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Research

# Clinician views on and ethics priorities for authorizing medical cannabis in the care of children and youth in Canada: a qualitative study

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## Abstract

**Background:** The use of cannabis for medical purposes by pediatric patients is expanding across Canada; however, supporting evidence, federal regulations and treatment guidelines are lacking. To understand factors affecting treatment decisions in this landscape, we sought to delineate clinician perspectives, ethics priorities and values for cannabis authorization.

**Methods:** We sampled participants purposefully through Canadian Childhood Cannabinoid Clinical Trials listservs, which include the majority of pediatric oncologists and palliative care physicians practising in Canada, among many other pediatric physicians and clinicians. Inclusion criteria were being a practising clinician in Canada, involvement in the care of children and willingness to be interviewed regardless of stance on medical cannabis. In November and December 2020, we conducted semistructured interviews focusing on principles, values and priorities, including medical, professional, regulatory, evidentiary and social considerations, for authorizing medical cannabis to children. Interviews were recorded, transcribed and analyzed by means of deductive and inductive thematic methods.

**Results:** We conducted 18 interviews with a diverse group of clinicians representing a range of specialties within pediatric care, including neurology, palliative care, oncology, family medicine and pharmacology. The interviews yielded 4 themes and 12 subthemes related to a priori (medical, professional, regulatory, evidentiary and social themes) and emergent themes. The 4 themes of access, relationships and relational autonomy (autonomy within relationships), medically appropriate use and research priorities were grounded in principles of harm reduction. Participants described problematic authorization procedures that negatively affect patient use. Principles associated with relational autonomy were highlighted as a feature of open clinical communication. Benefits of appropriate medical uses weighed positively over risks, even in the context of potential effects on neurodevelopment. Participants expressed that more research is essential to align medical cannabis with biomedical standards.

**Interpretation:** Clinicians reported pursuing ethical use of medical cannabis for pediatric patients and prioritizing their safety under principles of harm reduction. There is a need for evidence about neurodevelopmental risks, support for research, treatment guidelines and greater knowledge about stakeholder perspectives to alleviate burdens related to use of medical cannabis for pediatric patients in Canada.

The federal government of Canada provided a system for therapeutic access to cannabis in 2001 after a series of successful constitutional challenges on cannabis prohibitions.[1–3] Clinicians provide authorizations, rather than prescriptions, for medical cannabis owing to its current status and regulation within Health Canada.[4] Two decades later, the position of medical cannabis within Canadian legislation, health care and society continues to evolve.[1,5,6] Driven largely by public awareness, anecdotes of benefit and expanded approvals for oral administration of derivative products, medical cannabis has become an increasingly prevalent treatment option for children with neurodevelopmental and life-limiting conditions including brain and other cancers.[4,5,7–11]

Despite this trend, data on potential medical properties and clinical applications of cannabis are generally lacking, and standards regarding use in children are largely absent.[4,5] Clinicians are practising, therefore, in a landscape defined by high patient and caregiver interest, little medical data, and tensions arising from an absence of regulations and treatment

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guidelines. In situations of clinical uncertainty or hesitancy, principles of harm reduction, including pragmatism, humanism, focus on harms and prioritization of immediate goals, can be used to facilitate treatment decisions that respect patient dignity and safety.[12,13]

Past studies of factors affecting the views of clinicians on medical cannabis treatment are limited but yield converging results about knowledge base, legal regulations, authorization procedures and medical context.[14–19] These data are derived primarily from clinicians specializing in pain medicine, oncology, palliative care and family medicine.[7,20–24] There appear to be limited data on the ethics priorities or values that shape treatment decisions about medical cannabis for children and on the effects of legalization of recreational cannabis in Canada (*Cannabis Act*, Oct. 17, 2018).

Our objective was to obtain a greater understanding of how ethical priorities and values — mainly access, safety and autonomy — affect clinician decision-making. The importance of filling this knowledge gap lies in both practice considerations in this unregulated landscape and the inherent vulnerability of children, whose capacity to understand and participate in treatment decisions and provide consent is still evolving.

## Methods

### Study design

We developed a qualitative study under a pragmatic framework with the view that empirical evidence and a dynamic, interactive and interdisciplinary process will most effectively lead to solution-oriented action.[25–28] Using semistructured interviews, we facilitated flexible and exploratory dialogues with clinicians in which more nuanced thoughts and values surrounding medical cannabis were highlighted and examined in depth.[29] This study was reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist.[30]

### Sample selection

We sampled participants purposefully through Canadian Childhood Cannabinoid Clinical Trials (C4T) listservs. Canadian Childhood Cannabinoid Clinical Trials is an academic research team of youth, parents, clinicians and scientists studying cannabis for medical purposes in children (www.C4Trials.org). Its listservs include hundreds of Canadian clinicians working in various subspecialities related to pediatric care, at various career stages and with different backgrounds (e.g., English-speaking, French-speaking and multilingual practitioners) in urban and rural communities across British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec and Nova Scotia. The listservs include the majority of pediatric oncologists and palliative care physicians practising in Canada, among many other pediatric physicians and clinicians, such as psychiatrists, pain specialists, neurologists and pharmacologists. Members are known to have views regarding medical cannabis, and are often consulted by patients and caregivers, or are active authorizers.

Participants were eligible if they were a practising clinician (i.e., physician, pharmacist, clinician in allied health care) involved in the care of children in Canada and were willing to be interviewed regardless of their stance on medical cannabis. Emails were sent to all members of the C4T listservs in November 2020. Eligibility was confirmed before interviews were scheduled. After individual interviews were scheduled, a reminder email was sent 2 days prior.

### Data source

The interview guide was developed by M.G. and J.I. after engagement with C4T. It was piloted through group and one-on-one consultations with L.E.K., A.L.R., S.R.R., S.O., B.C. and additional C4T members such as researchers and patient advocates, and refined and finalized based on the feedback received. The interview guide consisted of 13 questions focusing on principles, values and priorities, including medical, professional, regulatory, evidentiary and social considerations, for authorizing medical cannabis to children (Appendix 1, available at www.cmajopen.ca/content/10/1/E196/suppl/DC1). We also collected information about participant gender, ethnicity, specialty, years in practice and location of practice.

One-on-one interviews were conducted in English by M.G. in November and December 2020. Interviews were conducted virtually on a video conferencing platform because of recruitment challenges during the COVID-19 pandemic. All participants provided verbal informed consent and were reminded that they could decline to answer any question or to end the interview at any time.

### Data analysis

Interviews were audio-recorded, transcribed verbatim by a professional service, checked manually, de-identified with the use of alphanumeric codes and managed in NVivo 12 (QSR International). We used deductive and inductive coding for content analysis.[31] M.G. and A.D.R. reviewed interviews and field notes to write memos capturing overarching narratives before building the initial codebook around a priori (medical, professional, regulatory, evidentiary and social themes) and emergent themes, subthemes and factors using 4 interviews selected with a random number generator.[32–34] M.G. and A.D.R. coded transcripts by paragraph using a rich coding strategy that allowed for the attribution of more than 1 unique code per paragraph.[33,34] We determined intercoder reliability using the Cohen $\kappa$ coefficient.[33–35] Discrepancies were discussed until consensus was reached. M.G. and A.D.R. coded the remaining interviews independently, which allowed for further refinement of thematic codes.

We calculated the proportion of coded references as the number of coded references per thematic code divided by the total number of references. We identified major subthemes and factors as the most frequently occurring subtheme and factor under each theme and subtheme, respectively.

### Ethics approval

This study was approved by the University of British Columbia Behavioural Research Ethics Board (REB H20-03084).

## Results

Interviews were conducted with 18 participants representing a range of specialties within pediatric care, including neurology, palliative care, oncology, family medicine and pharmacology (Table 1). Half of the cohort had been in practice for 10 or more years. Eleven participants self-identified as male and 7 as female. They were of white, Asian, Black and Latino ethnicity. Participants represented 6 provinces.

The median interview time was 34 (range 29–61) minutes. Cohen κ tests yielded an overall unweighted κ statistic of 0.90, which indicated good reproducibility of the coding hierarchy (Table 2).

### Themes

Overarching principles of harm reduction unified 4 a priori and emergent themes: access, relationships and relational autonomy (autonomy within relationships), medically appropriate use and research priorities (Table 2). There were 12 subthemes. Table 3 shows the proportion of interviews and of coded references ($n$ = 1886) supporting dominant subthemes and factors. Illustrative quotes are provided in Table 4.

### Access

Clinicians most frequently referred to the theme of access by comparing medical cannabis to other therapeutics and how

**Table 1: Demographic characteristics of study participants**

| Characteristic | No. (%) of participants $n$ = 18 |
|---|---|
| Profession | |
| Physician | 16 (89) |
| Academic clinical researcher | 1 (6) |
| Pharmacist | 1 (6) |
| Specialty | |
| Pediatric palliative care | 7 (39) |
| Pediatric oncology | 4 (22) |
| Other pediatric* | 4 (22) |
| Family medicine | 1 (6) |
| Clinical pharmacology | 1 (6) |
| Research pharmacology | 1 (6) |
| Years in practice | |
| < 10 | 9 (50) |
| ≥ 10 | 9 (50) |
| Gender† | |
| Male | 11 (61) |
| Female | 7 (39) |
| Location of practice | |
| Ontario | 8 (44) |
| British Columbia | 4 (22) |
| Manitoba | 2 (11) |
| Saskatchewan | 2 (11) |
| Alberta | 1 (6) |
| Quebec | 1 (6) |
| Ethnicity† | |
| White | 14 (78) |
| Asian | 2 (11) |
| Black | 1 (6) |
| Latino | 1 (6) |

*Includes pediatric neurology, general pediatrics and pediatric clinical pharmacology.
†Self-identified.

**Table 2: Coding hierarchy**

| Major theme; subtheme | Factor |
|---|---|
| **Access** | |
| Authorization burden | • Supply and quality<br>• Clinician<br>• Financial |
| Law and policy burden | • Federal<br>• Provincial<br>• Hospital policy |
| Patient burden | • Pragmatic use<br>• Conditional rights |
| **Relationships and relational autonomy** | |
| Clinical communication | • Individualistic approach<br>• Data transparency<br>• Informed consent |
| Clinical support | • Support and guide use<br>• Responsibility to educate<br>• Referrals |
| Nonclinical communication | • Misconceptions, misperceptions<br>• Public promotion of information |
| **Medically appropriate use** | |
| Risk–benefit calculus | • Harms<br>• Balance risk and benefit |
| Evidence-based treatment | • Considered option<br>• Not considered option |
| Consumption | • Various forms, routes, dosages<br>• Recommendations |
| **Research priorities** | |
| Necessary research | • Data from any scientific method<br>• Appropriate use<br>• Adverse effects<br>• Efficacy<br>• Safety<br>• Dosing<br>• Randomized controlled clinical trials |
| Barriers to research | • Study design<br>• Institutional |
| Research ethics | • Ethical considerations<br>• Obligations |

unique barriers can interfere with patient safety (18 interviews [100%]; 532 coded references [28.2%]). Obstacles to authorization was a notable subtheme. Major factors influencing authorization included considerations about product supply and quality, professional reputation and knowledge required to authorize. Participants also mentioned financial obstacles that patients and their families face, including high cost and lack of insurance coverage (Table 4).

**Table 3: Frequency of interviews and coded references endorsing themes, and dominant subthemes and factors**

| Theme; subtheme; factor | No. (%) of interviews *n* = 18 | No. (%) of coded references *n* = 1886 |
|---|---|---|
| **Access** | 18 (100) | 532 (28.2) |
| Authorization burden | 18 (100) | 269 (14.3) |
| Supply and quality | 17 (94) | 108 (5.7) |
| **Relationships and relational autonomy** | 18 (100) | 526 (27.9) |
| Clinical communication | 18 (100) | 313 (16.6) |
| Individualistic approach | 18 (100) | 169 (9.0) |
| **Medically appropriate use** | 18 (100) | 487 (25.8) |
| Risk–benefit calculus | 18 (100) | 267 (14.2) |
| Harms | 18 (100) | 132 (7.0) |
| Balance risk and benefit | 17 (94) | 135 (7.2) |
| **Research priorities** | 18 (100) | 341 (18.1) |
| Necessary research | 17 (94) | 235 (12.5) |
| Data from any scientific method | 15 (83) | 61 (3.2) |

Law and policy burdens were described by clinicians as regulations that impede authorization and patient access. Participants most often cited negative impacts of federal regulations on access (18 interviews [100%]; 99 coded references [5.2%]). For example, participants explained that Health Canada's refusal to provide a Drug Identification Number for medical cannabis lies directly upstream of authorization obstacles. They described the impact of federal legalization of adult use of recreational cannabis on patient access: although clinical decision-making did not change, participants perceived a decline in research barriers and in social and institutional stigma. Minor factors (i.e., provincial law and hospital policy) were cited infrequently as factors affecting access (< 5.0% of coded references).

Within the subtheme of patient burden, participants cited behaviours and rights that can create barriers to safe and effective treatment (18 interviews [100%]; 108 coded references [5.7%]). They suggested that patients and caregivers find and use cannabis for therapeutic purposes regardless of authorization status or clinical guidance. Participants also acknowledged that patients have a right to inquire about medical cannabis, but their right to receive medical cannabis is conditional on medical context.

**Table 4: Illustrative quotes for dominant subthemes**

| Theme | Subtheme | Illustrative quote |
|---|---|---|
| Access | Authorization burden | [There is a] lack of consistency from one licensed producer to another, content is not the same [which is different from other therapeutics]. The therapy and content might be different one batch to other. It's almost like witchcraft in some way. (Participant 02)<br>Money is the biggest [equity concern]. … For a child [for whom] I would [authorize] or think of [authorizing medical cannabis], if the family doesn't have … ways of getting it, then we're stuck. (Participant 05) |
| Relationships and relational autonomy | Clinical communication | Just being very transparent with families is important, and letting them know … the evidence that you have for it [cannabis], certain scenarios that you think it is beneficial in and why directly for the patient you think it is a good or it's beneficial or not beneficial. And then, helping to dispel some of their disbeliefs and asking … what their knowledge is of medical cannabis. (Participant 09)<br>It's really the parents who are making the third-party decision whether [the child is] neurologically intact or not. The only difference is when we're dealing more with adolescents … they're more capable. We definitely bring them in for the conversation because … they're capable. (Participant 05) |
| Medically appropriate use | Risk–benefit calculus | You start out with your most tried and true treatments and then you work up. Now, that's the approach in practice; what that means is the patients who are most severe are most likely to reach third-, fourth-line treatments. So, they would be more likely to be offered cannabis, but I'm not offering it because they're severe. I'm offering it because first-, second-line treatments [have] failed. (Participant 03) |
| Research priorities | Necessary research | I don't think you need to have a direct comparison for efficacy. … Is it safe in the context … even sort of more qualitative things would be fine. (Participant 07)<br>I don't even know that [evidence] needs to be at the randomized controlled trial level. We don't even have well-designed prospective trials, we don't have well-designed retrospective trials, we don't have anything to go by. (Participant 18) |

### Relationships and relational autonomy

Relationships and relational autonomy was the second most commonly referenced theme (18 interviews [100%]; 526 coded references [28%]). The main subtheme was clinical communication defined by an individualist approach: participants explained that they try to build conversations around patient and caregiver needs and beliefs as much as possible, while stressing the need for bidirectional judgment-free honesty and trust (Table 4). Minor factors (< 5.0% coded references) were the importance of data transparency, and obtaining informed consent from the patient or the surrogate decision-maker.

Two additional subthemes were demonstrating clinical support (17 interviews [94%]; 112 coded references [5.9%]) and addressing communication that patients and families receive from outside clinical settings (e.g., friends, Internet) (18 interviews [100%]; 101 coded references [5.4%]). In the context of clinical support, participants expressed a need to follow the wishes of the patient and the caregiver, even if those wishes were not supported by current medical evidence, as well as the responsibility to educate themselves and to provide referrals. They further discussed correcting misconceptions and misperceptions about medical cannabis that can arise from nonclinical sources of communication.

### Medically appropriate use

The third most commonly referenced theme was medically appropriate use (18 interviews [100%]; 487 coded references [25.8%]). Risk–benefit calculus was dominant here, with potential harms of medical use compared to expected benefits (Table 4). Participants cited specific harms, including negative impacts on neurodevelopment, drug–drug interactions and the potential for addiction. Benefits pertained to improvements in quality of life and reducing harms in a safely monitored way. Medical considerations that could mitigate risks were the number of tried and failed therapeutic attempts, a life-limiting prognosis, the presence of severe symptoms and a shorter duration of use (Table 5).

The subtheme of evidence-based treatment outlined the conditions for which medical cannabis may be considered an appropriate treatment option, not as a first-line option but, rather, as a low-priority symptom management tool. Commonly cited treatment contexts included cancer-related symptoms, seizure disorders, chronic nausea and chronic pain.

**Table 5: Medical considerations affecting risk–benefit calculus and the decision to authorize medical cannabis**

| Medical profile characteristic | No. (%) of interviews | No. (%) of coded references |
|---|---|---|
| No. of therapeutic attempts | 16 (89) | 46 (2.4) |
| Prognosis | 16 (89) | 46 (2.4) |
| Symptom severity | 13 (72) | 25 (1.3) |
| Duration of use | 3 (17) | 3 (0.2) |

Consumption captured clinical deliberation over the formulation (Δ-9-tetrahydrocannabinol–cannabidiol ratio) and route of administration. Nuances of dosing and recommendations against smoking dominated this subtheme.

### Research priorities

Participants believed that research was necessary for authorization of medical cannabis to children, expressing an urgency for more data in general, from any scientific method, in any population (Table 4). They expressed that studies directed at specific and diverse pediatric populations and conditions, as well as systematic investigations of adverse effects, efficacy, safety and dosing, would raise the evidentiary standard for medical cannabis to the standard to which therapeutics are generally held (Table 6). More than half of participants ($n$ = 13) expressed the need for randomized controlled clinical trials.

The subthemes of barriers to research and research ethics each represented less than 5.0% of coded references but reflected important concerns for developing future studies. Barriers to research included funding difficulties and study design considerations. Research ethics focused on the obligation to conduct studies in pediatric populations and special ethical considerations therein, such as a greater respect for impact on neurodevelopment.

## Interpretation

The clinicians who participated in our study were critical of Canada's medical cannabis landscape, expressing that regulatory obstacles impose downstream challenges to safe and controlled access for pediatric patients. Medical cannabis is held to the same evidence-based, biomedical standards as other treatments but cannot currently meet them. Participants identified a need to address access barriers and conduct further research. The ethics values that affect clinical decision-making about medical cannabis are perhaps unsurprising and reflect the importance of evidence-based treatment decisions, risk–benefit calculus, respecting relationships and autonomy, and informed choice. The findings highlight the significance of

**Table 6: Research necessary for clinical consideration of authorizing medical cannabis**

| Factor | No. (%) of interviews | No. (%) of coded references |
|---|---|---|
| Data from any scientific method | 15 (83) | 61 (3.2) |
| Appropriate use | 10 (56) | 42 (2.2) |
| Adverse effects | 11 (61) | 41 (2.2) |
| Efficacy | 10 (56) | 23 (1.2) |
| Safety | 10 (56) | 23 (1.2) |
| Randomized controlled clinical trials | 13 (72) | 19 (1.0) |
| Dosing | 9 (50) | 19 (1.0) |

interpersonal values such as quality of life in end-of-life and oncology settings,[7,15] and the need for methodologically sound systematic studies.[7,19,21–24,36–39]

The results of this study align with those of previous studies of clinician attitudes toward medical cannabis. Concerns remain about barriers to access, including supply, quality and financial burdens, identified in surveys among Canadian clinicians before legalization.[5,6,36,40] Insufficient regulations and policies continue to place a disproportionate responsibility on clinicians and create additional access barriers.[21,23,24] For example, medical cannabis has not undergone Health Canada's drug review and approval process and lacks a Drug Identification Number, which means that it has to be authorized, not prescribed. This has ramifications for clinicians, insurance providers, and patients or caregivers.[4,37]

Seminal to our findings is the potential benefit of a harm-reduction approach to manage behaviours that pose a risk to health in societal and clinical settings.[13,41–43] For example, harm-reduction techniques have been applied to reduce problematic use of substances including cannabis by youth.[43–45] Medical cannabis itself has been used as a substitute for prescription opioids and other drugs to reduce harm.[46–48]

Taken as a narrative whole, the present findings reflect harm-reduction principles of pragmatism, humanism, focus on harms and prioritization of immediate goals.[12,13] Participants acknowledged that pediatric patients may use cannabis for perceived medical purposes regardless of access barriers. The results show that, in the face of pragmatic use, clinicians can use harm-reduction strategies to prioritize patient safety. Clinicians take a humanistic approach in recognizing patients' rights to medical cannabis, and in striving for open and transparent communication. To mitigate risks, clinicians guide patients through treatment options with strong evidence before considering medical cannabis as a symptom-management tool. By understanding when and how patient medical profiles may allow potential benefits of medical cannabis to outweigh risks, clinicians are able to prioritize immediate treatment goals.

The expressed need for data, considered federal regulations and a harm-reduction approach support interdisciplinarity in the quest to resolve issues in Canada's medical cannabis system. Legislator, clinician, patient and key stakeholder views are critical to negotiate a system that aligns medical cannabis with treatment standards that do not violate rights to access and safeguards patient health. Many critical issues remain to be explored and addressed, including standardization of products available to patients and researchers, clinician education on dosing and adverse effects of medical cannabis, and clinical communication approaches that are patient-centred and culturally sensitive.

## Limitations

We were unable to recruit participants who do not consider authorizing medical cannabis, and diversity was limited. We did not return transcripts to participants and did not conduct member-checking. It is possible that bias was introduced owing to views and perspectives of the coders, who are both white and of European background. We did not assess the impact of patient demographic characteristics such as age and gender on clinician decision to authorize. The method of semi-structured interviewing yields a holistic, narrative understanding of a topic but, by its nature, evolves during data collection.

## Conclusion

Canadian clinicians described a treatment landscape for pediatric use of medical cannabis that is in need of reform. Current circumstances are fuelled by ineffective federal policies that prevent quality assurance but allow for indirect access without clinician involvement. Although clinicians reported approaching this landscape using a pragmatic harm-reduction strategy, this is untenable as a long-term solution. Changes to regulations and more research are necessary to improve the care of children and youth whose medical needs may include cannabis products.

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