ICSI

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Guideline:
Assessment and Management of Chronic Pain

Fifth Edition
November 2011

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and the following expert audiences:

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

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in your individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. An ICSI Health Care Guideline rarely will establish the only approach to a problem.

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Assessment Algorithm

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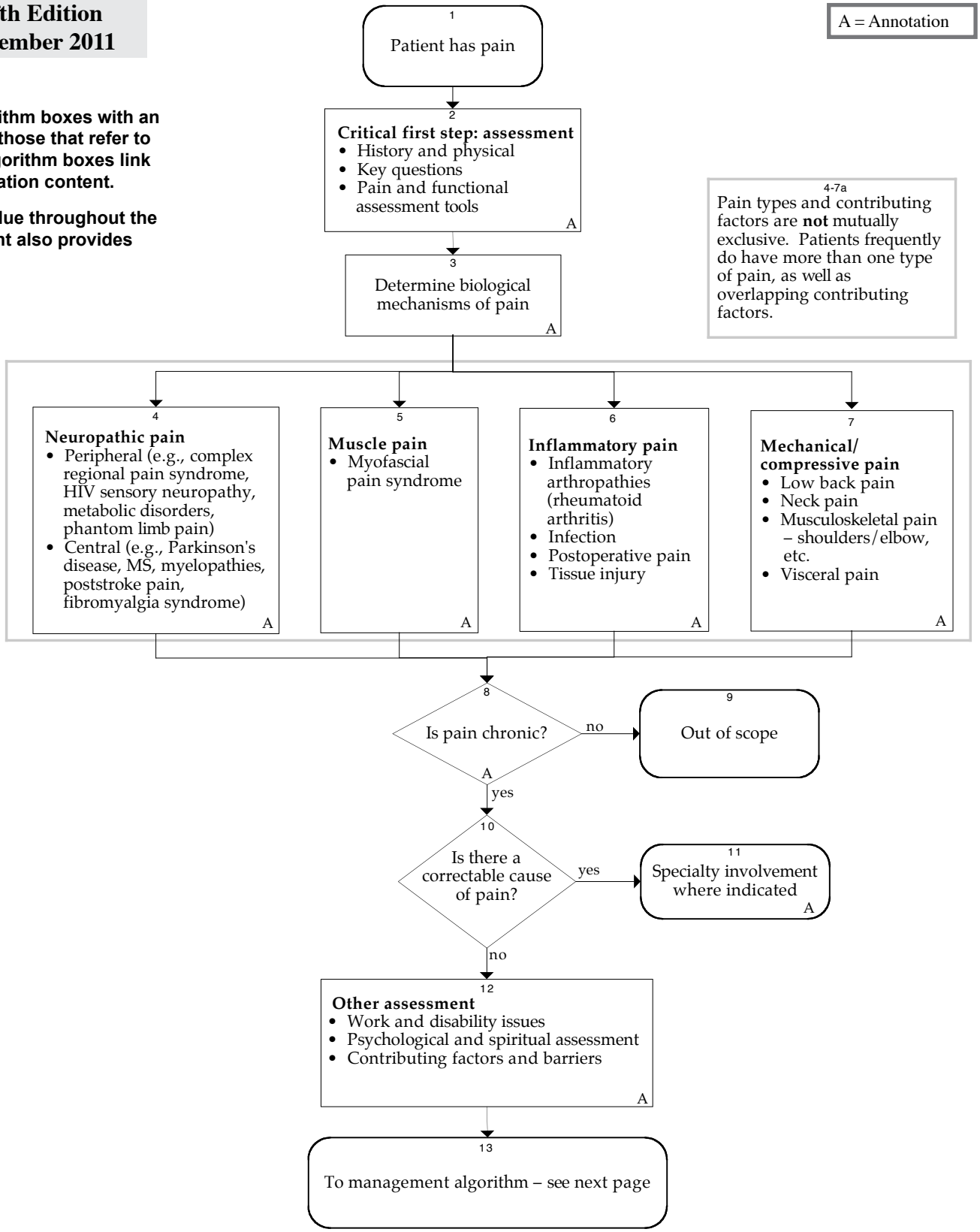
All algorithm boxes with an "A" and those that refer to other algorithm boxes link to annotation content.

Text in blue throughout the document also provides links.



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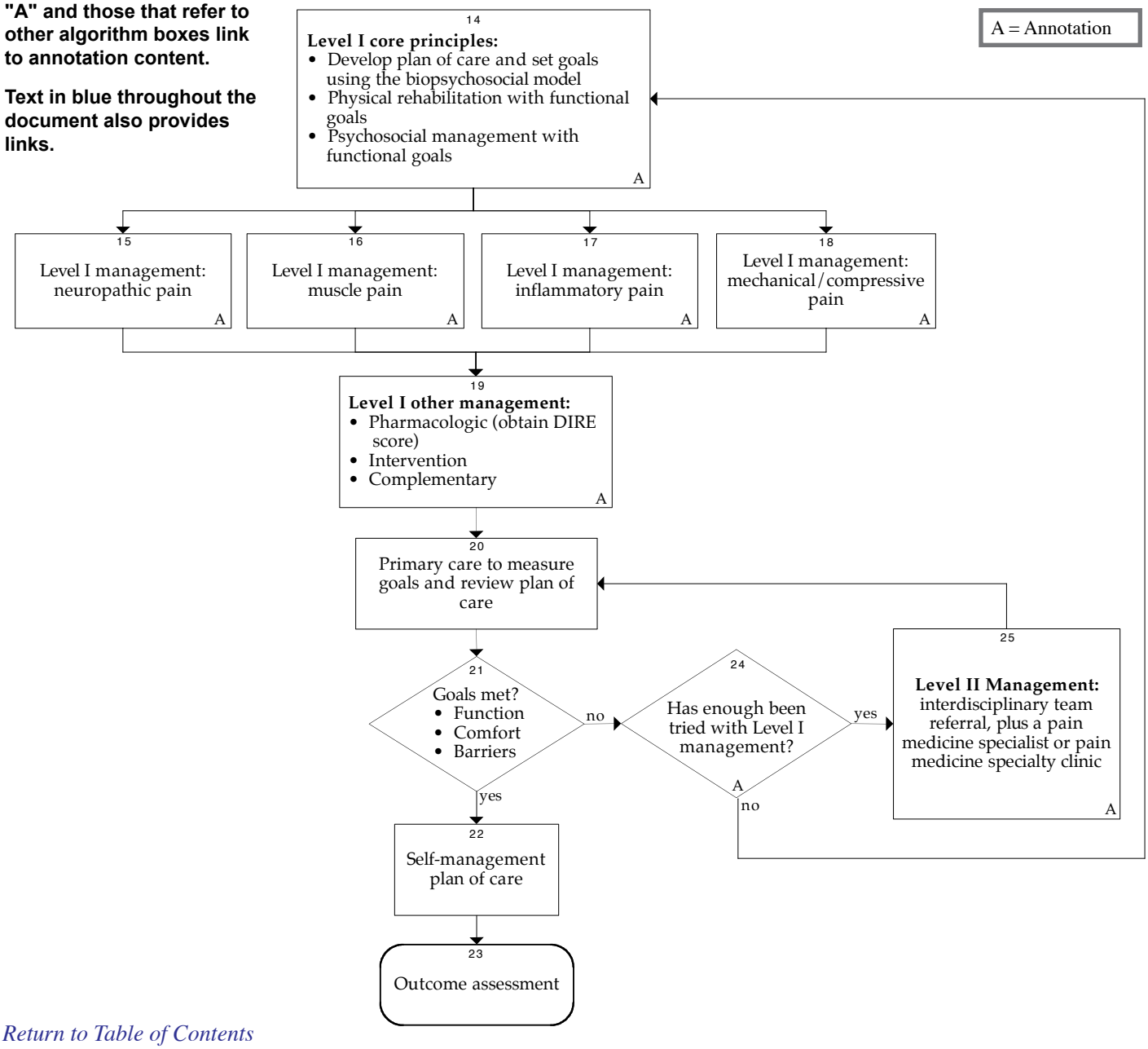
Management Algorithm

All algorithm boxes with an "A" and those that refer to other algorithm boxes link to annotation content.

Text in blue throughout the document also provides links.



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Disclosure of Potential Conflict of Interest

In the interest of full disclosure, ICSI has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. It is not assumed that these financial interests will have an adverse impact on content. They are simply noted here to fully inform users of the guideline.

Miles Belgrade, MD, received an honoria from Optum Health and has family-owned stock in Johnson & Johnson.

Louis Saegar, MD, is a board member of the Minnesota Society of Interventional Pain Physicians.

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

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Evidence Grading

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. Literature search terms for the current revision of this document include SI joint injection, facet joint injection, intradiscal electrothermal therapy (IDET), epidural corticosteroid injections, vertebroplasty and kyphoplasty, and trigger point injections from August 2008 through August 2011.

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- Developed by a widely representative group of international guideline developers
- Explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings
- Clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations
- Clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers
- Explicit acknowledgement of values and preferences and
- Explicit evaluation of the importance of outcomes of alternative management strategies.

At ICSI we have established a GRADE Implementation Team to provide overall direction for this transition. We intend to complete the transition in phases. In 2011 the following work to transition to GRADE will be done:

- Select documents that will undergo complete implementation of GRADE
- For all other documents, including Assessment and Management of Chronic Pain, beginning March 2011:
    - All original ICSI Class A (RCTs) and ICSI Class B (Cohort) studies were reviewed by work group members and the quality of evidence assessed using GRADE. Other literature was labeled by ICSI staff according to Crosswalk between ICSI Evidence Grading System and GRADE.
    - New literature was reviewed and graded by work group members using the new ICSI GRADE system.
    - Key Points in all documents become Recommendations.

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Crosswalk between ICSI Evidence Grading System and GRADE

Design of Study Current ICSI System		ICSI GRADE System
Class A:	Randomized, controlled trial	**High**, if no limitation **Moderate**, if some limitations **Low**, if serious limitations
Class B:	[observational] Cohort study	 **High,** if well done with large effect **Moderate,** if well done with effect **Low,** most studies
Class C:	[observational] Non-randomized trial with concurrent or historical controls Case-control study Population-based descriptive study Study of sensitivity and specificity of a diagnostic test	 **Low** **Low** ***Low**
* Following individual study review, may be elevated to Moderate or High depending upon study design		
Class D:	[observational] Cross-sectional study Case series Case report	 **Low**
Class M:	Meta-analysis Systematic review Decision analysis Cost-effectiveness analysis	**Meta-analysis** **Systematic Review** **Decision Analysis** **Cost-Effectiveness Analysis**
Class R:	Consensus statement Consensus report Narrative review Guideline	**Low** **Low** **Low** **Guideline**
Class X:	Medical opinion	**Low**
Class Not Assignable		**Reference**

Evidence Definitions:

High Quality Evidence = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

Supporting Literature:
In addition to evidence that is Graded and used to formulate recommendations, additional pieces of literature will be used to inform the reader of other topics of interest. This literature is not given an evidence grade and is instead identified as a **Reference** throughout the document.

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Foreword

Scope and Target Population

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

Definitions

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

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

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Aims

1. Improve the function of patients 16 years and older with chronic pain. *(Annotations #2, 14)*
2. Improve the assessment and reassessment of patients 16 years and older with chronic pain diagnosis utilizing the biopsychosocial model. *(Annotations #2, 3, 12)*
3. Improve the appropriate use of Level I and Level II treatment approaches for patients 16 years and older with chronic pain. *(Annotations #14, 19, 25)*
4. Improve the effective use of non-opioid medications in the treatment of patients 16 years and older with chronic pain. *(Annotations #15, 19)*
5. Improve the effective use of opioid medications in the treatment of patients 16 years and older with chronic pain. *(Annotations #15, 19)*

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Clinical Highlights

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

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Implementation Recommendation Highlights

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

1. It is important to take both a clinical and an operational approach for successful implementation of this guideline.
2. Develop a process that allows patients with chronic pain to see a dedicated care provider who has an interest or expertise in chronic pain.
3. Develop a process to work collaboratively with other care providers in prescribing opioids with shared patients (e.g., dentists, specialists).
4. Establish a policy for monitoring and maintaining opioid agreements for prescription refills with other clinics, pharmacies, dentists and specialists.
5. Develop a process for scheduling follow-up patient visits to deter drug-seeking behaviors with other care providers, for instance, support personnel calling patients to schedule follow-up appointments with a dedicated chronic pain physician.
6. Develop staff and physician training regarding the organization's process for treating patients with chronic pain that could include process of referrals to chronic pain provider within the system, follow-up visits, prescription refills and continuity of care.
7. Coordinate a chronic pain care team that minimally consists of a physician champion and medical support staff. Suggestions for care providers from other disciplines include pharmacy, chemical dependency, neurology, occupational medicine, anesthesiology/pain management, behavioral health, home care, social work, physical medicine and rehabilitation, and physical therapy.

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8. Determine population ICD-9 codes for data collection that is unique to patients with chronic pain in your facility. Examples of this would be:

    - Low back pain
    - Headache
    - Neck pain
    - Fibromyalgia
    - Chronic pain

9. Identify multidimensional pain assessment, functional assessment, psychological assessment, and opioid assessment tools that meet the needs of the care providers and are appropriate for the patient populations.

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

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

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

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

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Related ICSI Scientific Documents

Guidelines

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

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Definitions

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

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

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

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

DPNB: Dorsal Penile Nerve Block.

EMLA: Eutectic Mixture of Local Anesthetics.

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

Neuropathic: A pathological change in the peripheral nervous system.

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

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

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

✔ **Physical Dependence:** 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 comprising of Tetracaine, Adrenaline (Epinephrine) and Cocaine.

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

Visceral: Pertaining to a bodily organ.

* From "Model Policy for the Use of Controlled Substances for the Treatment of Pain" (5/98), Federation of State Medical Boards of the United States.

✔ From "Definitions Related to the Use of Opioids for the Treatment of Pain." 2001. American Academy of Pain Medicine, American Pain Society, and the American Society of Addiction Medicine.

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Algorithm Annotations

Assessment Algorithm Annotations

2. Critical First Step: Assessment

Recommendations:

- All patients should have an adequate pain assessment that includes 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 should be completed in assessing chronic pain.

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

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

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

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

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

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

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

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

Diagnostic Testing

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

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

MRI and CT are used very frequently, especially in spine-related pain. MRI is usually preferred for evaluating disc pathology. Some general information about MRI in the spine and pain is important in interpreting these studies. Bulging discs are usually not significant in the absence of spinal stenosis. Disc degeneration and arthritic changes per se are not necessarily painful. The size of a disc protrusion does not correlate with pain level. Most pain physicians like to have this information when evaluating the patient, especially if some anesthesiologic intervention is contemplated for the pain. CT and CT myelography are useful in patients who cannot undergo MRI or who are being considered for surgery. Electromyography and nerve conduction studies are of use in patients suspected of having lower motor neuron dysfunction, nerve or nerve root pathology, or myopathy.

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

Functional Assessment

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

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

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

Pain Assessment Tools

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

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

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

Table 1. Multidimensional Assessment Tools

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

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

Table 2: Single-Dimensional Assessment Tools

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

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

For additional information on pain assessment tools, the work group recommends 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 who are non-English speaking

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General approach:

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

(National Pharmaceutical Council, Inc, 2001 [Low Quality Evidence])

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

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

(American Pain Society, 2005 [Low Quality Evidence]; Herr, 2004 [Guideline]; Kaiser Permanente Medical Care Program, 2004 [Guideline]; McCaffery, 1999 [Guideline]; Daut, 1983 [Low Quality Evidence])

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3. Determine Biological Mechanisms of Pain

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

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

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

(Chen, 2004 [Low Quality Evidence]; Koltzenburg, 2000 [Low Quality Evidence]; Dickenson, 1995 [Low Quality Evidence])

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4. Neuropathic Pain

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

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

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

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

(Wolfe, 1990 [C])

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5. Muscle Pain

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

Myofascial pain is regional muscle soft tissue pain commonly involving the neck, shoulders, trunk, arms, low back, hips and lower extremities. It is characterized by painful muscle dysfunction in one or several muscles in a region of the body with loss of range of motion; and by tenderness at muscle sites that causes a referred pain in a typical distribution (trigger points). Commonly, taut bands of muscle are present and sometimes a muscle twitch is elicited with palpation or needling the affected muscle. Myofascial pain is common in patients seen in pain clinics. It usually presents after an injury or with occupational repetitive activity. Treatment consists more in restoring muscle balance and function through physical therapy techniques than with medication management. Identifying and managing perpetuating factors (posture, repetitive actions, occupational factors) is a priority in treatment. Trigger point injections or acupuncture can be useful adjunctive treatment that may hasten recovery. Consider myofascial pain when there is regional pain without any findings on imaging studies. Sometimes, persistent myofascial pain may be a muscle response to an underlying structural spine or visceral problem *(Kilkenny, 2008 [Low Quality Evidence])*.

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6. Inflammatory Pain

Inflammatory pain such as arthritis, infection, tissue injury and postoperative pain is also known as *nociceptive pain* because the inflammatory chemicals such as prostaglandins directly stimulate primary sensory nerves that carry pain information to the spinal cord. The clinical features include heat, redness and swelling at the pain site and a history of injury or known inflammation. Treatment involves managing the inflammatory process with antibiotic or antirheumatic therapies and using anti-inflammatory agents like NSAIDs or corticosteroids to manage symptoms and control inflammation.

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7. Mechanical/Compressive Pain

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

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 may require some sort of decompression or stabilization.

See also the ICSI Adult Low Back Pain guideline.

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8. Is Pain Chronic?

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

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11. Specialty Involvement Where Indicated

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

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

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12. Other Assessment

Recommendations:

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

Functional Assessment Tools

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

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

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

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

Psychological Assessment

Determine possible psychiatric contribution to clinical presentation.

Assessment questions to ask the patient:

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

Role of Psychological Assessment

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

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

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Depression

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

Anxiety

- Increased prevalence in chronic pain samples
- May be a risk factor for the development of chronic pain syndrome
- Psychophysiological mechanisms can maintain and/or exacerbate chronic pain
- Associated with fear of pain and fear of movement/reinjury, contributes to avoidant coping pattern

Substance Abuse and Dependence

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

The CAGE questionnaire is a useful tool for brief alcohol screening of the patient *(Ewing, 1984 [High Quality Evidence])* and can be located at http://www.psychology-tools.com/cage-alcohol-questionnaire/.

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

Sleep Disorders

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

Personality Disorders

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

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History of Abuse

- A review of the literature shows that abuse in childhood is a strong predictor of depression and physical complaints, both expanded and unexplained, in adulthood *(Arnow, 2004 [Low Quality Evidence])*.
- However, the specific relationship between childhood abuse and the development of chronic pain in adulthood is under question. If a patient presents with chronic pain and a history of abuse that has not been previously treated, referral for appropriate psychotherapy should be considered.

Coping Patterns and Resources

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

Spirituality

Assessment question to ask the patient:

- Is spirituality an important part of your life?

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

Work and Disability Issues

Assessment question to ask the patient:

- Are you working and where?
- If no, why not?

Chronic pain, whether associated with a work or non-work-related condition, can lead to physical impairments that may limit work activity. Physical impairments do not imply that an individual cannot work. An impairment may lead to a job modification. However, in most conditions associated with chronic pain, complete and permanent disability is not necessary. It is frequently a variety of factors such as psychosocial issues that may increase the likelihood of disability, which may be unnecessary if based on the physical impairment alone. Joint and low back symptoms are the first and second most frequent causes of disability in America and have become major public health issues.

Disability systems in the United States include workers compensation, private disability insurance and Social Security disability. Independent health consequences of disability are significant. Those disabled have an increased probability of poor mental and physical health. Mortality is increased. Financial consequences are severe as lifetime earnings may be decreased by as much as half. There is increased generational risk with threats to family and community stability.

Risk factors that increase the likelihood of chronic pain and disability are generally consistent across different conditions. They are similar for neck and jaw pain, joint pain, low back and other sources of pain. Risk is difficult to evaluate early from the onset of pain. In general, healing from many types of injuries

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occurs within the first four to eight weeks after onset. If pain is not improving during this time, risk factors should be evaluated.

In the last 20 years, numerous studies have been performed to identify risk for chronic pain and disability. The majority of these have been done in reference to low back pain. For that reason, most of the references identified refer to this area. Individual Risk Factors with Stronger Predictive Ability *(Chou, 2009 [Guideline]; Heymans, 2010 [Moderate Quality Evidence]; Haydyn, 2009 [Meta-analysis]; Hifiker, 2008 [Low Quality Evidence]; Steenstra, 2005 [Low Quality Evidence]; Pincus, 2002 [Low Quality Evidence])* include the following:

- Fear avoidance beliefs
- Catastrophizing
- Somatization
- Depressed mood
- Distress and anxiety
- Early disability or decreased function
- High initial pain levels
- Increased age
- Poor general health status
- Non-organic signs
- Compensation dependency

There are alternative approaches to identifying risk, including the international "The Flags Group" and risk tools such as the STarT Back originating in England. Please see the ICSI Adult Low Back Pain guideline for further discussion on these.

Secondary gain is considered a significant risk factor for chronic pain and disability. This may be a variety of levels including social, work, family and financial gain. A variety of conditions including pain lend themselves to reporting symptoms to achieve secondary gain. Estimates vary considerably; however, this is not a rare phenomena and should be considered when evaluating an individual for disability or certain treatment approaches including opioids *(Dworkin, 2007 [Moderate Quality Evidence])*.

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. However, chronic pain may 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 supportive guidance.

Contributing Factors and Barriers to Treatment

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 success of a treatment such as language barrier, comorbid chemical dependency, financial or legal factors,

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low motivation and long distance from pain management services. In chronic pain, 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.

Examples: 1) A patient who is reliant on opioids for chronic pain may always rate his pain at 9 or 10 out of 10, fearing that a lower rating may result in a reduced medication dosage. Thus, the opioid reliance presents as a barrier because it interferes with an accurate assessment of the patient's pain severity. Identifying the barrier and managing it when possible will improve pain outcomes. 2) A patient with postherpetic neuralgia has thoracic neuropathic pain. She has obstructive lung disease and chronic bronchitis from smoking. Whenever she coughs, the pain is unbearable. In this case, the lung disease and cough are *contributing factors* to this patient's postherpetic neuralgia because pain is made worse by coughing even though the cough itself is not the cause of pain. Here, optimal management of chronic bronchitis will improve overall pain control by managing the contributing factor.

Table 3: Common Barriers

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

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Management Algorithm Annotations

14. Level I Core Principles

Recommendations:

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

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Plan of Care Using Biopsychosocial Model

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

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

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

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

- Set personal goals
- Improve sleep
- Increase physical activity
- Manage stress
- Decrease pain

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

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

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

Patient focus group feedback

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

Objectives for conducting the focus group were:

- Learn the patient's perspective on living with chronic pain
- Hear what patients do to manage their pain
- Hear the patient's understanding of available options for treating pain

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- Determine how chronic pain influences changes in lifestyle and function
- Understand the patient's perspective of the provider's role

Key points from the patient focus group discussion include:

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

Level I Versus Level II Management

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

Physical Rehabilitation with Functional Goals

Exercise therapy is commonly recommended and used in managing patients with chronic pain. Hayden, et al. used the Cochrane Central Register of Controlled Trials to do an assessment of randomized controlled trials evaluating exercise therapy for adult nonspecific low back pain, and measuring pain, function, return to work/absenteeism and/or global improvement outcomes. Sixty-one randomized controlled trials involving 6,390 participants were assessed. The authors concluded that exercise therapy is effective in reducing pain and functional limitations in the treatment of chronic low back pain. There were limitations in the quality

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of the studies, and improvements were small but significant over other conservative treatment options. There was also some evidence of the effectiveness of a graded exercise program in subacute low back pain primarily in reducing work absenteeism *(Hayden, 2005 [Meta-analysis])*.

Clinical guidelines for managing patients with low back pain are available from at least 11 countries. Four countries included advice for chronic pain, and all guidelines recommend exercise therapy as useful *(Koes, 2001 [Guideline]; van Tulder, 1997 [Systematic Review])*. The American Pain Society published an evidence-based clinical practice guideline recommending consideration of an intensive multidisciplinary rehabilitation program for patients with non-radicular low back pain who did not improve with the usual conservative program *(Chou, 2009 [Guideline])*.

No one type of exercise has 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 strong need for high-quality studies to determine which type, and how much, of an exercise is necessary and effective. Cost effectiveness needs to be considered *(Faas, 1996 [Low Quality Evidence])*. Mannion found no significant difference in outcome comparing relatively inexpensive group aerobics/stretching to more traditional physical therapy and muscle conditioning, suggesting low cost alternatives may be effective *(Mannion, 1999 [High Quality Evidence])*.

Most patients with chronic pain are physically deconditioned from inactivity. The International Paris Task Force on Back Pain has recommended activity, both recreational as well as formal exercise, for patients with chronic low back pain *(Abenhaim, 2000 [R])*.

For patients with subacute low back pain, a graded, gradually progressive, exercise program has been shown to be effective in reducing work absenteeism *(Lindstrom, 1992 [Moderate Quality Evidence])*. Doing a baseline of the patient's present capacity to do exercise, and then using a graded, gradually progressive, program to improve fitness makes sense for all patients with pain.

Geriatric patients also can benefit from a physical rehabilitation program. The American Geriatric Society Panel of Exercise and Osteoarthritis encourages light to moderate intensity physical activity for both prevention and possibly restoration of health and functional capacity in patients with chronic disease (Exercise Prescription for Older Adults with Osteoarthritis Pain: Consensus practice recommendations *(American Geriatric Society, 2001 [M])*.

Passive modalities (TENS, ultrasound, corset, traction) have limited evidence of effectiveness and should be used only with an active exercise program *(Chou, 2007 [Low Quality Evidence])*. Patient should be taught self management techniques to help manage their pain including use of ice, heat and massage relaxation *(Atlas, 2001 [Low Quality Evidence])*.

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

Regular physical activity and exercise are important parts of a healthy lifestyle. In addition to playing a role in reducing pain and improving function in patients with chronic pain, physical fitness benefits people with arthritis, heart disease and diabetes. It helps with managing high blood pressure, balance problems and difficulty walking. A recent prospective cohort study, involving 416,175 individuals followed for an average of eight years, proposed that 15 minutes a day of moderate intensity exercise might be of benefit in improving quality of life and longer life expectancy *(Wen, 2011 [Moderate Quality Evidence])*.

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Patients can choose to be active or passive participants in their rehabilitation program. Chronic pain patients who actively participate in the rehabilitation program are more likely to benefit. Jordan, et al. published the article "Interventions to Improve Adherence to Exercise for Chronic Muscle Skeletal Pain in Adults." Forty-two clinical trials were assessed, with 8,243 participants, mainly with osteoarthritis and spine pain. They concluded that intervention such as supervised or individualized exercise, and self-management techniques may improve exercise adherence. However, it was felt that high-quality long-term follow-up randomized trials were necessary *(Jordan, 2010 [Systematic Review])*.

Physical rehabilitation is one of the basic level I core principles for managing patients with chronic pain. Goals are to provide the patient with tools for managing pain and restore function. It is important to use a multidimensional pain inventory as well as a functional activities tool. A patient-centered approach encourages the patient to be an active participant in the treatment program.

Psychosocial Management with Functional Goals

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

Depression

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

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

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

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

Some symptoms of depression including feelings of helplessness, dysphoria and frustration are generally expected in patients suffering from chronic pain, given the impact pain often has on ability to function

and enjoy life. If targeted intervention can improve level of physical functioning and quality of life, mild depressive symptoms will likely improve without specific intervention.

Cognitive-behavior therapy

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

Patients live in environments that exert powerful reinforcement for certain behaviors. Physicians, by their very role as health care providers, are powerful reinforcers of behavior. By changing the contingencies of reinforcement, patients can make gains toward 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 [Low Quality 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 *(Guzmán, 2002 [Systematic Review]; Morley, 1999 [Meta-analysis])*.

Cognitive-Behavioral Strategies for Primary Care Physicians

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

- Tell the patient that chronic pain is a complicated problem, and for successful rehabilitation, a team of health care providers is needed. Chronic pain can affect sleep, mood, levels of strength and fitness, ability to work, family members, and many other aspects of a person's life. Treatment often includes components of stress management, physical exercise, relaxation therapy and more to help them regain function and improve the quality of their lives.
- Let the patient know you believe that the pain is real and is not in his/her head. Let the patient know that the focus of your work together will be the management of his/her pain. ICSI Patient Focus Group feedback included patient concerns that their providers did not believe them/their child when they reported pain.
- Ask the patient to take an active role in the management of his/her pain. Research shows that patients who take an active role in their treatment experience less pain-related disability *(French, 2000 [Low Quality Evidence])*.
- Avoid telling patients to "let pain be their guide," whether it is stopping activity because of pain or taking medications or rest in response to pain.
- Prescribe time-contingent pain medications, not pain medications "as needed." Time-contingent medications allow a disruption in the associations between pain behavior and pain medication. The powerfully reinforcing properties of pain medicines are then not contingent upon high levels of pain and pain behavior.

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- Schedule return visits on a regular schedule, and don't let the appointments be driven by increasing levels of pain. Physicians are powerful reinforcers, too.
- Reinforce wellness behaviors such as increased activity or participation in an exercise program.
- Enlist the family and other supports to reinforce gains made toward improved functioning, too.
- Have the patient get involved in an exercise program or structured physical therapy.
- Assist the patient in returning to work. Do this in a stepwise fashion that is not dependent on level of pain.
- Fear of movement or fear of pain due to movement is a significant concern for many patients with chronic pain. Inactivity or avoidance of movement leads to physical deconditioning and disability. Try not to rely on sedative or hypnotic medications to treat the fear many chronic patients show of activity or fear of increased pain. When patients with chronic pain expose themselves to the activities that they fear, which simply means when they do the things they have been afraid of and avoiding, significant reductions are observed in fear, anxiety and even pain level *(Vlaeyen, 2002 [Moderate Quality Evidence])*. If patient's fears are excessive, relaxation strategies may be helpful or referral for more formal and intensive cognitive-behavioral therapy may be necessary.

Cognitive-Behavioral Interventions

Relaxation therapies

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

Biofeedback

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

Biofeedback has been found to be effective in headache management *(Haddock, 1997 [Meta-analysis])*, temperomandibular disorders *(Crider, 1999 [Meta-analysis])*, and other recurrent pain conditions *(National Institutes of Health, 1997 [Low Quality Evidence])*.

Mindfulness-based stress reduction (MBSR)

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

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.

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Imagery

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

Diaphragmatic breathing

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

Autogenic training

Autogenic training is another relaxation procedure that focuses attention to different desired somatic responses such as sensations of warmth and heaviness in the extremities. These responses are believed to facilitate increased blood flow to the extremities and thus promote peripheral warming and a reduction in sympathetic nervous system arousal.

Progresssive muscle relaxation training

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

Hypnosis

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

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

Cognitive techniques

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

Cognitive restructuring

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

Problem-solving

A four-step approach to problem-solving is used in this technique. The goal of problem-solving is to assist patients with chronic pain in seeing alternative solutions to their life difficulties. Identification

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of the problem, generation of possible solutions to the problem, prioritizing the solutions, and implementing a single strategy that is then evaluated for effectiveness are the steps in a problem-solving approach. Having patients experiment with different ways of tackling problems can be an effective way of changing habits or beliefs.

Culture and Chronic Pain

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

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

Age and Chronic Pain

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

Gender and Chronic Pain

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

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

Spirituality and Chronic Pain

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

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

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

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15. Level I Management: Neuropathic Pain

The first principle guiding any therapy is to eliminate the underlying causes of pain to the greatest possible extent with disease-specific measures *(Belgrade, 2003 [Guideline])*. 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.

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

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 and is used as a standard therapy for muscle pain.

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

Local or Regional Therapies

Topical therapies can be applied to localized peripheral tissues to reduce pain without significant systemic effects. Topical capsaicin applied three or four times per day can deactivate local C-polymodal nociceptors at the vanilloid receptor and reduce pathological pain. It has been studied in diabetic neuropathy *(The Capsaicin Study Group, 1991 [High Quality Evidence])* and postherpetic neuralgia *(Fusco, 1997 [Low Quality Evidence])*. 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 [Moderate Quality Evidence])*. Transcutaneous electrical nerve stimulation and other stimulation-based therapies can provide temporary relief in some cases of neuropathic pain caused by nerve root or plexus lesions, but such therapies may also be irritating, particularly when allodynia is present. In such cases, application of the stimulating electrode in adjacent, uninvolved dermatomes may be effective and better tolerated.

Drug Therapies for Neuropathic Pain

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

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

Other anticonvulsants have been utilized in neuropathic pain with variable success. Carbamazepine is still considered a good initial choice for idiopathic trigeminal neuralgia, but there is a lack of evidence of consistent success in other pain states. Oxcarbazepine is chemically similar to carbamazepine and may have benefits in the treatment of neuropathic pain, including trigeminal neuralgia.

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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 [Low Quality Evidence])*, painful HIV-associated neuropathy *(Simpson, 2000 [Low Quality Evidence])*, and complex regional pain syndrome type I *(McCleane, 2000 [Low Quality Evidence])*. Clonazepam, a benzodiazepine, is used by many providers for nocturnally predominant pain.

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

Although most opioids are not known to work through antineuropathic mechanisms, they are nevertheless potent analgesics. They have a role in reliable patients when other measures fail. Careful patient selection is critical to success with long-term opioid therapy. Two opioids, methadone and tramadol, may be more effective than others in neuropathic pain. Due to the complexity of dosing and potential for cardiac adverse effects, the use of methadone should be reserved for experienced practitioners. FDA-required information in the product labeling for methadone states, "Methadone has been associated with QTc interval prolongation and other cardiac adverse effects including hypotension and other cardiac dysrythmias. Patients should have a baseline ECG prior to initiation of methadone, which is repeated after 30 days and then annually. More frequent ECG monitoring should be done when methadone doses exceed 100 mg per day." See Appendix G, "Opioid Analgesics," for more information. Additionally, methadone possesses inhibitory properties at the N-methyl D-aspartate (NMDA) receptor in the spinal cord. The NMDA receptor is involved in central sensitization, windup, neurogenic hyperalgesia, and development of opioid tolerance. Thus, agents that block the NMDA receptor (such as methadone and dextromethorphan) may have antineuropathic pain properties. Tramadol is a weak opioid analgesic that also causes serotonin reuptake inhibition similar to that seen with the tricyclic antidepressants. This dual mechanism may make it advantageous for management of neuropathic pain or mixed pain disorders. At the time of this revision, tapentadol, a new opioid analgesic with norepinephrine reuptake inhibition properties, has just been released with an indication for the treatment of acute pain. Its role in chronic pain and neuropathic pain in particular remains to be clarified.

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16. Level I Management: Muscle Pain

- Currently, scientific evidence of the effectiveness of treatment is for muscle pain, such as diffuse non-specific myalgias, is lacking. Well-designed randomized controlled trials with long-term follow-up are necessary. The American Pain Society notes that "there is insufficient evidence to adequately evaluate benefit of local injections, botulinum toxin injection…" *(Chou, 2009 [Guideline])*. In the absence of evidence, the following assessments and treatment will support patient care.
- Screen for serious medical pathology, for psychological and social factors that may delay recovery.
- Use a numeric pain rating and functional scale to determine severity of pain disability.

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

(Rome, 2004 [Low Quality Evidence])

Additional considerations

For patients with fibromyalgia chronic pain, physical rehabilitation is the mainstay of management.

Determine the patient's baseline fitness, and then use a graded exercise program.

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

Invasive procedures lack evidence of efficacy.

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

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

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17. Level I Management: Inflammatory Pain

Arthritis, tendonitis and chronic infections are common examples of chronic inflammatory pain. They are associated with swelling and warmth of tissue and sometimes redness of the skin. This type of pain occurs through activation of nociceptors by inflammatory mediators like prostaglandins and can also become chronic through a process of sensitization. Treatment should start with efforts to control the inflammation and its causes when possible. NSAIDs, corticosteroids are the main anti-inflammatory agents. Consider a rheumatology consult if clinically indicated.

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18. Level I Management: Mechanical/Compressive Pain

Mechanical/compressive pain refers to tumors or cysts that may compress pain sensitive structures. Dislocations, instabilities, fractures, etc., may also cause a strain on pain sensitive structures. These causes of persistent pain may be effectively treated with surgical decompression or stabilization, splinting, strengthening and use of assistive devices can all address mechanical pain. Medications play a less prominent role and tend to be less effective when dealing with mechanical or compressive causes of persistent pain. Opioids may be used to manage the symptoms while other measures are being taken.

Manipulative Therapy and Chronic Pain

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

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19. Level I Other Management

Pharmacologic Management

Recommendations:

- NSAIDs should be used for periodic flare-ups of mild to moderate inflammatory or non-neuropathic pain.
- Clinicians should define the goals of therapy before prescribing medications, and tailor medications to meet the individual goals of each patient.
- Clinicians should identify and treat specific source(s) of pain.
- Clinicians should educate patients about the risks and benefits of all drugs, and watch for and manage side effects.
- For opioid therapy, clinicians should:
  - Use caution before starting a patient on long-term opioid therapy.
  - Follow the 4 A's (Analgesia, Adverse drug reactions, Activity, Adherence) *(Passik, 2000 [Guideline])*.
  - The work group recommends the use of a written opioid agreement for patients anticipated to be on long-term therapy. See Appendix F for an example of an opioid agreement form.

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

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

General Principles for Pharmacologic Management *(Wisconsin Medical Society Task Force on Pain Management, 2004 [Low Quality Evidence])*

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

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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 [Low Quality Evidence])*. Dosage should be restricted to a maximum of 3 grams per 24 hours, including acetaminophen contained in combination opioid products such as hydrocodone with acetaminophen. Acetaminophen should be used cautiously or avoided in patients with liver impairment.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

NSAIDs are indicated for the treatment of mild to moderate inflammatory or non-neuropathic pain. In general, NSAIDs should be used for periodic flair-ups rather than for long-term chronic use. All NSAIDs inhibit the enzyme cyclooxygenase (COX), inhibiting prostaglandin synthesis. The COX-2 inhibitor celecoxib appears to have fewer gastrointestinal side effects.

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

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

Opioids

When is it appropriate to use opioids?

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

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

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

The Four A's

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

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

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

Opioid management

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

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

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

- Webster's Opioid Risk Tool (ORT)
- Screener and Opioid Assessment for Patients in Pain (SOAPP®)
- Current Opioid Misuse Measure (COMM™)
- Prescription Drug Use Questionnaire (PDUQ)

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- Screening Tool for Addiction Risk (STAR)
- Screening Instrument for Substance Abuse Potential (SISAP)
- Pain Medicine Questionnaire (PMQ)

Patients should give informed consent before the start of opioid therapy, and the consent discussion should be documented in the medical record. This discussion should include the low risk of opioid addiction in patients under a physician's care, the necessity of adherence to prescribed dosing, the potential for cognitive impairment when taking the drug alone and/or in combination with sedative/hypnotics, and the likelihood that physical dependence will occur *(Portenoy, 2004 [Guideline])*. Chronic use of opioids has many other potential hazards. These hazards include the potential for addiction, tolerance, hyperalgesia and hyperkatifeia. Rates of overdose and associated deaths are increasing. This is in the context that chronic use of opioids may be effective in pain control in only 30% *(Noble, 2010 [Systematic Review])* of those with chronic pain. Aberrant use of opioids is common occurring in up to 24 % of this population *(Martell, 2007 [Systematic Review])*. In general, use of opioids may delay recovery *(Sjøgren, 2010 [Low Quality Evidence])* from chronic pain and have not been shown to increase function. They may decrease sexual and immune function as well as increase overall mortality rate *(Crofford, 2010 [Reference])*.

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

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

Substance abuse

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

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

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Random drug screens are one tool to monitor compliance with the opioid regimen. Random urine drug screens are used: (1) to check for diversion, seeking evidence the patient is taking the medication being prescribed, (2) to check for drugs of abuse, and (3) to test for the presence of the prescribed drug. Any evidence of street drug use indicates non-compliance with the opioid contract. The patient's opioids are tapered, and he/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, or use of a centralized database to identify and monitor usage (http://www.pmp.pharmacy.state.mn.us/).

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 non-malignant pain. However, careful patient selection and close monitoring of all non-malignant pain patients on chronic opioids is necessary to assess effectiveness and watch for signs of abuse. *[Conclusion Grade III: See Conclusion Grading Worksheet A – Annotation #19 (Chronic Pain and Chemical Use)]*

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

Opioid-independent pain

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

Opioid-induced hyperalgesia

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

Opioids and function

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

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

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Table 4: Considerations for Initiating and Discontinuing Opioid Therapy

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

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

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

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

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

Opioid doses should be titrated up until there is adequate pain relief, but generally not exceeding doses equivalent to morphine 200 mg/day. Rapid escalation of dose or use of higher doses may be a marker for a substance abuse disorder, and high doses are more likely to induce hyperalgesia and possibly immunosuppression *(Chou, 2009 [Guideline])*. Among patients receiving opioids for nonmalignant pain, the daily dose is strongly associated with opioid-related mortality, particularly at doses exceeding this threshold. An average dose of 200 mg or more morphine (or equivalent) was associated with a nearly threefold increase in the risk of opioid-related mortality relative to low doses (< 20 mg of morphine or equivalent). Significant but attenuated increases in opioid-related mortality were also seen with intermediate doses of opioids: 50-99 mg/day of morphine had an odds ratio of 1.92; 100-199 mg/day morphine had an odds ratio of 2.04. Adequate analgesia should be balanced against side effects, which are common in opioid users. Many side

effects are reduced in time due to tolerance. All patients should be on prophylactic bowel regimen including a stimulant laxative and stool softener such as senna and docusate.

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

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

Specific Opioid Characteristics

- Buprenorphine (Butrans) transdermal patch is specifically indicated for use in moderate to severe chronic pain. The patch requires a weekly change and could be used in patients requiring a continuous around-the-clock analgesic for long-term use.
- Codeine often has dose-limiting GI side effects and is therefore not a good choice for chronic use. Patients with multiple CYP2D6 gene copies metabolize codeine to morphine more rapidly (ultra-rapid metabolism), whereas patients who lack functional CYP2D6 genes do not metabolize codeine to morphine and do not experience analgesic effects – 5 to 10% of the Caucasian population. For more information, refer to http://www.micromedex.com.

  A recent FDA advisory has identified that infants of nursing mothers taking codeine may have an increased risk of morphine overdose if mother is an ultra-rapid metabolizer of codeine. When prescribing codeine to nursing mothers, physicians should choose their lowest dose for the shortest period of time and should closely monitor mother-infant pairs. For more information, refer to http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm054717.htm.
- Fentanyl is available in injectable, transdermal patches and transmucosal (lollipop) formulations. The topical patch is dosed every 72 hours, or every 48 hours if end-of-dose failure is seen at higher doses. It may be beneficial for use in a patient not compliant with more frequent oral-dosing regimens, and gives more control over the supply of opioid and lessens abuse potential in a high-risk patient. Transdermal fentanyl serum levels rise gradually over 12-24 hours. When removed, the half-life of the drug is 17 hours, and the patient should be monitored for opioid adverse effects for at least 24 hours. Patients should have alternative analgesics for initial pain control until fentanyl reaches steady-state levels.

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

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

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

- Hydrocodone is available only in combination with acetaminophen, and doses should be monitored to not exceed 4 grams acetaminophen per day.
- Hydromorphone is available in rapid-release oral and injectable dosage forms.
- Meperidine is metabolized to an active metabolite normeperidine, which has neurotoxic side effects. It is not an appropriate choice for chronic use.
- Morphine is available in rapid-acting and long-acting oral, injectable and rectal dosage forms. There are 12-hour sustained-release and 24-hour sustained-release dosage forms of morphine available.
- Methadone has a long half-life, initially 12-16 hours but may be 90-120 hours after one week of therapy. Due to the complexity of dosing and potential for cardiac adverse effects, the use of this opiate should be reserved for experienced practitioners. Methadone has been associated with QTc interval prolongation and other cardiac adverse effects including hypotension and other cardiac dysrythmias. Patients should have a baseline ECG prior to initiation of methadone, which is repeated after 30 days and then annually. More frequent ECG monitoring should be done when methadone doses exceed 100 mg per day *(Krantz, 2009 [Low Quality Evidence])*.
- Oxycodone is available in short-acting and long-acting dosage forms. A recent FDA warning stated that the concomitant use of oxycodone hydrochloride controlled-release tablets with all CYP3A4 inhibitors such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole) and protease inhibitors (e.g., ritonavir) may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression. Patients receiving oxycodone controlled-release tablets and a CYP3A4 inhibitors should be carefully monitored for an extended period of time, and dose adjustment should be made if warranted.
- 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, while rare, may occur when using seratonin-enhancing medications including anti-migraine, and anti-migraine and cyclobenzaprine.

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

Tricyclic Antidepressants (TCAs)

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

- Analgesic effects of TCAs are independent of their antidepressant effect, and analgesia may be seen with lower doses.
- Start low and increase doses gradually over several weeks to months. Maximum analgesic effect may takes several weeks or longer to be seen.

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- Baseline ECG is indicated in patients at risk for cardiac adverse effects.
- Common side effects include sedation, dry mouth, constipation and urinary retention. Use caution in patients with conditions that may be aggravated by TCAs, including heart disease, symptomatic prostatic hypertrophy, neurogenic bladder, dementia and narrow-angle glaucoma.

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

Other Antidepressants – SSRIs and SNRIs

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

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

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

Anticonvulsant or Antiepileptic Drugs

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

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

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

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

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

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

Topical Agents

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

Capsaicin, the active ingredient in the herbal product cayenne, is used topically to deplete the pain mediator substance-P from afferent nociceptive neurons. Topical creams and solutions have been used in treating both

neuropathic pain and arthritic pain. Capsaicin should be applied for at least six weeks to see full benefits. The side effect of local burning is common, and most patients become tolerant after a few days.

(Mason, 2004 [Systematic Review]; Galer, 2002 [High Quality Evidence]; Devers, 2000 [Low Quality Evidence])

Muscle Relaxants and Antispasmodics

Skeletal muscle relaxant may be useful along with analgesics for short-term management of muscle spasms and pain. There is mixed evidence supporting the use of these drugs for long-term use. Some drugs including benzodiazepines and Carisoprodol are centrally acting and carry the risk of physical dependence. Muscle relaxants are more beneficial for acute short-term use and are not recommended for chronic use.

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

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

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

(Borenstein, 1999 [Low Quality Evidence]; Cherkin, 1998 [Low Quality Evidence])

Anxiolytics

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

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

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

(King, 1990 [Low Quality Evidence])

Drugs for Insomnia

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

Tricyclic antidepressants are a good choice in the treatment of insomnia, especially if the patient has anxiety or depression *(Collins, 2000 [Systematic Review]; Sindrup, 2000 [Low Quality Evidence]; Sindrup, 1999 [Low Quality Evidence]; McQuay, 1996 [Systematic Review])*. 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.

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Intervention Management

Recommendations:

- Therapeutic procedures are used to alleviate or reduce chronic pain and should be used in conjunction with a comprehensive treatment plan developed by a chronic pain specialist.
- Interventional techniques should be performed in conjunction with a comprehensive treatment plan that includes pharmacologic, rehabilitative and psychological interventions.
- Many of the Level I procedures provide both diagnostic and therapeutic benefits, while Level II are reserved for patients who have failed conventional treatment.
- Diagnostic procedures are used to identify neural or musculoskeletal structures that are the source of the patient's pain symptoms.
- The role of intervention modalities is different for chronic pain than acute and should be carefully evaluated by a pain specialist.

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

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

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

Level I Diagnostic Procedures

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

Sacroiliac joint injection

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

Transforaminal epidural injection

Transforaminal epidural injections, also referred to as selective nerve root injections, can be used to determine the spinal level that is the source of radicular pain. The risks of cervical transforaminal epidural steroid injections have been well documented in recent case reports *(Beckman, 2006 [Low Quality Evidence]; Tiso, 2004 [Low Quality Evidence]; Furman, 2003 [Low Quality Evidence])*.

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Specifically, cervical transforaminal epidural steroid injections have been associated with spinal cord and brain injuries resulting in permanent neurological deficits and/or death. These adverse events are most likely related to penetration of radicular arteries or the vertebral artery followed by administration of particulate corticosteroids, which results in embolization and severe vasospasm. When this particular procedure is under consideration, it should be performed only by an experienced pain medicine physician with access to and knowledge of the use of appropriate imaging equipment and patient monitoring facilities *(Bogduk, 2008 [Low Quality Evidence])*. Furthermore, non-particulate corticosteroids should be utilized, and this procedure should be performed only in the context of a longitudinal care plan, as directed and coordinated by a pain medicine physician *(Tiso, 2004 [Low Quality Evidence])*.

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 [Guideline]; Walsh, 1990 [Low Quality Evidence])*.

Level I Therapeutic Procedures

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

Facet joint injection

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

Percutaneous radiofrequency neurotomy

Percutaneous radiofrequency (RF) neurotomy (sometimes erroneously referred to as facet rhyzotomy) is a treatment for neck or back pain generated by facet joints. Properly selected candidates for this procedure should experience complete or nearly complete relief of their pain following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves that innervate the pain-generating joint(s). To minimize false-positive results, an equivalent degree of relief of appropriate pharmacologic duration should be carefully documented on two separate occasions, using two different types of local anesthetic. The radiofrequency procedure is performed by placing an insulated needle electrode with an exposed tip adjacent to and in parallel with the medial branch nerves that supply the target joint(s). Radiofrequency current applied to the electrode then heats the adjacent tissues and coagulates the nerve supply to the joint. For the procedure to be effective, multiple lesions must be performed at each nerve location, using electrodes of sufficient diameter. The nerves do regenerate over time, so pain relief is not permanent, but the procedure can be repeated.

Radiofrequency neurotomy can provide pain relief for carefully selected patients, but this procedure should be performed only by an experienced pain medicine physician in the context of a longitudinal and comprehensive care plan. Proper patient selection and appropriate technique in positioning the radiofrequency electrodes are absolutely essential to the success of the procedure *(Bogduk, 2008 [Low Quality Evidence]; Nath, 2008 [A]; Hooten, 2005 [Guideline])*. Controversy in the literature regarding the efficacy of lumbar radiofrequency neurotomy has arisen from fundamentally flawed clinical trials that have used inappropriate patient selection criteria, and improper procedural technique.

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Epidural corticosteroid injections

Epidural corticosteroid injections are one of the most commonly performed interventions for treatment of spinal pain with a radicular component. All epidural injections should be performed by an experienced physician, under fluoroscopic guidance, using contrast injection to detect vascular uptake and to demonstrate the injectate spread pattern. There are three approaches to the epidural space, including a transforaminal, intralaminar and a caudal technique. Limited evidence was found to support the efficacy of this procedure *(Riew, 2000 [High Quality Evidence]; Carette, 1997 [High Quality Evidence]; Dilke, 1973 [High Quality Evidence])*.

Transforaminal epidural injection

Transforaminal epidural injections, also referred to as selective nerve root injections, can be used to determine the spinal level that is the source of radicular pain. The risks of cervical transforaminal epidural steroid injections have been well documented in recent case reports *(Beckman, 2006 [Low Quality Evidence]; Tiso, 2004 [Low Quality Evidence]; Furman, 2003 [Low Quality Evidence]*). Specifically, cervical transforaminal epidural steroid injections have been associated with spinal cord and brain injuries resulting in permanent neurological deficits and/or death. These adverse events have been caused by uptake of particulate corticosteroids into radicular or vertebral arteries, producing embolization, severe vasospasm, and either brain or spinal cord infarction. For cervical procedures, it is recommended that only non-particulate corticosteroids be utilized. These procedures should be performed only by an experienced pain medicine physician with access to and knowledge of the use of appropriate imaging equipment and patient monitoring facilities, and should be performed only in the context of a longitudinal care plan, as directed and coordinated by a pain medicine physician *(Bogduk, 2008 [Low Quality Evidence]; Tiso, 2004 [Low Quality Evidence])*.

Sacroiliac joint injection

The sacroiliac joint is a widely recognized source of low back and buttock pain. Associated symptoms can include lower extremity pain. Diagnostic blocks using local anesthetic can confirm this structure as a source of low back and leg pain. Pain can potentially be generated by the joint capsule, the overlying ligamentous complex, or both. Injection of the sacroiliac joint can be technically challenging, and must be performed by an experienced physician with fluoroscopic guidance, and using contrast to monitor for vascular uptake and to document intra-articular delivery of the injectate. Corticosteroids may be incorporated for potential therapeutic effect, which can benefit a subset of patients.

Complementary Management

Acupuncture

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

Acupuncture is one of the oldest healing practices in existence. The popularity of alternative medicine in the United States has drawn increasing attention to acupuncture and increased scrutiny of its value as a therapeutic tool *(Eisenberg, 1998 [Low Quality Evidence])*. 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

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supportive of it for both primary therapy and adjunctive therapy in a variety of common problems such as nausea, pain, addiction and stroke rehabilitation *(National Institutes of Health, 1997 [Low Quality Evidence])*. Basic scientific research has begun to elucidate the mechanisms of acupuncture analgesia, including the role of endorphins, serotonin and other neurochemicals *(Tavola, 1992 [Moderate Quality Evidence]; Mayer, 1977 [Low Quality Evidence])*.

Herbal products used for pain

Herbal products are widely used and it is important to question patients about their use when taking a medication history. Since many herbal products are not standardized, the content of the ingredients can vary substantially from the label and between lots of the same product *(Gurley, 2000 [Low Quality Evidence])*. Patients are often misinformed and believe that since herbals are natural products, they are safer than prescription medications. Patients who use herbal preparations should be cautioned about adverse effects, drug interactions and the potential impurities of these products *(Miller, 1998 [Guideline]; Winslow, 1998 [Guideline])*.

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

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

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

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

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

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

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

Healing touch

Healing touch (HT), Therapeutic Touch (TT) and Reiki may have a modest effect in pain in adults. Touch therapies for pain relief in adults.

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

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24. Has Enough Been Tried with Level I Management?

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

Reasons for consultation may include:

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

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

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

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

Recommendations:

- 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.

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

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

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

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

The subdivisions of this section are:

- Aims and Measures
  - Measurement Specifications
- Implementation Recommendations
- Resources
- Resources Table

Aims and Measures

1. Improve the function of patients 16 years and older with chronic pain. *(Annotations #2, 14)*

   Measures for accomplishing this aim:

   a. Percentage of patients diagnosed with chronic pain with functional outcome goals documented in medical record.

   b. Percentage of patients diagnosed with chronic pain with referral to physical rehabilitation and/or behavioral management therapy.

   c. Percentage of patients diagnosed with chronic pain with documentation of receiving education regarding their diagnosis of chronic pain, medications, importance of physical activity, and/or any interventional procedures in medical record.

2. Improve the assessment and reassessment of patients 16 years and older with chronic pain diagnosis utilizing the biopsychosocial model. *(Annotations #2, 3, 12)*

   Measures for accomplishing this aim:

   a. Percentage of patients with chronic pain diagnosis with documentation of a pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan.

   b. Percentage of patients diagnosed with chronic pain with documentation of reassessment of pain at follow-up visits using a standardized tool that addresses pain intensity, location, pattern and current functional status.

   c. Percentage of patients diagnosed with chronic pain with documentation of screening for major depression and chemical dependency.

3. Improve the appropriate use of Level I and Level II treatment approaches for patients 16 years and older with chronic pain. *(Annotations #14, 19, 25)*

   Measures for accomplishing this aim:

   a. Percentage of patients diagnosed with chronic pain who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management, and pain reduction in medical record and identifies potential barriers to patient follow-up on plan of care.

   b. Percentage of chronic pain patients who are referred to diagnostic and/or therapeutic procedures if the goals for pain control or functional status have not been met.

   c. Percentage of patients diagnosed with chronic pain who have not met pain control or functional status goals who are referred to pain specialist or interdisciplinary pain team.

4. Improve the effective use of non-opioid medications in the treatment of patients 16 years and older with chronic pain. *(Annotations #15, 19)*

   Measure for accomplishing this aim:

   a. Percentage of patients diagnosed with chronic pain with a diagnosis of neuropathic pain who are prescribed a tricyclic antidepressant OR anticonvulsant prior to use of opioids.

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5. Improve the effective use of opioid medications in the treatment of patients 16 years and older with chronic pain. *(Annotations #15, 19)*

   Measures for accomplishing this aim:

   a. Percentage of patients diagnosed with chronic pain who are receiving opioids who have documentation of the four A's assessment: 1) the degree of analgesia, 2) current opioid-related side effects, 3) current functional status, and 4) existence of aberrant drug-related behaviors documented at each visit.

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

   c. Percentage of patients diagnosed with chronic pain who are screened for chemical dependency before being prescribed opioid medication.

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Measurement Specifications

Measurement #1a

Percentage of patients diagnosed with chronic pain with functional outcome goals documented in medical record.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients with functional outcome goals documented in medical record}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients with functional outcome goals documented in medical record.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients who have functional outcome goals documented in the medical record.

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Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is an outcome measure, and improvement is noted as increase in the rate.

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Measurement #1b

Percentage of patients diagnosed with chronic pain with referral to physical rehabilitation and/or behavioral management therapy.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients with referral to physical rehabilitation and/or behavioral management therapy}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients with referral to physical rehabilitation and/or behavioral management therapy.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients with referral to physical rehabilitation and/or behavioral management therapy.

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Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #1c

Percentage of patients diagnosed with chronic pain with documentation of receiving education regarding their diagnosis of chronic pain, medications, importance of physical activity and/or any interventional procedures in medical record.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients with documentation of receiving education regarding their diagnosis of chronic pain, medications, importance of physical activity and/or any interventional procedures in medical record}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients with documentation of receiving education regarding their diagnosis of chronic pain, medications, importance of physical activity, and/or any interventional procedures in medical record.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients with documentation of receiving education regarding their diagnosis of chronic pain, medications, importance of physical activity, and/or any interventional procedures in medical record.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #2a

Percentage of patients with chronic pain diagnosis with documentation of a pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients with pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients with documentation of a pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients with documentation of a pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #2b

Percentage of patients diagnosed with chronic pain with documentation of reassessment of pain at follow-up visits using a standardized tool that addresses pain intensity, location, pattern and current functional status.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients with documentation of reassessment of pain at follow-up visits using a standardized tool that addresses pain intensity, location, pattern and current functional status}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients with with documentation of reassessment of pain at follow-up visits using a standardized tool that addresses pain intensity, location, pattern and current functional status.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients with documentation of a pain assessment completed at initial visit using a standardized tool that addresses pain intensity, location, pattern, mechanism of pain, current functional status and follow-up plan.

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Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #2c

Percentage of patients diagnosed with chronic pain with documentation of screening for major depression and chemical dependency.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients with documentation of screening for major depression and chemical dependency}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients with with documentation of screening for major depression and chemical dependency.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

Method/Source of Data Collection

Identify the number of patients with denominator ICD-9 diagnoses. Out of this number, determine from medical records the number of patients with documentation of screening for major depression and chemical dependency.

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Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #3a

Percentage of patients diagnosed with chronic pain who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management and pain reduction in medical record and identifies potential barriers to patient follow-up on plan of care.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

of patients who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management and pain reduction in medical record and identifies potential barriers to patient follow-up on plan of care

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# of patients with chronic pain diagnosis

Numerator/Denominator Definitions

Numerator: Number of patients diagnosed with chronic pain who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management and pain reduction in medical record and identifies potential barriers to patient follow-up on plan of care.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management, and pain reduction in medical record and identifies potential barriers to patient follow-up on plan of care.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #3b

Percentage of chronic pain patients who are referred to diagnostic and/or therapeutic procedures if the goals for pain control or functional status have not been met.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients who are referred to diagnostic and/or therapeutic procedures if the goals for pain control or functional status have not been met}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients diagnosed with chronic pain who have documentation of a plan of care that addresses personal goals, sleep, physical activity, stress management and pain reduction in medical record and identifies potential barriers to patient follow-up on plan of care.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients who are referred to diagnostic and/or therapeutic procedures if the goals for pain control or functional status have not been met.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #3c

Percentage of patients diagnosed with chronic pain who have not met pain control or functional status goals who are referred to pain specialist or interdisciplinary pain team.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients who have not met pain control or functional status goals who are referred to pain specialist or interdisciplinary pain team}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients who have not met pain control or functional status goals who are referred to pain specialist or interdisciplinary pain team.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients who have not met pain control or functional status goals who are referred to pain specialist or interdisciplinary pain team.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #4a

Percentage of patients diagnosed with chronic pain with a diagnosis of neuropathic pain who are prescribed a tricyclic antidepressant OR anticonvulsant prior to use of opioids.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients with a diagnosis of neuropathic pain who are prescribed a tricyclic antidepressant OR anticonvulsant prior to use of opioids}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients who have not met pain control or functional status goals who are referred to pain specialist or interdisciplinary pain team.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients with a diagnosis of neuropathic pain who are prescribed a tricyclic antidepressant OR anticonvulsant prior to use of opioids.

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Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #5a

Percentage of patients diagnosed with chronic pain who are receiving opioids who have documentation of the four A's assessment: 1) the degree of analgesia, 2) current opioid-related side effects, 3) current functional status and 4) existence of aberrant drug-related behaviors documented at each visit.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients who are receiving opioids who have documentation of the four A's assessment: 1) the degree of analgesia, 2) current opioid-related side effects, 3) current functional status and 4) existence of aberrant drug-related behaviors documented at each visit}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients who are receiving opioids who have documentation of the four A's assessment: 1) the degree of analgesia, 2) current opioid-related side effects, 3) current functional status and 4) existence of aberrant drug-related behaviors documented at each visit.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients who are receiving opioids who have documentation of the four A's assessment: 1) the degree of analgesia, 2) current opioid-related side effects, 3) current functional status and 4) existence of aberrant drug-related behaviors documented at each visit.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #5b

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

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Measurement #5c

Percentage of patients diagnosed with chronic pain who are screened for chemical dependency before being prescribed opioid medication.

Population Definition

Patients 16 years and older diagnosed with chronic pain.

Data of Interest

$$\frac{\text{\# of patients diagnosed with chronic pain who are screened for chemical dependency before being prescribed opioid medication}}{\text{\# of patients with chronic pain diagnosis}}$$

Numerator/Denominator Definitions

Numerator: Number of patients who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record.

Denominator: Number of patients 16 years and older diagnosed with chronic pain. Include the following ICD-9 diagnoses:

- Chronic Pain: 338.xx
- Cervical and Lumbar Pain: 720.x, 721.x, 722.x, 723.x, 724.x, 847.x
- Headache: 307.8x, 784.0
- Other disorders of soft tissues: 729.x
- Myalgia and myositis, unspecified fibromyositis, NOS: 729.1

Definitions

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

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Method/Source of Data Collection

Identify patients with denominator ICD-9 diagnoses. Then of those patients, determine from medical records the number of patients who are screened for chemical dependency before being prescribed opioid medication.

Time Frame Pertaining to Data Collection

Monthly.

Notes

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

This is a process measure, and improvement is noted as increase in the rate.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

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

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

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9. Identify multidimensional pain assessment, functional assessment, psychological assessment, and opioid assessment tools that meet the needs of the care providers and are appropriate for the patient populations.

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

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

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

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

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Resources

Criteria for Selecting Resources

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

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

Resources Available to ICSI Members Only

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

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

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Resources Table

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

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

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*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	Minnesota Prescription Monitoring Program	Collects prescription data on all controlled substances and provides a database of patients to improve patient care and to reduce the misuse of controlled substances.	Qualified Prescribers, Licensed Pharmacists, Agents or Employees Delegates of the above	http://www.pmp.pharmacy.state.mn.us/
	National Pain Foundation (NPF)	A non-profit 501(c)(3) organization advancing functional recovery of persons in pain through education, support and information. Information, education, and support is provided for individuals and families living with pain. Resources include educational materials on various diseases and conditions, contacts of pain care providers, and a personal pain journal.	Patients and Families	http://www.nationalpainfoundation.org
	PainKnowledge	An interactive educational resource on pain management, sponsored by Professional Postgraduate Services and in part by an educational grant from Endo Pharmaceuticals. Features of PainKnowledge.org include a comprehensive pain management slide library; pain CME activities, including pain newsletters and interactive case studies; physician tools; pain resources; patient handouts; and more.	Health Care Providers	http://www.PainKnowledge.org
	Substance Abuse and Mental Health Services Administration (SAMHSA)	Information on programs and publications for improving the quality and availability of substance abuse prevention, alcohol and drug addiction treatment, and mental health services. Includes information on the CAGE-AID screening tool.	Health Care Professionals	http://www.samhsa.gov

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The subdivisions of this section are:

- Conclusion Grading Worksheet Summary
  - Conclusion Grading Worksheets
- References
- Appendices

Conclusion Grading Worksheet Summary

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

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

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

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

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

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

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

– indicates that these issues have not been adequately addressed;

ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

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

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

Work Group's Conclusion: There is not enough evidence to permit generalizable conclusions regarding the abuse of opioids in chronic non-malignant pain. However, careful patient selection and close monitoring of all non-malignant 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 Veterans 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

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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)*
Zens, 1992	Case series	D	ø	-- 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 non-malignant pain management, with side effects that are comparable to those in treating cancer pain
Mahowald, 2005	Cross-sectional	D	ø	-- 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 Veterans 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 non-malignant pain

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Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – Brief Pain Inventory (Short Form)

STUDY ID# _____ HOSPITAL # _____

DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

Date: _____/_____/_____ Time: _____

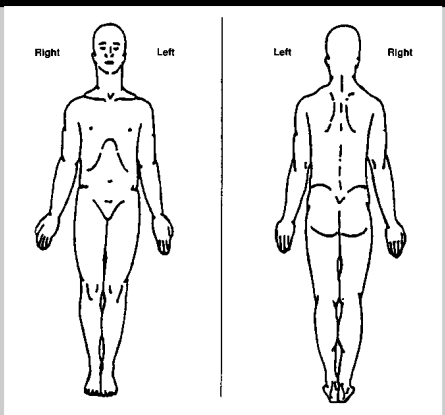
Name: _____ _____ _____

Last First Middlle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

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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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Appendix B – Patient Health Questionnaire (PHQ-9)

Patient Name: _____ Date: _____

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
1. Little interest or pleasure in doing things.	☐	☐	☐	☐
2. Feeling down, depressed, or hopeless.	☐	☐	☐	☐
3. Trouble falling/staying asleep, sleeping too much.	☐	☐	☐	☐
4. Feeling tired or having little energy.	☐	☐	☐	☐
5. Poor appetite or overeating.	☐	☐	☐	☐
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down.	☐	☐	☐	☐
7. Trouble concentrating on things, such as reading the newspaper or watching television.	☐	☐	☐	☐
8. 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.	☐	☐	☐	☐
9. Thoughts that you would be better off dead or of hurting yourself in some way.	☐	☐	☐	☐

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For initial diagnosis:

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

Consider Major Depressive Disorder

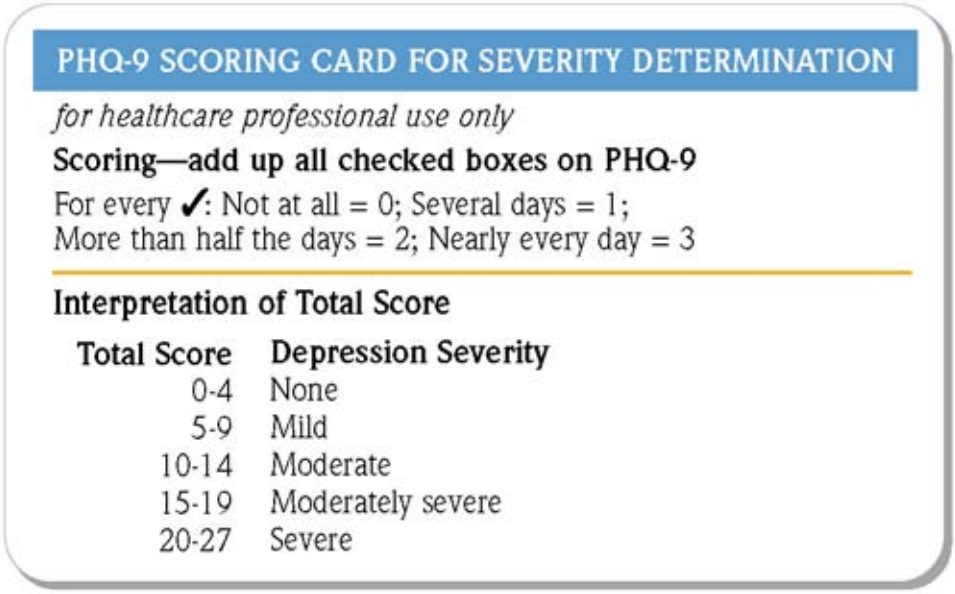
- if there are at least five ✔s in the two right columns (one of which corresponds to Question #1 or #2).

Consider Other Depressive Disorder

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

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

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



PHQ-9 SCORING CARD FOR SEVERITY DETERMINATION

for healthcare professional use only

Scoring—add up all checked boxes on PHQ-9

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

Interpretation of Total Score

Total Score	Depression Severity
0-4	None
5-9	Mild
10-14	Moderate
15-19	Moderately severe
20-27	Severe

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Appendix C – Physical Functional Ability Questionnaire (FAQ5)

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

Name: _____

Date: _____

Date of Birth: _____

MR #: _____

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

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

_____ **Self-care ability assessment**

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

_____ **Family and social ability assessment**

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

_____ **Movement ability assessment**

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

_____ **Lifting ability assessment**

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

_____ **Work ability assessment**

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

_____ **Physical Functional Ability (FAQ5) Score**

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Physical Functional Ability Questionnaire (FAQ5) Information Sheet

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

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

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

The utility of the FAQ5 is greatest in several areas:

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

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

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Appendix D – Personal Care Plan for Chronic Pain

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

1. Set Personal Goals

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

2. Improve Sleep (Goal: _____ hours/night, Current: ____hours/night)

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

3. Increase Physical Activity

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

  Strengthening
  1. Elastic, hand weights, weight machines (____ minutes/day, ____ days/week)

4. Manage Stress – list main stressors _____

- ☐ Formal interventions (counseling or classes, support group or therapy group)
  1. _____
- ☐ Daily practice of relaxation techniques, meditation, yoga, creative activity, service activity, etc.
  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: _____

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

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

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

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

_____Total score = D + I + R + E

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

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Appendix F – Opioid Agreement Form

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** that _____ recommends and will be ready to taper or discontinue the opioid medication as other effective treatments become available.
2. I will take my medications exactly **as prescribed** and will not change the medication dosage or schedule without _____ approval.
3. I will keep **regular appointments** at the clinic.
4. All opioid and other controlled drugs for pain must be prescribed only by _____.
5. If I have **another condition** that requires the prescription of a controlled drug (like narcotics, tranquilizers, barbituates or stimulants), or if I am **hospitalized** for any reason, I will inform the clinic within **one business day**.
6. I will designate **one pharmacy** where all of my prescriptions will be filled.

   Pharmacy Name: _____

   Phone Number: _____

   Fax Number: _____

   Address: _____

   _____
7. I understand that lost or stolen prescriptions will **not be replaced**, and I will not request early refills.
8. I agree to **abstain from all illegal and recreational drugs (including alcohol)** and will provide urine or blood specimens at the doctor's request to monitor my compliance.
9. I am responsible for keeping track of the medication left and plan ahead for arranging refills in a timely manners so that I will not run out of medication.
   - Refills will be made only during regular office hours, which are _____. Refills will not be made at night, on Fridays, weekends or during holidays.
   - Prescriptions will be mailed to my pharmacy. I must plan ahead for mailed prescriptions; it will take at least five days for a prescription to reach my pharmacy after my phone call.

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: _____

Provider Signature: _____ Date:_____

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

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Appendix G – Opioid Analgesics

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

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

(Derby, 1998 [R]; American Pain Society, 2003 [Low Quality Evidence]; Krantz, 2009 [Low Quality Evidence])

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

* This table reflects equianalgesic potencies, not recommended doses.
**** Methadone: Confer with pain specialist before use.**

*****Note:** Despite an FDA-issued Public Health Advisory in July 2005 regarding the appropriate and safe use of the transdermal system, death and life-threatening adverse events related to fentanyl overdose have occurred when the fentanyl patch was used to treat pain in opioid-naive patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The fentanyl patch is only indicated for use in patients with persistent moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are considered to be opioid tolerant.
Patients must avoid exposing the patch to excessive heat as this promotes the release of fentanyl from the patch and increases the absorption of fentanyl through the skin, which can result in fatal overdose. Directions for prescribing and using the fentanyl patch must be followed exactly to prevent death or other serious side effects from fentanyl overdose.

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

Doses of opioids that exceed the equivalent of morphine 200 mg per day should be considered a general limit, with higher doses indicating a possible concern for hyperalgesia or potential for abuse. Consider possible weaning or discontinuation of opiates if assessment indicates reduced analgesia, aberrant drug-related behaviors, or intolerable side effects. Practitioners should consider referral of patients requiring higher doses to chronic pain specialists. Oxycodone 120-180 mg/day and methadone 40 mg/day are approximate equivalents to morphine 200 mg and should be considered as relative maximum doses of these opiates. The concomitant use of oxycodone hydrochloride controlled-release tablets with all CYP3A4 inhibitors such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole) and protease inhibitors (e.g., ritonavir) may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression. Patients receiving oxycodone controlled-release tablets and a CYP3A4 inhibitors should be carefully monitored for an extended period of time and dose adjustment should be made if warranted.

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

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Appendix H – Pharmaceutical Interventions for Neuropathic Pain

Drug	Dosage	Side effects, contraindications, and comments
Daily Medications		
ANTICONVULSANTS		
Gabapentin *	100 to 300 mg at bedtime; increase by 100-300 mg every three days up to 1,800 to 3,600 mg per day taken in divided doses three times daily. Higher doses might be used.	**Initial drug of choice.** Side effects: drowsiness, dizziness, fatigue, nausea, sedation, edema, weight gain. No significant drug-drug interactions. Reduce dose/increase interval in renal failure (give 10x creatinine clearance per day).[1]
Pregabalin *	50 mg - 75 mg twice daily-three times daily to start. Up to 150 mg three times daily.	**Initial drug of choice.** Side effects: drowsiness, dizziness, fatigue, nausea, sedation, edema, weight gain. No drug-drug interactions. Reduce dose/increase interval in renal failure (give 5x creatinine clearance per day). Schedule V medication.[1]
Lamotrigine	25 mg per day; increase by 25 mg - 50 mg every one to two weeks up to 400 mg per day.	Side effects: Stevens-Johnson syndrome, rare life-threatening rash unlikely with gradual dose titration. Dizziness, drowsiness, headache, nausea, blurred/double vision.[1]
Oxcarbazepine	Start 150 mg - 300 mg twice daily. Increase by 600 mg per day each week to maximum 1,200 mg twice daily.	Similar adverse effects to carbamazepine but less likely. Fewer drug-drug interactions.[1]
Carbamazepine *	100 mg - 200 mg twice daily. Increase to maximum 600 mg twice daily.	**Initial drug of choice for trigeminal neuralgia.** Watch for hyponatremia, leucopenia, allergic rash (Stevens-Johnson syndrome). Other side effects: dizziness, drowsiness, blurred/double vision, ataxia. Not favored for other neuropathic pain. Available in extended release.[1,3]
Topiramate	25 mg twice daily to start; increase by 25-50 mg per week up to 200-400 mg per day.	Most evidence is for migraine prevention, other neuropathic pains may respond. Side effects: drowsiness, abnormal thinking, weight loss, urinary tract stones, increased intraocular pressure.[1]
ANTIDEPRESSANTS		
Serotonin & Norepinephrine Reuptake Inhibitors (SNRIs)		
Duloxetine *	20 to 60 mg per day taken once or twice daily in divided doses (for depression); 60 mg twice daily for fibromyalgia.	**Initial drug of choice.** Side effects: nausea, dry mouth, constipation, dizziness, insomnia.[2]
Venlafaxine	37.5 mg per day; increase by 37.5 mg per week up to 225 mg per day.	Side effects: headache, nausea, sweating, sedation, hypertension, seizures. Serotonergic properties in dosages below 150 mg per day; mixed serotonergic and noradrenergic properties in dosages above 150 mg per day. Available in extended-release formulation.[2]
Tricyclic Antidepressants Amitriptyline, Imipramine	10 to 25 mg at bedtime; increase by 10 to 25 mg per week up to 75 to 100 mg at bedtime or a therapeutic drug level.	**Initial drug of choice.** Tertiary amines have greater anticholinergic side effects and may cause arrhythmia, orthostatic hypotension; therefore, these agents should not be used in elderly patients.[2]
Desipramine, Nortriptyline	10 to 25 mg in the morning or at bedtime; increase by 25 mg per week up to 100 mg per day or a therapeutic drug level.	Secondary amines have fewer anticholinergic side effects, but should still be used cautiously in elderly patients.[2]

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

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

[1] FDA alert: Increased risk of suicidal behavior or ideation.

[2] Black box warning: Increased suicidal behavior in young adults

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

[4] Black box warning on oxycodone: the concomitant use of oxycodone hydrochloride controlled-release tablets with all CYP3A4 inhibitors such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole) and protease inhibitors (e.g., ritonavir) may result in an increase in oxycodone plasma concentrations and may cause potentially fatal respiratory depression. Patients receiving oxycodone controlled-release tablets and a CYP3A4 inhibitors should be carefully monitored for an extended period of time and dose adjustment should be made if warranted.

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

This table was completed using the following sources:
Argoff CE, Backonja MM, Belgrade MJ, et al. Consensus guidelines: treatment planning and options. *Mayo Clin Proc* 2006;81:S12-S25. (Guideline)
Chen H, Lamer TJ, Rho R, et.al. Contemporary Management of Neuropathic Pain for the Primary Care Physician. Mayo Clinic Proceedings. December 2004;79(12):1533-45. (Guideline)

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

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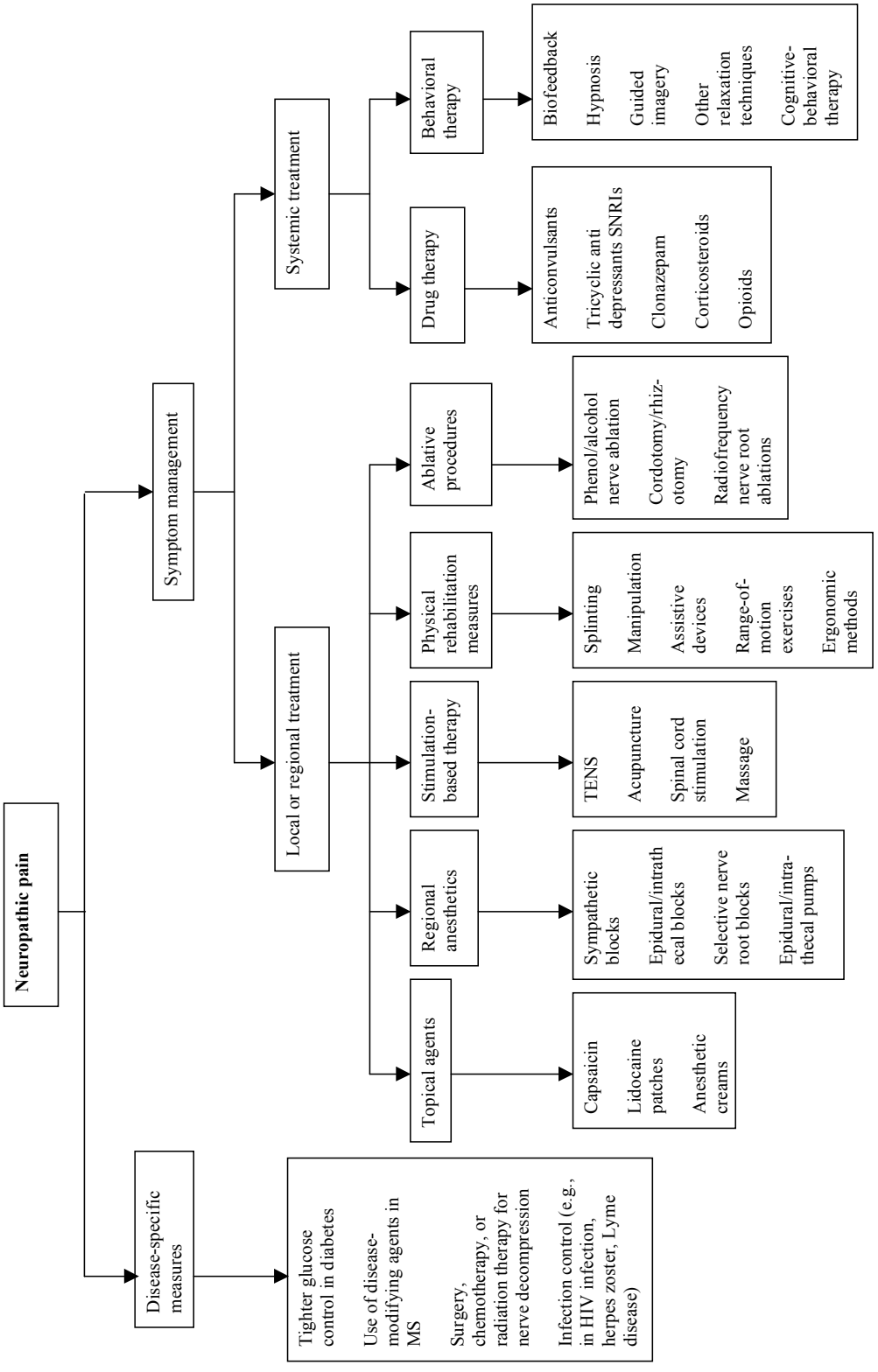
Appendix I – Neuropathic Pain Treatment Diagram



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

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

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

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

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

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- Converted to GRADE methodology for reviewing evidence
- Supporting specific initiative

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Document Development and Revision Process

The development process is based on a number of long-proven approaches. ICSI staff first conducts a literature search to identify pertinent clinical trials, meta-analysis, systematic reviews, regulatory statements and other professional guidelines. The literature is reviewed and graded based on the ICSI Evidence Grading System.

ICSI facilitators identify gaps between current and optimal practices. The work group uses this information to develop or revise the clinical flow and algorithm, drafting of annotations and identification of the literature citations. ICSI staff reviews existing regulatory and standard measures and drafts outcome and process measures for work group consideration. The work group gives consideration to the importance of changing systems and physician behavior so that outcomes such as health status, patient and provider satisfaction, and cost/utilization are maximized.

Medical groups that are members of ICSI, review each guideline as part of the revision process. The medical groups provide feedback on new literature, identify areas needing clarification, offer recommended changes, outline successful implementation strategies and list barriers to implementation. A summary of the feedback from all medical groups is provided to the guideline work group for use in the revision of the guideline.

Implementation Recommendations and Measures

Each guideline includes implementation strategies related to key clinical recommendations. In addition, ICSI offers guideline-derived measures. Assisted by measurement consultants on the guideline development work group, ICSI's measures flow from each guideline's clinical recommendations and implementation strategies. Most regulatory and publicly reported measures are included but, more importantly, measures are recommended to assist medical groups with implementation; thus, both process and outcomes measures are offered.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group mid-cycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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Acknowledgements

ICSI Patient Advisory Council

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Assessment and Management of Chronic Pain and thank them for their suggestion(s).

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

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