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Medical Marijuana Use in Children and Implication for Physical Therapists Professionals

Laura Borgelt, PharmD, FCCP, BCPS
Associate Dean and Professor
PhysicalTherapy.com Webinar
August 23, 2017

Disclosures
Dr. Borgelt has no relevant financial disclosures.
Dr. Borgelt will be discussing unapproved drugs and uses.
Dr. Borgelt has served as a member of six working groups:
- Colorado Department of Public Health and Environment (CDPHE):
  Amendment 64 (Marijuana Legalization) Task Force Working Group:
  Consumer Safety and Social Issues
- State Licensing Authority Labeling, Packaging, Product Safety and Marketing
- State Licensing Authority Medical and Retail Marijuana Mandatory Testing and Random Sampling
- State Licensing Authority Serving Size and Product Potency
- CDPHE Retail Marijuana Public Health Advisory Committee
- CDPHE Pregnancy and Breastfeeding Guidelines Committee
Objectives
As a result of this course, participants will be able to:

- Describe the current regulatory status of cannabis in the United States.
- Discuss the clinical pharmacology of cannabis and its active components.
- Compare and contrast various formulations of cannabis available to patients.
- Evaluate and discuss clinical studies performed in patients (especially children) with various conditions to determine the effectiveness and adverse effects of cannabis.
- Identify patient safety issues that should be considered with the use of cannabis.
- Discuss communication strategies for talking with patients that are using medical cannabis.

Audience Question

I know someone who consumes marijuana for medical or recreational purposes.

1. Yes, medical purposes only
2. No, recreational purposes only
3. Yes, both
4. No
**Audience Question**

I believe the most common reason people seek out marijuana is to...

1. relieve pain
2. improve symptoms of nausea and vomiting
3. relieve muscle spasms associated with multiple sclerosis
4. get high

**Overall goal for this presentation**...

...is to help physical therapists better understand the characteristics of marijuana and its effects so you can confidently talk with your patients about the potential benefits and risks of using marijuana.
Patient Case in Colorado

- 47 yo male with PMH of hypertension, diabetes, peripheral neuropathy, and chronic pain
- Pain Treatment Regimen
  - Oxycontin 30mg po BID and oxycodone 5 mg po prn
  - His pain medications have not changed in over one year
  - Today, he admits that he has also been smoking medical marijuana twice daily for the past two years to help his pain (decreased from 8/10 to 4/10)
  - He has been afraid to tell the healthcare team because he believes they will not “approve” of this treatment. He states he saw a different physician to get his card and recommendation for cannabis

A Few Questions to Consider

- Are there other ways for him to consume MMJ to avoid the risks of smoking?
- Is MMJ effective for the treatment of pain?
- What adverse effects might this patient experience with chronic use of inhaled MMJ?
- Are there any drug interactions with MMJ?
- How might MMJ impact his opioid use?
- What other issues might this patient need to consider? Legal issues?
- How can I create an environment where patients feel safe to talk with me about any/all treatments they use?
Objectives

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Cannabis (Marijuana)

- Single molecule pharmaceuticals
  - Dronabinol (Schedule III)
  - Nabilone (Schedule II)
- Liquid extract: nabiximols (Sativex®)
  - Approved in 28 countries; U.S. - Phase III trials
- Liquid extract: cannabidiol (Epidiolex®)
  - FDA: orphan drug status for Dravet and Lennox-Gastaut syndromes
  - Expanded access INDs to several independent investigators
- Phytocannabinoid-dense botanicals
  - Cannabis sativa – medicinal plant (Schedule I)
Cannabis in the United States

Sources of Information and Laws

<table>
<thead>
<tr>
<th>Source</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marijuana Policy Project</td>
<td><a href="https://www.mpp.org/states/">https://www.mpp.org/states/</a></td>
</tr>
<tr>
<td>DEA Website</td>
<td><a href="http://www.deadiversion.usdoj.gov/Resources.html">http://www.deadiversion.usdoj.gov/Resources.html</a></td>
</tr>
</tbody>
</table>
History of Medical Marijuana Use

A BLIP ON THE RADAR?

3000 BC

TODAY

1937-1996

Medical use of marijuana

*Not drawn to scale

Key Opinion

Considerations for medical use of marijuana are different than considerations for recreational use of marijuana.

Medical use: benefit – risk

Recreational use: risk - risk
Summary

- Documentation throughout the world regarding use of medical cannabis for thousands of years
- Cannabis remains Schedule I by U.S. federal government
- Legislation varies for states across United States
  - Medical and recreational

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Cannabis

- Plant-derived cannabinoids
  - Δ⁹-tetrahydrocannabinol - THC
  - Δ⁸-tetrahydrocannabinol - THC
  - Cannabidiol – CBD
  - Cannabinol - CBN
  - Cannabigerol - CBG
  - Cannabichromene - CBC
  - Cannabicyclol - CBL
  - Cannabielsoin - CBE
  - Cannabitriol - CBT
  - Miscellaneous
  - Cannabinodiol (air-oxidation)

- Terpenes
- Flavonoids
- And much more…

More than 104 different cannabinoids


AUDIENCE QUESTION

Which of the following receptors is a key target for THC?

1. Cannabinoid-1 receptor (CB1)
2. Cannabinoid-7 receptor (CB7)
3. Peroxisome Proliferator-Activated Receptors (PPAR)
4. G-protein receptor 55 (GPR55)
5. I have no idea 😊
Endogenous Cannabinoid System

- Endocannabinoids and their receptors found throughout body
- In each tissue, the cannabinoid system performs different tasks; goal is always homeostasis
- Endocannabinoids are substances our bodies make naturally to stimulate CB1 and CB2
  - Anandamide
  - 2-arachidonoylglycerol (2-AG)
- When cannabinoid receptors are stimulated, variety of physiologic processes
  - CB1 receptors: nervous system, connective tissues, gonads, glands, organs
  - CB2 receptors: immune system and associated structures


Functional Effects of Anandamide at CB1 and CB2 Receptors

<table>
<thead>
<tr>
<th>Structure</th>
<th>Anandamide regulates</th>
<th>Resultant effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal cord</td>
<td>Inhibit GLU and info transfer between body and brain</td>
<td>Decreased pain sensitivity</td>
</tr>
<tr>
<td>Parasympathetic system</td>
<td>Inhibit Ach release, HR regulation, urination regulation</td>
<td>HR stimulation, sometimes inhibits urination</td>
</tr>
<tr>
<td>Sympathetic system</td>
<td>Inhibit NE release, HR regulation, blood vessel constriction</td>
<td>Delayed reduction in HR and blood pressure</td>
</tr>
<tr>
<td>Neuronal cells</td>
<td>Inhibition GLU-induced excitotoxicity</td>
<td>Neuroprotective effect - prevent cell injury</td>
</tr>
<tr>
<td>Adipose tissue</td>
<td>Stimulates lipogenesis</td>
<td>Increased adiposity, insulin resistance</td>
</tr>
<tr>
<td>Reproductive tissue</td>
<td>Reduces testosterone, luteinizing hormone</td>
<td>Reduced fertility, altered menstrual cycle</td>
</tr>
<tr>
<td>Skin</td>
<td>Reduces histamine</td>
<td>Anti-pruritic effect</td>
</tr>
<tr>
<td>General</td>
<td>Role in relaxing, eating, sleeping, forgetting, protecting</td>
<td>Provide relief from stress, reduction of injury</td>
</tr>
<tr>
<td>General</td>
<td>Inhibits immune B lymphocytes, natural killer cells</td>
<td>Anti-inflammatory activity</td>
</tr>
</tbody>
</table>

Cannabis Pharmacology

What happens when there is potential endocannabinoid deficiency, dysregulation, destabilization, or decreased binding?

Endocannabinoid System

Photo credit: www.drugabuse.gov

Photo created by Dr. Kari Franson; used with permission.
Non-Cannabinoid Targets Linked to Cannabis

- Other G-protein receptors: GPR55, GPR55940, etc.

  G-protein-coupled receptors: noncompetitive inhibitor at μ- and δ-opioid receptors, NE, DA, 5-HT

- Ligand-gated ion channels: allosteric antagonism at 5-HT3, nicotinic, and enhance activation of glycine receptors

- Transient receptor potential channels (TRPVs): bind and activate TRPV1 similar to capsaicin, also CB1 receptors are located near TRPV1

- Ion channels: inhibition of Ca, K, Na channels by non-competitive antagonism

- Peroxisome Proliferator-Activated Receptors: PPARα and PPARγ are activated

Another Kid on the Block…Cannabidiol (CBD)

Little binding affinity to CB1/CB2
Suppresses enzyme fatty acid amide hydrolase ("FAAH") – enzyme that breaks down anandamide

Opposes THC at CB1 receptor
Stimulates release of 2-AG
TRPV-1 receptor agonist
5-HT1A receptor activation
GPR55 antagonist


Potential Physiologic Responses to Cannabis

- Improves sleep
- Anti-seizure effects and neuroprotection
- Reduces anxiety and psychotic symptoms/PTSD
- Prevents nausea and stimulates appetite
- Reduces intraocular pressure
- Bronchodilator
- Relaxes muscles and reduces muscle spasms
- Relieves pain (especially neuropathic)
- Anti-inflammatory
- Anti-proliferative
- Anti-viral
- With potential adverse effects.

POLL QUESTION

Which of the following is/are common adverse effects of marijuana?

1. Headache
2. Slowed reaction time
3. Decreased heart rate
4. Insomnia
5. All of the above

- Tachycardia
- Palpitations
- Hypertension
- Coughing
- Wheezing
- Sputum production
- Lethargy, Sedation, Slowed Reaction Time
- Psychological dysfunction: impaired coordination, memory formation, recollection, focus
- Visual Disturbances

Adverse Effects of Marijuana

Effects of Short-term Use
- Impaired short-term memory
- Impaired motor coordination
- Altered judgment
- Motor vehicle accidents (2x)
- Paranoia and psychosis (high doses)

Effects of Long-term/Heavy Use
- Addiction (9% overall)
- Altered brain development*
- Cognitive impairment (with lower IQ)*
- Diminished life satisfaction and achievement*
- Poor educational outcome
- Symptoms of chronic bronchitis
- Increased risk of chronic psychosis disorders
*Effect is strongly associated with initial marijuana use early in adolescence


Psychiatric Implications
- Acute cannabis psychosis
  - Very large dose of cannabinoid botanical consumed
  - Typically through oral ingestion (concentrated preparation)
  - Agitation, confusion, sedation
  - Self-limiting and generally disappears after metabolism/excretion

- Acute schizophreniform reaction
  - Young adults under stress and have other vulnerabilities to schizophreniform illness
  - Early and heavy cannabis exposure may increase the risk of developing a psychotic disorder such as schizophrenia
  - Carefully monitor or avoid in early teens or preteens with preexisting symptoms of mental illness or patients with significant family or personal history of mental illness

### Symptoms of Marijuana Withdrawal

<table>
<thead>
<tr>
<th>Common Symptoms</th>
<th>Physical Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Insomnia (few nights to months)</td>
<td>• Headaches (weeks to months)</td>
</tr>
<tr>
<td>• Depression</td>
<td>• Night sweats (days to month)</td>
</tr>
<tr>
<td>• Nightmares and vivid dreams (days to months)</td>
<td>• Eating problems (days to months) – loss of appetite, digestion</td>
</tr>
<tr>
<td>• “Using” dreams (years)</td>
<td>• Tremors, shaking, dizziness</td>
</tr>
<tr>
<td>• Anger, fear, anxiety</td>
<td></td>
</tr>
</tbody>
</table>


### Clinically Important Drug-Drug Interactions

- Chlorpromazine
- Clobazam
- Clozapine
- CNS depressants
- Disulfiram
- Hexobarbital
- Hydrocortisone
- Ketoconazole
- Protease inhibitors (indinavir, nelfinavir)
- MAO inhibitors
- Phenytoin
- Theophylline
- Tricyclic antidepressants
- Warfarin

*Note: significant synergistic interaction found between CBD and levetiracetam. Significant antagonistic interactions noted with CBD + clobazam and CBD + carbamazepine. (AES Annual Meeting December 2015)*

Drug Interactions

<table>
<thead>
<tr>
<th>Cannabinoid</th>
<th>CYP-450 2C9</th>
<th>CYP-450 2C19</th>
<th>CYP-450 3A4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Δ9-THC</td>
<td>*</td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Δ8-THC</td>
<td>*</td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>CBD</td>
<td></td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>CBN</td>
<td>*</td>
<td></td>
<td>*</td>
</tr>
</tbody>
</table>

Drug Metab Rev. 2014;46(1):86–95

Medical Cannabis and Opioid Use?
Medical Cannabis and Opioid Use

Limited evidence that there is less opioid overdose deaths than expected in states with legal medical marijuana.


From: Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010

States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate (95% CI: -37.5% to -9.5%; P = .003) compared with states without medical cannabis laws.

This association strengthened over time:
- Year 1 (-19.9%; 95% CI: -30.6% to -7.7%; P = .002)
- Year 2 (-25.2%; 95% CI: -40.6% to -5.9%; P = .01)
- Year 3 (-23.6%; 95% CI: -41.1% to -1.0%; P = .04)
- Year 4 (-20.2%; 95% CI: -33.6% to -6.8%; P = .02)
- Year 5 (-33.7%; 95% CI: -50.9% to -10.4%; P = .008)
- Year 6 (-33.3%; 95% CI: -44.7% to -19.6%; P < .001)
Medical Cannabis and Opioid Use

- 244 medical cannabis patients with chronic pain in Michigan
- Survey of 46 questions
  - Medical condition(s) for which cannabis was used
  - Method/frequency of cannabis use
  - Changes in noncannabis medication use
  - Changes in medication side effects
  - Quality of life changes since starting cannabis use
  - Demographic information
  - 2011 Fibromyalgia Survey Criteria (0-31 score)


<table>
<thead>
<tr>
<th>OUTCOME OF INTEREST</th>
<th>PATIENT RESPONSES (n=244) Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibromyalgia score (0-31)</td>
<td>9.23 (5.52)</td>
</tr>
<tr>
<td>Opioid use change</td>
<td>−63% (46%)</td>
</tr>
<tr>
<td>Degree to which side effects of medication affect daily function (before using medical cannabis); scale from 1 to 10</td>
<td>6.44 (2.91)</td>
</tr>
<tr>
<td>Degree to which side effects of medication affect daily function (after using medical cannabis); scale from 1 to 10</td>
<td>2.77 (2.35)</td>
</tr>
<tr>
<td>Number of medication classes used (before cannabis use)</td>
<td>2.35 (1.43)</td>
</tr>
<tr>
<td>Number of medication classes used (after cannabis use)</td>
<td>1.82 (.94)</td>
</tr>
<tr>
<td>Quality of life change</td>
<td>45% (28%)</td>
</tr>
</tbody>
</table>

Cannabis as a Substitute?

- 2,774 individuals with cannabis use at least 1x in previous 90 days
- Surveyed via online anonymous questionnaire
- 1,248 (46%) reported using cannabis as a substitute for prescription drugs

![Medication Substitutions]


Relevance for Physical Therapists

- Provide education
- Monitor effects of cannabis
  - Therapeutic (e.g., pain scales)
  - Adverse effects (e.g., cardiovascular effects during exercise, mood, cognition, memory)
- Assess balance and fall risk
- Monitor excessive use of cannabis

Summary: Endocannabinoid System and THC


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Medical Marijuana: Formulations

AUDIENCE QUESTION

Which of the following forms of marijuana has the slowest onset of action?

1. Intravenous
2. Inhaled
3. Oral
4. Buccal
Marijuana Through the Lungs

- Similar to IV bolus
- Passive diffusion into alveolar capillaries
- Bioavailability: 2-56%
- Fraction absorbed: 10-20%
- Rapid onset (sec-min)
- Maximal onset 30 minutes and lasting 2-3 hours
- Metabolism in liver, lung, and brain
- Elimination $t\frac{1}{2} = 20$ hrs (2-13 days)
- Elimination primarily via feces (65%) and urine (20%)


Marijuana Through the Gut

- Variable absorption
- Bioavailability ranges 4-20%
- Onset: 30 minutes-2 hours
- Duration: 5-8 hours
- Metabolized primarily in the liver
  - 11-hydroxy-THC
- Elimination t½ = 20-30 hrs
- High inter- and intra-patient variability

Pharmacodynamics in Action: Oral Formulations

85 mg THC
225 mg THC
200 mg THC
300 mg THC
100 mg THC
175 mg THC
10 mg/unit
50 mg THC
Marijuana Through the Oral Mucosa

- Onset: 15-40 minutes
- Duration: 45 minutes-2 hours
- May have inter- and intra-patient variability
- Plasma levels of THC and other cannabinoids are lower compared with the levels achieved following inhalation of cannabinoids at a similar dose (nabiximols)
- Metabolized in the liver
- Elimination via feces (65%) and urine (35%)

Summary

Given the wide variety of formulations available, it is important to consider various pharmacokinetic and pharmacodynamic parameters.

A patient-determined, self-titrated dosing model should be used. The most effective and tolerable formulation and dose will vary based on body type, weight, and condition.

Providers need to step into a shared decision making model with patients.
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POLL QUESTION
Which of the following is the most common reason for medical cannabis use?

1. Cancer
2. Epilepsy
3. Glaucoma
4. Muscle spasms
5. Nausea
6. Pain
Medical Cannabis Use

FIGURE 3-4 Number of medical cannabis patients in Colorado and Oregon in July 2016.
NOTE: Patients may report multiple qualifying ailments.

SOURCES: Adapted from CDPHE, 2016; ORA, 2016.

Existing “Qualifying Conditions”

COLORADO
- Cachexia
- Cancer
- Glaucoma
- HIV/AIDS
- Persistent muscle spasms
- PTSD
- Seizures
- Severe nausea
- Severe pain

CONNECTICUT
- Cachexia
- Cancer
- Crohn’s disease
- Epilepsy
- Glaucoma
- HIV/AIDS
- Intractable spasticity
- Multiple sclerosis
- Parkinson’s disease
- PTSD
- Wasting syndrome

MINNESOTA
- ALS
- Cancer with severe/chronic pain, nausea/severe vomiting, or cachexia/severe wasting
- Crohn’s disease
- Glaucoma
- HIV/AIDS
- Intractable pain
- PTSD
- Seizures/epilepsy
- Severe and persistent muscle spasms/MS
- Terminal illness with a life expectancy <1 year
- Tourette’s syndrome

Accessed April 18, 2016.
How Should MMJ Be Studied?

A. Blog
B. Case control study
C. Case report
D. Case series
E. Cohort study
F. Meta-analysis
G. My opinion
H. Randomized controlled trial
I. Review article

“HIGHEST” level of evidence

“LOWEST” level of evidence

Inhaled Cannabis for Neuropathic Pain: Meta-Analysis of Individual Data

- Synthesizes the individual participants’ original data obtained from the studies’ principal investigators
- Five randomized controlled trials evaluating inhaled cannabis
- Compared proportion of patients experiencing >30% clinical improvement in chronic neuropathic pain assessed with a continuous patient-reported instrument (e.g., visual analog scale) at baseline and after inhaled cannabis

**RESULTS**

- 178 patients with 405 observed responses
- Estimated OR (CRI) for >30% ↓ in pain score: 3.22 (1.59-7.24)
- Number needed to treat (CRI): 5.55 (3.35-13.7)

Note: gabapentin NNT 5.9 (4.6-8.3) for diabetic neuropathy

**Adverse Effects**

- **Serious Adverse Effects (SAEs)**
  - Placebo: 1 (psychosis)
  - Cannabis: 2 (hypertension, increased pain)

- **Mild adverse effects**
  - Anxiety, disorientation, difficulty concentrating, headache, dry eyes, burning sensation, dizziness, and numbness
  - Psychoactive effects (such as feeling “high”) were statistically significantly associated with treatment allocation in 2 studies and increased in frequency with increasing dose
Limitations and Conclusions

- Ineffective participant blinding
- Placebo effects likely
- Different causes of neuropathy
- Small number of studies and participants
- Difficult to estimate bioavailable cannabis
- Short-term data only (up to two weeks)

Inhaled cannabis results in short-term reductions in chronic neuropathic pain for 1 in every 5 to 6 patients treated.

Inhaled Cannabis: Painful Diabetic Neuropathy

- Randomized, double-blind, placebo controlled crossover study
- 16 patients
- Evaluated short-term efficacy and tolerability of inhaled (aerosolized) cannabis
  - Four single-dosing sessions separated by two weeks
    - Placebo
    - Low (1% THC)
    - Medium (4% THC)
    - High (7% THC)

SPONTANEOUS PAIN
Average pain intensity score for placebo dose:
• 0.44 points higher than the pain score in the low dose ($P = .031$)
• 0.42 points higher as compared to the medium dose ($P = .04$)
• 1.2 points higher as compared to the high dose ($P < .001$).

Results, cont’d

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Low Dose (1% THC)</th>
<th>Medium Dose (4% THC)</th>
<th>High Dose (7% THC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SPONTANEOUS PAIN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% reduction in pain</td>
<td>52.8 (±40)</td>
<td>63.8 (±37)</td>
<td>64.8 (±36)*</td>
<td>69.6 (±32)**</td>
</tr>
<tr>
<td>Pain reduction ≥30%</td>
<td>10 (62)</td>
<td>10 (67)</td>
<td>12 (80)</td>
<td>13 (81)</td>
</tr>
<tr>
<td><strong>EVOKED PAIN (FOAM BRUSH)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% reduction in pain</td>
<td>60.0 (±39)</td>
<td>63.8 (±39)</td>
<td>66.7 (±36)</td>
<td>68.6 (±33)</td>
</tr>
<tr>
<td>Pain reduction ≥30%</td>
<td>10 (62)</td>
<td>11 (73)</td>
<td>12 (80)</td>
<td>14 (88)</td>
</tr>
</tbody>
</table>

## Results, cont’d

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Low Dose (1% THC)</th>
<th>Medium Dose (4% THC)</th>
<th>High Dose (7% THC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EUPHORIA</strong> % (p-value)*</td>
<td>56.2</td>
<td>66.7 (.43)</td>
<td>86.7 (.042)</td>
<td>100 (.002)</td>
</tr>
<tr>
<td><strong>SOMNOLENCE</strong> % (p-value)*</td>
<td>37.5</td>
<td>26.7 (.49)</td>
<td>60.0 (.12)</td>
<td>73.3 (.018)</td>
</tr>
</tbody>
</table>

*Compared to placebo

---

### Limitations and Conclusions

- Ineffective participant blinding
- Placebo effects likely
- Small number of participants
- Difficult to estimate bioavailable cannabis
- Short-term data only

This trial of inhaled cannabis demonstrated a dose-dependent reduction in diabetic peripheral neuropathy pain in patients with treatment-refractory pain.

---

Crossover Study: Low-dose Vaporized Cannabis

- Objective: evaluate analgesic efficacy in patients with neuropathic pain despite traditional treatments
- Visual analog scale (0-100)
- 39 patients with previous cannabis exposure
  - 28 male/11 female
  - Avg age 50 years
- Vaporized cannabis
  - Medium-dose (3.53%)
  - Low-dose (1.29%)
  - Placebo

<table>
<thead>
<tr>
<th>INHALED CANNABIS</th>
<th>Number of episodes</th>
<th>230% ↓ in VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>10/38 [26% (15-42%)]</td>
<td></td>
</tr>
<tr>
<td>Low-dose</td>
<td>21/37 [57% (41-71%)]</td>
<td></td>
</tr>
<tr>
<td>Med-dose</td>
<td>22/36 [61% (45-75%)]</td>
<td></td>
</tr>
</tbody>
</table>

Statistical significance
- P vs Low: p=0.0069
- P vs Med: p=0.0023
- Low vs Med: p=0.7

NNT: Low 3.2
NNT: Med 2.9


Smoked Cannabis for Chronic Neuropathic Pain

- 21 adults post-traumatic or post-surgical neuropathic pain
- Cannabis 25 mg at 0%, 2.5%, 6%, and 9.4% THC smoked 3x/day
- Four 14-day periods in crossover trial
- Primary outcome: pain intensity (11-item scale)

RESULTS

- Pain intensity
  - 9.4%: score = 5.4
  - 0%: score = 6.1
  - (p=0.023; difference 0.7, 95% CI 0.02-1.4)
- Sleep (more drowsiness, getting to sleep more easily, faster, and with less wakefulness)
  - 9.4% vs 0%; p<0.05
- Anxiety and depression improved (EQ5D)
  - 9.4% vs 0%; p<0.05
- Adverse events
  - 248 mild; 6 moderate (fall, ↑pain, numbness, drowsiness, pneumonia)

[Reference: CMAJ 2010;182:E694 -701.]
MMJ in Painful HIV-Associated Sensory Neuropathy: Systematic Review and Meta-Analysis

- Objective: evaluate clinical effectiveness of various analgesics
- Total of 14 trials evaluated
- Smoked cannabis 1-8% and capsaicin 8% found to be effective

<table>
<thead>
<tr>
<th></th>
<th>SMOKE CANNABIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of episodes</td>
<td>122</td>
</tr>
<tr>
<td>≥30% improvement in VAS</td>
<td>31/61</td>
</tr>
<tr>
<td>≥50% improvement in VAS</td>
<td>15/61</td>
</tr>
<tr>
<td>RR (95% CI)</td>
<td>2.38 (1.38 to 4.10)</td>
</tr>
<tr>
<td>NNT (95% CI)</td>
<td>3.38 (2.19 to 7.50)</td>
</tr>
</tbody>
</table>

*NNT for capsaicin 8% = 6.46 (3.86-19.69)

Summary

Cannabis may have a role in chronic pain, especially neuropathic pain when patients have failed other treatments. Mortality from and use of opioids appears to decrease with cannabis use. Adverse effects do occur so benefits and risks should be weighed for individual patients while considering patient safety and public health concerns.
Pediatric Epilepsy

- Open label trial of oral cannabidiol
- 214 patients 1-30 years with severe, intractable, childhood-onset, treatment-resistant epilepsy
- Oral cannabidiol 2-5 mg/kg per day, up-titrated until intolerance or to max dose of 25-50 mg/kg per day

Objectives:

» Establish the safety and tolerability of cannabidiol
  - 162 patients with 12 weeks of treatment included in analyses
» Establish efficacy as median percentage change in the mean monthly frequency of motor seizures at 12 weeks
  - 137 patients with 12 weeks of treatment included in analyses

Results: Safety and Tolerability

- Adverse events reported in 128/162 (79%) patients
  » Somnolence (25%)
  » Decreased appetite (19%)
  » Diarrhea (19%)
  » Fatigue (13%)
  » Convulsion (11%)
- Five (3%) patients discontinued treatment
- Serious adverse events were reported in 48 (30%) patients
  » 20 (12%) patients had severe adverse events possibly related to cannabidiol use, the most common of which was status epilepticus (n=9 [6%]).
Results: Efficacy

Efficacy of Oral Cannabidiol

-36.5%

Baseline vs. Treatment for 12 weeks


Pediatric Epilepsy

- Retrospective chart review
- 119 patients 30 days-18 years
- 41% relocated to CO
- Parents of 58 patients (49%) reported at least some improvement in seizures.
- 24% considered to be responders to OCE treatment, which was defined as a > 50% reduction in seizure burden.

Pediatric Epilepsy: Israeli Experience

- Retrospective review of 74 patients (1-18 years) with intractable epilepsy using CBD-enriched medical cannabis
- Resistant to >7 antiepileptic drugs
- Treated with CBD-enriched product for at least 3 months
  - CBD:THC – 20:1
  - CBD dose ranged from 1-20 mg/kg/day
- Seizure frequency assessed by parental report

Results (n=74 patients)

Seizure Reduction with Cannabis Use

Adverse Effects

- Reported in 34/74 patients
  - Seizure aggravation: 13 (18%)
  - Somnolence/fatigue: 16 (22%)
  - Gastrointestinal problems and irritability: 5 (7%)
  Note: side effects led to withdrawal in 5 patients

Limitations and Conclusions

- Lack of a control group
- No consistent rate of dosage elevation
- Reliance upon parental report on seizure frequency
- Short duration of the study
- Lack of long-term outcome
- No EEG results and no measurement of other drug levels

Results of this multicenter study on CBD treatment for intractable epilepsy in a population of children and adolescents are highly promising.
Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurologic Disorders

In Patients with Multiple Sclerosis

<table>
<thead>
<tr>
<th>Condition</th>
<th>Effective</th>
<th>Possibly effective</th>
<th>Probably or possibly ineffective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spasticity</td>
<td>OCE</td>
<td>Nabiximols, THC</td>
<td></td>
</tr>
<tr>
<td>Central pain or painful spasms</td>
<td>OCE</td>
<td>Nabiximols, THC</td>
<td></td>
</tr>
<tr>
<td>Urinary dysfunction</td>
<td>Nabiximols</td>
<td>THC, OCE</td>
<td></td>
</tr>
<tr>
<td>Tremor</td>
<td>THC, OCE, nabiximols</td>
<td></td>
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</tr>
</tbody>
</table>

*OCE= oral cannabis extract

“The risks and benefits of medical marijuana should be weighed carefully.”
“Comparative effectiveness of medical marijuana vs other therapies is unknown for these indications.”

Neurology. 2014;82(17):1556-63

Indications for Whole Plant Extracts

**Nabiximols (Sativex®)**

- Spasticity (muscle stiffness/spasm) due to MS
- Neuropathic pain in MS
- Adjunctive analgesic treatment in patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain

**Cannabidiol (Epidiolex®)**

- Pediatric epilepsy
  - Lennox-Gastaut Syndrome
  - Dravet Syndrome
National Academies: Health Effects of Cannabis

**Conclusive or substantial evidence** that cannabis or cannabinoids are effective:

- for treatment of chronic pain in adults (cannabis)
- for improving patient-reported multiple sclerosis (MS) spasticity symptoms, but limited evidence for clinician-measured spasticity (oral cannabinoids)
- As anti-emetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids)


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National Academies: Health Effects of Cannabis

**Moderate evidence** that cannabinoids, primarily nabiximols, are an effective:

- to improve short-term sleep outcomes in patients with sleep disturbance associated with obstructive sleep apnea, fibromyalgia, chronic pain, and MS.

National Academies: Health Effects of Cannabis

- **Limited evidence that cannabis or oral cannabinoids are effective for**…
  - increasing appetite and decreasing weight loss associated with HIV/AIDS (cannabis and oral cannabinoids)
  - improving symptoms of Tourette syndrome (THC capsules)
  - improving anxiety symptoms in individuals with social anxiety (cannabidiol)
  - improving symptoms of posttraumatic stress disorder (nabilone)
  - better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage – statistical association

- **Limited evidence that cannabis or oral cannabinoids are ineffective for**…
  - improving symptoms of dementia (cannabinoids)
  - improving intraocular pressure associated with glaucoma (cannabinoids)
  - reducing depressive symptoms in individuals with chronic pain or MS (nabiximols, dronabinol, and nabilone)

---

National Academies: Health Effects of Cannabis

- **No or insufficient evidence** to support or refute that cannabinoids are effective for…
  - cancer-associated anorexia cachexia syndrome and anorexia nervosa
  - cancers, including glioma
  - irritable bowel syndrome
  - epilepsy
  - spasticity in patients with paralysis due to spinal cord injury
  - chorea and certain neuropsychiatric symptoms associated with Huntington’s disease
  - symptoms associated with amyotrophic lateral sclerosis (ALS)
  - Parkinson’s disease or levodopa-induced dyskinesia
  - dystonia
  - treatment for mental health outcomes in individuals with schizophrenia or schizophreniform psychosis
  - achieving abstinence in the use of addictive substances
Summary

Cannabis may have a role in a variety of conditions when patients have failed other FDA-approved treatments. Adverse effects do occur so benefits and risks should be weighed for individual patients while considering patient safety and public health concerns.

Objectives
As a result of this course, participants will be able to:

- Describe the current regulatory status of cannabis in the United States.
- Discuss the clinical pharmacology of cannabis and its active components.
- Compare and contrast various formulations of cannabis available to patients.
- Evaluate and discuss clinical studies performed in patients (especially children) with various conditions to determine the effectiveness and adverse effects of cannabis.
- Identify patient safety issues that should be considered with the use of cannabis.
- Discuss communication strategies for talking with patients that are using medical cannabis.
Patient Safety Issues

- Adverse effects
- Drug interactions
- Unintentional exposure
- Consistency (or lack thereof)
- Quality and purity
- Packaging
- Labeling
- Testing – content and contaminants
- Accuracy of education provided

Unintentional Cannabis Exposures in Children: Colorado

Children’s Hospital: 81 visits
Regional Poison Control: 163 cases

Other Vulnerable Populations

Scientific Literature Review: Health Topics

- Marijuana use during pregnancy and breastfeeding
- Unintentional marijuana exposures in children
- Marijuana use among adolescents and young adults
- Marijuana use and cancer
- Marijuana dose and drug interactions
- Marijuana use and neurological, cognitive and mental health effects
- Marijuana use and gastrointestinal and reproductive effects
- Marijuana use and respiratory effects
- Marijuana use and cardiovascular effects
- Marijuana use and driving
- Marijuana use and injury


Findings Summary: Effects on Birth Outcome

<table>
<thead>
<tr>
<th>Substantial evidence</th>
<th>Moderate evidence</th>
<th>Limited evidence</th>
<th>Insufficient evidence</th>
<th>Mixed evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stillbirth</td>
<td></td>
<td></td>
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<tr>
<td>Birth defects</td>
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<td></td>
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<tr>
<td>Including NTD,</td>
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<tr>
<td>Gastrochisis</td>
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<tr>
<td>Isolated simple</td>
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<tr>
<td>Ventricular septal</td>
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<tr>
<td>Defects</td>
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<tr>
<td>Preterm delivery</td>
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<tr>
<td>Decreased birth</td>
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<tr>
<td>Weight</td>
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<tr>
<td>Low birth weight</td>
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</tbody>
</table>

### Findings Summary: Effects on Exposed Offspring

<table>
<thead>
<tr>
<th>Substantial evidence</th>
<th>Moderate evidence</th>
<th>Limited evidence</th>
<th>Insufficient evidence</th>
<th>Mixed evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased growth</td>
<td>Decreased academic ability</td>
<td>Psychosis symptoms at adolescence</td>
<td>Newborn behavior issues</td>
<td></td>
</tr>
<tr>
<td>Decreased IQ scores in young children</td>
<td>Increased depression symptoms</td>
<td>Future initiation of marijuana use</td>
<td>Frequency of marijuana use during adolescence</td>
<td></td>
</tr>
<tr>
<td>Decreased cognitive function</td>
<td>Delinquent behavior</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attention problems</td>
<td>Failure to show association with SIDS (with use during pregnancy)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


### Findings Summary: Effects on Breastfeeding

<table>
<thead>
<tr>
<th>Substantial evidence</th>
<th>Moderate evidence</th>
<th>Limited evidence</th>
<th>Insufficient evidence</th>
<th>Mixed evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Breastfeeding and SIDS</td>
<td>Breastfeeding and infant motor development</td>
<td></td>
</tr>
</tbody>
</table>

Perinatal Outcomes: Meta-Analysis

- Systematic review and meta-analysis
  - Primary Outcomes: maternal, fetal or neonatal up to 6 weeks postpartum after cannabis exposure
  - Conducted meta-analyses when 3 or more studies available with same outcome (anemia, LBW, BW, neonatal length, NICU admission, GA at del, head circumference, PTB)
- Increased odds
  - Anemia - pooled OR=1.36 (95% CI: 1.10-1.69)
  - Decreased birth weight - pooled OR=1.77 (95% CI: 1.04-3.01)
  - NICU admit - pooled OR=2.02 (95% CI: 1.27-3.21)


Neonatal Outcomes: Meta-Analysis

- 31 studies total (12 LBW, 14 PTB)
- Pooled unadjusted data: demonstrated an association between THC and LBW/PTB
  - LBW (15.4% vs 10.4%, RR 1.43, 95% CI 1.27-1.62)
  - PTB (15.3% vs 9.6%, RR 1.32, 95% CI 1.14-1.54)
- After adjustment for tobacco and other confounders: no longer an association
  - LBW (pooled RR 1.16, 95% CI 0.98-1.37)
  - PTB (pooled RR 1.08, 95% CI 0.82-1.43)

Study Limitations: Potency of Marijuana


3 Routes of Administration

LUNGS
Vaporized or Smoked
Organic material, hash, hash oil

GUT
Oral Ingestion
Lipophilic, alcoholic, supercritical fluidic extracts of plant material

SKIN
Topical Application
Creams, buccal tinctures made from plant extracts
Marijuana and Breastfeeding

- THC excreted into human milk in moderate amounts
- Relative Infant Dose: 0.8%
- Milk:plasma ratio is 8:1 (chronic, heavy users)
- Animal studies show MJ could reduce quality and quantity of breastmilk
  » Inhibiting prolactin production
  » Direct action on the mammary glands
- Two studies in women who smoked while breastfeeding (1985, 1990)
  » No differences were noted in outcomes on growth, mental, and motor development
  » Slight decrease in infant motor (not mental) development at one year, especially when used during the first month of lactation
- Infants will test positive in urine screens for 2-3 weeks
- Marijuana may contain other harmful substances

Academy of Breastfeeding Medicine

- Breastfeeding mothers should be counseled to reduce or eliminate their use of MJ to avoid exposing their infants and advised of the possible long-term neurobehavioral effects from continued use.
  » Consider the wide range of occasional, regular medical, heavy exposure to MJ
  » At this time, although the data are not strong enough to recommend not breastfeeding with any marijuana use, we urge caution.

Breastfeeding AAP Statement

- American Academy of Pediatrics (AAP) policy statement on “Breastfeeding and the Use of Human Milk”
  - Breastfeeding contraindicated in women using illicit drugs including marijuana


ACOG Committee Opinion

- Women should not use marijuana during pregnancy or while lactating
  - Do not prescribe or suggest for medicinal purposes to pregnant or lactating women
    - What alternatives exist?
  - Insufficient evidence for effects on nursing infant; marijuana use discouraged

State of Colorado:
Talk about Marijuana with Patients

Marijuana Pregnancy and Breastfeeding Clinical Guidance Document

Marijuana and Your Baby Factsheet

Pregnancy and Breastfeeding Guidance

- Screening recommendations
- Talking points
- Medical marijuana
- Current relevant laws
- Mandatory reporters

- Secondhand smoke
- Breastfeeding
- Parenting and safety
- Common myths about marijuana
- Resources for health care providers and patients

Key Points: What We Can Tell Patients

- No known benefits of marijuana use in pregnancy
- Possible risks of marijuana use in pregnancy and lactation
- Advise patients not to use marijuana during pregnancy or lactation
- No known “safe” amount of marijuana in pregnancy or lactation

Evidence-based alternatives to cannabis should be used in pregnant or lactating women until more information is available.

Role Play

PATIENT COUNSELING VIDEO: PREGNANCY

https://www.youtube.com/watch?v=ZJfxdD_Rm3U
&feature=youtu.be
CANNABIS USE IN ADOLESCENTS

Prevalence of Past-year Drug Use Among 12th Graders in U.S.

High School Seniors

6.0% report daily use—
that’s about 1 in 16.

In 2016, daily marijuana use exceeded cigarette use -
6.0% vs. 4.8%

In 2016, perception of risk declined with 31.1%
reporting regular marijuana use in harmful
(58.3% in 2000).

https://www.drugabuse.gov/publications/drugfacts/high-school-youth-trends
## Evidence of Marijuana Effects: Adolescents and Young Adults

<table>
<thead>
<tr>
<th>Cognitive and Academic</th>
<th>Substantial</th>
<th>Moderate</th>
<th>Limited</th>
<th>Insufficient</th>
<th>Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less high school graduation</td>
<td>Impaired cognitive abilities and academic performance after 28 days abstinence</td>
<td>Less likely to earn college degree</td>
<td>Lower IQ after brief abstinence</td>
<td>Lower future IQ scores</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mental health</th>
<th>Substantial</th>
<th>Moderate</th>
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<th>Insufficient</th>
<th>Mixed</th>
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</thead>
<tbody>
<tr>
<td>Psychotic symptoms in adulthood</td>
<td>Psychotic disorder in adulthood (daily or near-daily users)</td>
<td>Depression or anxiety after adolescence</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance use, abuse, and addiction</th>
<th>Substantial</th>
<th>Moderate</th>
<th>Limited</th>
<th>Insufficient</th>
<th>Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can develop marijuana addiction‡</td>
<td>Increased MJ use and addiction‡ after adolescence</td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance use, abuse, and addiction</th>
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<th>Moderate</th>
<th>Limited</th>
<th>Insufficient</th>
<th>Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol or tobacco use and addiction‡ after adolescence</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefits of quitting</th>
<th>Substantial</th>
<th>Moderate</th>
<th>Limited</th>
<th>Insufficient</th>
<th>Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment for MJ addiction can reduce MJ use and dependence</td>
<td>Quitting MJ lowers risk of cognitive and mental health effects</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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[https://drive.google.com/file/d/0B0tmPQ67k3NVQ1F0nY5vzZG1mdFk/view](https://drive.google.com/file/d/0B0tmPQ67k3NVQ1F0nY5vzZG1mdFk/view) Accessed June 5, 2017.

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How to Talk to Youth about Marijuana

http://goodtoknowcolorado.com/youth-prevention/talking-to-youth

Youth Prevention Infographics

http://goodtoknowcolorado.com/content/resources/Good-to-Know-Colorado_Youth-Prevention_Infographics.pdf
Fact Sheets

- Marijuana and your baby
- Youth and marijuana
- Tips for parents
- Answers to common questions
- Retail marijuana: methods of use
- Retail marijuana: info for visitors
- Retail marijuana: laws and responsible use
- Retail marijuana: health effects
- Tips for youth-serving professionals


Summary

Marijuana consists of 60+ cannabinoids. The effects of marijuana are dependent on many factors and very complex. Benefits and risks should be weighed for individual patients while considering patient safety and public health concerns.
Objectives
As a result of this course, participants will be able to:

- Describe the current regulatory status of cannabis in the United States.
- Discuss the clinical pharmacology of cannabis and its active components.
- Compare and contrast various formulations of cannabis available to patients.
- Evaluate and discuss clinical studies performed in patients (especially children) with various conditions to determine the effectiveness and adverse effects of cannabis.
- Identify patient safety issues that should be considered with the use of cannabis.
- Discuss communication strategies for talking with patients that are using medical cannabis.

Patient Case

- 2 yo male with lethargy is brought to the emergency department of Children’s Hospital Colorado. Several tests are performed including:
  - Urinalysis
  - Comprehensive metabolic panel
  - Complete blood count
  - APAP/ASA levels
  - EKG
  - Urine toxicology
  - CT head
  - Chest X-ray

What are potential causes of his lethargy? Should he be admitted?

Patient Case, con’t

- Admitted to hospital
- Unintentional exposure to marijuana
- Source of marijuana: babysitter

What counseling should occur for this patient and/or family?


Patient Case

- 17 yo male displays unusual behavior in the classroom and is brought to the counselor’s office
- Counselor verifies that the student is high and obtained cannabis (gummy bears) from a friend
- Student admits to using cannabis several times per week; claims it reduces his anxiety and anger
- Student does not think it impacts his school grades or ability to play sports (football and basketball)

What counseling should occur for this student?
Patient Case

- 27 yo female comes to clinic for second trimester prenatal visit (24 weeks pregnant)
- Medications: prenatal vitamin once daily
- Social history: no alcohol, no tobacco, smokes cannabis one to two times daily
  - Initially started cannabis to relieve nausea in first trimester; continued cannabis because it "improved sleep"
- She has heard about cannabis having potential harm on the fetus, but does not think the studies were done well enough to make conclusions about harm; feels benefits outweighs any risks

What counseling should occur for this patient?

Patient Case

- 62 yo female with long-standing diabetes and severe neuropathic pain; other conditions include hypertension, dyslipidemia, and arthritis
- For neuropathic pain and arthritis, she has tried seven different FDA-approved or OTC medications; currently taking APAP, oxycodone and pregabalin
- Started cannabis about 3 months ago
  - Vaporizes THC:CBD (1:1) twice daily
- Reduced oxycodone dose by 30% since cannabis; has continued APAP, pregabalin and cannabis

What counseling should occur for this patient?
Counseling Strategies: Medical Cannabis

- **Reason for use**
  - "Patients use cannabis for many different conditions. For what condition(s) are you using cannabis?"

- **Cannabis use (formulation, dose, frequency)**
  - "By what method(s) do you use cannabis?"
  - "What strain and/or cannabinoid concentrations are you using?"
  - "How often are you using cannabis?"

- **Concurrent drug use**
  - "What other medications are you taking at this time?"
  - Screen for drug interactions

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Counseling Strategies: Medical Cannabis

- **What to expect**
  - "What benefits did your provider tell you to expect by using cannabis?"
  - "What adverse effects did your provider tell you to expect?"

- **When to seek further medical attention**
  - Bothersome psychoactive effects
  - Cannabinoid hyperemesis syndrome (cyclic vomiting)
  - Withdrawal symptoms (if discontinuing)

- **Follow-up when needed**
  - Contact pharmacist or prescriber if any adverse effect becomes too bothersome or if any questions about marijuana use

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Counseling strategies vary based on individual patient situations. Efforts should be made to determine medical history, medication history, social history, and other patient-specific factors to determine what, why, and how cannabis is being used.

Patient Experience with MMJ

- VIDEO: Teri Robnett

https://www.youtube.com/watch?v=3nmYePZWlK4
Conclusions

- The current status of marijuana is Schedule I federally, yet is allowed in most states.
- Marijuana and its active components impact the endocannabinoid system to provide various effects.
- Many dosage formulations of marijuana available to patients.
- Clinical studies performed in children and adults demonstrate some effectiveness for certain conditions; adverse effects are reported in all studies so benefits and risks must be carefully weighed.
- Potential drug interactions and patient safety concerns exist. Effective communication strategies should include the use of open-ended questions and language that is nonjudgmental.

QUESTIONS?
Laura.Borgelt@ucdenver.edu