

## **A Summary of the Guideline Development Process**

This document is meant to provide a succinct overview of the process used to develop the 2017 Draft Recommendations for Use of Opioids in Chronic Non-Cancer Pain.

### **Background**

In 2014 the Canadian Federal Government expanded the focus of the National Anti-Drug Strategy from illicit drugs to include measures to address prescription drug abuse. Health Canada subsequently tasked the Michael G. DeGroot National Pain Centre at McMaster University to create an evidence-based guideline for prescribing opioids in chronic non-cancer pain patients, to support decision-making by policy makers, patients, and prescribers of opioids across Canada. The project team for the 2017 guideline included researchers with expertise in chronic non-cancer pain, opioids, systematic reviews, and guideline development who engaged cooperatively with patients, pain specialists, and safety advocates to create an evidence-based guideline to support decision-making across Canada.

### **Guideline composition and management of conflicts of interest**

The guideline development process included the following groups:

- 1) A four-member steering committee
- 2) A 15-member guideline panel composed of 13 clinicians, most of whom had extensive methodologist training, one of whom was a medical regulator, and two patient representatives
- 3) A 13-member multi-disciplinary expert committee with expertise in the management of chronic pain and opioids
- 4) A 16-member patient advisory committee

Our guideline team placed high emphasis on the management of both intellectual and financial conflicts of interest in the development of our clinical practice recommendations. Voting on the guideline recommendations was limited to members of our guideline panel, no member of which had any significant financial or intellectual conflicts of interest.

To ensure that the necessary expertise in management of chronic pain and use of opioid therapy was present in the development of our guidelines, we enlisted 13 clinicians to serve on our multi-disciplinary expert committee. These individuals were not voting panel members and were not present when the recommendations were developed. We ensured this committee was constituted of nationally and internationally-recognized experts with a range of views on the role of opioids in the management of chronic pain, including several who viewed opioids as having an important role and several who viewed the practice with skepticism.

To maximize patient involvement in our guideline, in addition to the two patient representatives on our guideline panel, we created a patient advisory committee composed of chronic pain patients from across Canada. These patients provided feedback on our methodology and were engaged for feedback on all important decisions of the guideline development process. We also conducted focus group interviews with our patient advisors to inform our values & preferences statement (available in the materials posted online). Evidence alone is not enough for clinical decision-making, and patients'

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perspectives on trade-offs between benefits and harms of opioids for chronic pain is an essential consideration.

### **Formulating research questions**

Our team reviewed the 2010 Canadian Opioid Guideline as well as other published guidelines on the use of opioids for chronic non-cancer pain, and summarized all prior guideline recommendations. We held a national stakeholder meeting in July 2015 to discuss prior recommendations, and other recommendations that clinicians would find helpful in the 2017 Canadian Opioid Guideline. Each recommendation that was endorsed by the group was used to generate a research question to be informed by a systematic review of the published evidence. A research team was engaged to conduct all required systematic reviews.

We held a second meeting in December 2015, attended by our expert committee, guideline panel, and research team to discuss methodological challenges associated with the research questions. We also used the IMMPACT statement ([www.immpact.org](http://www.immpact.org)) for reporting patient-important outcomes in chronic pain research to guide our outcome selection. We selected a maximum of seven outcomes per question that represented both benefits and harms that can occur with opioid therapy. The guideline panel and patient advisory committee reviewed and approved the selected outcomes.

### **Evidence synthesis/development of recommendations**

Our systematic reviews either *identified sufficient evidence* to justify making a formal clinical practice recommendation or *identified a lack of sufficient evidence*, in which case we did not make a formal recommendation but instead convened a clinical expert subcommittee to offer expert impressions and guidance. For systematic reviews that identified sufficient evidence, we created an evidence profile to summarize the results.

We used the GRADE approach (<https://cebgrade.mcmaster.ca/aboutgrade.html>) to determine the quality of evidence on an outcome-by-outcome basis, based on study design (randomized trials or observational studies) and using the following domains: risk of bias, inconsistency, indirectness, imprecision, and the risk of publication bias, size of effect, dose-response gradient, and all apparent bias that would strengthen inferences. The quality of evidence was categorized into 1 of 4 levels: high, moderate, low, or very low.

To complement the research findings and to guide our panel in making recommendations, we developed a values and preferences statement. This statement informed by our evaluation of patient and societal values and preferences (interviews with our patient advisory panel, as well as a systematic review of the literature) with respect to opioid therapy, represented the values and preferences that underlie the panel recommendations.

We conducted a two-day, in-person meeting in January 2017. The first day was attended by both our guideline panel and clinical experts, and the primary purpose was to discuss issues for which there was no, or very limited, research evidence. These issues will appear in the guideline as expert guidance, and will be clearly distinguished from our formal recommendations.

The second day was attended only by the guideline panel (no clinical experts were present), and the evidence for each research question was reviewed along with the patient values & preferences statement. After each evidence review, all panel members used anonymous, online voting software to select their recommendation according to the GRADE approach: strong in favor, weak in favor, weak against, or strong against. For each recommendation, the panel considered the certainty in the evidence and the balance of benefits and harms of the options, in the context of our values and preferences statement. A recommendation had to be endorsed by 80% of panel members to pass. If we did not achieve 80% agreement, there was discussion and another vote. In all cases we were able to achieve consensus for the final recommendation.

The final wording of the recommendations, remarks, and qualifications were decided by consensus and approved by the guideline panel. After the meeting, the recommendations were shared with clinical expert committee for review and non-binding feedback, with the understanding that no changes to either the direction (for or against) or strength (weak or strong) would be made.

Using the GRADE approach, recommendations are labeled as either “strong” or “weak”; “recommend” is used for strong recommendations and “suggest” for weak recommendations. Table 1 provides the suggested interpretation of strong and weak recommendations by patients, clinicians and health care policy makers.

<b>Implications for:</b>	<b>Strong recommendation</b>	<b>Weak recommendation</b>
Patients	All or almost all informed individuals would choose the recommended course of action, and only a very small proportion would not.	The majority of informed individuals would choose the suggested course of action, but an appreciable minority would not.
Clinicians	All or almost all individuals should receive the intervention. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that clinicians must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
Policy makers	The recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Policymaking will require substantial debate and involvement of various stakeholders.

On Jan. 30, 2017, the 2017 Draft Recommendations for Use of Opioids in Chronic Non-Cancer Pain were posted for review on the website of the Michael G. DeGroot National Pain Centre (<http://nationalpaincentre.mcmaster.ca/>) in English and French. In addition, Evidence Summaries for each recommendation and Values and Preferences Statement will be posted. We invite stakeholders to comment on the 2017 Draft Recommendations for Use of Opioids in Chronic Non-Cancer Pain for a

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period of 30 days. The full 2017 Guideline for Use of Opioids in Chronic Non-Cancer Pain will be informed by the feedback we receive, and the final version will be released in March of 2017.