## **SickKid**s





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## First Canadian paediatric study of mixed THC/CBD cannabis oil shows promise for children with drug-resistant epilepsy

TORONTO ON – Researchers at The Hospital for Sick Children (SickKids) have established safe dosing and tolerability of a pharmaceutical formulation of tetrahydrocannabidiol (THC) and cannabidiol (CBD) given to reduce seizures and improve quality of life for children with drug-resistant epilepsy (DRE) due to Dravet syndrome. Suffering from prolonged and frequent seizures, Dravet syndrome is a rare, catastrophic, form of epilepsy that begins in the first year of life. Seizures are typically difficult to treat, and children have many other comorbidities such as developmental delay and significant learning disabilities. There is no cure and the disease is lifelong.

Despite the expansion of available anti-epileptic drugs, dietary and surgical therapies in the last 20 years, up to 30 per cent of children with epilepsy suffer from DRE and the effects are devastating. "Our study adds to a growing body of evidence that cannabinoids can exert anti-seizure effects and are safe and tolerable in treating paediatric DRE," says Dr. Blathnaid McCoy, Staff Neurologist at SickKids. The paper was published August 1 in <u>Annals Clinical Translational Neurology</u>.

Until recently, the clinical use of cannabis plant extracts in epilepsy has been limited by concern of the psychotropic effect of THC. Much of the evidence to date has focused on research with a single CBD-only product. Research suggests that THC-containing cannabinoid preparations may be superior to CBD-only preparations in their anticonvulsant effect and that the combination CBD/THC products may increase tolerance of THC by reducing its psychoactive properties. "Our study used a specific preparation containing both THC and CBD with a conservative dose of THC," says McCoy. "In the participants who reached the target treatment dose we saw a statistically significant reduction in motor seizures, and an increase in seizure-free days compared to those who did not reach the target dose. We observed promising clinically beneficial effect's including a reduction in seizure frequency and improvements in certain aspects of adaptive functioning and quality of life measures."

The realities and risks of severe DRE and the fears that families live with on a daily basis are what drive researchers to find new improved therapies. For Laura Weightman, mother of SickKids

patient Abigail, 16, this new therapy provides much-needed hope. "This therapy has turned our lives around," says Weightman. "Abigail's seizures started at eight months old at a frequency of up to 100 per month. At the time of the trial they had been reduced to 10 – 20 per month with medical and surgical interventions and since participating in this trial, Abigail has only had three seizures in the past year."

As the first study of its kind to examine with rigor the dosing and tolerability of a mixed cannabinoid product containing both CBD and THC in children with DRE due to Dravet Syndrome, these results set the foundation for further work to advance successful treatment and outcomes for this population of children who until now, had little hope for better health outcomes.

A limitation in this study concerns the small number of participants, the majority of whom were already taking a prescribed antiepileptic drug.

Next steps include a large open label study in children with drug resistant epilepsy to assess efficacy.

The medical cannabis oil studied in this trial was developed and formulated by Tilray Inc. Tilray also donated product for the trial and funded the research. Additional support was provided by The

Little Rocky Project. It is an example of how SickKids is making Ontario healthier, wealthier and smarter (<u>www.healthierwealthiersmarter.ca</u>).

## About The Hospital for Sick Children

The Hospital for Sick Children (SickKids) is recognized as one of the world's foremost paediatric health-care institutions and is Canada's leading centre dedicated to advancing children's health through the integration of patient care, research and education. Founded in 1875 and affiliated with the University of Toronto, SickKids is one of Canada's most research-intensive hospitals and has generated discoveries that have helped children globally. Its mission is to provide the best in complex and specialized family-centred care; pioneer scientific and clinical advancements; share expertise; foster an academic environment that nurtures health-care professionals; and champion an accessible, comprehensive and sustainable child health system. SickKids is proud of its vision for Healthier Children. A Better World. For more information, please visit www.sickkids.ca.

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