Weeding through the evidence for cannabis for medical purposes

Launette Rieb MD
Sharon Cirone MD
Lisa Graves MD
Mel Kahan MD

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Faculty/Presenter Disclosure

- **Faculty:** Launette Rieb MD
  Sharon Cirone MD
  Lisa Graves MD
  Mel Kahan MD
- **Relationships with financial sponsors:** Dr. Graves has an financial relationship with AFMC

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Disclosure of Financial Support

- This program has received no financial support.
- This program has received no in-kind.
- Potential for conflict(s) of interest: none declared

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Objectives

- Identify the evidence for the use of cannabinoids including CBD in the treatment of medical conditions
- Determine key factors in the use of cannabis in specific populations including children, adolescents, pregnant and breastfeeding women, people living with mental health conditions
- Plan clinical decision making including recommendations for CBD and various product strengths

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62 year old female care-aide

- Smoked cannabis 2 joints daily since age 13
- Injured 1 year ago – low back strain after lifting a patient, no neuro findings, still off work, insomnia, irritability, anxiety, amotivation
- After injury cannabis dispensary staff suggested other products, and now is smoking 6 joints a day and vaping 84% THC liquid hourly
- She thinks it helps calm her, assists with sleep, and helps with pain.
- She sees no side effects.

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Qs to consider

- Where are patients getting their advice?
- Who stands to profit?
- Is there evidence for the approach the patient before you is taking?
- Are there risks associated with that approach?
- What advice would you give?

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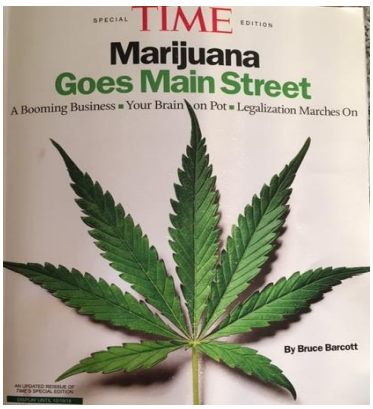

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Qs to consider

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Endocannabinoids

Endogenous cannabinoids = lipids released from post synaptic neurons, bind to receptors on presynaptic neurons. They play roles in infant bonding, regulate dopamine, can influence pain, mood, immune function, appetite, sleep, memory, cerebrovascular tone, and fertility

Anandamide (N-arachidonoylethanolamide)

2-AG (2-arachidonoyl glycerol)

CB1 central receptors (Amygdala, hippocampus, hypothalamus, basal ganglia, cerebellum, spinal cord, and neocortex)

CB2 peripheral receptors on immune cells (spleen, B lymphocytes, & macrophages)

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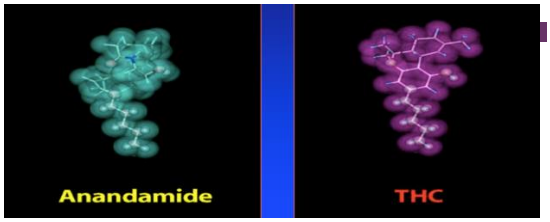

Some plants makes cannabinoids that bind to CB1 and CB2 receptors

THC is a partial agonist and mimics anandamide

CBD has agonist and antagonist properties and mimics 2-AG

When taken exogenously there is interference with the body's own endocannabinoid and endogenous opioid systems

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Issues with cannabis:

- 2000+ strains of cannabis with over 400 chemicals
- 120+ cannabinoids – no health information on most of these
- Terpenes – gives skunky odor/taste, unknown medical effect/risk
- In 1960/70s THC and CBD content in smoked cannabis was about 2-3% balanced, but not longer – can get extremes of THC
- As THC goes up, CBD goes down – unless plant is hybridized/mixed

Issues with studies:

- Cannabis studies attract experienced users with good experiences
- Meta-analyses typically pool data from smoked (with a variety of strains) and medications (synthetic and extracted)

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THC Δ-9-Tetrahydrocannabinol

- Binds to CB1 and CB2 receptors
- ↑Dopamine – which reinforces use = addictive
- Stimulant & depressant
- Pain relief shown in rat models via amygdala modulation, patients talk about dissociation
- Psychotropic – psychosis, paranoia, anxiety
- When Cannabis sativa was about 9% THC:
  - Withdrawal syndrome seen in 25% of people
  - Addiction in 9% = 1 in 11 people who ever use
  - Both rates are dose dependent as THC rises

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CBD - cannabidiol

- Non-addictive, not psychoactive
- **Anti-epileptic** 2 forms resistant childhood epilepsy (Devinsky, 2017) – humans phase 3 trials
- **Protective against THC induced psychosis** (Zuardi, 2012)
- **Anti-inflammatory** (Nagarkatti, 2009; Esposito, 2013)
- **Anxiolytic?** Current US VA trial underway
- **Side effects:** Sedating in 30%; anticholinergic: dry mouth, constipation, nausea, vomiting
- Anecdotally 2 cases of injury site pain flare in w/d - LR

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Cannabinoids on Prescription

- **Nabilone** – synthetic delta 9 THC
  - Does not show up on urine drug screen
  - Approved in Canada: Chemotherapy induced N+V
- **Nabiximols** – plant extract of delta-9-tetrahydrocannabinol 2.7 mg and cannabidiol 2.5 mg in an oro-mucosal spray
  - Approved in Canada for advanced cancer pain, MS associated pain and spasticity

Dried cannabis NOT FDA or Health Canada approved

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Cannabis

Dried – leaves, buds – smoked, vaporized, ingested
THC 0-30%+ and CBD 0-30%+

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Cannabis oils

Oil – extracted through pressing, boiling, solvent
Ingested, smoked, or vaporized = "Dabbing"
"Butter" – cannabis boiled down with oil/butter

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Shatter

"Wax" and "Shatter" – volatile solvent extracted
Shatter is 85-95% THC – highly hallucinogenic

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DSM V Cannabis Intoxication and Withdrawal

- **Intoxication:** May have euphoria, impaired judgement and motor skills and includes two of: conjunctival injection, increased appetite, dry mouth, tachycardia, dissociation, derealization, paranoia, panic, false novelty, arrhythmias, hyperemesis
- **Withdrawal:** Dysphoria, irritability, restlessness, insomnia, anorexia, anxiety, sweating, tremor & craving – withdrawal can be confused with mental health "reasons" to use cannabis

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THE CANNABIS USE DISORDER IDENTIFICATION TEST (CUDIT)

Have you used any cannabis over the past 6 months? Yes No

If YES, please answer the following questions about your cannabis use.

Please circle the response that is most correct for you in relation to your cannabis use *over the past 6 months.*

1 ..... How often do you use cannabis?

never	monthly or less	2-4 times a month	2-3 times a week	4 or more times a week

2 ..... How many hours were you "stoned" on a typical day when you had been using cannabis?

1 or 2	3 or 4	5 or 6	7 to 9	10+ or more

3 ..... How often were you "stoned" for 6 or more hours?

never	less than monthly	monthly	weekly	daily or almost daily

4 ..... How often during the past 6 months did you find that you were not able to stop using cannabis once you had started?

never	less than monthly	monthly	weekly	daily or almost daily

5 ..... How often during the past 6 months did you fail to do what was normally expected from you because of using cannabis?

never	less than monthly	monthly	weekly	daily or almost daily

6 ..... How often during the past 6 months did you need to use cannabis in the morning to get yourself going after a heavy session?

never	less than monthly	monthly	weekly	daily or almost daily

7 ..... How often during the past 6 months did you have a feeling of guilt or remorse after using cannabis?

never	less than monthly	monthly	weekly	daily or almost daily

8 ..... How often in the past 6 months have you had a problem with your memory or concentration after using cannabis?

never	less than monthly	monthly	weekly	daily or almost daily

9 ..... Have you or someone else been injured as a result of your use of cannabis over the past 6 months?

No	Yes

10 ..... Has a relative, friend or a doctor or other health worker been concerned about your use of cannabis or suggested you cut down over the past 6 months?

No	Yes

For development, scoring, and interpretation, see: Adamson SJ, Sellman JD. A Prototype Screening Instrument for Cannabis Use Disorder: The Cannabis Use Disorders Identification Test (CUDIT) in an Alcohol-Dependent Clinical Sample. Drug and Alcohol Review 2003;22:309-315. National Addiction Centre, Aotearoa NZ, www.addiction.org.nz

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"Average joint" = 0.5 gm

Not this

For cannabis use disorder:

- No proven drug treatment, safe to stop abruptly
- Supportive care, drug free environment
- Trazodone 50 mg hs for insomnia, may help
- Quetiapine or risperidone for paranoia, may help
- Early trials using nabilone for detox, maintenance

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Let's take a look at the evidence

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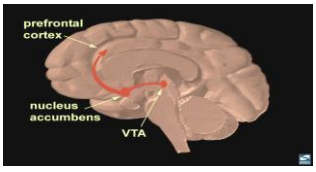

- All mood altering substances can reduce pain while intoxicated
- All substances (including pain medications) that cause dopamine release in the mesolimbic system can be overvalued – even in the absence of true addiction – hence the emotional attachment around discussing opioids, cannabinoids, benzos, etc., with patients

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Adverse Health Effects of Marijuana Use - Volkow N, et al. 2014

- **Short term**:
  - Impaired memory, making it difficult to learn
  - Impaired motor coordination, ↑ injury
  - Impaired driving – doubling MVA rates if driving after use, this increases with alcohol co-exposure (synergistic)
  - Altered judgment, ↑ risk of STIs
  - Acute drug related paranoia and psychosis - dose related, and genetic susceptibility

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Adverse Health Effects of Marijuana Use - Volkow N, et al. 2014

- **Long term**:
  - Addiction – 9% of experimenters, 25-50% of daily users
  - Altered brain development (hippocampus, prefrontal cortex)
  - Diminished life satisfaction and achievement
  - Chronic bronchitis, possibly COPD, increased pneumonia
  - ↑psychotic disorder risk (including schizophrenia) – risks:
    - Heavy use, high potency, younger age at initiation, genetics
  - ↑Anxiety and depression, but causality not established
  - L. Rieb adds hyperemesis – both with use and withdrawal

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Adverse Health Effects NASEM 2017

- Supports Dr. Volkow's conclusions…
- **IN ADDITION** their evidence supports…
  - + association between early initiation and developing CUD and other SUDs
  - + associations for schizophrenia, testicular CA, pre-DM, COPD, OD in peds, low birthweight neonates, bipolar, anxiety, suicide completion, increased severity of PTSD, MI & stroke (hemorragic and embolic)
  - No association with lung, head/neck CA, asthma
  - INEFFECTIVE for dementia, intraocular pressure, depression in pain patients

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Systematic review of systematic reviews for medical cannabinoids

Pain, nausea and vomiting, spasticity, and harms

G. Michael Allan MD CCFP Caitlin R. Finley MSc Joey Ton PharmD Danielle Perry
Jamil Ramji Karyn Crawford MLIS Adrienne J. Lindblad ACPR PharmD
Christina Korownyk MD CCFP Michael R. Kolber MD CCFP MSc

e78 Canadian Family Physician | Le Médecin de famille canadien ▸ Vol 64: FEBRUARY | FÉVRIER 2018

Conclusion There is reasonable evidence that cannabinoids improve nausea and vomiting after chemotherapy. They might improve spasticity (primarily in multiple sclerosis). There is some uncertainty about whether cannabinoids improve pain, but if they do, it is neuropathic pain and the benefit is likely small. Adverse effects are very common, meaning benefits would need to be considerable to warrant trials of therapy.

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Allen et al., 2018 – cont'd

- Average pain reduction with cannabinoids:
  - cannabinoids 1.5/10
  - placebo 1/10

N.B. This reduction (0.5/10) beyond placebo is about that of acetaminophen – L. Rieb comment

- NNT for a 30% neuropathic pain reduction = 11-14

N.B. This means we should be taking about 11 patients back off cannabinoids for every 12 we start, yet this rarely happens – especially if give 1 year authorization – L. Rieb comment

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Effect of cannabis use in people with chronic non-cancer pain prescribed opioids: findings from a 4-year prospective cohort study

Lancet Public Health 2018; 3: e341-50

Gabrielle Campbell, Wayne D Hall, Amy Peacock, Nicholas Lintzeris, Raimondo Bruno, Briony Larance, Suzanne Nielsen, Milton Cohen, Gary Chan, Richard P Mattick, Fiona Blyth, Marian Shanahan, Timothy Dobbins, Michael Farrell, Louisa Degenhardt

- Cannabis did not improve patient outcomes, instead…
  - Greater pain
  - Lower self-efficacy in managing pain
  - No opioid-sparing effect
  - No functional improvement

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Opinion

VIEWPOINT

Should Physicians Recommend Replacing Opioids With Cannabis?

Humphreys K, Saitz R. JAMA Published online February 1, 2019

"To date, no prospective evidence, either from clinical trials or observational studies, has demonstrated any benefit of treating patients who have opioid addiction with cannabis."

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Cannabis and PTSD

- Marijuana clinics often recommend cannabis for PTSD, anxiety
- O'Neil 2017, systematic review: 3 studies met inclusion criteria, two showed no relationship
- One (with least risk of bias) was cohort study of veterans admitted in inpatient program for PTSD
- Use of marijuana was associated with worse symptoms and worse behaviour (including violence); stopping marijuana was associated with improvement

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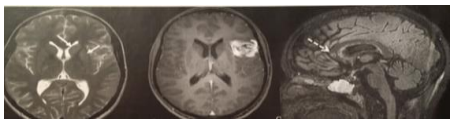
CVA

- The endocannabinoid system modulates cerebral blood flow. Numerous reports link cannabis use to hemorrhagic and thrombotic stroke, TIA, reversible cerebral vasoconstriction syndrome in adults (Hackam, 2015)
- In young adults, cannabis use associated with a 17% increased risk of hospitalization for ischemic stroke (Rumalla, 2016)
- 14 year old, only stroke risk 8-10 joints/d (Volpan 2017)



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Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products

(Vandrey et al., JAMA 2015)

- 75 products randomly selected & tested
  - 47 brands in shops in LA, SF, and Seattle
- THC accurately labeled in 17%
  - 60% over-labeled, 23% under-labeled
- 44 products had detectable CBD on testing
  - Only 13 of these were labeled
- CBD accurately labeled in 0%
  - Four products over-labeled, six under-labeled
- Mean THC:CBD ratio was 30:1
- Only one had ratio of 1:1

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Canadian Licensed Producers

- Health Canada requires that licensed producers monitor their products produced for medical purposes
- THC, CBD, and terpene content
- Fungus, pests
- Fungicides, pesticides
- There has been some reporting in the Globe and Mail that has called accuracy into question

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Marijuana in Pregnancy and Breastfeeding

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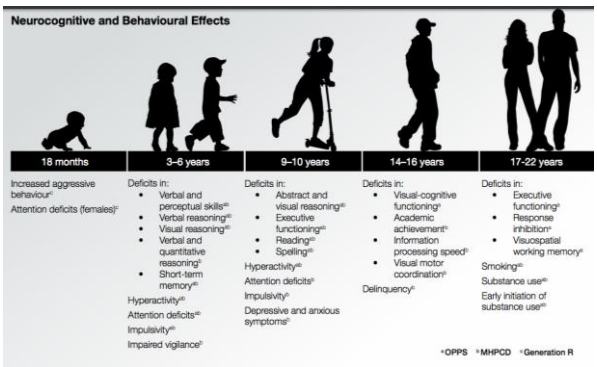
"Clearing the Smoke on Cannabis" CCSA



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Marijuana use during pregnancy

- Evidence-based data has shown that cannabis use during pregnancy can adversely affect the growth and development of the baby, and lead to long-term **learning and behavioural consequences**.
- There have been sufficient studies with comparable results, showing that cannabis use during pregnancy raises concerns of **impaired neurodevelopment of the fetus**, in addition to the adverse health consequences related to maternal and fetal exposure to the effects of smoking.
- Pregnancy is a critical time for the brain development of the baby and the adverse effects caused by cannabis exposure can be life-long.
- **Women who are pregnant or contemplating pregnancy should abstain from cannabis use during pregnancy.**
  - **Ordean, Wong and Graves (2017)**

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Association of Prenatal Cannabis Exposure With Psychosis Proneness Among Children in the Adolescent Brain Cognitive Development (ABCD) Study

Jeremy D. Fine[1]; Allison L. Moreau, BA[1]; Nicole R. Karcher, PhD[2]; et al

Author Affiliations

JAMA Psychiatry. Published online March 27, 2019. doi:10.1001/jamapsychiatry.2019.0076

Increase in past month cannabis use in pregnant women by 75 % from 2002 (2.85%) to 2016 (4.98%)

Perinatal cannabis exposure is associated with a small increased risk of psychosis proneness around age 10

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Marijuana and Breastfeeding

- THC is excreted into breast milk
- Lethargy, sedation, less frequent feeding and poor sucking
- May show signs of decreased motor development and reduced muscular tone
- Infants will test positive in urine screens
- Literature is variable on long term effects
- Abstinence is encouraged prenatally and while breastfeeding

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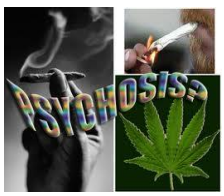
Youth cannabis use



Cognitive, IQ, school impacts

2x risk for developing psychosis in adolescent initiators of use

6x risk for heavy users

Earlier onset of psychosis with younger age of initiation, more frequent, and higher potency marijuana use

Some harms may never resolve

Gene x Environment

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Youth Cannabis Use

- Neurodevelopment: remodelling, vulnerability
- Youth awareness and misperceptions about risk
- Risk of addiction

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A Population-Based Analysis of the Relationship Between Substance Use and Adolescent Cognitive Development

Jean-François G. Morin, B.A., Mohammad H. Afzali, Ph.D., Josiane Bourque, M.Sc., Sherry H. Stewart, Ph.D., Jean R. Séguin, Ph.D., Maeve O'Leary-Barrett, Ph.D., Patricia J. Conrod ✉, Ph.D.

Published Online: 3 Oct 2018 | https://doi.org/10.1176/appi.ajp.2018.18020202

American Journal of Psychiatry

- 3,826 grade 7 students in Montreal, Quebec
- Assessed annually for 4 years on alcohol and cannabis use, recall memory, perceptual reasoning, inhibition, and working memory, using school-based computerized assessments

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Morin, et. Al. 2018, cont'd

- Cannabis use, but not alcohol consumption, showed lagged (neurotoxic) effects on inhibitory control and working memory and concurrent effects on delayed memory recall and perceptual reasoning (with some evidence of developmental sensitivity).
- Cannabis effects were independent of any alcohol effects.

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Association of Cannabis Use in Adolescence and Risk of Depression, Anxiety, and Suicidality in Young Adulthood

A Systematic Review and Meta-analysis

Gabriella Gobbi, MD, PhD[2]; Tobias Atkin, BA[1]; Tomasz Zytynski, MD[1]; et al

› Author Affiliations

JAMA Psychiatry. 2019;76(4):426-434. doi:10.1001/jamapsychiatry.2018.4500

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Gobbi et al 2019, key points

- Systematic review and meta-analysis of 11 studies, 23,317 patients
- Adolescent cannabis consumption was associated with an increased risk of depression and suicide later in life, even in the absence of premorbid condition
- No association with anxiety

Meaning:

- Preadolescents and adolescents should avoid cannabis
- Public policy and governments should apply preventative strategies in youth

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Cannabis and anxiety disorders

- Cannabis use associated with anxiety disorder in young adults (OR 2.5) Degenhardt 2012
- Eg Guttmanova 2017: prospective study of 808 subjects. Frequent use of marijuana in adolescence and young adulthood associated with generalized anxiety, cannabis use disorder, alcohol use disorder at age 33
- In preclinical studies, THC, especially at doses >5%, can induce fear, panic attacks de novo; whereas cannabidiol decreases anxiety

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What is a family doctor to do?

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Canada: Marijuana for Medical Purposes Regulation (MMPR) of 2013 was replaced by Access to Cannabis for Medical Purpose Regulations (ACMPR) on Aug 11, 2016

- "Document" from MD or NP given to patient specifies patient directions for use and amount to be dispensed per month for up to one year
- Patient receives dried cannabis or cannabis oil in mail from licensed producer in the mail (tested for TCH/CBD content, pests, fungus, chemicals, etc.), or…
- Patient (or designate) can grow up to 5 indoor plants/g or 2 outdoor plants/g, and make oil
- Possession limit = 150 grams meant for up to 5g/d x 30d
  - But can get delivery ≤ 2 weeks = 10g/d = 20 joints/d
- Not on PharmaNet – so cannot monitor

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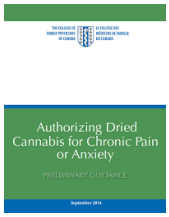
Dried Cannabis Guidance Document from the College of Family Physicians of Canada



- 2014
- Disclaimer: Dried cannabis differs from prescribed products in that Health Canada has…not approved it for therapeutic use, and the CMA and CMPA does not endorse its use
- Update in progress

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Indications for medical cannabis

Cannabis is indicated for:

- severe neuropathic pain that hasn't responded to an adequate trial of 3+ neuropathic pain agents
- Chemotherapy induced vomiting
- Spasticity caused by multiple sclerosis
- Palliative care
- Pain from spinal cord injury
- In all these conditions, nabilone (+/- sativex) should be tried before dried cannabis

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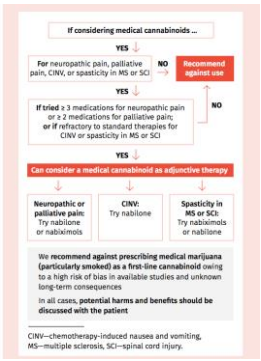
What advice is available for Family Physicians?

- Allan et al, 2018



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Cannabis for anxiety and PTSD

- In preclinical studies THC has been shown to precipitate anxiety de novo
- No RCT, to date, to support prescribing dried cannabis for anxiety, insomnia or PTSD

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Precautions and contraindications

- Cardiovascular disease
- Respiratory disease
- Age < 25 (contraindication)
- Current or past substance use disorder (alcohol, opioids, etc.)
- Personal or family history of psychosis
- Anxiety disorder
- Mood disorder

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Prescribing cannabis to experienced cannabis smokers

- Experienced cannabis smokers sometimes report medical benefit from smoking, and request an authorization so they don't have to buy from the black market
- Self-report of benefit is not enough to prescribe cannabis
- All drugs of abuse temporarily relieve anxiety, pain
  - Alcohol, opioids, cocaine, benzodiazepines
- How well is the patient functioning?
  - An effective analgesic/analgesic improves patients' psychosocial functioning
- How does the patient function immediately after smoking?
  - Intoxication vs. pain relief
  - Analgesia improves immediate function, intoxication reduces it

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Rule out cannabis use disorder in patients requesting cannabis

- **Signs of possible cannabis use disorder:**
  - Current/past history of substance use
  - Concurrent anxiety, depression
  - Spends large amounts of time using cannabis
  - Poor social, work, or school function
  - Insists that 'nothing else works' for pain
  - Gets angry if physician reluctant to prescribe
  - No clear medical indication
  - Can screen with the CUDIT

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****Dosing Example****

Document used should specify dose, percent THC, days, and amount dispensed:

- **"Dried cannabis 1-2 puffs q5-6h prn, 500 mg/day maximum, 9% THC maximum with high CBD, for 30 days, dispense 15 g"**
- Controlled trials show pain relief 400-700 mg/d = 1 joint/d

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ACMPR document

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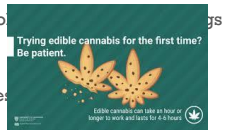
Harm Reduction Advice

- Use **vaporizer** instead of joint or pipe
  - Much lower levels of carbon monoxide
- Only use dried cannabis in vaporizer; don't use cartridges containing cannabis oil
  - Risk of severe lung disease with oil
- **Don't mix with tobacco**
- Caution with alcoho… …gs
- Don't breath hold
- Caution with edible…



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Take Care with Cannabis: www.uvic.ca

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Monitoring

- **See patient – weekly** to biweekly until dose established
- **Then monthly** monitoring visits x three to six months before visits every 1- 3 months
- At each visit, assess for subjective pain relief, mood, and changes in activities of daily living

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Discontinuation (Tapering)

- If no functional benefit is derived
- If driving under the influence
- If doing safety sensitive work
- If diverting
- If patient experiences cannabis-related adverse events: Fatigue, cognitive impairment, depression, anxiety, loss of interest, social isolation

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How to Decline

- If the patient refuses a trial of oral cannabinoids prior to any consideration of dried cannabis, explore the possibility that the patient is using dried cannabis for its effects on mood.
- If the patient remains dissatisfied:
  - I can't authorize the use of an untested therapy when we have other, carefully studied and effective treatments that are safer and subject to strict quality control.
  - I can refer you to a doctor who is a pain specialist, who can advise you on the risks and benefits of dried cannabis for your condition.
  - **If you suspect a cannabis use disorder:** In my opinion, your use of cannabis could be causing you harm. We need to talk about ways to reduce or stop your cannabis use.

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Referring to medical cannabinoid clinics

- Share these tips with your patients so they can actively choose good care
- Don't refer to a cannabinoid clinic unless:
  - The clinic does not charge fees; some regulatory colleges prohibit charging fees
  - The clinic provides comprehensive assessment and management
  - The clinic has explicit, prudent and evidence-based prescribing policies, consistent with the content of this talk

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What if considering "edibles"?

- We have **other medications** with better efficacy for all medical conditions considered by the patient
- Instead of edibles, the previously discussed medications (nabilone and nabiximols) are recommended
- The issue is there is no CBD weighted product available on prescription in Canada and patients wish to try (or MD rather authorize) CBD – **consider hemp products**
- Unfortunately **edibles often have lots more THC** than is indicated or even studied:
  - Nabilone capsule THC 1 mg/dose, up to 4 mg/**day**
  - **In combined THC/CBD cannabinoid studies 5-20 mg/day**
  - Yet high potency edible oils can have **THC/CBD 20-800 mg/dose 5x per day**, so patients can take **10-50x** beyond what is medically indicated or studied

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What if considering "edibles" (oral cannabis)? cont'd

- Virtually no literature on edibles – outside all guidelines
- Many formulations exist from Licensed Producers (LPs)
- Often very concentrated – check dose and concentration
- **Start with high CBD:THC ratio:**
  - One LP told me they can label "no THC" if under ~1.5% THC
  - "All CBD" or "20:1" oral solution are examples
- **Start with just one dose at night, titrate slowly**
- Introduce more THC cautiously, typically just at night and keep amounts low (avoid high THC low CBD products)
- **MD should monitor** if involved with the document
- Warn about driving – no authorization if safety sensitive or critical work – (even driving their own vehicle is a risk)

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66

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- Plan clinical decision making including recommendations for CBD and various product strengths

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Questions???

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Please fill out your session evaluation now!

Complete a session evaluation one of two ways:

- FMF app — Session #
- Fmf.cfpc.ca — Session Name:

YOUR FEEDBACK IS IMPORTANT TO US!

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