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Health Care Guideline

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- 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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Assessment Algorithm

A = Annotation

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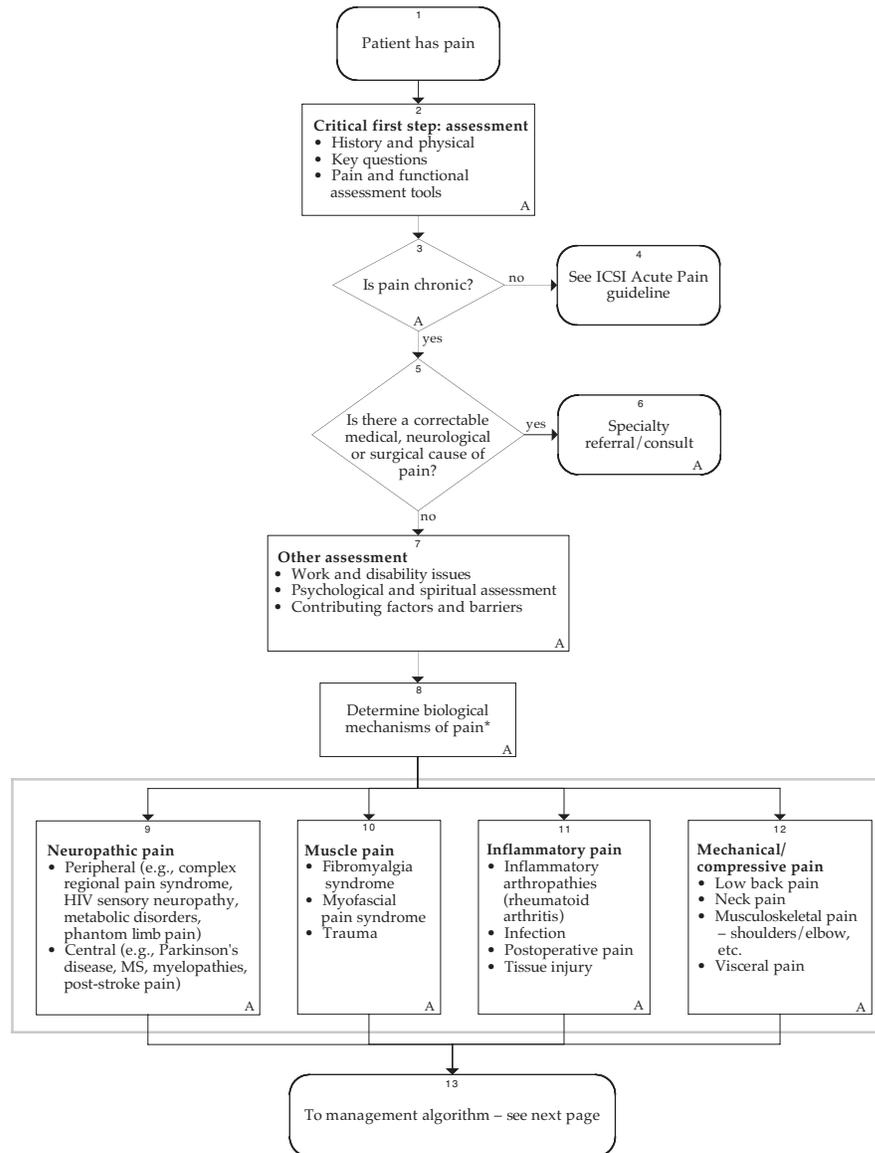
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These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.



* Pain types and contributing factors are not mutually exclusive. Patients frequently do have more than one type of pain, as well as overlapping contributing factors.

Management Algorithm

A = Annotation

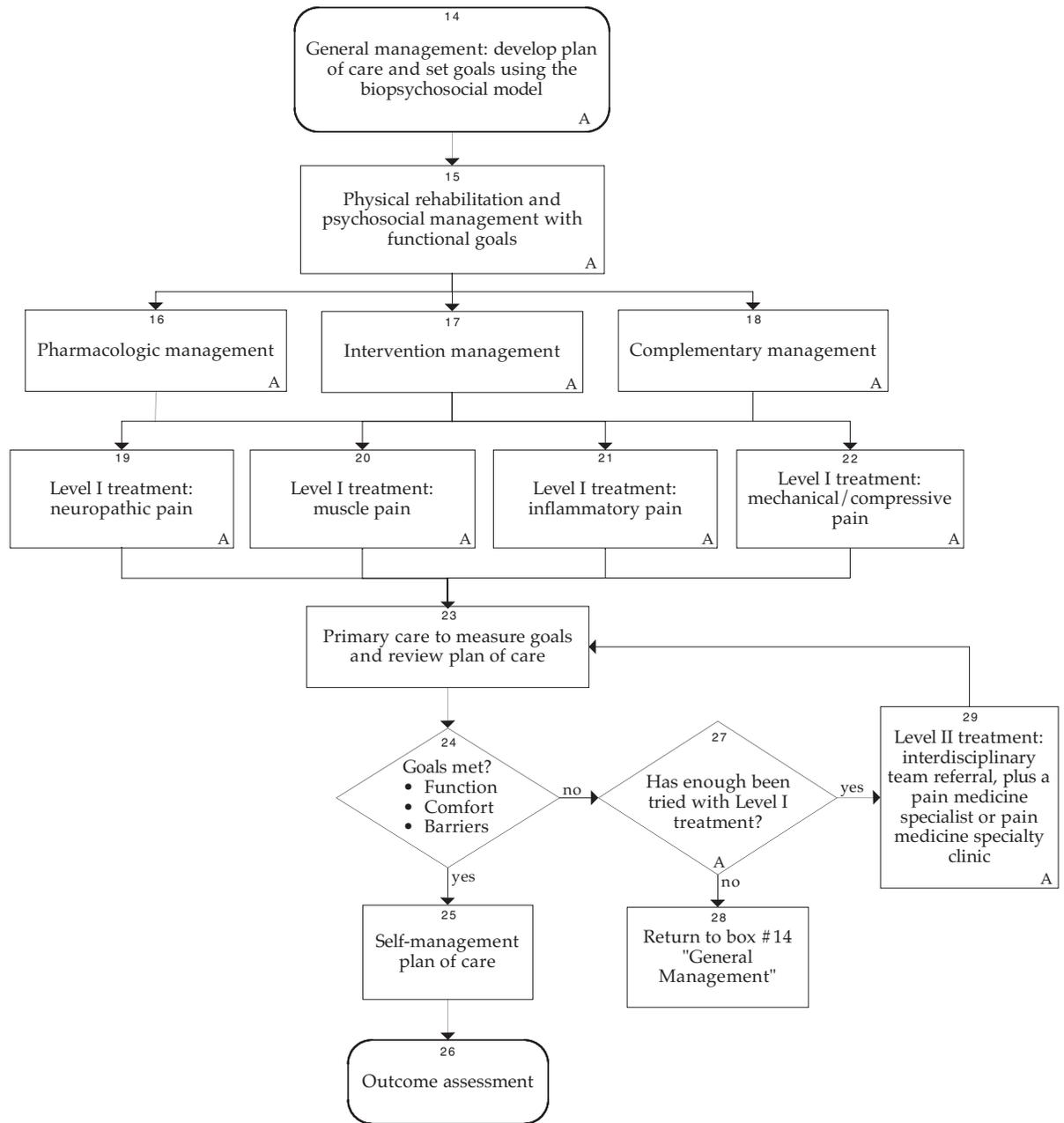


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Foreword

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 (The Management of Pain, Bonica). 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). This is not time dependent, however at 6 weeks (or longer than the anticipated healing time) patients should be thoroughly evaluated for the presence of chronic pain. At the end of the spectrum of chronic pain, is **Chronic Pain Syndrome** – the work group defines this as a constellation of behaviors related to persistent pain that represents significant life role disruption.

Clinical Highlights and Recommendations

1. Chronic pain is separate from acute pain and is a difficult clinical problem to treat. (*Annotations #2, 7*)
2. Chronic pain is a persistent, life-altering condition. The target is management not elimination. (*Annotation #14*)
3. A patient-centered, multi-factorial, comprehensive management plan is necessary, 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. (*Annotations #14, 15*)
4. The goals of treatment are an emphasis on improving function through the development of long-term, self-management skills including fitness and a healthy lifestyle. (*Annotations #14, 15*)

Priority Aims

1. Improve the treatment of patients with chronic pain by completing an appropriate biopsychosocial assessment.
2. Improve the function of patients with chronic pain by developing and using a comprehensive treatment plan that includes a multi-specialty team approach.
3. Improve the effective use of medications in the treatment of patients with chronic pain.
4. Ensure the appropriate use of interventional techniques as per guideline and technology assessment reports in the treatment of chronic pain.

Related ICSI Scientific Documents

Other ICSI guidelines whose scope and/or recommendations are closely related to the content of this guideline are:

1. Assessment and Management of Acute Pain
2. Adult Low Back Pain
3. Diagnosis and Treatment of Headache
4. Diagnosis and Treatment of Adult Degenerative Joint Disease (DJD) of the Knee
5. Major Depression in Adults in Primary Care

Technology Assessment Reports related to the content of this guideline are:

1. Acupuncture for Chronic Osteoarthritis Pain, Headache and Low Back Pain (#36, 2000)
2. Intradiscal Electrothermal Therapy (IDET) for Low Back Pain (#62, 2002)
3. Intrathecal Baclofen Infusion for Controlling Spasticity and Spasm (#19, 1994)
4. Fluoroscopically Guided Transforaminal Epidural Steroid Injections for Lumbar Radicular Pain (#85, 2004)
5. Percutaneous Radiofrequency Ablation for Neck and Back Pain (#88, 2005)
6. Extracorporeal Shock Wave Therapy for Plantar Fasciitis (#86, 2004)

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.

Key conclusions are assigned a conclusion grade: I, II, III, or Grade Not Assignable.

A full explanation of these designators is found in the Supporting Evidence section of the guideline.

Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

John Mullen, PhD., LP, received honoraria and travel support from Purdue Pharma.

Miles Belgrade, MD, has significant financial interest in Johnson & Johnson, is a consultant for Purdue Pharma, is a member of a scientific advisory board for Select Comfort, receives grant support from Janssen, received travel support from Pfizer, Janssen, Purdue Pharma, Select Comfort, and Elan, and is a member of the speaker's bureau for Pfizer, Purdue Pharma, Janssen, and Elan.

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

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at <http://www.icsi.org>.

Algorithm Annotations

Assessment Algorithm

2. Critical First Step: Assessment

Key Points:

- Joint Commission requires that 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.

Joint Commission requires that 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 are also helpful.

It is essential also to elicit any history of depression or other psychopathology that may affect the perception of pain. Past or current physical, sexual, emotional abuse is also an important factor. A history of chemical dependency is of interest in this patient population. The C.A.G.E. questionnaire is a useful tool for brief screening of the patient in regard to this issue.

CAGE Questionnaire

C - Have you ever felt you should **CUT** down on your drinking?

A - Have people ever **ANNOYED** you by criticizing your drinking?

G - Have you ever felt bad or **GUILTY** about your drinking?

E - Have you ever had a drink in the morning to steady your nerves or to get rid of a hangover (**EYE-OPENER**)?

Item responses on the CAGE are scored 0 or 1, with a higher score an indication of alcohol problems. A total score of 2 or greater is considered clinically significant.

Source: National Institute on Alcohol Abuse and Alcoholism

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.

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 chronic pain patients 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 cases of suspected complex regional 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 although PET scanning shows promise for establishing whether or not a patient is experiencing pain. It is important to remember that finding pathology does not necessarily prove that the identified pathology is causing the patient's pain. Nevertheless, diagnostic testing is useful in chronic pain patients 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). Dynamic x-rays of the spine are helpful in ruling out significant segmental instability.

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

Algorithm Annotations

anesthesiologic intervention is contemplated for the pain. CT and CT myelography are useful in patients who can not 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.

(VA/DoD, 2003; Wisconsin Medical Society, 2004; Carragee, 2005; Dworkin, 2003a; Schultz, 2004; Rasmussen, 2004; Zautra, 2005; Rommel, 2004)

Supporting evidence is of classes: B, C, D, 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
- 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.
- Address location, quality, sensory characteristics, intensity, duration, aggravating and alleviating factors, variability and predictability.
- Be used early in the process of patient evaluation.

Table 1. Assessment Tools for Adults

Multidimensional Tools

Scale	Administration	Validated in	Comments
Brief Pain Inventory (BPI)	written	cancer, arthritis English, Italian, Japanese	Assess location, intensity, and pattern. Reports meds, pain relief, patient beliefs, and interference in quality of life.
Chronic Pain Grade (CPG)	verbal	changes in chronic pain over time	Valid, reliable, easy to use, relevant to primary care setting.
Neuropathic Pain Scale (NPPS)	verbal	early study shows discriminative and predictive validity	Specifically addresses neuropathic pain qualities.
Body Outline Marking	written/drawn	Children ages 4-7	Useful in identifying patient's perception of pain location. May be drawn in color to represent pain intensity.

See Annotation Appendix H, "Brief Pain Inventory (Short Form)"

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Single Dimensional Tools

Scale	Administration	Validated in	Comments
Visual Analog Scale (VAS)	visual	chronic pain, rheumatic disease in children > 5	Poor reproducibility with cognitive dysfunction, post-op 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 Handbook of Pain Assessment. 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 are non-English speaking
- Use of a language interpreter

General approach:

- Allow sufficient time for the assessment.
- Give 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)
 - Rely on behavioral or objective indicators of pain (e.g., vital signs) only when no suitable alternative exists.

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.

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- Use specific tools such as the Neuropathic Pain Scale (NPPS) when appropriate.
- Avoid the use of single dimension pain assessment tools in chronic pain except to rate the intensity of specific pain episodes.

(Saverda, 1989; Van Cleve, 1993; National Pharmaceutical Council/JCAHO, 2001; Kaiser Permanente Medical Care Program, 2004; McCaffery, 1999; Herr, 2004; Daut, 1983; Cleeland, 1994; American Pain Society, 2005; Galer, 1997; Penny, 1998; Elliott, 2000; Smith, 1997)

Supporting evidence is of classes: C, R

3. 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, 2004*). This is not time dependent, however at 6 weeks (or longer than the anticipated healing time) patients should be thoroughly evaluated for the presence of chronic pain.

Supporting evidence is of class: R

6. Specialty Referral/Consult

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

It is important for physicians to distinguish between a consultation and a referral.

Consultation: An evaluation of a patient with recommended treatment options with the patient then returning to primary care physician for recommendation implementation.

Referral: Patient is being sent to a specialist for not only evaluation, but for on-going care with little or no long term involvement by the primary care (referring) physician.

7. 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 have 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.

Algorithm Annotations

- Palliative Performance Scale (Karnofsky Scale)
- Oswestry Low Back Disability Index
- 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.

Use of the ICSI Functional Ability Questionnaire (see Annotation Appendix A) has been designed for the following purposes:

- Self-assessment by the patient
- Observer assessment by family members or health care workers
- Short completion time (1-2 minutes for 5 multiple choice questions)
- Simple scoring (between 25 and 100), suitable for Electronic Medical Records
- Use at baseline and for periodic reassessment
- Use for establishing patient-specific functional goals within a care plan
- Use to measure the effectiveness of the care plan or treatment interventions

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

Algorithm Annotations

- PHQ-9: operationalized DSM criteria for Major Depression (See Appendix K, "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/re-injury, 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
- C.A.G.E. questions provide evidence of problematic use patterns (See Annotation #2)
- Substance use history needs to be considered in the decision to prescribe medication

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 explained and unexplained, in adulthood (*Arnou, 2004*).
- However, the specific relationship between childhood abuse and the development of chronic pain in adulthood is under question (*Raphael, 2004*). 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.

Supporting evidence is of class: R

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 their healing was a direct result of divine intervention (*Boudreaux, 2002*).

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, de-conditioning, 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 which 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; Williams, 1998*). 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 ICSI's Low Back Pain Guideline, Appendix B, "Psychosocial Screening and Assessment Tools."

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:

1. Are you currently working?
2. Do you enjoy your job and get along with your supervisor?
3. Do you engage in physical activity?
4. Do you have a support system of people that you can count on for help?
5. Do you have trouble sleeping?
6. Do you feel depressed?
7. Do you have decreased interest or pleasure in usual activities?
8. Do you have a history of mental health or psychiatric diagnosis or treatment?
9. Do you have a history of physical, psychological or sexual abuse?
10. Do you have a history of problems with alcohol or other drugs?
11. Do you have legal representation or other legal issues or problems?

The questions address several areas:

- Work: #1 work status, #2 Work APGAR (see ICSI Adult Low Back Pain Guideline)
- Locus of control/belief system compatible with rehabilitation: #3 exercise program
- Support system: #4
- Depression: #5-7
- Poor prognosticators: #8-11

How to use

Optimal responses are:

1-4: Yes

5-11: No

Risk Stratification for Poor Prognosis:

Number of Total Optimal Responses

8-11 Low Risk - continue primary care management

4-7 Moderate Risk - seek consultation with basic treatment team (MD, PT, Behavioral Health)

0-3 High Risk - consider referral to multidisciplinary chronic pain center

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 execu-

Algorithm Annotations

tion of a treatment such as language barrier, comorbid chemical dependency, financial, legal, low motivation, long distance from pain management services, etc. 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 2: Common Barriers

<p>Biological Comorbid disease Multiple allergies Conflicting therapies</p>	<p>Knowledge Deficit Lack of diagnosis Misinformation - e.g., from the internet Patient expectations</p>	<p>Health Care Provider/System Health care provider knowledge, training, inexperience in chronic illness Disease focus rather than patient focus Time constraints</p>
<p>Behavioral Passive patient Low motivation Unrealistic expectations Poor compliance Chemical dependency Poor communication</p>	<p>Social Language barrier Cultural barrier Health system obstacles Time constraints Lack of social support Regulatory fears Financial</p>	<p>Insurance Systems Formulary restrictions Coverage restrictions Behavioral health carve-out systems Health care provider reimbursement</p>

8. Determine Biological Mechanisms of Pain

Pain can be divided into four basic mechanisms or types:

- inflammatory
- mechanical/compressive
- neuropathic
- muscle dysfunction

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 NSAIDs, Tylenol 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.

(Chen, 2004; Dickenson, 1995; Koltzenburg, 2000)

Supporting evidence is of class: R

9. Neuropathic Pain

Neuropathic pain is pain produced by damage or dysfunction of the nervous system. Examples include sciatica from nerve root compression, diabetic peripheral neuropathy, trigeminal neuralgia, and postherpetic neuralgia. The clinical features are: the 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 post stroke 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).

10. Muscle Pain

Skeletal muscle pain is a common cause of chronic pain. Fibromyalgia syndrome and Myofascial Pain Syndrome are frequent diagnoses in pain clinics. Failure to properly diagnose muscle pain may result in poor treatment outcome, delayed recovery, and ineffective, unnecessary surgery.

Fibromyalgia syndrome and Myofascial pain syndrome both result in sore, stiff, aching, painful muscles and soft tissues. Both syndromes share other symptoms including fatigue, poor sleep, depression, headaches and irritable bowel syndrome. Occasional acute muscle pain is probably universal. Chronic muscle pain is extremely common. Most 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.

Fibromyalgia syndrome is characterized by widespread musculoskeletal aching, stiffness and tenderness. 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 3 months
- other symptoms are chronic but not diagnostic including insomnia, depression, stress, fatigue, irritable bowel syndrome

(Wolfe, 1990)

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.

Supporting evidence is of class: C

11. Inflammatory Pain

Inflammatory pain such as arthritis, infection, tissue injury and postoperative pain is also known as *nociceptive pain* because the inflammatory chemicals like 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.

12. 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*).

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.

Supporting evidence is of class: R

Management Algorithm

14. General Management: Develop Plan of Care and Set Goals Using the Biopsychosocial Model

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 their complexity, including physical and biologic factors, psychological state and beliefs, as well as the family, social and work environment (biopsychosocial model). To do this, it is important to have a multi-disciplinary 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 5 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 Annotation Appendix B, "Personal Care Plan for Chronic Pain."

"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 indicates that it appears that limited education is done early on and patients do a lot of research on their own. Education is critical by means of 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 self responsibility for their care.

Other Patient Focus Group key points include:

- 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.

Algorithm Annotations

- 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 is 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 complimentary 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 chronic pain patients who have failed more conservative treatment options. Level II treatments are designed for the most complex and challenging chronic pain patients. The treatment options included in Level II are expensive and require a significant investment on the part of the patient to be effective.

15. Physical Rehabilitation and Psychosocial Management with Functional Goals

Key Points:

- 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.
- 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 active patient participation in the care plan is essential.

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 monitor progress
- Use a Functional Activities of Daily Living tool (i.e., "Functional Ability Questionnaire" Annotation Appendix A) to document pain related disability (inability to function in normal manner) and monitor progress (*Kaiser Permanente Medical Care Program, 2004*).
- Determine baseline fitness, then set specific fitness goals with a gradual graded fitness program (*Lindstrom, 1992*).

Physical rehabilitation is essential for the patient with chronic pain as 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
- psychosocial management (i.e., 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*).

Fitness includes :

- endurance activities (aerobic - i.e., walking)
- strengthening
- balance activities
- 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; van Tulder, 1997*).

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*).

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*).

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

Encouraging activity (recreational as well as formal exercise) has been recommended (*Abenheim, 2000*).

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*).

Algorithm Annotations

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*).

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

Biopsychosocial rehabilitation with functional restoration reduces pain and improves function. Psychosocial rehabilitation includes strategies for managing chronic pain. This includes treatment of depression, stress, anxiety, anger, fear, avoidance, sleep disturbance, and chemical dependency. Relaxation techniques may be helpful (*Guzman, 2001*).

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. A cognitive behavioral approach with functional restoration may reduce pain and will improve function. Self management active patient participation in the care plan is essential.

Supporting evidence is of classes: A, M, R

Psychosocial Management

Chronic pain is frequently associated with psychological problems and even co-morbid 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 chronic pain patients were four times more likely to have comorbid depressive disorder than pain-free primary care patients (*Lepine, 2004*). The findings also showed that the more diffuse the pain complaints, the greater the risk of depression and the bigger impact on the 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; Magni, 1998*). Specifically assess if patient has considered harming him/herself or made plans to kill themselves. 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 #7, "Other Assessment" and Annotation #16, "Pharmacologic 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 is 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.

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.

Supporting evidence is of classes: C, D, R

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 many 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*).

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*).

Supporting evidence is of class: R

Cognitive-Behavioral Strategies for Primary Care Physicians

- 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*).
- 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.
- 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.
- 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 then are 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 well behaviors such as increased activity or participation in an exercise program.
- Enlist the family and other supports to reinforce gains made towards 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 step-wise 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 chronic pain patients. 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 chronic pain patients 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*). If patient's fears are excessive, relaxation strategies may be helpful or referral for more formal and intensive cognitive-behavioral therapy.

Supporting evidence is of classes: A, D

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 chronic pain patient's 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 which are not ordinarily under voluntary control or responses which 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.

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-great improvement in pain states four years after completing the MBSR program (*Kabat-Zinn, 1986*). One study demonstrated significant improvement with fibromyalgia patients utilizing mindfulness meditation and yoga (*Kaplan, 1993*).

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 referred, is a deceptively simple strategy that is easily under the patient's control. The goal is to teach patients correct diaphragmatic

Algorithm Annotations

breathing which incorporates both slowed breathing (5-8 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.

Progressive 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 1700's (*Stewart, 2005*). Hypnosis is believed to involve both muscle relaxation and perceptual alteration. All hypnotic techniques share 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.

Supporting evidence is of classes: D, R

Cognitive Techniques

Cognitive therapy techniques are based on the notion that a person's cognitions or how they think about themselves, 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 chronic pain patients 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 which 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.

Supporting evidence is of class: M

Evidence

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 (Guzman, 2005; Morley, 1999).

Biofeedback has been found to be effective in headache management, temporomandibular disorders, and other recurrent pain conditions (Crider, 1999; Haddock, 1997; National Institutes of Health, 1996). Other forms of relaxation therapy have found to be effective in these patient populations as well. Hypnosis has been found to be effective in patients with chronic pain and compared favorable to alternative treatment procedures (Montgomery, 2000).

Supporting evidence is of class: M

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 healthcare utilization, access, and attitudes have shown a variation amongst 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 subsequent 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 chronic pain patients, 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).

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 spirituality 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).

Supporting evidence is of class: R

16. 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 regardless of 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*).
 - The work group recommends the use of a written opioid agreement for patients anticipated to be on long-term therapy. See Annotation Appendix C for an example of an opioid agreement form.

Medications are often a critical component of a pain management plan. 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 towards pain relief, but 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, 2004*)

- 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 Annotation Appendix D, "Glossary of Terms."
- Define the goals of therapy before prescribing and tailor medications to meet the individual goals of each patient.

Algorithm Annotations

- 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 #19-22.
 - 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 regardless of prescribed or non-prescribed, all drugs have risks and benefits. Watch for and manage side effects. See Annotation Appendix E, "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, generally oral.
 - Patient factors (age, co-existing diseases, other medications, and response to previous treatments).
- Establish a pain management plan which 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 which 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 prn doses for break-through 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.

Supporting evidence is of class: R

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*). 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.

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 have 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*).

- 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.
- Chronic NSAID use increases the risk of renal insufficiency, especially those with diabetes, and patients should be monitored for signs of reduced renal function.
- Ketorolac should not be used for longer than 5 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.

See Annotation Appendix F, "Non-Opioid Analgesics."

Supporting evidence is of class: R

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 first-line therapies (TCA's 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 guideline, "Diagnosis and Treatment of Headache").
- 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.

Physicians should not feel compelled to prescribe opioids or any drug if it is against their honest judgement or if they feel uncomfortable prescribing the drug.

Algorithm Annotations

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*).

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*).

At each patient visit, the assessment should specifically address these goals (with clear documentation of the 4 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

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*):

- history of substance abuse or prior prescription drug misuse
- unsanctioned dose escalations on several occasions
- nonadherence 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 re-injury 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. (3) To test for the presence of the prescribed drug. Any evidence of street drug use indicates noncompliance 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 – Appendix A – Annotation #16 (Chronic Pain and Chemical Use)*]

When there is noncompliance or escalation of opioid use, consider whether this represents a response to inadequate pain control (pseudoaddiction, tolerance) or a behavioral problem indicating the patient is not a candidate for opioid therapy.

Supporting evidence is of classes: D, R

Table 3: Considerations for Initiating and Discontinuing Opioid Therapy

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 fails

This information was originally published in *Pain Research & Management* 2003;8:189-94.

Opioids have demonstrated efficacy in the management of both nociceptive and neuropathic chronic pain (*Mystakidou, 2003; Ytterberg, 1998*). 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. 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. There is no ceiling dose for most opioids, and doses should be increased 25-50% for moderate pain and 50% for more severe pain (*Wisconsin Medical Society, 2004*).

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*). 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.

Supporting evidence is of classes: C, D, R

Specific Opioid Characteristics

- Codeine often has dose limiting GI side effects and is therefore not a good choice for chronic use. It also is not metabolized to its active form morphine by 10% of Caucasians and therefore does not provide analgesia in this patient population.
- 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. Patients should have alternative analgesics for initial pain control until fentanyl reaches steady state levels.
- Hydrocodone is only available in combination with acetaminophen and doses should be monitored not to exceed 4 grams acetaminophen per day.
- Hydromorphone is available in rapid release oral and injectable dosage forms.
- Meperidine is metabolized to an active metabolite nor-meperidine 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. MS Contin and Oramorph release products last 8-12 hours and Kadian and Avinza 12-24 hours.
- Methadone has a long half-life, initially 12-16 hours but may be 90-120 hours after one week of therapy. Methadone is an exception due to its long half-life and doses should only be increased every 10-14 days. It should be used cautiously in elderly or medically compromised patients.
- Oxycodone is available in short acting and long acting dosage forms. Generic oxycodone sustained release tablets are routinely dosed every 12 hours.
- 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 SSRI's.

See Annotation Appendix G, "Opioid Analgesics."

Tricyclic antidepressants (TCA's)

Tricyclic antidepressants are the preferred initial therapy for neuropathic pain, especially if the patient has co-existing insomnia, anxiety, or depression (*McQuay, 1996; Sindrup, 1999; Collins, 2000; Sindrup, 2000*). TCA's 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 TCA's are independent of their antidepressant effect and analgesia may be seen with lower doses.

Algorithm Annotations

- Start low and increase doses gradually over several weeks to months. Maximum analgesic effect may take 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 TCA's including heart disease, symptomatic prostatic hypertrophy, neurogenic bladder, dementia and narrow-angle glaucoma.

See Annotation Appendix I, "Antidepressants and Antiepileptic Drugs Used in Chronic Pain Syndrome."

Supporting evidence is of class: M

Other (Non-Tricyclic) Antidepressants

The selective serotonin reuptake inhibitor class of antidepressants have reduced adverse effects compared with TCA's but efficacy in the treatment of neuropathic pain is generally not as good as that shown with TCA's. Bupropion (*Semenchuk, 2001*), venlafaxine (*Sindrup, 2003*), and duloxetine (*Arnold, 2004*) have also shown efficacy in the treatment of neuropathic pain. These drugs can be recommended for patients that do not have adequate response or can not tolerate TCA's. Duloxetine in doses of 60 mg twice a day has been shown to improve pain and global measures of fibromyalgia, compared with placebo (*Arnold, 2004*).

Supporting evidence is of class: A

Anticonvulsant or Antiepileptic Drugs

The first generation anticonvulsants carbamazepine 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*).

The second generation agent Gabapentin is approved for the treatment of post-herpetic neuralgia, but has been shown to have analgesic effects in many cases of neuropathic pain syndromes (*Backonja, 1998; Rowbotham, 1998; Rice, 2001; Serpell, 2002; Bone, 2002; Pandey, 2002; Tai, 2002*). To decrease the incidence of adverse effects, which are primarily somnolence and dizziness, start at low doses and titrate up gradually. An initial dose of 300 mg daily can be increased by 100-300 mg every 3 days, up to target doses of 1,800 to a maximum of 3,600 mg daily, taken in 3 divided doses.

Lamotrigine (Lamictal) has efficacy in trigeminal neuralgia, neuropathies associated with human immunodeficiency virus infection, and post-stroke pain.

Supporting evidence is of classes: A, M

Topical Agents

Topical lidocaine 5% patches (Lidoderm) are FDA approved for post-herpetic 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 a dosage schedule of 12 hours on, 12 hours off.

Capsaicin used topically depletes 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 6 weeks to see full benefits. The side effect of local burning is common and most patients become tolerant after a few days.

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

Algorithm Annotations

benzodiazepines and Carisoprodol (Soma) are centrally acting and carry the risk of physical dependence. They are more beneficial for acute short term use and are not recommended for chronic use.

Zanaflex (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.

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.

SSRI's, selective serotonin reuptake inhibitors, 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.

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 the preferred initial therapy for neuropathic pain, especially if the patient has co-existing insomnia, anxiety, or depression (*McQuay, 1996; Sindrup, 1999; Collins, 2000; Sindrup, 2000*). 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.

Supporting evidence is of class: M

17. Intervention Management

Key Points:

- 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.
- Therapeutic procedures are used to alleviate or reduce pain and should be used in conjunction with a comprehensive treatment plan.

Interventional techniques refer to procedures 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.

See also Annotation #29, "Level II Treatment: 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, as referred to as selective nerve root injections, can be used to determine the spinal level which is the source of radicular pain. The diagnostic information from this procedure can have clinical utility when persistent radicular pain is not explained by history, physical examination or imaging studies (*Institute for Clinical Systems Improvement, 2004*).

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 diagnose disk herniation. Discography is strictly a diagnostic procedure and there are no direct therapeutic benefits (*Bogduk, 1996; Walsh, 1996*).

Supporting evidence is of classes: C, R

Level I Therapeutic Procedures

Therapeutic procedures are used to alleviate or reduce pain and should be used in conjunction with a comprehensive treatment plan. 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 periarticular or intraarticular 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*).

Percutaneous Radiofrequency Neurotomy

Percutaneous radiofrequency (RF) neurotomy is a treatment for spinal pain stemming from the facet joints. This procedure is generally reserved for treatment of cervical and lumbar facet joint pain. Potential candidates for this procedure are patients who experience relief of pain following fluoroscopically guided nerve blocks of the medial branch of the dorsal ramus. This particular nerve provides innervation to the facet joints. The RF procedure is performed by placing an insulated needle electrode with an exposed tip adjacent to the medial branch nerve. A radiofrequency current applied to the electrode then heats the adjacent tissues and coagulates the nerve supply to the joint. Radiofrequency neurotomy has been a previous topic of an ICSI Technology Assessment Report where minimal evidence was found to support the efficacy of the procedure (*Institute for Clinical Systems Improvement, 2005*).

Intradiscal Electrothermal Therapy

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*). 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 annulus. 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. Intradiscal electrothermal therapy has been the topic of a previous ICSI Technology Assessment where minimal scientific evidence was found to support the efficacy of the procedure (*Institute for Clinical Systems Improvement, 2002*). More recently, a randomized placebo-controlled trial of IDET demonstrated modest improvements in pain intensity and function. However, serious methodological shortcomings, including failure to conduct intention-to-treat analyses in conjunction and an excessive dropout rate, limits the validity of the findings.

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. Epidural corticosteroid injections have been a previous topic of an ICSI Technology Assessment Report where limited evidence was found to support the efficacy of this procedure (*Riew, 2000; Carette, 1997; Dilke, 1973; Institute for Clinical Systems Improvement, 2004*).

Vertebroplasty and Kyphoplasty

Vertebroplasty and kyphoplasty are percutaneous procedures used to treat vertebral compression fractures. These procedures have been a previous topic of an ICSI Technology Assessment Report (*Institute for Clinical Systems Improvement, 2003*).

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. Evidence is limited regarding the efficacy of these procedures.

Supporting evidence is of classes: A, M, R

18. Complementary Management

Acupuncture

Clinical research with randomized, placebo-controlled trials supports the use of acupuncture for certain chronic pain conditions such as headache, back pain, neck pain, and osteoarthritis of the knee.

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. 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. Basic scientific research has begun to elucidate the mechanisms of acupuncture analgesia including the role of endorphins, serotonin and other neurochemicals.

(Eisenberg, 1998; National Institutes of Health, 1997; ICSI, 2000; Mayer, 1977; Vincent, 1989; Tavola, 1992; Berman, 1999; Vas, 2004; White, 2004; Wonderling, 2004; Vickers, 2004; Meng, 2003)

Supporting evidence is of classes: A, C, M, R

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

19. Level I Treatment: Neuropathic pain

(Modified from: Belgrade MJ: Radicular limb pain (book chapter). In: Neurological Therapeutics: Principles and Practice. J. H. Noseworthy (editor-in-chief). Mayo Foundation for Medical Education and Research/ Martin Dunitz- publisher 2003; pp. 178-92.)

The first principle guiding any therapy is to eliminate the underlying causes of pain to the greatest possible extent with disease-specific measures. 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. See Annotatoin Appendix J, "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 deplete substance P from local C-polymodal nociceptors and reduce pathological pain. It has been studied in diabetic neuropathy (*The Capsaicin Study Group, 1991*) and postherpetic neuralgia (*Fusco, 1997*). 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*). 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.

Spinal stimulation techniques are being used with increasing frequency. The best evidence, which remains limited to prospective and retrospective case series, is the use of these procedures in cases of unilateral radicular limb pain (*Kumar, 1998*). Compared with surgical approaches to the management of radicular pain caused by spondylosis and intervertebral disc disease, spinal stimulation appears promising. Advantages are that spinal stimulation is reversible and less invasive than most surgical procedures and that the parameters of treatment can be adjusted after the procedure. These procedures, however, are not first-line therapies for radicular limb pain. They are costly and require life-long maintenance, and evidence for efficacy relies mainly on case series.

Supporting evidence is of classes: A, D, R

Drug Therapies for Neuropathic Pain

See also Annotation #16, "Pharmacologic Management."

Among the many drugs used to manage neuropathic pain, gabapentin has growing acceptance among pain specialists and neurologists as a first-choice treatment. Gabapentin has recently proved effective in postherpetic neuralgia and diabetic neuropathy in multicenter controlled trials (*Rowbotham, 1998; Backonja, 1998*). Its 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 is reduced in patients with renal insufficiency.

Other anticonvulsants have been utilized in neuropathic pain with variable success. Carbamazepine is still considered first-line therapy 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*). 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*), painful HIV-associated neuropathy (*Simpson, 2000*), and complex regional pain syndrome type I (*McCleane, 2000*). Pregabalin, a neuromodulator like gabapentin that regulates the alpha-2delta subunit of the voltage-gated calcium channels, has been available in Europe and at the time of this writing is due to be launched in the United States. It has been shown to be effective in postherpetic neuralgia and diabetic peripheral neuropathy in randomized controlled multicenter trials (*Dworkin, 2003b; Lesser, 2004*).

Tricyclic antidepressants (amitriptyline, nortriptyline, desipramine, imipramine, and others) continue to hold a prominent 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; Max, 1988*). 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.

Pharmacological agents from other classes have also been shown to be effective for neuropathic pain. Mexiletine, an antiarrhythmic drug, blocks voltage-sensitive sodium channels, an effect similar to that of lidocaine. Mexiletine has been shown to be effective in the management of painful diabetic neuropathy (*Oskarsson, 1997; Wright, 1997*), but dose-limiting side effects such as dizziness and gastrointestinal discomfort often prevent continued therapy. Clonazepam, a benzodiazepine, may be useful in nocturnally predominant pain.

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 exert antineuropathic pain effects, 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. Methadone possesses inhibitory properties at the N-methyl D-aspartate (NMDA) receptor in the spinal cord. The NMDA receptor is involved in central sensitization, wind-up, 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.

Supporting evidence is of classes: A, D

20. Level I Treatment: 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.

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

Behavioral Management

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

Drug Therapy

- * pain and sleep
 - tricyclic antidepressants (nortriptyline low dose)
 - cyclobenzaprine (short term)
- * depression and pain
 - Duloxetine
- * **opioids rarely needed**
(Rome, 2004)

Pharmacotherapy

- 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
- Duloxetine in a dosage of 60 mg twice daily helps reduce pain in fibromyalgia

Algorithm Annotations

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

- Determine patients 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 the Functional Ability Questionnaire (see Annotation Appendix A).

21. Level I Treatment: 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.

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 (short term)
- * depression and pain
 - Duloxetine
- * **opioids rarely needed** (Rome, 2004)
- * NSAIDs
- * immunologic drugs
- * other antidepressants

Pharmacotherapy is not within the scope of this guideline. Consider referral to a specialist.

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.

Algorithm Annotations

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

Teach self management and measure outcome using pain rating and the Functional Ability Questionnaire (See Annotation Appendix A).

22. Level I Treatment: 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 (*Wisconsin Medical Journal, 2004; Kaiser Permanente Medical Care Program, 2004*).

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*)

Use a biopsychosocial team approach:

Physical Rehabilitation

- * graded fitness program
 - 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

Drug Therapy

- * pain and sleep
 - tricyclic antidepressants
 - nortriptyline low dose
- * antidepressants
- * depression and pain
- * **opioids rarely needed**
(*Rome, 2004*)
- * NSAIDs

Pharmacotherapy

- Short term use of 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-serotonergic 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.

Algorithm Annotations

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*).
- Cognitive-behavioral interventions encouraging activity and fitness work best for patients with chronic pain and are recommended (*Kaiser Permanente Medical Care Program, 2004*).
- 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 have limited scientific evidence (*Kaiser Permanente Medical Care Program, 2004*).
- Surgery for non-specific chronic low back 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*). See the ICSI Adult Low Back Pain guidelines for appropriate guidelines for surgical referral including Cauda Equina syndrome and progressive or significant neurological findings.
- Surgery for cervical radiculopathy and myelopathy lacks scientific evidence and surgery should be considered for carefully selected patients only (*Fouyas, 2001*).
- After surgery, the patient with chronic pain is best managed by an interdisciplinary team using a biopsychological social approach (*Wisconsin Medical Journal 2004*).

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 the Functional Ability Questionnaire (See Annotation Appendix A).

Supporting evidence is of classes: C, R

Osteopathic Manipulative Therapy and Chronic Pain

Studies of spinal manipulation for chronic pain have been shown to be inconclusive; but it has shown that the osteopathic manipulative therapy, including range of motion activities and time spent interacting with the patients, may have improved the pain and function of the patients suffering from the chronic pain (*Gamber, 2002; Licciardone, 2004; Knebl, 2002; Licciardone, 2003*).

Supporting evidence is of classes: A, R

27. Has Enough Been Tried with Level I Treatment?

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
- 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 multi-disciplinary 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.

29. Level II Treatment: 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 and surgery is 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 treatment (see above annotations #14-29), 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.

Level II interdisciplinary chronic pain team assessment should be obtained in a timely manner, sometimes as early as 4 to 8 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).

Algorithm Annotations

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; Gibson, 1999*).

- 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 Journal, 2004*). 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 Journal, 2004*). 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*).

- Surgery for chronic pain is usually elective
 - Do a psychosocial screen before doing elective surgery (screen for personality disorder, 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*)
- Check for serious medical and surgical pathology before starting pain management program
- Focus on improving function not just pain (*Turk, 2004*)
- Surgery for chronic low back pain may benefit some patients," but nearly half will not benefit" (*Bogduk, 2004*).
- Neurosurgical techniques for chronic pain resistant to an adequate conservative approach hold promise, but have limited scientific evidence (*Giller, 2003*):
 - Ablative techniques include cordotomy, myelotomy, cingulotomy, and mesencephalotomy
 - Stimulation techniques include motor cortex stimulation, deep brain stimulation, spinal cord stimulation

Patients with chronic pain are best managed with an interdisciplinary team approach (*Wisconsin Medical Journal, 2004*).

- 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

Algorithm Annotations

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

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

Supporting evidence is of classes: C, M, R

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*).

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*).

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*).

Supporting evidence is of classes: M, R

Palliative Interventions

Palliative interventions are used when conventional and less invasive procedures have failed. Patients should have documented compliance with a comprehensive care plan and surgery is 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*). To date, only anecdotal data exists to support the efficacy of the procedure (*Cohen, 2005*).

Spinal Cord Stimulation

Spinal cord stimulation was initially used to treat refractory radicular spine pain. However, the indications for spinal stimulation have been expanded to include complex regional pain syndrome, ischemic pain related to peripheral vascular disease, and painful peripheral neuropathic conditions. The neurostimulation system consists of one or two electrode leads, an implantable pulse generator and an external programmer. The electrodes are placed percutaneously in the epidural space and positioned so that the electrical field produces a tingling sensation in the distribution of the patient's pain. Prior to implantation of the full system, patients undergo a 3- to 5-day trial period. During this phase of treatment, the end of the electrodes are externalized and the patient and physician determine if symptomatic response warrants full implantation of the neuromodulatory system. Long term, approximately 60% of patients report a 50% reduction in pain intensity (*Cameron, 2004*). However, to date, no randomized controlled trials have been conducted.

(*North, 1991; Van Buyten, 2001; Burchiel, 1996*)

Implantable Intrathecal Drug Delivery System

Spinal administration of opioid and non-opioid medication can be utilized in patients that have failed to achieve improvement following conventional treatment. There is no evidence supporting the long-term efficacy of this intervention for noncancer pain patients.

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 2 hours weekly and 8 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 (*Guzman, 2005; Karjalainen, 2005a*). However, the benefits of multidisciplinary treatment for other painful conditions have not been clearly demonstrated (*Karjalainen, 2001; Karjalainen, 2005b*).

Supporting evidence is of classes: D, M, R

Annotation Appendix A – Functional Ability Questionnaire

Name: _____
Date: _____
Date of Birth: _____
MR #: _____

Instructions: Circle the number (1-4) in each of the groups which 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 or social activities
2. Able to perform some
3. Able to perform many
4. Able to perform all

_____ **Get up and go 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# occasionally
2. Able to lift up to 20# occasionally
3. Able to lift 20-50# occasionally
4. Able to lift over 50# 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

_____ **Functional Ability Score**

Created by Peter Marshall, MD as a member of the ICSI Chronic Pain guideline work group.

Annotation Appendix B – Personal Care Plan for Chronic Pain

1. Set Personal Goals

- Improve ICSI Functional Ability Score by ____ points by: Date _____
- Return to specific activities, tasks, hobbies, sports... by: Date _____
 1. _____
 2. _____
 3. _____
- Return to limited work /or normal work by: Date _____

2. Improve Sleep (Goal: ____ hours per night, Current: ____ hours per night)

- Follow basic sleep plan
 1. Eliminate caffeine and naps, relaxation before bed, go to bed at target bed time _____
- Take nighttime medications
 1. _____
 2. _____
 3. _____

3. Increase Physical Activity

- Attend physical therapy (days per week _____)
- Complete daily stretching (____ times per day, for ____ minutes)
- Complete aerobic exercise/endurance exercise
 1. Walking (____ times per day, for ____ minutes) or pedometer (____ steps per day)
 2. Treadmill, bike, rower, elliptical trainer (____ times per week, for ____ minutes)
 3. Target heart rate goal with exercise _____ bpm
- Strengthening
 1. Elastic, hand weights, weight machines (____ minutes per day, ____ days per week)

4. Manage Stress - list main stressors _____

- Formal interventions (counseling or classes, support group or therapy group)
 1. _____Daily practice of relaxation techniques, meditation, yoga, creative / service activity ...
 1. _____
 2. _____
- Medications
 1. _____
 2. _____

5. Decrease Pain (best pain level in past week: ____ / 10, worst pain level in past week: ____ / 10)

- Non-medication treatments
 1. Ice / Heat _____
 2. _____
- Medication
 1. _____
 2. _____
 3. _____
 4. _____
- Other treatments _____

Physician name: _____ Date: _____

Created by Peter Marshall, MD as a member of the ICSI Chronic Pain guideline work group.

Annotation Appendix C – Opioid Agreement Form

Agreement on Opioid Therapy

I understand that Dr. _____ is prescribing opioid medication to assist me in managing chronic pain that has not responded to other treatments and must assist me to function better. If my activity level or general function gets worse, the medication will be changed or discontinued. The risks, side effects and benefits have been explained to me and I agree to the following conditions of opioid treatment. Failure to adhere to these conditions will result in discontinuing the medication.

1. I will participate in **other treatments** which _____ 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 your pharmacy. Plan ahead for mailed prescriptions, it will take at least five days for a prescription to reach your pharmacy after your phone call.

I authorize _____ physicians and/or staff to discuss my care and treatment while undergoing opioid therapy with my primary care/referring physician and any other medical facilities involved in my care.

Patient Name (print): _____ Patient Signature: _____

Date: _____

Source: Adapted with permission from Pain Management Center, Fairview Health Services 2005

Annotation Appendix D – Glossary of Terms

✓ **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.

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.

* **Pain:** An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

✓ **Physical Dependence:** Physical 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 Guidelines 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.

Annotation Appendix E – Side Effects

Drug Category	Side Effect	Management	Adult Dose	Pediatric Dose	Comments
Opioids	Nausea & vomiting	Prochlorperazine (Compazine)	5-10mg PO/IV/IM q4h or 25mg PR q12h	> 10kg: PO/PR 0.4mg/kg/day in 3-4 divided doses; IM 0.1-0.15mg/kg/dose (usual 0.13mg/kg/dose) 2-12 years: 0.01-0.06 mg/kg/dose q 4-6 h 20-75mcg/kg IV/IM max. dose 2.5 mg	Consider changing opioid (i.e., to hydromorphone)
		Droperidol (Inapsine)	0.625 to 2.5mg IV/IM q2-4hr	Not recommended in <3yo	
		Haloperidol (Haldol)	0.5mg PO/IV/IM q8h	3-12yo: 50-75mcg/kg/day in 2-3 divided doses	
		Metoclopramide (Reglan)	10-20mg PO /IV q6h	0.4-0.8mg/kg/day in 4 divided doses	
		Ondansetron (Zofran)	Ondansetron: 4mg IV	Ondansetron: 2-12yo: 0.1mg/kg up to 4mg dose	
		Dolasetron (Anzemet), Granisetron (Kytril)	Dolasetron: 12.5 IV Granisetron: 1 mg IV	Dolasetron: 2-16yo: 0.35mg/kg up to 12.5mg Granisetron: 40 mcg/kg up to 1 mg	
		Non-drug	toast/crackers, sherbet, pretzels, oatmeal, soft & bland fruits and vegetables		
		Senna/docusate (Senokot S)	Senna 1-2 tabs bid or higher; 1 senna tablet for each 10mg IV MS/day	1mo-1yo: 54.5-109mg qhs; 1-5yo: 109-218mg qhs; 5-15yo: 218-436mg qhs	
		Bisacodyl (Dulcolax)	10mg PO /PRqhs	Avoid in newborns; <2yo: 5 mg PO/PR; >2-11yo: 5-10mg PO/PR >11yo: 10mg PO/PR	
		Milk of Magnesia (MOM)	15-30ml PO qhs	<2yo: 0.5ml/kg/dose; 2-5yo: 5ml/day; 6-11yo: 15-30ml/day	
		Magnesium Citrate	150-300 ml PO qd	<6yo: 2-4ml/kg once or in divided doses; 6-12yo: 100-150ml; >12: 150-200ml	
		Lactulose (Cephulac)	15-30ml PO TID-QID	Infants: 1.7-16grams/day in 3-4 divided doses Older children: 40-90ml/day in divided doses	

Drug Category	Side Effect	Management	Adult Dose	Pediatric Dose	Comments	
Opioids (cont.)	Constipation (cont.)	Sorbitol	15-30ml PO TID-QID	No recommendations		
		Non-drug	good hydration; if po intake: prunes, prune juice, Smooth Move Tea (1 tea bag=2.5 senna tablets); mobility			
	Pruritus	Diphenhydramine (Benadryl)	20-50mg q6h around the clock if opioid continues, then prn	5mg/kg/day divided in 3-4 doses	Consider changing opioid (i.e., to hydromorphone)	
		Naloxone (Narcan)	50mcg/hr		For epidural and intrathecal morphine	
		Propofol	10mg IV, may repeat in 5 min.		For epidural and intrathecal morphine	
	Delirium	Appropriate management			Consider changing opioid (i.e., to hydromorphone)	
		Myoclonus	Clonazepam (Klonopin)	0.5mg PO BID-TID	0.01-0.03mg/kg/day divided in 2-3 doses	Switch to another opioid (i.e., to hydromorphone)
	Lorazepam (Ativan)		0.5-1mg PO /IV	0.02-0.05mg/kg/dose (max 2mg) q4-8hr		
	Respiratory Depression		Naloxone (Narcan)	Dilute 0.4mg (1ml) Naloxone with 9ml of normal saline (total volume 10ml). Administer 0.02mg (0.5ml) boluses every minute until the patient's respiratory rate increases. Repeat as necessary.	< 20kg: 0.1mg/kg/dose IV/IM/SC/ETT > 20kg or > 5yo: 2mg/dose	
				Limit dose of acetaminophen to ≤ 4grams/day; consider lower total daily dose in patients with pre-existing liver disease	Infants and children: limit dose to 75mg/kg/day	
Acetaminophen	Hepatotoxicity					
Corticosteroids	Hyperglycemia	Appropriate mgmt			May consider changing to NSAID	

Drug Category	Side Effect	Management	Adult Dose	Pediatric Dose	Comments
NSAIDs	GI upset	Misoprostil (Cytotec)	200µg PO BID-TID		Consider taking with food, using antacids, H ₂ blockers or proton pump inhibitors, or discontinuing NSAID and switching to a COX-2 inhibitor
	Bleeding tendency				Use Trilisate, Disalacid, or Celecoxib: no effect on platelet aggregation
	Nephrotoxicity				Alternatives: Sulindac or Celecoxib (celecoxib has shown no benefit in post-op surgical pain)
Selective Cox II inhibitors	GI upset	Consider using a proton pump inhibitor or discontinuation of medication			
	Liver dysfunction	Monitor closely or consider discontinuation of medication			
	Nephrotoxicity	Discontinuation of medication			
Anticonvulsant Drugs	Somnolence	Decrease dose			
	Cerebellar symptoms	Decrease dose			
Carbamazepine (Tegretol)	Myelosuppression	Change to another antiepileptic drug			
Tricyclic Antidepressants	Brand Names	Sedation		Orthostatic Hypotension	
		Elavil	++++		++
		Adapin Sinequan	+++		++
		Tofranil	++		+++
		Norpramin	+		+
		Aventyl, Pamelor	++		+

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Annotation Appendix F – Non-Opioid Analgesics

Medication	Usual Adult Dose	Maximum Adult Daily Dose	Usual Pediatric Dose	Comments
Aminophenolol Derivatives				
Acetaminophen (Tylenol)	650-975 mg PO q 4-6 hr	4000 mg	10-15 mg/kg PO q 4-6hr	Lacks the peripheral anti-inflammatory activity of NSAIDs
Salicylates				
Aspirin	650-975 mg PO q 4-6 hr	4000 mg	10-15 mg/kg PO q 4-6 hr*	Inhibits platelet aggregation, may cause postop bleeding
Choline magnesium trisalicylate (Trilisate)	1000-1500 mg PO q 12 hr	3000 mg	10-25 mg/kg PO q 12 hr	Effectiveness compared to aspirin not clear; onset of analgesia probably slower; less gastropathy and impairment of platelet function
Diflunisal (Dolobid)	1000 mg PO initial dose followed by 500 mg q 12 hr	1500 mg		500 mg superior to 650 mg of aspirin or acetaminophen, with longer duration
Magnesium Salicylate (Doan's Pills)	650 mg PO q 4-6 hr			Many brands and generic forms available; does not effect platelet function
Salsalate (Disalcid)	500 mg PO q 4 hr	3000 mg		Appears to provide anti-inflammatory activity equivalent to aspirin; does not inhibit platelet aggregation
Sodium Salicylate	325-650 mg PO q 3-4 hr			
Other NSAIDs				
Sulindac (Clinoril)	200 mg PO q 12 hrs, after satisfactory response is achieved, dose may be decreased accordingly	400 mg		Comparable to aspirin with a lower overall incidence of total adverse effects.
Diclofenac potassium (Voltaren)	50 mg PO q 8 hr	150 mg		Comparable to aspirin with longer duration; available with misoprostol to decrease GI toxicity
Etodolac (Lodine)	200-400 mg PO q 6-8 hr	1200 mg		200 mg comparable to, and 400 mg possibly superior to 650 mg of aspirin
Fenoprofen calcium (Nalfon)	200-600 mg PO q 6 hrs	3200 mg		Comparable to aspirin; contraindicated in patients with impaired renal function
Ibuprofen (Advil, Motrin)	400-800 mg PO q 6-8 hrs	2400 mg	10 mg/kg PO q 6-8 hrs	200 mg equal to 650 mg of aspirin and acetaminophen; 400 mg superior to 650 mg of aspirin and acetaminophen; 400 mg comparable to acetaminophen/codeine combination
Indomethacin (Indocin)	25-50 mg PO q 8 hrs	200 mg	0.3-1 mg/kg or 10 mg PR	Max pediatric dose of 200 mg/day
Ketoprofen (Orudis)	25-75 mg PO q 6-8 hrs	300 mg		12.5 mg comparable to Ibuprofen 200 mg; 25 mg comparable to Ibuprofen 400 and superior to 650 mg of aspirin; 50 mg superior to acetaminophen/codeine combination
Ketorolac (Toradol)	Pts. < 65 yrs of age: 30-60 mg IM initially followed by 15-30 mg q 6 hr. Oral dose following IM dosage: 10 mg q 6-8 hr. IV Dosage: 30 mg IV q 6 hrs. Pts. > 65 yrs of age: 15 mg IV/IM q 6 hrs	Pts. < 65 yrs of age: 120 mg Pts. > 65 yrs of age: 60 mg	0.5 mg/kg/dose max 100 mg/24 hrs	IV/IM comparable to 10 mg morphine with longer duration; use should be limited to 5 days
Meclofenamate sodium (Meclomen)	50-100 mg PO 4-6 hrs	400 mg		Comparable to aspirin; approved for dysmenorrhea
Mefenamic acid (Ponstel)	500 mg PO initially followed by 250 mg PO q 6 hr	1250 mg		Comparable to aspirin; approved for dysmenorrhea; duration of use not to exceed 1 week
Naproxen (Naprosyn)	500 mg PO initially followed by 250 mg PO q 6-8 hrs	1250 mg the first day, then 1000 mg	5-10 mg/kg PO q 12 hrs	250 mg probably comparable to 650 mg aspirin with longer duration; 500 mg superior to 650 mg aspirin
Naproxen sodium (Anaprox)	550 mg PO initially, followed by 275 mg PO q 6-8 hrs	1375 mg the first day, then 1100 mg	5-10 mg/kg PO q 12 hrs	275 mg comparable to 650 mg of aspirin with longer duration; 550 mg superior to 650 mg of aspirin with longer duration
Selective COX-2 Inhibitors				
Celecoxib (Celebrex)	100-200 mg twice daily	400 mg		Caution in patients with sulfa allergy

Caution: Recommended doses do not apply to patients with renal or hepatic insufficiency or other illness that may effect drug metabolism and kinetics.

*Contraindicated in presence of fever or other evidence of a viral illness.

This table completed using the following resources:

- 1) 2002 Mosby's Drug Consult: A Comprehensive Reference for Brand and Generic Prescription Drugs. Mosby Publishing Company, 2002.
- 2) American Pain Society. Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain. 5th edition. American Pain Society, 2003.

Annotation Appendix G – Opioid Analgesics

Drug	Equianalgesic dose		Initial ADULT Parenteral Dose	Initial ADULT Oral Dose	Comments
	Oral	Parenteral			
Morphine	30 mg	10 mg	1 to 10 mg	10 to 30 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	0.2 to 1 mg	1 to 4 mg	Potent opioid. Good agent for patients with renal dysfunction.
Oxycodone	20 mg	NA	NA	5-10 mg	Long-acting form may be given orally/rectally every 12 hours.
Hydrocodone	30 mg	NA	NA	5-10 mg	Often combined with nonopioid analgesics which limits the total dose per day.
Oxymorphone	NA	1 mg	1 mg	NA	Available as suppository.
Tramadol			NA	50 mg	Maximum dose 400 mg/day.
Methadone	5 mg	*	*	2.5-5 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.
Fentanyl		100 mcg	25 to 100 mcg	NA	Short-acting. Available as transdermal patch (see conversion below)

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

* Methadone: Confer with pain specialist before parenteral use.

This table was completed using the following sources:

2002 Mosby's Drug Consult: A Comprehensive Reference for Brand and Generic Prescription Drugs. Mosby Publishing Company, 2002.

American Pain Society. Principles of analgesic use in the treatment of acute pain and cancer pain. 5th edition. American Pain Society, 2003.

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

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Annotation Appendix I – Antidepressants and Antiepileptic Drugs Used in Chronic Pain Syndromes

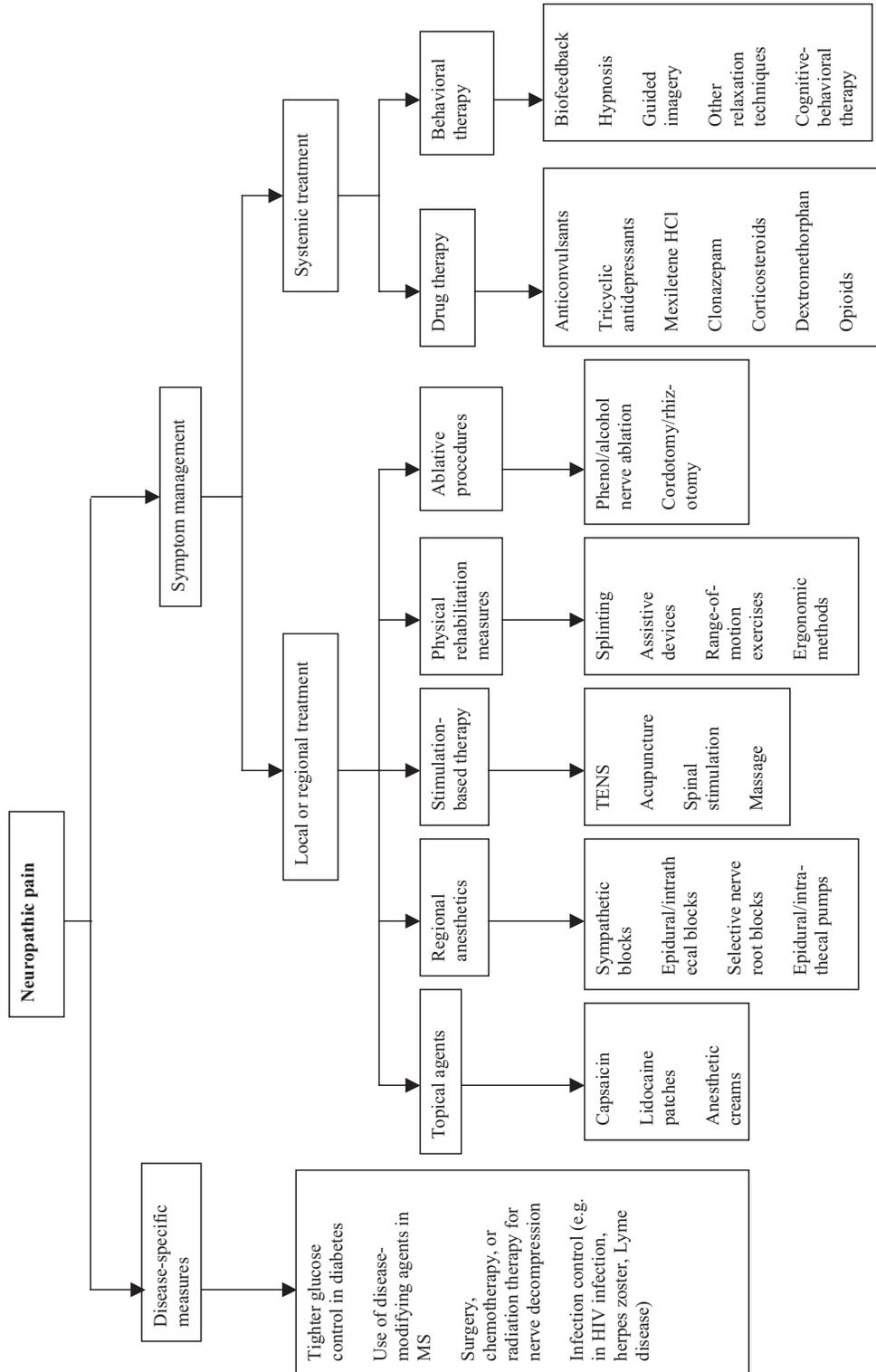
Drug	Dosage	Side effects, contraindications, and comments
Antidepressants		
Tricyclic antidepressants	—	Side effects: dry mouth, constipation, urinary retention, sedation, weight gain Contraindications: cardiac conduction abnormalities, recent cardiac events, narrow-angle glaucoma
Amitriptyline (Elavil),* imipramine (Tofranil)*	10 to 25 mg at bedtime; increase by 10 to 25 mg per week up to 75 to 150 mg at bedtime or a therapeutic drug level.	Tertiary amines have greater anticholinergic side effects; therefore, these agents should not be used in elderly patients.
Desipramine (Norpramin),* nortriptyline (Pamelor)*	25 mg in the morning or at bedtime; increase by 25 mg per week up to 150 mg per day or a therapeutic drug level.	Secondary amines have fewer anticholinergic side effects.
Selective serotonin reuptake inhibitors Fluoxetine (Prozac),* paroxetine (Paxil)*	10 to 20 mg per day; up to 80 mg per day for fibromyalgia.	Side effects: nausea, sedation, decreased libido, sexual dysfunction, headache, weight gain. Efficacy in pain syndromes is relatively poor.
Novel antidepressants Bupropion (Wellbutrin)*	100 mg per day; increase by 100 mg per week up to 200 mg twice daily (400 mg per day).	Side effects: anxiety, insomnia or sedation, weight loss, seizures (at dosages above 450 mg per day)
Venlafaxine (Effexor)*	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
Duloxetine (Cymbalta)*	20 to 60 mg per day taken once or twice daily in divided doses (for depression); 60 mg twice daily for fibromyalgia	Side effects: nausea, dry mouth, constipation, dizziness, insomnia
Antiepileptic drugs		
First-generation agents Carbamazepine (Tegretol)	200 mg per day; increase by 200 mg per week up to 400 mg three times daily (1,200 mg per day).	Side effects: dizziness, diplopia, nausea Treatment can result in aplastic anemia.
Phenytoin (Dilantin)*	100 mg at bedtime; increase weekly up to 500 mg at bedtime.	Side effects: dizziness, ataxia, slurred speech, confusion, nausea, rash. Treatment can result in blood dyscrasias and hepatotoxicity.
Second-generation agents Gabapentin (Neurontin)	100 to 300 mg at bedtime; increase by 100 mg every 3 days up to 1,800 to 3,600 mg per day taken in divided doses three times daily.	Side effects: drowsiness, dizziness, fatigue, nausea, sedation, weight gain
Pregabalin (Lyrica)	150 mg at bedtime for diabetic neuropathy; 300 mg twice daily for postherpetic neuralgia.	Side effects: drowsiness, dizziness, fatigue, nausea, sedation, weight gain
Lamotrigine (Lamictal)*	50 mg per day; increase by 50 mg every 2 weeks up to 400 mg per day.	Side effects: dizziness, constipation, nausea; rarely, life-threatening rashes

* Not approved by the U.S. Food and Drug Administration for treatment of neuropathic pain.

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Because doses for pain are lower than doses for depression, blood levels are not helpful.

Annotation Appendix J – Neuropathic Pain Treatment Diagram



Source: Belgrade, MI. Following the clues to neuropathic pain. PostGraduate Medicine, 106(6), November 1999.

Annotation Appendix K – Patient Health Questionnaire (PHQ-9)

Nine Symptom Checklist

Patient Name: _____ Date: _____

1. Over the *last 2 weeks*, how often have you been bothered by any of the following 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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Feeling down, depressed, or hopeless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Trouble falling/staying asleep, sleeping too much.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Feeling tired or having little energy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Poor appetite or overeating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Feeling bad about yourself - or that you are a failure or have let yourself or your family down.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Trouble concentrating on things, such as reading the newspaper or watching television.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Thoughts that you would be better off dead or of hurting yourself in some way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Instructions - How to Score PHQ-9

Major Depressive Syndrome is suggested if:

- Of the 9 items, 5 or more are checked as at least "More than half the days"
- Either #1.a or #2.b is positive, that is, at least "More than half the days"

Other Depressive Syndrome is suggested if:

- Of the 9 items, 2, 3, or 4 are checked as at least "More than half the days"
- Either item #1.a or #2.b is positive, that is, at least "More than half the days"

Also, PHQ-9 scores can be used to plan and monitor treatment. To score the instrument, tally each response by the number value under the answer headings, (not at all = 0; several days = 1, more than half the days = 2, and nearly every day = 3). Add the numbers together to total the score on the bottom of the questionnaire. Interpret the score by using the guide listed below:

PHQ-9 Scoring for Severity Determination

Scoring – add up all checked boxes on PHQ-9

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

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

Patient responses to the PHQ-9 questions can be one of four: (Not difficult at all, Somewhat difficult, Very difficult, Extremely difficult.) The last two responses suggest that the patient's functionality is impaired. After treatment begins, functional status is again measured to see if the patient is improving.

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Evidence Grading System

I. CLASSES OF RESEARCH REPORTS

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

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 Section I, above, and are assigned a designator of +, -, or \emptyset 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.

Evidence Grading System

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

The symbols **+**, **-**, **∅**, 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;

∅ 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 #16 (Chronic Pain and Chemical Use)

Work Group's Conclusion: 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

Author/Year	Design Type	Class	Quality +,-,Ø	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-sectional	D	Ø	403 pts from the Seattle Veterans 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 psychiatric clinic while on opioids but were not followed in the pain clinic, and 14 were no longer treated by the Seattle Veteran's Affairs health system; 9 out of the 14 were in or completed 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

Author /Year	Design Type	Class	Quality	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/ <i>Work Group's Comments (italicized)</i>
Zens, 1992	Case series	D	θ	-- 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	-- 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	-- Results demonstrate that opioids can be effective in chronic nonmalignant pain management, with side effects that are comparable to those in treating cancer pain
Mahowald, 2005	Cross-sectional	D	θ	-- 230 orthopedic spine clinic pts were studied through retrospective analysis of prescriptions for 3 years and cross-sectional analysis of opioid effectiveness and toxicity using interviews -- Opioids were prescribed for 152 (66%) of total pts; opioids were given for less than 3 months (short-term) in 94 pts; and for 3 months or more (long-term) in 58 pts -- Interviews were completed in 167 pts total -- Pts from Veteran's Affairs population	-- 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	-- Tolerance to opioid analgesia did not appear to occur in this group of pts on average -- Provides objective data to challenge position that opioids are inappropriate for chronic nonmalignant 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
- Knowledge Products
- Recommended Resources

Priority Aims and Suggested Measures

1. Improve the treatment of patients with chronic pain by completing an appropriate biopsychosocial assessment.

Possible measures for accomplishing this aim:

- a. Percentage of patients diagnosed with chronic pain that have documentation of a biopsychosocial assessment and depression screening relative to pain in the medical record.
 - b. Percentage of physicians who have documented completion of the screening questions as described in the guideline (Annotation #2).
2. Improve the function of patients with chronic pain by developing and using a comprehensive treatment plan that includes a multi-specialty team approach.

Possible measures for accomplishing this aim:

- a. Percentage of patients diagnosed with chronic pain that have functional outcome goals documented in the medical record.
 - b. Percentage of patients diagnosed with chronic pain that experience an improvement or sustained their score on a Functional Ability Questionnaire (i.e., ICSI Functional Ability Questionnaire) at 3, 6, 9 months of the treatment plan.
 - c. Percentage of patients diagnosed with chronic pain treated by a primary care physician who are referred to other specialties after no improvement in functional ability after 9 months of the treatment plan.
3. Improve the effective use of medications in the treatment of patients with chronic pain.

Possible measures for accomplishing this aim:

- a. Percentage of patients with neuropathic pain that are prescribed a tricyclic antidepressant OR anti-convulsant prior to use of opioids.
 - b. Percentage of patients diagnosed with chronic pain who are receiving opioids who have documentation of the four A's assessment at each visit.
 - c. Percentage of patients with inflammatory pain that are prescribed an NSAID as a first line analgesic unless clinically contraindicated.
 - d. Percentage of patients diagnosed with chronic pain that are prescribed an opioid that have documentation of a "contract of use" form in the medical record.
 - e. Percentage of patients diagnosed with chronic pain that are prescribed an opioid that have documentation of screening for risk of diversion or chemical dependency.
4. Ensure the appropriate use of interventional techniques as per guideline and technology assessment reports in the treatment of chronic pain.

Possible measures for accomplishing this aim:

- a. Percentage of patients treated for chronic pain who have appropriate indications for use of interventional techniques (See Technology Assessments).
- b. Percentage of patients treated for chronic pain who have completed physical therapy before referral to surgery or other invasive interventions.

At this point in development for this guideline, there are no specifications written for possible measures listed above. ICSI will seek input from the medical groups on what measures are of most use as they implement the guideline. In a future revision of the guideline, measurement specifications may be included.

Knowledge Products

Resources and knowledge products are developed by the guideline work group, member and non-member organizations, or identified by ICSI staff as useful implementation tools.

1. Scientific Documents

- Related guidelines
 - Assessment and Management of Acute Pain
 - Adult Low Back Pain
 - Diagnosis and Treatment of Headache
 - Diagnosis and Treatment of Adult Degenerative Joint Disease (DJD) of the Knee
 - Major Depression in Adults in Primary Care
- Technology Assessment Reports
 - Acupuncture for Chronic Osteoarthritis Pain, Headache and Low Back Pain (#36, 2000)
 - Intradiscal Electrothermal Therapy (IDET) for Low Back Pain (#62, 2002)
 - Intrathecal Baclofen Infusion for Controlling Spasticity and Spasm (#19, 1994)
 - Fluoroscopically Guided Transforaminal Epidural Steroid Injections for Lumbar Radicular Pain. (#85, 2004)
 - Percutaneous Radiofrequency Ablation for Neck and Back Pain (#88, 2005)
 - Extracorporeal Shock Wave Therapy for Plantar Fasciitis (#86, 2004)

2. Recorded Presentations

- Video
 - Patient Focus Group Video "Chronic Pain Focus Groups"

3. Educational Resources

- PIRs
 - Chronic Pain Patient Focus Group, #30

ICSI has a wide variety of other knowledge products including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Products, go to <http://www.icsi.org/knowledge>.

Many of the materials listed in the Knowledge Products resource are only available to ICSI members.

Recommended Resources

Title/Description	Audience	Author/Organization	Websites/Order Information
Founded in 1983 and has become the primary organization for physicians practicing the specialty of pain medicine in the U.S.	Professionals	American Academy of Pain Medicine	http://www.painmed.org
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. To raise awareness among the health care community, policy makers, and the public at large about issues of living with chronic pain.	Patients and professionals	American Chronic Pain Association	http://www.theacpa.org
Dedicated to eliminating the undertreatment of pain in America. Has resources for individuals who suffer from chronic pain, their families, friends, and the general public.	Patients	American Pain Foundation	http://www.painfoundation.org/
"Pain Notebook" is a tool to help patients maintain a record of their pain and communicate with their provider. "Target Chronic Pain Pocket Card" is a provider reference tool for pain assessment and management.	Patients and professionals	American Pain Foundation publications	Phone: 410-783-7292 x226 Email: publications@painfoundation.org Website: http://www.painfoundation.org/page.asp?file=page_publications.htm
A multidisciplinary scientific and professional society. CE's available. Several position statements available including pediatric chronic pain, use of opioids, and preventing abuse of pain meds.	Patients and professionals	American Pain Society	(patients) http://www.ampainsoc.org/advocacy/promoting/htm (professionals) http://www.ampainsoc.org/
To advance and promote optimal nursing care for people affected by pain. Position statement on treating pain for patients with addictive disease.	Professionals	American Society for Pain Management Nurses	http://www.aspmn.org/
Dedicated to providing comprehensive care of the highest quality in pain management and palliative care.	Professionals	Beth Israel Medical Center website	http://www.stoppain.org

Recommended Resources

Title/Description	Audience	Author/Organization	Websites/Order Information
<p>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 research in these areas for the benefits of physicians and the public; and to publish the highest quality scientific information on these subjects.</p> <p>This site seems to be very specific to the individual who is working in pain management. It will be interesting to see what kind of feedback we get from general physicians feel if this is helpful.</p>	Physicians	The American Society of Regional Anesthesia and Pain Medicine	http://www.arsa.com
A government site with many links to other sites and current research.	Patients	National Chronic Pain Outreach Association, Inc.	http://www.nih.gov
Pain experts Dr. Payne and Dr. Poutenoy seek to advance the clinical management of pain through education and communication.	Professionals	National Pain Education Council	http://www.npecweb.org
"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 communication skills, problem solving strategies, and guidance on setting realistic goals. Also includes excellent information on mind-body techniques.	Patients	Margaret Caudill	Guilford Press; http://www.guilford.com

Criteria for Selecting Resources

The preceding resources were selected by the *Assessment and Management of Chronic Pain* guideline work group as additional resources for practitioners and the public. The following criteria were considered in selecting these sites.

- The site contains information specific to the particular disease or condition addressed in the guideline.
- The site contains information that does not conflict with the guideline's recommendations.
- The information is accurate and/or factual. The author of the material or the sponsor of the site can be contacted by means other than e-mail. For example, a nurse line or other support is provided.
- The material includes the source/author, date and whether the information has been edited in any way. The site clearly states revision dates or the date the information was placed on the internet.
- The site sponsor is an objective group without an obvious or possible bias. For example, the site does not promote a product, service or other provider.
- The coverage of the topic is appropriate for the guideline's target audience. It is clearly written, well-organized and easy to read. The site is easy to navigate.