



CANNABINOIDS IN CLINICAL PRACTICE

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Process and Practicalities of Medical Cannabis in Canada

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Learning Objectives

By the end of this session participants will be able to:

- Review cannabis access in Canada under the “Cannabis Act” (Bill C-45)
- Understand the health care provider’s roles and responsibilities for patients interested in using medical cannabis
- Complete a medical document (prescription) and provide guidance on strain/dose

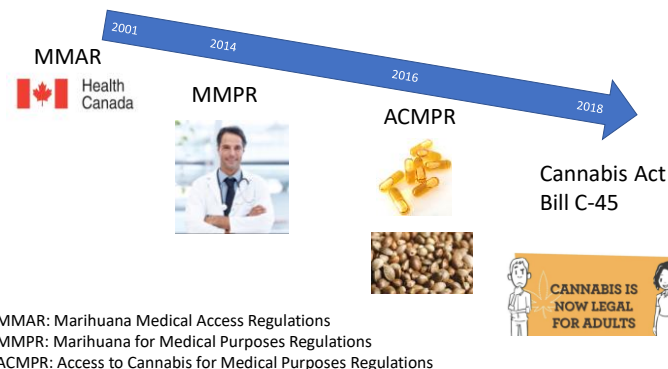
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FACULTY/PRESENTER DISCLOSURE

- Faculty/Speaker: Danial Schecter
- Relationships with commercial interests:
 - Director, Global Medical Services – Canopy Growth Corp
 - Speaker fees: CanniMed, Canabo, Tilray, Tweed, Bedrocan Australia, MariCann, Aphria, AstraZeneca, OrganiGram, Mettrum, Hydropharmacy, Shoppers Drug Mart
 - Medical Advisory Board: Canopy Growth Corp, Khiron Life Sciences, Sail Cannabis, Strainprint Technologies
 - Consultant: Aleafia Health Inc. (TSXV: ALEF)
 - Chief Medical Advisor: AusCann (AC8.ASX)

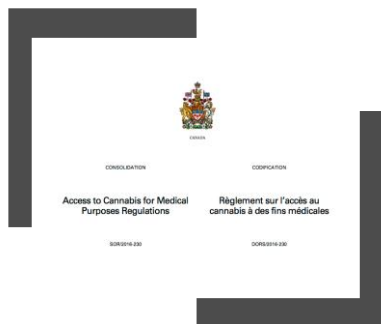
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The Changing Cannabis Legislation



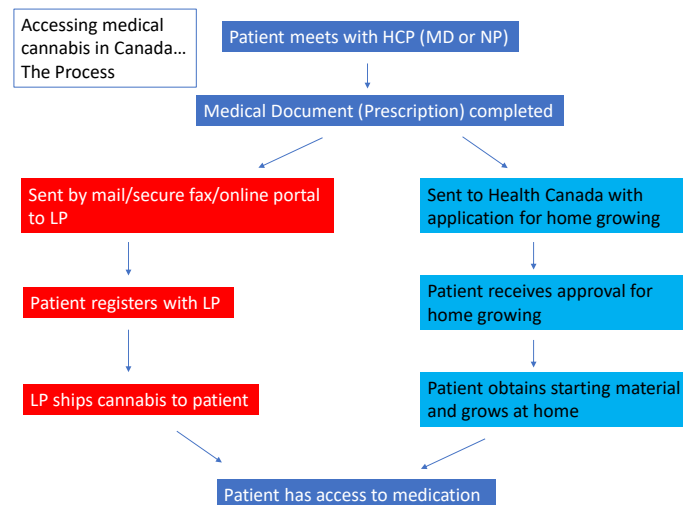
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Cannabis Act (Bill C-45)



- Regulates both the medical and recreational use of cannabis
- Uses the ACMPR framework to regulate the medical use of cannabis
 - Licensed Producers
 - Medical Document
 - Mail order/courier (no storefronts)

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Formats & Methods of Administration

- Currently under the Cannabis Act patients can access cannabis in two main forms:
 - Dried flower
 - Whole buds
 - Milled products ("vape ready")
 - Oils
 - Bulk oil in a bottle
 - Pre-packaged in capsules
- In 2019, other dosage forms will become available (e.g. edibles, topicals, concentrates)
- Method of administration can impact the onset and duration of action

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Medical Document = Authorization (A.K.A Prescription)

- Like a 'prescription'
- The authorization form is for cannabis and not for a specific strain, chemovar or formulation
- 1-year max authorization
- Ship up to 30 days of cannabis through the mail
- Provincial regulators may have other requirements
- Generic document available from Health Canada, each LP has their own med doc
- Can be sent by mail, by secure fax, or online portal for registered prescribers



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Completing the Med Doc – Patient Information and Dosage

- Complete patient information (Name/DOB)
 - Some LPs may request more information (phone/condition/email)
- Indicate Daily quantity of dried marihuana to be used by the patient in grams/day
 - This dictates how much a patient can purchase in a 30 day period
 - ie: 1 g/day = patient can purchase 30 g of dried cannabis flower monthly
 - Even if a patient is instructed to purchase cannabis oil you must provide an authorization in g/day of dried cannabis flower (WTF!)
- Indicate Period of Use
 - Maximum 12 months

Patient's Given Name and Surname:

Patient's Date of Birth (DD/MM/YYYY):

Daily quantity of dried marihuana to be used by the patient: grams / day

The period of use is day(s) or week(s) or month(s).

Note: The period of use cannot exceed one year

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The Medical Document

- Patients can purchase a combination of different cultivars and different formats (oils/caps/flowers)
 - Monthly allotment can be divided any way the patient wants
 - IE: Patient is allotted 30 grams/month. Patient purchases:
 5 grams of high CBD flower
 10 grams of 1:1 THC:CBD flower
 5 grams of high THC flower
 1 bottle of CBD oil (equivalent to 5 g of flower)
 1 bottle of THC oil (equivalent to 5 g of flower)
Total: 30 grams of "cannabis"
- While not mandatory most documents from LPs have an option to provide specific instructions:
 - Specify format: Dried and/or Oils and/or Caps
 - Specify max THC concentration: % THC for dried flower and mg/mL for oils



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Can the Medical Document be Transferred?

- ✓ Initially the authorization form was only valid with one LP
- ↔ New format allows for the transfer of authorization to LP
- 👤 This is beneficial as it can help to address supply issues
- 🕒 **Process:** Patient calls LP to request transfer. This normally takes 24-48 hours.

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Can a Patient have Multiple Authorization Forms?

- 📄 Patient can have multiple authorizations for cannabis. There is no central repository for the forms
- 👤 Patient can take forms to multiple LPs
- 🧠 Can be helpful as it can address shortages from any specific LP
- ⚠️ Be careful with multiple authorization forms. Consider splitting the daily amount over multiple forms
- ✓ If multiple forms are active, you can cancel a form with a LP

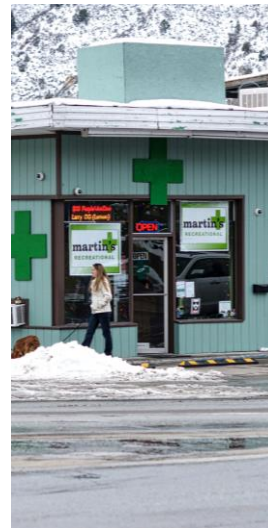
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What Happens if there is a Backorder?

- Backorders can occur with cannabis
- Authorization form is for any strain
- If one strain is on back order can consider:
 - Choosing another strain with a similar THC/CBD ratio
- Patient can ask LP about backorders on specific strains prior to starting

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Wouldn't it be Easier to Refer Them to Recreational Market?

- Easier to access cannabis through recreational market
- Strains for medical purposes may not be available in recreational retailers
- Potential stigmatization of patients through sending to recreational space
- Need access to education and support from a healthcare professional

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Employer	• Some Canadian employers and unions offer coverage
Veterans Affairs	• DVA offers reimbursement for medical cannabis
Income Tax Credit	• The Canada Revenue Agency (CRA) recognizes the costs of medical cannabis and some vaporizers as an eligible medical expense
Licensed Producers	• Many offer special pricing for individuals receiving federal or provincial social assistance
Health Care Spending Account	• It may be covered under a Health Care Spending Account

Coverage of Medical Cannabis

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After completing a medical document recommendations for product use and monitoring of patients is required:

1. Decide if inhaled (flower) or ingested (oils) is more appropriate
2. Recommend specific strain (THC:CBD ratio for oils or % THC/CBD for flower)
3. Provide dosing/titrating recommendations (inhalations for flower, mg of THC/CBD - in mL - for oils)
4. Monitor and manage common issues

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1. Decide if inhaled (flower) or ingested (oils) is more appropriate

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Patient characteristics:

- Pt preference based on experience
- Physical/cognitive challenges: Using a vaporizer/oils may be difficult for patients with impairments due to arthritis, stroke, decreased vision etc...
- Cannabis naïve vs cannabis experienced – If patients follow the approach of “start low – go slow” there is no benefit to one method over the other in these two patient populations

Disease characteristics:

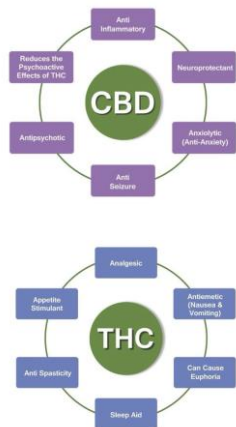
- Episodic or occasional symptoms: Benefit from inhaled cannabis b/c quicker onset of action and shorter duration of action.
- Chronic symptoms: Benefits from ingested cannabis that provides a longer duration of action and will less frequent dosing.



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2. Recommend specific strain (Mg of THC vs CBD for oils and % THC vs CBD for dried flower)

- Each strain can lead to a slightly different response
 - One of the key factors when considering a strain is the ratio of THC:CBD
 - Poor response or adverse effects with one strain can be mitigated with a change to another strain
- Many of the key adverse effects (e.g. psychosis, anxiety) are associated with THC component.
 - Conservative THC dosing in cannabis naïve patients, elderly and those with polypharmacy is recommended
- No perfect answer and it usually involves some trial and error



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How to Decide on a Strain (Variety) – THC:CBD

No absolute guidance but general recommendations available based on pathophysiology of presenting complaint, clinical experience and understanding of action of cannabinoids

Strain (Variety / Chemovar) Selection Based on Condition

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<p>Chronic Pain</p> <ul style="list-style-type: none"> • Neuropathic: THC=CBD (1:1 ratio) • Inflammatory: CBD 	<p>Spasticity</p> <ul style="list-style-type: none"> • THC=CBD (1:1 ratio) • THC if initial trial failed
<p>Nausea (& Vomiting)</p> <ul style="list-style-type: none"> • THC=CBD • THC if initial trial 	<p>“Cancer”</p> <ul style="list-style-type: none"> • Base on specific symptom
<p>Sleep</p> <ul style="list-style-type: none"> • THC=CBD (1:1 ratio) • THC if initial trial failed 	<p>Epilepsy</p> <ul style="list-style-type: none"> • CBD
<p>Anxiety Disorders and Depression</p> <ul style="list-style-type: none"> • CBD or THC=CBD • THC if initial trial failed 	<p>Autism</p> <ul style="list-style-type: none"> • CBD • Can consider other strain if insufficient

Indica vs Sativa?

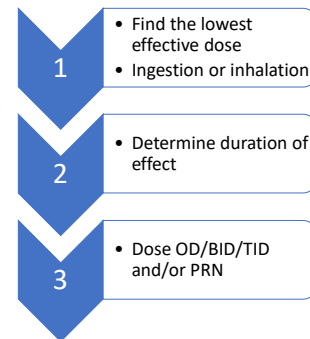
General Recommendations & Key Concepts

- It is commonly thought that feeling "high" or experiencing euphoria is a necessary side effect of using medical cannabis – this is not so and patients need to be educated and expectations managed. Patients obtain a symptomatic response at a point before they experience euphoria.
- Once an optimal dose is identified this usually remains stable and does not require escalating doses.
- If initiating & titrating cannabis do not change any other medication.

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3. Provide dosing/titrating recommendations (inhalations for flower, mg of THC/CBD - in mL - for oils)

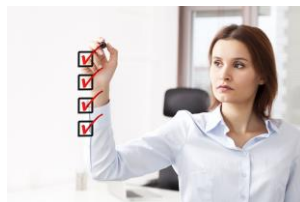
- When initiating patients on cannabis they will be instructed to titrate their dose in order to determine their lowest effective dose (or "optimal dose").
- Whether starting with cannabis oil or vaporized cannabis the approach will remain the same.



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4. Monitoring

- No biological markers required for monitoring
- Usually see within 2-4 weeks after initiating treatment
- Follow up every 1-3 months until stable then q 3-6 months
- Combination of clinical history/exam and validated patient questionnaires are beneficial



- Urine drug screen can be beneficial in some situations
- Monitor for Cannabis Use Disorder
- Monitor for side effects & drug interactions

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Summary

- Medical cannabis is regulated via the Cannabis Act allowing patients to either purchase cannabis from an LP or grow their own
- Medical documents should be considered equivalent to a prescription and HCPs should be comfortable in providing counselling surrounding this
- Health Care Providers play an important role in supporting a patient's journey in medical cannabis

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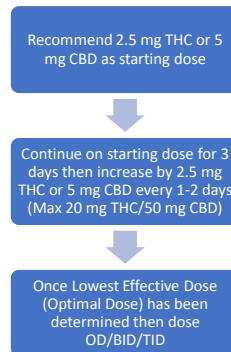
Muchas Gracias!
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How to Initiate & Titrates Oils

Starting dose:

- If using THC: 2.5 mg of THC is the recommended starting dose (1 mg of THC can be considered for older/younger patients, polypharmacy or very sensitive to medications/prone to side effects).
- 2.5 mg of THC should be used once daily for three days and then increased by 2.5 mg every 1-2 days until their optimal dose is reached.
 - If no effect is observed after reaching 20 mg THC equivalent then a patient's use of this product should be reevaluated (possible they are "non responders").
- If using CBD: 5 mg CBD is the recommended starting dose
- 5 mg CBD should be used once daily for three days and then increased by 5 mg every 1-2 days until an optimal dose is achieved.
 - If no effect is observed after reaching 50 mg CBD equivalent then a patient's use of this particular product should be reevaluated

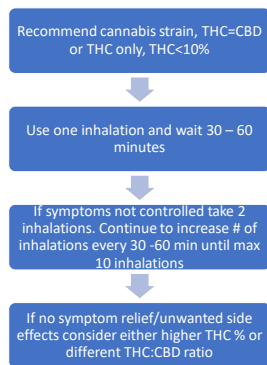


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How to Initiate & Titrates Flowers

Starting dose:

- If using a strain with THC recommend balanced THC:CBD, IE: 10% THC and 10% CBD
- Start with one inhalation. IF no effect after 30-60 mins take 2 inhalation. Continue to increase # of inhalations every hour until desired effect achieved or side effects occur
 - Can titrate to maximum of 10 inhalations
 - If no effect is observed after 10 inhalations, and no side effects experienced, then re-evaluate and consider different THC %, different THC:CBD ratio or different strain



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Medical vs. Recreational Use

	Medical	Recreational
Formats	Oils/Flowers/Caps	Oils/Flowers/Caps
Producer	Licensed Producer	Licensed Producer
Distributor	Licensed Producer	Provincially authorized retailer
Cost	Set by Licensed Producer	Set by retailer and government
Taxes	GST + Excise*	GST + Excise
Compassionate Pricing	Allowed	N/A
Coverage	Limited	N/A
Medical Oversight	Authorized by Health Care Provider	N/A – (Budtender?)
Pharmacist Involvement	Possible	N/A
Home Growing	Depends on g/day limit	4 plants per household

* Reflective of THC concentration

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Methods of Administration

Smoked	Vaporized	Oral
<ul style="list-style-type: none"> Water-pipe, pipe or joint 50% of THC in cannabis is converted to smoke Very fast acting Can be titrated easily Associated with the inhalation of known carcinogens 	<ul style="list-style-type: none"> Heats cannabis to level that activates phytocannabinoids but less noxious smoke Less cannabis waste Rapid onset, easy titration Higher up front costs for vaporizer 	<ul style="list-style-type: none"> Interindividual variation in dosing Higher amount needs to be consumed No smoke, more acceptable for some patients Delayed onset, longer duration and higher impairment



MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. *European Journal of Internal Medicine*. January 2018. doi:10.1016/j.ejim.2018.01.004

Methods of Administration

	Smoking	Vaporization	Oral
Onset (min)	5-10	5-10	60-180
Duration (h)	2-4	2-4	6-8
Benefits	Rapid onset	Rapid onset, less waste than smoking	Less odour, convenient, discreet
Cons	Carcinogens, loss of cannabinoids to side smoke, dexterity required	Cost of vaporizer, dexterity to prepare doses, may not be portable	Titration can be more challenging due to delayed onset
Role in therapy	Rarely recommended as more risks with no benefits over vaporization	Ideal for patients with episodic acute symptoms (fast onset)	Ideal for chronic conditions as long-acting requiring less dosage frequency

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