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Senate Public Health and Welfare
March 14, 2019

SB113 - Neutral

Chairman Sullentrop and Committee Members:

I am Cindy Luxem, President and CEO of the Kansas Health Care Association and the Kansas Center for Assisted Living. KHCA and KCAL represent the interests of Kansans long term care (LTC) providers- nonprofit and proprietary. Skilled Nursing (SNF), Assisted Living (AL), Home Plus (HP) Residential Care (RCF), Nursing Facilities for Mental Health (NFMH) and Home and Community Based Services (HCBS) make up our membership. We are considered a federation so we have affiliates in all fifty states with the American Health Care Association being our main group. Former Governor Mark Parkinson is the CEO of AHCA. Our members care for nearly 20,000 elders across the state each and every day. The communities that care for these elders employ almost 30,000 Kansans.

We would like to submit neutral testimony for SB113 and we want you to know how important that we think it is for this hearing to be held. As healthcare providers and consumers alike, we must continue to use every resource available to seek a solution to the opioid crisis. Our members who provide elder services are looking for alternatives to anti-psychotic medications which can have such devastating side-affects.

The time is now to discuss how Kansas wants to implement medical cannabis. There are so many Kansans who might benefit if appropriate trials and studies were conducted. Take for example veterans, this very important group of individuals who are addressed in SB 113. They deserve to have every resource, every stone turned to find treatment. However, they are not the only ones. Today we would like to draw your attention to another group who have benefited from a controlled study on medical cannabis - individuals in skilled nursing facilities in New York. In a 2018 article from AMDA (American Medical Directors Association) - The Society for Post-Acute and Long-Term Care Medicine, a study was highlighted which looked at medical cannabis as a means for improving symptom management and quality of life. Results were promising with participants reporting an improvement in pain complaints of 30% greater compared to the placebo group. The most promising result from this study was that it was actually put into trials with the cohort group it was meant to help - the elderly. When was the last time you saw a drug trial looking for participants over 60?

Please as you consider SB 113, remember HB 2303, Kansas Safe access so that Kansans as a whole could benefit from medical cannabis and be a part of the discussion. Medical cannabis is said to improve quality of life. Please continue the discussion and keep the door open for Kansans to benefit from an opioids and anti-psychotic alternative.

Cindy Luxem

Pragmatic Innovations in Post-Acute and Long-Term Care Medicine
Feasible new, practical products or approaches intended to improve outcomes or processes in post-acute or long-term care

Medical Cannabis in the Skilled Nursing Facility: A Novel Approach to Improving Symptom Management and Quality of Life

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Hebrew Home at Riverdale, Bronx, NY

ABSTRACT

Throughout the millennia, the cannabis plant has been utilized as a recognized therapy for pain relief and symptom management. Following the Prohibition-era stigmatization and criminalization of all forms of cannabis of the early 20th century, there has been a recent nationwide and worldwide resurgence in interest and use of the cannabinoid compounds extracted from the cannabis plant, that is, medical cannabis. Although at the Federal level, cannabis remains a Schedule I substance, 31 states have already decriminalized possession and use of medical cannabis for specific diagnoses. It is noteworthy that many of these indicated diagnoses are prevalent in the skilled nursing facility (SNF). This creates regulatory concerns as SNFs and other healthcare facilities must maintain compliance with Federal laws, while balancing the individual resident's rights to utilize medical cannabis where indicated. The authors developed an innovative program that affords their residents the ability to participate in a state-approved medical cannabis program while remaining compliant with Federal law. As medical cannabis use becomes more widespread and accepted, clinicians providing medical care in healthcare facilities will encounter residents who may benefit from and request this alternative therapy. Studies examining older adults that are utilizing medical cannabis legally have demonstrated significant decreases in prescription medication use, most notably a reduction in opioid analgesic usage. As such, medical cannabis should be viewed as an additional option in the clinician's toolbox of therapeutic interventions for symptom relief.

Keywords: Medical cannabis, medical marijuana, alternative medicine, skilled nursing facility, symptom management

Problem/Significance

An essential principle in the practice of geriatric medicine in the skilled nursing facility (SNF) is the need for ongoing drug regimen review, with a keen focus of attention on simplifying medication regimens, avoiding polypharmacy, and eliminating medications with potentially harmful side effect profiles. As in general outpatient practice, clinicians practicing in the SNF have traditionally considered options for symptom management based on currently available Food and Drug Administration (FDA)—approved over-the-counter and prescription medications. In recent years, however, there has been a significant nationwide resurgence in the use of cannabis as a medical therapy. In fact, to date, 31 states in the US have now approved the use of medical cannabis for a variety of chronic conditions. Given the fact that cannabis remains a Schedule I controlled substance, what role, if any, does medical cannabis play in the SNF?

To begin to answer this question, historical records dating back to China (2700 BC), India (1400 BC), and ancient Greece (77 CE) describe the widespread therapeutic use of the cannabis plant for pain, inflammation, and spasticity.[1] In 1850, cannabis extract was added to the United States Pharmacopeia. During the second half of the 19th century, medical use of cannabis became a commonly prescribed remedy, well documented in the medical literature for the treatment of rheumatic pain, spasm, seizure, emesis, and neuralgia. In 1915, Sir William Osler, the father of modern medicine, describes cannabis as the "most satisfactory remedy" for migraine.[2]

Despite the role that medical cannabis held as a botanical therapy with a documented history supporting its use for symptom management, therapeutic use of cannabis ceased during the early 20th century. Prohibition-era social and political factors in the United States led to a significant national stigma associated with cannabis use for both medicinal and recreational purposes. The passage of the Marihuana Tax Act of 1937 as well as subsequent legislation resulted in the criminalization of possession and/or use of cannabis for any purpose. The Controlled Substances Act of 1970 categorized cannabis as a Schedule I drug, labeling it as a substance with no currently accepted medical use and with high potential for abuse.

During the 1990s, the discovery of the primary endogenous cannabinoids arachidonoylethanolamine and 2-arachidonoylglycerol and their corresponding CB1 and CB2 receptor sites both in the central nervous system and peripherally led to a major resurgence of interest in the therapeutic benefits of cannabis. Since the legalization of medical cannabis in the state of California in 1996, 30 additional states and the District of Columbia have passed similar legislation legalizing medical cannabis use. Nevertheless, cannabis possession and administration continue to remain illegal at the Federal level, given its continued status as a Schedule I controlled substance. As a recipient of Medicare and Medicaid funding, SNFs are required to remain in compliance with Federal law. As such, neither can the SNF purchase and store medical cannabis nor can facility nursing staff administer it to residents, as is common practice for all other medications and treatments.

The authors declare no conflicts of interest.

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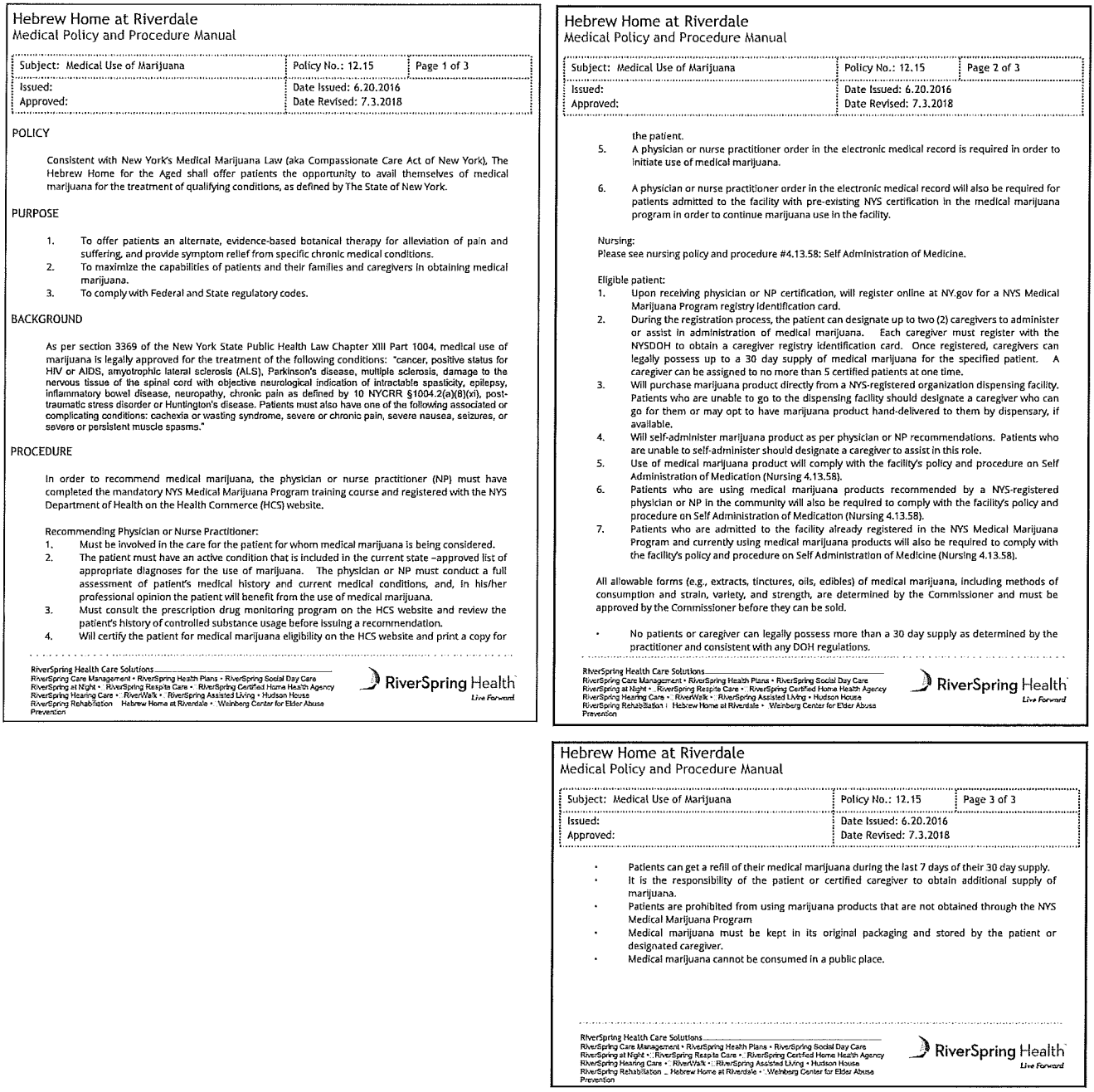
Innovation

In 2016, the Compassionate Care Act of New York legalized medical cannabis in New York State for patients with the diagnoses of cancer, HIV, AIDS, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, Huntington's disease, spinal cord damage with neurologic sequelae, as well as seizure disorder, inflammatory bowel disease, neuropathy, and chronic pain. In 2018, opioid use and post-traumatic stress disorder were also added as qualifying conditions. Although some variability does exist from state to state, these approved conditions are similar in most states in which medical cannabis has been legalized. We recognized the high prevalence rates of these chronic conditions, especially chronic pain, neuropathy, and Parkinson's disease, in the nursing home population. Appreciating the potential role that an alternative therapy such as cannabis may play, we sought to create a program at our facility that would afford our residents the ability to legally obtain and utilize medical cannabis for symptom management within the SNF.

Implementation

We composed and implemented a medical policy and procedure (Figure 1) at our SNF for the safe use and administration of this plant-based therapy for residents with a qualifying diagnosis. In order to avoid violation of Federal laws, our policy requires that residents participating in the NYS Medical Marijuana program must purchase their own cannabis product directly from a state-certified dispensary. The facility provides an individualized lockbox to each resident for



Hebrew Home at Riverdale
Medical Policy and Procedure Manual

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POLICY

Consistent with New York's Medical Marijuana Law (aka Compassionate Care Act of New York), The Hebrew Home for the Aged shall offer patients the opportunity to avail themselves of medical marijuana for the treatment of qualifying conditions, as defined by The State of New York.

PURPOSE

1. To offer patients an alternate, evidence-based botanical therapy for alleviation of pain and suffering, and provide symptom relief from specific chronic medical conditions.
2. To maximize the capabilities of patients and their families and caregivers in obtaining medical marijuana.
3. To comply with Federal and State regulatory codes.

BACKGROUND

As per section 3369 of the New York State Public Health Law Chapter XIII Part 1004, medical use of marijuana is legally approved for the treatment of the following conditions: "cancer, positive status for HIV or AIDS, amyotrophic lateral sclerosis (ALS), Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathy, chronic pain as defined by 10 NYCRR §1004.2(a)(8)(xi), post-traumatic stress disorder or Huntington's disease. Patients must also have one of the following associated or complicating conditions: cachexia or wasting syndrome, severe or chronic pain, severe nausea, seizures, or severe or persistent muscle spasms."

PROCEDURE

In order to recommend medical marijuana, the physician or nurse practitioner (NP) must have completed the mandatory NYS Medical Marijuana Program training course and registered with the NYS Department of Health on the Health Commerce (HCS) website.

Recommending Physician or Nurse Practitioner:

1. Must be involved in the care for the patient for whom medical marijuana is being considered.
2. The patient must have an active condition that is included in the current state –approved list of appropriate diagnoses for the use of marijuana. The physician or NP must conduct a full assessment of patient's medical history and current medical conditions, and, in his/her professional opinion the patient will benefit from the use of medical marijuana.
3. Must consult the prescription drug monitoring program on the HCS website and review the patient's history of controlled substance usage before issuing a recommendation.
4. Will certify the patient for medical marijuana eligibility on the HCS website and print a copy for

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the patient.

5. A physician or nurse practitioner order in the electronic medical record is required in order to initiate use of medical marijuana.
6. A physician or nurse practitioner order in the electronic medical record will also be required for patients admitted to the facility with pre-existing NYS certification in the medical marijuana program in order to continue marijuana use in the facility.

Nursing:
Please see nursing policy and procedure #4.13.58: Self Administration of Medicine.

Eligible patient:

1. Upon receiving physician or NP certification, will register online at NY.gov for a NYS Medical Marijuana Program registry identification card.
2. During the registration process, the patient can designate up to two (2) caregivers to administer or assist in administration of medical marijuana. Each caregiver must register with the NYSDOH to obtain a caregiver registry identification card. Once registered, caregivers can legally possess up to a 30 day supply of medical marijuana for the specified patient. A caregiver can be assigned to no more than 5 certified patients at one time.
3. Will purchase marijuana product directly from a NYS-registered organization dispensing facility. Patients who are unable to go to the dispensing facility should designate a caregiver who can go for them or may opt to have marijuana product hand-delivered to them by dispensary, if available.
4. Will self-administer marijuana product as per physician or NP recommendations. Patients who are unable to self-administer should designate a caregiver to assist in this role.
5. Use of medical marijuana product will comply with the facility's policy and procedure on Self Administration of Medication (Nursing 4.13.58).
6. Patients who are using medical marijuana products recommended by a NYS-registered physician or NP in the community will also be required to comply with the facility's policy and procedure on Self Administration of Medication (Nursing 4.13.58).
7. Patients who are admitted to the facility already registered in the NYS Medical Marijuana Program and currently using medical marijuana products will also be required to comply with the facility's policy and procedure on Self Administration of Medicine (Nursing 4.13.58).

All allowable forms (e.g., extracts, tinctures, oils, edibles) of medical marijuana, including methods of consumption and strain, variety, and strength, are determined by the Commissioner and must be approved by the Commissioner before they can be sold.

- No patients or caregiver can legally possess more than a 30 day supply as determined by the practitioner and consistent with any DOH regulations.

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- Patients can get a refill of their medical marijuana during the last 7 days of their 30 day supply.
- It is the responsibility of the patient or certified caregiver to obtain additional supply of marijuana.
- Patients are prohibited from using marijuana products that are not obtained through the NYS Medical Marijuana Program
- Medical marijuana must be kept in its original packaging and stored by the patient or designated caregiver.
- Medical marijuana cannot be consumed in a public place.

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Fig. 1. Hebrew Home at Riverdale policy and procedure on medical cannabis. A downloadable PDF of this form is available at www.sciencedirect.com.

Hebrew Home at Riverdale

riverspringhealth.org

October 17, 2018

Dear Family member,

We want to make you aware that the Hebrew Home at Riverdale has a program in place that enables residents with the following medical conditions to participate in the NYS Medical Marijuana Program:

Pain (chronic or acute)
Neuropathy
Seizures
Inflammatory bowel disease
Post-traumatic stress disorder
Huntington's disease
HIV/AIDS
Amyotrophic lateral sclerosis (ALS)
Parkinson's disease
Multiple sclerosis

At present, Medicare and private insurance carriers do not cover the cost of medical marijuana. The average monthly cost is approximately $200 per month.

Also important to note -- patients/families are responsible to obtain medical marijuana on their own and to self-administer it. Residents may designate up to two caregivers to be responsible to assist them in administering medical marijuana.

For more information or to find out if your family member qualifies for this program, please contact my office at 718-581-1200.

Thank you.

Cordially,

Zachary Palace MD

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Medical Director

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Fig. 2. Medical cannabis fact sheet for families.

secure cannabis storage. In addition, the policy stipulates that residents must be able to self-administer the medical cannabis or may designate a caregiver who is not a staff member to do so, thus avoiding concerns of facility involvement in the administration of a Schedule I drug.

Shortly after our program began in 2016, we provided educational sessions to residents that focused on dispelling myths about medical cannabis and viewing it as a therapeutic modality for symptom management. A medical cannabis fact sheet was distributed and is made available to family members (Figure 2) for additional information. In our experience, residents were eager to learn more about medical cannabis and were enthusiastic at the prospect of reducing or eliminating other medications that they were currently receiving. The most common concerns expressed were related to strongly held negative views about marijuana, based largely on personal observations or experiences associated with recreational usage.

Evaluation

As our facility has a no-smoking policy, which includes electronic cigarettes, cannabis administration is limited to capsule form or via orally administered cannabis oil drops. To date, a total of 10 residents have participated in our facility's program (Table 1). Seven residents have been receiving medical cannabis for more than 1 year. Residents range in age from 62 to 100. Six residents qualified because of a diagnosis of chronic pain, 2 residents qualified because of Parkinson's disease, and 1 patient as a result of both diagnoses. One resident is participating in the program for seizure disorder. Three residents have since withdrawn from the program because of financial constraints. As medical cannabis is not covered by Medicare or other health insurers, residents are financially responsible for the costs of medical cannabis. Out-of-pocket expense is also cited as a factor limiting other eligible residents from participating in the program.

Following initiation of medical cannabis therapy, residents have been informally interviewed periodically for comments and feedback regarding their experiences. Most residents receiving cannabis for pain have commented on sustained improvement in chronic pain severity, resulting in reductions of opioid dosage and an improved sense of well-being. Both residents receiving cannabis for Parkinson's disease reported mild improvement with rigidity complaints. The family of an 83-year-old female resident with severe Alzheimer's disease and seizure disorder requested that the resident be referred for cannabis therapy for management of breakthrough seizures occurring twice weekly. Since the addition of medical cannabis, there has been a marked reduction in seizure activity, which now averages 1 to 2 episodes per month without any other change in her medication regimen.

Comment

A meta-analysis evaluating medical cannabis in 27 placebo-controlled randomized clinical trials demonstrated results supporting an improvement in pain complaints of 30% or greater, compared with placebo. An analysis of 14 placebo-controlled trials also suggested improvements in spasticity due to multiple sclerosis or paraplegia. Results of the individual studies, however, did not reach statistical significance.[3] In a systematic review of randomized controlled trials of patients using medical cannabis as an adjunct to opioid therapy for chronic noncancer pain, statistically significant reductions in self-reported pain were observed. This review also found a greater incidence of neurocognitive side effects, poor concentration, and sedation that correlated with higher concentrations of delta-9-tetrahydrocannabinol (THC).[4]

Opponents of medical cannabis may argue that the common adverse events associated with cannabis use, including dizziness and confusion, should be a cause for major concern in a population where falls, altered mental status, and disorientation are prevalent. Of the many cannabinoids isolated from the cannabis plant, THC is responsible for the psychoactive effects of cannabis use and the potential for abuse when ingested in higher concentrations. Cannabidiol (CBD), the other primary cannabinoid in the cannabis plant, does not have psychoactive properties. Of note, however, is that medical-grade cannabis preparations are available that contain a standardized dose of CBD with little or no THC, thus putatively eliminating these deleterious effects in the elderly nursing home population, and improving its safety profile. We believe clinicians can safely recommend these products for the treatment of complaints common in the SNF, including chronic pain, inflammation, spasticity, and seizures.

In fact, a recent study of medical cannabis use in the elderly population demonstrated a low rate of discontinuation due to side effects and adverse events. The study also revealed significant reductions in the intensity of self-reported pain and clinically significant improvement in overall quality of life.[5] Another recent study found that initiation of medical cannabis use was associated with reductions in pain complaints, resulting in subsequent opioid dose reduction and discontinuation.[6] Access to medical cannabis has also been associated with significantly lower opioid overdose mortality rates.[7] A large multistate retrospective study of Medicare beneficiaries demonstrated large reductions in prescription drug use across states in which medical cannabis laws were implemented.[8]

It is important that 20th-century social and political stigmata associated with cannabis use for recreational purposes not be attached to the application of cannabis use for medicinal purposes. The potential for therapeutic benefit associated with medical cannabis use should be viewed as an important additional tool in the clinician's armamentarium of therapeutic options in the symptom management of many common nursing facility complaints. Much like every decision in medicine, the clinician must always weigh the risks and benefits of any clinical intervention. From a geriatric perspective, the principle of "start low and go slow" should always be followed, as is the case with the initiation of any new treatment. These are historic times as the tides of cannabis acceptance are shifting. Clinicians

Table 1
Resident Comments/Observations

Age	Gender	Indication	Resident Comments/Observations
71	Male	Pain	Less discomfort, coming out of room more
100	Female	Pain	Improved appetite, reduced opioid dose by 50%
62	Male	Pain	Participating more in activities
82	Female	Parkinson's disease	Minimal effect
86	Female	Pain	Improved sense of well-being, reduced opioid dose by 50%
88	Male	Parkinson's disease/pain	Mild improvement in pain
86	Female	Seizure	Resident nonverbal due to advanced dementia. Staff observing significant reduction in seizures.
88	Female	Pain	Feels better overall
79	Female	Parkinson's disease	Mild reduction in stiffness
80	Female	Pain	Pain improved, opioid changed to prn

should consider the wealth of historical experience as well as the results of more recent and contemporary research and appreciate the potential role of this novel, yet centuries old, alternative therapy.

Supplementary Data

Supplementary data related to this article can be found online at 10.1016/j.jamda.2018.11.013.

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The pragmatic innovation described in this article may need to be modified for use by others; in addition, strong evidence does not yet exist regarding efficacy or effectiveness. Therefore, successful implementation and outcomes cannot be assured. When necessary, administrative and legal review conducted with due diligence may be appropriate before implementing a pragmatic innovation.