

Children's Health

Submission to the House of Commons Standing Committee on Health (HESA)

October 24, 2022



THE CANADIAN
COLLABORATIVE
FOR CHILDHOOD
CANNABINOID
THERAPEUTICS

Overview

Across Canada, children with complex and refractory health conditions are using cannabis products, often without evidence or expertise from a health care provider. In 2017, half of Canadian Paediatricians reported managing at least one child using cannabis products, which include cannabinoids such as cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC), for a medical reason.[1] The use of cannabinoids is even higher in some subspecialties, for example 91.6% of paediatric oncologists reported managing children using cannabis products.[2]

With the exception of drug resistant epilepsy (DRE) and chemotherapy induced nausea and vomiting, evidence supporting the use of cannabinoids (cannabis-based products like CBD and THC) for other health indications in children is sparse to nonexistent despite widespread use. C4T, the Canadian Collaborative for Childhood Cannabinoid Therapeutics (www.medcannkids.ca), is a child health research team made up of 106 parents, youth, health care providers and scientists. Our mission is to conduct and share high-quality research on cannabis used by children for medical purposes informed by patients, parents, health care practitioners, policy makers, and the scientific community.

Families in Canada, including those whose children have DRE or cancer, can only access CBD for children legally through the medical cannabis stream.[3] Medical Cannabis Authorizations from a physician or nurse practitioner allow for patients under the age of majority to possess an "authorized" amount of dried cannabis (flower) legally. Children can require a daily CBD dose of up to 250mg twice per day, which can cost parents and caregivers thousands of dollars each month. In our interviews with parents of children who take cannabis, the cost has been described as "being equivalent to about a mortgage payment per month".[4] "Parents can claim medical cannabis as a tax refundable medical expense; however, a family earning \$50,000 per year spending \$12,000 per year on CBD can only claim an annual federal tax credit of \$1575 and a provincial/territorial tax credit ranging from \$420 to \$1134" depending on the jurisdiction.[5] This is not nearly enough to support these families. Parents report that cost concerns have caused them to use less CBD for their child than authorized, which can result in therapeutic failure.[6, 7]

[1] Bélanger R, Grant C, Côté M, Donner E, Breakey V, LaFlamme J, Pinard A-M, Rieder M. Canadian pediatricians' views and knowledge about cannabis use for medical purposes among children and adolescents. *Paediatr Child Health*. 2018;23 (S1):e53-4.

[2] Oberoi S, Protudjer JLP, Rapoport A, Rassekh SR, Crooks B, Siden H, et al. Perspectives of pediatric oncologists and palliative care physicians on the therapeutic use of cannabis in children with cancer. *Cancer Reports [Internet]*. 2022 Sep [cited 2022 Oct 18];5(9). Available from: <https://onlinelibrary.wiley.com/doi/10.1002/cnr2.1551>

[3] Cannabis Act, S.C. 2018, c.16

[4] Mansell H, Zaslawski Z, Mbabaali S, King PM, Kelly LE, Lougheed T, Anderson J, Huntsman RJ, Alcorn A. Medical cannabis in schools: The experiences of caregivers. *Paediatr Child Health*. 2022. [Accepted]

[5] Huntsman RJ, Elliot J, Lewis E, Moore-Hepburn C, Alcorn J, Mansell H, et al. Removing barriers to accessing medical cannabis for paediatric patients. *Paediatr Child Health*. 2022 [Embargoed]

[6] Gibbard M, Mount D, Rassekh SR, Siden H. Family attitudes about and experiences with medical cannabis in children with cancer or epilepsy: an exploratory qualitative study. *CMAJ Open*. 2012;9(2) E563-9. doi:10.9778/cmajo.20200212

[7] Elliot J et al. Barriers in accessing medical cannabis for children with drug-resistant epilepsy in Canada: A qualitative study. *Epilepsy Behav*. 2020;111:1-9. <https://doi.org/10.1016/j.yebeh.2020.107120>

Previously Canada enjoyed several regulatory advantages compared to other jurisdictions when it came to studying medical cannabis in children. However, recent regulatory changes under the Cannabis Act have resulted in researchers facing barriers that have effectively put a halt to paediatric clinical studies. While well intentioned, the implementation of institutional cannabis licenses resulted in researchers having to delay starting their research as their institutions await licensure. Due to a lack of resources at both an institutional level and within Health Canada there have been major delays in research institutions obtaining their licenses.

All medical cannabis products available to children must be certified under the Good Production Practices (GPP) requirements. Up until recently, products with GPP certification could be used in clinical trials. However, Health Canada recently introduced a requirement that all medical cannabis products used in clinical trials must have Good Manufacturing Practices (GMP) certification – the standard for pharmaceutical products in Canada. This disconnect has resulted in researchers being unable to study products that are currently being used by our paediatric patients. As only a limited number of cannabis Licensed Producers (LPs) have the financial and technical resources to obtain GMP certification for their products, researchers are restricted to a paucity of products to use in their studies. They often have to turn to medical cannabis products produced overseas that meet GMP certification through reciprocal regulatory agreements. Without a mandated investment in researchers, LPs have no financial incentive to obtain GMP certification for their products and work with Canadian researchers.[8]

A coordinated effort between all levels of government including Health Canada - cannabis, adverse events surveillance and clinical trials, with health care providers, research teams, and parents is needed to ensure safety for children using cannabis products for medical purposes and ensure surveillance systems are in place to track and respond to safety events.

The use of cannabis products for medical reasons among complex and chronically ill children is increasing, and concrete steps to support families and facilitate research are urgently needed.

Barriers to Access

Families whose children could potentially benefit from medical cannabis face several barriers in accessing it for their children. These barriers include: 1) a lack of evidence to support the safe, appropriate and effective use of medical cannabis especially in children, 2) a lack of education for families who often turn to inappropriate sources of information including on social media, 3) a lack of education for health care providers including paediatricians who often feel uncomfortable authorizing medical cannabis for children,

[8] Huntsman RJ, Kelly LE, Alcorn J, Appendino JP, Belanger RE, Crooks B, et al. Improving the regulation of medical cannabis in Canada to better serve pediatric patients. *Can Med Assoc J.* 2021;193:E1596-9. doi: 10.1503/cmaj.202169

4) prohibitively high costs of medical cannabis exacerbated by these products now becoming subject to taxation under the Cannabis Act. The increased cost of medical cannabis has resulted in inequalities in access and under dosing, and 5) a lack of requirement for LPs to notify parents and Health Canada of impending product shortages forcing parents to find a suitable alternative, often at short notice.

Our interviews with clinicians reiterated these barriers with one participant explaining how “unfortunately there’s this Google world out there and a lot of misinformation on the web. So, most parents are forced to gather the information through the internet, or chatting about experiences with their peer groups”.^[9] Clinicians further highlighted “there’s a lot of misunderstanding about the different cannabis products, the different ingredients, as well as the dosing. So, for the vast majority, it’s not well understood” with many “physicians who know nothing about this stuff. Like literally zero. And it’s a product of the medical education system, too in this point in time.”.^[9] These barriers are not insurmountable, however, facilitators listed below will require a collaborative effort between multiple layers of provincial and federal governments.

Barriers

Facilitators

Lack of Evidence

- Investment in paediatric cannabis research and infrastructure
- Expedite cannabis research licenses for children’s hospitals (sites)
- Permit clinical research on GPP products that are available on the medical cannabis stream and already being used by families
- Incentivize paediatric drug development in Canada
- Increase acceptability and knowledge of innovative clinical trial designs to improve research efficiency

Lack of Education

- Fund unbiased, expert education and mentorship opportunities for health care providers that should be evaluated by experts in communication science
- Support cannabis research infrastructure to translate knowledge to the bedside
- Harmonization in continuing education across provincial Medical Colleges and specialities

Prohibitive Costs

- Remove provincial and federal sales tax on medical cannabis for children
- Create compassionate pricing programs that consider medical expenses and continued discounts for patients who turn 18 years old
- Create regulatory incentives that encourage firms to conduct research and apply for a DIN so Canadian families can access these medicines
- Accept existing trusted foreign regulatory decisions for purified CBD

Product Shortages

- Mandate licensed producers report expected shortages to patients and health care providers
- Create pharmacist networks to support families with product selection, dosing and switching
- Mandate public disclosure of certificates of analysis to facilitate product switching safely

^[9] Mansell H, Zaslawski Z, Kelly LE, Lougheed T, Brace T, Alcorn J. Medical Cannabis in Schools: A Qualitative Study on the Experiences of Clinicians. *Paediatr Child Health*. 2022. [Accepted].

Calls to Action

1. Develop a comprehensive public health strategy that supports clinical trials on medical cannabis products to inform dosing, safety and efficacy, that is centered on patients, families and science.
2. Undertake an integrated and transparent review of policies across branches of government that affect medical cannabis authorization, drug approvals and medical research for children that includes scientists, health care providers and families who are affected by these policies.
3. Mandate the creation and implementation of a data capture system for Provinces to centrally report medical cannabis authorizations for patients under 18 years alongside reason for authorization and adverse events, to ensure Canadians have accurate population level data on the use of cannabinoids for medical purposes in Canadian children.

Conclusions

Families face immense barriers in accessing medical cannabis and evidence based, trustworthy information to keep their children safe. The current landscape in Canada prohibits research on cannabis products available through the medical cannabis stream and furthers inequities in health for these families. Given the financial burden of paediatric chronic disease on the healthcare system, and the potential cost-effectiveness of cannabinoid therapeutics, implementing our calls to actions will not only have a significant positive impact on individual families but also on reducing healthcare system burden.

We encourage industry, various levels of government, and funding agencies to work together to facilitate high-level, independent clinical research and education on cannabis to paediatric health care providers and their families, to ensure safe and equitable access to those who could potentially benefit from cannabinoid therapeutics.

This report was prepared by Sophia Mbabaali MA, Dr. Lauren Kelly PhD, Dr. Richard Huntsman MD, and Dr. Holly Mansell PharmD, PhD on behalf of C4T. You can learn more about us online www.medcannkids.ca or contact us by email at C4T.Canada@gmail.com.

