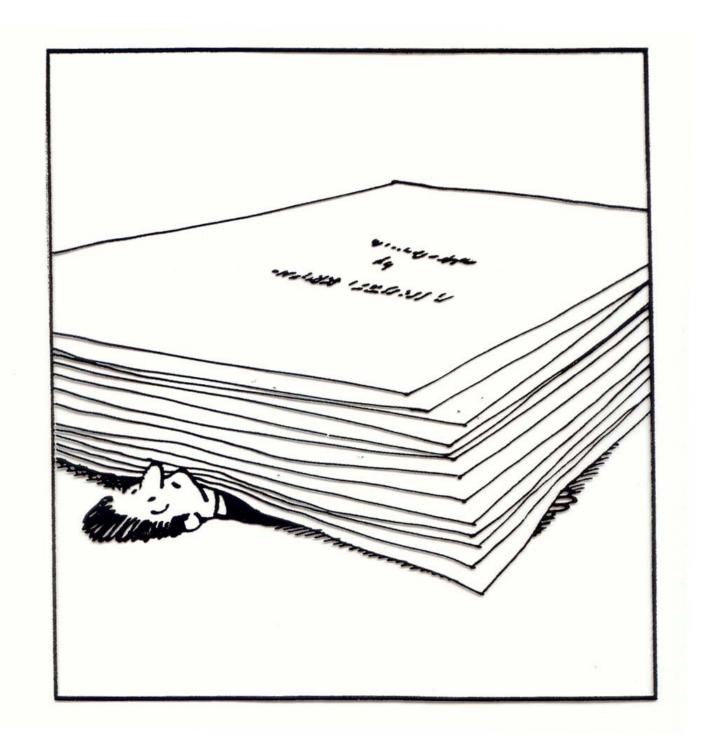
Canadian Guidelines for Safe and Effective use of Opioids for CNCP

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Guideline Anatomy

- Part A: Executive Summary and Background
- Part B: Recommendations for Practice
 - Canadian Guideline Recommendation Clusters
 (5)
 - Appendix (B-1 through B-13)

- Guideline development was in response to:
 - Physicians and other stakeholders seeking guidance regarding safe and effective use of opioids
 - A growing concern about opioid misuse creating patient and public safety issues, and
 - Lack of systematically developed national guidelines on opioid use for CNCP.

- Develop guideline that relies on the best available evidence and expert opinion consensus
- Develop and implement knowledge-transfer strategy that ensures transition of the guideline to practice as a useful decision-making tool for physicians who treat CNCP patients.
- Evaluate transfer of knowledge impact on practice
- Find a permanent home for the national guideline to ensure currency and ongoing transfer of evidence to practice

• The permanent home for this Guideline is the McMaster University's Michael G. DeGroote (Canadian Business man and philanthropist) National Pain Centre, which is responsible for keeping the document current, working collaboratively with national partners and alerting clinicians to new evidence. The center accepted responsibility of stewardship of the Guidelines, which includes updating the guideline when new evidence becomes available and continuing knowledge transfer to practice.

 Scope: to assist physicians with decisions to initiate appropriate trials of opioid therapy for patients with CNCP, to monitor longterm opioid therapy, and to detect and respond appropriately to situations of opioid misuse including addiction.

- CNCP, chronic non-cancer pain, is defined as pain lasting > 6 months; adolescent and adults with CNCP (does not address pediatric population).
- Target audience is PCP, medical and surgical specialists; others such as pharmacists, dentists, might find this helpful.
- Does not include use of opioids for acute pain and end-of-life pain or CNCP tx modalities and approaches other then opioids.

Literature Search Methods: Conducted three new literatures searches to answer

- 1. New RCT's since May of 2006
- Treatment of CNCP with opioids and managing patient with problematic opioid use
- Answer questions about long-term outcomes of opioid use.

Summary Of Canadian Guideline Recommendations

- I. Deciding to Initiate Opioid Therapy
- II. Conducting an Opioid Trial
- III. Monitoring Long-Term Opioid Therapy
- IV. Treating Specific Populations with Long-Term Opioid Therapy (LTOT)=COT (Chronic Opioid Therapy)
- V. Managing Opioid Misuse and Addiction in CNCP Patients

I. Deciding To Initiate Opioid Therapy

No.	Recommendations	Keyword
R01	Before initiating opioid therapy, ensure comprehensive documentation of the patient's pain condition, general medical condition and psychosocial history (Grade C), psychiatric status, and substance use history. (Grade B).	Comprehensive Assessment
R02	Before initiating opioid therapy, consider using a screening tool to determine the patient's risk for opioid addiction. (Grade B). Addiction-risk screening	Addiction-risk screening
R03	When using urine drug screening (UDS) to establish a baseline measure of risk or to monitor compliance, be aware of benefits and limitations, appropriate test ordering and interpretation, and have a plan to use results. (Grade C). Urine drug screening	Urine Drug Screening
R04	Before initiating opioid therapy, consider the evidence related to effectiveness in patients with chronic non-cancer pain. (Grade A). Opioid efficacy	Opioid Efficacy
R05	Before initiating opioid therapy, ensure informed consent by explaining potential benefits, adverse effects, complications and risks (Grade B). A treatment agreement may be helpful, particularly for patients not well known to the physician or at higher risk for opioid misuse. (Grade C). Risks, adverse effects, complications	Risks, adverse effects, complications
R06	For patients taking benzodiazepines, particularly for elderly patients, consider a trial of tapering (Grade B). If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. (Grade C).	Benzodiazepine tapering

II. Conducting Opioid Trial

Number	Recommendation	Keyword
R07	During dosage titration in a trial of opioid therapy, advise the patient to avoid driving a motor vehicle until a stable dosage is established and it is certain the opioid does not cause sedation (Grade C); and when taking opioids with alcohol, benzodiazepines, or other sedating drugs. (Grade B).	Titration and driving
R08	During an opioid trial, select the most appropriate opioid for trial therapy using a stepped approach, and consider safety. (Grade C).	Stepped opioid selection
R09	When conducting a trial of opioid therapy, start with a low dosage, increase dosage gradually and monitor opioid effectiveness until optimal dose is attained. (Grade C).	Optimal dose
R10	Chronic non-cancer pain can be managed effectively in most patients with dosages at or below 200 mg/day of morphine or equivalent (Grade A). Consideration of a higher dosage requires careful reassessment of the pain and of risk for misuse, and frequent monitoring with evidence of improved patient outcomes. (Grade C).	Watchful dose
R11	When initiating a trial of opioid therapy for patients at higher risk for misuse, prescribe only for well-defined somatic or neuropathic pain conditions (Grade A), start with lower doses and titrate in small-dose increments (Grade B), and monitor closely for signs of aberrant drug-related behaviors. (Grade C).	Risk: opioid misuse

III. Monitoring LTOT (COT)

No.	Recommendation	Keyword
<u>R12</u>	When monitoring a patient on long-term therapy, ask about and observe for opioid effectiveness, adverse effects or medical complications, and aberrant drug-related behaviours (Grade C).	Monitoring LTOT
<u>R13</u>	For patients experiencing unacceptable adverse effects or insufficient opioid effectiveness from one particular opioid, try prescribing a different opioid or discontinuing therapy (Grade B).	Switching or discontinuing opioids
<u>R14</u>	When assessing safety to drive in patients on long-term opioid therapy, consider factors that could impair cognition and psychomotor ability, such as a consistently severe pain rating, disordered sleep, and concomitant medications that increase sedation (Grade C).	LTOT and driving
<u>R15</u>	For patients receiving opioids for a prolonged period who may not have had an appropriate trial of therapy, take steps to ensure that long-term therapy is warranted and dose is optimal (Grade C).	Revisiting opioid trial steps
<u>R16</u>	When referring patients for consultation, communicate and clarify roles and expectations between primary-care physicians and consultants for continuity of care and for effective and safe use of opioids (Grade C).	Collaborative care

IV. Treating Specific Populations with LTOT

No.	Recommendation	Keyword
<u>R17</u>	Opioid therapy for elderly patients can be safe and effective (Grade B) with appropriate precautions, including lower starting doses, slower titration, longer dosing interval, more frequent monitoring, and tapering of benzodiazepines (Grade C).	Elderly patients
<u>R18</u>	Opioids present hazards for adolescents (Grade B). A trial of opioid therapy may be considered for adolescent patients with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed, risk of opioid misuse is assessed as low, close monitoring is available, and consultation, if feasible, is included in the treatment plan (Grade C).	Adolescent patients
<u>R19</u>	Pregnant patients taking long-term opioid therapy should be tapered to the lowest effective dose slowly enough to avoid withdrawal symptoms, and then therapy should be discontinued if possible (Grade B).	Pregnant patients
<u>R20</u>	Patients with a psychiatric diagnosis are at greater risk for adverse effects from opioid treatment. Usually in these patients, opioids should be reserved for well-defined somatic or neuropathic pain conditions. Titrate more slowly and monitor closely; seek consultation where feasible (Grade B).	Co-morbid psychiatric diagnoses

V. Managing Opioid Misuse and Addiction in CNCP

No.	Recommendation	Keyword
<u>R21</u>	For patients with chronic non-cancer pain who are addicted to opioids, three treatment options should be considered: methadone or buprenorphine treatment (Grade A), structured opioid therapy (Grade B), or abstinence-based treatment (Grade C). Consultation or shared care, where available, can assist in selecting and implementing the best treatment option (Grade C).	Addiction treatment options
<u>R22</u>	To reduce prescription fraud, physicians should take precautions when issuing prescriptions and work collaboratively with pharmacists (Grade C).	Prescription fraud
<u>R23</u>	Be prepared with an approach for dealing with patients who disagree with their opioid prescription or exhibit unacceptable behaviour (Grade C).	Patient unacceptable behaviour
<u>R24</u>	Acute or urgent health care facilities should develop policies to provide guidance on prescribing opioids for chronic pain to avoid contributing to opioid misuse or diversion (Grade C).	Acute care opioid prescribing policy

Cluster 1: Deciding to Initiate Opioid Therapy

R01: Recommendation

• R01: Discussion

R01: Summary of Peer-Reviewed Evidence

Cluster 1: Deciding to Initiate Opioid Therapy

R01: Recommendation Statement:

Before initiating opioid therapy, ensure comprehensive documentation of the patient's pain condition, and general medical condition, and psychosocial history, psychiatric status and substance use history. (Grade B)

Cluster 1: Deciding to Initiate Opioid Therapy

R01: Discussion

- 1. Comprehensive knowledge of the patient
 - 1. Pain condition
 - 2. Gen. medical and psychosocial history
 - 3. Psychiatric status
 - 4. Substance use history
- 2. Documentation

Cluster 1: Deciding to Initiate Opioid Therapy-Discussion

Comprehensive knowledge of the patient 1.1 Pain condition:

- Knowledge of the patient's pain condition includes a thorough history and physical examination to determine the type, cause and nature of the pain, including questions about past investigations and interventions for pain including medication trials.
- Estimate of the pain intensity in the functional impairment arises from it, for example the impact on work, school, home and leisure activities.
- Diagnoses

Cluster 1: Deciding to Initiate Opioid Therapy

R01: Summary of Peer-Reviewed Evidence

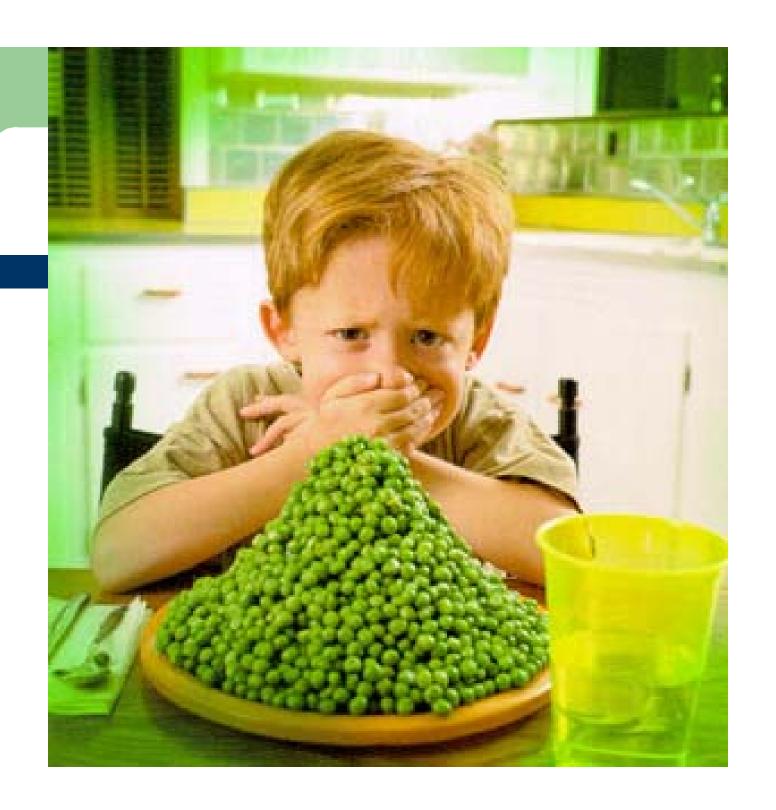
 Opioid addiction is estimated to have an overall prevalence of 3.3% in patients receiving opioids for CNCP, with wide variation between clinics and regions. Aberrant drug-related behaviors have a much higher prevalence. The major risk factor for addiction is a current or past history of addiction. (Fishbain, 2008)



Cluster 1: Deciding to Initiate Opioid Therapy

R01: Summary of Peer-Reviewed Evidence

 The prevalence of problematic substance use, including opioids, non-opioid substances and alcohol, is higher among patients on long-term opioid therapy for CNCP than in the general population.



R02: Addiction-Risk Screening Tool

- Opioid Risk Tool-high sensitivity and specificity
- Translates into low, moderate or high risk
- Information on personal and family hx of alcohol and substance abuse and psychiatric history
- Turk 2008: systematic review of predictors of opioid misuse concluded none of these tools can be recommended with confidence: samples small (Greatest risk: Opioids)

Opioid Risk Tool

Item	Вох	Female	Male
Family history of alcohol		1	3
Family history of illegal drugs		2	3
Family History of Prescription drugs		4	4
Personal History of Alcohol.		3	3
Personal History of Illegal drugs		4	4
Personal History of Prescription Drugs		5	5
Age (16-45 y/0)		1	1
Preadolescent sex abuse	0	3	0
Ψ D/O: ADD; OCD, Bipolar, Schizophrenic		2	1
Depression		1	1
Score: Low risk (0-3) Moderate Risk (4-7) High Risk (8 or above)			

R03: Urine Drug Screening

- POC
- Laboratory confirmation
- Baseline measure
- Compliance assessment
- Unexpected results
- Tampering
- Pharmacology knowledge

Urinary Drug Screen

Unexplained Result	Possible Explanation	MD/DO Action	
UDS (-) for Rx drug	False (-) Noncompliance Diversion	Lab confirm Ask patient Pill count	
UDS (+) for nonprescribed drug	False (+) Acquired from another source	Repeat UDS regularly Assess misuse/abuse and addiction	
UDS (+) illicit Rx	False (+) Addiction vs occasional user	UDS regularly Abuse/addiction	
Ur Cr <2-3	H20 added to sample	Repeat, supervise	
Cold Sample	H20 added; delayed handling	collection, 7 day hx, revise tx agreement	

R04: Opioid Efficacy

- Small to moderate benefits for nociceptive pain in improving function and relieving function
- Small populations
- Brief studies (</= 3 months)
- Many conditions not well studied such as HA, pelvic pain, whiplash, Repetitive Motion Injuries

R05: Risk, Adverse effects, complications

- Informed consent explains potential benefits, adverse effects, complications and risks.
- Treatment agreement/Contract-Appendix B-5.
- Goal setting: realistic expectations (pain elimination); 30% reduction in pain or improvement in function.
- Adverse effects: OSA, Driving, OD, neuroendocrine, Opioid-induced hyperalgesia
- Directions to patient and family (Table B-5.2)

R06: Benzodiazepine Tapering

- Consider tapering particularly for elderly
- Risk of combination of BZDP and Opioids

R07: Titration and driving

- Avoid driving until dose is stable: total daily dose fixed for at least two weeks and frequency is scheduled and spread throughout the day AND/OR at least 70% of the prescribed opioid is controlled release. (debatable)
- Cognitive impairment as dose increases
- Worse when combined with BZDP

R08: Stepped Opioid Selection

- Mild to moderate pain: codeine or tramadol
- Second line: morphine, oxycodone, hydromorphone
- First line for severe pain: Morphine, Oxycodone, hydromorphone
- Second line for severe pain: fentanyl
- Third line for severe pain: methadone

R09: Optimal Dose

- Start low, slowly increase until optimal dose is obtained
- Effectiveness: 30% reduction in pain
- Plateau: increasing dose yields negligible benefit
- Adverse effects/complications
- 200 MED mg/day (controversial?)

R10: Watchful dose

- 200 MED mg/day (controversial?)
- Reassess pain and risk for misuse, diversion, abuse, addiction for higher doses
- Is the diagnosis accurate?
- Further investigation?
- Additional consultation?
- Aberrant drug related behaviors?

R11: Risk: Opioid Misuse

 For patients at higher risk for opioid misuse, such as personal or family history of SUD, uncertain home circumstances, past aberrant drug-related behaviors, titrate slowly, small quantities, frequent visits, careful monitoring, UDS, Pill counts, screening tools

R12: Monitoring LTOT/COT

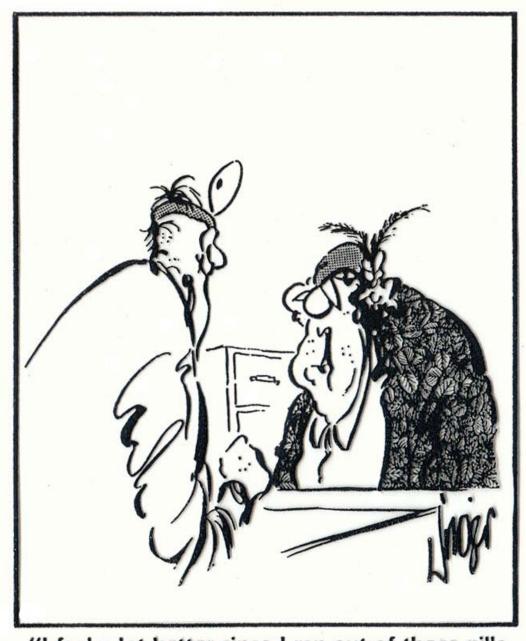
- Effectiveness? Progress reaching goals
- Adverse effects/medical complications: nausea, constipation, drowsy, dizzy, ED, hyperalgesia, OSA.
- Aberrant Drug-related behaviors: escalating dose, running out early, altering route of delivery
- PDMP

R12: Monitoring LTOT/COT

- Effectiveness? Progress reaching goals
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- Aberrant Drug-related behaviors: escalating dose, running out early, altering route of delivery
- PDMP

R13: Switching or discontinuing opioids

- If adverse effects are not acceptable or drug not effective, consider switching or d/c drug
- D/C if unresponsive after trial of several opioids
- Tapering or D/C may improve severe pain and improve mood.



"I feel a lot better since I ran out of those pills you gave me."

R14: LTOT and Driving

- ? impaired cognition and psychomotor ability
- Consistent VAS >7
- Sleep disorder or EDS
- BZDP, anticholoinergics, TCAD, AED, antihistamines, breakthrough medications.
- Chronic pain can impair cognitive abilities (Seminowicz and Davis)
- Evidence linking opioids and MVA (9 studies) sparse

R15:Revisiting Opioid Trial Steps

- For patients receiving opioids for prolonged period who may not have had an appropriate trial of therapy, take steps to ensure that LTOT is warranted and dose is optimal, eg. The transfer patient.
- Address: diagnosis, risk screening, goal setting, informed consent, appropriate opioid selected and dose, opioid effectiveness (R: 1, 2, 4,13, 3, 5, 8, 10, 9)

R16:Collaborative Care

- Communicate and Collaborate with consultant
- Referral for Consultation:
 - Expertise in Pain Management
 - Expertise in Addiction Medicine
 - Referral for Treatment Intervention
 - Multidisciplinary Pain Program
 - Addiction Treatment Program
 - Shared-Care Model

R17: Elderly Patients

- Can be safe and effective.
- Start with lower doses, slower titration, longer dosing intervals, more frequent monitoring, tapering of benzodiazepines.
- May be reluctant to report pain-lead to procedures, hospitalizations, fear of addiction
- Myth-less pain in the elderly
- Higher risk of overdose
- Oversedation, constipation, impaired cognition
- Monitor renal function

R18: Adolescent patients

- Present hazards. Trial consideration only for well-defined somatic or neuropathic pain when non-opioids have failed.
- 2. Misuse and OD greatest in this age group
- 3. Risk factors: poor academic performance, higher risk-taking behaviors, major depression, regular use of alcohol, cannabis, nicotine.
- 4. When feasible: seek consultation
- 5. Avoid BZDP when possible.
- 6. Very close monitoring.

R19: Pregnant Patients

- 1. Pregnant LTOT Patients: slow taper (avoid uterine smooth muscle irritability, premature labor and spontaneous abortion) then discontinue therapy if possible.
- 2. Neonatal-Abstinence Syndrome (NAS)
- 3. Breast feeding:
 - 1. Fast metabolizers to morphine- neonate at risk for fatal opioid toxicity
 - 2. Tramadol not recommended
- 4. Pregnant addicted: better outcomes on methadone

R20:Co-morbid Psychiatric Diagnoses

- 1. Greater risk for adverse effects-reserve for well-defined pain condition; titrate slowly; monitor closely; consult when feasible.
- 2. CNCP psychiatric pt: more likely to receive opioids then non-psych patient and less likely to receive benefit (when depressed or anxious)
- 3. Higher prevalence of SUD, OD, suicide
- 4. ↑ risk of falls and sedation when combined with other psychotropic drugs and BZDP

R21: Treatment Options for patient with CNCP and Opioid Addiction (3)

- 1. Methadone or buprenorphine treatment.
- 2. Structured Opioid Therapy
- 3. Abstinence-based treatment

R22: Prescription Fraud

- Take precautions when issuing a prescription.
- Check PDMP
- One pharmacy for dispensing
- Pharmacists are part of the "circle of care"

R23: Patient unacceptable behavior

- Be prepared to deal with patients who disagree with their opioid prescription or exhibit unacceptable behavior(s)
- Mitigate by:
 - Tx Agreements
 - Explanations: tx c/w Guidelines; △ not punitive
 - Book longer appointment
 - Arrange consultation: "team decision"
 - Document verbal agreement and past discussions

R24: Acute-Care opioid prescribing policy

- Acute and Urgent Care facilities should develop policies to provide guidance for prescribing.
- Involves all physicians at care center (and community if possible)
- Post policy or give as hand-out
- "Run out": contact the prescriber or pharmacist; limit doses to last until end of next business day; facility prescribes only once for patients that run out of medications; record visit to PCP.
- Be alert for abuse/addiction.

B-1	Examples of tools for assessing alcohol and other substance use:
B-2	Opioid Risk Tool
B-3	Urinary Drug Screening (UDS)
B-4	Opioid Information for Patients
B-5	Sample Opioid Medication Treatment Agreement

B-6	Benzodiazepine Tapering
B-7	Example of documenting Opioid Therapy
B-8	Opioid Conversion and Brand Availability in Canada
B-9	Brief Pain Inventory
B-10	Aberrant Drug-Related Behaviours (ADRB) Resources

B-11	SOAPP®-R and COMM®
	 Screener and Opioid Assessment for Patients with Pain- Revised
	Current Opioid Misuse Measure
B-12	Opioid Tapering
	Precautions for out-pt. tapering
	Opioid Tapering Protocol
B-13	Meta-analysis Evidence Table

B1	Examples of tools for assessing alcohol and other substance use:
B-1.1	Interview Guide for alcohol consumption
B-1.2	Interview Guide for Substance Use
B-1.3	CAGE (cut-annoyed-guilty-eye) Questionnaire



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Michael G. DeGroote

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Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

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> Interview with Norm Buckley

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Collaboration and Acknowledgments | Provide Feedback

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Overview of the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain

Summary of Recommendations Executive Summary and Background Recommendations Executive Summary and Background Recommendations For Practice Appendix A Recommendations For Practice

Summary of Recommendations

April 30 2010 V5.6

List of Figures and Tables

- Cluster 1: Deciding to Initiate Opioid Therapy
- Cluster 2: Conducting an Opioid Trial
- Cluster 3: Monitoring Long-Term Opioid Therapy (LTOT)
- Cluster 4: Treating Specific Populations with LTOT
- Cluster 5: Managing Opioid Misuse and Addiction in CNCP Patients

Recommendations Roadmap

When referencing the Canadian Opioid Guideline use the following format:

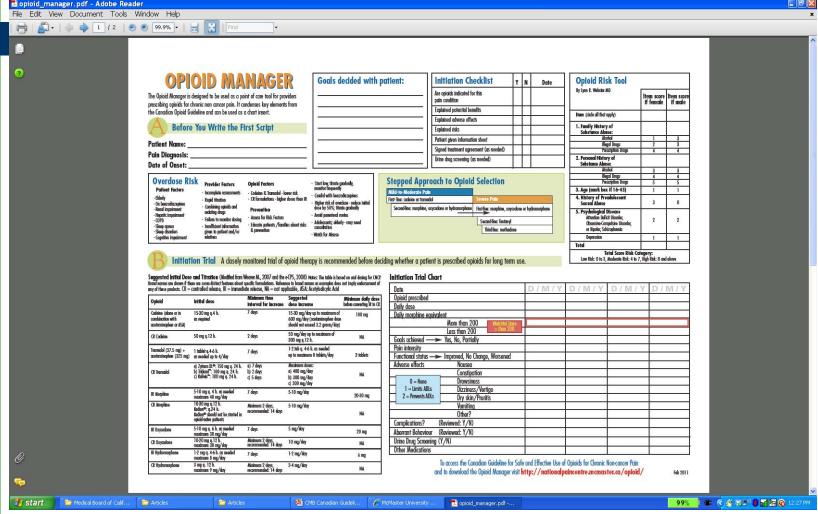
Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain. Canada: National Opioid Use Guideline Group (NOUGG); 2010 [cited year month date]. Available from: http://nationalpaincentre.mcmaster.ca/opioid/

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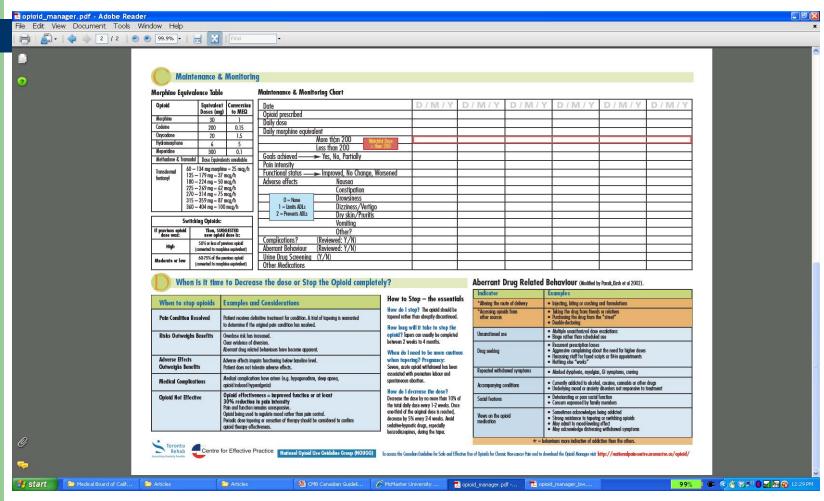
Opioid Manager

- Point-of-care e-Practice Tools
 - Tools to use before you prescribe
 - Tools to select the right opioid and titrate effectively.
 - Tools to monitor for safety and effectiveness
 - Opioid Tapering
- Downloadable for some electronic medical record platforms
- Opioid Manager Video

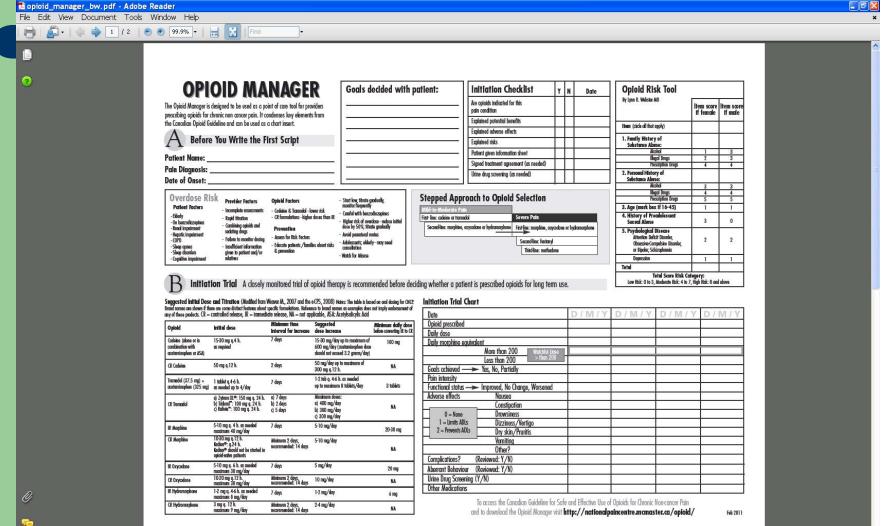
Opioid Manager-color format



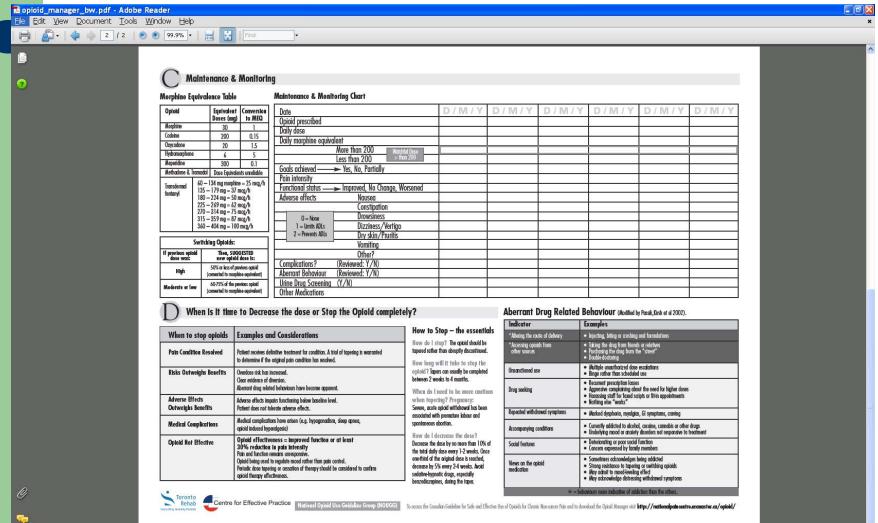
Opioid Manager-color format



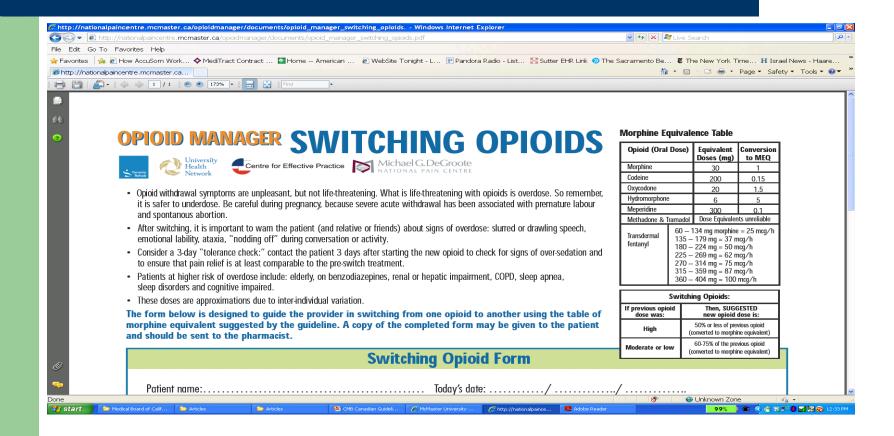
Opioid Manager-black/white format



Opioid Manager-black/white format



Opioid Manager-Switching Opioids



Shortcomings:

- No discussion on treatment of breakthrough pain.
- No management of side-effects
- No information re: selection of short- versus long-acting formulations
- No Discussion regarding special issues with methadone
- No information about state laws

Shortcomings

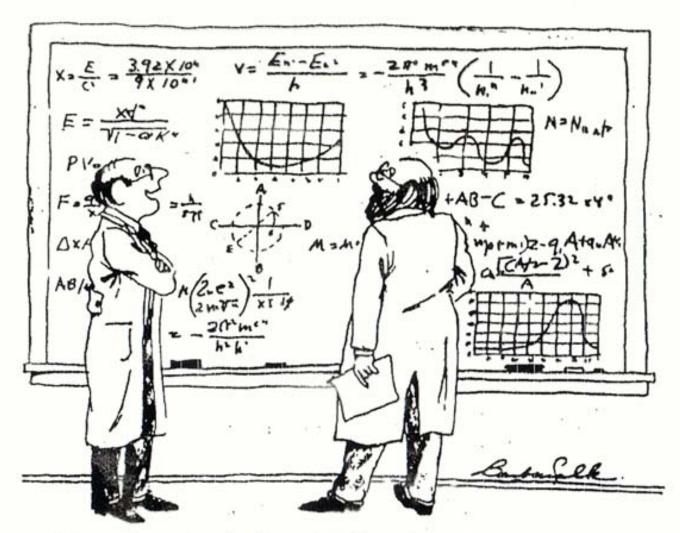
- Maximum daily dose: 200 MED mg/day higher than other guidelines vs 120 MED mg/day (Washington State) vs. 120-200 (Colorado State), 180 mg/day (U of Michigan).
- Incomplete information on association of death/overdose with type, formulation, route of drug use, i.e. ↑ torsades and QT prolongation with methadone (Dod/VA)

Shortcomings

- Good but incomplete information on drug-drug interactions: examples not included-
 - Erythromycin leads to ↑ opioid effects
 - Don't combine agonists and partial agonist/antagonists
 - metoclopramide leads to ↑absorption of CR formulations
 - TCAD's ↑opioid blood levels
 - macrolide antibiotics and protease inhibitors \(\psi \) metabolism of fentanyl .
- No recommendation re: duration of opioid trial (no study goes beyond six months, most only up to six weeks)

Shortcomings

- R-13: Switching opioids.
 - Indications considered: intolerable adverse effects, poor analgesic efficacy despite aggressive dose titration, drugdrug interactions, need for a different route of administration, clinical concerns (abuse, tolerance), financial concerns, and drug availability
 - Risky: "Old Conversion tables", genetic variability, incomplete understanding of metabolism.
 - According to the APS-AAPM guideline, there is insufficient evidence to recommend rotation as a routine practice to enhance opioid effectiveness in the treatment of pain (Chou R., et al., 2009).



"Fascinating! So that's why chocolate-chip cookie dough tastes better raw!"