Integrating Medical Cannabis into Standard Clinical Care
Feasibility overview of the MUHC Cannabis Pilot Project

Dr. Antonio Vigano
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Outline

• Federal and provincial legislative landscape
• Project overview
• Results
• Vision for the future
Federal Regulatory Framework

- In Canada, the production and sale of medical cannabis is overseen by Health Canada via the Access to Cannabis for Medical Purposes Regulations (ACMPR)
- Key Elements:
  - Patient information and consent
  - Quantity and duration of authorized product
  - Eligible health care professionals
- Process:
  - Medical Document signed by a HCP
  - Medical Document sent to a licensed producer or Health Canada (home growing)
  - Medical cannabis delivered directly to the patient residence
Quebec Regulatory Framework

• The use of cannabis for medical purposes is not a recognized treatment.
• An unrecognized treatment can only be used within a research framework.
  • At the time this pilot project was conducted only one research framework was approved in QC: “Quebec Cannabis Register: A Research Database on the Use of Dried Cannabis for Medical Purposes” (PI: Dr. Mark Ware).
• Before considering the use of cannabis to treat a medical condition provided for in the previous regulations, other therapeutic options must be considered, in particular other forms of cannabinoids authorized for prescription by Health Canada.
Project goal

The goal of our project was to determine feasibility of incorporating medical cannabis (as a complementary treatment option) into treatment options of Supportive/Palliative Care Programs in RCN.
Project objectives

• **Implement** the medical cannabis *clinic* care delivery model at the MUHC Palliative and Supportive Care Program
  
  • Patients seen by dedicated staff members during dedicated hours and at dedicated space and at a regular frequency
  
  • Clinic care model based on the model used at a private clinic (Sante Cannabis) in Montreal

• **Evaluate** the feasibility of integrating the medical cannabis *clinic care delivery model* into Supportive and Palliative Care Programs in RCN
  
  • Evaluation dimensions: patient-centeredness, integrated care, localized flexibility and equality of access, efficient use of resources, safety and quality of care, innovation,..
# Access to medical cannabis for MUHC oncology patients

<table>
<thead>
<tr>
<th>Before the Pilot</th>
<th>During the pilot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients referred (or self-referred) to Sante Cannabis (private clinic)</td>
<td>Patients referred to the <strong>Supportive Care Program</strong> (some patients still referred to a private clinic)</td>
</tr>
<tr>
<td>Information regarding cannabis use not part of the patient medical record (OASIS)</td>
<td>Information re: cannabis use part of the <strong>OASIS</strong></td>
</tr>
<tr>
<td>External medical oversight</td>
<td><strong>Internal medical</strong> oversight</td>
</tr>
<tr>
<td>Little knowledge by HCPs re: medical cannabis use</td>
<td><strong>FAQs</strong> distributed to all HCPs in oncology and two <strong>talks</strong> given to HCPs, but much more education still needs to be done</td>
</tr>
</tbody>
</table>
Overview of the clinic set-up

• Structure
  • Location: Glen, Cedars Cancer Center 2nd floor (clinic space and admin support shared with other Supportive Care Clinics)
  • Clinic hours: Monday and Tuesday (1:00-5:00pm)
  • Resources: one palliative care physician (available during clinic hours); one nurse (2 days/week); one data entry clerk (3 days/week)
  • Visit frequency: Initial consultation, monthly follow-ups

• Patient volumes
  • On average 2-3 pts. seen during clinic hours
  • In total: 54 patients seen during the pilot phase
Referral made by oncologist or palliative care physician at the MUHC

Referral verified by the Nurse in the Supportive Care Program (SCP)

Patient assessed by the supportive care physician for potential referral to other clinics first (i.e. CPC, CAREPRO etc)

Patient meets criteria for medical cannabis Tx?

YES

Treatment priority assigned

NO

Patient candidate to the conventional Tx first?

YES

Follow-up at the MUHC SCP medical cannabis (MC) clinic

NO

On-going QCR data collection

YES

Initial set of QCR data collected

Patient education on cannabinoid initiation and titration

Report done in OACIS

Standardized assessment performed

Info on clinical trials given to the patient

Consent given?

YES

Consent given

Consent given

NO

Consent not given

Patient asked to consent to the Quebec Cannabis Registry (QCR) protocol

Consent given?

YES

Info complete?

YES

Patient assessed by the supportive care physician for potential referral to other clinics first (i.e. CPC, CAREPRO etc)

Patient meets criteria for medical cannabis Tx?

YES

Treatment priority assigned

NO

Patient candidate to the conventional Tx first?

YES

Follow-up at the MUHC SCP medical cannabis (MC) clinic

NO

On-going QCR data collection

YES

Initial set of QCR data collected

Patient education on cannabinoid initiation and titration

Report done in OACIS

Standardized assessment performed

Info on clinical trials given to the patient

Consent given?
Patient characteristics
Age, gender, diagnosis

Average age = **61 years**
(min 22- max 83)

Gender:
Female = 57%    Male= 43%

63% of all cancer diagnoses - stage 4

Place of residence: 78% Montreal; 22 % outside of MI
### Primary symptoms (n=54)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>2%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2%</td>
</tr>
<tr>
<td>Anorexia</td>
<td>2%</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>2%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>4%</td>
</tr>
<tr>
<td>Inflammation</td>
<td>4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>8%</td>
</tr>
<tr>
<td>Pruritis</td>
<td>7%</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>9%</td>
</tr>
</tbody>
</table>

### Type of secondary symptoms

<table>
<thead>
<tr>
<th>Type of Symptom</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological symptoms (Depression and/or anxiety)</td>
<td>49%</td>
</tr>
<tr>
<td>Physical symptoms (SOB, pain, nausea, fatigue, insomnia)</td>
<td>51%</td>
</tr>
</tbody>
</table>

### Number of secondary symptoms

- **0**: 69%
- **1**: 7%
- **2 or more**: 21%
Cancer treatment modalities (n=54)

- 64% Chemotherapy
- 23% Hormonal therapy
- 7% Radiation therapy
- 3% Immunotherapy
- 3% No treatment

For personal use only
Not for distribution
Medical cannabis prescriptions
Pharmaceutical and natural products prescriptions

- 50% Natural cannabis only
- 50% Combination of pharmaceutical & natural products

Cannabis contains hundreds of chemical substances. Over 100 of these are known as cannabinoids. They affect cell receptors in the brain and body. Cannabinoids can change how these cells behave and communicate with each other. THC and CBD are two cannabinoid commonly found in marijuana. THC is psychoactive, and CBD is active, but not psychoactive. (Source: Health Canada)
Route of administration*

- Oral: 85%
- Inhale: 13%
- Both: 2%

*Data refers to the initial dose

55% of patients in our sample had used cannabis in the past.
Prevalence and Severity of Symptoms (baseline vs. follow-up)
Prevalence and severity of symptoms

ESAS-r symptom assessment:
- Pain, tiredness, drowsiness, nausea, lack of appetite, SOB, depression, anxiety, wellbeing, other problems.

Brief Pain Inventory assessment:
- Average pain, worst pain, pain interference (general activity, mood, work, relationships, sleep, enjoyment of life).

EQ5D assessment:
- Mobility, self-care, usual activities, pain/discomfort, anxiety/depression.

Patients reported their symptoms at regular intervals.
## ESAS-r scores at baseline

Table 1: Self-reported symptoms at baseline and follow-up

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Number (%) of patients rating ≥4 at baseline</th>
<th>Median scores at baseline (n=54)</th>
<th>Median scores at follow-up (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>32 (62)</td>
<td>5</td>
<td>4.5</td>
</tr>
<tr>
<td>Tiredness</td>
<td>39 (75)</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>22 (42)</td>
<td>3</td>
<td>2.5</td>
</tr>
<tr>
<td>Nausea</td>
<td>14 (27)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Lack of appetite</td>
<td>26 (50)</td>
<td>3.5</td>
<td>3</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>26 (51)</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
<td>17 (33)</td>
<td>2.5</td>
<td>2</td>
</tr>
<tr>
<td>Anxiety</td>
<td>17 (33)</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Wellbeing</td>
<td>42 (81)</td>
<td>5</td>
<td>4.5</td>
</tr>
<tr>
<td>Other problem</td>
<td>14 (40)</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>
Change on ESAS-r scores (initial consultation vs. follow-up)

% of patients

- Drowsiness
- Wellbeing
- Shortness of breath
- Depression
- Tiredness
- Pain
- Nausea
- Lack of appetite
- Anxiety

- Improvement
- No change
- Worsening

n=20
Brief Pain Inventory (BPI) Scores at baseline and follow-up

Table 2: BPI scores at baseline and follow-up (n=20)

<table>
<thead>
<tr>
<th></th>
<th>Median (IQR) [Range]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average pain</strong></td>
<td></td>
</tr>
<tr>
<td>Baseline (n=19 responses with at least one follow-up data)</td>
<td>5 (3-6.5) [0-9]</td>
</tr>
<tr>
<td>Follow-up (n=18 responses with baseline data)</td>
<td>3 (2-5.8) [0-9]</td>
</tr>
<tr>
<td><strong>Worst pain</strong></td>
<td></td>
</tr>
<tr>
<td>Baseline (n=19 responses with at least one follow-up data)</td>
<td>7 (4-8) [0-10]</td>
</tr>
<tr>
<td>Follow-up (n=18 responses with baseline data)</td>
<td>6 (3.3-7) [0-8]</td>
</tr>
<tr>
<td><strong>Pain interference</strong></td>
<td></td>
</tr>
<tr>
<td>Baseline (n=18 responses with at least one follow-up data)</td>
<td>4 (3-5) [0-9]</td>
</tr>
<tr>
<td>Follow-up (n=18 responses with baseline data)</td>
<td>3 (2-5) [0-7]</td>
</tr>
</tbody>
</table>
1. During each clinic*, data is collected in real-time via an **on-line tool (Toggl)**: iPad, Phone Desktop/Laptop

2. Data is then exported to Excel and analyzed

<table>
<thead>
<tr>
<th>Activity</th>
<th>Nurse Hours:min</th>
<th>Add starting April 23</th>
<th>TOTAL From Beginning Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Assessment</td>
<td>8:10</td>
<td>5:00</td>
<td>13:10 790</td>
</tr>
<tr>
<td>Progress Note Preparation</td>
<td>2:40</td>
<td>2:45</td>
<td>5:25 325</td>
</tr>
<tr>
<td>Nurse Chart Review</td>
<td>17:35</td>
<td>16:45</td>
<td>34:20 2060</td>
</tr>
<tr>
<td>Clinic Coordination</td>
<td>22:45</td>
<td>23:20</td>
<td>46:05 2765</td>
</tr>
<tr>
<td>Patient Education</td>
<td>8:05</td>
<td>0:00</td>
<td>8:05 485</td>
</tr>
<tr>
<td>Treatment Plan</td>
<td>5:40</td>
<td>2:10</td>
<td>5:50 350</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>22:45:00</strong></td>
<td><strong>50:00:00</strong></td>
<td><strong>112:45:00 6765</strong></td>
</tr>
<tr>
<td><strong>TOTAL Coordinator</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registry</td>
<td>22:25</td>
<td>24:05</td>
<td>46:30 2790</td>
</tr>
<tr>
<td>Consent</td>
<td>2:45</td>
<td>1:45</td>
<td>4:30 270</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>25:10:00</strong></td>
<td><strong>25:50:00</strong></td>
<td><strong>51:00:00 3060</strong></td>
</tr>
<tr>
<td><strong>TOTAL Physician</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Assessment</td>
<td>9:35</td>
<td>7:25</td>
<td>17:00 1020</td>
</tr>
<tr>
<td>Treatment Plan</td>
<td>6:50</td>
<td>4:05</td>
<td>11:55 705</td>
</tr>
<tr>
<td>Progress Note Preparation</td>
<td>5:05</td>
<td>3:35</td>
<td>9:40 580</td>
</tr>
<tr>
<td>Admin</td>
<td>4:30</td>
<td>0:00</td>
<td>4:30 270</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>26:00:00</strong></td>
<td><strong>15:05:00</strong></td>
<td><strong>41:05:00 2465</strong></td>
</tr>
<tr>
<td><strong>TOTAL HOURS ALL STAFF</strong></td>
<td><strong>113:55:00</strong></td>
<td></td>
<td><strong>12290</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>55.04%</td>
</tr>
<tr>
<td>Coordinator</td>
<td>24.90%</td>
</tr>
<tr>
<td>Physician</td>
<td>20.06%</td>
</tr>
</tbody>
</table>
Average Time Spent on Direct Patient Care by Staff Members per Half-Day Clinic

- Physician: 2.16
- Coordinator: 2.68
- Nurse: 4.2
Allocation of physician time per task

22% Patient Assessment
40% Treatment Plan
28% Progress Note Preparation
10% Admin

Allocation of nurse time* per task

28% Patient Assessment
13% Clinic Coordination
6% Patient Education
4% Treatment Plan
13% Nurse Chart Review
36% Data Entry

* Allocation based on 7 h workday and includes tasks involved in direct and indirect patient care
Time allocation for a coordinator: 91% data entry, 9% patient consent
Average Time Spent by Each Staff Member per Half-Day Clinic on a Monthly Basis
Nurse Call Support

~ 36% of patients require nurse call support

Frequency and type of questions

- Registration: 37%
- Prescription: 23%
- Questions on cannabis and/or usage: 28%
- Side effects and/or deterioration and/or management: 7%
- Miscellaneous questions: 5%

Data collection period: February to May 2018

83% of patient calls are returned on the same day
min= 0 days, max= 4 days

Average call duration: 12 min
## Evaluation of the cannabis care delivery model (key dimensions)

### This care delivery model*....

<table>
<thead>
<tr>
<th><strong>Is patient centric</strong></th>
<th>Yes (complementary cannabis treatment takes into account patient needs, values and choices; knowledge and information are freely shared between and among HCPs, patients and caregivers;)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Has localized flexibility and considers equity of access</strong></td>
<td>Not optimal (while the access to the pilot project was open to all cancer patients, the available resources limit the number of patients who could benefit from this service)</td>
</tr>
<tr>
<td><strong>Supports integrated care</strong></td>
<td>To a large degree (cannabis treatment is offered within the same setting as other supportive care treatment options, however it not supported by all palliative care HCPs)</td>
</tr>
<tr>
<td><strong>Supports efficient utilization of resources</strong></td>
<td>Not optimal for nursing (admin tasks done by nursing during the pilot phase could be done by administrative personnel)</td>
</tr>
<tr>
<td><strong>Supports safe, quality care for patients</strong></td>
<td>Yes (based on the scientific evidence derived from the preliminary research on the use of cannabis for medical purposes)</td>
</tr>
<tr>
<td><strong>Has a robust and standardized set of outcome measures and evaluation processes</strong></td>
<td>To a certain degree (ESAS-r, BPI and E5Q5 as part of the Quebec Cannabis Registry requirements)</td>
</tr>
<tr>
<td><strong>Is innovative, considers new ways of organizing and delivering care and sets the vison for services in the future</strong></td>
<td>Yes- the focus of this clinic based service was on an innovative treatment rather than a more general perspective in supportive/palliative care; the approach was structured to determine indication, contraindications and precautions for cannabis use along with “ad hoc” patient and family education.</td>
</tr>
</tbody>
</table>

* Based on the Guiding Principles of a MoC, Agency for Clinical Innovation, 2013
Moving forward

• In order to provide greater service coverage we should transition from a stand alone clinic model to a fully integrated care delivery model within the Supportive/Palliative Care Program
  • 5 days/ week coverage
  • Prescription and treatment monitoring of medicinal cannabis done within the supportive and palliative care teams (MD and nurses)
  • Ideally medical cannabis prescription and monitoring should follow specific protocols, which would facilitate safe access, research and training of health professionals.
• In order to optimize the use of nursing resources, administrative tasks should be allocated to the administrative staff
Vision for the future

• **Clinical service** provision
  • Transition from a stand alone clinic-based model to a consultation-service model that will help all clinicians to fully integrate medical cannabis in oncology care, starting from supportive and palliative care domains
  • Implementation of this care model across RCN

• **Research**
  • Recruitment of patients to clinical trials
  • Establishment of a **cannabis registry in oncology** to further advance a precision medicine approach

• **Education** of Health Care Providers and patients
  • Development of **educational material** and protocols for patients and health care professional
Acknowledgements

Project Team:
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RCN QI2 Program Lead: Dr. Ari Meguerditchian
Thank you!