

A Pediatric Hospital Policy for Medical Marijuana Use

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Most US states have now legalized medical marijuana (MMJ) use, giving new hope to families dealing with chronic illness, despite only limited data showing efficacy. Access to MMJ has presented several challenges for patients and families, providers, and pediatric hospitals, including the discrepancy between state and federal law, potential patient safety issues, and drug interaction concerns. Colorado was one of the first states to legalize MMJ and has remained at the forefront in addressing these challenges. Children's Hospital Colorado has created and evolved its MMJ inpatient use policy and has developed a unique consultative service consisting of a clinical pharmacist and social worker. This service supports patients and families and primary clinical services in situations in which MMJ is actively being used or considered by a pediatric patient. The first 50 patients seen by this consultative service are reported. Eighty percent of patients seen had an oncologic diagnosis. Symptoms to be ameliorated by active or potential MMJ use included nausea and vomiting, appetite stimulation, seizures, and pain. In 64% of patients, MMJ use was determined to be potentially unsafe, most often because of potential drug-drug interactions. In 68% of patients, a recommendation was made to either avoid MMJ use or adjust its administration schedule. As pediatric hospitals address the topic of MMJ use in their patients, development of institutional policy and clinical support services with specific expertise in MMJ is a recommended step to support patient and families and hospital team members.

Although much of the history of marijuana in the United States has revolved around safety and public policy advocating punitive control, there was a time in US history when marijuana was freely used medicinally. In the late 1800s, marijuana was used in many medicinal products and was widely available from public pharmacies.¹ It was included in the US Pharmacopeia beginning in 1850 and regulated under the Pure Food and Drug Act (1906) until 1942.² In the latter half of the 19th century, marijuana was studied in Europe and the United States in the attempt to characterize its properties and define

its usefulness in treating different pathologies.³ Pharmaceutical companies, such as Merck in Germany, Burroughs Wellcome in England, and Bristol-Meyers Squibb and Eli Lilly in the United States, developed preparations of marijuana to be sold as analgesic, antiinflammatory, and antispastic drugs.² The cultural landscape changed during the prohibition era, and the first major constraint on marijuana use came with passage of the federal Marijuana Tax Act in 1937.⁴ Marijuana was subsequently dropped from the US Pharmacopeia, and taxation limited access to the drug.³ By the 1950s,

abstract

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marijuana was federally criminalized, and mandatory sentences and fines were imposed.⁵ The passing of the Comprehensive Drug Abuse and Prevention and Control Act (Controlled Substances Act) in 1970 classified marijuana as a schedule I drug, labeling it as a high-risk drug of abuse and addiction with no medically accepted value.³

Throughout the 1970s, multiple states, including Colorado, decriminalized marijuana, making it a petty crime for possession of <1 oz, in contrast to federal law. In the 1980s, amid the War on Drugs, the AIDS epidemic played a significant role in inciting states to pursue legislation to legalize marijuana for medical use despite federal criminalization. After a prolonged battle, California passed the Compassionate Use Act in 1996, legalizing the right to use, access, and grow marijuana for medical use. Several other states followed, and in 2000, through popular referendum, Colorado legalized medical marijuana (MMJ).⁴

Currently, 33 states and Washington, District of Columbia, have passed MMJ legislation. However, under federal law, MMJ remains classified as a schedule I controlled substance. With state and federal law in conflict, pediatric hospitals have found themselves moving forward in uncharted territory. On the one hand, availability of MMJ has given new hope to many families caring for children with chronic illness, and many of these children have frequent contact with pediatric hospitals. On the other hand, pediatric hospitals and their medical staff are recipients of hundreds of millions of dollars of government funding through Medicaid and Medicare programs and federal research grants. Both sources of revenue could potentially be impacted by a violation of federal law. Moreover, as the MMJ industry has matured, the number of different MMJ products has expanded, allowing for significant diversity in the

concentration of specific cannabinoids and in route of delivery, details that are important in understanding the risks of use and the potential pharmacokinetic interactions with other prescribed medications. Patients and families may be unaware of the risks associated with MMJ use, of applicable federal and state laws, and of differences in psychoactive potential between different products. As health care providers find themselves walking the line of legality and patient safety, it is necessary for pediatric hospitals to engage and assist families and health care providers in making educated decisions. In this article, we describe the process created at Children's Hospital Colorado (CHCO) to address the use of MMJ within our hospital. We believe that our experience will be useful to hospitals around the country as they develop their own approach to MMJ. The data and experience shared herein were determined by an institutional review process at CHCO to represent quality improvement activity and not human subjects research.

THE COLORADO CONTEXT

CHCO is a freestanding, quaternary referral, academic pediatric hospital with >400 licensed beds located in Aurora, Colorado, a suburb of Denver. In addition to the state of Colorado, the catchment area for CHCO includes all or part of 6 adjoining states. Nearly all CHCO medical staff are academic faculty of the University of Colorado School of Medicine. Faculty members practicing at CHCO receive federal research funding through different granting agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense.

Colorado has been a focal point in the national conversation about MMJ legalization, having been an early adopter in legalization of both

medical and, later, recreational marijuana. At CHCO, we have attempted to find a path that negotiates multiple realities: (1) the paradox of current state and federal law and the importance of protecting the hospital and medical staff from prosecution or loss of federal funding, (2) the value that many of our families see in access to MMJ for treatment of their children, (3) the importance of addressing patient safety and potential pharmacokinetic interactions by encouraging transparency of use of MMJ products, and (4) the opportunity that inpatient hospitalization presents for educating families on the complex topic of MMJ.

Legalization of MMJ in Colorado in 2000 opened the door for families to pursue alternative therapies. For children <18 years of age, Colorado administrative law requires parental consent and 2 separate physician certifications of a qualifying medical condition to obtain a registry identification card for legal access to MMJ. Patients older than 18 require a single physician certification. Over the last 2 decades, many families of children with medical complexity moved to Colorado with the specific intent of securing access to MMJ products for their children. In this context, many questions emerged for CHCO health care teams. Should families be allowed to continue administration of MMJ products to children when admitted to CHCO? Would use of MMJ potentially disqualify CHCO or its medical staff from participation in federally funded research? Acknowledging the absence of data on most MMJ preparations, what constitutes safe use? If families do not disclose use of MMJ to health care teams, what is the negative impact on understanding possible drug-drug interactions that might influence disease treatment? To address these concerns, the hospital developed an interdisciplinary working group to draft its first MMJ policy.

MEDICAL MMJ POLICY (FIRST ITERATION)

The first CHCO MMJ policy was adopted in 2016 with the purpose of providing criteria and procedure for the therapeutic use of MMJ products while patients were treated at CHCO. Under this policy, patients were allowed to use oral or topical forms of MMJ while admitted to CHCO if they had obtained an MMJ registry identification card in compliance with state law. Use of MMJ was at the discretion of the CHCO attending provider, and inhaled forms of MMJ were specifically prohibited. In appreciation of the continued illegality of MMJ under federal law, CHCO team members were not allowed to prescribe, order, administer, or handle MMJ products. CHCO providers and teams acknowledged use, but families and patients were asked to sign a release and waiver of liability and assume full responsibility for administration of the MMJ product. Within the electronic health record (EHR), health care teams were able to track patient and family self-administration of MMJ products alongside the scheduled administration of other medications. This allowed clinical pharmacists to perform medication profile reviews to notify teams of any potential drug-drug interactions.

PROBLEMS WITH THE FIRST POLICY ITERATION

Under the scrutiny of application to clinical practice and with the evolution of MMJ law, it became clear that several features of our policy were unworkable.

First, the policy was written to address the context of residents of the state of Colorado, but CHCO attracts many out-of-state patients, who, on the basis of residency, would not be eligible for participation in the state MMJ registry. Second, access to MMJ products changed dramatically in Colorado in 2014, when legalization

of recreational marijuana took effect. These realities challenged our policy in one specific patient case. A 21-year-old patient from Kansas was readmitted to CHCO for treatment of a relapse of acute lymphoblastic leukemia. He and his oncology team had found from experience that the only successful antiemetic treatment for him was the use of oral MMJ products. Because he was a Kansas resident, he was not eligible for the state of Colorado MMJ registry, but as an adult older than 21 years, he was able to obtain recreational MMJ products legally. In this case, the hospital and the patient's clinical care team felt that it would be inappropriate to deny him the ability to treat his nausea with MMJ products, although it specifically violated hospital policy.

An additional important development impacting application of our MMJ policy was the reclassification of hemp for commercial use in the Agriculture Improvement Act of 2018 (2018 Farm Bill). Hemp refers to strains of the cannabis plant that contain <0.3% concentration of the psychoactive cannabinoid tetrahydrocannabinol (THC) on a dry weight basis. The change of the 2018 Farm Bill removed hemp and hemp-derived products from the Controlled Substances Act and from oversight of the US Drug Enforcement Agency. Although hemp has low tetrahydrocannabinol content, strains can be enriched in other cannabinoids, including cannabidiol (CBD), which is purported to have antiinflammatory and antiepileptic effects. As a result of the change in classification of hemp, manufacturers of high-cannabidiol products sourced from hemp are now able to avoid legal restrictions on sale. Our policy did not address the differences between products made from hemp and other cannabis sources.

In 2018, the US Food and Drug Administration (FDA) approved Epidiolex, a trademarked form of

cannabidiol, for the treatment of children with seizures associated with 2 rare forms of epilepsy, Dravet syndrome and Lennox-Gastaut syndrome. This represents the first FDA indication for any compound derived from the marijuana plant. Our policy had not addressed the question of FDA approval of any MMJ product, again challenging the relevancy of our existing policy.

We recognized that it was burdensome for our clinical teams to stay abreast of the evolving complexity of state and federal law on the topic of MMJ and recreational marijuana and feel confident in the application of hospital policy. There was a large educational gap to address with families, many of whom did not understand the MMJ registry process. Finally, our clinical teams were often unsure as to whether the administration of MMJ was safe in the context of the patients they were caring for. To address these needs and support our clinical care teams and families, we developed the CHCO Cannabinoid Education Consultation Service (CECS) in late 2016 before undertaking a revision of our MMJ policy in late 2018.

CECS

The CECS was created to support patients, families, and their primary clinical care teams in the provision of education, encouragement of open communication, and promotion of the safe use of MMJ and other cannabinoid products. This unique consultative team is composed of a group of hospital pharmacists and social workers who work in pairs to respond to inpatient consultation requests by a primary clinical service. The role of the social worker on the team is to assess the patient's safety, provide education around safe storage of MMJ, and guide the family in finding reputable online information. The social worker also educates families about the state and federal laws around MMJ products,

including the application process for the MMJ registry in the state of Colorado. It is always the team's recommendation that families obtain an MMJ registry card for their child and consult with a certified physician before using any MMJ products. During the consultation, emotional support is offered around the journey to seek effective treatments, and if additional support is needed, referrals are placed to ongoing hospital social workers. The pharmacist's role involves understanding why the family is interested in pursuing treatment with MMJ and discussing what treatment options have already been tried. The pharmacist also reviews the patient's current medication list and any future planned therapies to evaluate for potential drug interactions and drug therapy concerns. The team documents details of the consultation within the EHR and follows up with the primary care team to address any outstanding questions or concerns. This consultative service is provided without charge to the family. This team holds regular continuing education sessions focused on regulatory, research, and pharmacologic aspects of MMJ. CHCO supports the work of the CECS indirectly through salary support of the hospital pharmacists and social workers on the team. The estimated total time spent by team members in direct patient contact and clinical documentation has been 100 hours/year. Anecdotal feedback from inpatient teams has been strongly appreciative for the engagement of the CECS with families on a topic that may be distracting to the medical problems the primary service is focused on.

Here we report the first 50 patients seen by the CECS between March 2017 and June 2019 (Table 1). Consultations were ordered by 32 different providers representing multiple primary inpatient services. Data were extracted from the

TABLE 1 Patient Characteristics

	Value
Age, median (range)	11 y (2 mo to 23 y)
Sex (<i>N</i> = 50), % of total	
Male	56
Female	44
Diagnosis (<i>N</i> = 50), % of total	
Cancer	80
Leukemia	26
CNS tumor	14
Solid tumor	40
Cystic fibrosis	6
Seizure disorder	6
Other	8
Reason for use or potential use (>1 possible per patient), % of total	
Nausea and vomiting	40
Appetite stimulation	36
Pain	38
Seizures	6
Anticancer	20
Other	14
Product used (<i>N</i> = 50), % of total	
Tetrahydrocannabinol only	6
Cannabidiol only	20
Tetrahydrocannabinol and cannabidiol combination	12
No product at time of consultation	62

CNS, central nervous system.

templated consultative note in the EHR. Patients ranged in age from 2 months to 23 years old, with a median age of 11 years. The majority of patients had an oncologic diagnosis, and the most common reasons for MMJ use or potential use were nausea and vomiting (40%), appetite stimulation (36%), and pain (38%). The use category "other" included irritability, agitation, overall comfort and improved quality of life, depression, and sleep. In quantifying the type of product used, most patients (62%) were not using an MMJ product at the time of the consultation. In these cases, the family had questions about the safety of MMJ use or wanted to obtain more information before deciding if MMJ was the right treatment decision for their child. Of those currently using MMJ, the majority were using a cannabidiol-only product.

CHCO has an inpatient palliative care service, recently established in 2016, that provides inpatient consultative services. In 16% of CECS consultation patients, the palliative care service had also provided consultation during

or before the admission. Thirty-two percent of patients who received CECS consultation had a palliative care consultation during a subsequent admission. In 48% of CECS patients, the palliative care service was not involved.

During the 27-month period from which we gathered data about our CECS program activity, there were a total of 378 MMJ use acknowledgments within the medication administration record for inpatients admitted to our hospital. The fact that only 50 CECS consultations were requested during that period suggests that our inpatient programs are largely accustomed to the use of MMJ products by pediatric patients and are requesting additional consultative support in the minority of cases.

SPECIAL POPULATION AND DRUG INTERACTION CONSIDERATIONS

The highest proportion of consultation requests came from pediatric oncology. Oncology patients present unique challenges because of

their immunocompromised state and complicated drug therapy regimens. There are numerous reported cases of patients contracting fungal, mold, and bacterial infection through contaminated cannabis.⁶⁻¹⁰ Risk of microbiologic contamination is a safety issue that should be addressed when talking about MMJ use in patients who are immunocompromised.

Drug interactions were of particular concern when addressing the safety of cannabinoid use. Both tetrahydrocannabinol and cannabidiol affect the cytochrome P450 (CYP450) system through inhibition and induction, which could potentially affect numerous pharmacotherapies. Specific pathways include CYP450 enzymes 1A2 (tetrahydrocannabinol), 2C9 (cannabidiol), 2C19 (cannabidiol), 2D6 (cannabidiol), and 3A4 (cannabidiol). In addition, cannabinoids have also been noted to inhibit or upregulate both glucuronidation and p-glycoprotein pathways. Such interactions have far-ranging effects on numerous pharmaceutical classes, including antiretrovirals, chemotherapy, and immunomodulatory agents.¹⁰⁻¹⁸ Specific populations at highest risk for interactions were oncology and epilepsy patients. For the oncology population, etoposide, cyclophosphamide, ifosfamide, doxorubicin, and vinca alkaloids specifically require CYP450 pathways for metabolism and/or bioactivation.¹² In the epilepsy population, metabolism of phenytoin, topiramate, rufinamide, and desmethylclobazam (active metabolite of clobazam) could be inhibited, leading to increased adverse drug events.^{19,20}

ASSESSMENT OF SAFETY

For each consultation, a safety assessment of MMJ use was documented in the note by the pharmacist and social worker team

(Table 2). MMJ use was determined to be likely safe in 32% of patients, potentially unsafe in 64% of patients, and unsafe in 4% of patients. The primary safety concern identified was drug interactions (97%), and the posture of the team was conservative in its safety assessment in consideration of (1) the limited published data involving MMJ in pediatrics and (2) the higher-risk indications for prescribed therapies (chemotherapeutics, antiepileptics) in these patients. Only one safety concern did not involve a drug interaction and was concern over the use of a tetrahydrocannabinol-based product in a 2-month-old infant. Of the 34 patients for whom a safety concern was identified, our recommendation was to avoid MMJ use in only 26% of those patients. A recommendation to avoid use was usually based on the severity of the potential drug interaction(s). In 42% of patients, the recommendation was to adjust the MMJ administration schedule to minimize the risk of drug interactions. If a family had already decided to use MMJ in their child, and drug interactions were identified, we would make a recommendation to hold the MMJ around the administration of the interacting drugs. A large portion of families were only exploring the idea of MMJ use. If a safety concern was noted in the patients associated with these informational consultations, the pharmacists would provide recommendations to the family and primary care team to trial standard prescribed therapies before considering MMJ.

TABLE 2 Outcomes of Safety Assessments

	%
Assessment of use (N = 50)	
Likely safe	32
Potentially unsafe	64
Unsafe	4
Safety concern (n = 34)	
Drug interaction	97
Tetrahydrocannabinol use in newborn	3
Recommendation (N = 50)	
Avoid use or do not initiate	26
Adjust administration schedule	42
No change	32

MMJ POLICY: A SECOND TAKE

In 2019, the CHCO MMJ policy was revised to correct deficiencies noted in the original and to account for changes in federal law. CHCO no longer requires active status on the state of Colorado MMJ registry for a patient to have MMJ administered by their family. This policy change was a recognition that CHCO could not reasonably perform the policing function of state law and that our duty was rather to provide education to families on the details of both state and federal law. The revised policy does not govern FDA-approved products derived from cannabis, such as Epidiolex. Because hemp-derived products are now exempt from US Drug Enforcement Agency oversight, these products are not governed by our revised policy and are treated as nutritional supplements. Finally, in recognition of the ever-evolving legal landscape and the development of new products and new research, the policy strongly advises our clinical teams to avail themselves of the expertise of the CECS in management of their patients using MMJ products.

CONCLUSIONS

Most states in the United States now allow for MMJ use by patients with chronic disease. Pediatric hospitals should be prepared to manage requests for use of MMJ for admitted patients and should develop policy to guide team members and families. As a pioneer state in the legalization of marijuana, our experience in Colorado may be instructive to other facilities caring for children. We recognize that our report may not be generalizable to all pediatric facilities in other states with different MMJ regulations. Creation of a consultative service to advise front-line clinical teams on MMJ use has proven to be a beneficial strategy for consolidation of expertise on this topic at our hospital, but this could be approached tactically in different ways. The

indication for most patients and families to use or consider MMJ was symptom relief for nausea, inappetence, and pain. Discussion of use of MMJ and guidance provided for families might therefore be properly considered in the context of existing palliative care services and relationships. Alternatively, because 80% of patients receiving consultative services had a diagnosis of cancer, expertise on legal and pharmacologic aspects of MMJ could be housed within pediatric oncology.

With our hospital's approach, we attempt to acknowledge both the interest our patients and families have in MMJ products and the major uncertainties around their safety and pharmacologic interactions. Transparency of MMJ use benefits care teams by allowing for assessment of safe use and potential pharmacokinetic interactions. Both state and federal legislation governing MMJ are likely to evolve quickly, and expertise on this topic will be difficult to maintain broadly. Our reported consultative experience was limited to admitted patients, but an ideal future state would extend this service into the ambulatory environment as well.

ABBREVIATIONS

CECS: Cannabinoid Education Consultation Service
 CHCO: Children's Hospital Colorado
 CYP450: cytochrome P450
 EHR: electronic health record
 FDA: US Food and Drug Administration
 MMJ: medical marijuana

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