

EXECUTIVE SUMMARY

real world medicannabis

2020 symposium

Day One: Thursday, December 3, 2020, 7:30pm–9:30pm

Day Two: Saturday, December 5, 2020, 11:00am–1:00pm

in collaboration with



REAL WORLD DATA • REAL WORLD EVIDENCE

real world medicannabis 2020 symposium

This report, prepared for the exclusive use of delegates attending the Real World Medicannabis Symposium, provides an overview of “Real World Data · Real World Evidence” and its implications for potential uses for medical cannabis. This report also provides background information and resources for further reading on select topics to be presented during the two-day Symposium.

Real World Data · Real World Evidence

Real World Data (RWD) are data relating to patient status and/or the delivery of health care, collected from a variety of sources including: electronic health records (EHRs); insurance claims; product and disease registries; patient-generated data including during home-use; and health trackers such as mobile device apps or wearable sensors. These data constitute an alternative source of information that can produce evidence of drug safety, efficacy, and effectiveness across its life cycle.

Real World Evidence (RWE) is the evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of RWD. Factors to consider when evaluating the quality of RWE include the data quality, the study design, statistical analysis and the manner in which the results are interpreted relative to the scientific question being posed, which should be precise and clear. Better leveraging RWE throughout a medical product’s life cycle can optimize its safety and efficacy and improve accessibility, affordability and appropriate use.

In the United States, the FDA [announced in 2016](#) its intention to place additional focus on RWD/RWD to support regulatory decision-making, including approval of new indications for approved drugs.

In early 2019, Health Canada [announced its decision](#) to consider submissions of high-quality RWE in making regulatory determinations. Health Canada continues to consider prospectively planned clinical trials the most robust tool for providing evidence of drug safety and efficacy but encourages RWE where conducting clinical trials is not always feasible or ethical for certain diseases/disorders (such as rare diseases) or patient populations (such as children, pregnant women, or seniors).

[Further Reading: Elements of real world data/evidence quality](#)

Real World Medicannabis

As of 2020, 42 countries, including Canada and Australia, and 35 U.S. states allow the use of cannabis for treatment of medical conditions, and indications for medical cannabis have rapidly expanded in recent years. There has thus been increased focus on evaluating the safety and efficacy of cannabis through randomized controlled trials (RCTs).

However, since RCTs evaluate efficacy in a narrow group of individuals with similar characteristics consuming a standardized dose or product, these trials are often unable to determine precisely for whom the drug is effective or safe once it is used by a broader population. RWE studies offer an opportunity to supplement clinical understanding where RCTs may fall short.

Among other factors, there is a lack of RCT data for medical cannabis use among elderly patients or those with multiple comorbidities, populations in which medical cannabis use is increasing. RWE studies can also provide deeper insights into toxicity, long-term safety, and rare adverse effects than typically short RCTs. RWE showing utilization and safety in more representative populations could allow healthcare providers to make better evidence-based decisions for initiating or continuing cannabis-based therapies.

[Further Reading: The missed opportunity for real-world evidence to shape our understanding of medical cannabis](#)

Cannabis and the Healing Process: Sports Medicine

Cannabidiol (CBD), the major non-intoxicating cannabinoid, and is the only cannabinoid no longer prohibited by the World Anti-Doping Agency. There is currently no evidence that cannabis use improves exercise performance or exercise recovery; however, it may benefit athletes recovering from exercise-induced injury in various ways, possibly by enhancing muscle repair and reducing inflammation. CBD may be particularly useful to athletes for managing pain and improving sleep quality.

[Further Reading: Cannabis and the health and performance of the elite athlete](#)

CBD's Proven Benefits in the Treatment of Epilepsy

The anticonvulsant properties of cannabidiol (CBD) have recently received significant interest. Class I evidence based on placebo-controlled RCTs has become available for the efficacy and tolerability of CBD as a therapy for drug-resistant seizures in severe pediatric epilepsies. CBD's demonstrated neuroprotective and anti-inflammatory effects may further benefit patients with refractory epilepsy. Evidence from observational studies has suggested an association between CBD and a reduction in seizure frequency and, in rare cases, even seizure freedom.

[Further Reading: Epilepsy and cannabidiol, a guide to treatment](#)

Cannabis for Treating Skin Conditions

Both CB1 and CB2 endocannabinoid receptors are present in the skin, in cutaneous nerves, mast cells, macrophages, keratinocytes, epithelial cells of hair follicles, sebocytes, and eccrine glands. Accordingly, preclinical research has suggested that cannabinoids may serve a useful role as an anti-itch or anti-inflammatory medication; as an anti-proliferative, for treatment of psoriasis; in moderating sebum production, for treatment of acne; and potentially for anti-tumour effects. Further research into dosing and cannabinoid combinations is needed.

[Further Reading: Prospects for Cannabinoids in Dermatology](#)

Use of Cannabis for Wound Healing

Chronic wounds—those that fail to heal within three months of their onset—affect up to 6% of the global population and are drivers of global health crises: the opioid crisis and the proliferation of antibiotic-resistant “superbugs.” Applied topically, cannabinoids including THC and CBD exhibit anti-inflammatory properties that allow wounds to progress toward subsequent stages of healing. Cannabinoids may also improve tissue perfusion and oxygenation. In an open-label study conducted by Dr. Vincent Maida, topical cannabinoids also provided significant pain relief, reduced scarring, and reduced the need for antibiotics and opioids.

[Further Reading: Topical Cannabis-Based Medicines, a novel epigenetic paradigm for wound management](#)

Evidence for Cannabis in Long-Term Care

Evidence supports the use of cannabinoid-based medicines for seniors, particularly those in long term care (LTC), for conditions including pain, sleep, dementia-related behaviours, anxiety/agitation, and poor appetite. The multimodality of cannabinoid medicines is particularly beneficial for seniors, as it can largely reduce polypharmacy with no serious increase in side effects. Cannabinoids can help reduce the prescription of opioids, antidepressants, antipsychotics, and sleep aids and can improve overall quality of life for LTC residents.

[Further Reading: The health effects of cannabis and cannabinoids](#)

Speakers

Symposium Committee Chair

Dr. Wayne Gulliver is a dermatologist experienced as a clinician, educator, administrator, and clinical and basic science researcher. He has authored or co-authored over 80 published papers as well as over 100 published abstracts. He is a Professor of Medicine and Chair of the Division of Dermatology at Memorial University of Newfoundland.

Panellists – Day One

Maja Kalaba is a Senior Project Manager, Real World Evidence, within the Human and Animal Health Research program at Canopy Growth Corporation. She obtained her Master of Public Health (MPH) with a specialization in Epidemiology from Lakehead University, Northern Ontario School of Medicine. Since 2017, she has been involved in numerous cannabis research projects which have been presented and published internationally.

Dr. Alistair Vickery is an academic and general practitioner with over 30 years' medical experience. He is an Associate Professor of Primary Health Care at the University of Western Australia and the Deputy Chair of the Postgraduate Medical Council of WA. He is interested in exploring new clinical models of care and developing research protocols to ensure regulator-grade data in community-based care.

Dr. Danial Schecter is a practicing family physician and co-founder of the Canabo Medical Clinic, the first referral-only clinic network specializing in medical cannabis in Canada. Outside of cannabinoid medicine, he holds a fellowship in Hospital Medicine and is an active hospitalist at the Royal Victoria Regional Health Centre in Barrie, Ont. He is currently Acting Director of Clinical Education at Santé Cannabis, where he leads the development of clinical education programs and materials.

Dr. Tyler Churchward-Venne is an Assistant Professor in the Department of Kinesiology and Physical Education at McGill University. His research focuses on skeletal muscle protein metabolism and how it is regulated in response to nutrition, exercise, aging, and physical inactivity. His research is currently funded by the Natural Sciences and Engineering Council of Canada (NSERC), the Canadian Institutes of Health Research (CIHR), the Fonds de Recherche du Québec – Santé (FRQS), and the Canada Foundation for Innovation.

Dr. Evan Lewis is a Pediatric Neurologist and Clinical Neurophysiologist with expertise in epilepsy, epilepsy surgery, electroencephalography (EEG), teleneurology, and medical cannabis for the treatment of neurologic disorders. He is the director of the Neurology Centre of Toronto (NCT) and an Assistant Professor at the University of Toronto.

Panellists – Day Two

Dr. Hance Clarke is the director of Pain Services and the Medical Director of the Pain Research Unit at the Toronto General Hospital. His research interests include identifying novel acute pain treatments following major surgery, identifying the factors involved in the transition of acute postsurgical pain to chronic pain, studying the genetics of acute and chronic pain after surgery, and identifying risk factors associated with continued opioid use and poor health related quality of life after major surgery as well as the efficacy of hyperbaric medicine. Over the past five years he has authored 47 peer-reviewed manuscripts.

Dr. Sheldon Pollack is a national leader in the field of dermatologic surgery. He is an Associate Professor of Medicine at the University of Toronto and is Medical Director at the Toronto Cosmetic Skin Surgery Centre. He is also a popular lecturer and speaks at meetings around the world on various surgical topics. He has written two textbooks and approximately 70 articles in medical journals.

Dr. Guy Chamberland, PhD, is a drug development specialist with over 25 years' experience in the pharmaceutical industry. He is an expert in drug safety and regulatory affairs and has specific expertise in the development of drug-device combination products, biologics, and botanical medicines. He currently serves as Tetra Bio-Pharma's Chief Executive Officer and Chief Regulatory Officer and is a thought leader in botanical medicine.

Dr. Vincent Maida is one of Canada's most qualified cannabinoid medicine experts with over two decades of experience in cannabinoid advocacy, clinical experience, education, research, and publishing. He was the original discoverer of the potential for cannabinoids to treat integumentary and wound conditions in humans. He is President and CEO of VinSan Therapeutics Inc. He is also an Associate Professor at the University of Toronto, Division of Palliative Care.

Dr. Blake Pearson is a recognized expert in the field of cannabinoid-based medicine and has treated patients with a range of complex conditions. He has recently specialized in cannabinoid therapies in long-term elder care settings, with a focus on improved end-of-life and palliative care. He is also Primary Care Lead for the Erie St. Clair Local Health Integration Network's Opioid Reduction Strategy; in this capacity, he is responsible for leading the development and implementation of the region's opioid reduction plan.

Symposium Moderator

Dr. Shafiq Qaadri is a Toronto family physician, Continuing Medical Education (CME) lecturer, medical writer, and broadcaster. He has delivered over 250 medical lectures and has published over 700 articles on a wide range of topics. A long-time advocate of quality public healthcare and a compassionate society, he was elected to the Government of Ontario as the Member of Provincial Parliament (MPP) for Etobicoke North in 2003, serving until June 2018.