Medical Marijuana in PA

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August 4, 2017
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Vision

- The Pennsylvania Department of Health’s vision is to have a high quality, efficient, and compliant medical marijuana program for commonwealth residents with serious medical conditions as defined by Act 16
- As physicians, you are a key part in making this vision possible

Who Can Receive Medical Marijuana?

Patients with any of the following serious medical conditions:
- Amyotrophic Lateral Sclerosis
- Autism
- Cancer
- Crohn’s Disease
- Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity
- Epilepsy
- Glaucoma
- HIV (Human Immunodeficiency Virus) / AIDS (Acquired Immune Deficiency Syndrome)
- Huntington’s Disease
- Inflammatory Bowel Disease

Pennsylvania Department of Health
Who can Receive Medical Marijuana?

Patients with any of the following serious medical conditions:

- Intractable Seizures
- Multiple Sclerosis
- Neuropathies
- Parkinson’s Disease
- Post-traumatic Stress Disorder
- Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective
- Sickle Cell Anemia

What Does Medical Marijuana Do?

- Recent clinical studies have provided evidence for the use of medical marijuana to:
  - Act as an antiemetic for cancer patients
  - Reduce chronic pain
  - Decrease spasticity related to MS
- Studies conducted on animals and cells suggest that cannabis may augment the ability of traditional therapies such as chemotherapy or irradiation in inhibiting tumor growth

Medical Marijuana and the Opioid Epidemic

Overdose Deaths Involving Opioids, United States, 2000-2015

- Opioid
- Non-Opioid, Naturally Occurring
- Synthetic Opioids
Medical Marijuana and the Opioid Epidemic

- “Relief from chronic pain is by far the most common condition cited by patients for the medical use of cannabis.”

- “There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.”


Medical Marijuana and the Opioid Epidemic


Medical Marijuana and the Opioid Epidemic

- Legalizing medical marijuana is associated with decreases in:
  - Overdose deaths from prescription opioids
  - Opioid prescribing
  - Self-reports of opioid misuse
  - Treatment admissions for opioid addiction

Clinical Use - Neuropathy

- There was a significant difference in spontaneous pain scores between doses (P < .001). Specific significant comparisons were placebo versus low, medium, and high doses (P = .031, .04, and <.001, respectively) and high versus low and medium doses (both P < .001). There was a significant effect of the high dose on foam brush and von Frey evoked pain (both P < .001). There was a significant negative effect (impaired performance) of the high dose on 2 of the 3 neuropsychological tests."


Clinical Use - Neuropathy

- Clinical trials show medical marijuana has a significant pain reducing effect compared to a placebo on diabetic, HIV associated, and post surgical neuropathy

- Evidence suggests low doses have an analgesic effect and can be titrated up for a stronger effect if necessary

Clinical Use - Multiple Sclerosis

- "There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity."

Clinical Use - Multiple Sclerosis

- Evidence suggests cannabis may reduce spasticity in MS patients
- Some studies have also shown reduction in incontinence and pain symptoms
- Oral and oral mucosal forms are recommended

Clinical Use - Cancer

- "There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting."

Clinical Use - Cancer

- Alleviate pain from cancer
- Oral cannabinoids are the form with the most evidence based support
- More research is being conducted to determine the role cannabis can play in treating cancer and/or cancer symptoms
Clinical Use - Cancer

- Recent studies (2011 & 2014 Journal of Molecular Cancer Therapeutics)
  
- Katherine A. Scott, Angus G. Dalgleish and Wai M. Liu. The Combination of Cannabidiol and Δ9-Tetrahydrocannabinol Enhances the Anticancer Effects of Radiation in an Orthotopic Murine Glioma Model. Mol Cancer Ther. December 1 2014 (13) (12) 2955-2967; DOI: 10.1158/1535-7163.MCT-14-0402

- Torres et al. A Combined Preclinical Therapy of Cannabinoids and Temozolomide against Glioma. Mol Cancer Ther, January 1 2011 (10) (1) 90-103; DOI: 10.1158/1535-7163.MCT-10-0688

Clinical Use - Cancer

- Studies conducted on animals and human cells transplanted into animals as xenografts suggest that cannabis may augment the ability of traditional therapies such as chemotherapy or irradiation in inhibiting tumor growth.

- Studies have not yet demonstrated conclusive evidence that cannabis has the same effect on humans

Clinical Use - Cancer

- Data from a mouse xenograft model of glioma
**Clinical Use - Epilepsy**

- "In conclusion, we find that the evidence describing the effects of major plant cannabinoids that do not act as CBR ligands, most notably cannabidiol and cannabinvarin, exerts consistently beneficial therapeutic effects in preclinical models of seizures, epilepsy, epileptogenesis, and neuroprotection, consistent with emerging human clinical trial results."


**Clinical Use - Intractable Seizures**

- "The results of this multicenter study on CBD enriched cannabis oil treatment for intractable epilepsy in a population of children and adolescents are highly promising. Further prospective, well-designed clinical trials using enriched CBD medical cannabis are warranted to validate our findings."


**Clinical Use - Intractable Seizures**

- Also called refractory epilepsy

- Several retrospective studies show medical marijuana use is associated with seizure reduction

- Controlled studies including a placebo are needed
“Pennsylvania Medical Marijuana Program”
Rachel L. Levine, MD

Clinical Use - Research and the Future

- “To address the research gaps outlined throughout this report, a comprehensive national research agenda will be required. The aspirational goal and organizing principle of this agenda should be to maximize the population-health impact of cannabis research.”

- The National Academies of Science, Engineering, and Medicine

Clinical Use - Research and the Future

- The state, NIH, and NIDA are all providing money for medical cannabis research

- Does cannabis increase the efficacy of currently available cancer treatments?

- How well can cannabis treat tremors, anxiety, weight loss, and other symptoms caused by serious medical conditions?

How Can Physicians Be Involved?

- Medical marijuana can be counted as one of many tools in a physician’s toolbox to treat serious medical conditions

- In order to recommend medical marijuana to patients, physicians must register with the Pennsylvania Department of Health and complete the required 4-hour training course
The Medical Marijuana Act

• The Medical Marijuana Act allows patients and registered caregivers with patient certifications provided by a practitioner to obtain medical marijuana from a dispensary.

• Physicians are not "subject to arrest, prosecution or penalty in any manner, or denied any right or privilege, including civil penalty or disciplinary action by a Commonwealth licensing board or commission." (Act 16)

• Physicians will not be punished for recommending medical marijuana as treatment because it is not considered prescribing.

Becoming a Practitioner

[Images of registration pages]
The Role of the Practitioner

- A practitioner can issue a patient certification if:
  - The practitioner has determined that the patient has a serious medical condition and has included the condition in the patient's health care record.
  - The patient is under the practitioner's continuing care for the serious medical condition.
The Role of the Practitioner

• A practitioner can issue a patient certification if:
  • In the practitioner's professional opinion and review of past treatments, the practitioner determines the patient is likely to receive therapeutic or palliative benefit from the use of medical marijuana.

Practitioner Prohibitions

• A practitioner may not accept, solicit or offer any form of remuneration from or to a prospective patient, patient, prospective caregiver, caregiver or medical marijuana organization, including an employee, financial backer or principal, to certify a patient, other than accepting a fee for service with respect to the examination of the prospective patient to determine if the prospective patient should be issued a patient certification to use medical marijuana.

• A practitioner may not hold a direct or economic interest in a medical marijuana organization.

• A practitioner may not advertise the practitioner's services as a practitioner who can certify a patient to receive medical marijuana.
**Issuing Patient Certifications**

- Necessary items to include on a patient certification can be found in the regulations and on the website.
- The practitioner may specify which form of medical marijuana the patient can receive, but it is not necessary to specify the form or dose.
- The patient certification is valid for one year unless the practitioner specifies that a patient would benefit for a specific period less than one year.

**Consulting the PDMP**

- A practitioner shall review the prescription drug monitoring program prior to:
  - Issuing a patient certification to determine the controlled substance history of a patient.
  - Recommending a change of amount or form of medical marijuana.

- A practitioner may access the prescription drug monitoring program to do any of the following:
  - Determine whether a patient is being treated with a controlled substance by another physician or other person.
  - Review the patient's controlled substance history.
  - Provide to the patient, or caregiver on behalf of the patient if authorized by the patient, a copy of the patient's controlled substance history.
Legal Forms of Medical Marijuana

- Pills
- Oil
- Liquid
- Tincture
- Topical including cream, gel, and ointment
- Medically appropriate forms for administration by vaporization or nebulization
- No dry leaf or plant form is allowed

How will the Patient Obtain Medical Marijuana?

- The doctor who recommends the medical marijuana must:
  - Be registered as a practitioner in the program
  - Provide the patient with a patient certification

Practitioner and Dispensary Relationship

- The dispensary dispenses medical marijuana to patients in accordance with the patient certification issued by the practitioner
- The practitioner may recommend that the patient consult with a medical professional employed by a dispensary regarding the appropriate form and dosage of medical marijuana to be dispensed
Locations of Permitted Dispensaries

Notifying the Department of Health

- A copy of each patient certification issued by a practitioner will be captured and maintained electronically by the Department of Health
- A practitioner must notify the Department in writing immediately if the physician knows or has reason to know that:
  - The patient no longer has the serious medical condition for which the certification was issued.
  - Medical marijuana would no longer be therapeutic or palliative.
  - The patient has died.

Next Steps

- Go to Pennsylvania’s medical marijuana website
- Sign up with the physician registry
- Complete the four hour training course
- Use your knowledge and abilities as a trained, registered practitioner to provide your patients with the best care possible - now with an additional tool in your toolbox
Thank You!

Questions?