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Position Statement

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Medical cannabis for children: Evidence and recommendations

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ABSTRACT

Interest in using cannabis products for a medical purpose in children under the age of 18 years is increasing. There are many medical cannabis products available that can include cannabidiol (CBD) or delta-9-tetrahydrocannabinol (THC), or both. Despite many therapeutic claims, there are few rigorous studies to inform the dosing, safety, and efficacy of medical cannabis in paediatric clinical practice. This statement reviews the current evidence and provides recommendations for using medical cannabis in children. Longer-term (2-year) reports support the sustained tolerability and efficacy of cannabidiol therapy for patients with Lennox-Gastaut and Dravet syndromes. CBD-enriched cannabis extracts containing small amounts of THC have been evaluated in a small number of paediatric patients, and further research is needed to inform clinical practice guidelines. Given the widespread use of medical cannabis in Canada, paediatricians should be prepared to engage in open, ongoing discussions with families about its potential benefits and risks, and develop individualized plans that monitor efficacy, reduce harms, and mitigate drug–drug interactions.

Keywords: Cannabinoids; CBD; Children; Delta-9-tetrahydrocannabinol; Medical cannabis; Pharmacotherapy.

BACKGROUND AND SCOPE

Cannabis contains a complex mixture of hundreds of bioactive compounds (1). Of the more than 140 cannabinoids it contains, the two most abundant and well-studied are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), although other cannabinoids may have therapeutic potential (2). THC and a few other minor cannabinoids produce euphoric effects associated with cannabis use, while CBD elicits broad antioxidant, anti-inflammatory, and neuroprotective effects (3,4). The endocannabinoid system includes CB1 and CB2 receptors. Both are G-protein-coupled receptors, which means they work as cellular surface trans-membrane proteins that convert extracellular signals, such as from drugs, hormones, and neurotransmitters, into intracellular responses. CB1 receptors are found primarily in the central and peripheral nervous system, though recently they have also been found outside the nervous system, while CB2 receptors are found throughout the human immune system (4). THC exerts its primary effects as a partial agonist of CB1 receptors, while CBD is a negative allosteric modulator of CB1 and acts via several other receptors, such as serotonergic and vanilloid receptors (3,4). Literature has suggested that minor cannabinoids and terpenoids may have synergistic effects, possibly through competition for drug metabolic enzymes (5,6) or direct receptor activation (7,8). The pharmacodynamics of cannabinoids are affected by their formulation, the route of administration, and gastric contents (9). The mechanisms of action for CBD are still under investigation.

The focus of this statement is on medical cannabis use in paediatric patients (<18 years). In Canada, the medical cannabis stream allows physicians and nurse practitioners to authorize cannabis use for young people (Figure 1) (10,11). A medical cannabis authorization provides paediatric patients with the legal ability to possess cannabis products used for a therapeutic indication. Cannabis products include many different combinations of cannabinoids (or isolates) in different formulations, such as dried flower, extracts (oils), edibles, topicals, suppositories, waxes or resins, and beverages. Many cannabis products accessible through the medical cannabis stream are also available in the recreational and illicit markets.

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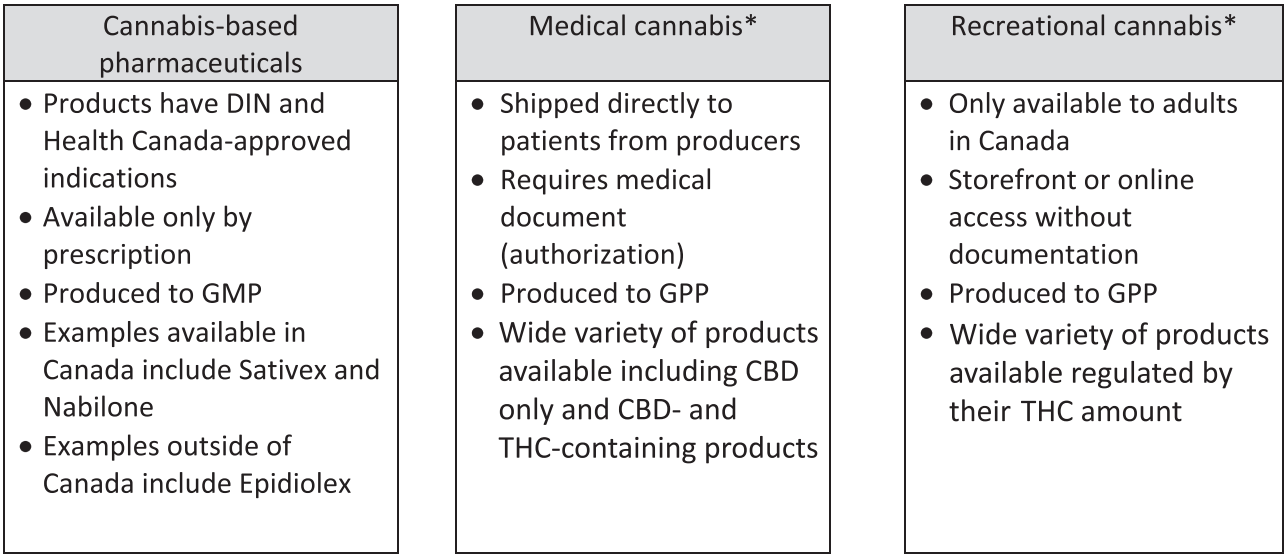

Figure 1. Overview of different types of cannabis products available in Canada. *Regulated under the Cannabis Act, 2018. *CBD cannabidiol; DIN Drug identification number; GMP Good manufacturing practices; GPP Good production practices; THC delta-9-tetrahydrocannabinol.* References (10,11)

At present only two cannabis-based pharmaceuticals with a drug identification number (DIN) are available in Canada: Sativex and Nabilone. Both have been prescribed off-label to children. Sativex (nabiximols) is a cannabis-based oromucosal spray that contains 27 mg/mL of THC and 25 mg/mL of CBD and is marketed for spasticity in adults with multiple sclerosis. Nabilone is an oral synthetic THC analogue, available in 1 mg, 0.5 mg, and 0.25 mg capsules, indicated for chemotherapy-induced nausea and vomiting in adults. In 2018, the US Food and Drug Administration approved Epidiolex, a cannabis-derived, purified CBD preparation, for two drug-resistant epilepsy (DRE) syndromes in adults and children 2 years and older. Epidiolex was also approved by the European Medicines Agency in 2019, and by the Therapeutic Goods Administration (Australia) in 2020. Despite global authorizations for the management of DRE, Epidiolex (or any other purified CBD drug) is not yet marketed in Canada. However, Epidiolex was submitted to Health Canada for DIN review and approval in late 2022.

Medical cannabis is used for a variety of therapeutic indications, with each warranting an assessment of potential risks and benefits. The evidence and opinions contained in this statement are specific to the use of cannabis-based products for medical purposes, always acknowledging that the impacts of recreational cannabis use on the developing brain and rising rates of accidental cannabis poisonings in children (12) are public health concerns. The statement replaces a previous CPS statement on medical cannabis from 2016 (13), based on the evolving literature, new cannabis-based pharmaceuticals, and changes to medical cannabis access under the 2018 Cannabis Act.

Evidence on efficacy in paediatric patients

While claims regarding the potential effectiveness of medical cannabis in children are widespread, few placebo-controlled clinical trials beyond those focused on DRE have included children (14) or yielded results to support such claims. Indications, dosing, and adverse events from cannabis products that have been prospectively studied in children are summarized in the eTable 1 (CBD only) and eTable 2 (CBD with THC).

Epilepsy

Clinical trials in children with DRE exploring the use of purified CBD have consistently demonstrated efficacy, with mean reductions in seizure frequency ranging between 36% and 49%, as well as improved quality of life (15–22). Adverse events (10% or more and greater than placebo) for purified CBD include somnolence, decreased appetite, diarrhea, fatigue, malaise and asthenia, rash, sleep disorders, infections, and transaminase elevations. Open-label expanded access program data support sustained tolerability and long-term benefit with doses up to 25 mg/kg CBD per day (23–26). Aside from administration of anticonvulsants by mouth, 48 children who received CBD transdermally, twice daily for 6.5 months, reported a reduction in seizures and reduced disease burden (27). Experiences and reported benefits of CBD use in children with DRE have been reported in Argentina (28), Australia (29,30), Israel (31), Slovenia (32), Switzerland (33), the UK (34), and the USA (24).

While randomized controlled trials (RCTs) have focused on purified CBD oils, CBD-enriched extracts (that contain small amounts of THC and other cannabinoids) may require lower doses of CBD to produce comparable or improved safety and efficacy outcomes (35,36). Two Canadian open-label dose-escalation studies using CBD-enriched extracts in 50:1 and 20:1 ratios of CBD to THC reported seizure reduction (37–40). CBD-enriched extracts (25:1 CBD:THC) also demonstrated benefit in one small observational study of children with treatment-resistant West syndrome (41), while several observational studies highlighted the benefits of CBD-enriched cannabis extracts in DRE (31,34,42). Furthermore, when using a CBD-enriched cannabis extract (20:1 CBD:THC, up to 12 mg CBD per day), there were low plasma levels of THC reported (42,43). However, while longitudinal observational data from children with epilepsy who used a 20:1 CBD-enriched extract

have demonstrated seizure reduction, adverse events were also common (46%) (44,45).

Autism

A recent scoping review of medical cannabis in children with autism (46) identified eight retrospective studies (total: 346 children). Observational reports have suggested improvements in behavioural problems, anxiety, and communication, along with mild adverse events including somnolence, changes in appetite, gastrointestinal symptoms, restlessness, and sleep disturbances (46,47). CBD has been associated with reducing self-injury, rage attacks and hyperactivity, and with improving sleep (48). A randomized trial from Israel compared CBD-enriched extract (20:1 CBD:THC) and purified cannabinoids in the same ratio to placebo in a three-arm crossover design in 150 patients with autism aged 5 to 21 years. The authors reported tolerability with improvements in disruptive behaviours and core autism symptoms (48). Benefits were more pronounced using the CBD-enriched extract (compared to a combination of isolates with the same ratio), supporting entourage effects and encouraging regulators to create pathways that incentivize research on cannabis extracts. Definitive placebo-controlled trials are needed to determine the potential therapeutic benefits and harms of medical cannabis in children with autism (48,49).

Other neurological conditions

A better understanding of CBD may lead to promising therapies for several neurodevelopmental disorders in children (50). While nabiximols is indicated for spasticity in adults with multiple sclerosis, a randomized, placebo-controlled trial of nabiximols (1:1 CBD:THC) in 72 children (aged 8 to 18 years) with spasticity due to cerebral palsy or traumatic non-progressive brain injury reported no improvement in this symptom over a 12-week period (when titrated up to a maximum dose of 32.4 mg THC and 30 mg CBD per day) (51). This trial, which was conducted in the Czech Republic, Israel, and the UK, reported that nabiximols was reasonably tolerated, although three patients experienced neuropsychiatric adverse events, specifically hallucinations, during the randomization and open-label study phases that included 72 participants (51). A small open-label Israeli study showed that CBD-enriched cannabis extracts (CBD:THC ratios of 6:1 and 20:1) improved spasticity and dystonia in children (52).

A pilot RCT (53) in eight children comparing purified CBD oil (titrated up to 20 mg/kg CBD per day) with placebo in children with intellectual disabilities and severe behavioural problems found that CBD was well tolerated and reduced severe behavioural problems, warranting further investigation in a larger RCT (54). Also, case reports and two small studies have suggested benefits for patients with Tourette's syndrome (55,56), as did a small case series of patients with fragile X syndrome (57). A Phase II, industry-sponsored, randomized, placebo-controlled trial evaluated doses up to 250 mg of a transdermal CBD gel in children with fragile X. It was well tolerated, and preliminary findings in 20 children (aged 6 to 17 years) suggest reduced anxiety, improved social interactions, and less irritable behaviours (58,59).

Cancer and palliative care

In 2020, 92% of Canadian paediatric oncologists and palliative care physicians had provided care to at least one child who had used cannabis for medical purposes within the previous 6 months, with or without an authorization from a health care provider (60). Despite limited research on cannabis use in children with cancer, reported reasons for using cannabis products in this population vary widely, from managing cancer and cancer treatment-related symptoms to aiming for a cancer cure (61). Synthetic cannabinoids (nabilone in Canada) are used as third-line antiemetics in children, with demonstrated benefit in chemotherapy-induced nausea and vomiting (62), when compared with conventional agents (70% versus 30%, respectively) (63,64). There may be additional safety considerations around the use of cannabis products during therapy with immune checkpoint inhibitors. Observational data in adults (65) reported an increase in tumour progression and a decrease in overall survival, though neither finding was replicated in mouse models of non-small cell lung cancer (65). There is significant interest among families regarding the reputed antitumor properties of cannabis, based in part on in vitro and in vivo work, case reports, online anecdotes, and ongoing adult studies, but as yet there have been no clinical trials evaluating the antineoplastic effects of cannabis in children (63). Two clinical trials in Canada and Australia are planned or ongoing to investigate combinations of THC and CBD and evaluate use of cannabinoids to manage symptoms in children with cancer (66,67).

Prognosis remains a key consideration for Canadian physicians who authorize medical cannabis for a child (68). One observational report of 21 Canadian children (aged 3 months to 19 years) who were followed by a paediatric palliative care team found they all experienced symptoms improvement after receiving cannabis for pain or nausea and vomiting. The effects of medical cannabis on seizures was mixed, however (69). Adverse events were reported in 33% of children, and included somnolence, insomnia, and vomiting (69). In Italy, one study of six children who received palliative care with cannabis oils reported reduced pain and seizure frequency, with mild and transient side effects (70). Dronabinol has been used to successfully manage spasticity in children with neurological complexities and receiving palliative care (71). This evidence has informed international pharmacovigilance work (72) on the safety and efficacy of medical cannabis for children receiving palliative care.

Evidence gaps

Medical cannabis has demonstrated potential efficacy in several conditions in adults (73), such as anxiety and pain, for which there is, as yet, insufficient evidence in children (74–76). There are more than 32 clinical trials focused on cannabinoid use for chronic non-cancer pain in adults (77), but none studying either acute or chronic pain in children (74–76). Chronic pain is common in young people (78), and an upcoming clinical trial in Canada will be the first to evaluate a cannabis product in adolescents with chronic headaches (79). Consensus-based recommendations for slowly titrating cannabinoids in the context of opioids and chronic pain are available for adults (80).

Attention-deficit hyperactivity disorder (ADHD) and attention-deficit disorder are conditions for which there has been demonstrated benefit for cannabis use in adults (81–83). Large observational studies have reported that adults with ADHD believed cannabis had improved their medication-related side effects (82). A Canadian case series involving three young adults with ADHD reported improved depressive and anxious symptoms, and enhanced emotional regulation, when they consumed medical cannabis alongside their other medications (84). These studies did not specify recommended doses and included a range of cannabis products and formulations. Clinical trials are needed to evaluate the potential efficacy and safety of cannabis products for managing paediatric ADHD.

Safety considerations

Cannabis-related adverse events should be discussed with children and adolescents, as appropriate for age and stage, and with family whenever possible. Such conversations should differentiate clearly between what is known about individual product components (THC, CBD, terpenes, other cannabinoids) versus indications, product types, and dosing information that have (and have not) been studied in children and youth. To date, long-term safety data for this age group are restricted to purified CBD. In DRE, the incidence of adverse events related to CBD seems comparable to that of other anticonvulsant drugs, and CBD use does not appear to lead to further impairment (85–87). The most common short-term adverse effects of CBD were drowsiness, fatigue, decreased appetite, diarrhea, and vomiting (78,88). Longer-term adverse events of CBD include changes in mood, weight gain or loss, and an increase in seizure frequency. Some adverse effects may be due to the interaction between cannabinoids and other drugs, such as the anticonvulsant clobazam (89,90). However, CBD clinical trials found no differences in plasma drug concentrations or seizure frequency between patients taking clobazam versus those who did not (91). Elevated transaminases and thrombocytopenia were observed in some patients, often during concurrent therapy with valproic acid (92). CBD adverse events were dose-related, with higher rates occurring when dose approached 20 mg/kg/day (87,88).

Little is known about the short- or long-term safety of THC in medical cannabis formulations, due to a paucity of early phase studies and poorly characterized exposures. THC levels can vary based on interactions with other drugs, cannabinoids, and terpenes (e.g., limonene). Due to the lipophilic nature of THC, blood levels do not correlate well with clinical effects, intoxication, or central nervous system effects (93). Research suggests that THC may alter white and grey matter distribution in the developing brain, and may impair memory (55,63,73,94). It is not known to what extent safety risks apply to high-CBD (versus no or low-THC) products. THC can cause cardiovascular effects, including severe hypotension, in children (95,96). Adverse effects of THC include euphoria, reduced level of consciousness, nausea or cannabis-hyperemesis syndrome, dizziness, forgetfulness, and tiredness (97,98). Intoxication in young children may manifest with respiratory depression, including apnea, and coma (99). The potential for adverse neurodevelopmental effects must be considered in the context of each child's overall condition and prognosis and the risk to benefit ratios of alternative therapies (100).

Drug–drug interactions are a potential consideration for THC and CBD (101,102). THC and CBD are both metabolized by CYP enzymes and are known to interact with a number of them, including CYP3A4, CYP2C9, and CYP2C19 (103–105), and may thus variably inhibit the metabolism of other drugs (105,106). The pharmacokinetics of CBD and THC in children and youth have only been studied in a small number of patients and were found to vary widely among individuals (106,107).

Family and caregiver considerations

Parents who seek medical cannabis for their children report barriers to access and a need for unbiased information (61,108). They often report using cannabis as a last therapeutic resort. A lack of reputable resources may push them to seek information from social media, cannabis storefronts, or friends. The palatability of oil-based products and their impact on gastric tube degradation should be considered carefully when authorizing use for children, especially when large volumes should be consumed. Procedures for administering medicine at school, and travel considerations, should also be discussed with families. Cost is another important consideration. Purified CBD and CBD-enriched oils are expensive, especially in the doses recommended for seizure control. Cost can be a significant burden to families already struggling with the expense of managing a child's chronic illness. Some insurance providers cover the cost of medical cannabis while restricting indications. Others specifically exclude such coverage for children and youth. Some licensed producers discount medical cannabis for use by paediatric patients, but such offerings are inconsistent.

Authorizing medical cannabis in children

As with any pharmacotherapy, the first step toward authorizing medical cannabis is determining its potential benefits and risks for each child or youth. Medical considerations should include the number and nature of other therapeutic attempts, prognosis, and symptom severity (68). In adults, dried cannabis flower is conventionally smoked or inhaled to activate cannabinoids by carboxylation and facilitate absorption (106). Smoking is not recommended in paediatric patients for several reasons, including unpredictable dosing and smoking-related respiratory hazards. Cannabinoid oils are mostly administered orally for this age group, and the literature on transdermal CBD administration is evolving. Cannabis carrier oils often have an unpleasant taste that is difficult to mask. They may also contain allergens or cause nausea and diarrhea, particularly at higher doses. A wide variety of cannabis "edibles", such as gummies or chocolates, is available for purchase in Canada. The composition of these products tends not to be clinically practical (e.g., no or insufficient CBD, too much THC, or both) and geared rather to recreational consumption. Also, cannabinoids may be inconsistently distributed throughout a given product. Use of edibles for paediatric medical purposes is not recommended.

The amount of dried cannabis that is considered equivalent to the oral cannabis extract a young patient may need or use will vary by manufacturer. In Canada, no purified CBD products with a DIN were available at time of writing. Even when there is strong evidence of benefit for a child or youth with DRE, the only way to access CBD legally is through a medical cannabis

authorization. Yet the number of clinicians who are trained and comfortable with this process is small. Both the lack of strong data to support the use of medical cannabis in children—and the omnipresence of misinformation—make the need to establish evidence-based parameters for safe and beneficial use of medical cannabis in paediatrics all the more urgent. Several large initiatives, including the Canadian Consortium for Childhood Cannabinoid Therapeutics (C4T), an academic research team, are working to advance research and disseminate knowledge in this area, with support from the Canadian Institutes of Health Research.

There are indications for which risks may outweigh benefits, and part of a health care professional's duty of care is to have individualized, open discussions with families concerning the evidence for the benefit and risk of medical cannabis (68,109). As with other medications, being sure to set clear goals, dosing schedules, timelines (including when to assess dose and treatment success), and parameters for discontinuation in the case of adverse events, are all important for treatment planning. Pharmacists have a growing role to play in minimizing drug–drug interactions (110). Adverse events related to medical cannabis use should be reported to MedEffect Canada.

SUMMARY

There is a growing body of research, of variable quality evidence, suggesting benefit of medical cannabis for some conditions in some children. Medical cannabis should only be authorized in cases where the benefits clearly outweigh the risks. The efficacy and safety of medical cannabis have been documented with varying degrees of strength for DRE, cancer-induced nausea and vomiting, and autism. In the available paediatric literature, purified CBD has been well tolerated but may interact negatively with other medications. There is less evidence to support THC-containing medical cannabis product use in children, and safety concerns have been raised. Many clinical trials are ongoing with focus on CBD-enriched extracts and purified CBD for paediatric indications such as chronic headaches, spasticity, symptom management in cancer, palliative care, and behavioural problems in children living with a cognitive impairment.

RECOMMENDATIONS

- When appropriate, and particularly when requested by families, clinicians should be willing and able to engage in open discussions about the potential benefits and risks of medical cannabis. Counselling should:
  - be evidence-based and unbiased,
  - help parents make informed, shared decisions about their child's care,
  - alert parents to the risks and implications of accessing cannabis through recreational sources.
- Therapeutic considerations should focus on the child's or youth's specific condition and prognosis, potential benefits and risks based on the best available data, a clear treatment plan, and follow-up to evaluate efficacy, monitor safety, and avoid adverse events, including drug–drug interactions.
- For indications established by RCTs, the administration of medical cannabis products should involve slow titration and be tailored to the individual child and condition.
- Rigorous research is urgently needed to establish the role of medical cannabis in paediatric conditions for which there is biological plausibility or evidence of efficacy based on adult research. As the evidence-base for medical cannabis grows, clinicians should seek up-to-date evidence on potential safety risks, including drug–drug interactions.
- Given the already widespread use of medical cannabis, unbiased education for clinicians wanting to learn more about how THC, CBD, and other cannabinoids work, along with potential risks and benefits for children and youth, should be developed.

SUPPLEMENTARY DATA

Supplementary data are available at *Paediatrics & Child Health* Online.

eTable 1. Overview of dosing and reported safety events from published clinical trials (interventional studies) enrolling children investigating cannabidiol (CBD)

eTable 2. Overview of dosing and reported safety events from published clinical trials (interventional studies) enrolling children investigating CBD and other cannabinoids, including THC

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POTENTIAL CONFLICT OF INTEREST

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CANADIAN PAEDIATRIC SOCIETY DRUG THERAPY COMMITTEE (JULY 2022)

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