dose may be administered depending on the individual patient’s requirement. The suggested total dose target for treatment on Day 1 is within the range of 8 and 12 mg”
  - If pharmacists see doses prescribed outside of established clinical guidelines, or have concerns about prescribed doses, should consult prescriber and document rationale for deviations in the patient record

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Key Points related to Buprenorphine-Naloxone

- Witnessed ingestion
  - The pharmacist is required to directly observe the patient ingesting the dose
    - May not be delegated to a pharmacy technician or any other member of the pharmacy team
  - Patient should be instructed to place buprenorphine-naloxone under the tongue and stay within the sight of the pharmacist observing the dose since it can take 1-10 minutes for buprenorphine-naloxone tablets to dissolve completely
    - Ask the patient to open their mouth and lift up their tongue to ensure the entire dose has dissolved
    - Appropriately document the dose on the Administration Log (see sample in Appendix VI)

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Key Points related to Buprenorphine-Naloxone

- Take-home doses
  - General principles (Table 6-1, p. 56, Isaac, Janecek, Kalvik, & Zhang, 2015)
    - Health Canada states that all doses are to be observed, except on weekends and holidays, for at least the first two months of taking buprenorphine-naloxone
    - If additional regular take-home doses are prescribed before two months, justification should be documented in the patient record, and patient needs to be counselled and provide consent regarding the off-label prescription
    - If appropriate, after 2 months of treatment take-home doses can be increased to a suggested maximum of 1-2 weeks, with observed doses in between

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Key Points related to Buprenorphine-Naloxone

- Take-home doses (cont'd)
  - Do not need to be processed as individual transactions or dispensed in individual vials as they would for methadone
  - In addition to usual labelling requirements, must also be labelled with:
    - Total number of tablets in the vial
    - Specific directions for use (such as "Take X tablets on (insert date or days of week).")
    - Date of dispense
    - Cautionary labels:
      - Keep out of reach of children
      - Special cautionary label such as: "May be toxic or lethal if ingested by a child or adult other than the intended patient. Accidental ingestion is considered a medical emergency and requires immediate medical attention."
    - See labelling requirements outlined in Section 6.4 of the Standards
  - Must be recorded in administration log and patient sign for take-home doses

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New References for Review

- Canadian Agency for Drugs and Technologies in Health (CADTH), Rapid Response Report: Peer-reviewed Summary with Critical Appraisal
  - Buprenorphine/Naloxone Versus Methadone for the Treatment of Opioid Dependence: A Review of Comparative Clinical Effectiveness, Cost-effectiveness, and Guidelines
    - Released September 2, 2016
    - Cited in the Federal Action on Opioids
    - Concluded that, overall, buprenorphine/naloxone appears to be a safe, effective, and cost-effective alternative for treating opioid use disorder compared with methadone

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New References for Review

- British Columbia Centre on Substance Use
  - A Guideline for the Clinical Management of Opioid Use Disorder
    - Published June 5, 2017
    - Recommendations
      - Strongly recommends against withdrawal management alone based on increased risk of Hepatitis C and HIV transmission, increased rates of overdose, and universal relapse when long-term evidence-based opioid agonist treatments are not provided
      - Strongly endorses buprenorphine-naloxone as a preferred first-line treatment when no contraindications exist
        - 6x safer than methadone for overdose risk
      - Emphasizes the need for a stepped and integrated care approach
        - Treatment adjusted over time to meet patient needs and circumstances
        - Many patients may need to move between treatments

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Table 2. Advantages and disadvantages of methadone vs. buprenorphine/naloxone

METHADONE	BUPRENORPHINE
ADVANTAGES	
• Potentially better treatment retention • May be easier to initiate treatment • No maximum dose • Potentially better alternative if buprenorphine was unsuccessful in relieving withdrawal symptoms, or was associated with severe side effects • Approved in Canada for the primary purpose of pain control (as split dose BID or TID dosing; Health Canada exemption to prescribe methadone for analgesia also required)	• Less risk of overdose due to partial agonist effect and ceiling effect for respiratory depression (in the absence of benzodiazepines or alcohol) • Reduced risk of injection, diversion, and overdose due to naloxone component, allowing for safer take-home dosing schedules • Milder side effect profile • Easier to rotate from buprenorphine/naloxone to methadone • More flexible take-home dosing schedules may contribute to increased cost savings and patient autonomy • Shorter time to achieve therapeutic dose (1–3 days) • Potentially more effective analgesic for treatment of concurrent pain (however, see disadvantages) • Fewer drug interactions • Milder withdrawal symptoms and easier to discontinue, thus may be a better option for individuals with lower intensity opioid dependence (e.g., oral opioid dependence, infrequent or non-injectors, short history of opioid dependence, currently abstinent but risk of relapse), and individuals anticipated to be successfully tapered off maintenance treatment in a relatively short period of time • Alternate day dosing schedules (as daily witnessed or take-home doses) are possible • Optimal for rural and remote locations where daily witnessed ingestion at a pharmacy is not possible
DISADVANTAGES	
• Higher risk of overdose, particularly during treatment initiation • Generally requires daily witnessed ingestion • More severe side effect profile (e.g., sedation, weight gain, erectile dysfunction, cognitive blunting) • More expensive if daily witnessed ingestion required • Longer time to achieve therapeutic dose (see Appendix 1) • More difficult to transition to buprenorphine once on methadone • Higher potential for adverse drug-drug interactions (e.g., antibiotics, antidepressants, antiretrovirals) • Higher risk of non-medical or other problematic use • Increased risk of cardiac arrhythmias as a result of QTc prolongation • At high doses, may block some of the analgesic effect of concurrent opioid medications administered for pain	• Potentially higher risk of drop-out • If appropriate dose induction schedules are not used (see Appendix 2), may cause precipitated withdrawal • Doses may be suboptimal for individuals with high opioid tolerance • At high doses, may block the analgesic effect of concurrent opioid medications administered for pain • Not approved in Canada for the primary purpose of pain control, though moderate evidence of efficacy • Reversing effects of overdose can be challenging due to pharmacology of buprenorphine

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Summary

- The evidence supporting harm reduction approaches, including opioid agonist treatment, is growing
- Addressing the opioid crisis is a primary component of the federal and provincial health care agenda
- The goal is to reduce stigma associated with mental health and addiction, and make treatments for opioid use disorder readily accessible
- Currently, there is a shortage of pharmacy services for provision of methadone and buprenorphine-naloxone
- Pharmacists and pharmacy technicians have an ethical obligation to consider the health and safety of each patient, respect patient's right to receive care, and contribute to health care system and societal health needs

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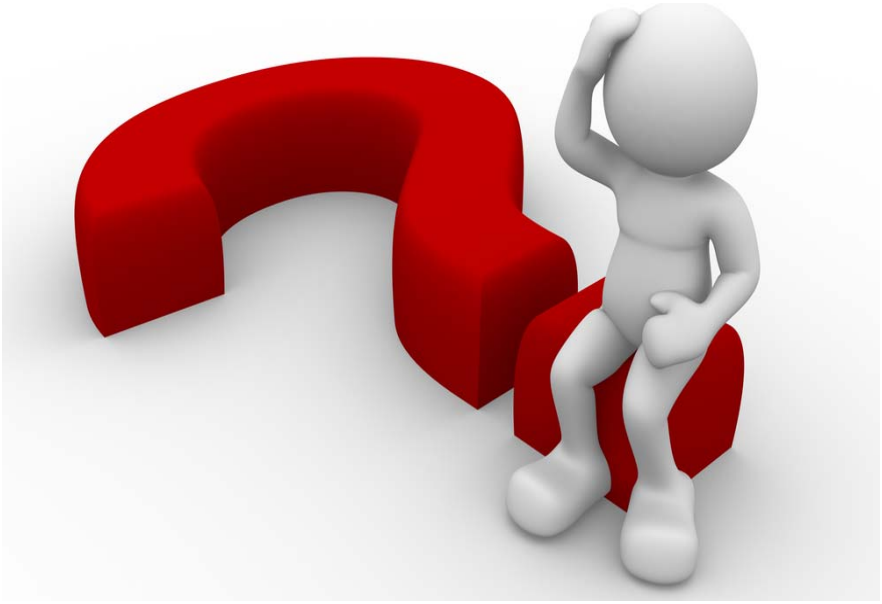

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