PAIN MANAGEMENT: A FLOWSHEET FOR PROVIDERS

A Scholarly Project

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree

Of Doctor of Nursing Practice

by

Lisa Marianne Swezey

Liberty University

Lynchburg, VA

August 2018

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ABSTRACT

Many different factors led to the trend of providers prescribing opioids for chronic pain. However, the misuse of and many deaths related to opioid prescriptions have caused the trend to reverse its direction. National organizations call for providers to stay clear of opioid medication and increase the use of nonpharmacological pain management, but also to treat pain adequately. There are still many barriers to decreasing the use of opioids and increasing the use of nonpharmacological methods. This scholarly project hoped to use an educational flowsheet to assist providers in meeting the demands from national organizations to decrease the use of pain medications and patients to treat pain adequately.

Keywords: pain management, opioids, nonpharmacological management, pain flowsheet,

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List of Abbreviations

Centers for Disease Control and Prevention (CDC)

Department of Health and Human Services (HSS)

Institute of Medicine (IOM)

Nonsteroidal anti-inflammatory drugs (NSAIDs)

Prescription drug monitoring program (PDMP)

The National Academy of Medicine (NAM)

Transcutaneous electrical nerve stimulation (TENS)

Disease modifying antirheumatic drugs (DMARDs)

INTRODUCTION

All practicing nurses and providers will most likely encounter a patient with some form of pain. Pain usually occurs as a natural response to alert a person to real or possible injury to the body as a protective mechanism (Buttaro, Trybulski, Polgar-Bailey, & Sandberg-Cook, 2017). One definition of chronic pain is pain that lasts longer than three months or pain that is no longer in response to real or possible injury to the body (Buttaro et al., 2017). Many explanations currently trend to defining pain as a subjective feeling different to each person and situation. While acute pain (pain lasting less than three months) is not as complicated to deal with, current trends have made the treatment of chronic pain more difficult.

Current trends that make the treatment of chronic pain more difficult include the disparities between the former, customary treatment of pain and the new, nationally recommended treatment of pain. The mainstay treatment of chronic pain for many years was prescription opioid medications, including oxycodone, morphine, codeine, hydromorphone, meperidine, fentanyl, and methadone (Schreier, 2014). The misuse of opioids led national organizations to change guidelines for all providers in treatment of chronic pain.

People live in chronic pain and control of that pain is important, as it can affect quality of life. This scholarly project attempted to guide provider practice in a clinical setting in treatment of chronic pain through an evidenced-based flowsheet and provider education (Appendix A) on nonpharmacological methods to manage chronic pain.

Background

As with many health care issues, the issue of new guidelines to combat misuse of opioid medications is multifaceted. The issue began with the realization that prescription opioid medications cause harm. According to the Centers for Disease Control and Prevention (CDC),

between the years 1999 and 2015 about 183,000 Americans died from an overdose of a prescription opioid medication (CDC, 2017). Studies also found that patients sold their opioid prescriptions on the street. About half of all opioid related deaths were caused by an opioid that had been prescribed to the patient (CDC, 2017). In the other cases, the prescription did not belong to the patient. This misuse of narcotics called leaders and national organizations to make changes to national guidelines for the treatment of chronic pain.

This is not a new issue. In 2011, the Department of Health and Human Services (HSS) and the National Institute of Health (NIH) encouraged the Institute of Medicine (IOM) to conduct and publish a study on current knowledge of pain and pain control (IOM, 2011). They also made recommendations for research in response to the epidemic (IOM, 2011). This landmark report defined the issue and gave recommendations for further research. It also expanded their definition of pain from a protective response to a physical threat to a protective response to any threat; physical, psychological, or social (IOM, 2011). This expanded definition served providers and patients better because pain is a subjective experience and cannot always be seen or accurately measured. The IOM recognized the misuse of opioids as a problem but also recognized the importance of adequately treating pain (2011). This includes not only treating the physical pain, as most providers did, but also the psychological and social symptoms that come with it.

Providers do not always treat patients' pain adequately. Low back pain is the leading cause of disability in the world, attaining the number one cause in 12 out of 21 countries (Hoy et al., 2014). Not adequately treating chronic pain can lead to an impaired quality of life, physically and mentally. In fact, patients report decreased levels of sleep with higher reported levels of pain compared to lower levels of pain (Gerhart et al., 2017). It is difficult to state whether the pain

caused decreased levels of sleep or if decreased sleep caused increased pain, but there seems to be a causal relationship between the two. This study stated that patients reported decreased levels of pain related to better sleep (Gerhart et al., 2017). Decreased sleep and decreased functioning can cause a decreased quality of life in patients and may cause them to not participate in daily life. Those who continued to work through chronic pain showed decreased levels of overall pain compared to patients that did not work (Gerhart et al., 2017).

The other aspect of life that chronic pain can impact includes the patients' relationships with others. Those in chronic pain who cannot participate in daily life also cannot build or maintain healthy relationships with others. This is related to the psychological effects of pain as well. Psychological effects of uncontrolled pain include depression, anxiety, decreased self-efficacy, decreased self-esteem, shame, and guilt (Burke, Mathias, & Denson, 2015). While, in some cases, there is a question if the chronic pain caused the psychological side effects or if the psychological history is the cause of the chronic pain, there is no question that the two occur simultaneously. Patients living in chronic pain consistently report feeling as though they had little control over their pain (Burke, Mathias, & Denson, 2015). Those who focused intensely on their pain demonstrate less effective coping strategies (Shreier, 2014).

Challenges to the adequate treatment of chronic pain come from every angle: national organizations, providers, patients, and other stakeholders. National organizations call for a complete overhaul of the way providers treat chronic pain but are not considering perceptions of the patients (Anson, 2016). Patients feel that their pain is treated inadequately and that providers do not understand the experience of chronic pain.

Providers contribute to the issue through bias and knowledge deficit. Many providers show bias towards patients who request certain narcotics for their chronic pain (IOM, 2011).

Opioids can be addictive, and when patients come in requesting a specific opioid and/or stating that they are allergic to many other forms of pain medications except one, most providers cannot help but assume the patient is a drug seeker. Part of the bias toward narcotics also comes from administration and national organizations calling for their decreased use and the current research that shows the ineffectiveness of narcotics in the management of chronic pain. With these current trends, many prescribers stay away from prescribing any narcotics at all to protect their licenses.

There is also a significant provider knowledge deficit. Studies show that many medical education programs do not provide adequate education on pain management and contribute to provider bias toward patients in chronic pain (Loeser & Schatman, 2017). Many medical education programs focus on pain as a symptom, but the IOM calls for the treatment of pain as a patient-centered experience (IOM, 2011; Bradshaw et al., 2017). Little has been done in medical education programs to rectify this. The IOM (2011) called for more thorough research into chronic pain management because of the many weaknesses in current research. For example, many providers associate depression with chronic pain. Newer research is showing that it is more common for patients in chronic pain to have symptoms associated with anxiety rather than depression (Burke, Mathias, & Denson, 2015). While similar, the approach to treat anxiety is different than treatment of depression. But this is not commonly known among providers, who are stuck in the middle of this issue. They are called to care for others, and that includes adequately treating patients' pain. However, they also need to follow laws designed to protect both themselves and their patients.

The knowledge deficit also occurs in patients. Across the U.S., 1,000 emergency room visits result from misuse of an opioid prescription, usually from not following provider instructions (CDC, 2017). In a public survey, 97% of patients on chronic opioids stated they

were not addicted to their pain medications and had never needed any formal rehab (Anson, 2016). Yet the CDC states one in four patients who have a long-term opioid prescription from a primary care setting struggle with addiction (CDC, 2017). This indicates a patient knowledge deficit regarding the definition of addiction. This could also indicate a denial in the patient. Also, many patients deny the efficacy of nonpharmacological methods of pain control (Becker et al., 2017). Research supports the efficacy of many nonpharmacological treatments of pain, especially physical therapy for musculoskeletal pain and over-the-counter analgesics for arthritis (Schreier, 2014). There is a lack of knowledge in patients of the many different methods of pain treatment, pharmacological and nonpharmacological.

Other stakeholders include pharmaceutical companies and families of the patients in pain. Drug companies have been known to encourage education on the risks of opioids, but they also fund patient advocacy groups to encourage the use of opioids as a treatment of chronic pain (Loeser & Schatman, 2017). Families are also stakeholders in this issue, as they watch their loved one in pain if not adequately treated.

The changes in national guidelines for opioid prescriptions provides an opportunity to educate patients and primary providers in treatment of chronic pain, specifically nonpharmacological treatments of pain. Many national organizations are developing initiatives and plans toward managing the opioid crisis, but not all clinical areas have fully adopted the recommendations or have only adopted some of the recommendations. The implications of this project for nursing improvement are the development of a standardized treatment plan for chronic pain for a local clinic and to urge this clinic to base all changes in evidenced based practice.

Problem Statement

Because of changes in national guidelines, many clinics and primary care settings need to reevaluate and change their approach to chronic pain management. To maintain an adequate quality of life, patients need adequate treatment of their pain. Patients living with chronic pain experience more emotional stress related to their physical condition than patients who do not (Burke, Mathias, & Denson, 2015). On the other hand, the national misuse of opioids opened this issue to become a national health and safety movement.

This issue needs to be addressed because providers are in the middle of a public health issue from which they receive pressure from patients and national organizations to make a change. In a public survey of 2,000 patients on chronic opioid medications, 75% stated they were not getting adequate relief of pain and 44% stated they also had issues getting their opioid medication from the pharmacy (Anson, 2016). Many national organizations are calling for restriction in opioid prescriptions in the treatment of chronic pain (IOM, 2011). With all this pressure from all sides, providers need to find a middle ground to address every stakeholder's concerns.

Many patients also reported that trust in their provider decreased because providers were telling them that they had to decrease or stop their opioid medication or be released by the practice (Anson, 2016). A positive provider-patient relationship is an integral part of patients' health care outcomes. But this issue of calling for decreasing the use of opioids in chronic pain management is causing a lot of friction between provider and patient (Becker et al., 2017). These issues open up the door to educate patients and providers on the proper use of narcotics and nonpharmacological methods of pain management.

Purpose of the Project

The purpose of this project is to provide a better method for chronic pain management that includes building the patient-provider relationship, education, and balance of pharmacological and nonpharmacological methods. Specifically decreasing the use of narcotics and increasing the use of nonpharmacological methods are chief purposes.

To address this issue, the provider and the patient need education. This project focused on educating providers. Education for the provider focused on development of a productive provider-patient relationship and different methods of nonpharmacological pain management. The education given to the provider included education to provide to the patient. Education for the patient discussed the pathophysiology of chronic pain, self-management techniques, benefits and risks of narcotic use, and the efficacy of nonpharmacological methods of pain management.

Governmental and national agencies attempt to address the opioid epidemic through tightening of opioids, leaving providers and patients at a loss. Providers are at a loss because they are stuck between national recommendations and guidelines. On top of that, they face restrictions from those national organizations, insurances, and pharmacies. Patients because they feel unsupported because their providers are telling them that they cannot prescribe the opioid anymore without offering a full explanation. This project hopes to accomplish a balance between providing support to patients dealing with chronic pain and staying within national recommendations. The significance of this project is that it will attempt to balance national guidelines and adequate treatment of pain through education.

Clinical Question

Would educating providers about different chronic pain management methods decrease pain scores in patients with chronic musculoskeletal pain? The population considered patients

with chronic musculoskeletal pain, ages 21 to 64. The intervention was education directed at the providers of the clinic for themselves and education to provide the patient. The results compared the patient's pain before and after implementation of the provider education. The desired outcomes of this project are increased control of pain and increased provider knowledge and comfort with treating chronic pain. Another desired outcome was the increased patient use of nonpharmacological pain management.

LITERATURE REVIEW

Trends led to an overhaul in the management of chronic pain. In response, national organizations made changes to laws and policies to force providers to change their normal methods of pain management. While the changes are meant to decrease the misuse of opioid medications and protect patients' lives, it leaves providers and patients in a situation that is difficult to navigate. This project will attempt to find a balance and equip providers and patients with tools to adequately manage chronic pain.

Key words used for the initial review of the literature included chronic pain, nonpharmacological pain management, physical effects, psychological effects, patient provider relationship, and pain education, among others. Articles published between 2013 and 2018 remained included in the literature review, except the IOM's report on chronic pain due to its constant use throughout the literature. Databases accessed for this literature review included CINAHL Plus with Full Text, MEDLINE, Healthsource, and articles that allowed for public access.

The IOM's (2011) landmark report, Relieving pain in America: A blueprint for transforming prevention, care, education, and research became the source of the definition of pain and the initial guide for treatment of pain. While it is constantly cited by studies regarding

chronic pain management, its level of evidence from the level of evidence pyramid is 4 because of no controlled randomization and because the report stated that they did not exhaust the literature (IOM, 2011). Their report called for increased provider and patient knowledge, a positive provider-patient relationship, and a public health education approach to the issue misuse of opioids (IOM, 2011). This project attempted to address the first two issues in hope that the education will disseminate to the public.

This literature review addresses current recommendations for pharmacological and nonpharmacological treatment of chronic pain, other treatments of pain including addressing concurrent psychological issues associated with chronic pain, and issues with providers and patients and chronic pain management.

Pharmacological Treatment of Pain

The pharmacological treatment of pain does not only include opioid medications, though that is the major concern. Pharmacological medication classes used to treat pain along with opioid medications include acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDS), anticonvulsants, local anesthetics, and antispasmodics (Shreier, 2014). The choice of medication depends on the patient's pain. Schreier (2014) wrote a continuing education course for pain management (level 5 evidence). It taught that pain management requires multiple modalities of treatment, from opioids and nonopioid medications to nonpharmacological options (Schreier, 2014). Most incidents of chronic pain will require the use of medications. There is no evidence in the literature that only nonpharmacological treatments can be used in treatment of severe acute pain or a severe exacerbation of chronic pain. On the other hand, most sources do not currently recommend daily use of any single medication for pain (opioid or nonopioid) because all have possible adverse effects with long-term use (Shreier, 2014).

One of the national organizations that responded to the opioid epidemic included the CDC. They developed 12 recommendations for safe prescription of opioid medications for chronic pain management, each with their own level of evidence (Dowell, Haegerich, & Chou, 2016). The following levels of evidence come from the CDC. Recommendations for the initiation of opioids include exhausting nonpharmacological and nonopioid treatments before considering opioids (level 3 evidence), establishing pain control goals with the patient before beginning opioid therapy (level 4 evidence), and discussing risks verses benefits of opioid therapy before and periodically after initiation (level 3 evidence) (Dowell, Haegerich, & Chou, 2016). Recommendations for prescribing opioids include prescribing immediate-release opioids over long-acting opioids (level 4 evidence), prescribing the lowest effective dose (level 3 evidence), prescribing medications for acute pain for only seven days at most (level 4 evidence), and following up with patients in one to four weeks to evaluate appropriate dosage (level 4 evidence) (Dowell, Haegerich, & Chou, 2016). To assess risks and address potential harms of opioids, the CDC recommends that providers assess for patient risk factors for abuse (level 4 evidence), review the state prescription drug monitoring program (PDMP) before prescribing opioid (level 4 evidence), use urine drug screenings before prescribing opioid (level 4 evidence), avoid prescribing opioid and benzodiazepines together (level 3 evidence), and follow treatment recommendation for patients that have a known opioid addiction/misuse (level 2 evidence) (Dowell, Haegerich, & Chou, 2016). The clinical site for the project recently implemented a narcotic prescription policy based on these recommendations but did not address other methods of chronic pain control or screening for opioid misuse.

As shown by the level of evidence associated with each recommendation and the concerns from patients mentioned in the background, the CDC recommendations will not solve

the problem. They cover a broad issue that affects many people. It is the same principle with medications prescribed to the patient: one method of pain management will not apply to every patient in chronic pain. Any treatment plan will need to put the patient in the center and adapt evidenced-based interventions to best treat the patient's pain. Overall, reviews by the CDC show no long-term benefit of chronic opioid use, multiple harms associated with opioid use, and benefits to the use of nonpharmacological pain interventions (Dowell, Haegerich, & Chou, 2016). This falls in line with many recommendations to use nonpharmacological methods of chronic pain control over opioids.

Nonpharmacologic Treatment of Pain

Current recommendations push for use of nonpharmacological methods of pain control, despite both patient and provider hesitation (Becker et al., 2017; Dowell, Haegerich, & Chou, 2016). Nonpharmacological methods of pain control include, but are not limited to, exercise, massage therapy, heat and cold therapy, TENS therapy, acupuncture, interventions to improve sleep, coping skills training, mind-body interventions, and cognitive behavioral therapy (Schreier, 2014; NAM, 2017). While many providers are familiar with interventions such as exercise, massage and heat/cold therapy, there is still a knowledge deficit. Exercise therapy is a common method of pain management that has proven efficacy, but it is only talked about as a general way to improve health instead of a way to treat chronic pain (Dowell, Haegerich, & Chou, 2016; Simson et al., 2017). The provider may not consider other methods of pain management because of limited knowledge. Mind-body interventions include yoga, meditation, Tai Chi, and stress reduction (NAM, 2017). Cognitive behavioral therapy techniques include distraction, deep breathing, mindfulness meditation, imagery, hypnosis, music therapy, and biofeedback (Schreier, 2014).

Becker et al. (2017) completed a qualitative study to find barriers perceived by providers and patients for nonpharmacological treatment of chronic pain (level 6 evidence). Barriers to nonpharmacological treatment for chronic pain identified included knowledge deficit, cost, transportation to outpatient therapies, scheduling, and doubt of efficacy of therapies (Becker et al., 2017; Fu et al., 2016). The barrier this project attempted to address is the knowledge deficit in providers.

Other Methods of Pain Management

Many different methods of treatment of chronic pain are available. The issue is that providers do not know about all of them. Other treatments of pain fall under interventional pain therapies. These include non-sympathetic pain procedures, sympathetic nerve blocks, and spinal cord stimulation (Schreier, 2014).

Many studies call for an interdisciplinary team for management of chronic pain, stating that it is more effective in treatment of pain overall versus the responsibility falling on one provider (Dowell, Haegerich, & Chou, 2016; NAM, 2017; Ernstzen, Louw, & Hillier, 2017). Members of the team include primary providers, pain specialists, psychiatrists, social workers, nurses, and any other provider the patient may encounter (NAM, 2017). The team also includes providers who specialize in nonpharmacological treatments of chronic pain, including physical and occupational therapists, physical trainers, and masseuses, among others.

Treatment of Concurrent Psychologic Symptoms

As stated previously, a high incidence of somatic and mood disorders occur in patients with chronic pain. In fact, pharmacological treatment options for pain include antidepressants and benzodiazepines for treatment of concurrent depression and/or anxiety (Schreier, 2014). One of the goals of pain management is for patents to actively participate in their care (IOM, 2011). Adequate treatment of depression shows improvement in patients taking an active role in their

care (Sheier, 2014). This project will address screening and appropriate referral for concurrent psychological conditions in the patient. Issues such as anxiety and depression cannot be adequately treated if screening for the condition does not take place.

Provider-Patient Relationship

The provider-patient relationship is an important element in the treatment of chronic pain (IOM, 2011). Most patients go see their provider in times of need to be "fixed" and to seek guidance. If the provider-patient relationship is not adequately built, approaching a patient about taking away their only perceived method of pain control may not go well. The patient may only see that the provider is attempting to take away their only means of pain relief. While the provider is only attempting to stay within new guidelines and protect the patient, the patient may not be inclined to understand that viewpoint.

Fu, McNichol, Marczewski, and Closs (2016) completed a qualitative systematic review to assess views of patients regarding the provider-patient relationship and self-management in chronic back pain (level 5 evidence). Facilitators of patient participation in nonpharmacological treatment options included good rapport between patient and provider, empathy from the provider, open communication, tailoring treatment plan to the patient, and shared decision making (Becker et al., 2017; Fu et al., 2016).

Provider

The National Academy of Medicine (NAM) (2017) published a report, with level 5 evidence, detailing responsibilities of providers to address the opioid epidemic. These include taking an active role in the patient's pain treatment, actively monitoring for abuse of opioids, and treating chronic pain with the most current evidence-based guidelines (NAM, 2017).

Current research shows that present education for providers is lacking in relation to pain management. Other common provider barriers to effective pain management include providers not believing the patient's report of pain and provider distrust in nonpharmacological pain treatments (Becker et al., 2017). One of the IOM's recommendations was to increase provider knowledge (IOM, 2011). This calls for an increase in provider education for treatment of chronic pain management. Education should focus different methods of nonpharmacological pain management and education on assessment and treatment of substance abuse.

Providers place stigmas on patients who do not respond to initial treatment of pain, especially when patients specifically ask for stronger pain medication (IOM, 2011). This occurs due to the lack of understanding between addiction to pain medication and tolerance to pain medication (Schreier, 2014). This calls for providers to fully understand, assess, and know how to treat patients with a substance abuse disorder. Educating providers on detection and management of substance abuse falls in with recommendation from the IOM (2011) and the CDC (Dowell, Haegerich, & Chou, 2016). The CDC calls for providers to use instances of possible opioid addiction/abuse to educate and help patients rather than dismissing them from the practice (Dowell, Haegerich, Chou, 2016). This is safer for patients, providers, and the public.

Patients

Patients also need consideration as they experience the chronic pain. Many studies and articles show a knowledge deficit in patients about pain and different management strategies (IOM, 2011; Becker et al., 2017). Some research cites improvement in self-management of pain in patients who understood the pathophysiology of their pain (Fu et al., 2016; Becker et a., 2017). Education for patients needs to focus on where their pain is coming from and different methods of nonpharmacological pain management. The hope is that increased knowledge in

patients will encourage them to actively participate in their own care and encourage use of a pain management regimen that will match the patient.

Written Policy

The clinical practice where this project was completed at has an evidence-based written policy in place for chronic pain management based on the CDC guidelines. This project will add on to the written policy by addressing education needs for the patient, including nonpharmacological pain management and building on the patient-provider relationship.

Conceptual Framework

The conceptual framework for this project is the Iowa Model of Research-Based practice to Promote Quality Care (Iowa Model Collaborative, 2017) (Appendix B). The trigger for this project was provider issues with adapting to new guidelines for treatment of chronic pain from national organizations and from insurance companies. Providers requested an alternative approach to patients in chronic pain that falls in line with guidelines but also will consider the patient perspective. This topic is a priority for the organization. Current research evaluated to define the problem and expanding areas that could be addressed.

Theoretical Framework

The theoretical framework for this project is the theory of symptom management (Smith & Leihr, 2014). This framework takes a symptom that a patient is experiencing and looks at in in terms of symptom experience, symptom management strategies, and symptom status outcomes (Smith & Leihr, 2014). This project will address these issues. The symptom management framework also takes into account the patient, environment, and health and illness (Smith and Leihr, 2014). The project will attempt to incorporate the patient and environment into the

intervention but will not incorporate other illness (acute or chronic) because of time and other constraints to the project.

METHODOLOGY

As per the Iowa Model, this scholarly project will design an evidence-based education and implement a pilot clinic (Iowa Model Collaborative, 2017).

Measurable Outcomes

1. Increased provider comfort and knowledge of different methods of treatment of pain as evidenced by provider feedback.
2. Increased patient use of nonpharmacological methods of pain control as evidenced by patient surveys and increased provider referrals. Referrals will include physical therapy, occupational therapy, orthopedic injections, and chiropractors, among others.
3. Decreased overall pain scores of patients in chronic musculoskeletal pain. This will objective will be met through provider and patient education.

Subjects

Subjects included patients with chronic musculoskeletal pain, ages 21-64. Special populations were not considered. The inclusion criteria for the study subjects included patients with chronic (more than three months) musculoskeletal pain. Examples included patients with osteoarthritis, rheumatoid arthritis, low back pain, history of bone fracture, and herniated disc. The total number of patients was 15. Limiters included patients with acute pain (as in recent knee surgery) and patients that fall under special populations. There were no limiters placed on previous or current treatments for pain control. Providers received the majority of the education, but tool measured the patients' pain levels.

Patients agreed to informed consent to participate in the survey. The writer informed them of the purpose of the project and asked to complete another survey after 6 weeks of implementing of the education. Confidentiality of the subjects was protected through identifying them by a designated number and password protected computers and files.

Setting

This project, conducted at a non-profit community health center in central Virginia, is a federally funded clinic for an underserved population (CVHS, 2017). The values of the site include providing patient-centered care, display integrity, professionalism, and compassion, and to continuously improve practice (CVHS, 2017). The project will encourage these values by giving providers tools to provide patient-centered care and improving practice through evidence-based guidelines.

The site director of the clinic came forward with the project, stating a need for a different method to approach patients with chronic pain. The site director also supports dissemination of the project throughout the organization and encourages the project leader to speak with leaders of the organization.

Tools

The tool used to measure patients' pain scores was the Brief Pain Inventory (Long Form) (Figure 2). The Brief Pain Inventory requires the patient to divulge where the pain is located, to rate their pain both on average and at the moment, pharmacological and nonpharmacological treatments for their pain, and how their pain affects their daily life (Shreier, 2014). Permission to use the tool has been obtained (Appendix D).

This tool was chosen because it has been developed and is currently used in practice to assess patients' pain. It also takes into account different methods of pain management the patient

currently uses and measures their mood and quality of life. The education will attempt to address patients' mental health as well, which this tool partially measures.

The Intervention

A flowsheet and simplified education in the form of a Word document was created for the clinic. The flowsheet consisted of nine possible items to address with each visit with a patient in any form of chronic pain. The flow sheet developed from information based on the literature review and the 2016 CDC guidelines for pain management. The steps included addressing patient airway, breathing, circulation (ABC's), defining the patient's pain, screening patients for comorbid psychological conditions, addressing the most pressing issue to the patient, educating on pain and pain management, developing pain management plan with the patient, teaching behavioral or emotional adaptations to pain, discussing dangers of narcotics or tapering of narcotics, and addressing other needs to stabilize patient condition as needed.

The education gave basic definitions for the three most common types of pain (musculoskeletal pain, neuropathic pain, and cancer pain), information on some of the herbal supplements that can be used in pain management, a review of nonpharmacological pain management, and a review of behavioral adaptations to chronic pain. Information for the herbal supplements came from the NIH. The nonpharmacological pain management information included reminders for the importance of diet and exercise in relation to chronic pain. It also included the effectiveness of different nonpharmacological interventions, including physical therapy, heat therapy, acupuncture, massage, transcutaneous electrical nerve stimulation (TENS) unit, and dry needling. The effectiveness of the therapies was included to assist providers in whether they wished to recommend the therapy to their patients.

Data Collection

Initially, data collection occurred over a two-week period on site. Patients came in for various reasons and approached if their charts documented some form of chronic musculoskeletal pain. Patients were approached as they were waiting for the providers in examination rooms. The writer discussed the project, risks and benefits. Participants were offered the consent form and the survey and left alone to fill out to prevent bias.

After providing written education to providers, the same survey was mailed to patients to assess for change. Patients received the same survey as before implementation to measure their levels of pain, mood, and to see which new methods of pain management they have tried.

The team consisted of the project leader and organizational site leader. The project leader developed the patient and provider education and administer the surveys to patients and providers. The site leader and organizational team member approved the educational materials for site use and assist in implementation of the policy and integration of the education materials into the clinical site.

RESULTS

Over a two-week data collection period, 15 participants completed the initial survey from a convenience sample of patients who came into the clinic with a documented diagnosis of a chronic musculoskeletal issue that could lead to chronic pain. Of the initial sample, three participants mailed back the survey after implementation of the intervention.

Demographics

Of the initial sampling, 27% were male (4) and 73% were female (11). Ages of the participants ranged from 30 years old to 62 years. Current marital status included 27% single, 27% married, 12% widowed, and 27% separated or divorced. The participants' education varied

from ninth grade to twelfth grade, with one participant stating that he or she had completed an associate's degree. Seven of the participants stated that they were employed full time (41%), one stated that he or she had part-time employment (7%), two stated they were homemakers (12%), three stated they were unemployed (18%), and two wrote other (12%). The chronic musculoskeletal issues that the participants diagnosed with included low back pain present longer than 3 months and arthritis in various joints. Some took prescription medication for their pain, while others did not.

Demographichs	
Sex	
Male	27%
Female	73%
Marital Status	
Single	27%
Married	27%
Widowed	13%
Seperated/Divorced	27%
Employment	
Employed, full-time	47%
Employed, part-time	7%
Homemaker	13%
Retired	0%
Unemployed	20%
Other	13%

Table 1

Initial Survey Results

Sixty-five percent of the participants put down that their pain was due to their present disease, 18% said the pain was not due to their present disease, and 7% said they were uncertain. Narrative responses for how long the participants lived with their pain range from two to twenty-five years, with 20% unsure of how long. 82% of the participants stated that pain was one of the first symptoms they received when they were diagnosed, and 7% stated they were uncertain. The next question asked the participants if they had other types of pain (acute "everyday" pain such

as headaches or sprains) other than their chronic pain; 87% said yes (13 participants) and 13% (2 participants) said no. 60% of the participants (9) stated they felt that they had "some form of pain" that called for medication every day while 40% (6) said no. Regarding if the participant took any pain medications in the previous seven days, 71% said yes, 13% said no, and 7% said they were uncertain.

Some of the questions required the participants to complete narrative answers. The areas that the participants complained of pain included the neck, back, hip, knees, shoulders, and hands. 33% of the participants complained of pain in only one area, and 67% complained of pain in multiple areas. Interventions that made the patients pain feel better included "work," laying flat, rest, medicine, sitting down in the upright position, heat, nothing, "not using hand," and "pain meds." Multiple responses included rest and pain medicine. Responses for what made the participants' pain worse included lifting, sitting, "standing after sitting for a while," walking, "sleep on my stomach," bending over, "laying down more than seven hours in a row," "overhead arm reach," stairs, bending, and "washing dishes and clothes." Those that were often repeated included standing, walking, bending, and lifting. Medications that the participants took for the pain included Tylenol, tramadol, gabapentin, hydrocodone with Tylenol, leflunomide (a disease-modifying antirheumatic drugs (DMARDs)), "nerve blockers," ibuprofen, and tizanidine (a muscle relaxant). Other responses included none and "medication."

The participants' pain on the survey was measured on a scale from 0 to 10. Regarding the worst that their pain level had been in the previous week, scores ranged from five to ten out of ten (see table 2). The participants' pain level on average ranged from one to six (7% rated their pain 1/10, 2/10, and 4/10, 12% a 3/10, 24% a 6/10; and 35% a 5/10). When the patients completed the initial survey, they were in the clinic, and not all came in for a follow-up for their

chronic pain. Participants rated their pain at the time of the appointments ranged from zero to ten (7% for 0, 1, 4, 5, 6, and 10 out of 10; 12% for 8 and 9 out of 10; and 29% at 7 out of 10). The next question asked how long it took for the pain to return after taking the pain medication. One participant answered that he or she did not take pain medication. For those that took pain medications, 18% stated that pain medication did not help at all, 7% stated that the pain returned after one, two, and three hours; 18% in four hours, and 29% in five to twelve hours.

Pain At Its Worst	
5/10	13%
6/10	7%
7/10	20%
8/10	27%
9/10	13%
10/10	20%

Table 2

The next section asked the patient what they believed caused their chronic pain. Seven percent believed it to be a result of a treatment (such as a medication they took or a surgical procedure) and 80% because of a disease process (whether is was a primary disease or another medical condition).

Next, the participants were able to describe their pain. Each description allowed the patient to reply yes or no. 76% described their pain as aching, 47% as throbbing, 59% as shooting, 41% as stabbing, 12% as gnawing, 59% as sharp, 35% as tender, 35% as burning, 29% as exhausting, 47% as tiring, 29% as penetrating, 53% as nagging, 53% as numb, and 47% as miserable.

On a scale of zero to ten, the participants then rated their pain based on how it affected areas of their lives, which included general activity, mood, walking ability, normal work, relationships with others, sleep, and enjoyment of life. Table 3 shows these results.

	0	1	2	3	4	5	6	7	8	9	10
General Activity	1	0	0	1	1	1	0	1	5	2	3
Mood	3	0	1	0	0	2	0	3	3	2	1
Walking Ability	1	1	0	1	2	4	3	0	1	0	2
Normal Work	2	0	0	0	0	1	1	2	3	2	4
Relationships with other people	5	1	1	0	2	3	0	1	2	0	0
Sleep	2	0	0	1	0	3	3	1	2	0	3
Enjoyment of Life	2	0	0	0	0	3	1	3	2	2	2

Table 3

The next section asked the participants more specifics about their pain medication use. 33% of the participants indicated that they took their pain medication daily, 60% took their medication only when necessary, and 7% did not take any pain medicine. The next question inquired how often they took their pain medication in the last 24 hours, with 33% stating they did not take it every day, 40% stating they took one to two times per day, 20% taking it three to four times per day, and 7% taking it five to six times per day. None stated that they took it more than six times per day. 33% of the participants stated they the felt they needed a stronger type of pain medication, 53% said no, and 13% were uncertain. The next question asked the participants if they felt they needed to take more pain medication than their doctor had prescribed them. 27% stated yes, 67% said no, and 7% stated they were uncertain. Seven percent of the participants were concerned that they were taking too much pain medication, while 93% of the participants were not concerned. Regarding side effects, 7% were having problems with side effects and 93% said they were not having any problems. The only written side effect was a rash. The participant did not indicate if he or she had continued to take this specific pain medication or not. Seven percent of the participants felt they needed more information on their pain medication, while the other 93% stated they did not need to receive more information. The nonpharmacological options that the participants used included warm compresses, relaxation techniques, stretches, bio freeze, and braces for joints. Medications used by the participants included Tylenol, ibuprofen, and tramadol. This specific question asked the patient what medications they took that were not prescribed by their doctor.

Second Survey Results

Of the 15 second surveys mailed to the participants homes, three were returned (two males and one female). One was employed full-time, one was a homemaker, and one was unemployed. All three stated a need for some form of pain medication daily, but only two stated that they had taken pain medication in the last seven days. Participants complained of pain in their neck, back, hip, and knees. All three complained of pain in multiple areas.

On a scale of zero to ten, one rated their pain a four of ten at its worse in that past seven days, while the other rated it at a nine out of ten. On average, the participants rated their pain a two, four, and five out of ten. At the time the filled out the survey, they rated their pain a two, seven, and nine out of 10. “Written in” answers for things that helped their pain included “nothing really,” medications, rest, heat, and muscle rub. “Written in” answers for things that made their pain worse included walking, standing, bending, lifting, turning, and going up stairs. Medications the patients took for pain control included gabapentin, over-the-counter medications, tramadol, Zanaflex, and ibuprofen. One patient stated that he or she was beginning physical therapy. One participant indicated that he or she got no relief from medication, another stated 50% relief, and then 30% relief. One participant indicated that his or her pain occurred because of a primary disease while the other two indicated that it occurred because of another medical condition. The two that indicated their pain came from another medical condition were able to indicate medical conditions their pain originated from.

Two of the participants stated they only took their pain medications when necessary, while one took it on a regular basis. The participant who took medication on a regular basis took pain medications three to four times per day and was the only participant who felt the need for stronger pain medications and for the doctor to prescribe them more pain medications. None of these participants felt they needed more information about their pain medications. These

participants used warm compresses and cold compresses along with pain medications to treat their pain.

Study Limitations

The short time frame limited the results of this project. Because the participants did not have enough time to return to the clinic over multiple visits with providers, the effectiveness of the intervention could not be accurately measured. The intervention is designed to be done over multiple visits, and the short time frame and other unforeseen constraints did not allow for a full evaluation. A period of six months to one year is a more appropriate time frame. Another limiter included the lack of provider involvement in the education and willingness to implement the flowsheet. While the providers stated that the education and reminders were helpful, none guaranteed the use of the flowsheet in their practice with chronic pain patients.

The sample also limited the results of the study as it was a convenience sample of patients who came into the clinic for various reasons. The participants could fill out the survey without the provider or the author in the room, that allowed the participants to answer questions based on their interpretation of the question. The survey did not ascertain about the specific education the participants previously had on pain management and medications. The survey also did not have a way to measure their feelings about their relationship with their provider. While the survey did ask about the participants' general mood, it did not inquire about specifics or if they felt that their provider addressed their mood. The intervention was meant to address both of these issues, but the survey did not allow for accurate measurement.

DISCUSSION

The results of this pilot study cannot be generalized to the clinic's population but may give insight in weaknesses in the current method of pain management. Many of the surveys

indicated a need for further evaluation with these participants. One of the participants was unsure if he or she had taken any pain medications in the last seven days. While this may be due to poor memory, the lack of recollection may be due to that the participant being unaware if the medication taken is for pain. Two participants complained that their pain completely (10/10) interfered with their ability to walk and three complained that their pain completely interfered with their ability to sleep. These are areas that can impact other areas of a person's life and can exacerbate the pain. Many of the participants indicated that their pain interfered with their ability to work and their general activity, but not their relationships with others as much. This would give the providers insight to focus on the patient's functionality.

In the first survey, none of the participants indicated that they were using physical therapy, occupational therapy, massage, acupuncture, herbal adjunct therapy, or other less well-known forms of pain management. Physical and occupational therapy are forms of pain management that could increase functionality in those participants that indicated their general activity was decreased. In the second survey, one participant indicated that he or she intended to begin physical therapy. It is unknown if the patient sought out this treatment or if the provider prescribed it. Many simpler forms of pain management are not being utilized in the primary care setting.

This intervention was built based on the gaps in literature to address the areas of pain management that national organizations are not addressing. Many of the participants did not indicate that they wished for more information on the pain medication they were taking. If the clinic staff find the flowsheet and education helpful, a larger pilot study with a longer time frame and larger sample size should be conducted to show clinical evidence that it assists providers in chronic pain management. To build patient knowledge, providers should evaluate each patient on

their current knowledge of the cause of their chronic pain and their knowledge on pain management. Feedback from some potential participants that did not fill out the form was because it was too long. A shorter survey and a longer data collection time may increase the number of participants for a future study. Another tool or an addition to the Brief Pain Inventory that measures the patient's perceptions of the provider-patient relationship.

There are many national recommendations and guidelines for pharmacological treatment of chronic pain that limit providers in treatment of one aspect of chronic pain: opioids that are used to take the pain away. There are few specific recommendations for providers to ensure that patients' educational and psychological needs are also met. This pilot study does not show enough evidence that the flowsheet and education made a difference. It does not change the fact that chronic pain management needs a holistic approach that not only addresses patient prescription opioid use.

Dissemination Plan

If the providers continue using the flowsheet, the next step in dissemination of this project is to complete chart audits to evaluate if the different aspects of the flowsheet are being addressed. This would include documentation of pain, how pain affected the patient's life, depression and anxiety screenings, patient education, and patient referrals. The referrals that the audit would evaluate an increase for would include physical therapy, psychology or counseling, behavioral cognitive therapy, or pain management.

If the flowsheet showed an improvement in the management of pain patients, the flowsheet could be presented on a system wide scale to be implemented at all the clinic sites.

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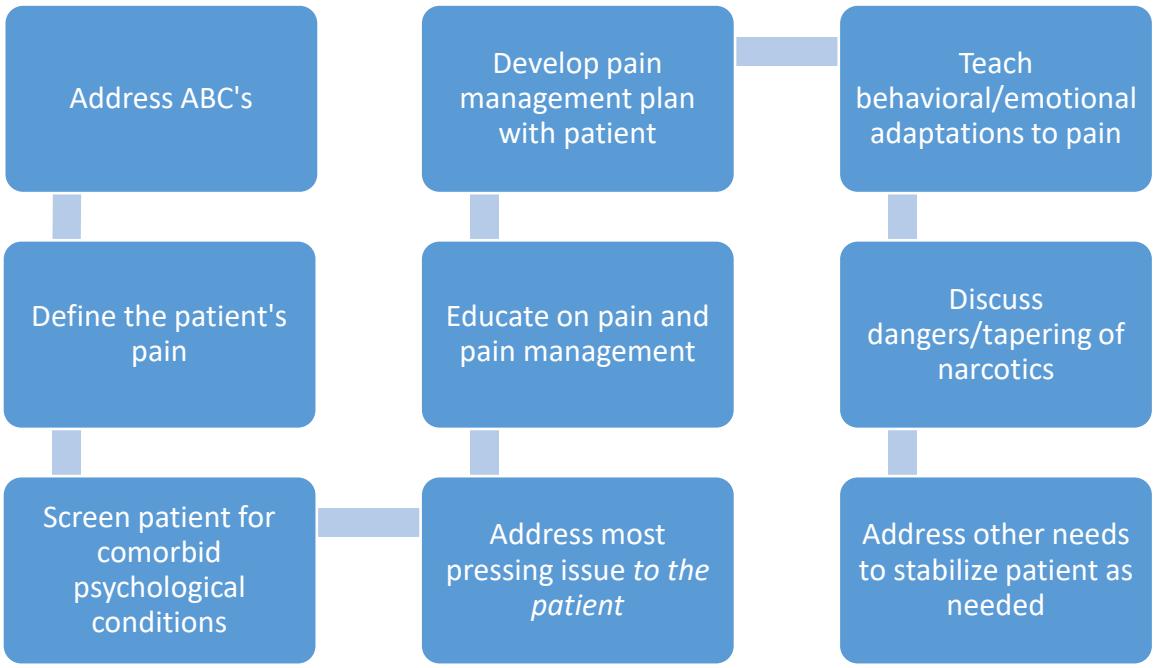
Appendix A-Education for Providers
Chronic Pain Management Plan for Providers



Address ABC's

I. Address patient safety first: airway, breathing, and circulation (ABC's)
II. Address suicidal/homicidal ideation

Define the Patient's Pain Experience

I. Ask/chart the patient's pain and their experience with pain.
   a. Chart OLD CARTS (onset, location, duration, character, aggravating factors, relieving factors, timing, and severity) of pain.
II. Find out how the chronic pain affects the patient's life.
   a. Completion of activity of daily living (ADL's)
   b. Sleep
   c. Ability to work
   d. Family life and relationships
III. Assess how the patient feels (anxious, fear, etc.) and attempt to discuss the root of those feelings.
   a. Screen for anxiety and depression (*See "Screen the patient for psych conditions").
IV. Ask about the patient's cultural perception of their pain.
   a. Is the pain punishment for something?
   b. What do you associate your pain with? (ie. death, failure, etc.).
V. Ask about current and previous treatments of chronic pain.
   a. Chart current and previous treatments, what worked and what failed: medications, nonpharmacological treatments, previous imaging or tests done and expert notes.
VI. If the patient is currently on opioid medications, ensure "Controlled Substance Agreement" is signed and in the chart.

Screen the Patient for Psych Conditions

I. Complete depression and anxiety screenings on the patient.
   a. Assess for bipolar disorder, post-traumatic stress disorder, history of trauma/abuse, etc.
II. Screen the patient for narcotic abuse/risk factors.
   a. Free assessment tool for providers:
      i. https://www.mdcalc.com/opioid-risk-tool-ort-narcotic-abuse#next-steps
III. Consider specialist referral for a complete evaluation.

Address Most Pressing Issue to the Patient

I. Ask patient what is most important to them and address that issue.
II. Chart shared short- and long-term goals.

a. Make goals realistic. Educate on unrealistic goals.
b. Make a copy for the patient.
c. Use this as an opportunity to build rapport with the patient.

Educate on Pan and Pain Management

I. Discuss the patient's type of pain and its etiology. Educate based on knowledge deficit.
   a. Musculoskeletal pain
   b. Neuropathic pain
   c. Cancer pain
II. Discuss the best method of pain management for the patient and why certain methods work better than others (ex. narcotics do not work for chronic neuropathic pain).
III. Link education to patient goals.
IV. Always be honest with the patient.
V. Start opioid education
VI. Define: physical dependence, tolerance, addiction
VII. Teach patients: "Some pain is unavoidable. Narcotics just make you care less about the pain."

Develop Pain Management Plan with Patient

I. Develop an individualized pain management plan with the patient. Use short-/long-term goals that have been discussed previously.
   a. Pitfalls of providers when developing shared goals: starting to late and expecting too much too soon.
II. Add in provider goals for the patient with rationale.
III. Pharmacological options
   a. See facility pain policy.
IV. Herbal Options
V. Nonpharmacological Options
VI. Include patient family/friends if desired in every treatment option.

Teach Behavioral/Emotional Adaptations to Pain

I. Teach behavioral techniques to manage chronic pain (cognitive behavioral therapy, mindfulness meditation, etc.). Encourage interventions and/or techniques to control emotional responses to pain.
II. Provider Education on Behavioral/Emotional Adaptations to Pain
III. Refer to specialist as needed.

Discussing Dangers/Tapering of Narcotics

I. For patient currently on narcotic medication: discuss risks versus benefits. Use points reinforced from previous pain education and pain management education.

Address other Needs to Stabilize Patient as Needed

I. Ensure patient safety.
II. Review provider-patient goals every visit, revise as needed.
III. Point out patient successes throughout the process. Provide emotional support.

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Pain Education Review for Providers

I. Types of Pain
   a. Musculoskeletal Pain
   b. Neuropathic Pain
   c. Cancer Pain

II. Definitions
   a. Physical Dependence:
      i. A physical state in which the body will develop withdrawal symptoms if a drug is stopped abruptly.
      ii. This is an expected result of opioid use.
   b. Tolerance:
      i. A physical state that is a result of chronic drug use where a patient needs increased dose to get the same initial effect.
      ii. Teach patients that if the highest/safest dose is reached on their narcotic, there will be no other medication that will be able to take their pain away.
   c. Addiction:
      i. A psychological dependence on a drug; compulsive use despite possible harm.
      ii. Complete risk factor screening.

Pain Education for Patients

I. Types of Pain
   a. Musculoskeletal Pain
      i. Examples: arthritis, back pain, most sports injuries
      ii. Definition: Pain caused by trauma/deterioration to bone, muscle, tendon, or ligaments.
   b. Neuropathic Pain
      i. Examples: migraine headaches, diabetic neuropathy, sciatica
      ii. Definition: Pain caused by a dysfunction in the nervous system.
   c. Cancer Pain
      i. Definition: Any pain related to cancer.

II. Definitions
   a. Physical Dependence: a physical state in which the body will develop withdrawal symptoms if a drug is stopped abruptly, this is an expected result of opioid use.
   b. Tolerance: a physical state that is a result of chronic drug use where a patient needs increased dose to get the same initial effect.
   c. Addiction: a psychological dependence on a drug; compulsive use despite possible harm.

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Herbal Pain Management Options

Herb	Uses	Side Effects	Contradictions/Interactions
St. Johns Wart	• Depression • Menopause • OCD/ADHD	Include anxiety, dry mouth, dizziness, GI symptoms, fatigue, headache, sexual dysfunction, and sensitivity to light.	Can weaken the effects of antidepressants, birth control, digoxin, warfarin, and many others.
Ginger	• Nausea • Rheumatoid arthritis • Osteoarthritis	Abdominal discomfort, diarrhea, heartburn, gas,	Possible interaction with anticoagulants.
Ginseng	• Depression/Anxiety • Erectile dysfunction • Improves physical stamina and concentration	Headaches, sleep problems, digestive problems.	Interacts with warfarin. Not recommended for children or pregnant women. Suggested effect on blood sugar and blood pressure.
Feverfew	• Headache Prevention • Rheumatoid arthritis • Psoriasis • Asthma/Allergies • Tinnitus • Dizziness • Nausea/vomiting	Nausea, digestive problems, bloating,	Do not stop abruptly, will cause difficulty sleeping, headaches, anxiety, and stiff and painful muscles. Contraindicated in pregnancy.
Lavender (topical or inhaled)	• Anxiety • Depression • Pain • Intestinal problems	Skin irritation, stomach upset, joint pain, headache.	Lavender oil, if taken by mouth, may be poisonous.

*Information retrieved from National Institute of Health (NIH),

Nonpharmacological Methods of Pain Management

I. Diet Management-Reminders for Providers
   a. Suggestions of weight loss as appropriate for musculoskeletal pain (low back pain, knee/hip arthritis).
   b. Headaches:
      i. Some headaches are triggered by certain foods, including processed meats, fermented food, aged cheese, chocolate, and caffeine. Keep a food/headache diary to see if there are any correlations between what you eat and your headaches.
   c. *If patient is overweight or if their weight has an impact on their chronic pain, consider dietary referral.

II. Exercise-Reminders for Providers
   a. Regular exercise (150 minutes/week or 30 minutes, 5 days/week) shows a decrease in severity of pain and improved physical function.
   b. Physical activity should be personalized to patient and condition. It should be enjoyable to the patient, safe, and financially feasible.
   c. Consider/Suggest: walking, yoga, tai chi, swimming, Pilates, community-based
   d. Osteoarthritis (OA)
      i. Research shows a correlation between upkeep of an exercise regimen and benefits of reduction of pain and joint mobility.
      ii. Aquatic therapy and Tai Chi may be effective for pain management.

III. Sleep-Reminders for Providers
   a. Encourage about 8 hours of uninterrupted sleep.
   b. Discuss
   c. Avoid medication as first or second line treatment because we do not wish to reinforce that issues can be solved by “taking a pill.”

IV. Physical Therapy/Occupational Therapy
   a. Generally recommended. CDC recommends this as first line treatment.
   b. PT generally not recommended for acute low back pain, unless they are at risk to develop chronic pain.

V. Heat Therapy
   a. *Studies have shown moderate, short-term relief with the use of heat.
   b. Educate patients about the risk of burns to the skin.

VI. Acupuncture
   a. Definition: a therapy that has a practitioner put pressure on anatomical points on the body; may be done with needles (not as often), heat, ultrasound, electrical current, magnets, and physical pressure. Historically, goal is to achieve harmony in the body.
   b. *There is evidence for the possible benefit of acupuncture in acute and chronic pain, acute dental pain, and headaches. There is insufficient evidence for recommendation for depression and fibromyalgia.

VII. Massage

a. *Research results are mixed for use of massage therapy for chronic pain. Seems most effective for musculoskeletal pain but is never used for first-line therapy.

VIII. Transcutaneous electrical nerve stimulation (TENS) therapy
   a. Device that can be applied to the area of pain, delivers an electrical current to the area of pain. Can be bought over the counter.
   b. *Research is conflicting on effectiveness of TENS units, mostly due to lack of research.

IX. Dry Needling
   a.
   b. Available at Southside Community Hospital
      i. Studies are limited in support of efficacy.

X. Surgical Approaches
   a. Refer as appropriate
   b. Spinal fusions, spinal cord stimulation, etc.

Behavioral/Emotional Adaptations to Pain

I. Self-Care
   a. Encouraging the patient to take a part in their own care. Includes regular physical activity and maintaining ADL's.
   b. Research supports use of self-care. No evidence to support bedrest unless there is a severe exacerbation of pain.
   c. Include therapies such as diet, ice/cold, physical therapy, stress management, coping strategies.

II. Cognitive behavioral therapy
   a. Mostly used in the treatment of OCD disorders and anxiety, but the techniques taught can be used for other issues.
   b. Controlling emotional responses to pain, any maladaptive behaviors.
      i. The physiology of pain leads to exaggerated reactions to pain.
   c. Getting rid of negative thinking, encourage positive thinking.
   d. Acceptance of pain.
   e. Include family. Refer to specialist as necessary.

III. Mind/Body Interventions
   a. Mindfulness-meditation/relaxation training
      i. All include controlled breathing, a safe environment, relaxation of the body, and focus on the present.
      ii. Ted Talk Resource for patients: Fadel Zeidan
         1. https://www.youtube.com/watch?v=OLQJJDrbj6Q
      iii. May or may not include use of relaxing music or imagery (YouTube videos)
         1. https://www.youtube.com/watch?v=J69ffbvR4-0
   b. Meditation
   c. *Suggest the need for more evidence, but initial trials show some effect.

[redacted]

[redacted]

Appendix B-Iowa Model Permission

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Appendix D-Tool/Brief Pain Inventory Permission

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5.	**Permitted Use (description of study):** Student research (thesis, dissertation)	
6.	**Licensed Territory (place "x" in all boxes that apply):** ☑**Within worldwide facilities of Licensee** ☐**Within any clinics or hospitals participating in the study described in the Permitted Use** ☐**Other (Specify here):**	

7.	**License Fee:** $100.00 ***For payment instructions, see Article V of Part II.***	
8.	**Notice Address for MD Anderson:**	In the case of first class mail to MD Anderson: [redacted] or in the case of reputable overnight courier to MD Anderson: [redacted]
9.	**Notice Address for Licensee:**	Attn: Addr [redacted]
10.	**Email Address for conveyance of the Agreement and Invoices**	[redacted]
11.	**Subscription Term (time period)**	N/A
12.	**Licensee**	Liberty University

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

Licensee (See Section 12 above)

By [redacted]
Name
Title

The University of Texas M. D. Anderson Cancer Center

By [redacted]
Name
Title

PART II TERMS & CONDITIONS

I. DEFINITIONS

As used in this Agreement, the following terms have the meanings indicated:

1.1. **Derivative Work(s)** has the meaning set forth in 17 U.S.C. Section 101 of the copyright laws of the United States. For the avoidance of doubt, Derivative Works include language translations of the Symptom Assessment Tool.

1.2. **Effective Date** means the date set forth in Section 1 of Part I.

1.3. **License Fee** means the license fee set forth in Section 7 of Part I.

1.4. **Licensed Territory** means the territory set forth in Section 6 of Part I.

1.5. **Permitted Use** means the use set forth in Section 5 of Part I.

1.6. **Symptom Assessment Tool** means any and all tools specified in Section 2 of Part I.

1.7. **Term** means the term of this Agreement which shall commence on the Effective Date and, unless earlier terminated pursuant to this Agreement, will continue in effect until the earliest to occur of: (i) the time period set forth in Section 11 of Part I (if applicable) following the Effective Date; (ii) completion or termination of the relevant clinical study or activity described in the Permitted Use; or (iii) five (5) years following the Effective Date.

II. RIGHTS GRANTED

2.1. License Grant. Subject to the terms and conditions of this Agreement, MD Anderson hereby grants to Licensee, during the Term, a non-exclusive, non-sublicensable, non-transferable, license in the Licensed Territory to:

(A) use the Symptom Assessment Tool solely for the Permitted Use;

(B) reproduce, via the form of reproduction set forth on Part I, copies of the Symptom Assessment Tool to the extent necessary for the Permitted Use; and

(C) distribute, via the form of distribution set forth on Part I, copies of the Symptom Assessment Tool to the extent necessary for the Permitted Use.

2.2. Use Restrictions. Except as expressly permitted under Section 2.1 above, Licensee shall not, and shall not permit any person to:

(A) distribute or disclose the Symptom Assessment Tool (or any copies or Derivative Works thereof) to any third party, regardless of the means, form, or format of distribution or disclosure;

(B) make any modification to, adaptation to, improvement of, enhancement to, translation of or Derivative Work of the Symptom Assessment Tool;

(C) remove, alter or obscure any copyright or other proprietary notice appearing on or within the Symptom Assessment Tool;

(D) make the Symptom Assessment Tool (or any copies or Derivative Works thereof) available over a computer network or other electronic environment permitting access or use by multiple users at the same time; or

(E) incorporate the Symptom Assessment Tool (or any copies or Derivative Works thereof) into software that will be commercialized, sold, or licensed to end users.

III. OWNERSHIP

3.1. MD Anderson (or its licensor) will remain the sole and exclusive owner of all right, title and interest in and to the Symptom Assessment Tool, including any copyright relating thereto, subject only to the limited license granted to Licensee under this Agreement.

3.2. Licensee hereby unconditionally and irrevocably assigns to MD Anderson (or MD Anderson's designee), its entire right, title and interest in and to any rights, including, without limitation, any copyright, that Licensee may now or hereafter have in or relating to any Derivative Work impermissibly created by Licensee during the Term, whether held or acquired by operation of law, contract, assignment or otherwise.

IV. AUDIT

4.1. MD Anderson or its nominee may, upon reasonable request, inspect and audit Licensee's exercise of rights under this Agreement at any time during the Term. Licensee shall upon such reasonable request give full cooperation to such audit. If the audit determines that Licensee's exercise of rights under this Agreement are outside of the scope of rights granted under Section 2.1 above, in addition to any other available legal or equitable remedies, Licensee shall reimburse MD Anderson for any reasonable costs incurred by MD Anderson in conducting the audit and MD Anderson may terminate this Agreement pursuant to Section 7.2.

V. PAYMENTS

5.1. In consideration of the rights granted to Licensee under this Agreement, Licensee shall pay to MD Anderson the License Fee within thirty (30) calendar days of receipt of invoice. MD Anderson shall provide the Symptom Assessment Tool and issue the invoice upon mutual execution of this Agreement.

5.2. All amounts payable hereunder by Licensee will be paid in United States funds without deductions for taxes, assessments, fees, or charges of any kind. **Licensee shall make payment in accordance with the instructions set forth in the invoice.**

VI. WARRANTY AND INDEMNIFICATION

6.1. Except for the rights of the government of the United States (if any), MD Anderson represents and warrants its belief that: (i) it is an authorized licensee of the right, title, and interest in and to the Symptom Assessment Tool; (ii) it has the right to grant licenses thereunder; and (iii) it has not knowingly granted licenses thereunder to any other entity that would restrict rights granted hereunder.

6.2. Licensee shall indemnify and hold harmless The University of Texas System, its Board of Regents ("Board"), MD Anderson, and their respective Regents, officers, agents and employees from and against any claims, demands, or causes of action whatsoever, including, without limitation, those arising on account of Licensee's impermissible use, reproduction, distribution, modification or enhancement of the Symptom Assessment Tool or otherwise caused by, or arising out of, or resulting from, the exercise or practice by Licensee, it officers, employees, agents or representatives of the license granted hereunder.

6.3. Disclaimer. LICENSEE ACKNOWLEDGES AND AGREES THAT THE SYMPTOM ASSESSMENT TOOL IS PROVIDED ON AN "AS IS" BASIS AND THAT ITS USE OF OR RELIANCE UPON THE SYMPTOM ASSESSMENT TOOL IS AT ITS SOLE RISK AND DISCRETION. MD ANDERSON HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS, WARRANTIES AND GUARANTEES REGARDING THE SYMPTOM ASSESSMENT TOOL, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

6.4. Limitation on Liability. EXCEPT TO THE EXTENT REQUIRED BY APPLICABLE LAW, IN NO EVENT WILL BOARD, SYSTEM OR MD ANDERSON BE LIABLE TO LICENSEE ON ANY LEGAL BASIS OR THEORY FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES ARISING OUT OF THIS LICENSE OR THE USE OF THE SYMPTOM ASSESSMENT TOOL, EVEN IF BOARD, SYSTEM OR MD ANDERSON HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

VII. TERM AND TERMINATION

7.1. Subject to Section 7.2 below, this Agreement shall enter into force upon signature by both Parties, with effect from the Effective Date, and remain valid for the Term.

7.2. Subject to any provisions herein that survive termination, this Agreement will earlier terminate in its entirety: (a) automatically, if Licensee becomes bankrupt or insolvent and/or if the business of Licensee shall be placed in the hands of a receiver, assignee, or trustee, whether by voluntary act of Licensee or otherwise; (b) automatically, if Licensee breaches its obligation under Section 8.3 of this Agreement; (c) immediately, upon written notice from MD Anderson, if Licensee fails to timely pay the License Fee specified in Section 5.1; (d) upon thirty (30) calendar days written notice from MD Anderson if Licensee breaches or defaults on any other obligation under this Agreement, unless, before the end of the thirty (30) calendar day period, Licensee has cured the default or breach to MD Anderson's satisfaction and so notifies MD Anderson, stating the manner of the cure; or (e) at any time by a written document signed by both Parties.

7.3. Upon termination or expiration of this Agreement, (i) Licensee shall cease all use of the Symptom Assessment Tool (and any copies or Derivative Works thereof), (ii) Licensee shall delete or destroy any and all unused copies of the Symptom Assessment Tool (and Derivative Works thereof) in Licensee's possession and in the possession of any third party that has received the Symptom Assessment Tool from Licensee, and (iii) upon MD Anderson's request, a duly authorized representative or officer of Licensee shall certify in writing the deletion or destruction of any and all such copies of the System Assessment Tool (and Derivative Works thereof).

VIII. GENERAL PROVISIONS

8.1. **Nonassignability.** Licensee may not assign this Agreement or any rights or obligations under this Agreement without obtaining prior written consent of MD Anderson and any attempts to do so are hereby deemed null and void and of no effect.

8.2. **Integration.** This Agreement sets forth the entire agreement between the Parties with respect to the subject matter hereof, and may not be modified or amended except by written agreement executed by the Parties hereto.

8.3. **Export Regulation**. Licensee shall not, and shall not permit any person to, export, re-export or release, directly or indirectly, the Symptom Assessment Tool to any country, jurisdiction or person to which the export, re-export or release of the Symptom Assessment Tool is prohibited by any applicable law, including, but not limited to, the United States Export Administration Act and its associated regulations without first completing all required undertakings (including obtaining any necessary export license or other governmental approval (e.g., 31 CFR 501.801)). In addition,

the Parties hereby acknowledge and agree that this Agreement shall be rendered null and void and of no effect if mutual execution of the Agreement violates any applicable law, including, but not limited to, the United States Export Administration Act.

8.4. **Confidential Information**. The terms of this Agreement and the Symptom Assessment Tool (and any copies or Derivative Works thereof) shall be deemed confidential and proprietary to MD Anderson (hereinafter "Confidential Information"). Licensee may not use or disclose Confidential Information (except as permitted under this Agreement) without the prior written consent of MD Anderson. The confidentiality obligations described herein shall survive termination or expiration of this Agreement for a period of five (5) years.

8.5. **Severability**. If any provision of this Agreement shall be held by a court of competent jurisdiction to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect.

8.6. **Government Rights**. Licensee understands that the Symptom Assessment Tool may have been developed under a funding agreement with the government of the United States of America and, if so, that the government may have certain rights relative thereto. This Agreement is explicitly made subject to the government's rights under any such agreement and any applicable law or regulation, if any. To the extent that there is a conflict between any such agreement, applicable law or regulation and this Agreement, the terms of such government agreement, applicable law or regulation shall prevail.

8.7. **Governing Law; Forum.** This Agreement shall be governed by the laws of the State of Texas without regard to conflicts of law principles. The Texas state courts of Harris County, Texas (or, if there is exclusive federal jurisdiction, the United States District Court for the Southern District of Texas) shall have exclusive jurisdiction and venue over any dispute arising out of this Agreement, and Licensee hereby consents to the jurisdiction of such courts. Notwithstanding the foregoing, to the extent that Chapter 2260, Texas Government Code, as it may be amended from time to time ("Chapter 2260"), is applicable to this Agreement, Licensee acknowledges and agrees that the dispute resolution process provided for in Chapter 2260 shall be Licensee's sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Board and/or MD Anderson or the State of Texas.

8.8. **Notice.** Any notice required by this Agreement must be given by prepaid, first class mail or by reputable overnight courier (e.g., Federal Express or UPS) addressed as set forth in Sections 8 and 9 of Part I, or other addresses as may be given from time to time under the terms of this notice provision; provided, however, the Parties may convey executed versions of the Agreement by email and MD Anderson may issue Licensee an invoice via email. Any such email correspondence shall be sent to MD Anderson and Licensee at the email addresses set forth in Section 10 of Part I.

8.9. **Counterparts.** This Agreement may be executed in one (1) or more counterparts, by original, facsimile or PDF signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

8.10. **State agency.** MD Anderson, as an agency of the State of Texas and a member institution of The University of Texas System, is subject to the constitution and laws of the State of Texas and, under the constitution and laws of the State of Texas, possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted under the constitution and laws of the State of Texas. Nothing in this Agreement shall be deemed as a waiver by MD Anderson of its sovereign immunity.

Appendix E- Liberty IRB Approval

LIBERTY UNIVERSITY.
INSTITUTIONAL REVIEW BOARD

May 31, 2018

Lisa Swezey
IRB Approval 3284.053118: Pain Management: A Treatment Plan for Providers

Dear Lisa Swezey,

We are pleased to inform you that your study has been approved by the Liberty University IRB. This approval is extended to you for one year from the date provided above with your protocol number. If data collection proceeds past one year, or if you make changes in the methodology as it pertains to human subjects, you must submit an appropriate update form to the IRB. The forms for these cases were attached to your approval email.

Thank you for your cooperation with the IRB, and we wish you well with your research project.

Sincerely,

[redacted]

Administrative Chair of Institutional Research
The Graduate School

LIBERTY
UNIVERSITY.
Liberty University | Training Champions for Christ since 1971

Appendix F-Site Letter of Approval

cvhs
CENTRAL VIRGINIA HEALTH SERVICES

Central Virginia Health Services, Inc.

[redacted]

April 23, 2018

To whom it may concern,

Liberty University student, Lisa Swezey has permission to complete her Doctor of Nursing Practice (DNP) capstone project at the Health Center for Women and Families.

Sincerely,

[redacted]

Chief Executive Officer

Appendix G-Literature Matrix

Author (Year)	Study Purpose/Objectives	Design, Sampling, Method, & Subjects	Level of Evidence	Interventions & Outcomes	Results	Study Strengths & Limitations
Anson, P. (2016).	n/a-opinions of people in regard to opioid prescriptions	Convenience sampling from a newspaper.	n/a	n/a	Patients are unhappy and feel unsupported.	n/a-public survey
Becker, W.C., Dorflinger, L., Edmond, S.N., Heapy, A.A., & Fraenkel, L. (2017).	Purpose was to identify barriers and facilitators on the patient, RN, and PCP level of pain management.	Nominal Group Technique, Qualitative, 26 patients, 14 nurses, 12 PCPs, convenience sample	6	n/a	Barriers and facilitators to nonpharmacological pain management were identified.	Received viewpoints from different levels in practice;
Bradshaw, Y. S., Patel Wacks, N., Perez-Tamayo, A., Myers, B., Obionwu Jr., C., Lee, R. A., & Carr, D. B. (2017).	The purpose was to better educate medical students on pain management as a disease instead of just a symptom.	Evidence-based practice project; 104 medical students, survey,	6	New class discussing pain management;	The concluded that medical students should be taught that pain is a disease and not a symptom.	Evidenced-based proposal; only generalizable to this school
Burke, A.L.J., Mathias, J.L., & Denson,	To identify psychological issues associated with chronic pain.	Meta-analytic review; 10 studies	5	n/a	Showed that the relationship between chronic pain	Systematic review of 10 studies, limited by the 10

L.A. (2015).		were included			and psychological symptoms are more complex than initially thought.	studies allowed in.
Buttaro, T.M., Trybulski, J., Polgar-Bailey, P., & Sandberg-Cook, J. (2017).	Primary care textbook, informational.	n/a	n/a	n/a	Information for students.	n/a
Centers for Disease Control and Prevention. (2017).	Statistics from the CDC, informational.	Based on reported data.	n/a	n/a	Statistics	n/a
Central Virginia Health Services. (2016).	Informational,	n/a	n/a	n/a	n/a	n/a
Dowell, D., Haegerich, T.M., & Chou, R. (2016).	Review of literature to made new recommendations for opioid prescribing.	Systematic review; guideline developments; multiple study types included.	3	n/a	Recommendations for practice based on current research.	Recommendations made based on current information.
Ernstzen, D.V., Louw, Q.A., &	To review different clinical practice guidelines in primary	Systematic review of 12	5	n/a	Recommendations for primary care offices	Systematic review; only discussed

Hillier, S.L. (2017).	care for patients in chronic p	clinical practice guidelines.			for clinical practice guidelines, including seeking patient preferences in care.	guidelines regarding musculoskeletal pain.
Fu, Y., McNichol, E., Marczewski, K., & Closs, S. J. (2016).	Inquire the affect of the patient-provider relationship on self-management of chronic back pain.	Systematic review; 10 qualitative research studies	5	n/a	Found seven common themes that impact the patient-provider relationship.	Systematic review; limited by only using certain keywords.
Gerhart, J., Burns, J., Post, K., Smith, D., Porter, L., Burgess, H., & ... Keefe, F. J. (2017).	Looking at the relationship between chronic back pain and sleep.	Descriptive survey; 105 patients in chronic pain	6	Survey Results.	The authors concluded that chronic pain management should include assessing and treating patient sleep.	Assessed patient's pain at different times of the day; short sampling period of 14 days.
Hall, H.R. & Roussel, L.A. (2014).	Textbook: Discusses evidenced based practice in relation to healthcare, including integrating it into practice.	n/a	n/a	n/a	n/a	n/a
Hoy, D., March, L., Brooks, P., Blyth, F., Woolf, A., Bain, C., & ... Buchbinder, R. (2014).	Gather statistics about the global incidence of low back pain.	Systematic review; 117 studies about low back pain	3	n/a	Low back pain is one of the leading causes of disability globally.	Systematic review with a lot of different data sets; data is from 2010.
Institute of Medicine	To describe the issues with pain management	Systematic review	3	n/a	Pain must be viewed as a disease,	Recommendations from a

(IOM). (2011).	and offer recommendations.	of availabl e data.			not a symptom. Recommen dations for further research.	group of experts; not all the data was exhausted.
Iowa Model Collaborat ive. (2017).	Revision and validation of the Iowa Model of evidenced based practice.	Survey, 299 returned surveys from those who used the model.	6	The Iowa Model used in practice .	Some revisions to the model were made. It will still guide the evidenced based practice process.	Gathered informatio n from those who used the Iowa model; convenienc e sample.
Loeser, J. D., & Schatman, M. E. (2017).	Opinion of how pain management is addressed in medical schools.	Editorial ; n/a	7	n/a	Educating on pain managemen t lacks in medical schools and also contributes to provider bias.	Based on personal experience.
National Academy of Medicine (NAM).	Looking at the providers role in the current opioid epidemic.	Opinion s of a panel; n/a	7	n/a	Defines the opioid epidemic and details the different aspects different providers have to address.	Completed and written by a panel of experts; based on statistics and opinion.
Shreier, A. (2014).	CEU course on pain management, from definitions to pharmacological/nonp harmacological management.	n/a	n/a	n/a	n/a	n/a
Simson, K.J., Miller, C.T.,	To see how conservative back pain treatment affects the patient.	Random ized controlle d trail;	2	Motor control and manual	Will inform clinical practice for providers.	Randomize d controlled trail;

Ford, J., Hahne, A., Main, L., Rantalainen, T., …Belavy, D.L. (2017).		40 participants		therapy and general strength and conditioning.		results may not be generalizable.
Smith, M.J. & Liehr, P.R. (Ed.) (2014).	Textbook on middle range nursing theories.	n/a	n/a	n/a	Information on evidence-based nursing theories.	n/a
Sollecito, W.A. & Johnson, J.K. (2013).	Textbook discussing quality improvement methods in the healthcare system.	n/a	n/a	n/a	n/a	n/a

Figure 1-Iowa Model for Evidence Based Practice

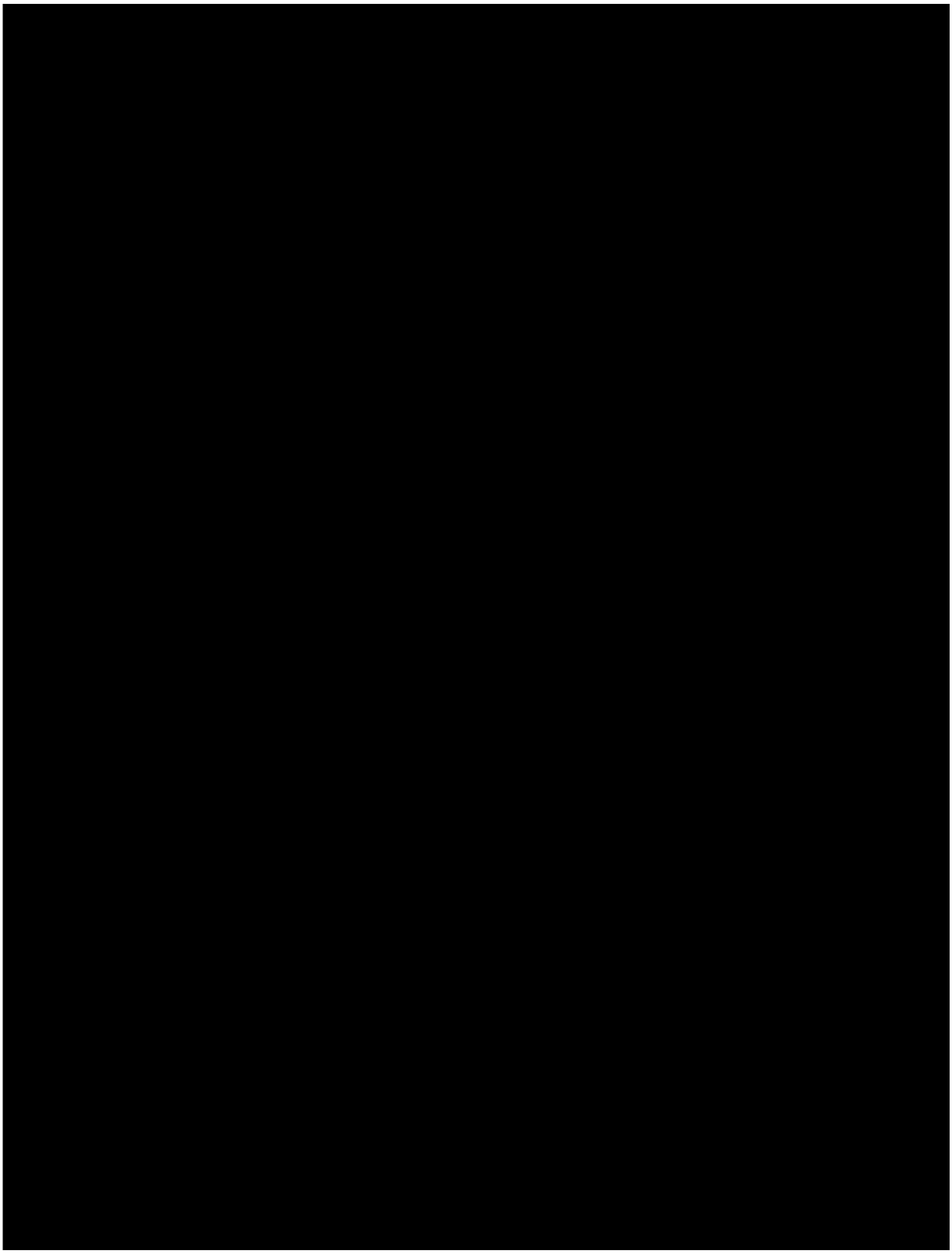

Figure 2-Brief Pain Inventory