

CHRONIC NONINTERVENTIONAL, NONCANCER PAIN

PROTOCOL

The effective management of the patient with chronic pain involves the coordination of multiple medical and psychiatric specialties, and the implementation of a systematic assessment of an affected individual's biopsychosocial parameters, as well as the provision of an organized methodology of routine reassessment and adjustment of a proactive, functionally based program to restore health and return to a productive life. The goal of chronic pain management is to improve function with minimal intervention. There is often a delicate balance between under and overtreatment of chronic non-cancer pain. This protocol outlines optimal strategies for patient management, and should not be viewed as being prescriptive or prohibitive in nature.

The treating medical practitioner's judgement, supported by an evidence-based medical plan, is paramount in the implementation of care for any specific patient. This protocol, therefore, is intended to assist in the provision of a guide to improve health care services for injured workers by outlining the appropriate evaluation and treatment procedures for the management of chronic, non-cancer pain in injured workers who do not have acute pain, and are not acutely postoperative in nature and in whom the cause is determined to be work-related.

This protocol provides information on the scope of the challenge, recommendations for prudent treatment, including prescribing and monitoring, advice on when and how to seek consultations, and patient education resources.

DEFINITIONS

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience with actual or potential tissue damage". It is a complex experience involving physical, mental, social, and behavioral processes that often compromise the quality of life. Pain can be perceived without tissue damage or a clearly identified pathophysiologic cause.

Chronic pain, or "Pain Disorder", represents a specific diagnosis. Chronic pain is often defined as pain originating from an injury and lasting in excess of three months. It also refers to pain outlasting an expected duration of healing for the tissue injury incurred, as defined by evidence based guidelines based on the diagnosis. It is manifested by inappropriate pain, or an out of proportion amount of pain related to an injury or illness. It is not predicted by acute pain levels. Common clinical manifestations include persistent pain complaints, anxiety symptoms, impaired function beyond that anticipated based on the injury and degree of physical injury, depression, and anger/fear. It is often associated with psychosocial problems. Addictive behaviors, marked somatic over focus, and factitious disorders can form barriers to recovery. Chronic pain is not a phenomenon limited to anatomical or physiologic parameters. Expectations of a cure may not be

reasonable. Lifelong management is necessary in some cases, and may require repeat cycles of chronic pain treatment.

There are several pain classifications. Nociceptive pain originates from visceral origins or other tissues. Myofascial pain is nociceptive pain characterized by myofascial trigger points limited to specific muscles, in predictable locations, and can have possible psychogenic components. Neuropathic pain originates from the central nervous system (CNS) or peripheral nervous system (PNS). In injured workers, central and neuropathic mechanisms may confound nociceptive processes. Psychogenic pain originates in social, characterological, mood, or psychophysiological processes. Pain can involve neural remodeling within the spinal cord as well as higher levels of the CNS, changes in membrane responsiveness and connectivity leading to larger and more intricate pain pathways, and neurotransmitter recruitment. In addition, alterations in gene function/expression can lead to functional changes which, in turn, can lead to chronic pain in other body regions than that involved in the original injury.

INITIAL EVALUATION

Key components of the initial evaluation of a patient with chronic pain include:

- Thorough history and physical exam
- Completion of appropriate pain questionnaire(s)
 - Includes drug/alcohol use (past and present)
 - Includes nicotine use
- Psychiatric history
- Full medication list
- Social history
- Work history
- Legal history
- Employment history
- Evaluation of patient expectations

HISTORY

As with any other medical problem, a thorough medical history should be obtained and documented in the medical record. This should include the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. A thorough psychosocial history, medical management history, as well as description of history of any other

factors that may affect treatment outcome should also be addressed. Many evidence based guidelines are available for reference regarding more detailed descriptions of specific questions to be addressed. Inquiries for psychological and psychiatric issues are an important component of the evaluation of a patient presenting with chronic pain. Strong consideration, therefore, should be given to the implementation of disability questionnaires and pain diagrams in the evaluation of patients presenting with chronic pain. Many are readily available, such as the Zung Self-Rating Depression Scale, Modified Somatic Perception Questionnaire, Oswestry Disability Index, and the Fear Avoidance Behavior Questionnaire. There is currently no consensus agreement as to which specific questionnaires are preferable for use. The use of questionnaires that are brief, simple to understand and complete would be preferred. All health care practitioners who choose to incorporate specific questionnaires into their practices should thoroughly familiarize themselves with the correct interpretation and application of results.

PHYSICAL EXAM

Physical examination of the affected region should include inspection of any atrophy, posture and gait abnormalities, observation of non-organic signs, and general assessment of vital signs, speech and thought. Both active and passive range of motion testing should be done. Strength testing, including core stability, should be evaluated. Reflexes, sensation and neural tension should be tested.

In addition to conducting and documenting a focused examination of the relevant body systems affected by the original work injury, a psychologic evaluation should be conducted. As many physicians without specific training or expertise in this field may feel uncomfortable in this evaluation, strong consideration should be afforded for referral to a licensed, board certified mental health or behavioral medicine expert (commonly a psychiatrist or psychologist) for a full psychosocial evaluation. If available, referral to such an expert with experience in the treatment of injured workers/workers' compensation patients is preferred.

DIAGNOSTIC TESTING

Treatment modalities may be utilized sequentially or concomitantly, depending on chronicity and complexity of the problems. Care should be exercised to avoid duplicative services/testing. The focus of testing should be to most accurately diagnose any underlying illnesses or physical residua of the original injury, as well as the determination of level of function, physical conditioning, and delineation of contributing biopsychosocial factors delaying recovery. Any testing should only be considered if there is a potential for meaningful subsequent intervention, based on the testing results. Additionally, testing considerations are defined by the clinical entity and body part being investigated. Testing for the identification of other disorders is often required to omit the possibility of other diagnoses. They should be ordered only if there is a reasonable expectation that an additional diagnosis is present, with appropriate medical

documentation for the ordering of the test. The diagnostic procedures protocol outlines these tests and their indications.

FUNCTIONAL/WORK/PHYSICAL CAPACITY EVALUATION. A systematic, structured evaluation of the injured worker's level of physical function, conducted by an appropriately trained individual (usually an occupational or physical therapist). Functional Capacity Evaluations (FCEs) are a battery of performance based tests conducted to determine a patient's ability to work and perform activities of daily living (ADL). There are several models used, each with assessment of inter-and intra-rater reliability. FCEs are performed for several reasons in chronic pain patients. These include: 1) identification of an individual's ability to perform *specific* job tasks; 2) to assess an individual's ability to perform physical activities associated with *any* job; and 3) to assist in the objective determination of impairment. In general, an FCE is utilized to assist in goal-setting and rehabilitation planning, monitor a patient's rehabilitation progress, assess an individual's participation level and performance consistency.

JOB SITE EVALUATION. A thorough review of the injured worker's worksite and essential functions required to perform her/his job should be considered, again using a systematic approach, using well accepted methodology. Strong consideration should be given to inclusion of the injured worker in this review, to insure the accuracy of the results. This review should include all potential alternative jobs available to the worker upon her/his return to work.

VOCATIONAL ASSESSMENT. Particularly if return to the former place/position of employment seems unlikely to be an option for return to work, an assessment of the worker's vocational capabilities/qualifications should be considered, again usually utilizing the services of an occupational therapist or vocational counselor.

WORK TOLERANCE SCREENING. Should be conducted upon initial evaluation, as well as at regular intervals (every 3 to 4 weeks, up to a total of 6 evaluations). Can be conducted as part of a functional capacity evaluation (FCE).

PSYCHOLOGICAL SCREENING. Referral to an interdisciplinary program as part of the initial care of a chronic pain patient should be strongly considered to minimize disability and maximize function. Documentation should be provided regarding the causal connection of the ongoing disability to a work event/injury/illness, as part of a referral to such a center. This concept is addressed in the Treatment section below. Identification of psychosocial issues should be a major aspect of the initial evaluation or consultation for a new patient with chronic pain.

TREATMENT

All treatment rendered should be based on the prevailing underlying original diagnosis, utilizing appropriate diagnostic procedures, and should be accompanied by an aggressive return to work (full or modified capacity) program. Frequent reassessment, focusing on functional improvement with effective pain reduction, should be documented.

INITIAL CARE

Intervention should be time-limited and goal-oriented. In general, injured workers returning to work sooner after an injury tend to have better outcomes. The focus of chronic pain management, therefore, is on proactive, function-based approaches to care. Keeping the patient as physically active as possible is key to recovery. Construction of a program with gradually increasing or graded activities to incrementally regain a fully functional status, while learning how to interpret and manage pain is the goal. Medical, surgical, pharmaceutical, chiropractic and physical therapy treatment paradigms are outlined in the protocols that have been established by the Workers' Compensation Court.

Optimally, a referral to an interdisciplinary rehabilitation treatment program should be made. In such programs, one medical practitioner should serve as the primary source for the coordination of care and monitoring of the treatment plan in conjunction with other health care specialists.

Identification of psychosocial issues constitutes a major aspect of initial evaluation or consultation of patients with suspected chronic pain. Depression, anxiety, fear avoidance behavior, catastrophization, poor coping and poor self-efficacy correlate with poor outcomes. Mental health issues as concomitant presentations or, in the past medical history or family history, should be identified. Dysfunctional relationships with family members, friends, co-workers, or supervisors can be indicative of underlying behavioral medicine needs, thoroughly explored in a comprehensive manner. Substance abuse related concerns are paramount to explore, as well. Any suspicion of barriers to progress from these psychosocial issues will necessitate involvement of a behavioral medicine team member.

Initial visits should include obtaining more information from the patient, confirming the accuracy of the relevant injury medical history, observing for illness/injury behaviors, diagnosis confirmation, as well as an assessment of the need for psychological referral and evaluation.

Patients should be educated regarding their specific injury, assessment findings, and treatment plan. They should be encouraged to take an active role in establishing functional outcome goals.

ONGOING CARE

TREATING PHYSICIAN VISITS. The initial evaluation with the primary treating physician should be comprehensive, utilizing diagnostic tools such as pain questionnaires and diagrams, assessing the accuracy of the relevant medical history, assessing pain behaviors, medication use (particularly opiates), and the psychosocial milieu of the patient. Additionally, it is imperative to institute the education process of informing the patient about functional status, as well as the need to engage in a functional rehabilitation program focusing on restorative exercises. The use of pharmaceuticals should be clearly and concisely discussed, often with the provision and discussion of a pain contract. Such contracts thoroughly outline the basis for use of medications (particularly Schedule II, III, and IV drugs), the conditions of prescription, use of random drug

screening, as well as conditions for termination, both of ongoing prescriptions and, if appropriate, ongoing care by that provider. Follow-up visits should initially be quite frequent (every 1-2 weeks), but later can be tailored to the patient's needs. Once the patient has reached a point of maximum medical improvement, a follow-up visit schedule of every 6 to 12 months may be appropriate.

If objective clinical improvement is delayed or slower than expected, the treating provider must justify the necessity of continued care with a valid clinical rationale, with supporting objective clinical findings. Timeframes for specific interventions commence once treatments are initiated, not on the date of injury.

INTERDISCIPLINARY REHABILITATION FACILITY. As stated previously, the proper evaluation and management of a chronic pain patient requires significant time commitments and expertise beyond the simple treatment of the initial causative work injury/illness. Many HCPs do not possess the required resources to individually provide effective care for these individuals. Additionally, reimbursement for medical services is often insufficient to allow a concerned HCP to effectively address and manage the many parameters involved in the care of a chronic pain patient. The availability of an interdisciplinary or multidisciplinary rehabilitation program, therefore, can be crucial in providing the appropriate care necessary for the comprehensive care of an injured worker with chronic pain.

There are two fundamental types of multispecialty rehabilitation programs. The first, a multidisciplinary program, involves one or two specialists who direct the services of a number of team members, with each specialist often having independent goals. These programs can be subdivided further into four pain program levels: multidisciplinary pain centers (often associated with academic centers and include a research arm); multidisciplinary pain clinics; pain clinics; and modality-oriented clinics.

The second type of program is an interdisciplinary pain program (IPRP). Such a program involves a team approach that is outcome focused and coordinated, offering goal-oriented interdisciplinary services. At least weekly communication between team members is stressed. Most intensive of this type of program is a Functional Restoration Program, which stresses maximization of function vs. minimizing pain. Components of an interdisciplinary pain program include: physical treatment; medical care and supervision; psychological and behavioral care; psychosocial care; vocational rehabilitation and training; and education. This interdisciplinary treatment generally involves various combinations of physicians, physician assistants, psychologists, chiropractors, nurses, nurse practitioners, physical therapists, occupational therapists, dentists, pharmacists, and other healthcare professionals.

Interdisciplinary pain rehabilitation programs are currently the gold standard of treatment of chronic pain that does not respond to less intensive treatment modes, are chronic pain management programs that incorporate a biopsychosocial paradigm, usually with a proactive

functional restorative approach, that aims to enhance function, reduce pain and illness behavior, while mitigating disability associated with chronic pain. IPRPs utilize an integrated team of professionals who collectively provide intensive, goal-oriented, coordinated care. The team is usually supervised by a physician who is directly involved with the program and routinely examines and evaluates the patient for relevant parameters as well as benchmarks consistent with reasonable programmatic progress. The composition of the team often includes a physical and/or occupational therapist, psychologist, vocational counselor, nurse, and case manager. It is preferable that all team members have extensive experience with the workers' compensation system.

The purpose of IPRPs is to manage the psychological, social, physical, and occupational factors associated with chronic pain patients. The components offered, as well as the approach to care, may differ between programs. Most, however, include progressive physical activity, working toward the goal of self maintenance with a home exercise program, with gradual increases in personal as well as occupational tasks. Most programs begin with 5 day per week attendance. Physical reconditioning (framed on the essential functions of the patient's occupation), patient education, fear avoidance, behavior modification, stress management (biofeedback), and group interactions are core components of most programs. Routine monitoring of outcomes and progress, flexible tailored treatment plan adjustments, as well as interdisciplinary communications and meetings are critical to success. Successful programs emphasize principles of functional restoration. When evaluated in consideration of cost-effectiveness (in terms of direct health care expenditures), disability costs, as well as other economic indicators, such programs are desirable, when available. There is a wide range of programs, with many factors (economic, etc.) influencing the breadth of services available in any given program. Work conditioning and work hardening programs, including functional capacity evaluations, are often a key component to IPRPs. Inpatient programs are occasionally indicated for high risk, medically unstable patients, those with moderate to severe physical or functional impairment or pain behaviors, or significant cognitive/emotional impairment, or those requiring inpatient withdrawal or around the clock nursing.

Criteria for admission to IPRPs include:

- Presence of an identified etiology underlying the chronic pain condition.
- Failure of appropriate medical/invasive care to restore functional status.
- Initial screening/assessment indicates rehabilitation potential.
- No contraindications to program participation (such as substance abuse disorder, cognitive limitations, or unstable medical conditions).

No specific timeframe exists to guide referral to an IPRP. Many patients manifest signs of chronic pain early on in their case; others do not.

Treatment objectives of IPRPs generally include:

- Functional improvement, including activities of daily living (ADLs).
- Relevant psychosocial improvement.
- Improvement in medical management parameters, including medication usage. This includes withdrawal from opioid, sedative-hypnotic, as well as muscle relaxant medications.
- Productivity improvement, including return to work in full/limited capacity.

If these benchmarks are not achieved within a reasonable amount of time (determined by the IPRP guidelines), the program is terminated. Note should be made, however, that there exists variability in the rate of patient response and progress, with some patients worsening before improving. Some patients may initially require inpatient care, including detoxification.

The median duration of IPRPs is 20 business days, including a 10 day initial trial with assessment of patient compliance, attendance, participation, and progress. Some flexibility need be allowed, however, on a case-by-case basis. Weekly attendance is usually all day, 5 days per week.

In the absence of an available interdisciplinary functional rehabilitation center, a “virtual center” may be useful. Such a center is comprised of the appropriate staff outlined above, however, there is no one structure/facility in which all treatment is rendered, but rather, a system is established whereby all staff members routinely meet, either telephonically, via skype, or in person, to manage each case appropriately.

MEDICATIONS

NSAIDs. NSAIDs may be indicated for use in chronic pain. Acetaminophen is recommended for those patients with contraindications for NSAIDs. Cytoprotective agents may need to be employed in patients with a history of gastrointestinal issues.

ANTIDEPRESSANTS. Antidepressants have been utilized for many years for the treatment of chronic pain. Where depression is moderate to severe, the dosage of antidepressants should be based primarily on the treatment of the depression, not of the chronic pain. In such cases, it is advisable to consult a mental health professional for guidance.

There are two main antidepressant classes used for chronic pain management, tricyclic antidepressants (TCAs) and serotonin norepinephrine reuptake inhibitors (SNRIs). This group includes duloxetine, venlafaxine and milnacipran. An additional group of agents, known as serotonin reuptake inhibitors (SSRIs) are not generally useful in the treatment of neuropathic pain. Included in this group of agents are fluvoxamine, citalopram, escitalopram, fluoxetine, sertraline, and paroxetine.

While SSRIs are not recommended for treatment of chronic persistent pain, these agents may be considered in those cases in which use of NSAIDs, exercise, manipulation, and a trial of TCAs has proven ineffective.

ANTICONVULSANTS. These agents have most commonly been used over the last 50 years for the treatment of neuropathic pain. Agents included in this category include: carbamazepine, valproic acid, phenytoin, clonazepam, lamotrigine, tiagabine, topiramate, levetiracetam, oxcarbazepine, and zonisamide. Two agents, namely, pregabalin and gabapentin, are used the most widely. In general, these agents are not recommended for use in nonradicular chronic pain. An exception to this may be topiramate, which may be considered as a fourth or fifth line agent in chronic low back pain. As with all agents, the length of medication use is indefinite and should be addressed routinely in all chronic pain cases, utilizing the lowest effective doses. Anticonvulsant use for chronic radicular or peripheral nerve pain is recommended.

BISPHOSPHONATES. Bisphosphonates reduce osteoclastic bone activity, with accompanying net gain of bone mass. They have been evaluated for potential analgesic properties. In patients with Chronic Regional Pain Syndrome (CRPS), they have been recommended in patients after failure of NSAIDs and exercise based therapy. However, they are not recommended for chronic pain patients other than those with CRPS.

GLUCOCORTICOSTEROIDS. Steroids have been used frequently for acute radicular pain, and for CRPS. Their use via systemic or topical routes is not recommended for trigger point/myofascial pain, nor are they recommended for use in chronic persistent pain, or nonradicular pain. The adverse effects of steroids are well known.

CALCITONIN. Calcitonin is a hormone secreted by the parafollicular cells of the thyroid gland. It is a treatment option for CRPS patients who remain significantly symptomatic despite a trial of NSAIDs, corticosteroids, active physical therapy, and bisphosphonates. Duration of use varies, and may be indefinite. It has not been shown to be an effective treatment option in other forms of chronic pain, however.

CLONIDINE. Clonidine is an alpha-agonist commonly used as an antihypertensive and has been used in CRPS patients, owing to its impact on nociceptive processing. Also in those with a history of CRPS, it is used with intravenous regional anesthesia prior to surgery, to minimize the recurrence of CRPS. It is not recommended for use in non-CRPS chronic pain patients, although it is used occasionally for epidural injections.

HERBAL PREPARATIONS, ALTERNATIVE TREATMENTS. Many complementary or alternative methods are available, including homeopathic, herbal, and naturopathic treatments. Unfortunately, the use of most of these interventions is not supported by quality evidence of efficacy.

DIETARY SUPPLEMENTS, VITAMINS. Evidence is generally poor that vitamin or mineral supplementation in normally over-nourished Western societies, is necessary. Vitamin D deficiency may be an exception to this, as Vitamin D deficiency has been associated with various pain syndromes. When a deficiency of 25-OH-Vitamin D is identified on laboratory testing, supplementation is medically appropriate.

GLUCOSAMINE has not been shown to improve pain related disability in chronic low back pain.

NMDA RECEPTOR ANTAGONISTS. N-methyl-D-aspartate (NMDA) antagonists work by blocking receptors of neurotransmitters that are necessary to long-term memories. They are also thought to assist in preventing acute pain from transitioning into chronic pain, as well as potentially help reduce opioid tolerance and enhance opioid analgesia. As the most investigated member of this group, dextromethorphan has been found to be useful in select chronic pain patients who have failed a course of NSAIDs, TCAs, as well as anti-convulsant agents, and have a peripheral neuropathy, diabetic or otherwise. They are not, however, recommended for use in other chronic pain patients, or in CRPS cases.

SKELETAL MUSCLE RELAXANTS. There are many agents comprising this group, designed to effect muscle relaxation through, primarily, CNS effects, not effects on skeletal muscle. It is a diverse group, consisting of sedative-hypnotics, tranquilizers, CNS depressants, and neuromuscular blocking agents. Due to the high possibility of adverse effects exceeding anticipated beneficial impact, these agents are not recommended for mild to moderate chronic pain, nor for treatment of trigger points/myofascial pain. Their benefit in CRPS has been insufficiently studied to date.

TOPICAL MEDICATIONS. This also is a diverse group, including agents such as patches, sports creams, NSAIDs, dimethyl sulfoxide (DMSO), capsaicin and N-Acetylcysteine (NAC). One additional agent in this group, capsaicin, is considered to reduce pain by stimulating nerve fibers removed from the site of pain, these agents are thought to work by distraction. One of the purported benefits of these agents is the relatively low incidence of adverse systemic effects.

LIDOCAINE PATCHES. Increasingly popular, topical lidocaine patches can be used to treat chronic pain syndromes, including carpal tunnel syndrome and postherpetic neuralgia, when localized pain is present.

OPIOIDS . Opioids are potent analgesics used widely to manage moderate to severe acute pain and pain arising from cancer. Use of opioids has increased dramatically in recent years, owing in part to national initiatives for quality improvement mandating assessments and treatment of pain. Management of chronic non-malignant pain with long-term, high dose opiates, however, is controversial, and requires a structured program of frequent follow-ups with documentation of improved function and compliance. Approximately 50% of patients tolerate opioid side effects and receive acceptable levels of pain relief with their use.

If opiates are determined as being necessary as part of a function-based chronic pain rehabilitation program, one health care provider should act as the sole provider of prescriptions, with use of a single pharmacy. Evaluation of refill records through pharmacies to determine appropriateness of a prescription regimen should be undertaken. Evaluating the effectiveness/impact on function with past medication regimens should also occur. The HCP should utilize, where available, programs such as the Prescription Monitoring Program (PMP) offered by the Rhode Island Department of Health, to ensure that there is no prescription duplications, and that a comprehensive, accurate accounting of a chronic pain patient's current prescriptions is reviewed. The health care provider (HCP) should not rely on the accuracy of medication use provided by the patient. The provider should ensure that other members of the patient's treatment team (consultants, nurse case managers, etc.) are aware of the relevant medications prescribed, as well as any adjustments to a patient's physical or mental restrictions that accompany use of the medications, thus minimizing the risk of further injury or illness to both the patient as well as any other individuals who may come into contact with the patient (e.g., driving restrictions, performance of dangerous or safety sensitive functions).

In general, routine use of opiates for chronic non-malignant pain is not recommended. However, carefully selected patients may benefit from the judicious use of this group of medications. Those with chronic, persistent pain that is not well controlled with non-opioid treatment (physical functional restoration, behavioral modifications, modalities, non-opioid medications), as evidenced by a lack of functional improvement, may benefit. In addition, patients who have demonstrated sustained improvement in function and pain levels in a previous opioid trial may be considered reasonable candidates for opioid treatment. The goal of opioid use should be to achieve sustained pain and physical function improvement. Initial prescription should not exceed a five day supply of medication, with follow-up scheduled before prescription renewal occurs. It is critical that, if no improvement in either parameter (sustained pain and physical function improvement) occurs, appropriate consultation with a chronic pain specialist/program be strongly considered.

Several risk factors warrant close scrutiny when prescribing opiates. Those patients with depression, prior psychological disorders, history of alcohol and/or drug abuse/dependence, nicotine use, as well as a history of a personality disorder are at increased risk of a poor outcome. The use of nicotine has been associated with an increased risk of substance abuse and should, therefore, be explored with the patient. Numerous medical conditions, when present, should preclude consideration of opiates:

- Chronic obstructive pulmonary disease
- Congestive heart failure
- Sleep apnea
- Current/past alcohol or substance abuse

- History of renal/hepatic dysfunction
- Concurrent use of sedative-hypnotics, benzodiazepines, or barbiturates. Do not initiate use of opiates with these agents unless a specific medical and/or psychiatric indication for combined use is present, and increased monitoring is instituted.

In addition to the above, there are several high risk warning signs for possible drug abuse/addiction, including:

- Active alcohol or other substance abuse
- Untreated mood or psychotic disorder (depression)
- Decreased physical or mental function with continued opioid use
- Addictive behaviors
 - Drug preoccupation
 - Medication taper refusal
 - Demanding a specific opioid (all others deemed as ineffective)
 - Preference for short over long-acting opioids
 - Multiple prescribers/pharmacies
 - Street drug use
 - Use of other's drugs
 - Non-compliance with prescriptive use
 - Multiple medication losses
 - Criminal behavior associated with obtaining drugs

An opioid trial is defined as the period of time during with the effectiveness of using opioids in a given patient is tested to see if the goals of functionality and decreased pain are met. Such a trial should be initiated prior to treating a patient with long-acting opioids, and should include clearly delineated treatment goals. If the trial goals are not met, the trial should be discontinued, and an alternative approach should be pursued to treat pain. After prescribing opiates to a chronic pain patient, frequent medical follow-up visits, at every 2 to 4 weeks initially, should be scheduled to monitor efficacy, compliance, adverse effects, and surreptitious medical use. Assessments must measure the same elements serially to determine progress. Documentation of objective functional improvement is a paramount component of the prescription program for opiates in a given individual. At least 30% reduction in pain with corresponding improvement in function (including returning to work and/or improvement in activities of daily living (ADLs) should be documented. Failure of initial trial to result in objective functional improvement or resolution of

pain should warrant strong consideration of cessation of further prescriptions. Several tools are available to assess opioid treatment on function and pain, as there is currently no universally accepted standard scale. Some tools commonly used include:

- Graded Chronic Pain Scale
- Brief Pain Inventory
- Quick Dash
- Oswestry Disability Index
- DIRE (Diagnosis Intractability Risk and Efficacy) Score

Prior to the initial prescription of opiates to a patient with chronic pain, who is not currently taking opiates, several procedures should occur. Screening of patients regarding prior alcohol/drug abuse can be facilitated by use of several assessment vehicles, such as the CAGE tool for alcohol use, the PHQ-9 screening test for severity of depression, and Graded Chronic Pain Scale for baseline assessment of function and pain, as well as similar tools that are readily available, for use in populations on or considering institution of opioid therapy. Individuals with a prior history of alcohol/drug abuse, and/or psychological problems are at increased risk of developing opioid related use/abuse issues. As many health care providers may not feel comfortable with the degree of complexity involved in the assessment and management of chronic pain patients, particularly those with a history of alcohol/drug abuse and/or nicotine use, strong consideration should be given for early referral to an appropriate pain or addiction specialist/psychologist/psychiatrist.

The use of a treatment agreement to document patient understanding and agreement with the expectations of opioid use, known as an “Opioid Contract”, is strongly recommended (see the Rhode Island Department of Health guidelines). It is recommended that this document be a "trilateral opioid agreement" which outlines an understanding among the patient, prescribing doctor and primary care provider. The primary care provider typically has the best understanding of a patient's medical history and, as an integral part of a patient's health care team, may wish to opine on the appropriateness of opioid medications. Because these medications tend to be ongoing once initiated, the primary care provider should be invited to communicate their beliefs about opioid use in chronic, benign pain and their willingness to assume the prescriptions once frequent visits with the occupational health professional or other specialist is no longer needed. Many versions of such a contract are available. Contractual components usually include medication side effects, requirement for continued active therapy, urine drug screening parameters, clearly delineated reasons for opioid management termination, referral to addiction specialists, as well as reasons for tapering opioids. The provision of a contract should accompany an explicit decision and agreement between the prescriber and patient prior to initiating opioid therapy. All reasonable attempts should be made to ensure that

the patient understands the contents and intent of the document, and attests to this understanding by signing the contract. The document should be available in a written language that the patient comprehends fully, with verbal explanation if the patient is illiterate. Patients should be informed regarding the responsible use of opioids and the proper process for obtaining their medications. As part of the initiation of a contract, the medical record should include documentation of failure of pain management alternatives (active therapies, cognitive behavioral therapy, pain self-management techniques, and any other appropriate medical interventions) in a motivated patient.

Unfortunately, it is well accepted that many patients do not adhere to prescribed treatment, even with the use of a contract. Therefore, in order to maximize the probability of adherence to the program, a urine drug screening program should be implemented. Screening can aid in the identification of aberrant behavior, undisclosed drug use and/or abuse, improve the safety and appropriateness of opioid therapy management, and verify compliance with treatment. Screening is recommended at baseline on all transferring patients already taking opioids as well as patients about to be placed on chronic opioids (usually not sooner than 6 weeks after acute injury). In addition to baseline testing, testing should also be conducted randomly at least twice, and up to four times per year, as well at termination of the testing interval. In addition, “for cause” testing should be pursued whenever the HCP suspects drug use in excess of prescriptions, the appearance of over-sedation, drug intoxication, a motor vehicle accident (as well as other accidents or injuries), driving while intoxicated, premature prescription renewals, self-directed dose changes, lost or stolen prescriptions, use of more than one prescriber, non-pain use of medications, use of alcohol for pain treatment, excessive alcohol use, missed appointments, medication hoarding, and evidence of selling medications. These are but recommendations for testing intervals, however, as there should remain flexibility in testing schedules, depending on the HCP’s judgement in a given case. Random testing should be conducted at frequencies determined by the specific patient’s risk category, based on screening, behavioral factors (in which the inclusion of family and friends’ input can be helpful), with referral to an appropriate laboratory.

In many states, the choice of which opioids to prescribe, as well as the dosing of agents, utilizes comparison of the relative potencies of opioids compared with a corresponding dose using morphine, termed the Morphine Equivalency Dose (MED). In general, the choice of any opiate should be the lowest dose that is effective for decreasing pain while increasing function. Most studies focus on the use of opiates in the treatment of nociceptive pain, with few studies focusing on neuropathic pain. Evidence to support opiate use in neuropathic pain is weak. Some studies indicate that tramadol can be effective in this scenario, as well as oxycodone. Carbamazepine is more effective than morphine. In general, opioids are not effective in the treatment of radicular pain. The use of opioids for the treatment of myofascial pain/trigger points is not recommended. Also in general, the effectiveness of opioids for pain reduction and increased function, as well as a significant quality of life improvement, in chronic, non-visceral pain conditions is debatable,

although the use of short-acting, as well as medium-term opioids may lead to pain decrease when compared to placebo. Although the use of other medications and treatments are superior to opioids for most chronic pain patients, a select number of patients may show significant improvement with their carefully implemented and monitored use. In this subset of patients, however, the goal should remain the maximization of function with the integration of the use of opioids with a structured rehabilitation program, with reduction or eventual elimination of the need for opioid use. In some patients, the development of hyperalgesia can occur, which leads to an increase in pain due to the use of opioids. The development of this should prompt discontinuance of the medication in a gradual manner designed to avoid drug withdrawal.

Long acting oxycodone and oxymorphone have equal analgesic effects, as well as side effects. Long-acting opioids are not superior to short-acting opioids in improving function or pain, or inciting less addiction. Long-acting opioids result in less pronounced euphoria and are less likely to lead to addiction. The lowest opioid dose should be used when prescription of these agents is initiated. Many states recommend that 100-120mg MED be considered a cut-off for mandated referral to a board-certified addiction/noninterventional chronic pain specialist. Doses in excess of 100 mg MED are associated with increased duration of disability and, therefore, dictates close monitoring.

Opioid abstinence syndrome is rarely medically serious, and can include symptoms such as nausea, diarrhea, myalgias, and myoclonus. It can be treated with clonidine, 0.1-0.2 mg. p.o. q 6 hrs. (0.1 mg transdermal patch/24 hrs. weekly during the tapering interval). Monitoring for anticholinergic side effects, as well as hypotension, is recommended. Mild opioid withdrawal symptoms may persist for up to 6 months after discontinuance of the drug. A rapid reoccurrence of tolerance can occur for months to years after prior chronic use. Withdrawal symptoms should not be treated with opioids or benzodiazepines after discontinuing opioids. If considering withdrawal from an opiate for a chronic patient, strong consideration should be given to referral for appropriate management. In all instances, the prescriber should remain sensitive to preserving the therapeutic relationship to avoid behavioral issues and doctor shopping.

Deciding to begin the use of opioids in a chronic pain patient requires a thorough knowledge of the risks involved. HCPs who do not feel comfortable with this should strongly consider consultation/referral to a specialist with experience and expertise in the management of chronic pain (preferably with experience in the nuances involved in the treatment of injured workers).

Specialty consultation indications include:

- Ongoing severe pain symptoms without significant functional improvement or improvement in pain control, despite opioid treatment.
- Persistent pain with minimal or absent underlying tissue pathology, and correlation between the original injury and severity of impairment is unclear.

- Pain behaviors are present, and risk behaviors are present, with unsuccessful standard treatment measures.
- Strong evidence of worsening pain behaviors.
- Unusual knowledge of controlled substances
- Request for specific agents, or claims of allergies/ineffectiveness of other medications
- Demands for assessment/medications after hours
- Unscheduled refill requests
- “Loss” of prescriptions
- Mood disorder/other psychiatric condition
- Drug abuse physical signs
- No apparent interest in diagnosis, noncompliance with appointments.
- Feigning/exaggeration of physical problems
- Exertion of pressure (via solicitation of sympathy, guilt, or via direct threats) on HCP
- Subjective complaints exceeding objective findings
- “Firing” of physician after refusal to fill prescriptions
- No work for greater than 6 months with minimal functional improvement with active therapy.

From time to time, specialist consultation may be necessary to assist in the care of a patient with chronic pain. Reasons for referral may include identification of any undiagnosed conditions, assistance in pain management, identification of undiagnosed psychological conditions affecting treatment, identification of alternative treatments, and addiction management, as well as assistance in opioid tapering, methadone treatment inquiries, and management of aberrant behaviors. Consultations do not necessarily equate to transfer of care. Appropriate consultation with ABMS (American Board of Medical Specialties) certified/eligible physicians may be utilized as part of the care of an injured worker with chronic pain.

PROTOCOL HISTORY

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