



Medical Marijuana & TBI:

Where Have We Been,
Where Are We Now, and
Where Are We Heading?

10/10/22

Scott Peters, MS, OTR/L

Prevalence of Cannabis Use in United States

- Greater than 100 million adult Americans report marijuana use
- The prevalence of cannabis use peaked in the late 1970's when more than 1/3 of high school seniors (37% in 1976) and one in eight Americans over 12 years old (12.8% in 1979) reported past month use
- Reduction in the 1980's and 1990's with rapid increase then remained stagnant
- Since 2007 steady year over year increase rising from 5.8% to 8.4% increase in 2014 (45% increase)
- In 2015 estimated 22.2 million of more than 265 million Americans age 12 and older reported having used cannabis in the past month
- Primary use of cannabis in US is recreational (89.9% of users) with only 10.5 percent for solely medical purposes and 36.1 % for mixed medical and recreational
- Greater than 2.3 million legal medical marijuana patients registered in the United States
- Over 116,000 medical marijuana patients have registered in PA and over 83,000 have been issued medical marijuana cards

Prevalence of Cannabis Use in Rehab

- 2018 study published in Archives of PM&R entitled “Cannabis Use in Individuals with SCI or Moderate to Severe TBI in Colorado
- Survey of 51 individuals with SCI and 65 individuals with moderate to severe TBI taking part in SCI or TBI model systems programs
- Specific Cannabis Survey Questions
- Summary of results
 - 70% reported use prior to injury; and 50% since injury
 - Overall preinjury to post injury use declined (22% SCI and 32% in TBI)
 - High percentage in both groups endorsed recreational cannabis use
 - SCI also listing a number of medicinal reasons for use (spasticity, pain, sleep, anxiety)
 - TBI group did not endorse as many medicinal reasons for use. After recreational use they listed reducing anxiety, improving sleep and “other” reasons “mellowing out”

History of Cannabis

- ❏ **First recorded cannabis** as medicine nearly **5000 years ago** when Chinese used it to treat malaria, constipation, rheumatic pain and as an analgesic in childbirth
- ❏ **European physician were published in 1839** regarding cannabis as a muscle – relaxant, anticonvulsant, antiemetic, and analgesic properties Eventually **listed in the US Dispensatory as early as 1845** and made readily available in British Pharmacies for over 100 years
- ❏ **1906:** Congress passes the **Pure Food and Drug Act**. Cannabis is regulated as a drug.
- ❏ **1910:** Congress lists cannabis as a narcotic and regulates it as a poisonous substance. Various states begin regulating marijuana in the following years, adding it to a list of habit – forming drugs.
- ❏ **1930's:** In the 1930's the **Federal Bureau of Narcotics** is formed causing increased scrutiny of cannabis use. This bureau headed by Harry J. Anslinger, an alleged racist who saw marijuana regulation as a weapon against African Americans, Hispanic and other groups deems undesirable. **“Reefer Madness”** propaganda.
- ❏ **1937: The Marijuana Tax Act of 1937** made the possession and transfer of cannabis illegal except for medical and industrial uses. Cannabis was now being regulated and taxed.
- ❏ **1938: The Pure Food, Drug and Cosmetics Act** resulting in the creation of the **Food and Drug Administration**. Marijuana remains listed as a dangerous drug.
- ❏ **1940's:** During World War II farmers cultivated hemp until 1947 when Dupont Corporation invented nylon ending hemp as a fiber material in need. Medical efficacy of marijuana is still ignored.
- ❏ **1950's:** things got worse for cannabis when Congress instituted severe mandatory sentences for a variety of drugs including cannabis. Penalty for cannabis possession as of 1956 was minimum of 2 – 10 years in prison and a \$20,000 fine.
- ❏ **1960's:** ironically the decade of rampant drug use was a time of virtually no antidrug legislation.
- ❏ **1970's:** In 1970 the Nixon Administration went to war on drugs beginning with the **Controlled Substances Act** and the creation of the Schedule List of Drugs. 1973 The DEA – **The Drug Enforcement Administration** was formed and the war on drugs was on

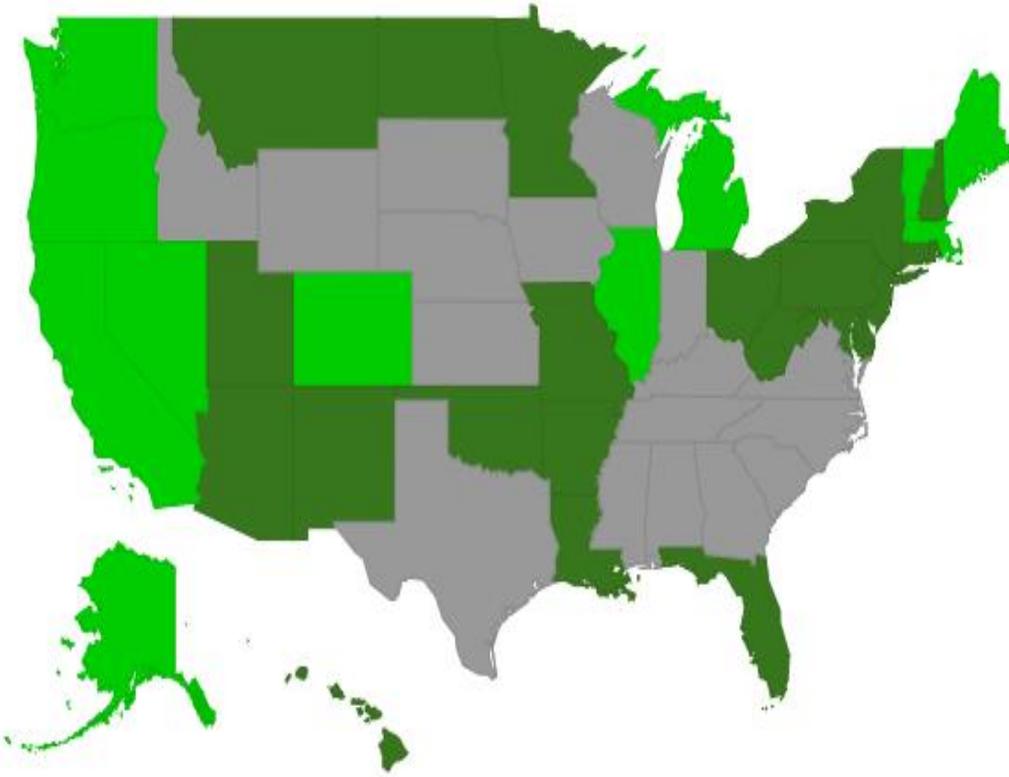
Comprehensive Drug Abuse Prevention and Control Act of 1970

Label	Characteristics
Schedule I	Highly addictive; high potential for abuse; no acceptable medicinal use
Schedule II	Highly addictive; high potential for abuse; have an acceptable medicinal use
Schedule III	Moderate to low risk for dependence; less risk for abuse
Schedule IV	Lower potential for abuse relative to Schedule III
Schedule V	Low potential for abuse; preparations containing limited quantities of certain narcotics

History of Cannabis

- ❑ **1980's:** criminal penalties associated with drugs become much harsher under the Reagan administration with the institution of the mandatory minimum sentences and the Three Strikes Rule. Nancy Reagan “just say no” and “ this is your brain on drugs”
- ❑ **1990's: California Proposition 215 passed in 1996** legalizing medical cannabis
- ❑ **Current:** 33 states have some form of medical and / or recreational use protections for cannabis
- ❑ **Pennsylvania Medical Marijuana Act in 2016**

Marijuana Legalization Status (as of June 25, 2019)



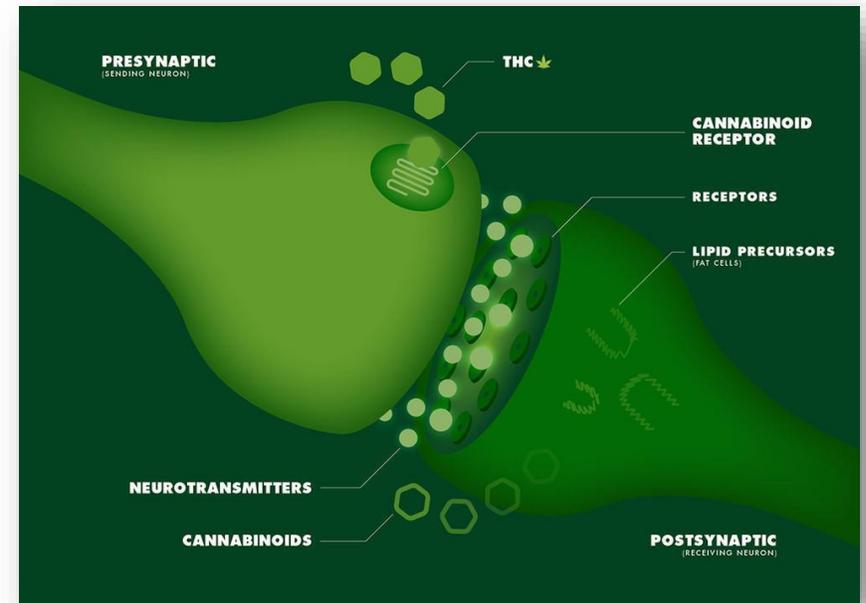
- Medical marijuana broadly legalized
- Marijuana legalized for recreational use
- No broad laws legalizing marijuana

The FDA has licensed three drugs based on cannabinoids:

- ❑ **Dronabinol:** generic name for synthetic Delta 9 THC, is marketed under the trade name **Marinol** – used to combat nausea and vomiting associated with chemotherapy and to stimulate appetite in AIDS patient due to wasting syndrome
- ❑ **Nabilone (Cesamet):** is a synthetic analog of Delta 9 THC and is used in the same manner as Dronabinol
- ❑ **Epidiolex:** an investigational new drug which is a concentrated CBD oil (98% CBD) developed as an anti seizure drug for Dravet and Lennox – Gastaut syndromes. FDA approved in 2013
- ❑ **Nabiximols (Sativex):** is an ethanol cannabis extract composed of THC and CBD in a one to one ratio, its an oralmucosal spray used for symptomatic relief of MS and an adjunctive analgesic treatment in cancer. Launched in 15 countries, approved in 12 but not in US as of 2017

Cannabinoid Receptors

- ❑ 1990's two types of cannabinoid receptors were identified: the Cannabinoid - 1 (CB1) and the cannabinoid – 2 (CB2) receptors
- ❑ CB1 receptors are located primarily throughout the CNS and to a lesser extent in the peripheral tissue. CB1 receptors are spread throughout the brain and are found in high densities in the neuron terminals of the basal ganglia, cerebellum, hippocampus, neocortex, hypothalamus and the limbic cortex
- ❑ CB2 receptors are present mainly on immune cells and peripheral tissues and can have anti-inflammatory, immunosuppressive and antinociceptive (negates pain sensation) activities



Cannabinoids

- ❓ To date more than 104 different cannabinoids (group of psychoactive chemical compounds found in the cannabis plant) have been identified as well as other compounds (terpenoids, flavonoids, nitrogenous compounds)
- ❓ **Delta 9 tetrahydrocannabinol (THC)** is a partial agonist for CB1 receptors. Known to be psychoactive.
- ❓ **Cannabidiol (CBD)** is the most abundant cannabinoid in hemp. Not psychoactive. Known to negatively modulate CB1. Also a known agonist of serotonin 5 – HT1A receptors (treatment and symptom relief of various neurological disorders including anxiety, seizures, movement disorders)
- ❓ **Endocannabinoids:** there are two (2-archidonoylglycerol [2-AG] and anandamide)
 - ❓ 2-AG utilized during neuronal development and for synaptic communication between neurons); and for brain development and inflammation
 - ❓ Anandamide can act as a retrograde modulator of neurotransmitter release

Cannabis – Derived Products and Routes of Administration

Products

- ❑ Cannabis “buds” (dried cannabis flowers)
- ❑ Cannabis resin (hashish, bubble hash)
- ❑ Cannabis oil (butane honey oil, shatter, wax, crumble) can contain up to 75% THC

Routes of Administration

- ❑ Smoked
- ❑ Vaporized
- ❑ Oral
- ❑ Absorption through skin and mucosal tissues (creams, patches, vaginal sprays, rectal suppositories)

Cannabis Route of Administration – Potency

Can affect the onset, intensity and duration of psychoactive effects

- ❑ Inhalation (smoking, pipes, water pipes, vaporizing)
 - ❑ THC quickly diffuses to brain. Perceived high in seconds to minutes
 - ❑ Blood levels reach maximum after about 15 - 30 minutes then rapidly subside within 1 to 3.5 hours duration
- ❑ Dabbing (term for flash vaporizing butane hash oil – based concentrates)
 - ❑ Different and stronger intoxicating effect as smoking / vaping
- ❑ Oral (edibles, juice / tea, oils, capsules, tinctures, lozenges)
 - ❑ Does not produce effect for 30 minutes to 2 hours; high lasts 5 to 8 hours
- ❑ Application on Skin (Topicals)
 - ❑ Variable time for effect; only local effects
- ❑ Oromucosal (spray)
 - ❑ Maximum effect 15 – 45 minutes; 6 -8 hour duration

Medical Marijuana

THC versus Cannabidiol (CBD)

- ❑ Anti seizure effects
- ❑ Neuroprotective and Anti – Inflammatory Effects
- ❑ Analgesic Effects
- ❑ Anti – Tumor Effects
- ❑ Anti – Anxiety Effects
- ❑ Anti Psychotic Effects
- ❑ Non psychoactive
- ❑ No receptors in the brainstem

The Health Effects of Cannabis & Cannabinoids: The Current State of Evidence & Recommendations for Research 2017

The National Academies of Science, Engineering and Medicine (NASEM, 2017)



Weight of Evidence Categories (NASEM 2017)

- ❑ Conclusive Evidence
- ❑ Substantial Evidence
- ❑ Moderate Evidence
- ❑ Limited Evidence
- ❑ No or Insufficient Evidence

Health Topics & Prioritized Health Endpoints: Therapeutic Effects (NASEM 2017)

- ❑ Chronic Pain
- ❑ Cancer
- ❑ Chemotherapy – induced nausea / vomiting
- ❑ Anorexia and Weight Loss
- ❑ Irritable Bowel Syndrome
- ❑ Epilepsy
- ❑ Spasticity related to SCI or MS, Tourette Syndrome
- ❑ ALS
- ❑ Huntington's Disease
- ❑ Parkinson's disease
- ❑ Dystonia
- ❑ Dementia
- ❑ Glaucoma
- ❑ TBI
- ❑ Addiction

Therapeutic Effects (NASEM, 2017)

Chronic Pain

- There is **substantial evidence** that cannabis is an effective treatment for chronic pain in adults

Epilepsy

- There is **insufficient evidence** to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy

Therapeutic Effects (NASEM, 2017)

Spasticity Associated with Multiple Sclerosis or Spinal Cord Injury

- There is **substantial evidence** that oral cannabinoids are an effective treatment for the improving patient – reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician – measured spasticity.
- There is **insufficient evidence** to support or refute the conclusion that cannabinoids are an effective treatment for spasticity in patients in paralysis due to spinal cord injury.

Traumatic Brain Injury / Intracranial Hemorrhage

- There is **limited evidence** of a statistical association between cannabinoids and better outcomes (i.e. mortality, disability) after a traumatic brain injury or intracranial hemorrhage.

Therapeutic Effects (NASEM, 2017)

Anxiety:

- There is **limited evidence** that cannabidiol is an effective treatment for the improvement of anxiety symptoms as assessed by a public speaking test, in individuals with social anxiety disorders

Depression:

- There is **limited evidence** that nabiximol, dronabinol and nabilone are ineffective treatments for the reduction of depressive symptoms in individuals with chronic pain or multiple sclerosis

Therapeutic Effects (NASEM, 2017)

Sleep Outcomes:

- There is **moderate evidence** that cannabinoids, primarily nabiximols, are an effective treatment to improve short – term sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain and multiple sclerosis

PTSD:

- There is **limited evidence** (a single, small fair quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder.

Health Topics & Prioritized Health Endpoints: Risk Factors (NASEM, 2017)

- ❑ Cancer
- ❑ Cardiometabolic Risk
- ❑ Respiratory disease
- ❑ Immunity
- ❑ Injury and Death
- ❑ Prenatal, Perinatal and Postnatal Exposure to Cannabis
- ❑ Psychosocial – Cognition, Employment and Social Functioning
- ❑ Mental Health – Schizophrenia, Bipolar Disorder, Depressive and Anxiety Disorder, Suicide
- ❑ Problem Cannabis Use
- ❑ Cannabis Use and Abuse of Other Substances

Risk Factors: PsychoSocial (NASEM, 2017)

Cognition, Employment and Social Functioning

- ❑ There is **moderate evidence** of a statistical association between acute cannabis use and impairment in cognitive domains of learning, memory and attention
- ❑ There is **limited evidence** of a statistical association between sustained abstinence from cannabis use and impairments in the cognitive domains of learning, memory and attention
- ❑ There is **limited evidence** of a statistical association between cannabis use and impaired academic achievement and education outcomes
- ❑ There is **limited evidence** of a statistical association between cannabis use and increased rates of unemployment and / low income
- ❑ There is **limited evidence** of a statistical association between cannabis use and impaired social functioning or engagement in developmentally appropriate social roles

Risk Factors: Mental Health (Schizophrenia) (NASEM, 2017)

Is There an Association between Cannabis use and the Development of Schizophrenia and Other Psychosis?

- There is **substantial evidence** of a statistical association between cannabis use and the development of schizophrenia and other psychoses, with the highest risk among the most frequent users

Is there an Association between Cannabis Use and the Course or Symptoms of Schizophrenia or Other Psychoses?

- There is **moderate evidence** that among individuals with psychotic disorders, there is a statistical association between a history of cannabis use and better cognitive performance
- There is **limited evidence** of a statistical association between cannabis use and an increase in positive symptoms of schizophrenia (e.g. hallucinations) among individuals with psychotic disorders.
- There is **moderate evidence** for no statistical association between cannabis use and worsening of negative symptoms of schizophrenia (e.g. blunted affect) among individuals with psychotic disorders.

Risk Factors: Mental Health (Bipolar Disorder)

Is There an Association between Cannabis Use and the Development of Bipolar Disorder or Mania?

- There is **limited evidence** of a statistical association between cannabis use and the likelihood of developing a bipolar disorder, particularly among regular or daily users.

Is There an Association Between Cannabis Use and the Course or Symptoms of Bipolar Disorder?

- There is **moderate evidence** of a statistical association between regular cannabis use and increase symptoms of mania and hypomania in individuals diagnosed with bipolar disorders.

Risk Factors: Mental Health (Depressive Disorder)

Is There an Association Between Cannabis Use and the Development of Depressive Disorders or Symptoms?

- There is **moderate evidence** of a statistical association between cannabis use and a small increased risk for the development of depressive disorders.

Is There an Association Between Cannabis Use and the Course or Symptoms of Depressive Disorder?

- There is **no evidence** to support or refute a statistical association between cannabis use and changes in the course or symptoms of depressive disorders.

Risk Factors: Mental Health (Anxiety Disorders)

Is There an Association Between Cannabis Use and the Development of Anxiety Disorders?

- ❑ There is **limited evidence** of a statistical association between cannabis use and the development of any type of anxiety disorder, except social anxiety disorder.
- ❑ There is **moderate evidence** of a statistical association between regular cannabis use and increased incidence of social anxiety disorder.

Is There an Association Between Cannabis Use and the Course or Symptoms of Anxiety Disorders?

- ❑ There is **limited evidence** of a statistical association between near daily cannabis use and increased symptoms of anxiety.

Risk Factors: Mental Health (Suicide)

Is There an Association Between Cannabis Use and Suicidal Ideation, Suicide Attempts, and Suicide?

- ❑ There is **moderate evidence** of a statistical association between cannabis use and increased incidence of suicidal ideation and suicide attempts, with a higher incidence among heavier users.
- ❑ There is **moderate evidence** of a statistical association between cannabis use and increased incidence of suicide completion.

Pennsylvania Medical Marijuana Program

- ❑ Signed into law on April 17, 2016
- ❑ Serious medical condition
- ❑ Certified by an approved physician
- ❑ Patients must be registered
- ❑ Caregivers approved to deliver medical marijuana to patients
- ❑ Approved marijuana dispensary
- ❑ Approved forms of medical marijuana



Pennsylvania Medical Marijuana Program

Serious Medical Conditions

- ❑ Amyotrophic Lateral Sclerosis
- ❑ Autism
- ❑ Cancer including remission therapy
- ❑ Crohn's Disease
- ❑ Damage to the nervous tissue of the central nervous system (brain – spinal cord) with objective neurological indication of intractable spasticity and other associated neuropathies
- ❑ Dyskinetic and spastic movement disorders
- ❑ Epilepsy
- ❑ Glaucoma
- ❑ HIV / Aids
- ❑ Huntington's Disease
- ❑ Inflammatory Bowel Disease
- ❑ Intractable Seizures
- ❑ Multiple Sclerosis
- ❑ Neurodegenerative Diseases
- ❑ Neuropathies
- ❑ Opioid Use Disorder for which conventional therapeutic interventions are contradicted or ineffective, for which adjunctive therapy is indicated in combination with primary therapeutic interventions
- ❑ Parkinson's Disease
- ❑ Post-Traumatic Stress Disorder
- ❑ Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain
- ❑ Sickle Cell Anemia
- ❑ Terminal Illness

Healthcare Facilities Policy: PA

(Richard Holzworth, Fox Rothschild LLP, March 2018)

- ❑ Healthcare administrators must remember that Medical Marijuana, despite being legal in PA is still classified by the federal government as a Schedule 1 Controlled Substance
- ❑ Laws vary from state to state so that hospitals and healthcare associations have developed and implemented a wide range of policies addressing the use and possession of medical marijuana products
- ❑ Policies range from strict prohibitions to sanctioned self-therapy during hospital admission
- ❑ Looked at examples from other states (Washington, Minnesota)

Healthcare Facilities Policy: PA

- ❓ The Medical Marijuana Act enables qualified patients to designate a “caregiver” who is registered with the Department of Health to purchase, transport, and administer medical marijuana products.
- ❓ Therefore hospitals and other residential facilities could permit a caregiver to possess and administer medical marijuana to a patient then remove the unused product from the premises
- ❓ Samples from the Washington Health Care Association for use with long term care facilities that outlines a protocol very similar to Pennsylvania Department of Health’s guidance for school districts.



Washington Health Care Association

- ❑ Washington policy requires each patient to designate a provider who will bring the medical marijuana product into the facility, administer the medication and then remove the unused product.
- ❑ Policy also states that staff will not assist patients in obtaining or using medical marijuana, store medical marijuana or ensure medical marijuana is being used appropriately.
- ❑ Staff involvement is to be limited to confirming a patient's status as a medical marijuana user and that the use of medical marijuana does not impact any other residents.
- ❑ Failure to follow the policy, the facility reserves the right to enforce appropriate consequences including discharge from the facility.

The health care practitioner may only continue medical cannabis as a patient's home medication if:

- ❑ The patient has their own supply
- ❑ The patient's condition warrants continuation of medical cannabis
- ❑ The reason for admission is not due to adverse event from medical cannabis
- ❑ The health care practitioner and designated hospital personnel are able to verify that the patient is currently enrolled in the registry program and the supply is from a licensed distributor
- ❑ Medical cannabis from states other than state of current residence are considered as contraband and should follow the same policy for securing unauthorized drugs

Documentation/Administration & Storage

- ❓ The provider will determine if medical cannabis is necessary to continue use while hospitalized and authorize continuation of self – directed therapy
- ❓ Questions or concerns with medical cannabis should be directed to the manufacturer's dispensary
- ❓ Medical cannabis will be administered by the patient or registered designated caregiver per labeled instructions by the dispensary
- ❓ Medical cannabis will not be left unsecured at any time. The medical cannabis will be stored securely in the patient's room or designated area as defined by the hospital via locked box, safe or with a registered caregiver (on their person).
- ❓ Nurses and other health care professionals will not retrieve medical cannabis from storage or administer / observe administration of medical cannabis
- ❓ Documentation of medical cannabis administration will not be required in the medical record

Discharge from Facility

- ❑ Upon discharge the remaining medical cannabis will be removed by the patient or registered designated caregiver
- ❑ The provider is not obligated to address the ongoing use of medical cannabis at the time of discharge
- ❑ Consider having the patient or registered designated caregiver sign an acknowledgment / waiver indicating acceptance of full responsibility for storage and administration of the medical cannabis while hospitalized.

Policy and Procedure Recommendations

(Michael Hynam, Esq., Hynam Law 2017)

- ❑ Consult state survey agency
- ❑ Consult state Departments of Health and DEA
- ❑ Obtain consent from resident, POA or guardian
- ❑ Consult competent legal counsel
- ❑ Review guidance from professional organizations
- ❑ Develop and implement appropriate policies and procedures
- ❑ Adopt appropriate guidelines
- ❑ Involve compliance and ethics programs
- ❑ Consult insurance carrier / broker
- ❑ Enroll in list services

Practical Implications for Rehab

An Introduction to Medical Cannabis and OT, Alison Bell, January 2019

- ❑ Rehab practitioners should provide education about medical cannabis (refer specific questions back to physician)

- ❑ Acknowledge that acute cannabis use:
 - ❑ Impairs balance – evaluate for falls risk / falls prevention
 - ❑ Impairs cognition – evaluate for impact on cognition and mood
 - ❑ Impacts tone – be prepared to assess and manage changes in tone

Practical Implications for Rehab

An Introduction to Medical Cannabis and OT, Alison Bell, January 2019

Clinicians should consider:

- ❑ Schedule treatment outside of acute use
- ❑ Counsel medical cannabis users to avoid driving for four hours after inhalation and six hours after ingestion
- ❑ Development of activity patterns that account for medication schedules
- ❑ Because cannabis can increase blood pressure and heart rate advise users to monitor their vital signs during exercise
- ❑ Counseling patients about possible risk for return to work and having a positive drug screen results
- ❑ Counseling patients that qualification for federal housing is subject to federal laws (Section 8 housing is a federal program). Applicants may be disqualified for marijuana use.

Considerations for Treatment

(Medical Marijuana In Neurology, 2014)

- ❑ Medical marijuana should be available for the most refractory patients.
- ❑ Until we have more and better data, medical marijuana should be only considered after more standard and proven treatments have been exhausted
- ❑ Medical marijuana should not be offered out of order to patients who are not compliant with or want to bypass standard treatments



Conclusion:

Where we are now:

- ❑ Advancing approval for medical and recreational marijuana
- ❑ Continued limitations in research to confirm use efficacy, effective dosing and subsequent distribution methods
- ❑ Challenge of incorporating medical marijuana into treatment plans within current state and federal guidelines.

Where we are heading:

- ❑ Decriminalization of marijuana with further steps toward legalization at a state level and federal level
- ❑ Changing marijuana from a schedule I drug to a schedule II or III so that research can be done
- ❑ Formalization of marijuana as a medication that is FDA approved and can be dispensed by pharmacies as prescribed by physicians
- ❑ Coverage under health insurance plans

Thank you!

Medical Marijuana & TBI:

Where Have We Been,
Where Are We Now, and
Where Are We Heading?

Scott Peters, MS, OTR/L
