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Practical Tips for Paediatricians

Authorizing medical cannabis for children

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Since legalization of medical cannabis in Canada in 2001, there has been growing interest in the use of medical cannabinoids for treatment in children, fuelled by social media and a public perception of safety and efficacy. Legalization of medical and recreational cannabis appears to have, in some cases, altered the public perception of potential benefit and harm. However, despite enthusiasm, there is scant evidence for efficacy of medical cannabis for most health problems in children and there is concern as to potential for harm (1).

The disorders for which there is most evidence are neurological, specifically treatment-resistant epilepsy (2). There are clinical trials showing efficacy of high cannabinidiol (CBD) content oil for this indication (3). Epidiolex is a high CBD content pharmacological preparation approved in the USA but not in Canada. There is good evidence for efficacy of cannabis-derived products as antiemetics; nabilone and dronabinol are synthetic cannabinoids approved for this indication. While there is promising pilot work in areas such as autism, clear evidence for efficacy and safety is lacking. There are clinical trials underway to evaluate the use of medical cannabis for other conditions in children such as spasticity and pain that hopefully will provide evidence to guide the use (or non use) of medical cannabis for these conditions.

When deciding to authorize medical cannabis for a child, a number of practical considerations must be borne in mind. The decision to authorize use of medical cannabis for children involves considerably more effort than the prescription of other pharmaceuticals in that both patient/family and prescribers must complete much more documentation to obtain access to medical cannabis. An additional consideration is the degree of comfort that the practitioner has with the disorder in question, as by and large the authorization of medical cannabis for a child is the domain of sub-specialists, for example paediatric

epileptologists. In some circumstances authorizing and follow-up may be most appropriately done by a general paediatrician, in which case dialogue and frequent communication between the paediatrician, family, and sub-specialist is essential.

If medical cannabis is a therapeutic consideration, there must be a comprehensive conversation with patient and family as to potential benefits and potential risks attached to the use of medical cannabis. This may require more than one office visit and patience in addressing both expectations and concerns is well advised and should be well documented in the patient's health records.

If the decision is made to proceed with authorizing medical cannabis for a child, there are a series of decisions that need to be made and communicated to the patient and family. The first question is the therapeutic goal. What is the desired outcome and how and when will it be monitored? At what point is success or lack of response determined? As well, the question of safety must be explored. Cannabinoids can produce a number of adverse events, most commonly fatigue, drowsiness, lethargy, abdominal pain, and diarrhoea. The patient and family should be clear as to the potential for adverse effects, how to deal with them and when to report them to the health care team. The rate of significant adverse events varies but appears to be dose dependent and ranges from 5 to 15% of patients (4). Cannabinoids also are known to interact with other medications (5). As well, there are potential developmental issues in children requiring fulsome consideration and discussion (1,6).

The next question relates to the type of medical cannabis. Cannabis is a complex mixture of compounds, the two most common being delta-9 tetrahydrocannabinol, which produces euphoriant effects associated with marijuana, and CBD, which is essential for antiepileptic effects. For seizures, high CBD content preparations appear to be most effective. This raises

the question of dose. Trials have suggested a dose of CBD oil between 5 and 20 mg/kg/day. A dose–efficacy relationship has not been established but adverse effects seem to be more common at higher doses.

Many of these considerations apply to the authorizing of any drug to children, but are coloured in the case of medical cannabis by social media and public perception. There are also issues unique to medical cannabis. Once the cannabinoid of choice and dose have been selected, the next issue is supply. Unlike other drugs, patients and their families may have to deal directly with a licensed producer of medical cannabis. The selection of producer is critical, as it is important that the cannabinoid used be in a child friendly formulation, the concentration be consistent lot-to-lot and that there is an assured supply. This often requires research on the part of the treatment team and the family well beyond the norm for a prescription.

Once a supplier has been identified, families face several practical issues. The first is cost. Medical cannabinoids are not inexpensive and do not have a Drug Identification Number (DIN). Many insurance companies do not reimburse for products without a DIN, placing the burden of payment on the family. An additional issue is palatability. Cannabionoid oils are bitter and can be difficult to administer to young children. Taste masking may be necessary. It cannot be over-emphasized that therapy should only be undertaken with cannabis products designed for medical use, and that using edibles intended for recreational use such as edible candy or 'gummy'

formulations is not appropriate given the wide lot-to-lot variability in cannabinoid content.

The decision to authorize medical cannabinoids to children is difficult as is the authorization and monitoring process. Research is urgently needed to establish efficacy, safety and to address the pragmatic issues facing clinicians and families planning to use medical cannabinoids in children. There are research teams, including the Canadian Paediatric Surveillance Program, working to ensure that Canada is a leader in establishing the effective and safe use of medical cannabis in children.

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