Cannabinoids in Treating Chronic Non-Cancer Pain:
Updating the 2017 US National Academies of Sciences, Engineering, and Medicine findings in "The health effects of cannabis and cannabinoids: The current state of evidence and recommendations for research"

By

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About this report

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About the Evidence-Based Practice Group

The Evidence-Based Practice Group was established to address the many medical and policy issues that WorkSafeBC officers deal with on a regular basis. Members apply established techniques of critical appraisal and evidence-based review of topics solicited from both WorkSafeBC staff and other interested parties such as surgeons, medical specialists, and rehabilitation providers.

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Background

In January 2017, the US National Academies of Sciences, Engineering, and Medicine published a comprehensive, systematic review-based paper titled "The health effects of cannabis and cannabinoids: The current state of evidence and recommendations for research"[407]. The National Academies investigated the therapeutic effects cannabis and cannabinoids on numerous disease conditions, including chronic pain, several types of cancer, chemotherapy-induced nausea/vomiting, anorexia, and weight loss, irritable bowel syndrome, epilepsy, spasticity related to multiple sclerosis or spinal cord injury, Tourette syndrome, amyotrophic lateral sclerosis, Huntington's disease, Parkinson's disease, dystonia, dementia, glaucoma, traumatic brain injury, addiction, anxiety, depression, sleep disorders, post-raumatic stress disorder, schizophrenia and other psychoses. The report also investigated the potential side effects of cannabis and cannabinoids including potential associations with certain cancers including lung cancer, head and neck cancer, testicular cancer, esophageal cancer; cardiometabolic risk to acute myocardial infarction, stroke, metabolic dysregulation, metabolic syndrome, prediabetes, and diabetes mellitus; potential effects on respiratory disease and pulmonary function chronic obstructive pulmonary disorder, respiratory symptoms (including chronic bronchitis) and asthma, as well as potential effects on immune function and infectious diseases.

With regard to efficacy and/or effectiveness of cannabis and cannabinoids in treating chronic pain, the National Academy concluded that in adults with chronic pain, patients who were treated with cannabis or cannabinoids are more likely to experience a clinically significant reduction in pain symptoms. This conclusion was largely based on the findings of systematic reviews and meta-analysis conducted by Whiting et al[393] and to some extent by Andreae et al[13] (*although Andreae et al[13] conducted an individual patient data meta-analysis, the five primary studies included in their meta-analysis were also included in Whiting et al[393] meta-analysis*). In discussing the findings from Whiting et al[393], the Academy stated that the majority of studies on pain cited in Whiting et al[393] evaluated nabiximols outside the United States with only a handful of primary studies evaluating the use of cannabis in the United States, and all of the studies evaluated cannabis in flower form provided by the National Institute on Drug Abuse; all the cannabis provided were either vaporized or smoked. The Academy further stated that while the use of cannabis for the treatment of pain was supported by well-controlled clinical trials as reviewed, very little was known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the United States. The National Academy then updated Whiting's[393] systematic review literature search and found two new primary studies by Wallace et al[380] and Wilsey et al[419]. The Academy stated that the findings of these two more

recent primary studies are in line with conclusion from Whiting's[393] systematic review and concluded that there was substantial evidence to support the use of cannabis as an effective treatment for chronic pain in adults.

In their systematic review and meta-analysis covering published medical literature up to April 2015, Whiting et al[393] investigated the benefits and adverse events associated with the use of cannabinoids. Seventy-nine trials (totaling 6462 participants) were included in this high quality systematic review. In general, the authors stated that most trials included in this systematic review showed improvement in symptoms associated with the use of cannabinoids but these associations did not reach statistical significance in all trials. Specifically, compared with placebo, the use of cannabinoids was associated with a greater average number of patients showing a complete nausea and vomiting response (47% vs 20%; odds ratio (OR) 3.8 (95% CI, 1.6-9.4); from 3 trials), reduction in pain (37% vs 31%; OR, 1.4 (95% CI, 1.0-2.0); from 8 trials), a greater average reduction in numerical rating scale pain assessment (on a 0-10-point scale; weighted mean difference (WMD) of -0.5 (95% CI, -0.8 to -0.1); from 6 trials), and an average reduction in the Ashworth spasticity scale (WMD, -0.1 (95% CI, -0.2 to 0.01); from 5 trials). The authors also noted that there was an increased risk of short-term adverse events (AEs) with cannabinoids, including serious AEs. Common AEs included dizziness, dry mouth, nausea, fatigue, somnolence, euphoria, vomiting, disorientation, drowsiness, confusion, loss of balance, and hallucination. *It should be noted that of 79 trials included in this systematic review only four (5%) trials were appraised to be at low risk of bias while 55 (70%) were judged at high risk of bias and 20 (25%) at unclear risk of bias (by employing Cochrane risk of bias tool). The authors found that the major potential source of bias in these trials was incomplete outcome data with > 50% of trials reporting substantial withdrawals, which were not adequately accounted for this in the analysis.* With regard to chronic pain, 28 primary studies (from 63 reports, totaling 2454 participants) were included in this systematic review. Of these 28 studies, 13 trials evaluated nabiximols, four evaluated smoked tetrahydrocannabinol (THC), five evaluated nabilone, three evaluated THC oromucosal spray, two evaluated dronabinol, one evaluated vaporized cannabis (included two doses), one evaluated ajuvenic acid capsules and one evaluated oral THC. The conditions causing chronic pain varied between studies and included 12 studies on neuropathic pain (central, peripheral, or not specified), three for cancer pain, three for diabetic peripheral neuropathy, two for fibromyalgia, two for HIV-associated sensory neuropathy, and one study each on refractory pain due to multiple sclerosis or other neurological conditions, for rheumatoid arthritis, for non-cancer pain (nociceptive and neuropathic), central pain (not specified further), musculoskeletal problems, and chemotherapy-induced pain. Studies

generally suggested improvements in pain measures associated with cannabinoids but these did not reach statistical significance in most primary studies. *Further, it should be strongly noted that of these 28 trials, only two studies were judged at low risk of bias while 9 studies were appraised at unclear risk and 17 studies were appraised at high risk of bias (supplementary material eAppendices 13. Risk of bias in each included study. Grouped by Indication. Downloaded from https://jamanetwork.com/journals/jama/fullarticle/2338251?resultClick=1). Also, the fact that these primary studies investigating the efficacy and/or effectiveness of treatment for a chronic disease condition were conducted within only a matter of hours or at most for 14 weeks, raised further questions on any outcomes presented.*

Meta-analysis on eight trials showed that the average number of patients who reported a reduction in pain of at least 30% was greater with cannabinoids than with placebo (OR, 1.4 with 95% CI, 1.0-2.0). *It should be noted that of these eight primary studies, seven investigated nabiximols and one reported on smoked THC. These eight trials were judged to be of high or unclear risk of bias, with the trial reporting on smoked THC being judged for high risk of bias while reporting the greatest beneficial effect (OR 3.4 with 95% CI 1.0-11.5). It should further be noted that the majority of these 28 primary studies/trials were in the form of crossover trials (as opposed to parallel design). Although crossover trials may be more efficient when compared to parallel design since the cases become their own controls, the fact remains that potential treatment-period interaction and carry-over effects (i.e. from treatment to placebo or vice versa)[422,423] are seldom taken into account in the analysis of the primary studies as well as in the meta-analysis. These types of potential problems observed in the primary studies included in the systematic review by Whiting et al[393] are also equally as problematic within the individual patient data meta-analysis presented by Andreae et al[13].*

This published systematic review and meta-analysis by Whiting et al[393] was actually produced by Kleijnen Systematic Review Ltd., York, UK[424]. The full protocol of this systematic review was available as part of supplementary documentation of the published paper and available in https://jamanetwork.com/data/Journals/JAMA/934167/JOI150059supp1_prod.pdf. Since the objective of our systematic review is to update the published review by Whiting et al(393), focusing exclusively on the efficacy and/or effectiveness of cannabis and cannabinoids in treating chronic non-cancer pain, the Evidence-Based Practice Group (EBPG) will be following the search strategy reported in the protocol developed by Kleijnen Systematic Review Ltd[424].

Methods

In order to update the chronic pain part of the systematic review conducted by Whiting et al[393], the EBPG conducted a comprehensive systematic literature search on September 15, 2017 by closely following the search strategy outlined in the protocol published by Kleijnen Systematic Review Ltd[424].

The systematic literature search was done on commercial medical literature databases, including Cochrane Database of Systematic Reviews® (2005 to September 13, 2017), ACP Journal Club® (1991 to August 2017), UK York University Database of Abstracts of Reviews of Effects® (1st Quarter 2016), Cochrane Central Register of Controlled Trials (August 2017), UK NHS Health Technology Assessment® (4th Quarter 2016), UK NHS Economic Evaluation Database® (1st Quarter 2016), BIOSIS Previews® (1969 to 2008), Embase® (1974 to 2017 Week 37), Medline Epub Ahead of Print®, Medline In-Process & Other Non-Indexed Citations®, Medline Daily Update® and Medline® (1946 to Present), that are available through the Ovid® platform.

These searches were done by employing combinations of keywords, as follows:

1. (cannabaceae **OR** cannabinoid)
2. (marijuana **OR** marihuana **OR** cannabis **OR** canabis)
3. (hashish **OR** hash **OR** bhang **OR** ganja **OR** ganjah **OR** hemp **OR** charas)
4. (cannador **OR** eucannabinolide **OR** 8001-45-4 **OR** 8063-14-7 **OR** 38458-58-1)
5. (9tetrahydrocannabinol$ **OR** delta3-thc **OR** sp-104 **OR** sp104 **OR** 1972-08-3)
6. (dronabinol **OR** marinol **OR** ea-1477 **OR** ea1477 **OR** tetranabinex **OR** qcd-84924 **OR** qcd84924 **OR** 7663-50-5)
7. (delta-9-THC **OR** 5957-75-5 **OR** 1972-08-3)
8. delta9?11?tetrahydrocannabinol
9. (THC **OR** CBD **OR** AEA)
10. (nabidiolex **OR** 13956-29-1)

11. (dexanabinol **OR** Hu-210 **OR** Hu-211 **OR** hu210 **OR** hu211 **OR** 112924-45-5)
12. (cannabichromene **OR** 521-35-7)
13. (nabilone **OR** cesamet **OR** cesametic **OR** cpd109514 **OR** cpd-109514 **OR** lilly-109514 **OR** lilly109514 **OR** 51022-71-0)
14. (nabiximols **OR** Sativex **OR** Gw-1000 **OR** gw1000 **OR** sab-378 **OR** sab378 **OR** 56575-23-6)
15. (anandamide **OR** N-arachidonoylethanolamine)
16. (canabinoid$ **OR** canabidiol$ or cannabinoid$ **OR** Tetrahydrocannabinol$ **OR** tetrahydrocannabinol$ **OR** endocannabinoid$ **OR** cannabidiol **OR** cannabinol)
17. (nantradol **OR** cp-44001 **OR** cp-44001-1 **OR** cp440011 **OR** cp44001-1 **OR** 72028-54-7)
18. (Random$ **OR** clinical **ADJ** trial$ **OR** health **ADJ** care **ADJ** quality)
19. 1 **OR** 2 **OR** 3 **OR** 4 **OR** 5 **OR** 6 **OR** 7 **OR** 8 **OR** 9 **OR** 10 **OR** 11 **OR** 12 **OR** 13 **OR** 14 **OR** 15 **OR** 16 **OR** 17
20. 18 **AND** 19
21. limit 20 to yr="2015 -Current"
22. (animal **OR** (animal **ADJ** experiment))
23. (rat **OR** rats **OR** mouse **OR** mice **OR** murine **OR** rodent **OR** rodents **OR** hamster **OR** hamsters **OR** pig **OR** pigs **OR** porcine **OR** rabbit **OR** rabbits **OR** animal **OR** animals **OR** dogs **OR** dog **OR** cats **OR** cow **OR** bovine **OR** sheep **OR** ovine **OR** monkey **OR** monkeys)
24. 22 **OR** 23
25. 21 **NOT** 24
26. remove duplicates from 25
27. limit 26 to human
28. (pain **OR** (chronic **ADJ** pain))

29. 27 **AND** 28

Four hundred and four[1-404] published studies were identified through these searches. Upon examination of the titles and abstract of these 404 studies,
56[12,13,17,19,23,29,31,32,36,39,40,41,45,73,75,79,84,88,98,101,103,113,114,126,128,143,144,145,148,150,155,
169,175,211,221,222,224,225,243,246,260,262,270,293,330,349,357,361,378,386,392,393,397,398,399,401]
published studies (including the systematic reviews by Whiting et al[393] and Andreae et al[13]) were thought to be relevant and were retrieved in full for further appraisals. Manual searches were also conducted on the references of the fully retrieved studies.

Results

- Search results:

  Of the 56[12,13,17,19,23,29,31,32,36,39,40,41,45,73,75,79,84,88,98,101,103,113,114,126,128,143,144,145,148,150,155,169,175,211,221,222,224,225,243,246,260,262,270,293,330,349,357,361,378,386,392,393,397,398,399,401] published studies that were retrieved in full 21[13,40,41,45,98,101,113,114,126,143,150,169,222,243,270,293,349,361,378,393,398] were in the form of systematic reviews (level of evidence 1. Appendix 1), 30[12,17,19,29,31,32,36,39,73,75,79,84,103,128,144,148,155,175,211,221,224,225,246,260,262,330,357,392,397,399] were in the form of expert reviews (level of evidence 5. Appendix 1) and five[23,88,145,386,401] were primary studies of various study designs.

  Manual searches conducted on the references of these 56[12,13,17,19,23,29,31,32,36,39,40,41,45,73,75,79,84,88,98,101,103,113,114,126,128,143,144,145,148,150,155,169,175,211,221,222,224,225,243,246,260,262,270,293,330,349,357,361,378,386,392,393,397,398,399,401] published studies yielded another 16[405,406,408-421] studies that were retrieved in full. Five[405,411,412,417,418] of these 16[405,406,408-421] studies were in the form of systematic reviews (level of evidence 1. Appendix 1), six[406,408,409,410,413,414] in the form of expert reviews (level of evidence 5. Appendix 1) and 5[415,416,419,420,421] were primary studies of various study designs.

  Thus, overall, there were 26[13,40,41,45,98,101,113,114,126,143,150,169,222,243,270,293,349,361,378,393,398,405,411,412,417,418] systematic reviews, 36[12,17,19,29,31,32,36,39,73,75,79,84,103,128,144,148,155,175,211,221,224,225,246,260,262,330,357,392,397,399, 406,408,409,410,413,414] expert reviews and 10[23,88,145,386,401, 415,416,419,420,421] primary studies which were retrieved in full for further appraisals.

- Critical appraisals:

  Of the 36[12,17,19,29,31,32,36,39,73,75,79,84,103,128,144,148,155,175,211,221,224,225,246,260,262,330,357,392,397,399, 406,408,409,410,413,414] expert reviews, none will be discussed further, due to the fact that these expert reviews were either not relevant to our objective, did not provide any data for analysis, or did not provide any new data/primary studies in addition to those included in the Whiting et al[393] systematic review.

  Of the 26[13,40,41,45,98,101,113,114,126,143,150,169,222,243,270,293,349,361,378,393,398,405,411,412,417,418] systematic reviews, one[41] did not provide any data (published in the form of abstract only), three[398,412,418] were not relevant

to the objective of this systematic review and twelve[40,45,98,101,113,114,126,222,293,361,378,417] employed the same primary studies (in full or in part) already included in the Whiting et al[393] systematic review. As such, including the systematic review by Whiting et al[393], there were ten[13,143,150,169,243,270,349,393,405,411] systematic reviews/meta-analysis that were relevant to this systematic review.

Of the 10[23,88,145,386,401,415,416,419,420,421] primary studies that were retrieved in full, five[23,88,401,415,416] were not relevant to the objective of this systematic review and will not be discussed further.

- Outcomes:

Although the meta-analysis by Andreae et al[13] was mentioned in the January 2017, the US National Academies of Sciences, Engineering, and Medicine publication on the health effects of cannabis and cannabinoids, the details within this meta-analysis was not discussed. Andreae et al[13] published an individual patient data meta-analysis, by employing a novel Bayesian responder (*responder was defined as reduction in continuous pain outcome > 30% after* treatment) meta-analysis, investigating the use of inhaled cannabis in treating chronic neuropathic pain. This high quality meta-analysis identified 178 participants with 405 observed responses in five randomized controlled trials (RCT). The authors found that inhaled (pre-rolled cigarettes in three studies, one through Volcano vaporiser and one gelatin capsules smoked through a pipe) cannabis provided short-term reductions in chronic neuropathic pain for 1 in every 5 to 6 patients treated (number needed to treat = 5.6 with a Bayesian 95% credible interval ranging between 3.4 and 14). Although this finding was insensitive to model assumptions, priors, and parameter choices (in the Bayesian methods), it should be strongly noted that the quality of the primary studies were low (especially due to problems with allocation concealment, attrition bias and potential placebo effects on pain level), the meta-analysis only involved a small number of primary studies with a small number of participants who were only followed for a few hours up to two weeks; the short follow-up and co-interventions thus limit the conclusions that can be drawn from this meta-analysis. It should also be noted that the five primary studies included in the Andreae et al[13] meta-analysis were also included in the systematic review by Whiting et al[393].

In 2015, Hill[143] published a systematic review investigating the efficacy/effectiveness of medical marijuana in treating chronic pain and other medical and psychiatric problems. With regard to pain, the author included six trials of 325 patients with chronic pain and six trials of 396 patients with neuropathic pain. It should be noted that the 12 trials included in this systematic review were already included in the Whiting et al[393] systematic review. Although Hill[143] concluded that the use of

marijuana for chronic pain and neuropathic pain was supported by high-quality evidence (*which was defined as multiple randomized controlled trials with positive* results) which some provided positive results, it should strongly be noted that this low quality systematic review (low quality, as a result of unclear search methods which may introduce selection bias, and the absence of critical appraisals of the primary studies) did not provide any critical appraisals of the primary studies at all to justify the conclusion that there was high quality evidence. Further, it should be noted that the majority of the primary studies investigated nabilone, dronabinol and nabiximol, and only three primary studies investigated smoked cannabis.

Two[150,169] comprehensive scoping reviews investigating the application of medical cannabis in treating pain were published in 2016. It should be noted that all primary studies identified in these scoping reviews were included in the systematic review by Whiting et al[393] and will not be discussed further. These scoping reviews also provided evidence on the fact that the primary studies investigating cannabis employed small sample sizes and provided only short follow-up durations.

In a high quality meta-analysis, Meng et al[243] reported the comparative effectiveness of selective cannabinoids (i.e. dronabinol, nabilone or nabiximols) with conventional treatments (such as pharmacotherapy, physical therapy, or a combination of these) or placebo in patients with chronic neuropathic pain of various origins. Eleven RCTs of totaling 1219 patients (614 in selective cannabinoid and 605 in comparator groups) were included in this systematic review. The authors found that patients who received selective cannabinoids reported a statistically significant, but most likely not clinically significant, reduction in mean numerical rating scale pain scores (0–10 scale) compared with comparator groups (-0.65 points; 95% confidence interval -1.06 to -0.23 points; P = .002). The authors also noted the variability in the quality of the primary studies, in the etiology of neuropathic pain, and the type and dose of selective cannabinoids.

Nugent et al[405] published a systematic review investigating the benefits of plant-based cannabis preparations for treating chronic pain in adults and the harms of cannabis use in chronic pain and general adult populations. This high quality systematic review conducted a literature search up to March 2017 and included RCTs as well as observational studies reporting on the potential harm of cannabis. The authors identified 22 RCTs on chronic pain trials (*most of these were included in the Whiting et al[393] systematic review)* and concluded that, overall, there was low quality evidence (*primary studies with high risk of* bias) suggesting that cannabis might alleviate neuropathic pain in some patients. The authors stated that the primary studies generally did not find clinically significant between-group differences on continuous pain

scales, but a higher proportion of intervention patients had clinically significant pain relief up to several months later. Across nine studies, intervention patients were more likely to report at least 30% improvement in pain (risk ratio, 1.43; 95% CI, 1.16 to 1.88). However, most RCTs were small with few reported outcomes beyond 2 to 3 weeks, and none reported long-term outcomes. With regard to potential harms, the authors found that according to 11 systematic reviews and 32 primary studies, harms in general population studies included increased risk for motor vehicle accidents, psychotic symptoms, and short-term cognitive impairment. Further, the authors stated that although adverse pulmonary effects were not seen in younger populations, evidence on most other long-term physical harms, in heavy or long-term cannabis users, or in older populations was still insufficient at present. The authors cautioned on the fact that there was only a small number of RCTs with rigorous method, to the fact that the cannabis formulations studied might not reflect commercially available products and to the potential of increased risk for adverse mental health effects.

Stevens and Higgins[349], in a good quality systematic review, reported on the efficacy of cannabinoids medications in treating acute pain. The authors found seven controlled post-operative trials comprising of 611 patients. In five studies, cannabinoids were found to provide equivalent analgesia to placebo, in one study the analgesia provided by cannabinoids was superior to placebo, and in one study cannabinoids provided analgesia that was inferior to that provided by placebo. No synergistic or additive analgesic effect was observed when cannabinoids were used in combination with opioids. In five of the seven studies, certain adverse effects, such as sedation, agitation, hallucination, were more frequent with cannabinoid treatment than with placebo or active comparator. The authors concluded that given the available evidence, at present, cannabinoids (such as nabilone, Δ-9-THC) have no role in the management of acute pain.

A medium quality systematic review (*medium quality as a result of unclear search strategy and the mixing of different level of evidence in their summary*) investigating the opioid sparing effect of cannabinoids was reported by Nielsen et al[270]. The authors identified 19 pre-clinical animal and nine clinical studies that met their search criteria. Seventeen of the 19 animal studies provided evidence of synergistic effects from opioid and cannabinoid co-administration. The meta-analysis of the animal studies indicated that the median effective dose (ED_{50}) of morphine administered in combination with Δ-9-THC was 3.6 times lower than the ED_{50} of morphine alone. In addition, the ED_{50} for codeine administered in combination with Δ-9-THC was 9.5 times lower than the ED_{50} of codeine alone. On the other hand, even though larger controlled trials in human showed some clinical benefits of cannabinoids, opioid dose

changes were rarely reported and mixed findings were observed for analgesia. Only one case series (n=3) provided very-low-quality evidence of a reduction in opioid requirements with cannabinoid co-administration. The authors concluded that, at present, although animal studies provided strong evidence of the opioid-sparing effect of cannabinoids, none of the high quality human studies provided any evidence on the opioid-sparing effects of cannabinoids.

In a low quality (due to lack of appraisals on the included primary studies and unclear search results) systematic review-based meta-analysis, Borges et al[411] investigated the association of cannabis use and suicidality. With regard to the association between acute cannabis used and suicidality, the literature generally described toxicology reports. The authors found only one study which hinted at the possibility that acute cannabis use could induce suicidal ideation in a case study describing a patient who presented to the emergency department with suicidal ideation and urged to attempt suicide by fall, anxiety and agitation after smoking cannabis a few hours prior. With regard to the association between chronic cannabis used and suicidality, the authors found four primary studies providing estimates for any chronic cannabis use and death by suicide (OR: 2.6, 95 CI 1.5–5.3); six studies on any cannabis use and suicide ideation (OR: 1.4, 95%CI 1.1–1.8); five studies on heavy cannabis use and suicide ideation (OR: 2.5, (1.0–6.4)), 6 studies on any cannabis use and suicide attempt (OR:2.2, 95%CI 1.2–4.0) and 6 studies on heavy cannabis use and suicide attempt (OR:3.2, 95% CI 1.7–5.9). However, the available evidence on the association between chronic cannabis used and suicidality has to be interpreted cautiously due to potential publication bias that was detected in this meta-analysis, heterogeneity on the evidence and perhaps most importantly, the lack of known confounders adjustment to account for other suicide risk factors such as alcohol used and depression. Ultimately, the authors concluded that, at the time of publication, there was no evidence to support an association between acute cannabis used and suicidality, while the available evidence on chronic cannabis used and suicidality needs to be interpreted with caution until better quality evidence is available.

In a small-medium size (intervention=165 and placebo=215) open label controlled trial (level of evidence 2. Appendix 1) billed as follow-up (up to 38 weeks long of intervention) of previously multicentre RCTs Hoggart et al[145] reported the effect, tolerance and safety of a THC/CBD oromucosal spray. Of the 280 cases and controls who had consented to participation at the beginning of this study, only 234 (62%) patients completed the 38-weeks follow-up; the data was analyzed as such. At one and nine month follow-up, the mean pain (0-10 numerical rating scale) (± SD) of the intervention and placebo were:

- At one month: Intervention 4.6 ± 2.4, Placebo 4.1 ± 2.3
- At nine months: Intervention 5.0 ± 2.3, Placebo 4.3 ± 2.4

These differences were neither statistically or clinically significant. It should also be noted that the controlled trial suffered from potential selection bias, and multiple comparisons and did not take into account the role of co-interventions in both groups.

A medium size (215 exposed and 216 non-exposed) cohort study (level of evidence 3. Appendix 1) investigating the safety issues of medical cannabis used among chronic non-cancer pain (CNCP) patients was reported by Ware et al[386]. In this study the exposed group received a standardized herbal cannabis product (12.5%±1.5% tetrahydrocannabinol (THC)) that was dispensed for a 1-year period. The non-exposed were individuals with chronic pain from the same clinics who were not cannabis users; both groups were recruited from seven clinical centers across Canada.

The primary outcome consisted of serious adverse events and non-serious adverse events as defined by the International Conference on Harmonization. Secondary outcomes included neurocognitive function, pulmonary function and other safety measures such as hematological profiles, liver, kidney and endocrine functions. *The authors provided a sample size calculation based on a rate ratio of 1.5 times difference in serious adverse events following a Poisson distribution of rare events. The authors calculated that they would require about 350 participants in each group; as such, this study is under-powered to detect differences between groups in their serious adverse events occurrences.* It was reported that the median daily cannabis dose was 2.5 g/day with a median duration of follow-up of 11.9 months (range = 7–551 days) in the exposed (cannabis) group and 12.1 months (range = 28–567 days) in the non-exposed group. The authors found that there was no difference in risk of serious adverse events (adjusted incidence rate ratio = 1.1, 95% CI 0.6–2.0) between groups. Medical cannabis users were at increased risk of non-serious adverse events (adjusted incidence rate ratio = 1.7, 95% CI 1.4–2.1) and they did not find any differences in secondary outcomes assessments. *Although the authors found that the increased risk of serious adverse events in the cannabis group was not statistically significant, it should strongly be noted that this study was under-powered; as such, any conclusion has to be interpreted cautiously. Further, the data presented demonstrated that the participant drop-out rate was higher among the cannabis group, and this study also suffered from multiple comparisons.* With regard to the effectiveness of medical marijuana, the authors stated that compared with baseline, a significant reduction in average pain intensity over 1 year was observed in the cannabis group (change = .9; 95% CI 0.6–1.2) but not in the control

group (change = .2; 95% CI = 0.1-to .5) and further, in statistical modelling with adjustments for confounders (including age, sex, alcohol use, prior marijuana use, tobacco use, disability status, baseline concomitant pain medication), a greater reduction in pain was observed among cannabis users than among controls (difference = 1.1, 95% CI = .7–1.6). *It should, however, be strongly noted that this conclusion is somewhat misleading when considering the fact that multiple comparisons and co-intervention are not taken into account in interpreting the results. Further, the differences in pain level (after adjustment of potential confounders) most likely not clinically significant.*

Wilsey et al[419] reported on the outcome of a small (n=42) randomized, double-blind, placebo-controlled crossover trial (level of evidence 1. Appendix 1) using 3 different strengths of cannabis (placebo, 2.9%, and 6.7% Δ-9-THC) performed among patients with injury and disease (such tumors, multiple sclerosis) of the spinal cord. Patients underwent a standardized procedure for inhaling 4 puffs of vaporized cannabis containing either placebo, 2.9%, or 6.7% Δ-9-THC on 3 separate occasions, with a second dosing administered 3 hours later, for which they could choose to inhale between 4 to 8 puffs. The primary outcome in this study was an 11-point numerical pain intensity scale. At the end of the follow-up period (*i.e. at 420 minutes or seven hours post intervention*), the authors found a significant analgesic response for vaporized cannabis compared to placebo in term of pain intensity (main outcome), pain relief, allodynia as well as other pain characteristics such as pain intensity, sharpness, burning/aching, itching deep pain, superficial pain, etc., with the 2 active doses did not significantly differing from each other in terms of analgesic potency. *This findings has to be interpreted with cautiously since this study is of low quality due to the absence of a stated hypothesis and a corresponding sample size calculation, and the use of a small sample size with multiple comparisons performed. Further, the differences in the pain intensity at 7 hours follow-up between placebo - 2.9% THC and placebo – 6.7% THC were approximately 1 and 0.8 (out of 10 point numerical pain scale), respectively, which should be interpreted as clinically not significant.*

In research letters, Bonn-Miler et al[420] and Vandrey et al[421] reported small (n=84 and 75, respectively) case series (level of evidence 5. Appendix 1) investigating the accuracy of the labelling of cannabinoid extracts and edible medical cannabis products that were sold online. Both studies found discrepancies between the listed and tested active ingredients (cannabidiol and also THC) contents. These two studies[420,421] concluded that edible and cannabis extracts sold online failed to meet basic label accuracy standards for pharmaceuticals. The authors found that the majority of the products evaluated had significantly less cannabinoid content than labeled, with some products containing some

amounts of THC. Such products may not produce the desired medical benefit. Other products contained significantly more THC than labeled, placing patients at risk of experiencing adverse effects.

Summary/Conclusions

Early this year, the US National Academies of Sciences, Engineering, and Medicine published a comprehensive systematic review investigating the health effects of cannabis and cannabinoids. This paper concluded that in adults with chronic pain, patients who were treated with cannabis or cannabinoids are more likely to experience a clinically significant reduction in pain symptoms. In relation to chronic pain, this conclusion, which is largely based on a systematic review conducted by Whiting et al, should be interpreted with caution due to the fact that, of the 28 primary studies investigating the efficacy/effectiveness of cannabis and cannabinoids, 13 trials evaluated nabiximols, four for smoked THC, five for nabilone, three for THC oromucosal spray, two for dronabinol, one for vaporized cannabis, one for ajuvenic acid capsules and one for oral THC. Although these studies generally suggested improvements in pain measures associated with cannabinoids, the data provided did not reach statistical significance in most primary studies. Of these 28 trials, only two studies were judged at low risk of bias while 9 studies were appraised at unclear risk, and 17 studies at high risk of bias. The fact that these primary studies investigating the efficacy/effectiveness of treatment for a chronic disease condition, were conducted in a matter of hours or at most for 14 weeks, raised further questions as to any outcomes presented. The meta-analysis presented, which was based on only eight trials, demonstrated that the average number of patients who reported a reduction in pain of at least 30% was greater with cannabinoids than with placebo (OR, 1.4 with 95% CI, 1.0-2.0). It should be noted that of these eight primary studies, seven investigated nabiximols and one reported on smoked THC. These eight trials were judged to be of high or unclear risk of bias, with the trial reporting on smoked THC being judged at high risk of bias while reporting the greatest beneficial effect.

Since the publication of the systematic reviews by Whiting et al and the US National Academies of Sciences, Engineering, and Medicine paper, several other systematic/reviews and primary studies investigating the efficacy/effectiveness of cannabis and cannabinoids in treating chronic non-cancer pain have been published. None of the identified systematic/reviews on chronic non-cancer pain were of high quality, and all of them included primary studies that were already part of the Whiting et al systematic review.

A good systematic review on the use of cannabinoids as treatment for acute pain concluded that there is no role of cannabinoids in treating acute pain. Another systematic review investigating the opioids sparing effect of cannabis or cannabinoids concluded that there was no evidence on the opioids sparing effects of cannabis and cannabinoids in human subjects.

Primary studies identified after the publication of the Whiting et al systematic review did not provide any new evidence on the efficacy/effectiveness of cannabis and cannabinoids in treating chronic non-cancer pain while at the same time providing some evidence on the potential, serious and non-serious, adverse effects of cannabis and cannabinoids. Some studies also provided evidence on the inaccuracy of the active ingredients labelling regarding some of the numerous cannabis products sold online, that can affect the effectiveness, if any, of these cannabis related products.

As such, it can be concluded that, at present, there may be some evidence on the efficacy/effectiveness of cannabis and cannabinoids in providing short term pain relief among patients with chronic non-cancer pain. This evidence has to be interpreted with a high degree of caution due to the quality of primary studies presenting this evidence. Further, the evidence on the efficacy/effectiveness of smoked cannabis in treating chronic non-cancer pain may still be lacking.

Postscript:

Following the same search strategy listed in the **Methods** section of this systematic review, systematic literature search update was conducted on March 28, 2018.

One hundred ninety two[1-192] (on the **Reference Update** section) published studies were identified through thise search. Examination on the titles and abstracts of these 192[1-192] (on the **Reference Update** section) studies did not reveal any new study since previous search in November 2017.

As such, it can concluded that there is no changes to the findings of our November 2017 systematic review investigating cannabinoids in treating chronic non-cancer pain.

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Appendix 1

WorkSafeBC - Evidence-Based Practice Group Levels of Evidence (adapted from 1,2,3,4)

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic review of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

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