

SYSTEMS IMPROVEMENT

Health Care Guideline:

Assessment and Management of Chronic Pain

Fourth Edition November 2009

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- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

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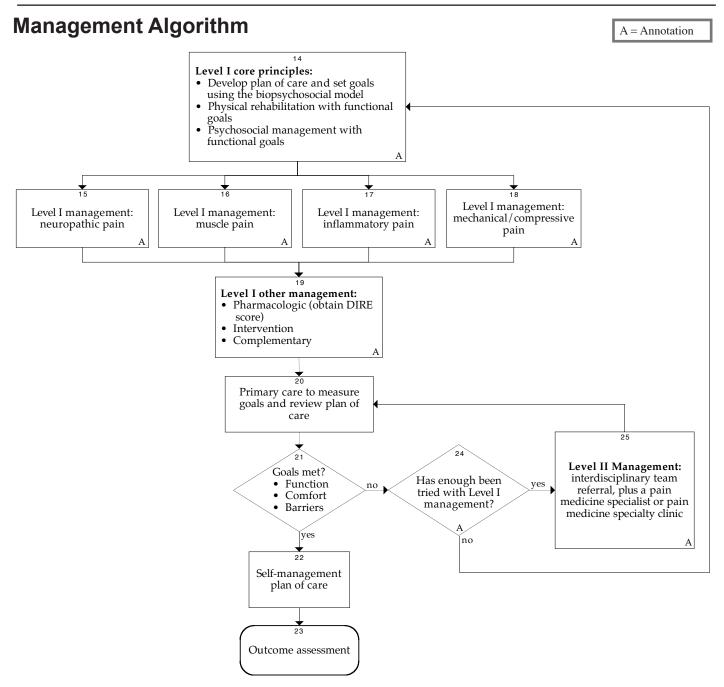
Health Care Guideline:

Assessment and Management of Chronic Pain

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

> **Fourth Edition** November 2009

Assessment Algorithm A = AnnotationPatient has pain Critical first step: assessment History and physicalKey questions Pain and functional Pain types and contributing assessment tools factors are **not** mutually exclusive. Patients frequently do have more than one type of pain, as well as Determine biological overlapping contributing mechanisms of pain factors. Neuropathic pain Muscle pain Inflammatory pain Mechanical/ • Peripheral (e.g., complex Myofascial Inflammatory compressive pain regional pain syndrome, pain syndrome arthropathies Low back pain HIV sensory neuropathy, (rheumatoid Neck pain metabolic disorders, arthritis) Musculoskeletal pain phantom limb pain) Infection - shoulders/elbow, Central (e.g., Parkinson's disease, MS, myelopathies, Postoperative pain Tissue injury Visceral pain poststroke pain, fibromyalgia syndrome) Is pain chronic? Out of scope yes Is there a yes correctable cause Specialty involvement of pain? no Other assessment Work and disability issues Psychological and spiritual assessment Contributing factors and barriers To management algorithm - see next page



Management of Chronic Pain: Evidence Grid

Evidence cited in the guideline regarding Level I and II treatment for chronic pain is summarized below. Please see the annotations for more detailed information for or against a particular type of treatment.

Level I Treatment		В	C	D	M	R	X
Plan of care using biopsychosocial model							
Physical rehabilitation				•			
Fitness/exercise program						Ι.	
Massage							
Other passive modalities							
Psychosocial management			•				
Cognitive-Behavioral Therapy						١.	
Mindfulness-Based Stress Reduction							
Hypnosis							
Biofeedback							
Pharmacologic management							
• NSAIDs							
Opioids							
Other antidepressants – SSRIs and SNRIs							
Anticonvulsants							
Topical agents							
Muscle relaxants							
Anxiolytics							
Drugs for insomnia							
Intervention management							
Diagnostic procedures							
Therapeutic procedures					•		
Complementary management							
Acupuncture					•		
Herbal products	•						
		_	_	_		_	
Level II Treatment	A	В	C	D	M	R	X
Surgical management			•		•	•	
Palliative interventions				•	•	•	
Nucleoplasty				•			
Spinal Cord Stimulation					•		
Intrathecal medication delivery		•					
Multidisciplinary pain rehabilitation				•	•	•	
Management for Specific Types of Pain		В	C	D	M	R	X
Neuropathic pain							
Muscle pain							
Inflammatory pain							
Mechanical/compressive pain			•			•	

ICSI Evidence Grading System				
Class A:	Randomized, controlled trial	Class M:	Meta-analysis	
			Systematic review	
Class B:	Cohort study		Decision analysis	
			Cost-effective analysis	
Class C:	Non-randomized trial with concurrent or historical controls			
	Case-control study	Class R:	Consensus statement	
	Study of sensitivity and specificity of a diagnostic test		Consensus report	
	Population-based descriptive study		Narrative review	
Class D:	Cross-sectional study	Class X:	Medical opinion	
	Case series		•	
	Case report			

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Foreword

Scope and Target Population

The guideline will address the management of chronic pain for physiologically mature adolescents (between 16-18 years) and adults. It can be applied to pediatric populations where noted. It is not intended for the treatment of migraine headaches, cancer pain, advanced cancer pain, or in the context of palliative care or end-of-life management.

Definitions

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (International Association for the Study of Pain).

- Acute pain states can be brief, lasting moments or hours, or they can be persistent, lasting weeks or several months until the disease or injury heals (*Bonica*, 1990 [R]). The condition has a predictable beginning, middle and end.
- Chronic pain is defined as persistent pain, which can be either continuous or recurrent and of sufficient duration and intensity to adversely affect a patient's well-being, level of function, and quality of life (Wisconsin Medical Society Task Force on Pain Management, 2004 [R]). If the patient has not been previously evaluated, attempt to differentiate between untreated acute pain and ongoing chronic pain. If a patient's pain has persisted for six weeks (or longer than the anticipated healing time), a thorough evaluation for the course of the chronic pain is warranted.
 - **Chronic Pain Syndrome** is at the end of the spectrum of chronic pain. The work group defines this as a constellation of behaviors related to persistent pain that represents significant life role disruption.

Clinical Highlights and Recommendations

- Chronic pain assessment should include determining the mechanisms of pain through documentation of pain location, intensity, quality and onset/duration; functional ability and goals; and psychological/social factors such as depression or substance abuse. (Annotations #2, 3, 12; Aim #2)
- The goal of treatment is an emphasis on improving function through the development of long-term self-management skills including fitness and a healthy lifestyle in the face of pain that may persist. (Annotation #14; Aim #1)
- A patient-centered, multifactorial, comprehensive care plan is necessary, one that includes addressing biopsychosocial factors. Addressing spiritual and cultural issues is also important. It is important to have a multidisciplinary team approach coordinated by the primary care physician to lead a team including specialty areas of psychology and physical rehabilitation. (Annotation #14; Aim #3)
- Level I treatment approaches should be implemented as first steps toward rehabilitation before Level II treatments are considered. (*Annotation #14; Aim #3*)
- Medications are not the sole focus of treatment in managing pain and should be used when needed to
 meet overall goals of therapy in conjunction with other treatment modalities. (Annotations #14, 19;
 Aims #4, 5)
- Careful patient selection and close monitoring of all non-malignant pain patients on chronic opioids is
 necessary to assess the effectiveness and watch for signs of misuse or aberrant behavior. (Annotation
 #19; Aim #5)

Priority Aims

- 1. Improve the function of adult patients with chronic pain. (Annotations #2, 14)
- 2. Improve the assessment and reassessment of adult patients with chronic pain utilizing the biopsychosocial model. (*Annotations* #2, 3, 12)
- 3. Improve the appropriate use of Level I and Level II treatment approaches for adult patients with chronic pain. (*Annotations #14, 19, 25*)
- 4. Improve the effective use of non-opioid medications in the treatment of adult patients with chronic pain. (*Annotations #15, 19*)
- 5. Improve the effective use of opioid medications in the treatment of adult patients with chronic pain. (Annotations #15, 19)

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- 1. It is important to take both a clinical and an operational approach for successful implementation of this guideline.
- 2. Develop a process that allows patients with chronic pain to see a dedicated care provider who has an interest or expertise in chronic pain. The care provider is responsible for care management involving chronic pain in order to foster continuity while allowing the primary care physician to focus on medical diagnosis.
- 3. Develop a process for handing off patients to a dedicated chronic pain provider within the clinic.
- 4. Develop a process to work collaboratively with other care providers in prescribing opioids with shared patients (e.g., dentists, specialists).
- 5. Establish a policy for monitoring and maintaining opioid agreements for prescription refills with other clinics, pharmacies, dentists and specialists.
- 6. Develop a process for scheduling follow-up patient visits to deter drug-seeking behaviors with other care providers, for instance, support personnel calling patients to schedule follow-up appointments with a dedicated chronic pain physician.
- 7. Develop staff and physician training regarding the organization's process for treating patients with chronic pain that could include process of referrals to chronic pain provider within the system, follow-up visits, prescription refills and continuity of care.
- 8. Train a chronic pain care team that minimally consists of a physician champion and medical support staff. Suggestion for care providers from other disciplines include pharmacy, chemical dependency, neurology, home care, social work, physical medicine and rehabilitation, and physical therapy.
- 9. Determine population ICD-9 codes for data collection that is unique to patients with chronic pain in your facility. Examples of this would be:
 - · low back pain
 - headache
 - neck pain

- fibromyalgia
- · chronic pain
- 10. Identify multidimensional pain assessment, functional assessment, psychological assessment, and opioid assessment tools that meet the needs of the care providers and are appropriate for the patient populations.

Examples of pain assessment, functional assessment, and psychological assessment tools are, but are not limited to:

- Brief Pain Inventory (BPI)
- Physical Functional Ability Questionnaire (FAQ5)
- Oswestry Low Back Disability Index (refer to ICSI Adult Low Back Pain guideline)
- PHQ-9

Examples of opioid and substance abuse assessment tools are, but are not limited to:

- CAGE and CAGE-AID
- Webster's Opioid Risk Tool (ORT)
- DIRE Tool
- Screener and Opioid Assessment for Patients in Pain (SOAPP®)
- Current Opioid Misuse Measure (COMMTM)
- Prescription Drug Use Questionnaire (PDUQ)
- Screening Tool for Addiction Risk (STAR)
- Screening Instrument for Substance Abuse Potential (SISAP)
- Pain Medicine Questionnaire (PMQ)

Related ICSI Scientific Documents

Guidelines

- Adult Low Back Pain
- Diagnosis and Treatment of Headache
- Major Depression in Adults in Primary Care
- Palliative Care

Disclosure of Potential Conflict of Interest

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee and Respiratory Steering Committee).

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Miles Belgrade, MD, received speaker's fees from Pfizer, Purdue Pharma, and PriCara; and has family-owned stock in Johnson & Johnson.

Michael Hooten, MD, participated in research projects through Mayo Clinic funded by Pfizer.

No other work group members have potential conflicts of interest to disclose.

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining input from and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at http://www.icsi.org.

Evidence Grading System

A. Primary Reports of New Data Collection:

Class A: Randomized, controlled trial

Class B: Cohort study

Class C: Non-randomized trial with concurrent or historical controls

Case-control study

Study of sensitivity and specificity of a diagnostic test

Population-based descriptive study

Class D: Cross-sectional study

Case series Case report

B. Reports that Synthesize or Reflect Upon Collections of Primary Reports:

Class M: Meta-analysis

Systematic review Decision analysis

Cost-effectiveness analysis

Class R: Consensus statement

Consensus report Narrative review

Class X: Medical opinion

Citations are listed in the guideline utilizing the format of (*Author*, *YYYY* [*report class*]). A full explanation of ICSI's Evidence Grading System can be found at http://www.icsi.org.

Definitions

✓ Addiction: Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

Allodynia: Sensitivity to a non-noxious stimulus like light touch or rubbing.

* Analgesic Tolerance: Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evidenced during opioid treatment and does not equate with addiction.

Biopsychosocial Model: Addressing the whole person in all his/her complexity, including physical and biologic factors, psychological state and beliefs, as well as the family, social and work environment.

DPNB: Dorsal Penile Nerve Block.

EMLA: Eutectic Mixture of Local Anesthetics.

LET: Anesthetic solution comprised of Lidocaine, Epinephrine and Tetracaine.

Neuropathic: A pathological change in the peripheral nervous system.

Nociception: The process of detection and signaling the presence of a noxious stimulus.

Opioid-Induced Hyperalgesia: Opioids may lead to a paradoxical increase in pain despite receiving increasing doses of opioids.

- * Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
- ✓ Physical Dependence: Physicial dependence is a state of adaptation that is manifested by a drug-class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
- * **Pseudoaddiction:** Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Radicular: Pertaining to a nerve root.

Somatic: Pertaining to the body wall, in contrast to the viscera.

* Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes, or use of medication for purposes other than those for which it is prescribed.

TAC: Anesthetic solution comprised of Tetracaine, Adrenaline (Epinephrine) and Cocaine.

✓ **Tolerance:** Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

Visceral: Pertaining to a bodily organ.

- * From "Model Policy for the Use of Controlled Substances for the Treatment of Pain" (5/98), Federation of State Medical Boards of the United States.
- ✓ From "Definitions Related to the Use of Opioids for the Treatment of Pain." 2001. American Academy of Pain Medicine, American Pain Society, and the American Society of Addiction Medicine.

Algorithm Annotations

Assessment Algorithm Annotations

2. Critical First Step: Assessment

Key Points:

- All patients have the right to an adequate pain assessment including documentation of pain location, intensity, quality, onset/duration/variations/rhythms, manner of expressing pain, pain relief, what makes it worse, effects of pain and a pain plan.
- A general history and physical exam are essential for assessment of chronic pain.
- Baseline functional ability assessment can provide objectively verifiable information about a patient's quality of life and ability to participate in normal life activities.

All patients have the right to an adequate pain assessment including documentation of pain location, intensity, quality, onset/duration/variations/rhythms, manner of expressing pain, pain relief, what makes it worse, effects of pain and a pain plan. The plan should include pain assessment tools that are appropriate for the individual, with self-report being the primary source, which includes the facilitation of regular reassessment and follow-up according to criteria developed by the individual organization.

In the evaluation of the patient with chronic pain, it is essential to perform a good general history and physical examination of the patient. In addition, certain areas deserve specific attention.

The history of the chronic pain patient may be very revealing and helpful. Carefully identifying the onset and progression of the problem may help to focus how a problem developed from localized pain to a more generalized or multifocal pain experience for the patient. For example, a patient who develops a low back injury may go on to develop neck and upper limb symptoms, as well. The history should also include the location, quality, intensity (such as on a visual analog scale), duration, aggravating and relieving factors of the pain. This can also include responses to and enumeration of prior treatments. Some inquiry of sleep and diet is also helpful.

It is essential also to elicit any history of depression or other psychopathology that may affect the perception of pain (*Carragee*, 2005 [B]; *Rommel*, 2004 [D]; *Schultz*, 2004 [B]; *Zautra*, 2005 [B]). Past or current physical, sexual or emotional abuse is also an important factor. A history of chemical dependency is of interest in this patient population. Also see Annotation #12, "Other Assessment."

Chronic pain frequently involves the musculoskeletal system and the nervous system, especially the spine and its contents. These areas should be examined more carefully and with attention to possible generators of pain relative to the patient's history.

Musculoskeletal: Observe for obvious deformity or atrophy. If atrophy is suspected, it should be measured. Asymmetry of the iliac crests can be a sign of sacroiliac joint pathology. Scoliosis per se is usually not a cause of pain.

Cyanosis or pallor of an extremity is also useful information, as is asymmetry of limb temperature. Examine posture gait and station. Range of motion of the spine does not correlate well with pathology. It has more significance in peripheral joint pathology. Involved joints should be examined for signs of effusion, instability, ligament or cartilage pathology. Palpation for areas of spasm or tenderness and for identification of trigger points is useful (*Rasmussen*, 2004 [C]).

Neurological: Some brief assessment of mental status is appropriate. Patients with significant cognitive or language function impairment will be much more challenging to treat. Much of the identifiable findings in patients with chronic pain will be referable to the peripheral nervous system. Therefore careful evaluation of muscle strength, sensation and muscle stretch reflexes is important. Findings of allodynia (sensitivity to a non-noxious stimulus like light touch or rubbing) and hyperalgesia are useful in any pain syndrome. Signs and symptoms of upper motor neuron dysfunction will provide clues to the existence of potentially painful conditions such as multiple sclerosis or myelopathy due to cervical spinal stenosis. Patients with hemiplegia or hemiparesis may present with central type pain syndromes.

Diagnostic Testing

There is no diagnostic test for chronic pain. It is important to remember that finding pathology on diagnostic tests does not necessarily prove that the identified pathology is causing the patient's pain. Nevertheless, diagnostic testing is useful in patients with chronic pain for helping to direct treatment and referral.

Plain radiography is helpful in musculoskeletal pain to rule out pathology that might require more immediate attention (e.g., an unrecognized fracture or mass lesion).

MRI and CT are used very frequently, especially in spine-related pain. MRI is usually preferred for evaluating disc pathology. There are no good data to support or refute the use of MRI in chronic pain of musculoskeletal origin. Some general information about MRI in the spine and pain is important in interpreting these studies. Bulging discs are usually not significant in the absence of spinal stenosis. Disc degeneration and arthritic changes per se are not necessarily painful. The size of a disc protrusion does not correlate with pain level. Most pain physicians like to have this information when evaluating the patient, especially if some anesthesiologic intervention is contemplated for the pain. CT and CT myelography are useful in patients who cannot undergo MRI or who are being considered for surgery. Electromyography and nerve conduction studies are of use in patients suspected of having lower motor neuron dysfunction, nerve or nerve root pathology, or myopathy.

(Dworkin, 2003a [R]; VA/DoD, 2003 [R]; Wisconsin Medical Society Task Force on Pain Management, 2004 [R])

Functional Assessment

Many patients with chronic pain have significant losses in ability to perform normal life activities. Baseline functional ability assessment can provide objectively verifiable information about a patient's quality of life and ability to participate in normal life activities. This information may then be used for:

- identifying significant areas of impairment or disability,
- · establishing specific functional outcome goals within a care plan, and
- measuring the effectiveness of the care plan or treatment interventions.

Standardized assessment tools are available. Personalized goal-setting, such as regaining ability to perform a specific job task, hobby or family activity, may also be used.

Pain Assessment Tools

Patient self-report is the "most reliable indicator of the existence and intensity of pain" (National Institutes of Health) and is a key component of chronic pain assessment. Tools to assess chronic pain should:

- be appropriate to the person regardless of age, race, creed, socioeconomic status and psychological or emotional background;
- include a multidimensional scale since chronic pain affects a person's entire being (*Penny*, 1999 [C]);

- address location, quality, sensory characteristics, intensity, duration, aggravating and alleviating factors, variability and predictability; and
- be used early in the process of patient evaluation.

Table 1. Multidimensional Assessment Tools

Multidimensional tools rate several aspects of pain (for example, intensity, location, pattern and quality).

Scale	Administration	Validated in	Comments
Brief Pain Inventory (BPI) (Cleeland, 1994 [R])	Written	Cancer, arthritis English, Italian, Japanese	Assesses location, intensity and pattern. Reports meds, pain relief, patient beliefs, and interference in quality of life. See Appendix A, "Brief Pain Inventory (Short Form)."
Chronic Pain Grade (CPG) (Elliott, 2000 [C]; Smith, 1997 [C])	Verbal	Changes in chronic pain over time	Valid, reliable, easy to use, relevant to primary care setting.
Neuropathic Pain Scale (NPS) (Galer, 1997 [C])	Verbal	Early study shows discriminative and predictive validity	Specifically addresses neuropathic pain qualities.
Body Outline Marking (Savedra, 1989 [C]; VanCleve, 1993 [C])	Written/drawn	Children ages 4-7	Useful in identifying patient's perception of pain location. May be drawn in color to represent pain intensity.

Table 2: Single-Dimensional Assessment Tools

Single-dimensional tools are those that rate only one aspect.

Scale	Administration	Validated in	Comments
Visual Analog Scale (VAS)	Visual	Chronic pain, rheumatic disease in children > 5	Poor reproducibility with cognitive dysfunction, postop or dementia.
Numeric Rating Scales (NRS)	Verbal or visual	Chronic pain, rheumatic disease, trauma, cancer, illiterate	Detects treatment effects. Decreased reliability at extremes of ages, preverbal, visual, auditory or cognitive dysfunction.
Verbal Descriptive Scales	Verbal or visual	Adults	May be easier for older adults than the VAS or NRS.
Faces Pain Scales (FPS)	Visual	Bieri: adults, children Wong Baker: children	Easier than NRS or VAS, no influence on culture, gender or ethnicity.

For additional information on pain assessment tools, the work group recommends <u>Handbook of Pain Assessment</u>. Edited by Dennis C. Turk and Ronald Melzack, 2nd Edition, 2001. The Guilford Press.

Patients with barriers to communication that can affect assessment include:

- children
- individuals of advanced age (e.g., greater than 85 years)
- patients with emotional or cognitive dysfunction
- patients who are seriously ill
- patients in whom English is a second language or who are non-English speaking

General approach:

- Use a language interpreter.
- Allow sufficient time for the assessment.
- Give the patient the opportunity to use a rating scale or other tool appropriate for that population.
- Use indicators of pain according to the following hierarchy of importance:
 - Patient self-report
 - Pathological conditions or procedures known to be painful
 - Pain-related behaviors (e.g., grimacing, restlessness, vocalization)
 - Reports of pain by family members or caretakers
 - Physiological measures (vital signs)
 - Reliance on behavioral or objective indicators of pain (e.g., vital signs) only when no suitable alternative exists

(National Pharmaceutical Council/JCAHO, 2001 [R])

General approach to use of pain assessment tools in chronic pain:

- On initial visit, use a multidimensional tool such as the Brief Pain Inventory to obtain a comprehensive picture of the pain experience. The patient should complete this assessment tool before the physician visit.
- With follow-up visits, continue to use a multidimensional pain assessment tool filled out by the
 patient before seeing the physician.
- Use specific tools such as the Neuropathic Pain Scale (NPS) when appropriate.
- Avoid the use of single-dimensional pain assessment tools in chronic pain except to rate the intensity of specific pain episodes.

(American Pain Society, 2005 [R]; Daut, 1983 [C]; Herr, 2004 [R]; Kaiser Permanente Medical Care Program, 2004 [R]; McCaffery, 1999 [R])

3. Determine Biological Mechanisms of Pain

There are many ways to classify types of pain. Based on consensus, the work group found it most helpful to classify this guideline by the following four types: neuropathic, inflammatory, muscle and mechanical/compressive.

It is important to determine which of these mechanisms are at work in the chronic pain patient because the treatments depend on the type of pain. Two decades ago, the type of pain was not so important because all pain was treated in a similar way with a very narrow scope of drugs and therapies – basically non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen and sometimes opioids. We now have available mechanism-specific treatments for neuropathic pain, inflammatory pain, bone pain and muscle dysfunction.

Remember that patients often will present with pain that has more than one mechanism. The clinician should determine the relative contribution of each mechanism to the total pain condition and devise treatment strategies to address the relevant mechanisms. If there is diagnostic uncertainty, the clinician may refer to or consult a pain specialist.

(Chen, 2004 [R]; Dickenson, 1995 [R]; Koltzenburg, 2000 [R])

4. Neuropathic Pain

Neuropathic pain is pain produced by damage to or dysfunction of the nervous system. Examples include sciatica from nerve root compression, diabetic peripheral neuropathy, trigeminal neuralgia, and postherpetic neuralgia. The features that indicate neuropathic pain are the clinical setting, the distribution, the character of the pain and the physical examination findings. The clinical setting is usually the first clue to neuropathic pain. A diabetic who complains of persistent pain is likely to have neuropathic pain since about 50% of diabetics develop neuropathy-related pain. A patient who develops pain after a stroke in the same territory is most likely having poststroke neuropathic pain. The character of neuropathic pain is usually described as burning or shooting/stabbing. If the pain follows a nerve distribution (e.g., median nerve for carpal tunnel syndrome), neuropathic pain should be considered. Other examples are stocking-glove distribution for peripheral neuropathy, trigeminal distribution for trigeminal neuralgia and dermatomal distribution for postherpetic neuralgia. The physical findings to look for with neuropathic pain are numbness in the pain territory, sensitivity to a non-noxious stimulus like light touch or rubbing (allodynia), or coolness of the skin in the pain territory (sympathetically mediated pain).

Fibromyalgia syndrome is characterized by widespread musculoskeletal aching, stiffness and tenderness. Accumulating research suggest fibromyalgia is a centrally mediated neuropathic pain syndrome and may be considered a special case within neuropathic pain. It is one of the most common pain clinic diagnoses.

The American College of Rheumatology Criteria for Classification of fibromyalgia include:

- widespread pain (trunk and upper/lower extremities)
- pain in 11/18 tender spots
- pain present for at least three months
- other symptoms that are chronic but not diagnostic including insomnia, depression, stress, fatigue, irritable bowel syndrome

(Wolfe, 1990 [C])

5. Muscle Pain

Skeletal muscle pain is a common cause of chronic pain. Failure to properly diagnose muscle pain may result in poor treatment outcome, delayed recovery, and ineffective, unnecessary surgery.

Myofascial pain is regional muscle soft tissue pain commonly involving the neck, shoulders, arms, low back, hips and lower extremities. Trigger points refer pain. Myofascial pain is common in patients seen in pain clinics. Etiology, diagnosis and management are controversial (*Kilkenny*, 2008 [M]).

Occasional acute muscle pain is probably universal. Chronic muscle pain is extremely common. Most people are able to function satisfactorily in daily activities despite chronic muscle pain. Some report pain-related disability and present a challenge to the health care system.

6. Inflammatory Pain

Inflammatory pain such as arthritis, infection, tissue injury and postoperative pain is also known as *nocice-ptive pain* because the inflammatory chemicals such as prostaglandins directly stimulate primary sensory nerves that carry pain information to the spinal cord. The clinical features include heat, redness and swelling at the pain site and a history of injury or known inflammation.

7. Mechanical/Compressive Pain

Mechanical pain is aggravated by activity and temporarily relieved by rest. Neck and back pain are commonly related to muscle/ligament strain sprain, degeneration of disks or facets, or osteoporosis with compression fractures (*Atlas*, 2001 [R]).

Mechanical/compressive pain is also a type of nociceptive pain because mechanical pressure or stretching directly stimulates the pain sensitive neurons. In this setting, the history and radiological findings usually tell the story. Examples include fracture, obstruction, dislocation or compression of tissue by tumor, cyst or bony structure. The treatment will usually require some sort of decompression or stabilization.

See also the ICSI Adult Low Back Pain guideline.

8. Is Pain Chronic?

Chronic pain is defined as persistent pain, which can be either continuous or recurrent and of sufficient duration and intensity to adversely affect a patient's well-being, level of function, and quality of life (Wisconsin Medical Society Task Force on Pain Management, 2004 [R]). If the patient has not been previously evaluated, attempt to differentiate between untreated acute pain and ongoing chronic pain. If a patient's pain has persisted for six weeks (or longer than the anticipated healing time), a thorough evaluation for the cause of the chronic pain is warranted.

11. Specialty Involvement

Possible correctable causes of pain should be evaluated by the appropriate medical/surgical consultant for evaluation and, if indicated, appropriate correctable treatment.

Involvement of a pain specialist in the care of a patient with chronic pain occurs optimally when the specialist assumes a role of consultation, with the primary care provider continuing to facilitate the overall management of the patient's pain program. It is recommended that the primary care provider receive regular communications from the pain specialist and continue visits with the patient on a regular schedule, even if the patient is involved in a comprehensive management program at a center for chronic pain. The primary care provider should not expect that a consulting pain specialist will assume primary care of a patient unless there has been an explicit conversation in that regard between the consultant and the primary care provider. This is particularly true in regard to the prescribing of opioids: the primary care provider should expect to continue as the prescribing provider, and ensure the responsible use of the opioids through contracts, urine toxicology screens, etc. (the exception to this may occur with the admission of the patient into a opioid tracking program). Conversely, the consulting pain specialist should not initiate opioids without the knowledge and consent of the primary care provider.

12. Other Assessment

Key Points:

- Tools to assess chronic pain should be appropriate to the person, include a multidimensional scale and be used early in the process of patient evaluation.
- Identification and management of comorbid psychological disorders will facilitate appropriate biopsychosocial care.
- A comprehensive pain assessment begins with a determination of the biological type of pain, followed by a listing of contributing factors and barriers to treatment.

Functional Assessment Tools

A variety of assessment tools has been used in the medical literature for measuring, estimating or describing aspects of a patient's functional ability. These tools often also include measures of pain perception and psychological status, as well as function.

- Palliative Performance Scale (Karnofsky Scale) (see the ICSI Palliative Care guideline)
- Oswestry Low Back Disability Index (see the ICSI Adult Low Back Pain guideline)
- SF-36
- U.S. Department of Labor Physical Demand Table
- American Pain Foundation Scale (adapted from Oken, M.M.)

These tools all have limitations, including difficulties with administration and scoring, disease- or condition-specific design or failure to provide clinically useful information, which have probably contributed to a lack of widespread clinical use.

See also Appendix C for The Physical Functional Ability Questionnaire (FAQ5).

Psychological Assessment

Determine possible psychiatric contribution to clinical presentation.

Assessment questions to ask the patient:

- Are you depressed or anxious?
- Are you under any psychiatric care?
- Do you have a history of substance abuse?
- Do you have a history of verbal, physical or sexual abuse?

Role of Psychological Assessment

Psychological factors may influence the experience, report and display of pain.

Identification and management of comorbid psychological disorders will facilitate appropriate biopsychosocial care. Unmanaged disorders may interfere with the patient's ability to meaningfully participate in a collaborative plan of care and likely diminish treatment effectiveness.

Depression

- Commonly comorbid with persistent pain condition
- Research suggests prevalence of 35%-50% of pain patients have depression
- Duration and magnitude may signal need for specialty consultation/referral
- PHQ-9: operationalized DSM-IV criteria for Major Depression (see Appendix B, "Patient Health Questionnaire [PHQ-9]," and also the ICSI Major Depression in Adults in Primary Care guideline)

Anxiety

- Increased prevalence in chronic pain samples
- May be a risk factor for the development of chronic pain syndrome

- Psychophysiological mechanisms can maintain and/or exacerbate chronic pain
- Associated with fear of pain and fear of movement/reinjury, contributes to avoidant coping pattern

Substance Abuse and Dependence

- Increased prevalence of substance use disorders in chronic pain patient groups
- Attend to historical and current use patterns, history of formal treatment
- CAGE questions provide evidence of problematic alcohol use patterns
- Substance use history needs to be considered in the decision to prescribe medication

The CAGE questionnaire is a useful tool for brief alcohol screening of the patient (Ewing, 1984 [A]).

The CAGE Questionnaire			
Felt need to	Cut down drinking?		
Ever felt	Annoyed by criticism of drinking?		
Had	Guilty feelings about drinking?		
Ever take morning	Eye-opener?		

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See also the Resources Available table for "Substance Abuse and Mental Health Services Administration" for the CAGE-AID and other screening tools.

Sleep Disorders

- Disruption of diurnal rhythms/chronobiology
- Lack of restorative sleep perpetuates pain syndrome and reduced function

Personality Disorders

- DSM-IV-TR recognizes three clusters of personality disorders
 - Cluster A: Odd or eccentric (Paranoid, Schizoid, Schizotypal)
 - Cluster B: Dramatic, emotional or erratic (Antisocial, Borderline, Histrionic, Narcissistic)
 - Cluster C: Anxious or fearful (Avoidant, Dependent, Obsessive-Compulsive)
- Presence of personality disorder is associated with poorer prognosis
- Characterological vulnerabilities may be magnified by the chronic stress of persistent pain
 - Appropriate treatment may lead to a reduction of stress and a resolution of problematic behavior.

History of Abuse

• A review of the literature shows that abuse in childhood is a strong predictor of depression and physical complaints, both expanded and unexplained, in adulthood (*Arnow*, 2004 [R]).

• However, the specific relationship between childhood abuse and the development of chronic pain in adulthood is under question (*Raphael*, 2004 [R]). If a patient presents with chronic pain and a history of abuse that has not been previously treated, referral for appropriate psychotherapy should be considered.

Coping Patterns and Resources

- Passive and avoidant behavioral patterns or lack of active engagement in self-management activities can contribute to diminished activity and perpetuation of chronic pain syndrome.
- Social support resources:
 - Quality and nature of supportive relationships will influence pain-related adjustment
 - Spirituality

Spirituality

Assessment question to ask the patient:

Is spirituality an important part of your life?

A medical patient with chronic pain who identifies him- or herself as a spiritual being will report the link to divine help as empowering them to use strategies to heal themselves. The religious patient is more apt to report that healing was a direct result of divine intervention (*Boudreaux*, 2002 [R]).

Work and Disability Issues

Assessment question to ask the patient:

- Are you working and where?
- If no, why not?
- If yes, do you enjoy your job? Do you get along with your supervisor?

Chronic pain, whether due to an occupational injury or a personal medical condition, can impair an individual's ability to perform normal work. Physical impairment is often magnified by additional factors including sedating medications, deconditioning, sleep disturbance, psychosocial stressors and depression, cultural or personal beliefs regarding pain and disability, additional time demands for medical care and activities of daily living, etc.

Occupational disability, which can be described as "inability to perform gainful work," is an issue that often must be addressed in patients with chronic pain. Some medical conditions that cause chronic pain may truly impair an individual to such a degree that gainful employment is not possible. However, for most patients, work at a sedentary to light physical capacity (ability to lift 10-20 lbs. occasionally) is possible. Personal beliefs and catastrophizing thinking may lead to thoughts of permanent disability and applications for Social Security Disability Insurance (SSDI). In most cases this should be discouraged, and efforts should be redirected toward physical and psychological functional rehabilitation.

Job dissatisfaction is highly correlated with the development of chronic low back pain (Bigos, 1991 [B]; Williams, 1998 [B]). Work APGAR is a validated questionnaire for assessing work-related psychosocial risk factors for delayed recovery for low back pain. The two questions "Do you enjoy your job?" and "Do you get along with your supervisor?" are the most highly correlated with adverse outcome (chronic pain and impairment). See also "Psychosocial Screening and Assessment Tools" in the ICSI Low Back Pain guideline.

A job can serve a strongly positive role in the life of an individual living with chronic pain. Possible benefits include ongoing income, health insurance coverage, a reason to get up in the morning and get out of the house, a social support system, a sense of normalcy and a place in useful society, and improved self-esteem. Chronic pain may, however, limit the ability to perform some normal job activities. In this situation the physician can greatly assist the working patient by accurately assessing physical limitations, including need for time away from the workplace for medical treatments. Physical restrictions and recommendations should be clearly and simply written in order to provide the employer with necessary information for providing job accommodations. Employers are required by the Americans with Disabilities Act (ADA) to provide reasonable accommodations for employees with disabilities, and to allow at least 12 weeks per year of unpaid leave for care of significant health conditions under the Family Medical Leave Act (FMLA).

Contributing Factors and Barriers to Treatment

Key questions for assessing barriers to functional improvement:

- Are you currently working?
- Do you enjoy your job and get along with your supervisor?
- Do you engage in physical activity?
- Do you have a support system of people whom you can count on for help?
- Do you have trouble sleeping?
- Do you feel depressed?
- Do you have decreased interest or pleasure in usual activities?
- Do you have a history of mental health or psychiatric diagnosis or treatment?
- Do you have a history of physical, psychological or sexual abuse?
- Do you have a history of problems with alcohol or other drugs?
- Do you have legal representation or other legal issues or problems?

A comprehensive pain assessment begins with a determination of the biological type of pain, followed by a listing of contributing factors and barriers to treatment. *Contributing factors*, like habitually poor head and neck posture in a patient with a whiplash syndrome, are factors that do not cause the pain but amplify it or perpetuate it. *Barriers* to treatment include anything that interferes with a thorough assessment or the execution of a treatment such as language barrier, comorbid chemical dependency, financial, legal, low motivation and long distance from pain management services. Contributing factors are often the only things that can be modified to improve pain control. Barriers are often difficult or impossible to overcome, so identifying them early in the pain assessment process provides the clinician with a more realistic expectation of what can and cannot be accomplished.

Table 3: Common Barriers

Behavioral	Social	Insurance Systems
Passive patient	Language barrier	Formulary restrictions
Low motivation	Cultural barrier	Coverage restrictions
Unrealistic expectations	Health system obstacles	Behavioral health carve-out systems
Poor compliance	Time constraints	Health care provider reimbursement
Chemical dependency	Lack of social support	
Poor communication	Regulatory fears	
	Financial	

Management Algorithm Annotations

14. Level I Core Principles

Key Points:

- A written plan of care using the biopsychosocial model is the essential tool for ensuring a comprehensive approach to treatment of a patient with chronic pain.
- All patients with chronic pain should participate in an exercise fitness program to improve function and fitness.
- A cognitive behavioral approach with functional restoration may reduce pain and will
 improve function. Cognitive behavioral strategies and interventions can be organized
 by the primary care physician with the inclusion of a multidisciplinary plan of care.
 The members of the multidisciplinary team will vary depending on the resources in the
 community.
- The presence of psychological difficulties should in no way invalidate a patient's complaint of pain nor should it eliminate the possibility that a general medical condition may also be present that is causing the pain.
- The medical decision-making for treatment of chronic pain needs an understanding of the patient's ethnic and cultural background, age, gender and spirituality in order to work with the patient's chronic pain symptomatology.
- Self-management insures active patient participation in the care plan is essential.

Plan of Care Using Biopsychosocial Model

A study by Clark et al to determine family practice providers' views on how to improve management of chronic pain in the primary care setting suggests physicians view chronic pain as a chronic illness, and they need to use the chronic care model as an appropriate framework for quality improvement (*Clark*, 2007 [D]). A randomized controlled trial of over 400 patients and 42 primary care clinicians adds support to the collaborative care model for chronic pain (*Dobscha*, 2009 [A]).

The collaborative care model is an approach to health care delivery that includes providing care management and system support (*Katon*, 1999 [A]). It utilizes a team approach including the patient as a team member and specialty consultation support. Elements of this model include dedicated staff to coordinate, support and educate patients; methods for reliable and systematic patient follow-up; and consistent use of evidence-based treatment practices.

A written plan of care is the essential tool for ensuring a comprehensive approach to treatment of a patient with chronic pain. To maximize the success of treatment, a care plan must address the whole person in all of his/her complexity, including physical and biologic factors, psychological state and beliefs, as well as the family, social and work environment (biopsychosocial model). It is important to have a multidisciplinary team approach coordinated by the primary care physician to lead a team including specialty areas of psychology and physical rehabilitation.

A plan of care for all patients with chronic pain should address all of the following five major elements:

- Set personal goals
- Improve sleep

- · Increase physical activity
- Manage stress
- Decrease pain

Specific and measurable goals and clearly described specific treatment elements give patients a framework for restructuring a life that has often been significantly altered by chronic pain. Failure to improve pain and function when a patient is following the Plan of Care should lead to changes of the plan. Failure to follow a Plan of Care should lead to addressing barriers and further evaluation of stressors, psychosocial factors or motivations.

See Appendix D, "Personal Care Plan for Chronic Pain," for an example care plan.

"People who take an active role in their treatment tend to have better quality of life, reduce their sense of suffering, and feel more empowered." – Penny Cowen, American Chronic Pain Association. It is important that realistic goals be set with patients early on regarding the potential benefits of treatment.

Patient focus group feedback

In 2005, ICSI conducted a focus group of patients who had received care for chronic pain. The information gained from these discussions was summarized and presented to the work group as part of the guideline development process. Findings were later shared with ICSI member organizations when the guideline became available for use.

Objectives for conducting the focus group were:

- Learn the patient's perspective on living with chronic pain
- Hear what patients do to manage their pain
- Hear the patient's understanding of available options for treating pain
- Determine how chronic pain influences changes in lifestyle and function
- Understand the patient's perspective of the provider's role

Key points from the patient focus group discussion include:

- Patient experience is that limited education is done early on and patients do a lot of research on their
 own. Education is critical and includes setting realistic goals, providing education to patients about
 their disease state, explaining medications and also any interventional procedures. Well-informed
 patients will be able to take more responsibility for their care.
- Be aware that the term chronic pain may elicit a highly emotional response. Patients may feel discouraged that the pain will never go away despite their hope a cure will be found.
- Although patients would like a quick fix to their pain, frustration occurs when interventions that only provide temporary relief are found or utilized.
- Patients want to be included in the treatment plan. They are often proactive in seeking ways to alleviate or eliminate their pain. They may see several types of physicians and may have also tried to find relief from their pain in additional varieties of ways. **Teamwork and empathetic listening in the development of a treatment plan are critical.**
- When the physician acknowledges that chronic pain affects the whole person and really listens, patients are more likely to be open to learning how to live by managing their pain versus curing their pain.

- Most patients want to return to a normal routine of completing activities of daily living (e.g., playing with children/grandchildren, going for a walk, and working within their limitations). The focus should be on improving function.
- Many patients have utilized a variety of interventions including medications and complementary therapies.

Level I Versus Level II Management

The treatment approaches described in this algorithm for the management of chronic pain are divided into two levels. Level I treatment encompasses the standard approaches to the treatment of chronic pain including pharmacologic management, intervention management, non-pharmacologic management and complementary medicine management. These treatment approaches should be implemented as first steps towards rehabilitation before Level II treatments are considered. Level II treatment includes referral for multidisciplinary pain rehabilitation or surgery for placement of a spinal cord stimulator or intrathecal pump. Level II treatments may be effective interventions for patients with chronic pain who have failed more conservative treatment options. Level II treatments are designed for the most complex and challenging patients with chronic pain. The treatment options included in Level II are expensive and require a significant investment on the part of the patient to be effective with either level of management. This should ideally be coordinated by the primary care provider.

Physical Rehabilitation with Functional Goals

Rehabilitation/functional management

Managing pain and restoring function are basic goals in helping the patient with chronic pain.

- Use a multidimensional inventory to rate average severity of the last weeks' pain and to monitor progress.
- Use a functional activities tool to document pain-related disability (inability to function in normal manner) and to monitor progress (*Kaiser Permanente Medical Care Program*, 2004 [R]).
- Determine baseline fitness, then set specific fitness goals with a gradual graded fitness program (Lindström, 1992 [A]).

Physical rehabilitation is essential for the patient with chronic pain because most are significantly deconditioned. Focus on specific goals to restore function.

Self-management insures active patient participation and includes:

- a graded gradually progressive exercise program, and
- psychosocial management (e.g., cognitive behavioral therapy).

Encourage overall fitness, activity and a healthy lifestyle. "Lack of exercise and poor diet are the second largest underlying cause of death in the United States" (*National Institutes of Health*, 2001 [R]).

Fitness includes:

- endurance activities (aerobic, e.g., walking),
- strengthening,
- balance activities, and
- flexibility.

Exercise has been shown to benefit patients with chronic low back pain. Clinical guidelines for managing low back pain are available from 11 countries. Four countries include advice for chronic pain and all recommend exercise therapy as useful (*Koes*, 2001 [R]; van Tulder, 1997 [M]).

No one type of exercise has been shown to be more effective than another. Studies have shown benefit of flexion exercises, extension exercises (McKenzie), isokinetic intensive machine muscle strengthening, and group aerobic low-impact exercises. There is a need for high-quality studies to determine which type of exercise is best, how much exercise is necessary, and other factors related to cost effectiveness (*Faas*, 1996 [M]).

Mannion found no significant difference in outcome comparing relatively inexpensive group aerobics/stretching to more traditional physiotherapy and muscle conditioning, suggesting low-cost alternatives may be effective (Mannion, 1999 [A]).

Most patients with chronic pain are deconditioned from inactivity (often iatrogenic). A graded exercise program should start well within the deconditioned patients' chronic pain capacity and gradually increase intensity (*Lindström*, 1992 [A]).

Encouraging activity (recreational, as well as formal exercise) has been recommended (*Abenhaim*, 2000 [R]).

There is limited evidence showing the effectiveness of exercise in patients with neck and shoulder pain. Further high-quality randomized controlled trails are needed (*Karjalainen*, 2001 [M]).

Passive modalities (Tens, ultrasound, massage, corsets, traction, acupuncture) should be limited and used only with an active exercise program. Patients should be taught self-management treatments to help manage pain (use of ice, heat, massage, relaxation, cognitive behavioral) (*Atlas*, 2001 [R]).

Randomized controlled trials support massage therapy for certain types of chronic pain. Reduced pain scores were found for patients receiving massage who had low back pain (*Cherkin*, 2001 [R]; Hsieh, 2006 [A]), osteoarthritis of the knee (*Perlman*, 2006 [A]), juvenile rheumatoid arthritis (*Field*, 1997 [A]), and fibromyalgia (*Brattberg*, 1999 [A]). It remains to be determined what is the optimal amount of sessions and duration in order to be efficacious.

The American Geriatrics Society Panel on Chronic Pain in Older Persons recommends "... non-pharmacologic approaches used alone or in combination with pharmacologic strategies should be an integral part of care plan for most patients with chronic pain" (AGS Panel on Chronic Pain in Older Persons, 1998 [R]).

Biopsychosocial rehabilitation with functional restoration reduces pain and improves function. Self-management ensures active patient participation in managing pain and achieving reasonable goals of functional restoration.

Conclusion: All patients with chronic pain should participate in a physical activity program to improve function and fitness. Self-management insures active patient participation in the care plan and is essential.

Psychosocial Management with Functional Goals

Chronic pain is frequently associated with psychological problems and even comorbid psychiatric diagnoses. The presence of psychological difficulties should in no way invalidate a patient's complaint of pain nor should it eliminate the possibility that a general medical condition may also be present that is causing the pain. If psychological difficulties or psychiatric comorbidities are found, the patient's treatment plan should include specific steps to address them.

Depression

A high percentage of patients with chronic pain have co-existing depression. In 2004, data were examined from primary care centers worldwide by the World Health Organization. They found that 22% of all primary care patients suffer from chronic debilitating pain. Further, they found that patients with chronic pain were four times more likely to have comorbid depressive disorder than pain-free primary care patients (*Lépine*, 2004 [R]). The findings also showed that the more diffuse the pain complaints, the greater the risk of depression and the bigger the impact on quality of life.

If depression in a chronic pain patient is severe or comorbid major depressive disorder is present in a patient with chronic pain (see ICSI Major Depression in Adults in Primary Care Guideline), it is important to note that such patients are at increased risk of suicide (*Breslau*, 1991 [D]; Magni, 1998 [C]). Specifically assess if patient has considered harming him/herself or made plans to kill him/herself. If suicidal thoughts are present, assess whether patient has a concrete plan for self-harm; assess if they have the means to carry out the plan; and assess lethality of the plan. Suicidal risk is higher in individuals who are struggling with substance use/abuse, because judgment can be impaired. Past suicide attempt(s) increase risk of future attempts.

See also Annotation #12, "Other Assessment," and Annotation #19, "Level I Other Management," for more information on substance use/abuse.

If suicidality and/or major depressive disorder is present in the context of chronic pain, get psychiatric consultation immediately, because of risk of suicide. Also, management of chronic pain and work towards rehabilitation goals are not possible when severe depression is present. If comorbid major depressive disorder is diagnosed concurrently with chronic pain, depressive symptoms should be the primary focus of treatment. In those patients with either pain or depressive symptoms, assess both domains. Depression may be more than a facet of chronic pain when significant depression symptoms are present. If comorbidity is found between chronic pain and **mild** to **moderate** major depression, treat both conditions for optimal outcomes (*Bair*, 2003 [M]). If comorbid **severe** major depressive disorder is diagnosed concurrently with chronic pain, depressive symptoms should be the primary focus of treatment.

Some symptoms of depression including feelings of helplessness, dysphoria and frustration are generally expected in patients suffering from chronic pain, given the impact pain often has on ability to function and enjoy life. If targeted intervention can improve level of physical functioning and quality of life, mild depressive symptoms will likely improve without specific intervention.

Cognitive-behavior therapy

Cognitive-behavioral approaches to the rehabilitation of patients with persistent and unremitting chronic pain are considered to be among the most helpful available. Patients may be referred to a cognitive-behavioral therapist, counselor, social worker or psychologist for treatment. However, there are initial cognitive-behavioral steps that can be implemented by primary care physicians within the busy structure of their practice to assist their patients towards rehabilitation (*Waters*, 2004 [R]). Depending on resources, components of this may be organized in a community setting.

Patients live in environments that exert powerful reinforcement for certain behaviors. Physicians, by their very role as health care providers, are powerful reinforcers of behavior. By changing the contingencies of reinforcement, patients can make gains towards significant rehabilitation goals with the help of their physicians. The goals of cognitive-behavioral strategies in the management of chronic pain are to improve physical functioning, assist patients in returning to work, reduce disability, reduce pain-related fear/avoidance, and reduce psychological distress and depression (*Eccleston*, 2003 [R]).

Cognitive-behavioral therapy has been used in the treatment of chronic pain for over 30 years. A specific technique is rarely used in isolation; rather, cognitive-behavioral components are most often combined in a multidisciplinary structure. Significant literature exists that supports positive outcomes for cognitive-

behavioral approaches, and these strategies are considered to be among the most effective for the treatment of chronic pain. Specific outcomes have been noted in randomized controlled trials and other treatment evaluation studies and include evidence for the efficacy of cognitive-behavioral treatment in improving function and mood, and in reducing pain and disability-related behavior, particularly in low back pain (*Guzmán*, 2002 [M]; Morley, 1999 [M]).

Cognitive-Behavioral Strategies for Primary Care Physicians

There are a number of cognitive-behavioral strategies that primary care providers can utilize to help their patients manage chronic pain.

- Tell the patient that chronic pain is a complicated problem and for successful rehabilitation, a team of health care providers is needed. Chronic pain can affect sleep, mood, levels of strength and fitness, ability to work, family members, and many other aspects of a person's life. Treatment often includes components of stress management, physical exercise, relaxation therapy and more to help them regain function and improve the quality of their lives.
- Let the patient know you believe that the pain is real and is not in his/her head. Let the patient know that the focus of your work together will be the management of his/her pain. ICSI Patient Focus Group feedback included patient concerns that their providers did not believe them/their child when they reported pain.
- Ask the patient to take an active role in the management of his/her pain. Research shows that
 patients who take an active role in their treatment experience less pain-related disability (French,
 2000 [D]).
- Avoid telling patients to "let pain be their guide," whether it is stopping activity because of pain or taking medications or rest in response to pain.
- Prescribe time-contingent pain medications, not pain medications "as needed." Time-contingent
 medications allow a disruption in the associations between pain behavior and pain medication. The
 powerfully reinforcing properties of pain medicines are then not contingent upon high levels of pain
 and pain behavior.
- Schedule return visits on a regular schedule and don't let the appointments be driven by increasing levels of pain. Physicians are powerful reinforcers, too.
- Reinforce wellness behaviors such as increased activity or participation in an exercise program.
- Enlist the family and other supports to reinforce gains made toward improved functioning, too.
- Have patient involved in an exercise program or structured physical therapy.
- Assist the patient in returning to work. Do this in a stepwise fashion that is not dependent on level of pain.
- Fear of movement or fear of pain due to movement is a significant concern for many patients with chronic pain. Inactivity or avoidance of movement leads to physical deconditioning and disability. Try not to rely on sedative or hypnotic medications to treat the fear many chronic patients show of activity or fear of increased pain. When patients with chronic pain expose themselves to the activities that they fear, which simply means when they do the things they have been afraid of and avoiding, significant reductions are observed in fear, anxiety and even pain level (*Vlaeyen*, 2002 [A]). If patient's fears are excessive, relaxation strategies may be helpful or referral for more formal and intensive cognitive-behavioral therapy may be necessary.

Cognitive-Behavioral Interventions

Relaxation therapies

Relaxation therapies include a number of strategies aimed towards lowering general arousal and promoting a state of relaxation, and include biofeedback, imagery, diaphragmatic breathing, autogenic training, and progressive muscle relaxation training. It is believed that relaxation reduces levels of anxiety in patients with chronic pain, which enhances pain tolerance and decreases reports of pain. Further, relaxation techniques place greater responsibility on patients to expand their repertoire of coping strategies for managing their pain.

Biofeedback

Biofeedback has been defined as a process in which a person learns to reliably influence physiological responses of two kinds: either responses that are not ordinarily under voluntary control or responses that ordinarily are easily regulated but for which regulation has broken down due to trauma or disease. Biofeedback-assisted relaxation is commonly used in the treatment of various pain conditions. Biofeedback has also been used in a specific way to attempt to directly modify the physiological parameters thought to underlie a pain condition, such as frontalis muscle tension in headache sufferers.

Biofeedback has been found to be effective in headache management (*Haddock*, 1997 [M]), temperomandibular disorders (*Crider*, 1999 [M]), and other recurrent pain conditions (*National Institutes of Health*, 1996 [R]).

Mindfulness based stress reduction (MBSR)

MBSR is a structured program teaching greater present-moment awareness and self-acceptance by means of formal and informal meditative practices. Training in mindfulness meditation, in the context of MBSR, has been shown to be effective in the regulation of chronic pain. Jon Kabat-Zinn reported 60% moderate to great improvement in pain states four years after completing the MBSR program (*Kabat-Zinn*, 1986 [D]). One study demonstrated significant improvement with fibromyalgia patients utilizing mindfulness meditation and yoga (*Kaplan*, 1993 [D]).

Mindfulness meditation encourages acceptance of the pain experience, rather than distraction. This helps separate the specific pain sensations from the patient's suffering (emotional reaction and worry), leading to improved coping and acceptance. Mindfulness is becoming a mainstream practice in assisting patients in pain programs.

Imagery

Imagery is a simple procedure designed to promote general relaxation. This technique involves imagining a pleasant or relaxing scene such as lying in the sun listening to the waves on a beach. With practice, imagery can be used to reduce autonomic arousal and be used as an effective attention diversion strategy.

Diaphragmatic breathing

Diaphragmatic breathing or breathing retraining, as it is sometimes called, is a deceptively simple strategy that is easily under the patient's control. The goal is to teach patients correct diaphragmatic breathing, which incorporates both slowed breathing (five to eight breaths per minute) and even breathing with the same rate for exhaling and inhaling.

Autogenic training

Autogenic training is another relaxation procedure that focuses attention to different desired somatic responses such as sensations of warmth and heaviness in the extremities. These responses are believed

to facilitate increased blood flow to the extremities and thus promote peripheral warming and a reduction in sympathetic nervous system arousal.

Progresssive muscle relaxation training

In this relaxation strategy, attention is focused on 14 different muscle groups throughout the body. With this strategy, patients learn to discriminate various forms of muscle tension and with this focus are able to achieve a state of deep relaxation with practice.

Hypnosis

Hypnosis has been used in the treatment of pain and other medical conditions in one form or another since the 1700s (*Stewart*, 2005 [R]). Hypnosis is believed to involve both muscle relaxation and perceptual alteration. All hypnotic techniques share the common goal of shifting the focus to accepting pain rather than fearing pain. Hypnosis strives to create distance from the pain in an effort to lessen the impact of the pain or transform the experience of pain into something that is more bearable.

Hypnosis has been found to be effective in patients with chronic pain and compared favorably to alternative treatment procedures (*Montgomery*, 2000 [M]).

Cognitive techniques

Cognitive therapy techniques are based on the notion that a person's cognitions or how one thinks about oneself, others and the future can have a major impact on his/her mood, behavior and physiology. The use of cognitive therapy in pain is focused upon helping patients notice and modify the negative thought patterns that increase the experience of pain, increase distress, and increase pain behavior and the avoidance of activity.

Cognitive restructuring

This technique involves several steps that help to modify the way in which a patient with chronic pain views pain and his/her ability to cope with pain. The identification of automatic thoughts that lead to negative emotions is targeted in this approach. The negative thoughts are challenged and coping strategies are substituted.

Problem-solving

A four-step approach to problem-solving is used in this technique. The goal of problem-solving is to assist patients with chronic pain in seeing alternative solutions to their life difficulties. Identification of the problem, generation of possible solutions to the problem, prioritizing the solutions, and implementing a single strategy that is then evaluated for effectiveness are the steps in a problem-solving approach. Having patients experiment with different ways of tackling problems can be an effective way of changing habits or beliefs.

Culture and Chronic Pain

People use different coping strategies or styles when dealing with chronic pain that show cultural influences. Human responses to pain are quite variable, but they have never been associated with biological mechanisms; rather, they appear to reflect cultural expectations and psychological predisposition.

The demographic differences involving health care utilization, access and attitudes have shown a variation among cultures. Medical decisions for the treatment of chronic pain requires an understanding of the patient's ethnic and cultural background. This understanding allows medical providers to work with the patient's chronic pain symptomatology.

Age and Chronic Pain

Age has been determined a predictor of chronic pain status and susequent treatment strategies. Despite the large number of predisposing factors, pain is not a physiological result of the aging process. There have been important age differences in clinical presentation of patients with chronic pain, and this reflects cohort differences and/or physiological or psychological adjustment processes in the distinct chronic pain presentation.

Gender and Chronic Pain

Chronic pain conditions have been reported more frequently in women as compared to men. Gender differences in pain perception may have an important implication for pain management, and it is crucial that the relationship between pain, gender and anxiety be examined.

Gender differences do play a role in the evaluation and treatment modalities for chronic pain and need to be considered when making a comprehensive chronic pain program.

Spirituality and Chronic Pain

The mechanisms of action of spirituality and chronic pain include relaxation, sense of control and an increased positive affect (*Ledbetter*, 2001 [R]).

Spiritual concerns and questions often have no clear answers or solutions, yet they can significantly affect the quality of a patient's suffering. Spirituality with adjuvant care may help to modify the treatment modalities and develop a comprehensive pain management plan.

Findings suggest that spirtuality may not have a specific effect on chronic pain over nonspecific factors, but there has been evidence that concludes patients with serious medical illness commonly use spiritual methods to manage and deal with their illnesses (*Boudreaux*, 2002 [R]).

15. Level I Management: Neuropathic Pain

The first principle guiding any therapy is to eliminate the underlying causes of pain to the greatest possible extent with disease-specific measures (*Belgrade*, 2003 [R]). For example, better diabetes management should minimize the complications of diabetes, including pain. Chemotherapy or surgery that reduces tumor bulk will decrease pain caused by a tumor that is compressing nerve roots.

Symptomatic pain control can take the form of local or regional interventions, including nerve blocks, topical agents, or physical rehabilitative measures. In addition, systemic therapies can be applied, such as drug therapies or behavioral techniques that reduce pain.

Fibromyalgia may be considered a special case within neuropathic pain due to mechanisms that are less well defined and a distribution that is widespread. Treatments proven effective include aerobic exercise, behavioral therapies such as relaxation, multidisciplinary management and acupuncture (*Karjalainen*, 2008 [M]; Martin, 2006 [A]). Pharmacological therapy with FDA indication for fibromyalgia includes pregabalin and duloxetine. Other agents that have been shown to be effective in controlled trials include gabapentin, cyclobenzaprine, tramadol, and tricyclic antidepressants (*Nishishinya*, 2008 [M]).

See Appendix H, "Pharmaceutical Interventions for Neuropathic Pain," and Appendix I, "Neuropathic Pain Treatment Diagram."

Local or Regional Therapies

Topical therapies can be applied to localized peripheral tissues to reduce pain without significant systemic effects. Topical capsaicin applied three or four times per day can deactivate local C-polymodal nociceptors at the vanilloid receptor and reduce pathological pain. It has been studied in diabetic neuropathy (*The Capsaicin Study Group*, 1991 [A]) and postherpetic neuralgia (*Fusco*, 1997 [R]). Preparations of topical lidocaine

in the form of a cream or a patch have also been used for relief of localized neuropathic pain syndromes (*Rowbotham*, 1995 [A]). Transcutaneous electrical nerve stimulation and other stimulation-based therapies can provide temporary relief in some cases of neuropathic pain caused by nerve root or plexus lesions, but such therapies may also be irritating, particularly when allodynia is present. In such cases, application of the stimulating electrode in adjacent, uninvolved dermatomes may be effective and better tolerated.

Drug Therapies for Neuropathic Pain

See also Annotation #19, "Level I Other Management: Pharmacologic."

Among the many drugs used to manage neuropathic pain, gabapentin and pregabalin have growing acceptance among pain specialists and neurologists as first-choice treatments. Gabapentin and pregabalin have proved effective in postherpetic neuralgia and diabetic neuropathy in multicenter controlled trials (*Backonja*, 1998 [A]; *Dworkin*, 2003b [A]; *Lesser*, 2004 [A]; *Rowbotham*, 1998 [A]). Their favorable side effect profile and paucity of adverse interactions with other drugs contribute to its widespread use in neuropathic pain. Since excretion of the drug is virtually 100% renal, the dose and frequency of administration are reduced in patients with renal insufficiency. Pregabalin, like gabapentin modulates the alpha2delta subunit of the N-type voltage-gated calcium channels, and thus regulates the influx of calcium into the nerve and reduces the outflow of excitatory neurotransmitters that transmit pain. Pregabalin is indicated for treatment of diabetic neuropathy, postherpetic neuralgia and fibromyalgia, as well as for partial onset seizures. Gabapentin has an indication for diabetic neuropathy pain, postherpetic neuralgia, fibromyalgia, and partial onset seizures. Oxcarbazepine is chemically similar to carbamazepine and may have benefits in the treatment of neuropathic pain, including trigeminal neuralgia and diabetic neuropathy.

Other anticonvulsants have been utilized in neuropathic pain with variable success. Carbamazepine is still considered a good initial choice for idiopathic trigeminal neuralgia, but there is a lack of evidence of consistent success in other pain states. One study demonstrated efficacy of carbamazepine for diabetic peripheral neuropathy compared with nortriptyline-fluphenazine (*Gomez-Perez*, 1996 [A]). Newer anticonvulsants are beginning to be investigated for their neuromodulating effects on various non-epileptic conditions such as mood, behavior and pain. Among these drugs are topiramate, lamotrigine, oxcarbazepine and tiagabine. Some preliminary studies have indicated a possible role for lamotrigine in trigeminal neuralgia (*Zakrzewska*, 1997 [A]), painful HIV-associated neuropathy (*Simpson*, 2000 [A]), and complex regional pain syndrome type I (*McCleane*, 2000 [D]). Clonazepam, a benzodiazepine, is used by many providers for nocturnally predominant pain.

Tricyclic antidepressants (amitriptyline, nortriptyline, desipramine, imipramine and others) continue to hold a place in the management of a broad range of pain disorders, including neuropathic pain. Their mechanism of action is believed to involve potentiation of descending inhibitory pathways, especially at the level of the lower brainstem. Among the large number of controlled and uncontrolled studies, two comparative trials have demonstrated superior efficacy for amitriptyline or desipramine over fluoxetine or lorazepam in diabetic neuropathy and postherpetic neuralgia (Max, 1992 [A]; Max, 1988 [A]). These trials showed that the effect of the tricyclic antidepressant on pain was independent of its effect on depression. A screening electrocardiogram is recommended for elderly patients and others at risk of the conduction delay that these drugs can cause. Duloxetine and venlafaxine also have been shown to be effective in certain neuropathic states such as painful diabetic neuropathy and fibromyalgia (Arnold, 2004 [A]; Sindrup, 2003 [A]). For more information see Annotation #19, "Level I Other Management: Pharmacologic" section.

Corticosteroids have a beneficial effect on neuropathic pain, probably through multiple mechanisms, including membrane stabilization and anti-inflammatory effects. Corticosteroids may be useful for short-term control of neuropathic radicular pain caused by tumor edema, tumor invading bone, and acute or subacute disc herniation.

Although most opioids are not known to work through antineuropathic mechanisms, they are nevertheless potent analgesics. They have a role in reliable patients when other measures fail. Careful patient selection

is critical to success with long-term opioid therapy. Two opioids, methadone and tramadol, may be more effective than others in neuropathic pain. Due to the complexity of dosing and potential for cardiac adverse effects, the use of methadone should be reserved for experienced practitioners. FDA-required information in the product labeling for methadone states, "Methadone has been associated with QTc interval prolongation and other cardiac adverse effects including hypotension and other cardiac dysrythmias. Patients should have a baseline ECG prior to initiation of methadone, which is repeated after 30 days and then annually. More frequent ECG monitoring should be done when methadone doses exceed 100 mg per day." See Appendix G, "Opioid Analgesics," for more information. Additionally, methadone possesses inhibitory properties at the N-methyl D-aspartate (NMDA) receptor in the spinal cord. The NMDA receptor is involved in central sensitization, windup, neurogenic hyperalgesia, and development of opioid tolerance. Thus, agents that block the NMDA receptor (such as methadone and dextromethorphan) may have antineuropathic pain properties. Tramadol is a weak opioid analgesic that also causes serotonin reuptake inhibition similar to that seen with the tricyclic antidepressants. This dual mechanism may make it advantageous for management of neuropathic pain or mixed pain disorders. At the time of this revision, tapentadol, a new opioid analgesic with norepinephrine reuptake inhibition properties, has just been released with an indication for the treatment of acute pain. Its role in chronic pain and neuropathic pain in particular remains to be clarified.

16. Level I Management: Muscle Pain

Screen for serious medical pathology and screen for psychological and social factors that may delay recovery.

Scientific evidence of the effectiveness of treatment is lacking. Well-designed studies need to be done.

Use a numeric pain rating and functional scale to determine severity of pain disability.

Use a biopsychosocial interdisciplinary team approach with a cognitive-behavioral component encouraging exercise and active participation of the patient in the plan of care (*Wisconsin Medical Society Task Force on Pain Management*, 2004 [R]).

A graded exercise program starting within baseline and gradually increasing in a time-contingent manner works best.

Use the biopsychosocial interdisciplinary team approach with cognitive-behavioral component encouraging exercise and active participation of the patient in the plan of care:

Physical Rehabilitation

- fitness program
 - gentle graded strength
 - cardiovascular
 - flexibility
 - balance
- · body mechanics
- · modalities
 - ice/heat
 - massage
 - self management
- aquatic therapy

Pharmacotherapy

Behavioral Management

- depression/stress
- relaxation techniques
- cognitive behavioral
- chemical dependency
- anger management
- · biofeedback

Drug Therapy

- pain and sleep
 - tricyclic antidepressants (nortriptyline low dose)
- cyclobenzaprine
- depression and pain
- opioids rarely needed (Rome, 2004 [C])

Tricyclic antidepressants (amitriptyline) have been shown to have a modest benefit in patients with fibromyalgia in reducing pain short term and reducing insomnia.

 Cyclobenzaprine also has modest benefit in patients with fibromyalgia and is used as a standard therapy for muscle pain.

Physical rehabilitation is the mainstay of management of patients with fibromyalgia chronic pain.

- Determine patient's baseline fitness.
- Use a graded exercise program.

Psychosocial rehabilitation including cognitive behavioral therapy (management of depression, stress, anger, fear avoidance, chemical dependency and nonrestorative sleep) is helpful. A biopsychosocial interdisciplinary team approach is most effective.

Invasive procedures lack evidence of efficacy.

Self-management insures active patient participation in managing pain and achieving reasonable functional goals.

Teach self-management and measure outcome using pain rating and a function tool.

17. Level I Management: Inflammatory Pain

Screen for serious medical pathology and screen for psychological and social factors that may delay recovery.

Use a numerical pain rating and functional scale to assess severity of pain related disability.

Use a biopsychosocial interdisciplinary team approach with cognitive-behavioral component encouraging exercise and active participation of the patient in the plan of care (Wisconsin Medical Society Task Force on Pain Management, 2004 [R]).

Physical Rehabilitation

- graded fitness program
 - graded strengthening
 - cardiovascular
 - flexibility
 - balance
- · body mechanics
- modalities
 - ice/heat
 - massage
 - self-management
- aquatic therapy

Behavioral Management

- depression/stress
- relaxation techniques
- cognitive behavioral
- chemical dependency
- anger management
- biofeedback
- coping

Drug Therapy

- pain and sleep
 - tricyclic antidepressants (nortriptyline low dose)
 - cyclobenzaprine
- depression and pain
- opioids rarely needed (Rome, 2004 [C])
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- immunologic drugs
- other antidepressants

Physical rehabilitation is a key to managing pain and improving function. Use a graded exercise program.

- Determine baseline fitness.
- Start a gentle, nonfatiguing exercise program.
- Advance repetitions and intensity slowly on a time-contingent schedule.

Psychosocial rehabilitation should address depression, stress, anger, fear avoidance, chemical dependency and sleep impairment. A biopsychosocial interdisciplinary team approach is most effective in managing pain and improving function.

Invasive procedures lack scientific evidence.

Self-management insures active patient participation in managing pain and reaching reasonable functional goals.

Teach self-management and measure outcome using pain rating and a function tool.

18. Level I Management: Mechanical/Compressive Pain

Screen for serious underlying medical or neurological pathology and refer to appropriate specialist if indicated.

Screen for biopsychosocial and vocational factors that may delay recovery such as depression, stress, work injury, personal injury, fear avoidance, substance abuse, or severe deconditioning (*Kaiser Permanente Medical Care Program*, 2004 [R]; Wisconsin Medical Society Task Force on Pain Management, 2004 [R]).

Screen for degree of pain using the numerical rating scale (0-10).

Screen for degree of disability using a disability rating scale.

- Patients with low degree of pain and low disability may benefit from simple evidence-based exercises and cognitive behavioral counseling.
- Patients with high level of pain and high degree of disability require a more comprehensive approach, including a multidisciplinary team with coordinated philosophy, evidence-based exercise and more intensive psychosocial assessment and management.

(Kaiser Permanente Medical Care Program, 2004 [R])

Use a biopsychosocial team approach:

Physical Rehabilitation

- graded fitness program
 - strengthening
 - cardiovascular
 - flexibility
 - balance
- body mechanics
- modalities
 - ice/heat
 - massage
 - self-management
- aquatic therapy

Pharmacotherapy

Behavioral Management

- depression/stress
- relaxation techniques
- cognitive behavioral
- chemical dependency
- anger management
- biofeedback

Drug Therapy

- pain and sleep
 - tricyclic antidepressants
 - nortriptyline low dose
- antidepressants
- depression and pain
- opioids rarely needed (Rome, 2004 [C])
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Short-term use of non-steroidal anti-inflammatory drugs (NSAIDs) can be recommended. There are no studies examining the use of long-term NSAIDs, and significant complications include bleeding ulcers, renal failure and cardiac problems. Acetaminophen should be considered as an option.
- Noradrenergic or noradrenergic-serotoninergic antidepressants can be recommended for pain relief.
- Muscle relaxants have limited evidence of effectiveness.
- Opioids may be considered in selected patients who do not respond to comprehensive conservative treatment.

Physical rehabilitation to restore function and allow resuming normal daily activities is essential. Exercise therapy is recommended for patients with chronic pain.

- Use a graded exercise program determine baseline fitness for strength, aerobic endurance, flexibility and balance. Gradually increase repetitions and intensity in a time-contingent manner (*Kaiser Permanente Medical Care Program*, 2004 [R]).
- Cognitive-behavioral interventions encouraging activity and fitness work best for patients with chronic pain and are recommended (*Kaiser Permanente Medical Care Program*, 2004 [R]).
- Invasive treatments including epidural steroids, intra-articular (facet) steroid injections, local facet nerve blocks, intradiscal injections, trigger point injections, botulinum toxin injections, prolotherapy, radiofrequency facet denervation, intradiscal radiofrequency lesioning, intradiscal electrothermal therapy, and spinal cord stimulation in which there is controversial efficacy have limited scientific evidence (*Kaiser Permanente Medical Care Program*, 2004 [R]).
- Surgery for non-specific chronic spinal pain lacks scientific evidence of effectiveness. A multidisciplinary, combined program of exercises and cognitive intervention should be tried first, and surgery considered only for carefully selected patients (*Kaiser Permanente Medical Care Program*, 2004 [R]). See the ICSI Adult Low Back Pain guideline for appropriate guidelines for surgical referral, including Cauda Equina syndrome and progressive or significant neurological findings.
- Surgery for cervical or lumbar radicular pain lacks scientific evidence and surgery should be considered for carefully selected patients only (*Fouyas*, 2001 [R]).
- After surgery, the patient with chronic pain is best managed by an interdisciplinary team using a biopsychological social approach (Wisconsin Medical Society Task Force on Pain Management, 2004 [R]).

Psychosocial rehabilitation provides the patient with tools to manage chronic pain. This may involve treatment of depression, stress, anger, sleep management, chemical dependency and fear avoidance.

Conclusions:

- All patients with chronic mechanical pain should have a screen for serious underlying medical and neurological pathology.
- Assess for psychological social factors that may contribute to delayed recovery.
- Utilize biopsychological social interdisciplinary team approach using cognitive-behavioral therapies to encourage functional activity and exercise.
- Self-management ensures active patient participation in managing pain and reaching reasonable functional goals.

Teach self-management and measure outcome using pain rating and a function tool.

Manipulative Therapy and Chronic Pain

A growing body of evidence supports the integration of manipulative therapy, within the context of interdisciplinary treatment, to be an efficient and efficacious treatment in improving pain and function. As such, osteopathic assessment and treatment should be considered as a viable option in the management of chronic pain, especially when integrated with other interdisciplinary treatments. (*Degenhardt*, 2007 [C]; Gamber, 2002 [A]; Knebl, 2002 [A]; Licciardone, 2003 [A]; Licciardone, 2004 [R])

19. Level I Other Management

Pharmacologic Management

Key Points:

- A thorough medication history is critical to the development of an effective treatment plan.
- Define the goals of therapy before prescribing, and tailor medications to meet the individual goals of each patient.
- Identify and treat specific source(s) of pain, and base the initial choice of medication(s) on the severity and type of pain.
- Patients need to know that whether prescribed or non-prescribed, all drugs have risks and benefits. Watch for and manage side effects.
- For opioid therapy:
 - Use caution before starting a patient on long-term opioid therapy.
 - Follow the 4 A's (Analgesia, Adverse drug reactions, Activity, Adherence) (*Passik*, 2000 [R]).
 - The work group recommends the use of a written opioid agreement for patients anticipated to be on long-term therapy. See Appendix F for an example of an opioid agreement form.

Medications are not the sole focus of treatment in managing pain. They should be used when needed to meet overall goals of therapy in conjunction with other treatment modalities: psychosocial and spiritual management, rehab and functional management, non-pharmacologic and complementary medicine, and intervention management. Pharmacotherapy may include agents to treat specific types of pain, such as neuropathic pain, or adjunctive therapies to treat other comorbidities such as depression and anxiety. Use of medications, therefore, should be directed not just toward pain relief, but for increasing function and restoring overall quality of life.

The basic elements to include anytime opioids are used are a diagnosis, a care plan, regular visits with the physician, follow-up and documentation. See the Federation of State Medical Boards at: http://www.fsmb.org for complete information.

General Principles for Pharmacologic Management (Wisconsin Medical Society Task Force on Pain Management, 2004 [R])

- A thorough medication history is critical to the development of an effective treatment plan.
 - Include use of over-the-counter drugs and herbals and other supplements.
 - Look for drug-related fears and misconceptions, as they may lead to poor compliance with a therapeutic regimen. Differentiate between tolerance, physical dependence and addiction. See "Definitions" earlier in this guideline.
- Define the goals of therapy before prescribing, and tailor medications to meet the individual goals of each patient.

- Identify and treat specific source(s) of pain, and base the initial choice of medication(s) on the severity and type of pain.
 - Types include neuropathic, muscular, inflammatory, and mechanical/compressive pain. See Annotations #15-18.
 - Give drugs an adequate therapeutic trial. When treating inflammatory or neuropathic pain, benefits may take weeks or longer to appear.
- Patients need to know that whether prescribed or non-prescribed, all drugs have risks and benefits.
 Watch for and manage side effects.
- Select an appropriate drug based on:
 - Characteristics of the agent (onset, duration, available routes of administration, dosing intervals, side effects). The least invasive route of administration is preferred; it's generally oral.
 - Patient factors (age, co-existing diseases, other medications, and response to previous treatments).
- Establish a pain management plan that may include the addition of other drugs: non-opioid, plus opioid, plus adjuvant analgesics when indicated.
 - Rational poly-pharmacy may include the use of two or more drugs with complementary mechanisms of action that may provide greater pain relief with less toxicity and lower doses of each drug.
 - Avoid prescribing two drugs in the same class at the same time.
 - Be alert for possible interactions with other medication the patient is taking or additive side effects.
- Titrate doses to achieve optimal balance between analgesic benefit, side effects and functional improvement.
 - Some medications require gradual upward titration to achieve optimal analgesia and to minimize adverse effects.
 - Optimize administration of analgesics. Generally, better pain control is obtained with regularly scheduled doses and supplemented with as-needed doses for breakthrough pain.
- Taper and discontinue drugs that don't meet treatment goals. If a drug does not produce the desired therapeutic outcome, there is no need to continue it. This practice helps to prevent expensive and potentially dangerous poly-pharmacy.

Non-Opioid Analgesics

Non-opioid analgesics to consider for use in the treatment of chronic pain include acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs).

Acetaminophen is an analgesic that may be used initially for the treatment of mild chronic pain or to supplement other agents in treating mild to moderate pain. It lacks anti-inflammatory effects, but is generally well tolerated at therapeutic doses. It does not damage the gastric mucosa but may have chronic renal or hepatic adverse effects (*American Pain Society*, 2005 [R]). Dosage should be restricted to a maximum of 4 grams per 24 hours, including acetaminophen contained in combination opioid products such as hydrocodone with acetaminophen. Acetaminophen should be used cautiously or avoided in patients with liver impairment.

Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs are indicated for the treatment of mild to moderate inflammatory or non-neuropathic pain. All NSAIDs inhibit the enzyme cyclooxygenase (COX), inhibiting prostaglandin synthesis. The COX-2 inhibitor celecoxib appears to have fewer gastrointestinal side effects.

However, high-dose, long-term use of COX-2 agents has a higher rate of cardiovascular adverse effects. Recent reports indicate that cardiovascular adverse effects are not limited to the COX-2 agents alone (U.S. Food and Drug Administration, 2004 [Not Assignable]).

- All NSAIDs have GI risks of gastritis and possible bleeding. Risk benefits should be weighed, especially when treating elderly patients or those at higher risk for GI adverse effects. Consider using in combination with the gastroprotective agent misoprostol or a proton pump inhibitor.
- Use with caution in patients with coagulopathies or thrombocytopenia and those at risk for bleeding. At recommended doses, celecoxib does not appear to affect platelet counts, prothrombin time, partial thromboplastin time, or platelet aggregation. Celecoxib, at doses 2 to 4 times the maximum doses for rheumatoid arthritis (RA) and osteoarthritis (OA) (400 mg twice a day), respectively, was associated with a decreased incidence of anemia when compared with patients receiving NSAIDs (diclofenac and ibuprofen) at accepted RA and OA doses (2% versus 4.4%, respectively; p value less than or equal to 0.05) (Silverstein, 2000 [A]).
- Chronic NSAID use increases the risk of renal insufficiency, especially those with diabetes, and patients should be monitored for signs of reduced renal function and hypertension.
- Ketorolac should not be used for longer than five days and therefore is not an appropriate choice of NSAID in the treatment of chronic pain.
- NSAIDs have significant opioid dose-sparing properties and in turn may reduce opioid-related side effects.
- Monitor all NSAID use including patient use of non-prescription drugs, to prevent duplication of therapy and adverse effects.

Opioids

When is it appropriate to use opioids?

Prior to consideration of opioid use for the patient with chronic pain, a thorough evaluation as recommended in this document should have been completed. If the ethical imperative to relieve pain requires opioid therapy prior to such a thorough evaluation, proceed using good clinical judgement.

It is appropriate to consider opioid therapy for patients with persistent moderate to severe pain in the following circumstances:

- Clinical evidence suggests opioids are likely to be effective in neuropathic pain that is not responsive to initial therapies (TCAs or gabapentin). Opioids are rarely beneficial in the treatment of inflammatory or mechanical/compressive pain and are not indicated for chronic use in treatment of headache (see ICSI Diagnosis and Treatment of Headache guideline).
- Opioids have an equal or better therapeutic index than alternative therapies.
- The medical risk of opioid therapy is relatively low.
- The patient is likely to be responsible in using the drug.
- Opioid therapy is considered part of the overall management for the pain syndrome.

The Four A's

The goal of opioid therapy is to provide partial analgesia, and maintain or improve function with acceptable side effects. (Four A's: Analgesia, Adverse drug effects, Activity, Adherence) (*Passik*, 2000 [R]).

At each patient visit, the assessment should specifically address these goals (with clear documentation of the four A's in the patient's medical record):

- Comfort (degree of analgesia)
- Opioid-related side effects
- Functional status (physical and psychosocial)
- Existence of aberrant drug-related behaviors

Opioid management

Opioids have the potential to alleviate pain but also the potential for aberrant drug related behavior, drug abuse, or misuse. Therefore, a single physician/provider should prescribe and supervise opioids used for chronic non-cancer pain. Often the primary care provider is best suited to do so based on knowledge of the whole person (*Chou*, 2009 [M]). Physicians should not feel compelled to prescribe opioids or any drug if it is against their honest judgment or if they feel uncomfortable prescribing the drug. Additionally, those who prescribe opioid pain medication should be aware of current federal and state laws and regulations related to the use of chronic opioid therapy (*Chou*, 2009 [M]).

Before prescribing an opioid and other potentially addictive medications, or medications of potential abuse or misuse, the work group recommends completion of a comprehensive biopsychosocial assessment. This should include pain history/examination plus administration of an opioid assessment tool to recognize potential risks of addiction, abuse or misuse. Prior medical records, particularly pertaining to pain medications, should be reviewed before deciding to start chronic opioid pain medications.

Opioid assessment tools, such as the DIRE tool, determine a patient's appropriateness for long-term opioid management (see Appendix E, "DIRE Score: Patient Selection for Chronic Opioid Analgesia"). In a reliability and validity study, higher scores (14 or higher) predicted a more successful prescribing process with respect to patient compliance and efficacy of treatment (*Belgrade*, 2006 [A]). Other opioid assessment tools include:

- Webster's Opioid Risk Tool (ORT)
- Screener and Opioid Assessment for Patients in Pain (SOAPP®)
- Current Opioid Misuse Measure (COMMTM)
- Prescription Drug Use Questionnaire (PDUQ)
- Screening Tool for Addiction Risk (STAR)
- Screening Instrument for Substance Abuse Potential (SISAP)
- Pain Medicine Questionnaire (PMQ)

Patients should give informed consent before the start of opioid therapy, and the consent discussion should be documented in the medical record. This discussion should include the low risk of opioid addiction in patients under a physician's care, the necessity of adherence to prescribed dosing, the potential for cognitive impairment when taking the drug alone and/or in combination with sedative/hypnotics, and the likelihood that physical dependence will occur (*Portenoy*, 2004a [R]).

General opioid management principles: (Chou, 2009 [M])

- If the physician is not the initial prescribing provider, it is important to be aware that he/she is not under any obligation to assume responsibility for prescribing without adequate communication and hand-off. Nor is it appropriate to prescribe chronic opioid medications when not aware of the patient's past medical history.
- Most patients with acute exacerbation of chronic pain don't require opioid pain medications, but if
 the primary care physician feels a short trial of opioid pain medication is necessary, consider writing
 a two-week supply of a short-acting medication. If the patient is not improving from a functional
 point of view, consider getting a consult from a pain specialist before writing a second prescription.
- Most pain specialists do not feel it appropriate to prescribe opioid pain medications at the first visit.
 The prescribing provider should not expect or assume the pain specialist will take over the care of the patient or management of opioid pain medications.
- Patients with aberrant drug-related behaviors or drug abuse/ misuse should be tapered off the opioid pain medication. A referral to a chemical dependency program may be necessary.
- Patients who don't meet functional goals should be tapered off chronic opioid pain medications.

Substance abuse

Patients should be carefully screened for risk of diversion or abuse. The following behaviors suggest relative contraindications to opioid use. With these patients, referral to pain or addiction specialist is advisable (*VA/DoD*, 2003 [*R*]):

- History of substance abuse or prior prescription drug misuse
- Unsanctioned dose escalations on several occasions
- Non-adherence to other recommendations for pain therapy
- Unwillingness or inability to comply with treatment plan
- Social instability
- Unwillingness to adjust at-risk activities resulting in serious reinjury requiring additional opioid prescriptions

Random drug screens are one tool to monitor compliance with the opioid regimen. Random urine drug screens are used: (1) to check for diversion, seeking evidence the patient is taking the medication being prescribed; (2) to check for drugs of abuse; and (3) to test for the presence of the prescribed drug. Any evidence of street drug use indicates non-compliance with the opioid contract. The patient's opioids are tapered and he or she is referred to a chemical dependence specialist or treatment program. Primary care physicians need to be aware of the limits of a drug screen. Other useful tools include periodic pill counts or consultation with an addiction medicine specialist.

Evidence of aberrant drug-related behaviors must be carefully assessed. In some cases tapering and discontinuation of opioid therapy will be necessary. Other patients may appropriately continue therapy if the structure for monitoring is tightened. Consideration should be given to consultation with an addiction medicine specialist.

There is not enough evidence to permit generalizable conclusions regarding the abuse of opioids in chronic nonmalignant pain. However, careful patient selection and close monitoring of all nonmalignant pain patients on chronic opioids is necessary to assess effectiveness and watch for signs of abuse. [Conclusion Grade III: See Conclusion Grading Worksheet A – Annotation #19 (Chronic Pain and Chemical Use)]

When there is non-compliance, escalation of opioid use, or increasing pain not responding to increasing opioids, consider whether this represents a response to inadequate pain control (pseudoaddiction, tolerance or opioid-induced hyperalgesia) or a behavioral problem indicating the patient is not a candidate for opioid therapy (Angst, 2006 [M]; Carroll, 2004 [R]; Mao, 2002 [R]).

Opioid-independent pain

Morphine and other strong opioids have been considered the gold standard analgesics for all types of pain. However, advances in our understanding of chronic pain reveal a heterogeneous group of mechanisms. Many of these mechanisms operate outside the influence of the opioid system; thus, chronic pain may be relatively resistant to opioid analgesia. Neuropathic pain may respond to opioids, but many believe the response is limited and may require higher doses with intolerable side effects before pain relief is achieved.

Opioid-induced hyperalgesia

Recent evidence has shown that opioids, in higher doses or over a prolonged period, can produce a state of hyperalgesia, i.e., amplified pain response. Doses of opioids that exceed the equivalent of morphine 200 mg per day should be considered a general limit, with higher doses indicating a possible concern for hyperalgesia or potential for abuse (*Chou*, 2009 [M]). More and more clinicians, when faced with increasing pain in spite of increasing opioid doses, are recognizing this phenomenon as opioid-induced hyperalgesia and treating it with opioid reduction or withdrawal.

Opioids and function

The goals of treatment for chronic pain include improvement in physical functioning and restoration of life roles like work, relationships and school. Opioids have never been proven to improve function. A Danish epidemiologic study of people with chronic pain showed that those taking opioids had more pain, greater health care utilization, poorer health-related quality of life, and poorer function than the population with chronic pain who were not taking opioids (*Eriksen*, 2006 [D]).

Physicians must bear in mind that opioids are not required for everyone with chronic pain. The decision to use or continue opioids depends on many factors including type of pain, patient response and social factors. Physicians must have the fortitude to say no to opioids when they are not indicated, and to discontinue them when they are not working.

Table 4: Considerations for Initiating and Discontinuing Opioid Therapy

The following chart is intended to provide guidelines for initiation and use of opioids when there is clinical evidence that opioids may be effective, for example, neuropathic pain that is not responsive to initial therapies. It is not intended to be a recommendation to initiate opioids for any chronic pain unresponsive to non-opioid analysesics.

Observation	Consideration	Endpoint/Goal	Strategy When Goal Is Not Met
Pain unrelieved by non-opioid analgesics	Pain too severe for NSAIDs, acetaminophen or other analgesics	Pain relief of at least 40% of baseline measurement(s)	Ensure realistic expectations of therapy Add potent opioid in low initial dose
Pain unrelieved despite use of opioids	Patient does not respond adequately to opioid selection and/or dose	Pain relief of at least 40% of baseline	Adjust dose if tolerated Consider alternate opioid
Pain unrelieved despite use of opioids and multiple side effects	Pain syndrome not responsive to opioid alone and requires different therapy (e.g., neuropathic pain)	Pain relief of at least 40% of baseline Decreased side effects	Reduce opioid to a dose that produces manageable side effects Add an adjunct or non-opioid analgesic
Patient insists on rapid escalation of opioid dose	Patient does not respond adequately to opioid and requires different therapy	Sufficient analgesia from prescribed medications for a sustained period of time, i.e., months to years	Consider behavioral evaluation for untreated anxiety or affective disorder Informed consent for continued use of opioids
Patient engages in unsanctioned abuse behaviors with opioids	Patient may have an underlying substance disorder	Adequate pain relief from prescribed regimen Lack of aberrant behaviors in obtaining opioids	Consult with addiction medicine specialist if repeated attempts to manage pain with opioids fail

Source: Pain Research & Management 2003;8:189-94.

Opioids have demonstrated efficacy in the management of both nociceptive and neuropathic chronic pain (*Mystakidou*, 2003 [D]; Ytterberg, 1998 [C]). Opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone and tramadol.

Various dosage forms are available including oral rapid and sustained-release products, injectable opioids, transdermal fentanyl, and suppositories.

There are numerous short-acting and long-acting opioids available. While analgesic efficacy and side effects are similar, long-acting agents aid in compliance and help patients sleep through the night. Short-acting opioids may be used to titrate pain relief until patients are on a stable dose of a long-acting dosage form, and then for acute pain exacerbations. Long-acting products are not recommended for use on an as needed (PRN) basis. Clinicians should use caution when prescribing opioids for a patient with a history of substance abuse.

Opioid doses should be titrated up until there is adequate pain relief, but generally not exceeding doses equivalent to morphine 200 mg/day. Rapid escalation of dose or use of higher doses may be a marker for a substance abuse disorder, and high doses are more likely to induce hyperalgesia and possibly immunosup-

pression (*Chou*, 2009 [M]). Adequate analgesia should be balanced against side effects, which are common in opioid users. Many side effects are reduced in time due to tolerance. All patients should be on prophylactic bowel regimen including a stimulant laxative and stool softener such as senna and docusate.

If a patient does not receive adequate pain relief from one opioid, or side effects are not tolerable, a trial with an alternative opioid may be considered. When switching from one opioid to another or an alternative route, it is generally recommended to decrease the equi-analgesic dose by 30% due to incomplete cross tolerance (*Kaiser Permanente Medical Care Program*, 2004 [R]). The new opioid dose can then be titrated up until adequate analgesia is obtained.

Discontinuing of opioids is recommended when it is felt they are not contributing significantly to improving pain control or functionality, despite adequate dose titration. It is recommended that the primary care physician discontinue when there is evidence of substance abuse or diversion. In these cases, consider referral to substance abuse counseling. It is recommended not to abruptly discontinue but to titrate off by decreasing dose approximately 10%-25% per week. When a patient is unable to taper as an outpatient, a clonidine patch or tablets is one potential option, or referral to a detox facility.

Specific Opioid Characteristics

- Codeine often has dose-limiting GI side effects and is therefore not a good choice for chronic use. Patients with multiple CYP2D6 gene copies metabolize codeine to morphine more rapidly (ultrarapid metabolism), whereas patients who lack functional CYP2D6 genes do not metabolize codeine to morphine and do not experience analgesic effects 5% to 10% of the Caucasian population. For more information, refer to www.micromedex.com.
 - A recent FDA advisory has identified that infants of nursing mothers taking codeine may have an increased risk of morphine overdose if mother is an ultra-rapid metabolizer of codeine. When prescribing codeine to nursing mothers, physicians should choose their lowest dose for the shortest period of time and should closely monitor mother-infant pairs. For more information, refer to http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm054717.htm.
- Fentanyl is available in injectable, transdermal patches and transmucosal (lollipop) formulations. The topical patch is dosed every 72 hours, or every 48 hours if breakthrough pain is seen at higher doses. It may be beneficial for use in a patient not compliant with more frequent oral-dosing regimens, and gives more control over the supply of opioid and lessens abuse potential in a high-risk patient. Transdermal fentanyl serum levels rise gradually over 12-24 hours. When removed, the half-life of the drug is 17 hours, and the patient should be monitored for opioid adverse effects for at least 24 hours. Patients should have alternative analgesics for initial pain control until fentanyl reaches steady-state levels.

Despite an FDA-issued Public Health Advisory in July 2005 regarding the appropriate and safe use of the transdermal system, death and life-threatening adverse events related to fentanyl overdose have occurred when the fentanyl patch was used to treat pain in opioid-naive patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The fentanyl patch is indicated only for use in patients with persistent moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are considered to be opioid tolerant.

Patients must avoid exposing the patch to excessive heat as this promotes the release of fentanyl from the patch and increases the absorption of fentanyl through the skin, which can result in fatal overdose. Directions for prescribing and using the fentanyl patch must be followed exactly to prevent death or other serious side effects from fentanyl overdose.

The FDA has received reports of serious side effects including death in patients who have taken the fentanyl buccal tablets. These reports describe prescribing to non-opioid tolerant patients, misunder-

standing of dosing instructions, or inappropriate substitution of fentanyl for oral transmucosal fentanyl citrate by pharmacists and prescribers. The directions for using fentanyl must be followed exactly to prevent death or other severe side effects from overdosing fentanyl. To see the full alert, refer to FDA alert (9/2007) addressing fentanyl buccal tablets information at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113690.htm.

- Hydrocodone is available only in combination with acetaminophen and doses should be monitored to not exceed 4 grams acetaminophen per day.
- Hydromorphone is available in rapid-release oral and injectable dosage forms.
- Meperidine is metabolized to an active metabolite normeperidine, which has neurotoxic side effects. It is not an appropriate choice for chronic use.
- Morphine is available in rapid-acting and long-acting oral, injectable and rectal dosage forms. There are 12-hour sustained-release and 24-hour sustained-release dosage forms of morphine available.
- Methadone has a long half-life, initially 12-16 hours but may be 90-120 hours after one week of therapy. Due to the complexity of dosing and potential for cardiac adverse effects, the use of this opiate should be reserved for experienced practitioners. Methadone has been associated with QTc interval prolongation and other cardiac adverse effects including hypotension and other cardiac dysrythmias. Patients should have a baseline ECG prior to initiation of methadone, which is repeated after 30 days and then annually. More frequent ECG monitoring should be done when methadone doses exceed 100 mg per day (Krantz, 2009 [R]).
- Oxycodone is available in short-acting and long-acting dosage forms.
- Propoxyphene is a weak analgesic and has CNS adverse effects more commonly seen in the elderly and people with renal insufficiency. Use with caution for chronic use.
- Tramadol is a weak mu-opioid agonist and also is a serotonin and norepinephrine reuptake inhibitor.
 Doses should not exceed 400 mg daily. Serotonin syndrome may occur if used concurrently with SSRIs (selective serotonin reuptake inhibitors).

See Appendix G, "Opioid Analgesics," and Appendix H, "Pharmaceutical Interventions for Neuropathic Pain."

Tricyclic Antidepressants (TCAs)

Tricyclic antidepressants have a role in the treatment of neuropathic pain, especially if the patient has co-existing insomnia, anxiety or depression (Collins, 2000 [M]; McQuay, 1996 [M]; Sindrup, 1999 [M]; Sindrup, 2000 [A]). TCAs are categorized as secondary amines (nortriptyline or desipramine) or tertiary amines (amitriptyline and imipramine). Both classes are effective in the treatment of neuropathic pain, but the tertiary amines have more anticholinergic side effects and generally should be avoided in the elderly.

- Analgesic effects of TCAs are independent of their antidepressant effect, and analgesia may be seen with lower doses.
- Start low and increase doses gradually over several weeks to months. Maximum analgesic effect may takes several weeks or longer to be seen.
- Baseline ECG is indicated in patients at risk for cardiac adverse effects.
- Common side effects include sedation, dry mouth, constipation and urinary retention. Use caution in patients with conditions that may be aggravated by TCAs, including heart disease, symptomatic prostatic hypertrophy, neurogenic bladder, dementia and narrow-angle glaucoma.

See Appendix H, "Pharmaceutical Interventions for Neuropathic Pain."

Other Antidepressants - SSRIs and SNRIs

Tricyclic drugs are often used first line for fibromyalgia, but other antidepressants could be used concurrently or to replace tricyclics in patients who do not have adequate response or can not tolerate side effects.

The selective serotonin reuptake inhibitor class of antidepressants has reduced adverse effects compared with TCAs, but efficacy in the treatment of neuropathic pain is generally not as good as that shown with TCAs. Buproprion (Semenchuk, 2001 [A]), venlafaxine (Sindrup, 2003 [A]) and duloxetine (Arnold, 2004 [A]) have also shown efficacy in the treatment of neuropathic pain. Duloxetine has been shown to improve pain and global measures of fibromyalgia, compared with placebo (Arnold, 2004 [A]). Duloxetine dosed 60 mg twice daily is indicated in the treatment of fibromyalgia.

Dual reuptake inhibitors increase norepinephrine and serotonin without producing the cardiac adverse effects associated with the tricyclics. In addition to duloxetine, milnacipran is indicated in the treatment of fibromyalgia. Milnacipran is initiated at a dose of 12.5 mg once daily and titrated over seven days to a target dose of 50-100 mg two times per day.

Anticonvulsant or Antiepileptic Drugs

The first-generation anticonvulsants carmabazepine and phenytoin are effective in the treatment of neuropathic pain but may have unwanted CNS side effects. Carbamazepine is approved for the treatment of trigeminal neuralgia, and benefits are well established (*McQuay*, 1995 [M]).

Pregabalin is indicated for treatment of diabetic neuropathy, postherpetic neuralgia and fibromyalgia.

Oxcarbazepine is chemically similar to carbamazepine and may have benefits in the treatment of neuropathic pain, including trigeminal neuralgia and diabetic neuropathy.

The second-generation agent gabapentin is approved for the treatment of postherpetic neuralgia, but has been shown to have analgesic effects in many cases of neuropathic pain syndromes (*Backonja*, 1998 [A]; Bone, 2002 [A]; Pandey, 2002 [A]; Rice, 2001 [A]; Rowbotham, 1998 [A]; Serpell, 2002 [A]; Tai, 2002 [A]). To decrease the incidence of adverse effects, which are primarily somnolence and dizziness, start at low doses and tritrate up gradually.

See also, Appendix H, "Pharmaceutical Interventions for Neuropathic Pain."

Lamotrigene has efficacy in trigeminal neuralgia, neuropathies associated with human immunodeficiency virus infection, and poststroke pain.

Topical Agents

Topical lidocaine 5% patches are FDA approved for postherpetic neuralgia and have shown efficacy in other neuropathic pain syndromes. Systemic absorption of lidocaine is minimal, and the patch has a clean safety profile with the correct dosage schedule.

Capsaicin, the active ingredient in the herbal product cayenne, is used topically to deplete the pain mediator substance-P from afferent nociceptive neurons. Topical creams and solutions have been used in treating both neuropathic pain and arthritic pain. Capsaicin should be applied for at least six weeks to see full benefits. The side effect of local burning is common and most patients become tolerant after a few days.

(Devers, 2000 [D]; Galer, 2002 [A]; Mason, 2004 [M])

Muscle Relaxants and Antispasmodics

Skeletal muscle relaxant may be useful along with analgesics for short-term management of muscle spasms and pain. There is mixed evidence supporting the use of these drugs for long-term use. Some drugs including

benzodiazepines and Carisoprodol are centrally acting and carry the risk of physical dependence. Muscle relaxants are more beneficial for acute short-term use and are not recommended for chronic use.

Cyclobenzaprine, which is structurally a tricyclic muscle relaxant, has shown benefits in the treatment of fibromyalgia at doses of 10 to 40 mg daily (*Toefferi*, 2004 [M]). It is structurally a tricyclic amine and has side effects similar to the tricyclic antidepressants, including drowsiness/dizziness, dry mouth and an increased risk for arrhythmias. Concurrent use of cyclobenzaprine with tricyclic antidepressants is not contraindicated, but patients should be monitored for the potential increase in these related adverse effects.

Tizanidine is a muscle relaxant that may be used for longer periods of time due to its mechanism of action (alpha-2 sympathomimetic). It may provide benefits as an adjunct in the treatment of fibromyalgia.

Baclofen may have benefits in the treatment of lancinating, paroxysmal neuropathic pain.

(Borenstein, 1999 [R]; Cherkin, 1998 [M])

Anxiolytics

Benzodiazepines are beneficial for treatment of acute anxiety and muscle spasms associated with acute pain, but have minimal benefits in treating chronic pain. Benzodiazepine side effects of sedation and respiratory depression may limit the amount of opioids that can be used safely. They also result in physical dependence when used long term.

SSRIs or SNRIs are generally the drugs of choice for treatment of anxiety. Onset of effect is slow and may take several weeks for maximum benefits.

Buspirone is an anxiolytic that is relatively low sedating. It may take several weeks to see maximum benefits.

(King, 1990 [D])

Drugs for Insomnia

Insomnia may improve along with adequate pain relief. Sleep disorders such as sleep apnea should be ruled out. Other measures should include minimizing caffeine use and establishing regular sleep habits.

Tricyclic antidepressants are a good choice in the treatment of insomnia, especially if the patient has anxiety or depression (*Collins*, 2000 [M]; *McQuay*, 1996 [M]; *Sindrup*, 1999 [M]; *Sindrup*, 2000 [A]). OTC antihistamines such as diphenhydramine may be beneficial but have mixed efficacy. The sedative antidepressant trazodone may be effective in treating insomnia associated with chronic pain. Benzodiazepines generally should be limited to short-term management of insomnia. Common agents include temazepam, triazolam and the benzodiazepine receptor agonists zolpidem and zaleplon.

Intervention Management

Key Points:

- Therapeutic procedures are used to alleviate or reduce chronic pain and should be used in conjunction with a comprehensive treatment plan developed by a chronic pain specialist.
- Interventional techniques should be performed in conjunction with a comprehensive treatment plan that includes pharmacologic, rehabilitative and psychological interventions.
- Many of the Level I procedures provide both diagnostic and therapeutic benefits, while Level II are reserved for patients who have failed conventional treatment.

- Diagnostic procedures are used to identify neural or musculoskeletal structures that are the source of the patient's pain symptoms.
- The role of intervention modalities is different for chronic pain than acute and should be carefully evaluated by a pain specialist.

Interventional techniques refer to procedures including spinal injections, nerve blocks, spinal cord stimulators and implantable intrathecal drug delivery systems that are performed in an attempt to diagnose and treat chronic pain. If used alone, the evidence is limited in its success. These procedures should be performed in conjunction with a comprehensive treatment plan that includes pharmacologic, rehabilitative and psychological interventions. Commonly performed interventional procedures will be categorized as Level I (diagnostic and therapeutic) and Level II (palliative). Many of the Level I procedures provide both diagnostic and therapeutic benefits, while Level II interventions are reserved for patients who have failed conventional treatment.

The role of intervention modalities is different for chronic pain than acute and should be carefully evaluated by a pain specialist.

See also Annotation #25, "Level II Management: Interdisciplinary Team Referral, Plus a Pain Medicine Specialist or Pain Medicine Specialty Clinic."

Level I Diagnostic Procedures

Diagnostic procedures are used to identify neural or musculoskeletal structures that are the source of the patient's pain symptoms. Most diagnostic procedures are associated with a significant placebo response, and either comparative or controlled blocks should be used to improve the diagnostic accuracy of the intervention. Additionally, the response to a diagnostic block should be interrupted in association with relevant physical examination findings and disease specific symptomatology. Examples of commonly performed diagnostic procedures include the following.

Sacroiliac joint injection

The sacroiliac joint is a widely recognized source of low back and buttock pain. Associated symptoms included lower extremity pain. Diagnostic blocks performed with fluoroscopic guidance using local anesthetic can confirm this structure as a source of low back and leg pain.

Transforaminal epidural injection

Transforaminal epidural injections, also referred to as selective nerve root injections, can be used to determine the spinal level that is the source of radicular pain. The risks of cervical transforaminal epidural steroid injections have been well documented in recent case reports (*Beckman*, 2006 [D]; Furman, 2003 [D]; Tiso, 2004 [D]). Specifically, cervical transforaminal epidural steroid injections have been associated with spinal cord and brain injuries resulting in permanent neurological deficits and/or death. These adverse events are most likely related to penetration of radicular arteries or the vertebral artery followed by administration of particulate corticosteroids, which results in embolization and severe vasospasm. When this particular procedure is under consideration, it should be performed only by an experienced pain medicine physician with access to and knowledge of the use of appropriate imaging equipment and patient monitoring facilities (*Bogduk*, 2008 [R]). Furthermore, non-particulate corticosteroids should be utilized, and this procedure should be performed only in the context of a longitudinal care plan, as directed and coordinated by a pain medicine physician (*Tiso*, 2004 [D]).

Discography

Discography is used to determine if a disk is intrinsically painful. The procedure is generally performed prior to spinal fusion or in preparation for a percutaneous disk procedure. This procedure does not diag-

nose disk herniation. Discography is strictly a diagnostic procedure and there are no direct therapeutic benefits (*Bogduk*, 1996 [R]; Walsh, 1990 [C]).

Level I Therapeutic Procedures

Therapeutic procedures are used to alleviate or reduce pain and should be used in conjunction with a comprehensive treatment plan. Ideally, choice of procedure should be done in consultation between the primary care provider and pain specialist. Examples of commonly used therapeutic procedures are as follows.

Facet joint injection

Facet joints are an important source of spinal pain in the cervical and lumbar regions. These joints can be reliably anesthetized by way of fluoroscopically guided joint injections. Generally, a depot corticosteroid is concomitantly administered. However, clinical trials have failed to demonstrate any sustained therapeutic benefits following facet joint corticosteroid injections (*Nelemans*, 2005 [M]).

Percutaneous radiofrequency neurotomy

Percutaneous radiofrequency (RF) neurotomy (sometimes erroneously referred to as facet rhyzotomy) is a treatment for neck or back pain generated by facet joints. Properly selected candidates for this procedure should experience complete or nearly complete relief of their pain following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves that innervate the pain-generating joint(s). To minimize false-positive results, an equivalent degree of relief of appropriate pharmacologic duration should be carefully documented on two separate occasions, using two different types of local anesthetic. The RF procedure is performed by placing an insulated needle electrode with an exposed tip adjacent to and parallel with the medial branch nerves that supply the target joint(s). Radiofrequency current applied to the electrode then heats the adjacent tissues and coagulates the nerve supply to the joint. The nerves do regenerate over time, so pain relief is not permanent, but the procedure can be repeated. Proper patient selection and appropriate technique in positioning the RF electrodes are essential to the success of the procedure (*Bogduk*, 2008 [R]; Hooten, 2005 [R]). Controversy in the literature regarding the efficacy of lumbar RF neurotomy has arisen from fundamentally flawed clinical trials that have used inappropriate patient selection criteria, and improper procedural technique. There is limited evidence for cervical RF neurotomy for whiplash-related facet pain (*Lord*, 1996 [A]).

Lumbar facet radiofrequency neurotomy can provide pain relief for carefully selected patients, but this procedure should be performed only by an experienced pain medicine physician in the context of a longitudinal and comprehensive care plan (Bogduk, 2008 [R]; Hooten, 2005 [R]; Nath, 2008 [A]). Several systematic reviews have concluded that there is inconclusive evidence to support use of radiofrequency neurotomy for low back pain, but the available randomized trials are flawed by important procedural limitations (Gofeld, 2008 [R]; Lord, 1996 [A]). In open prospective studies, reductions in pain intensity have been observed when the procedure is performed by an experienced pain medicine physician following the appropriate procedural guidelines.

Intradiscal electrothermal therapy (IDET)

Intradiscal electrothermal therapy (IDET) is a percutaneous procedure used to treat discogenic spinal pain. Generally accepted indications for IDET include annular fissuring and contained nuclear herniations (*Fenton*, 2003 [R]). Prior to IDET, patients must undergo discography to identify the painful disc or discs. The procedure is performed by placing a 17-gauge introducer needle into the nuclear cavity of the disc under fluoroscopic guidance. A thermal catheter is then advanced so that it coils along the internal aspect of the posterior anulus. The distal 5 cm of the catheter is heated to 80°C to 90°C for 15 to 17 minutes. The antinociceptive mechanisms of IDET remain undetermined but are hypothesized to include thermal destruction of annular nociceptive nerve fibers. Further studies are needed to test the

mechanism of action and compare long-term results of IDET to established therapies, such as conservative care and spinal fusion (*Derby*, 2000 [D]; *Karasek*, 2000 [C]); *Saal*, 2000a [D]; *Saal*, 2000b [D]).

Epidural corticosteroid injections

Epidural corticosteroid injections are one of the most commonly performed interventions for treatment of spinal pain. All epidural injections should be performed under fluoroscopic guidance. There are three approaches to the epidural space, including a transforaminal, intralaminar and a caudal technique. Limited evidence was found to support the efficacy of this procedure (*Carette*, 1997 [A]; Dilke, 1973 [A]; Riew, 2000 [A]).

Vertebroplasty and kyphoplasty

Vertebroplasty and kyphoplasty are percutaneous procedures used to treat vertebral compression fractures. The procedures are done under local anesthesia using conscious sedation or general anesthesia with fluoroscopy or some other imaging technique to guide the placement of the needle(s) and the injection of the bone cement (Garfin, 2001 [R]; Hardouin, 2002 [R]). Vertebroplasty may be indicated only in carefully selected patients whose pain is not controlled by conservative management (typically when severe pain has persisted for more than 10 to 12 weeks). However, there is insufficient evidence to identify a best time for intervention (Grados, 2000 [D]; Peters, 2002 [D]; Zourski, 2002 [D]).

Trigger point injections

Trigger point injections commonly involve the injection of local anesthetic and a depot corticosteroid into soft tissue structures that are tender or painful.

Complementary Management

Acupuncture

Clinical research with randomized, placebo-controlled trials supports the use of acupuncture for certain chronic pain conditions such as fibromyalgia (*Berman*, 1999 [M]; Martin, 2006 [A]), headache (*Vickers*, 2004 [A]; Wonderling, 2004 [M]), back pain (Meng, 2003 [A]), neck pain (White, 2004 [A]) and osteoarthritis of the knee (Scharf, 2006 [A]; Vas, 2004 [A]).

Acupuncture is one of the oldest healing practices in existence. The popularity of alternative medicine in the United States has drawn increasing attention to acupuncture and increased scrutiny of its value as a therapeutic tool (*Eisenberg*, 1998 [C]). Acupuncture involves stimulation of tissue with fine needles at specific sites called acupuncture points. Acupuncture points lie along channels or meridians. Traditional Chinese medicine postulates that a life force or energy flows along these meridians, maintaining health. Acupuncture reestablishes the normal flow of energy when it is blocked or disturbed by disease. Common complications of acupuncture include fainting, discomfort and bruising. Infrequent complications include infection, pneumothorax and nerve injury. The NIH consensus statement on acupuncture is very supportive of it for both primary therapy and adjunctive therapy in a variety of common problems such as nausea, pain, addiction and stroke rehabilitation (*National Institutes of Health*, 1997 [R]). Basic scientific research has begun to elucidate the mechanisms of acupuncture analgesia, including the role of endorphins, serotonin and other neurochemicals.

(Mayer, 1977 [C]; Tavola, 1992 [A])

Herbal products used for pain

Herbal products are widely used and it is important to question patients about their use when taking a medication history. Since many herbal products are not standardized, the content of the ingredients can vary substantially from the label and between lots of the same product (*Gurley*, 2000 [D]). Patients are often misinformed and believe that since herbals are natural products, they are safer than prescription medications.

Patients who use herbal preparations should be cautioned about adverse effects, drug interactions and the potential impurities of these products (Miller, 1998 [R]; Winslow, 1998 [R]).

There is limited evidence of efficacy for many of these agents. Some have known toxicities and significant drug interactions, and their use should be discouraged. While there are many herbal products used for pain, the following have some supporting data for use in the treatment of pain, but may still have significant potential for drug interactions and adverse effects. Dimethylsulfoxide is mentioned due to the frequency of use, despite evidence of toxicity and lack of documented efficacy.

Devil's Claw has conflicting evidence about efficacy as an anti-inflammatory or analgesic agent. There are wide variations in chemical components of products. It may have benefits in the treatment of lower back pain. Devil's Claw may increase gastric acid secretion and antagonize the effects of H-2 antagonists, and also has anticoagulant effects (*Gagnier*, 2007 [M]).

Dimethylsulfoxide (DMSO) is a commonly used chemical solvent. It is often used topically as an analgesic due to purported anti-inflammatory effects. There is inadequate evidence of efficacy and potential toxicity of this agent, and its use should be discouraged (*Kingery*, 1997 [M]).

Feverfew is used for treatment of migraine headaches, and there is some evidence it helps to reduce the frequency of migraine attacks. The active ingredient, parthenolide, has anti-inflammatory properties (*Diener*, 2005 [A]).

Glucosamine and Chondroitin are usually used together and have anti-inflammatory properties. They are used in the treatment of osteoarthritis and articular disease. Efficacy in knee and hip pain is conflicting, with no evidence of efficacy when used for back pain. Glucosamine may affect blood glucose and should be avoided or used cautiously in diabetics (McAlindon, 2000 [M]).

Willow Bark contains the active ingredient salicia, the precursor of aspirin. Products should be standardized to 60-120 mg salicia per day. Patients allergic to aspirin or NSAIDs may be allergic to Willow Bark. Adverse effects are similar to aspirin therapy. Willow Bark may be useful in the treatment of low back pain (*Gagnier*, 2007 [M]).

See also the "Topical Agents" section previously in this annotation.

Research on other complementary therapies is underway at the National Institutes of Health. For more information go to: http://www.nccam.nih.gov.

24. Has Enough Been Tried with Level I Management?

Failing to achieve improvement in chronic pain management using Level I management strategies, the primary care physician should consider a consultation and/or referral to a pain medicine specialist or pain medicine specialty clinic.

Reasons for consultation may include:

- diagnostic assistance,
- advice on availability of current care plan and treatment strategies,
- advice on optimal pharmacotherapy, and
- help with treatment planning for long-term pain management.

Referral to a comprehensive pain management program should be strongly considered when a patient needs an intensive comprehensive evaluation by a pain management team (physician, psychologist, physical therapist, pharmacist, etc.). The team should have extensive training and experience in pain management, and each professional should be working as part of a multidisciplinary team in a pain management center to meet the patient's needs.

The team works as part of a structured, integrated long-term program where the goal is effective, stabilization of the patient's pain, development of a pain management care plan, and return of the patient to be a functioning member of society.

25. Level II Management: Interdisciplinary Team Referral, Plus a Pain Medicine Specialist or Pain Medicine Specialty Clinic

Key Points:

- The Level II interdisciplinary team should do a thorough biopsychosocial assessment of the patient with chronic pain, and a comprehensive plan of care should be developed with active input from the patient and primary care provider.
- Surgery alone for chronic pain relief lacks compelling evidence of efficacy.
- Palliative interventions are used when conventional and less-invasive procedures have failed, and patients should have documented compliance with a comprehensive care plan, with surgery not a viable option.

Level II management of patients with chronic pain is indicated when the patient has had a thorough trial of Level I management (see Annotations #14-24), yet has not met the goals of comfort/pain control and function. Level II management should include an interdisciplinary team including the primary care provider, a medical pain specialist, a behavioral health pain specialist, and a physical therapist trained in a biopsychosocial approach to chronic pain. If possible, this management should be provided in the patient's community. If an interdisciplinary Level II pain team is not available in the community, it may be necessary to obtain these services outside the community. As with Level I management, Level II management should continue to be coordinated by the primary care provider.

Level II interdisciplinary chronic pain team assessment should be obtained in a timely manner, sometimes as early as four to eight weeks after the onset of acute pain. The goal is to prevent or effectively manage chronic pain syndrome (disability in work or personal function related to pain).

The Level II interdisciplinary team should do a thorough biopsychosocial assessment of the patient with chronic pain. A comprehensive plan of care should be developed with active input from the patient and primary care provider. The plan of care should focus on objective functional goals and pain management. Elective surgery and invasive procedures should be done after the Level II interdisciplinary team assessment. Specific goals to integrate the patient back into the community and to usual activities should be a part of the plan of care.

Surgical Management of Patients with Chronic Pain

Surgery alone for chronic pain relief lacks compelling evidence of efficacy (Bogduk, 2004 [R]; Gibson, 1999 [M]).

- Cauda equina syndrome is a neurosurgical or orthopedic spine surgery emergency. See the ICSI Adult Low Back Pain guideline.
- For sudden, progressive or severe neuromotor deficit (e.g., foot drop or elbow extensor weakness, difficulty walking), consult a spine surgery specialist (*Wisconsin Medical Society Task Force on Pain Management*, 2004 [R]). See also the ICSI Adult Low Back Pain guideline.
- Patients with persistent radicular pain after appropriate conservative treatment may be candidates for surgical treatment (Wisconsin Medical Society Task Force on Pain Management, 2004 [R]). See also the ICSI Adult Low Back Pain guideline.

Surgery for patients with chronic pain may not be helpful and may be harmful (Cherkin, 1992 [C]).

- Surgery for chronic pain is usually elective.
 - Do a psychosocial screen before doing elective surgery (screen for personality disorder or psychopathology that may interfere with good outcome).
 - Be sure patient has had a thorough conservative management program before considering elective surgery.
 - Be sure patient expectations of surgery are reasonable by providing clear evidence-based information (*Atlas*, 2001 [R]).
- Check for serious medical and surgical pathology before starting pain management program.
- Focus on improving function, not just pain (Turk, 2004 [R]).
- Surgery for chronic low back pain may benefit some patients, "but nearly half will not benefit" (Bogduk, 2004 [R]).
- Neurosurgical techniques for chronic pain resistant to an adequate conservative approach hold promise but have limited scientific evidence (*Giller*, 2003 [R]):
 - Ablative techniques include cordotomy, myelotomy, cingulotomy and mesencephalotomy.
 - Stimulation techniques include motor cortex stimulation, deep brain stimulation and spinal cord stimulation.

Patients with chronic pain are best managed with an interdisciplinary team approach (Wisconsin Medical Society Task Force on Pain Management, 2004 [R]).

- Before doing elective surgery, obtain an interdisciplinary team assessment.
- Discuss realistic outcome before surgery (effect of surgery on pain and function including activities of daily living and vocation).
- After surgery, the patient with chronic pain is best managed by an interdisciplinary team using a biopsychosocial approach.

Patients with chronic pain should have outcome measurement before and after surgery to determine efficacy (*Deyo*, 1998 [R]).

After surgery, patient should have an active pain rehabilitation program and should start an independent lifetime fitness program.

Cochrane review

The practice of surgical and chemical potential sympathectomy is based on poor evidence, uncontrolled studies and personal experience. Complications may be significant. Clinical trials are required to establish effectiveness (*Mailis*, 2002 [M]).

The available small randomized trials do not provide reliable evidence of effects of surgery for cervical spondylotic radiculopathy or myelopathy. It is not clear whether the risks of surgery are offset by any long-term benefits (*Fouyas*, 2001 [R]).

There is no scientific evidence about the effectiveness of any form of decompression or fusion for degenerative lumbar spondylosis compared with natural history or conservative treatment (*Gibson*, 1999 [M]).

Palliative Interventions

Palliative interventions are used when conventional and less invasive procedures have failed. Patients should have documented compliance with a comprehensive care plan, with surgery not a viable option. Examples of palliative interventions include the following.

Nucleoplasty

Nucleoplasty is a percutaneous spinal procedure used to treat, or decompress, contained disc herniations. The procedure is performed by placing a radiofrequency electrode into the nuclear cavity. A radiofrequency current is then applied to the nuclear material, and 7 to 12 small channels are created within the disc, which serves to decompress the intervertebral structure (*Chen*, 2003 [D]). To date, only anecdotal data exists to support the efficacy of the procedure (*Cohen*, 2005 [D]).

Spinal cord stimulation (SCS)

Patients with lumbar and cervical radiculopathy who are not surgical candidates, patients with post-laminectomy syndrome, and patients with complex regional pain syndrome (CRPS) type 1 or (RSD) are the best candidates for SCS. Recently, Taylor reported that there is Grade B evidence for radicular pain and postlaminectomy syndrome and Grade A evidence for CRPS Type 1 (*Taylor*, 2006 [M]). SCS seems beneficial in a small subgroup of patients with peripheral vascular disease (*Ubbink*, 2005 [M]).

Intrathecal medication delivery systems

Intraspinal therapy can provide an excellent therapeutic effect for nonmalignant and cancer pain (*Deer*, 2004 [B]). However, it should be reserved only for patients who have failed other conservative approaches for the treatment of pain and should be used cautiously. Before starting intrathecal treatment in a patient with chronic pain the expectations and plans should be discussed in detail. The best candidates are patients who respond well to oral opioids but who cannot tolerate the side effects (e.g., sedation, nausea, constipation).

Multidisciplinary pain rehabilitation

Multidisciplinary pain rehabilitation is delivered in either an outpatient or inpatient setting where the goal of treatment is functional restoration. In general, a cognitive-behavioral model serves as the basis for treatment and incorporates physical reconditioning, occupational therapy and educational group sessions aimed at improving psychosocial functioning. The intensity of treatment varies between two hours weekly and eight hours daily. Similarly, the length of treatment varies from 2 weeks to 12 weeks. The benefits of multidisciplinary pain rehabilitation have been demonstrated in randomized trials for treatment of low back pain (Guzmán, 2002 [M]; Karjalainen, 2005a [M]). However, the benefits of multidisciplinary treatment for other painful conditions have not been clearly demonstrated (Karjalainen, 2001 [M]; Karjalainen, 2005b [M]).

Appendix A – Brief Pain Inventory (Short Form)

STUD	Y ID#					WOITE	: ABOVE	: THIS LI	NIE.	HOSPIT	ΓAL #
			Е					(Shor		m)	
Date	3	_/	/								Time:
Nam			Last					First		Mid	dlle Initial
1.	heada		our liv sprain	s, and	d tootha					to time	(such as minor nan these every-
				Yes					2.	No	
2.		e diagi the mo		hade i	n the a	reas w	here y	ou feel	oain. I	Put an X	on the area tha
3.	worst 0 No	se rate in the				ig the o	one nu	mber th	at bes	t descril	pes your pain at 10 Pain as bad as
4.	Pain Pleas	e rate	your p	ain by	circling	g the o	ne nuir	nber th	at bes	t descrik	you can imagi bes your pain at
	least 0 No Pain	n the I	ast 24 2	hours 3	4	5	6	7	8	9	10 Pain as bad as you can imagi
5.		e rate ⁄erage		ain by	circling	g the o	ne nun	nber tha	it best	describ	es your pain on
	0 No Pain	1	2	3	4	5	6	7	8	9	10 Pain as bad as you can imagi
6.	Pleas right r		your p	ain by	circlin	g the o	ne nur	nber tha	at tells	how mu	uch pain you hav
	0 No Pain	1	2	3	4	5	6	7	8	9	10 Pain as bad a you can imagi

			medic							
	ed? P	lease o					at mos			lications / much <mark>relie</mark>
0% No Relief	10%	20%	30%	40%	50%	60%	70%	80%	90%	100% Complete Relief
		e num th your		t descr	ibes ho	ow, dur	ing the	past 2	4 hou	rs, pain has
Α.	Gene	ral Acti	vity							
0 Does Interfe		2	3	4	5	6	7	8		10 Completely Interferes
0 Does Interfe	1 not	2	3	4	5	6	7	8		10 Completely Interferes
C.	Walki	ng Abil	ity							
0 Does Interfe		2	3	4	5	6	7	8		10 Completely Interferes
D.	Norm									ousework)
0 Does Interfe		2	3	4	5	6	7	8		10 Completely Interferes
E.	Relati	ons wi	th othe	r peopl	е					
0 Does Interfe		2	3	4	5	6	7	8		10 Completely Interferes
F.	Sleep									
0 Does Interfe	re	2	3	4	5	6	7	8		10 Completely Interferes
G.	Enjoy	ment o	f life							
0 Does Interfe		2	3	4	5	6	7	8		10 Completely Interferes
			Cor	oyright 199 Pair All	1 Charles Researc rights res	S. Cleelar h Group served.	nd, PhD			

Appendix B – Patient Health Questionnaire (PHQ-9)

Pa	tient Name:			Date	:	-
1.	Over the last 2 weeks, how often have you been bother	ered by any	of the following	ng problems?		
		Not at all	Several days	More than half the days	Nearly every day	
		0	1	2	3	
a.	Little interest or pleasure in doing things.					
b.	Feeling down, depressed, or hopeless.					
c.	Trouble falling/staying asleep, sleeping too much.					
d.	Feeling tired or having little energy.					
e.	Poor appetite or overeating.					
f.	Feeling bad about yourself – or that you are a failure or have let yourself or your family down.					
g.	Trouble concentrating on things, such as reading the newspaper or watching television.					
h.	Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual.					
i.	Thoughts that you would be better off dead or of hurting yourself in some way.					

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For initial diagnosis:

If there are at least four \checkmark s in the two right columns (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

Consider Major Depressive Disorder

• if there are at least five ✓s in the two right columns (one of which corresponds to Question #1 or #2).

Consider Other Depressive Disorder

• if there are two to four ✓s in the two right columns (one of which corresponds to Question #1 or #2).

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician, and a definitive diagnosis is made on clinical grounds, taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient. Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational or other important areas of functioning and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication or other drug as the biological cause of the depressive symptoms.

To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

PHQ-9 SCORING CARD FOR SEVERITY DETERMINATION

for healthcare professional use only

Scoring—add up all checked boxes on PHQ-9

For every \checkmark : Not at all = 0; Several days = 1; More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

Total Score Depression Severity

0-4 None

5-9 Mild

10-14 Moderate

15-19 Moderately severe

20-27 Severe

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Appendix C – Physical Functional Ability Questionnaire (FAQ5)

This tool has not been validated for research; however, work group consensus was to include it as an example due to the lack of other validated and easy-to-use functional assessment tools for chronic pain.

Name:
Date:
Date of Birth:
MR #:

Instructions: Circle the number (1-4) in each of the groups that best summarizes your ability.

Add the numbers and multiply by 5 for total score out of 100.

_____ Self-care ability assessment

- 1. Require total care: for bathing, toilet, dressing, moving and eating
- 2. Require frequent assistance
- 3. Require occasional assistance
- 4. Independent with self-care

— Family and social ability assessment

- 1. Unable to perform any: chores, hobbies, driving, sex and social activities
- 2. Able to perform some
- 3. Able to perform many
- 4. Able to perform all

Movement ability assessment

- 1. Able to get up and walk with assistance, unable to climb stairs
- 2. Able to get up and walk independently, able to climb one flight of stairs
- 3. Able to walk short distances and climb more than one flight of stairs
- 4. Able to walk long distances and climb stairs without difficulty

_____ Lifting ability assessment

- 1. Able to lift up to 10 lbs. occasionally
- 2. Able to lift up to 20 lbs. occasionally
- 3. Able to lift up to 50 lbs. occasionally
- 4. Able to lift over 50 lbs. occasionally

Work ability assessment

- 1. Unable to do any work
- 2. Able to work part-time and with physical limitations
- 3. Able to work part-time or with physical limitations
- 4. Able to perform normal work

——— Physical Functional Ability (FAQ5) Score

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Physical Functional Ability Questionnaire (FAQ5) Information Sheet

The Physical Functional Ability Questionnaire (FAQ5) was developed as a clinical assessment tool for patients with chronic pain and disability issues. This tool can provide a "snapshot" of the patient's self-perception of his or her physical functional ability at one point in time, without reference to pain perception. The tool was developed for ease of use in a busy clinical practice. The time for a patient, or family member, to complete the questionnaire is usually one to two minutes, and scoring is easily completed within seconds. This tool is adaptable to electronic medical records (EMR) to allow tracking over time, and total and/or subset numerical scores may be entered into the EMR by support staff, medical provider or patient.

All references to pain perception have been excluded, and all elements of physical function referenced by this questionnaire are directly observable or measurable, except for Work Ability. Self-Care Ability is the equivalent of Activities of Daily Living (ADLs), and Family and Social Ability is the equivalent of Instrumental Activities of Daily Living (IADLs). Movement Ability is easily observed indirectly by clinicians, and Lifting Ability could be simply tested by observing the patient lifting one or more reams of copy paper (each 500 sheet ream weighs about five pounds). Lifting Ability weight levels correlate with U.S. Department of Labor and Industry physical demand work levels and energy requirements: Sedentary – 10 pounds occasional/1.5 to 2.1 METs; Light – 20 pounds occasional/2.2 to 3.5 METs; Medium – 20-50 pounds occasional/3.6 to 6.3 METs; Heavy – 50 to 100 pounds occasional/6.4 to 7.5 METs.

Because this tool measures an individual's self-perception of physical function, it is not by itself a measure of impairment (any loss or abnormality of anatomical or physiological structure or function, permanent or temporary) or disability (inability to perform a major life activity, including work, because of an impairment). Disability is usually defined by an insurance company or governmental agency, such as the Veterans Administration or Social Security Administration.

The utility of the FAQ5 is greatest in several areas:

- 1. Establishing a simple baseline measure of physical function from which to begin a physical rehabilitation program.
- 2. Establishing a simple physical functional goal toward which to aim a physical rehabilitation program.
- 3. A periodic measure of progress (or lack of progress) toward a functional rehabilitation program goal.
- 4. Establishing a subjective baseline and framework against which objective findings of physical dysfunction may be compared during a clinical evaluation or assessment of patients claiming disability benefits.

Use of the FAQ5 global score (25-100) provides a simple numerical score for comparison of past or current perceptions with future goals. Most patients with chronic pain or those seeking disability benefits have initial scores in the range of 40 to 60. In patients with chronic pain and those seeking disability benefits, discordance is common between elements within the FAQ5, or between the FAQ5 and observed physical function. Discordances may provide clues to psychosocial risk factors, which can contribute to perpetuation of chronic pain and disability behaviors, that need to be addressed as part of a treatment and rehabilitation program. For example, discordance between the patient's perception of physically observable elements (ADLs, IADLs, movement and lifting) and self-perceived work capacity may indicate some degree of reluctance to return to work.

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Appendix D – Personal Care Plan for Chronic Pain

This tool has not been validated for research; however, work group consensus was to include it as an example of a patient tool for establishing a plan of care.

1.	Set Personal Goals
	☐ Improve Functional Ability Score by points by: Date
	Return to specific activities, tasks, hobbies, sportsby: Date
	1
	2
	3
	☐ Return to ☐ limited work/or ☐ normal work by: Date
2.	Improve Sleep (Goal: hours/night, Current:hours/night)
	Follow basic sleep plan
	Eliminate caffeine and naps, relaxation before bed, go to bed at target bedtime
	☐ Take nighttime medications
	1
	2
	3
3.	Increase Physical Activity
	Attend physical therapy (days/week)
	Complete daily stretching (times/day, forminutes)
	Complete aerobic exercise/endurance exercise
	1. Walking (times/day, forminutes) or pedometer (steps/day)
	2. Treadmill, bike, rower, elliptical trainer (times/week, for minutes)
	3. Target heart rate goal with exercise bpm
	Strengthening
	1. Elastic, hand weights, weight machines (minutes/day, days/week)
4.	Manage Stress – list main stressors
	Formal interventions (counseling or classes, support group or therapy group)
	Daily practice of relaxation techniques, meditation, yoga, creative activity, service activity, etc.
	1
	2
	☐ Medications
	1
5.	Decrease Pain (best pain level in past week: / 10, worst pain level in past week: / 10)
3.	Non-medication treatments
	I. Ice/heat
	2.
	☐ Medication
	1.
	2.
	3.
	4.
	Other treatments
Phy	/sician name: Date:
,	

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Appendix E – DIRE Score: Patient Selection for Chronic Opioid Analgesia

The DIRE Score is a clinician rating used to predict patient suitability for long-term opioid analgesic treatment for chronic non-cancer pain. It consists of four factors that are rated separately and then added up to form the DIRE score: Diagnosis, Intractability, Risk and Efficacy. The Risk factor is further broken down into four subcategories that are individually rated and added together to arrive at the Risk score. The Risk subcategories are Psychological Health, Chemical Health, Reliability and Social Support. Each factor is rated on a numerical scale from 1 to 3, with 1 corresponding to the least compelling or least favorable case for opioid prescribing, and 3 denoting the most compelling or favorable case for opioid prescribing. The total score is used to determine whether or not a patient is a suitable candidate for opioid maintenance analgesia. Scores may range from 7 at the lowest (patient receives all 1s) to 21 at the highest (patient receives all 3s). In a reliability and validity study, higher scores (14 or higher) predicted a more successful prescribing process with respect to patient compliance and efficacy of treatment (*Belgrade*, 2006 [A]).

For each factor, rate the patient's score from 1 to 3 based on the explanations in the right-hand column.

Score Factor	Explanation
--------------	-------------

<u>D</u> iagnosis	1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis.
	Examples: fibromyalgia, migraine headaches, non-specific back pain.
	2 = Slowly progressive condition concordant with moderate pain, or fixed condition with
	moderate objective findings. Examples: failed back surgery syndrome, back pain with
	moderate degenerative changes, neuropathic pain.
	3 = Advanced condition concordant with severe pain with objective findings. Examples:
	severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis.
<u>Intractabilit</u>	1 = Few therapies have been tried and the patient takes a passive role in his/her pain
<u> </u>	management process.
	2 = Most customary treatments have been tried but the patient is not fully engaged in the pain
	management process, or barriers prevent (insurance, transportation, medical illness).
	3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate
	response.
<u>R</u> isk	(R= Total of P+C+R+S below)
Psychological:	1 = Serious personality dysfunction or mental illness interfering with care. Example:
	personality disorder, severe affective disorder, significant personality issues.
	2 = Personality or mental health interferes moderately. Example: depression or anxiety
	disorder.
	3 = Good communication with clinic. No significant personality dysfunction or mental illness.
Chemical Healt	
	2 = Chemical coper (uses medications to cope with stress) or history of CD in remission.
	3 = No CD history. Not drug focused or chemically reliant.
Reliability:	1 = History of numerous problems: medication misuse, missed appointments, rarely follows
_ ,	through.
	2 = Occasional difficulties with compliance, but generally reliable.
	3 = Highly reliable patient with meds, appointments & treatment.
Social Support:	1 = Life in chaos. Little family support and few close relationships. Loss of most normal life
	roles.
	2 = Reduction in some relationships and life roles.
	3 = Supportive family/close relationships. Involved in work or school and no social isolation.
<u>E</u> fficacy	1 = Poor function or minimal pain relief despite moderate to high doses.
	2 = Moderate benefit with function improved in a number of ways (or insufficient info – hasn't
score	tried opioid yet or very low doses or too short of a trial).
	3 = Good improvement in pain and function and quality of life with stable doses over time.

_____Total score = D + I + R + E

Score 7-13: Not a suitable candidate for long-term opioid analgesia Score 14-21: May be a good candidate for long-term opioid analgesia

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Appendix F – Opioid Agreement Form

	nderstand that Dr is prescribing opioid medication to assist me in
If i	anaging chronic pain that has not responded to other treatments and must assist me to function better. my activity level or general function gets worse, the medication will be changed or discontinued. The ks, side effects and benefits have been explained to me and I agree to the following conditions of opioid atment. Failure to adhere to these conditions will result in discontinuing the medication.
1.	I will participate in other treatments that recommends and will be ready to taper or discontinue the opioid medication as other effective treatments become available.
2.	I will take my medications exactly as prescribed and will not change the medication dosage or schedule without approval.
3.	I will keep regular appointments at the clinic.
4.	All opioid and other controlled drugs for pain must be prescribed only by
5.	If I have another condition that requires the prescription of a controlled drug (like narcotics, tranquilizers, barbituates or stimulants), or if I am hospitalized for any reason, I will inform the clinic within one business day .
6.	I will designate one pharmacy where all of my prescriptions will be filled.
	Pharmacy Name:
	Phone Number:
	Fax Number:
	Address:
7.	I understand that lost or stolen prescriptions will not be replaced , and I will not request early refills.
8.	I agree to abstain from all illegal and recreational drugs (including alcohol) and will provide urine or blood specimens at the doctor's request to monitor my compliance.
9.	I am responsible for keeping track of the medication left and plan ahead for arranging refills in a timely manners so that I will not run out of medication.
	• Refills will be made only during regular office hours, which are Refills will not be made at night, on Fridays, weekends or during holidays.
	• Prescriptions will be mailed to my pharmacy. I must plan ahead for mailed prescriptions; it will take at least five days for a prescription to reach my pharmacy after my phone call.
go	thorize physicians and/or staff to discuss my care and treatment while undering opioid therapy with my primary care/referring physician and any other medical facilities involved my care.
Pat	tient Name (print): Patient Signature:
Da	te:
Pro	ovider Signature: Date:
Sou	arce: Adapted with permission from Pain Management Center, Fairview Health Services 2005

Appendix G – Opioid Analgesics

If a patient does not receive adequate pain relief from one opioid, or side effects are not tolerable, a trial with an alternative opioid may be considered. When switching from one opioid to another or an alternative route, it is generally recommended to decrease the equi-analgesic dose by 30% due to incomplete cross tolerance (*Kaiser Permanente Medical Care Program*, 2004 [R]). The new opioid dose can then be titrated up until adequate analgesia is obtained.

Drug	ug Equianalgesic Potency*		Comments		
	Oral	Parenteral			
Morphine	30 mg	10 mg	Long-acting forms may be given orally every 8 to 12 hours. Some long-acting dosage forms may be given rectally. Metabolites may cause myoclonus in patients with renal failure.		
Hydromorphone	7.5 mg	1.5 mg	Potent opioid. Good agent for patients with renal dysfunction.		
Oxycodone	20 mg	-	Long-acting form may be given orally/rectally every 8 to 12 hours.		
Methadone	5 mg	**	Half-life > 24 hrs, so dosing adjustments should be made cautiously. Given every 6 to 8 hrs for pain management. May have role in management of neuropathic pain. Equialanalgesic ratios change with oral morphine doses > 100 mg/day – consult a specialist. Some N-methyl-D-asparatate (NMDA) antagonist activity. For the experienced practitioner only. Pharmakenetics are highly variable and there is non-dose related cardiotoxicity. ECG monitoring is recommended prior to initiation of methadone, at 30 days, and annually due to the possibility of QTc interval prolongation and other cardiac dysrythmias.		
Levorphanol	4 mg	2 mg	Potent opioid with some NMDA antagonist activity.		
Meperidine	300 mg	75 mg	Metabolized to normeperidine, a CNS stimulant, which may cause seizures in patients with renal failure.		
Fentanyl***	-	100 mcg	Available as transdermal patch (see conversion below) and buccal products.		
Codeine	200 mg	130 mg	5%-10% of Caucasians lack the enzyme to metabolize codeine to morphine. May cause more nausea and constipation than other opioids. Profound narcosis has occurred in chronic renal failure patients.		
Hydrocodone	30 mg	-	Often combined with non-opioid analgesics, which limits the total dose per day.		
Oxymorphone	10 mg	1 mg	Oral administration with food or alcohol may result in excessive sedation.		
Nalbuphine	-	10 mg	May precipitate withdrawal in opioid-dependent patients.		
Butorphanol	-	2 mg	Available as nasal spray.		
Pentazocine	50 mg	30 mg	Mixed agonist/antagonist. May precipitate withdrawal in opioid-dependent patients.		
Buprenorphine	-	0.4 mg	Mixed agonist/antagonist. May precipitate withdrawal in opioid-dependent patients.		
Propoxyphene	180-240 mg	-	Metabolized to norpropoxyphene, which may cause seizures.		

(Derby, 1998 [R]; American Pain Society, Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain, 5th Edition, 2003 [R]; Krantz, 2009 [R])

Transdermal Fentanyl Conversion

Remember 1:2:3 This ratio represents the absolute number equivalent doses for the number of mgs daily intravenous morphine, to the number of hourly mcg of fentanyl, to the number of mgs of daily oral morphine respectively.

1 : 2 : 3

25 mg/daily IV morphine = Fentanyl 50 mcg/hr q 3 days = 75 mg/day PO morphine

Patients must avoid exposing the patch to excessive heat as this promotes the release of fentanyl from the patch and increases the absorption of fentanyl through the skin, which can result in fatal overdose. Directions for prescribing and using the fentanyl patch must be followed exactly to prevent death or other serious side effects from fentanyl overdose.

^{*} This table reflects equianalgesic potencies, not recommended doses.

^{**} Methadone: Confer with pain specialist before use.

^{***}Note: Despite an FDA-issued Public Health Advisory in July 2005 regarding the appropriate and safe use of the transdermal system, death and life-threatening adverse events related to fentanyl overdose have occurred when the fentanyl patch was used to treat pain in opioid-naive patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The fentanyl patch is only indicated for use in patients with persistent moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are considered to be opioid tolerant.

Appendix G - Opioid Analgesics

The FDA has received reports of serious side effects including death in patients who have taken the fentanyl buccal tablets. These reports describe prescribing to non-opioid tolerant patients, misunderstanding of dosing instructions or inappropriate substitution of fentanyl buccal tablets for oral transmucosal fentanyl citrate by pharmacists and prescribers. The directions for using fentanyl buccal tablets must be followed exactly to prevent death or other severe side effects from overdosing fentanyl. To see the full alert, refer to the FDA alert (9/2007) addressing fentanyl buccal tablets information at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113690.htm.

Black Box warning on Propoxyphene:

• Do not prescribe propoxyphene for patients who are suicidal or addiction-prone. Prescribe propoxyphene with caution for patients taking tranquilizers or antidepressant drugs, and patients who use alcohol in excess. Patients should not exceed the recommended dose and alcohol intake should be limited. Propoxyphene products in excessive doses, either alone or in combination with other CNS depressants, including alcohol, are a major cause of drug-related deaths.

Doses of opioids that exceed the equivalent of morphine 200 mg per day should be considered a general limit, with higher doses indicating a possible concern for hyperalgesia or potential for abuse. Consider possible weaning or discontinuation of opiates if assessment indicates reduced analgesia, aberrant drug-related behaviors, or intolerable side effects. Practitioners should consider referral of patients requiring higher doses to chronic pain specialists. Oxycodone 120-180 mg/day and methadone 40 mg/day are approximate equivalents to morphine 200 mg and should be considered as relative maximum doses of these opiates.

This information is current as of September 2009. See prescribing information for complete details. For the most up-to-date medication information, consider the following sources: www.epocrates.com, www.micromedex.com, www.uptodate.com, www.pdr.net.

Appendix H – Pharmaceutical Interventions for Neuropathic Pain

Drug	Dosage	Side effects, contraindications, and comments
Daily Medications		
ANTICONVULSANTS		
Gabapentin *	100 to 300 mg at bedtime; increase by 100-300 mg every 3 days up to 1,800 to 3,600 mg per day taken in divided doses three times daily. Higher doses might be used.	Initial drug of choice. Side effects: drowsiness, dizziness, fatigue, nausea, sedation, edema, weight gain. No significant drug-drug interactions. Reduce dose/increase interval in renal failure (give 10x creatinine clearance per day). ¹
Pregabalin *	50 mg – 75 mg twice daily-three times daily to start. Up to 200 mg three times daily.	Initial drug of choice. Side effects: drowsiness, dizziness, fatigue, nausea, sedation, edema, weight gain. No drugdrug interactions. Reduce dose/increase interval in renal failure (give 5x creatinine clearance per day). Schedule V medication. ¹
Lamotrigine	25 mg per day; increase by 25 mg-50 mg every 1-2 weeks up to 400 mg per day.	Side effects: Stevens-Johnson syndrome, rare life- threatening rash unlikely with gradual dose titration. Dizziness, drowsiness, headache, nausea, blurred/double vision. ¹
Oxcarbazepine	Start 150 mg - 300 mg twice daily. Increase by 600 mg per day each week to max 1200 mg twice daily.	Initial drug of choice for trigeminal neuralgia. Similar adverse effects to carbamazepine but less likely. Fewer drug-drug interactions. ¹
Carbamazepine *	200 mg-400 mg twice daily. Increase to max 600 mg twice daily.	Initial drug of choice for trigeminal neuralgia. Watch for hyponatremia, leucopenia, allergic rash (Stevens-Johnson syndrome). Other side effects: dizziness, drowsiness, blurred/double vision, ataxia. Not favored for other neuropathic pain. Available in extended release. 1,3
Topiramate	25 mg twice daily to start; increase by 25-50 mg per week up to 200-400 mg per day.	Most evidence is for migraine prevention, other neuropathic pains may respond. Side effects: drowsiness, abnormal thinking, weight loss, urinary tract stones, increased intraocular pressure.
ANTIDEPRESSANTS		
Serotonin & Norepinephrine Reuptake Inhibitors (SNRIs)		
Duloxetine *	20 to 60 mg per day taken once or twice daily in divided doses (for depression); 60 mg twice daily for fibromyalgia.	Initial drug of choice. Side effects: nausea, dry mouth, constipation, dizziness, insomnia. ²
Venlafaxine	37.5 mg per day; increase by 37.5 mg per week up to 300 mg per day.	Side effects: headache, nausea, sweating, sedation, hypertension, seizures. Serotonergic properties in dosages below 150 mg per day; mixed serotonergic and noradrenergic properties in dosages above 150 mg per day. Available in extended-release formulation. ²
Tricyclic Antidepressants Amitriptyline, Imipramine	10 to 25 mg at bedtime; increase by 10 to 25 mg per week up to 75 to 100 mg at bedtime or a therapeutic drug level.	Initial drug of choice. Tertiary amines have greater anticholinergic side effects and may cause arrhythmia, orthostatic hypotension; therefore, these agents should not be used in elderly patients. ²
Desipramine, Nortriptyline	25 mg in the morning or at bedtime; increase by 25 mg per week up to 100 mg per day or a therapeutic drug level.	Secondary amines have fewer anticholinergic side effects, but should still be used cautiously in elderly patients. ²

Drug	Dosage	Side effects, contraindications, and comments
Topical Medications		
Lidocaine 5% patch *	Up to 3 patches to intact skin 12 hrs per day (12 hrs on/12 hrs off)	Indicated for postherpetic neuralgia. Commonly used for other neuropathic conditions. May be used daily or as needed.
Capsaicin	0.025% or 0.075% apply to intact skin 3-4 times per day	Burning irritation of skin, eyes, airway. Requires regular application for four to six weeks to achieve effect; then maintenance. Available without prescription.
As-Needed Medications		
Tramadol	50-100 mg 4 times daily as needed. Max 400 mg per day	Side effects: abdominal discomfort, dizziness, constipation, seizures. May interact with other serotonergic drugs to cause serotonin syndrome. Abuse potential despite unscheduled status. Available in extended-release form for daily use and in combination with acetaminophen.
Oxycodone	5 mg-10 mg every 4 hours as needed	Schedule II medication. Side effects: constipation, drowsiness, confusion, nausea, itching, dependence, abstinence syndrome upon abrupt withdrawal at doses > 20 mg per day. Available in combination with acetaminophen.

^{*} Approved by the U.S. Food and Drug Administration for treatment of neuropathic pain.

- ¹ FDA alert: Increased risk of suicidal behavior or ideation.
- ² Black box warning: Increased suicidal behavior in young adults
- ³ Two black box warnings on carbamazepine:
 - Aplastic anemia and agranulocytosis have been reported in association with the use of carbamazepine.
 - The genetic testing is recommended prior to initiation of therapy in most patients of Asian ancestry for the presence of the HLA-B*1502 allele genetic marker to decrease the risk of developing Stevens-Johnson syndrome (SJS) and/or toxic epidermal necrolysis (TEN).

Drugs labeled **initial drug of choice** based on a combination of evidence for efficacy from randomized controlled trials and safety profile. Does not imply superiority.

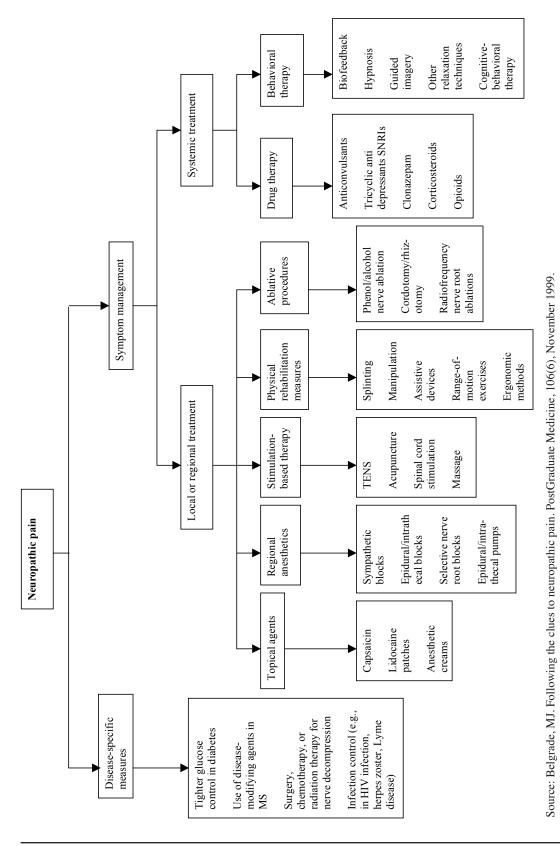
This table was completed using the following sources:

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This information is current as of September 2009. See prescribing information for complete details. For the most up-to-date medication information, consider the following sources: www.epocrates.com, www.micromedex.com, www.uptodate.com, www.pdr.net.

Appendix I – Neuropathic Pain Treatment Diagram



Appendix J – * Suggested Maximum Daily Opioid Doses for Primary Care Clinicians

Opioid	Dose
Morphine	200 mg/day
Methadone	40 mg/day
Oxycodone	120 mg/day
Fentanyl (transdermal)	100 mcg/hour
Oxymorphone	30 mg/day

^{*}Higher doses require close, careful documentation and may prompt consultation with a pain specialist.

Source: Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J of Pain* 2009;10:113-30. (Class M)



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Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in the Foreword and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols +, -, \emptyset , and N/A found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

- + indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;
- indicates that these issues have not been adequately addressed;
- ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

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Conclusion Grading Worksheet – Appendix A – Annotation #19 (Chronic Pain and Chemical Use)

onclusion Grade: III

Work Group's Conclusion:

There is not enough evidence to permit generalizable conclusions regarding the abuse

of opioids in chronic non-malignant pain. However, careful patient selection and close monitoring of all nonmalignant pain patients on chronic opioids is necessary to assess effectiveness and watch for signs of abuse.

Author/Year	Design Type	Class	Qual- ity +,-,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions / Work Group's Comments (italicized)
Chabal, 1997	Cross-sec-tional	Ω	0	ans Affairs Medical Center who were actively enrolled in the pain clinic – 19% (76) of all pain clinic patients were using opioids for longer than 6 months – Staff developed a list of behaviors consistent with prescription opioid abuse – Internal reliability of the scale was ascertained by two attending physicians performing independent ratings of patients who were using opioids chronically – Chart review and computer search was done for each abuser 1 year after initial abuse criteria were developed – 96% of chronic opioid users were male, with an average age of 48 years with mean duration of pain of 115 months – Musculoskeletal pain, joint and limb pain, abdominal pain, and neuropathic pain accounted for most of the pain diagnoses	Of the chronic opioid users (for > 6 months), 34% (26/76) met one or more of the 5 criteria for abuse, 27.6% (21/76) of chronic opioid users met 3 or more criteria Independent physician assessments using the survey had an inter-rater reliability of > 0.9 No difference was found between chronic opioid users (n = 76) and opioid abusers (n = 21) in terms of a past history of substance abuse Opioid abusers had similar levels of self-reported pain and depressive symptoms on entry into the pain clinic as non-abusers One-year follow-up of the 21 patients who met abuse criteria noted that 3 remained in the pain clinic on stable opioid doses, 4 pts were followed in the pain clinic, and 14 were not followed in the pain clinic, and 14 were not followed in the pain clinic, and 14 were not followed in the pain clinic, and 14 were not pleted drug treatment or had documented legal issues over their use of opioids	A significant minority of patients had problems related to opioid use Inter-rater reliability of questionnaire was high, and may be used to identify pts in need of more intensive intervention or treatment Abuse data fall within spectrum of other reports Since VA patients may have been referred to the clinic specifically to deal with opioid management problems, the abuse results may have been biased upward The prevalence of pseudoaddiction is unknown Past hx substance abuse, depressive symptomatology, or intensity of pain should not be contraindications to opioid treatment of chronic pain VA patient population used is likely more prone to substance abuse overall, thus biasing the percentage addiction upward

Authors' Conclusions / Work Group's Comments (italicized)	Results demonstrate that opioids can be effective in chronic non-malignant pain management, with side effects that are comparable to those in treating cancer pain	Tolerance to opioid analgesia did not appear to occur in this group of pts on averageProvides objective data to challenge position that opioids are inappropriate for chronic non-malignant pain
Primary Outcome Measure(s)/Results (e.g., pvalue, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	 The pain relief surveys and scales showed the following: Good pain relief: 51% of pts Partial pain relief: 28% of pts No benefit: 21% of pts The correlation between the sum and the peak VAS values was statistically significant (r = 0.983, p < 0.0001) Pain reduction was associated with an increase in performance (p < 0.0001) Constipation and nausea were the most common side effects No cases of addiction to opioids or respiratory depression were noted 	- There was no difference in pain severity in pts with different spinal pathologies - No evidence found for a decrease in opioid efficacy in patients with longer-term use (3 months or more) - Opioids significantly reduced back pain severity from an avg of 8.3 to 4.5 (0-10 scale) - Constipation, sedation and other mild side effects were reported in 58% of the opioid treated patients, and only rarely led to discontinuation of treatment - No significant increase in the avg initial dosage of opioid as compared to the mean peak dosage and the mean recent dosage, - 3 patients on long-term opioids with dosage escalations displayed abuse behaviors - Abuse behavior was not more frequent in those with or without a history of abuse/addiction
Population Studied/Sample Size	100 pts chronically given opioids for the treatment of non-malignant pain Most pts were diagnosed with neuropathic or back pain Drugs used included sustained-release morphine, sustained-release dihydrocodeine, and buprenorphine Visual-analog scales (VAS) and the Karnofsky Performance Status Scale were used to assess patient symptoms and function	230 orthopedic spine clinic pts were studied through retrospective analysis of prescriptions for 3 years and crosssectional analysis of opioid effectiveness and toxicity using interviews Opioids were prescribed for 152 (66%) of total pts; opioids were given for less than 3 and for 3 months or more (long-term) in 58 pts Interviews were completed in 167 pts total Pts from Veterans Affairs
Qual- ity +,-,0	Ø	0
Class	Ω	О
Design Type	Case	Cross-sec-tional
Author/Year	Zens, 1992	Mahowald, 2005



Support for Implementation:

Assessment and Management of Chronic Pain

This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
 - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

1. Improve the function of adult patients with chronic pain. (Annotations #2, 14)

Possible measures for accomplishing this aim:

Outcome Measures:

- a. Percentage of patients diagnosed with chronic pain who have returned to work.
- b. Percentage of patients diagnosed with chronic pain who have returned to normal life activities identified in care plan.

Process Measures:

- Percentage of patients diagnosed with chronic pain with functional outcome goals documented in medical record.
- Percentage of patients diagnosed with chronic pain with referral to physical rehabilitation and/or behavioral management therapy.
- c. Percentage of patients diagnosed with chronic pain with documentation of receiving education regarding their diagnosis of chronic pain, medications, importance of physical activity, and/or any interventional procedures in medical record.
- 2. Improve the assessment and reassessment of adult patients with chronic pain utilizing the biopsychosocial model. (Annotations #2, 3, 12)

Possible measures for accomplishing this aim:

Process Measures:

- a. Percentage of patients with pain symptoms with documentation of a pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan.
- b. Percentage of patients diagnosed with chronic pain with documentation of reassessment of pain at follow-up visits using a standardized tool that addresses pain intensity, location, pattern and current functional status.
- c. Percentage of patients diagnosed with chronic pain with documentation of screening for major depression and chemical dependency.
- 3. Improve the appropriate use of Level I and Level II treatment approaches for adult patients with chronic pain. (*Annotations #14, 19, 25*)

Possible measures for accomplishing this aim:

- a. Percentage of patients diagnosed with chronic pain who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management, and pain reduction in medical record.
- b. Percentage of patients diagnosed with chronic pain who fail to follow their plan of care with documentation of identified barriers and changes to the care plan in the medical record.
- c. Percentage of patients diagnosed with chronic pain who have not met goals for pain control or function referred for diagnostic and/or therapeutic procedures, e.g., Facet Joint Injection.

- d. Percentage of patients diagnosed with chronic pain who have not met pain control or function goals who are referred to pain specialist or interdisciplinary pain team.
- e. Percentage of physicians surveyed who agree or strongly agree that the primary care physician and specialty physician collaboratively managed the patient's plan of care.
- 4. Improve the effective use of non-opioid medications in the treatment of adult patients with chronic pain. (*Annotations #15, 19*)

Possible measures for accomplishing this aim:

- a. Percentage of patients diagnosed with chronic pain with a diagnosis of inflammatory pain who are prescribed an NSAID as an initial analgesic unless clinically contraindicated.
- b. Percentage of patients diagnosed with chronic pain with a diagnosis of neuropathic pain who are prescribed a tricyclic antidepressant OR anticonvulsant prior to use of opioids.
- 5. Improve the effective use of opioid medications in the treatment of adult patients with chronic pain. (*Annotations #15, 19*)

Possible measures for accomplishing this aim:

- a. Percentage of patients diagnosed with chronic pain who are receiving opioids who have documentation of the four A's assessment: 1) the degree of analgesia, 2) current opioid-related side effects, 3) current functional status, and 4) existence of aberrant drug-related behaviors documented at each visit.
- b. Percentage of patients diagnosed with chronic pain who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record.
- c. Percentage of patients diagnosed with chronic pain who are prescribed an opioid who have documentation of screening for risk of diversion or chemical dependency in the medical record.

Measurement Specifications

Possible Success Measure #5b

Percentage of patients diagnosed with chronic pain who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record. (Annotation #19)

Population Definition

Patients age 16 years and older with chronic pain.

Data of Interest

of records with documented opioid agreement form and a urine toxicology screen in medical record for patients with chronic pain

total # of patients who present with chronic pain (or diagnosis with identifier related to chronic pain) whose medical records are reviewed

Numerator/Denominator Definitions

Numerator: Those medical records that are reviewed that have evidence of an opioid agreement form and

a urine toxicology screen.

Denominator: All patients 16 and older who meet the criteria for chronic pain or related diagnosis as identified by the following ICD-9 codes. A few examples are:

• Chronic Pain: 338.xx

Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x

• Headache: 307.8x, 784.0

Other disorders of soft tissues: 729.x

Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

- Chronic pain is defined as:
 - persistent pain,
 - either continuous or recurrent, and
 - of sufficient duration and intensity to adversely affect a patient's well-being, level of function, and quality of life (Wisconsin Medical Society Task Force on Pain Management, 2004 [R]).
- At six weeks (or longer than the anticipated healing time), patients should be thoroughly evaluated for the presence of chronic pain.
- Chronic pain syndrome is defined by the work group as a constellation of behaviors related to persistent pain that represents significant life role disruption that occurs at the end of the spectrum of chronic pain.

Method/Source of Data Collection

Each month, a sample of patients with chronic pain seen in the past month is identified by the above ICD-9 codes or other ICD-9 codes identified by the organization.

A chart abstraction is conducted to determine whether or not there is any evidence of an "Opioid Agreement" and a urine toxicology screen in the medical record.

Time Frame Pertaining to Data Collection

Suggested data collection time frame is monthly.

Notes

Other diagnoses that are related to chronic pain include low back pain, neck pain and fibromyalgia. Please refer to the Key Implementation Recommendations for suggestions on identifying other ICD-9 codes.

Please refer to the International Classification of Diseases 2008 ICD-9-CM, page 13, regarding specifications for the 338 ICD-9 code.

Key Implementation Recommendations

- 1. It is important to take both a clinical and an operational approach for successful implementation of this guideline.
- 2. Develop a process that allows patients with chronic pain to see a dedicated care provider who has an interest or expertise in chronic pain. The care provider is responsible for care management involving chronic pain in order to foster continuity while allowing the primary care physician to focus on medical diagnosis.
- 3. Develop a process for handing off patients to a dedicated chronic pain provider within the clinic.
- 4. Develop a process to work collaboratively with other care providers in prescribing opioids with shared patients (e.g., dentists, specialists).
- 5. Establish a policy for monitoring and maintaining opioid agreements for prescription refills with other clinics, pharmacies, dentists and specialists.
- 6. Develop a process for scheduling follow-up patient visits to deter drug-seeking behaviors with other care providers, for instance, support personnel calling patients to schedule follow-up appointments with a dedicated chronic pain physician.
- 7. Develop staff and physician training regarding the organization's process for treating patients with chronic pain that could include process of referrals to chronic pain provider within the system, follow-up visits, prescription refills and continuity of care.
- 8. Train a chronic pain care team that minimally consists of a physician champion and medical support staff. Suggestion for care providers from other disciplines include pharmacy, chemical dependency, neurology, home care, social work, physical medicine and rehabilitation, and physical therapy.
- 9. Determine population ICD-9 codes for data collection that is unique to patients with chronic pain in your facility. Examples of this would be:
 - · low back pain
 - headache
 - neck pain
 - fibromyalgia
 - chronic pain
- 10. Identify multidimensional pain assessment, functional assessment, psychological assessment, and opioid assessment tools that meet the needs of the care providers and are appropriate for the patient populations.

Examples of pain assessment, functional assessment, and psychological assessment tools are, but are not limited to:

- Brief Pain Inventory (BPI)
- Functional Ability Questionnaire
- Oswestry Low Back Disability Index (refer to ICSI Adult Low Back Pain guideline)
- PHQ-9

Examples of opioid and substance abuse assessment tools are, but are not limited to:

- CAGE and CAGE-AID
- Webster's Opioid Risk Tool (ORT)
- DIRE Tool
- Screener and Opioid Assessment for Patients in Pain (SOAPP®)
- Current Opioid Misuse Measure (COMMTM)
- Prescription Drug Use Questionnaire (PDUQ)
- Screening Tool for Addiction Risk (STAR)
- Screening Instrument for Substance Abuse Potential (SISAP)
- Pain Medicine Questionnaire (PMQ)

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Assessment and Management of Chronic Pain guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are *only* available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to http://www.icsi.org/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American Academy of Pain Medicine	Founded in 1983 and has become the primary organization for physicians practicing the specialty of pain medicine in the U.S.	Health Care Providers	http://www.painmed.org
	American Chronic Pain Association	To facilitate peer support and education for individuals with chronic pain and their families so that these individuals may live more fully in spite of their pain.	Patients and Families; Health Care Providers	http://www.theacpa.org
		To raise awareness among the health care community, policy makers, and the public at large about issues of living with chronic pain.		
	American Pain Foundation	Dedicated to eliminating the undertreatment of pain in America. Has resources, such as the "Target Chronic Pain Notebook" for individuals who suffer from chronic pain, their families, friends and the general public. Additional publications include: • Pain Resource Guide • Treatment Options: A Guide for People Living with Pain	Patients and Families	http://www.painfoundation.org/
	American Pain Society	A multidisciplinary scientific and professional society. CEs available. Several position statements available including pediatric chronic pain, use of opioids, and preventing abuse of pain meds.	Patients and Families; Health Care Providers	http://www.ampainsoc.org/
	American Society for Pain Management Nurses	To advance and promote optimal nursing care for people affected by pain. Position statement on treating pain for patients with addictive disease.	Health Care Providers	http://www.aspmn.org/

^{*} Available to ICSI members only.

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American Society of Regional Anesthesia and Pain Medicine	The mission of the American Society of Regional Anesthesia and Pain Medicine is to associate physicians and scientists who are engaged in regional anesthesia for surgery, obstetrics and pain medicine; to encourage education and to publish the highest quality scientific information on these subjects. The site provides information for patients and members that address education and research regarding pain medicine.	Health Care Providers; Patients and Families	http://www.asra.com
	Beth Israel Medical Center Web site	Dedicated to providing comprehensive care of the highest quality in pain management and palliative care for physicians, nurses and pharmacists.	Health Care Providers	http://www.stoppain.org
	Margaret Caudill	"Managing Pain Before It Manages You"; workbook for patients providing education on pharmacological and non- pharmacological management of pain, as well as effective coping and commu- nication skills, problem-solving strate- gies, and guidance on setting realistic goals. Also includes excellent informa- tion on mind-body techniques.	Patients and Families	Guilford Press; http://www.guilford.com
*	ICSI	Patient Education Materials: Communicating About Your Pain (Mayo Clinic)	Health Care Providers/ Patients and Families	http://www.icsi.org/ guidelines_and_more/patient_ education_resources/musculo- skeletal_disorders/
*	ICSI	Chronic Pain Patient Focus Group Video	Health Care Providers	http://www.icsi.org/improve- ment_resources/knowledge_ resources/recorded_presenta- tions/videos/
*	ICSI	PIR #30: Pain, Chronic – Patient Focus Group Report	Health Care Providers	http://www.icsi.org/improvement_ resources/knowledge_resources/ summary_reports/patient_focus_ group_reports/
*	ICSI	Guideline Pilot Summary: Assessment and Management of Chronic Pain	Health Care Providers	http://www.icsi.org/improvement_resources/knowledge_resources/summary_reports/guideline_pilot_reports_15302/
	International Association for the Study of Pain (IASP)	The preeminent organization for science, practice and education in the field of pain. This site provides publications for clinicians that include a peer-reviewed journal and clinical updates.	Health Care Providers	http:// www.iasp-pain.org

^{*} Available to ICSI members only.

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	National Pain Education Council	A non-profit organization that provides educational information to Primary Care Physicians, Specialists, and Allied Health Care Professionals via a Web based format.	Health Care Providers	http://www.npecweb.org
	National Pain Foundation (NPF)	A non-profit 501(c)(3) organization advancing functional recovery of persons in pain through education, support and information. Information, education, and support is provided for individuals and families living with pain. Resources include educational materials on various diseases and conditions, contacts of pain care providers, and a personal pain journal.	Patients and Families	http:// www.nationalpainfoundation.org
	PainKnowledge	An interactive educational resource on pain management, sponsored by Professional Postgraduate Services and in part by an educational grant from Endo Pharmaceuticals. Features of Painknowledge.org include a comprehensive pain management slide library; pain CME activities, including pain newsletters and interactive case studies; physician tools; pain resources; patient handouts; and more.	Health Care Providers	http://www.PainKnowledge.org
	Substance Abuse and Mental Health Services Administration (SAMHSA)	Information on programs and publications for improving the quality and availability of substance abuse prevention, alcohol and drug addiction treatment, and mental health services. Includes information on the CAGE-AID screening tool.	Health Care Professionals	http://www.samhsa.gov

^{*} Available to ICSI members only.