Complete Summary

GUIDELINE TITLE

VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain.

BIBLIOGRAPHIC SOURCE(S)

Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar. various p. [51 references]

GUIDELINE STATUS

This is the current release of the guideline.

*** * REGULATORY ALERT * ***

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide

to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web site for more information.

Additional Notice

On July 8, 2005, Janssen and FDA notified healthcare professionals of changes to the BOXED WARNING/WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION sections of the prescribing information for Duragesic. These changes include important safety information in the following areas of the labeling: Use Only in Opioid-Tolerant Patients, Misuse, Abuse and Diversion, Hypoventilation (Respiratory Depression), Interactions with CYP3A4 Inhibitors, Damaged or Cut Patches, Accidental Exposure to Fentanyl, Chronic Pulmonary Disease, Head Injuries and Intracranial Pressure, Interactions with Other CNS Depressants, and Interactions with Alcohol and Drugs of Abuse. See the Food and Drug Administration (FDA) Web site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
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IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Chronic pain

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Anesthesiology
Family Practice
Internal Medicine

Pharmacology
Physical Medicine and Rehabilitation

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To promote evidence-based management of individuals with chronic pain
- To identify the critical decision points in management of patients with chronic pain who are candidates for opioid therapy
- To allow flexibility so that local policies or procedures, such as those regarding referrals to or consultation with substance use specialty, can be accommodated.
- To decrease the development of complications
- To improve patient outcome (i.e., reduce pain, decrease complications, increase functional status, and enhance the quality of life)

TARGET POPULATION

Veterans and Department of Defense beneficiaries with chronic non-cancer pain

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Comprehensive history and physical examination (age, gender, present illness, past medical and surgical history, past psychiatric history, substance use history, family and social history, medications, allergies, mental status examination, review of diagnostic studies, evaluation of occupational risks)
2. Adequate trial of non-opioid therapy
3. Urine drug screen test (UDS)
4. Complete assessment of pain using numerical rating scale (NRS) 0-10
5. Assessment of contraindications to opioid therapy
6. Referral to a pain specialist or multidisciplinary pain clinic for patients with complex pain conditions

Treatment and Management

1. Patient and family education regarding treatment options
2. Written treatment plan agreement that defines the responsibilities of the patient and the provider

3. Identification of appropriate opioid therapy using medication that provides the best pain relief with the fewest adverse effects at the lowest effective dose
4. Timely, accurate, and thorough documentation of drug therapy in compliance with the federal Controlled Substances Act (CSA)
5. Evaluation of treatment plan for adverse effects, patient adherence, and drug efficacy
6. Dosage/agent adjustment for stable pain relief
7. Modification of the treatment plan to achieve minimal harm and adverse effects
8. Discontinuation of opioid therapy in cases of:
    - Diversion (sale or provision of opioids to others)
    - Prescription forgery
    - Stealing or "borrowing" drugs from others
    - Arrest related to opioid or illicit drug or alcohol intoxication or effects
    - Intentional overdose or suicide attempt
    - Aggressive, threatening, or belligerent behavior in the clinic
9. Referral to addiction/substance specialist for redirecting addictive behavior and/or tapering off opioids
10. Appropriate long-term surveillance

<u>Pharmacological Treatment</u>

Short-acting Opioids

1. Codeine (alone or in combination with acetaminophen [APAP] or aspirin (acetylsalicylic acid [ASA])
2. Hydrocodone (in combination with APAP, ASA, or ibuprofen [IBU])
3. Hydromorphone
4. Morphine
5. Oxycodone (alone or in combination with APAP or ASA)
6. Propoxyphene (alone or in combination with APAP)
7. Tramadol (alone or in combination with APAP)

Long-acting Opioids

1. Fentanyl Transdermal System
2. Levorphanol
3. Methadone
4. Morphine Control Release (CR), Sustained Release (SR), Extended Release (ER)
5. Oxycodone Controlled Release

MAJOR OUTCOMES CONSIDERED

- Pain reduction
- Complication rates
- Functional status
- Quality of life
- Adverse effects of therapeutic interventions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The following six documents were identified by the Working Group as appropriate seed guidelines. They served as the starting point for the development of questions and key terms.

- American Academy of Pain Medicine and American Pain Society. The Use of Opioids for the Treatment of Chronic Pain. (1997)
- Canadian Pain Society. Use of opioid analgesics for the treatment of chronic noncancer pain - A consensus statement and guidelines from the Canadian Pain Society. (1998)
- College of Physicians and Surgeons of Ontario. Evidence-Based Recommendations for Medical Management of Chronic Non-Malignant Pain. (2000)
- Harden, R. Norman MD. Chronic Opioid Therapy: Another Reappraisal. (2002)
- Portenoy, R.K. Opioid therapy for chronic nonmalignant pain: a review of the critical issues. (1996)
- Washington State Department of Labor and Industries. Guideline for Outpatient Prescription of Oral Opioids for Injured Workers with Chronic, Noncancer Pain. (2000)

Five researchable questions and associated key terms were developed by the Working Group after orientation to the seed guidelines and to goals that had been identified by the Working Group. The questions specified:

- Population - characteristics of the target population
- Intervention - diagnostic, screening, therapy, and assessment
- Control - the type of control used for comparison
- Outcome - the outcome measure for this intervention (morbidity, mortality, patient satisfaction, and cost)

A systematic search of the literature was conducted for each key question, starting with studies at the top of the hierarchy of study types: evidence-based reviews and clinical trials. In addition to PubMed, the following databases were searched: Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness (DARE), and Cochrane Central Register of Controlled Trials (CCTR). For PubMed, limits were set for language (English), data of publication (1998 through July 2002), and type of research (randomized controlled trial [RCT] and meta-analysis). For the CCTR, limits were set for date of publication (1998 through 2002).

The results of the literature search were organized and reported using reference manager software. At this point, additional exclusion criteria were applied. Typical exclusions were studies with physiological endpoints or studies of populations that were not comparable to the population of interest. Once definitive clinical studies that addressed the question were identified, the search stopped. It was extended to studies/reports of lower quality only if there were no high quality studies.

The Working Group suggested some additional references. Copies of specific articles were provided to participants on an as-needed basis.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

I: At least one properly done randomized controlled trial (RCT)

II-1: Well designed controlled trial without randomization

II-2: Well designed cohort or case-control analytical study

II-3: Multiple time series, dramatic results of uncontrolled experiment

III: Opinion of respected authorities, case reports; and expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Evidence Appraisal Reports for each of the five questions were prepared by the Center for Evidence-Based Practice at the State University of New York, Upstate Medical University, Department of Family Medicine and by ACS staff. (These reports are available by request from the guideline developer.) Each report covered:

- Summary of findings
- Methodology
- Search terms

- Resources searched
- Articles critically appraised
- Findings

The clinical experts and the research team evaluated the evidence for each question according to criteria proposed by the U.S. Preventive Services Task Force (USPSTF) (See Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med. 2001 Apr;20(3 Suppl):21-35. http://www.ahrq.gov/clinic/ajpmsuppl/harris1.htm.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Guideline for the Management of Opioid Therapy for Chronic Pain is the product of many months of diligent effort and consensus building among knowledgeable individuals from the Veterans Administration (VA), Department of Defense (DoD), academia, and guideline facilitators from the private sector. An experienced moderator facilitated the multidisciplinary Working Group, which included primary care physicians, pain specialists, rehabilitation specialists, anesthesiologists, psychiatrists, psychologists, pharmacists, nurses, and social workers, as well as consultants in the field of guideline and algorithm development.

The process of developing this guideline was evidence-based whenever possible. Evidence-based practice integrates clinical expertise with the best available clinical evidence derived from systematic research. Where evidence is ambiguous or conflicting, or where scientific data are lacking, the clinical experience of the multidisciplinary Working Group was used to guide the development of consensus-based recommendations.

The Working Group participated in two face-to-face sessions to reach a consensus about the guideline recommendations and to prepare a draft document. The draft was revised by the experts through numerous conference calls and individual contributions to the document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendation:

A. A strong recommendation that the intervention is always indicated and acceptable

B. A recommendation that the intervention may be useful/effective

C. A recommendation that the intervention may be considered

D. A recommendation that a procedure may be considered not useful/effective or may be harmful

I. Insufficient evidence to recommend for or against - the clinician will use clinical judgment

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline presents evidence-based recommendations that have been thoroughly evaluated by practicing clinicians.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the management of opioid therapy for chronic pain are organized into 1 major algorithm. The algorithm, the objectives and annotations that accompany it, and the evidence supporting the recommendations are presented below. The strength of recommendation grading (A, B, C, D, I), quality of evidence grading (I, II-1, II-2, II-3, III), and overall quality of evidence supporting the recommendations (good, fair, poor), are defined at the end of the "Major Recommendations" field.

Management of Opioid Therapy for Chronic Pain

A. Patient with Chronic Non-cancer Pain

The patient managed within this guideline suffers from chronic non-cancer pain. The patient has been previously assessed and treated, over a period of time, with non-opioid therapy or non-pharmacologic pain therapy. Because the response to treatment has not provided adequate pain relief, the patient is considered to be a candidate for a trial of opioid therapy.

In addition, because of the regulatory restrictions on the prescription of controlled substances, the guideline addresses the special considerations and documentation issues that are required for the safe and effective management of opioid therapy.

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such

damage. The perception of pain is influenced by physiological, psychological, and social factors. The human reaction to the sensory experience, suffering, takes an added dimension in patients who have chronic, non-cancer pain. Some of these patients may have, in addition to the persistent pain, overriding affective components and learned responses that can lead to severe psychological disability and a pattern of repeated interaction with the health care system.

B. History and Physical Examination to Obtain Comprehensive Assessment

Objective

Obtain clinical data required to manage the patient with chronic non-cancer pain.

Recommendations

1. A comprehensive patient assessment should be completed to identify clinical conditions that may interfere with the appropriate and safe use of chronic opioid therapy.

   The comprehensive assessment should include:

   - Age, sex
   - History of present illness, including a complete pain assessment (see Annotation C below)
   - Pain-related history (pain-related fear, pain interference with function, prior pain treatment)
   - Past medical and surgical history
   - Past psychiatric history (including depression, anxiety, other emotional disorders)
   - Substance use history
   - Family history
   - Social history (including employment, cultural background, social network, marital history, and legal history, other behavioral patterns [i.e., impulse behaviors])
   - Review of systems
   - Medications
   - Allergies
   - Physical examination
   - Mental status examination
   - Review of diagnostic studies and assessments
   - Evaluation of occupational risks and ability to perform duty

2. Information from the pain history and physical exam should be reviewed to ensure that the patient has had an adequate trial of non-opioid therapy.

3. Consider the use of a urine drug screen (UDS) or other laboratory tests to screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use.

Evidence

Complete assessment for every patient: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = C (Canadian Pain Society Task Force, 1998; Working Group Consensus)

Assess age: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Herr, 2002; Leipzig et al., 1999; Pappagallo, 1999)

Assess gender: Quality of Evidence = II-1; Overall Quality = Fair; Strength of Recommendation = B (Zacny, 2001)

Consider a Urine Drug Screen (UDS): Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Canadian Pain Society Task Force, 1998; Working Group Consensus)

C. Complete Assessment of Pain; Determine Cause of Pain, If Possible

Objective

Obtain pain-related data required to manage the pain intervention.

Recommendation

1. Pain intensity should be evaluated at each visit.
    - Intensity of pain should be measured using a numerical rating scale (0-10 scale) for each of the following:
        - Current pain
        - Least pain in last week
        - "Usual" or "average" pain in the last week
    - The patient's response to current pain treatments should be assessed at each visit using the following questions:

      (Note: some interventions may temporarily increase pain, so it may not be appropriate to ask these questions.)

        - "What is your intensity of pain after taking (use of) your current treatment/medication?"
        - "How long does your pain relief last after taking your medication?"
    - Other attributes of pain should be assessed as part of the comprehensive pain assessment:
        - Onset and duration
        - Location

        - Description (quality)
        - Aggravating and alleviating factors
        - Behavioral manifestations of pain
        - Impact of pain
        - Current and past treatments for pain
        - Patients' expectations for pain relief
    - If possible, determine type of pain:
        - Differentiate between nociceptive and neuropathic pain
        - Consider further evaluation if needed (such as electromyography [EMG] or consultation)
2. Assessment of function should include:
    - Cognitive function (attention, memory, and concentration)
    - Employment
    - Enjoyment of life
    - Emotional distress (depression and anxiety)
    - Housework, chores, hobbies, etc.
    - Sleep
    - Mobility
    - Self-care behaviors
    - Sexual function
3. Information from the pain history and physical exam should be reviewed to ensure that the patient has had an adequate trial of non-opioid therapy.

Evidence

Evaluate pain intensity using 0-10 scales: Quality of Evidence = II-2; Overall Quality = Fair; Strength of Recommendation = B (Breivik & Skoglung, 1998; De Conno et al., 1994; Jensen et al., 1996; Ogon et al., 1996; Serlin et al., 1995)

Evaluate function related to pain: Quality of Evidence = I, III; Overall Quality = Good; Strength of Recommendation = A (Caldwell et al., 1999; Jensen et al., 1992; Peloso et al., 2000; Roth et al., 2000)

If possible, determine type of pain: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

D. Are There Contraindications to Opioid Therapy That Cannot Be Resolved?

Objective

Avoid inappropriate or harmful therapy.

Recommendations

1. Opioid therapy should not be used in the following situations (absolute contraindications):
    - Allergy to opioid agents (may be resolved by switching agents)
    - Co-administration of drug capable of inducing life-limiting drug-drug interaction
    - Active diversion of controlled substances (providing the medication to someone for whom it was not intended)
2. Opioid therapy should be used only after careful consideration of the risks and benefits (relative contraindications):
    - Acute psychiatric instability or high suicide risk
    - History of intolerance, serious adverse effects, or lack of efficacy of opioid therapy
    - Meets Diagnostic and Statistical Manual - Version IV (DSM-IV) criteria for current substance use disorder
    - Inability to manage opioid therapy responsibly (e.g., cognitively impaired)
    - Unwillingness or inability to comply with treatment plan
    - Unwillingness to adjust at-risk activities resulting in serious re-injury
    - Social instability
    - Patient with sleep apnea not on Continuous Positive Airway Pressure (CPAP)
    - Elderly patients
    - Chronic obstructive pulmonary disease (COPD) patients
3. Consider consultation with an appropriate specialist if legal or clinical problems indicate that more intensive care related to opioid management is indicated. A patient with substance use problem should be referred to a substance use specialty for concurrent treatment of substance use.

Evidence

Absolute contraindications to opioid therapy: (Legal)

Relative contraindications to opioid therapy: Quality of Evidence = I, III; Overall Quality = Fair; Strength of Recommendation = C (Harden, 2002; Joranson et al., 1992; Becker et al., 2000; Large & Schug, 1995; Working Group Consensus)

Consultation with an addiction specialist: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

E. Indication for Referral/Consultation?

Objective

Assure appropriate care for complicated chronic pain patients.

Recommendations

1. The patient with complex pain conditions should be referred to a pain specialist for evaluation and treatment.
2. The patient with long-standing pain problems or multiple issues beyond pain alone should be referred to a multidisciplinary pain clinic for evaluation and treatment.
3. In the patient with a history of addiction or substance use disorder, or if drug screens are indicative of a drug or alcohol use problem, consider consultation with an addiction specialist to evaluate the risk of recurrent substance abuse or to assist with ongoing management.

Evidence

Refer to pain specialist: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Refer to multidisciplinary pain clinic: Quality of Evidence = I; Overall Quality = Fair; Strength of Recommendation = B (Becker et al., 2000; Flor, Fydrick, & Turk, 1992; Malone, Strube, & Scogin, 1988; Guzman et al., 2001)

Refer to substance abuse specialist: Quality of Evidence = II-III; Overall Quality = Fair; Strength of Recommendation = C (Dunbar & Katz, 1996; Working Group Consensus)

F. Is Opioid Therapy Indicated at This Time?

Objective

Consider opioid therapy for suitable candidates.

Recommendations

1. The use of opioid therapy is indicated for moderate to severe pain that has failed to adequately respond to other non-opioid therapeutic interventions.
2. The ethical imperative to relieve pain should be considered when evaluating therapeutic options.

Evidence

Opioid therapy is indicated for moderate to severe pain that has failed other therapeutic interventions: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Breivik, 2001)

Consider the ethical imperative to relieve pain: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Joranson et al., 2002; Laval et al., 2002)

G. Educate Patient and Family about Treatment Options; Share Decision about Goal and Expected Outcome of Therapy

Objective

Reduce barriers and address concerns regarding opioids so that the patient and caregiver/family can make informed decisions about pain management, patient outcomes, and adherence to therapy.

Recommendations

1. The patient and family/caregiver should be involved in the educational process.
2. Written educational material should be provided in addition to discussion with patient/family.
3. The opioid agreement should be discussed in detail (See Annotation H).
4. Patient education should be documented in the medical record.
5. The following topics should be included (See also Appendix B: Patient Education in the original guideline document):
    - General information: goals and expectations, addiction, tolerance, physical dependency, withdrawal symptoms
    - Patient responsibilities: prescriptions, adherence to treatment plan, obtaining medications from a single source, pain diary, feedback to the provider
    - Legal issues
    - Instruction on how to take medication: importance of dosing and timing, interaction with other drugs
    - Prophylactic treatment of adverse effects and management of constipation

Evidence

Education of patient and family/caregiver in an interactive and written format: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Brown et al., 1996; Cohen, Chopra, & Upshur, 2001; Hancock & Burrow, 2002; Jacobson et al., 1996; Knight & Avorn, 2001; McCaffery & Pasero, 1998)

Discussion of the opioid agreement: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Documentation of patient and family education in the medical record: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

H. Obtain a Treatment Agreement

Objective

Define the responsibilities of the patient and the provider for the management of the chronic opioid therapy.

Recommendations

1. A patient consent in the form of a written treatment agreement should be obtained before initiating opioid therapy. The patient's responsibilities during therapy should be discussed with patient and family, addressing the following issues (for a sample agreement see Appendix C in the original guideline document):
    - Goals of therapy -- Partial relief and improvement in physical, emotional, and/or social functioning
    - The requirement for a single provider or treatment team
    - The limitation on dose and number of prescribed medications and the proscription against changing dosage without permission; discuss the use of "pill counts"
    - A prohibition on use with alcohol, other sedating medications, or illegal medications without discussing with provider
    - Agreement not to drive or operate heavy machinery until medication-related drowsiness is cleared
    - Responsibility to keep medication safe and secure
    - Prohibition of selling, lending, sharing, or giving any medication to others
    - Limitation on refills: only by appointment, in person, and no extra refills for running out early
    - Compliance with all components of overall treatment plan (including consultations and referrals)
    - The role of urine drug screening, alcohol testing
    - Acknowledgement of adverse-effects and safety issues such as the risk of dependence and addictive behaviors
    - The option of sharing information with family members and other providers, as necessary
    - Need for periodic re-evaluation of treatment
    - Consequences of non adherence

Evidence

Discuss opioid use issues with patient and obtain patient's consent in writing: Quality of Evidence = II, III; Overall Quality = Fair; Strength of Recommendation = C (Burchman & Pagel, 1995; Dunbar & Katz, 1996; Fishman et al., 2000; Fishman et al., 1999; Kirkpatrick et al., 1994)

Use of written patient opioid agreement: Quality of Evidence = II, III; Overall Quality = Fair; Strength of Recommendation = C (Burchman & Pagel, 1995; Dunbar & Katz, 1996; Fishman et al., 1999; Kirkpatrick et al., 1994)

I. Determine and Document Treatment Plan

Objective

Identify and describe key elements of the opioid treatment plan.

Recommendation

1. The treatment plan should be individually tailored to the patient's circumstances and to the characteristics of the patient's pain.
2. Consider the use of other treatment approaches (supervised therapeutic exercise, biofeedback, and cognitive behavior approaches), which should be coordinated with the opioid therapy.
3. Consider establishing a referral and interdisciplinary team approach, if indicated.
4. Establish a follow-up schedule to monitor the treatment and patient progress.
5. The treatment plan and patient preferences should be documented in the medical record.

Evidence

A treatment plan that has been individually tailored to the patient's circumstances and the characteristics of the patient's pain: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Canadian Pain Society Task Force, 1998)

The use of other treatment approaches, which should be coordinated with the opioid therapy: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Frost et al., 1998; Kuukkanen & Malkia, 1998; Moffett et al., 1999; Crider & Glaros, 1999; Stetter & Kupper, 2002)

A referral and multidisciplinary team approach: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Regular monitoring of the treatment process and patient progress: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Documentation of the treatment plan and patient preferences in the medical record: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

J. Candidate for Opioid Therapy, with Consent

Opioid therapy can be initiated in the form of a therapeutic trial. Prior to such a trial, the patient should be fully informed and should consent to the therapy. As treatment is administered, close monitoring of outcomes (pain relief, adverse effects, physical and psychosocial functioning, or any aberrant drug-related behaviors) along with careful titration, can establish successful long-term therapy.

A trial of opioid therapy consists of several phases: initiation, titration, and maintenance. The initiation phase involves selecting an appropriate opioid agent and dose for the individual patient, after considering the information obtained in the comprehensive assessment of the patient. The titration phase involves adjustment of the dosage to achieve the desired clinical outcomes (pain relief and improved function with minimal or tolerable adverse effects). During this phase, a lack of response despite dose escalation may indicate that the patient has opioid non-responsive pain and opioid therapy should be discontinued (see Annotation W below). The patient has entered the maintenance phase when the required daily dose remains relatively stable. This may be the longest phase of opioid therapy. Worsening pain after a period of stable evaluation maintenance may indicate disease progression, increased activity level, environmental factors (exposure to cold or reduced barometric pressure), development of psychosocial stressors, tolerance, or development of hyperalgesia. Additional evaluation may be indicated to determine the cause. Supplemental doses of non-opioids, short-acting opioids, or both should be considered during treatment (see Appendix E, Table E5 in the original guideline document).

With repeated administration of opioids, the patient will develop certain expected responses, including opioid tolerance and physical dependence.

During the opioid trial, a patient with opioid responsive pain (e.g., osteoarthritis) will obtain pain relief with initiation and titration of treatment. Over time, the patient may require a larger dose of medication to achieve the same degree of pain relief possibly because of tolerance, or because of increase in activity level as a result of initial pain relief. Physical dependence may be manifested as symptoms of withdrawal upon rapid taper or abrupt discontinuation of medication, which may arise when the patient forgets to pack medication when traveling away from home. Tolerance and withdrawal are two of the criteria for a potential diagnosis of substance dependency, but should not (per the DSM-IV) apply in the context of a patient receiving prescribed opioids on a chronic basis.

Addiction and pseudo-addiction are behaviors a patient may or may not develop. Repeated exposure to opioids in the context of pain treatment only rarely causes addiction. There are a variety of biological, psychological, social, and spiritual factors that may increase the risk of addiction in susceptible patients who are prescribed opioid therapy. Tolerance to the analgesic effects of opioids may occur with regular therapeutic use in some patients. Most people taking opioids regularly will have characteristic withdrawal symptoms in the event of abrupt cessation or rapid taper.

The distinction between addiction and physical dependence (i.e., tolerance and/or withdrawal) means that clinicians should never label patients who are presumed to be at risk for a withdrawal syndrome (that is, physically dependent) as addicted. Such a description

misrepresents the situation and stigmatizes the patient. For the same reason, use of the imprecise general term dependent should be avoided.

K. Initiate Trial of Opioid Therapy

Recommendations

Initiation Phase

Objective

To find the medication(s) that provides the best pain relief with the fewest adverse effects at the lowest effective dose

Effective therapy is achieved when the patient reports improvement in pain relief and/or function along with minimal or acceptable adverse effects.

The general strategy for the initiation phase:

1. For intermittent pain begin with short-acting opioids (such as morphine, oxycodone, or hydrocodone), trying one medication at a time.
2. For continuous pain an agent with a long duration of action, such as controlled-release morphine or methadone is recommended.
3. A trial should be considered for either nociceptive or neuropathic pain. Neuropathic pain often requires higher doses of medication than nociceptive pain.
4. Begin with a low test-dose to make sure that the medication has no serious or intolerable adverse effects. Administration by the least invasive route is recommended; oral administration is preferred.
5. For patients with specific medical conditions, choice of agent will depend on route and special cautions. Preferred choices are suggested in Table 2 in the original guideline document, "Use of Opioids for Chronic Pain in Special Populations."
6. In opioid-naïve patients, one medication should be tried at a time, with frequent evaluations to titrate the dose. Patients with prior experience with opioid medications for pain relief should use the medication that worked well in the past, at the dose to which the patient was accustomed.
7. Education that addresses anticipated adverse effects, the use of medication, and symptoms of opioid withdrawal should be provided to the patient and family.
8. Constipation, which is anticipated with all opioids, should be treated prophylactically.
9. Failure to show partial analgesia with incremental dose titration may be evidence for pain that is not opioid responsive and suggests that the opioid therapy should be discontinued.

There is no evidence of the superiority of long- over short-acting opioids with respect to pain relief, adverse effects, or the rate at which tolerance develops. Generally, long-acting medications, with the exception of methadone, are more expensive than their short-acting versions. Patient preferences, in terms of prescription regimen, number of pills per day, etc., are factors that affect that decision.

Titration Phase

Objective

To adjust the dose of opioid to achieve satisfactory pain relief and tolerable adverse effect profile

Once a medication has been found that provides pain relief, it is likely to continue to provide pain relief, as long as the dose is increased to compensate for analgesic tolerance if it develops.

Opioids almost always need to be titrated upwards, and effective doses are commonly higher than the starting dose. The eventual dose must be one at which the clinician can comfortably maintain the patient. Personal discomfort by the clinician at the apparent level of opioid requirement is a valid reason not to proceed and may warrant the referral of the patient to a physician who has more expertise in chronic pain management.

The general strategy for the titration phase:

10. Once a pain relief response has been achieved at a particular dose, repeat that dose as the level of pain begins to rise; this approach helps establish the dosing interval.
11. If necessary, the initial daily dose may be increased by 25 to 100%. If the new dose is well tolerated but ineffective, additional increases in dose can be considered. See R3 below for dosage titration recommendations.
12. As the patient develops tolerance, adverse effects noted during the initial period of exposure to a medication are likely to disappear.
13. If a medication provides less than satisfactory pain relief or uncontrollable adverse effects, consider rotating to an alternate opioid medication.
14. In general, there is no pharmacological rationale for using a predetermined maximal dose for pure agonist opioids. Long-term opioid therapy should be started at a low dose and carefully titrated until an adequate level of analgesia is obtained or until unmanageable and persistent adverse effects warrant a decreased dose or a change in therapy. For some patients, however, opioids do not exert an appreciable analgesic effect until a threshold dose has been achieved.
15. If short-acting medications are effective and well tolerated, it may be possible to achieve equivalent pain relief with fewer daily doses of medication by substituting an equivalent dose of

long-acting opioid medication (such as methadone, morphine controlled release [CR], or oxycodone controlled release). These long-acting medications may provide steadier serum levels and smoother pain control and can be supplemented with doses of short-acting medication to control pain exacerbation.

16. During the titration phase, reasonable doses of rescue opioid may be provided and can be used to assess the adequacy of the overall opioid dose (see Appendix E, Table E-5 in the original guideline document).
17. The conversion to a long-acting opioid should be based on an equianalgesic conversion (see Appendix E, Table E3 in the original guideline document for conversion factors) and consideration of the incomplete cross-tolerance between opioids. To allow for incomplete cross-tolerance, in most cases the starting conversion dose should be 50 to 67% of the calculated equianalgesic dose.
18. Precise record keeping of the time and dose of medication, the degree of pain relief, and the occurrence of adverse effects is essential for successful titration. Maintaining close communication with patients and families and explicitly laying out the criteria for evaluating the effects of analgesic medications can help in defusing the anxiety that often accompanies visits to the physician.

The daily consumption of the rescue drug can be an indicator of the adequacy of the sustained-release drug. By titrating the sustained-release drug accordingly, the minimum dose needed to ameliorate the pain can usually be quickly established. Patients sometimes do well at the beginning of opioid therapy and then seem to lose ground within a few weeks. In those who have been severely limited in their activities, the recurrence of pain is not necessarily a sign of growing tolerance to the medication; the patient may be experiencing more pain because of increased activity. In this case, the patient can be reassured that more medication is required to alleviate the pain of someone with a busy schedule than of someone lying in bed all day.

Maintenance Phase

Objective

To maintain reliable pain control and improvement in function by repeating the effective dose in a routine schedule, varying the timing or dose only to accommodate changes in activity level or exacerbations of pain

The general strategy for the maintenance phase:

19. The dose should not be lowered once a plateau has been achieved that provides adequate pain relief and satisfactory functional status and is tolerated.
20. To ensure patient safety, continue routine patient reporting and monitoring. Patients should be asked to report not only on their

medical conditions and medication requirements, but also any changes in their activity, employment, or social situation.

21. When prescribing an opioid analgesic for around-the-clock pain, it should also be dosed around-the-clock using a pharmacologically appropriate, time-contingent, dosing schedule.
22. In addition to the maintenance opioid analgesic, supplemental doses of short-acting medications may be considered to control break-through occasional episodes of pain exacerbation, such as those listed below (also see Appendix E, Table E5 in the original guideline document).

    a. Incidental pain: pain related to an increase in activity
    b. End-of-dose pain
    c. Natural conditions: pain related to predictable phenomena, such as changes in the weather.
    d. Specific medical conditions.

    Higher doses of the long-acting maintenance medication may also be useful in certain situations, but the potential for drug accumulation and adverse effects should be considered. If episodes of pain exacerbation occur frequently, re-evaluation of the adequacy of the maintenance dosage regimen is warranted.

23. Patients need to be assessed every 1 to 6 months, keeping the following in mind:
    a. No specific visit frequency applies to all patients.
    b. The visit frequency should be adjusted based on patient characteristics, comorbidities, type of pain, and type and dose of opioids. The provider should select a frequency that allows close follow-up of the patient's adverse effects, pain status, and appropriate use of medication.
    c. The patient should be able to request an early evaluation.
    d. In general, any change of dose or drug should be done during a clinic visit.

Individuals who develop a tolerance to the analgesic effects of opioids vary in the extent to which they become tolerant. Some maintain adequate pain relief at modest doses for very long periods of time. Others require frequent dosage increases to maintain effect. Most patients treated with opioids for chronic pain do not seem to develop a problem due to analgesic tolerance. Most patients reach a plateau within the first few months of treatment, after which only small adjustments in dose are necessary.

Although the choice of medication and dose are relatively routine during this phase, circumstances arise which require adjustments in the regimen or more aggressive clinical support. First, new adverse effects may emerge or become more clinically significant with prolonged opioid administration, and their treatment may require dosage adjustment or the addition of adjunctive medications. Second,

the underlying condition causing pain may worsen, requiring new evaluation and therapeutic intervention. And third, a patient may experience new medical or psychological symptoms, the evaluation and treatment of which is complicated by the medications to treat pain. See Table 2 in the original guideline, "Use of Opioids for Chronic Pain in Special Populations."

Evidence

A trial of opioids for chronic pain when other analgesic approaches are insufficient: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I ("The use of opioids," 1997)

No single agent is superior; in most patients, trials with several medications may be required; rotation among opioids may improve long-term efficacy: Quality of Evidence = II; Overall Quality = Fair; Strength of Recommendation = B (Quang-Cantagrel, Wallace, & Magnuson, 2000 (SR))

Long-acting agents are effective for continuous, chronic pain: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Caldwell et al., 1999; Caldwell et al., 2002; Hale et al., 1999; Lloyd et al., 1992; Peat et al., 1999; Salzman et al., 1999)

Try one medication at a time for opioid-naïve patient. Discontinue opioid trials if opioid naïve patient does not experience at least partial analgesia with incremental dose titrations: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Joranson et al., 1992)

Start with agent and dose that have been effective in the past for patient who has used opioid therapy: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Canadian Pain Society Task Force, 1998)

An opioid trial for either nociceptive or neuropathic pain: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Huse et al., 2001; Leung et al., 2001; Sindrup et al. "Tramadol relieves pain," 1999; Sindrup et al., "The effect of Tramadol," 1999; Watson, 2000)

Time-contingent dosing schedule: Quality of Evidence = I, III; Overall Quality = Good; Strength of Recommendation = A (Hale et al., 1999; Canadian Pain Society Task Force, 1998; The College of Physicians and Surgeons of Ontario Task Force, 2000)

Set dose levels based on patient need, not predetermined maximal dose: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Allan et al., 2001; Caldwell et al., 1999; Caldwell et al., 2002; Harati et al., 2000)

Titrate until an adequate level of analgesia is obtained: Quality of Evidence = I; Overall Quality = Good, Strength of Recommendation = A (Jamison et al., 1998; Petrone, Kamin, & Olson, 1999; Ruoff, 1999)

During the titration phase, reasonable doses of rescue opioid may be provided: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Canadian Pain Society Task Force, 1998; College of Physicians and Surgeons of Ontario Task Force, 2000)

L. Document Therapy

Objective

Guide proper use and documentation of opioid therapy.

Recommendations

1. When writing a prescription for opioid therapy, be certain to record the name of the drug, the strength, the number of dosage units (written numerically and in text) and how the drug is to be taken. Record any changes to therapy and the reason for the changes. For methadone, indicate on the prescription that it is for chronic pain.
2. The Veterans Administration (VA) regulations for the use of controlled substances (Controlled Substances [Pharmacy Stock], VHA Handbook 1108.1) must be followed by clinicians within the VA system, and provide a useful guide for other clinicians.
    - All prescriptions for controlled substances will be dated as of and signed on the day when issued and bear the full name and address of the patient, and the name, address, and Drug Enforcement Administration (DEA) registration number of the practitioner. Prescriptions should not be filled if they are more than 7 days old when presented.
    - An intern, resident, mid-level practitioner, foreign-trained physician, physician, or dentist on the staff of a VA facility exempted from registration (21 Code of Federal Regulation [CFR] 1301.24) will include on all prescriptions issued the registration number of the VA facility and the special internal code number assigned by the VA facility in lieu of the registration number of the practitioner required by law (21 CFR 1306.05b). Each written prescription will have the name of the physician or authorized practitioner stamped, typed, or hand printed on it, as well as the signature of the physician or authorized practitioner.
    - The label of any drug listed as a "Controlled Substance" in Schedule II, III, IV, or V of the Controlled Substances Act will, when dispensed to or for a patient, contain the following warning: "CAUTION: Federal law prohibits the

transfer of this drug to any person other than the patient for whom it was prescribed."

M. Assess Therapy

M1. Assess Adverse Effects

Objective

Identify adverse effects that may potentially change the treatment plan.

Recommendations

1. Evaluate patient for opioid adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritus, dizziness, tiredness, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation.
2. Many adverse effects spontaneously resolve with continued administration and development of tolerance. Consider individual levels of tolerability to different opioid agents.
3. If not already done, anticipate and consider preventive treatment for common adverse effects, particularly constipation and nausea.
4. Modifying the dose and rotating the opioid agents should successfully treat most adverse effects.

Evidence

Evaluate patient for adverse effects: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Many adverse effects resolve: Quality of Evidence = II; Overall Quality = Fair; Strength of Recommendation = C (Roth et al., 2000)

Anticipate and treat adverse effects: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Treat adverse effects by modifying dose or by drug rotation: Quality of Evidence = I; Overall Quality = Fair; Strength of Recommendation = B (Ruoff, 1999)

M2. Assess Adherence

Objective

Determine whether patient is adhering to the essential components of the treatment plan.

Recommendations

1. At every visit, assess and document adherence with appropriate use of opioid analgesics, including evidence of misuse, abuse, or addiction. (Consider random pill counts or urine drug screens to assess adherence.)
2. Assess and document adherence to other components of the treatment plan, such as follow-up with referrals, tests, and therapies.
3. Assess and document patient motivation and barriers to adherence.
4. Assess patients for behaviors that are predictive of addiction.
5. If the meaning of the behavior is not clear, some time may be required to assess the patient correctly and observe the reaction to additional requirements, such as frequent clinic visits or periodic drug screens.

Evidence

Assess adherence to opioid therapy and other components of the treatment plan: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Assess motivation and barriers to adherence: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Assess patients for behaviors that are predictive of addiction: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Portenoy, "Opioid therapy," 1996)

Address safety risks immediately and apply legal mandate as appropriate: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

If the meaning of the behavior is not clear, assess patient over time and frequent clinic visits or periodic drug screens: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

M3. Assess Efficacy (Pain, Function, and Satisfaction)

Objective

Evaluate the pain treatment plan in a timely manner to ensure appropriate opioid titration, evaluation of adverse effects, and progress towards goal attainment.

Recommendations

1. The provider should evaluate pain intensity at each visit.

- Intensity of pain should be measured in the following manner using a Numerical Rating Scale (NRS) (0–10) scale:
    - Current pain
    - Least pain in last week
    - "Usual" or "Average" pain in the last week
    - The patient's response to current pain medications should be assessed each visit using the following questions:
        - "What is your intensity of pain after taking your current treatment/medication?"
        - "How long does your pain relief last after taking your medication?"

2. Providers should evaluate pain-related function using validated instruments or numerical rating scale on a monthly basis during titration and every six months after the patient is on stable opioids. Assessment of function should include:
    - Employment
    - Enjoyment of life
    - Emotional distress (depression and anxiety)
    - Housework, chores, hobbies, etc.
    - Sleep
    - Mobility
    - Self-care behaviors
    - Sexual function

3. The patients' satisfaction with pain control should be assessed at each visit.

Evidence

Evaluate pain intensity using 0-10 scales: Quality of Evidence = II-1, II-2, III; Overall Quality = Fair; Strength of Recommendation = B (Breivik & Skoglund, 1998; De Conno et al., 1994; Jensen et al., 1996; Ogon et al., 1996; Serlin et al., 1995)

Evaluate function related to chronic pain after initiation of therapy: Quality of Evidence = I, II-1; Overall Quality = Good; Strength of Recommendation = A (Caldwell et al., 1999; Jensen et al., 1992; Peloso et al., 2000; Roth et al., 2000)

Frequent reassessment: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

N. Indication to Stop Opioid Therapy

N1. Are There Severe and Uncontrollable Adverse Effects?

Objective

Determine whether adverse effects warrant adjustment of opioid therapy or discontinuation of opioid therapy.

Recommendations

1. When therapy is a greater detriment than benefit as determined in consultation with the patient and family, opioid therapy should be discontinued.

Evidence

Terminate opioids when harm outweighs benefit of therapy: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

N2. Serious Non-Adherence: Illegal, Criminal or Dangerous Behaviors?

Objective

Identify serious non-adherence to opioid use that may warrant discontinuation of opioid therapy.

Recommendations

1. Address safety issues immediately. Apply legal mandates as appropriate.
2. Dangerous or illegal behaviors may require immediate cessation of the opioid therapy with appropriate treatment of potential withdrawal symptoms.
3. Consider notifying police about criminal behaviors. Consult with counsel prior to doing so to clarify current confidentiality laws and regulations.

Evidence

Address safety issues immediately. Apply legal mandate as appropriate: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Document and refer to police/legal actions those patients demonstrating criminal be behaviors: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

N3. Non-effective Therapy or Other Indications to Stop Therapy?

Objective

Determine when to discontinue chronic opioid therapy due to lack of efficacy or change in need.

Recommendations

1. Consider tapering off opioid medication if the patient claims or exhibits:
    - Lack of efficacy:
        - Continuing pain despite titration of dose to intolerable adverse effects
        - Lack of response despite trials of several different kinds of opioids
        - Decrease in overall function
    - Resolution of the pain problem:
        - Pain problem may be resolved due to surgical intervention.
        - Pain problem may be resolved due to physical therapy or other modalities.
        - Pain may now be responding to non-opioid medications.
    - Desire to discontinue therapy:
        - Patient desires to stop opioid due to personal goals or interference with lifestyle, work, or quality of life.
        - Patient desires to change to non-opioid therapy.
        - Patient had been using opioids to enable other therapy which is now completed.

Evidence

Taper off opioid if the patient exhibits evidence of a lack of efficacy: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Galer et al., 1992; Portenoy, "Opioid analgesics," 1996; Working Group Consensus)

Taper off opioid if the pain problem is resolved: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Taper off opioid if the patient no longer desires opioid therapy: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

O. Is There Evidence of Non-Adherence or Medication Misuse Suggestive of Addiction to Prescribed Opioid?

Objective

Identify patients who may need referral to addiction therapy or to a substance use disorder specialist.

Recommendations

1. Screen for substance use disorders in patients who are unable or unwilling to adhere to the treatment plan.
2. Document and refer to addiction specialists those patients demonstrating behaviors suggesting addiction to prescribed opioids or substance use disorders.
3. Consider referring patients with significant, chronic, substantiated pain who develop addiction behaviors in the context of chronic opioid therapy. An addiction specialist may be better able to evaluate the risks and benefits of continuing opioid therapy in such a situation.

Evidence

Screen for substance use disorders in patients who are unable or unwilling to adhere to the treatment plan: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Document and refer to addiction specialists those patients demonstrating behaviors suggestive of addiction: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Consultation/referral to substance use disorder (SUD) specialty for redirecting addiction behaviors and continue opioid therapy: Quality of Evidence = I, III; Overall Quality = Fair; Strength of Recommendation = B (Dunbar & Katz, 1996; Pappagallo & Heinberg, 1997)

P. Is Treatment Effective and Tolerable?

Objective

Determine whether the treatment trial should be continued.

Recommendations

1. Assess the safety and efficacy of the opioid trial, using the following criteria:
    - Patient's report of pain intensity and/or functional status
    - Persistence of analgesia between doses (i.e., pain relief is of adequate duration)
    - Patient satisfaction with the level of pain relief
    - Patient's improvement in functional status, quality of life
    - Patient's ability to participate in other modalities such as physical therapy

- Patient's tolerance and management of adverse effects

2. Emphasis should be given to capitalizing on improved analgesia by gains in physical and social function; opioid therapy should be considered complementary to other analgesic and rehabilitative approaches.

Evidence

Assess effectiveness of treatment; revise treatment plan when pain rating is greater than 3: Quality of Evidence = II; Overall Quality = Fair; Strength of Recommendation = B (Cleeland & Syrjala, 1992; Twycross, Harcourt, & Bergl, 1996; Jensen, Turner, & Romano, 2001)

Emphasis should be given to capitalizing on improved analgesia by gains in physical and social function: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (McCaffery & Pasero, 1999)

Q. Are There Complications, Comorbidities or Other Indications for Referral?

Objective

Identify patients who may benefit from referral to pain specialty care.

Recommendations

1. Referral to a specialist in pain medicine may be warranted depending on the expertise of the provider and the complexity of the problem.
2. Referral to a psychiatrist or psychologist may be indicated in cases of significant psychiatric comorbidity
3. Patients with other psychosocial problems or comorbidities may benefit from disease or case management.

R. Adjust Therapy

R1. Address Minor Non-adherence or Medication Misuse

Objective

Redirect the treatment to address emergent issues or relatively minor behavioral problems, so that appropriate opioid therapy can be continued.

Recommendations

1. Consider adjustment of the initial treatment agreement, with emphasis upon specific adherence issues that have been identified; a more rigid approach may be required.

   Possible responses to medication misuse might include:

   - Education and discussion along with restatement of the opioid management plan or agreement
   - Reviewing the written opioid prescribing agreement
   - Recommending or insisting on consultation with a pain and/or addiction specialist
   - Discussion, including discussion with others involved in the patient's care
   - Administration of medications under supervision or with the assistance of others
   - Change of medication or amount dispensed
   - More frequent clinic contacts (telephonic, physician extenders, or clinic visits)
   - Instituting regular or random urine toxicology screens as a condition for prescription renewal

2. Consider consultation with or referral to mental health if exacerbation of an underlying psychotic disorder is an issue.
3. Consider setting up a grievance procedure with the patient.
4. Consider whether the patient requires a living situation with greater structure (e.g., nursing home, assisted living facility).
5. Strongly consider involving the patient's family or significant others in finding solutions to non-adherence, as well as monitoring future adherence.

Evidence

Adjustment of the initial treatment consent or agreement, with emphasis upon specific adherence issues that have been identified; a more rigid approach may be required: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Consultation/referral to mental health if exacerbation of an underlying psychotic disorder is an issue: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Set up a grievance procedure with the patient: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (JCAHO, Behavioral Health Standards-Appendix B: Standards for Substance Abuse Programs)

R2. Address Adverse Effects

Objective

Modify treatment to achieve effective pain control with minimal harm and adverse effects.

Recommendations

Adverse effects can be minimized through the use of preventive therapy, or by switching to a different opioid:

1. A general strategy to minimize adverse effects is modifying the dose of medication during titration or rotating the opioid agent.
2. The following adverse effects are the most common. A prophylactic treatment and specific patient education should be provided together with initiation of therapy. Symptomatic treatment should be augmented with dose modification and/or opioid rotation.

    a. Constipation- Provide prophylactic treatment for the predictably constipating effects of opioid therapy. Constipation can be managed with a stepwise approach that includes an increase in fiber and fluids, osmotic agents (e.g., sorbitol or lactulose), or with a combination stool softener and a mild peristaltic stimulant laxative such as senna or bisacodyl as needed.
    b. Nausea and vomiting - Consider prophylactic antiemetic therapy.
    c. Itching - Rule out an allergic reaction; consider treatment with antihistamines.

3. Opioids may cause adverse behavioral or cognitive effects. Evaluation and treatment may be indicated and consultation or referral to a mental health specialist may be considered. Specific attention should be given to other non-opioid medications that the patient is using.
    a. Cognitive adverse effects - Sedation, confusion, and deterioration of cognitive function can be managed effectively using such measures as dosage reduction (with or without co-analgesia); change of opioid agent; addition of psychostimulant; elimination of other drugs or conditions that may contribute to adverse effects. Concurrent sedative use may cause cognitive deficits in patients on chronic opioid therapy. Cognitive deficits may worsen on opioid therapy; therefore caution is advised.
    b. Perceptual or affective adverse effects (hallucinations, depression) Evaluation of

hallucinations is often performed by "trial and error" techniques. All nonessential central nervous system (CNS)-acting medications (e.g., steroids) should be eliminated.

4. Sexual dysfunction - Hypogonadism may occur with chronic opioid therapy. Further evaluation and treatment should be considered.
5. The following adverse effects are best treated by dose reduction during titration or opioid rotation:
    - Sweating
    - Peripheral edema
    - Urinary retention
    - Myoclonus
    - Hyperalgesia
    - Dyspepsia

Evidence

Recommend modifying the dose or rotating the opioid agent to minimize adverse effects: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Cherny et al., 2001)

For constipation: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Passik & Weinreb, 2000; Sykes, 1996)

For nausea & vomiting: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Canadian Pain Society Task Force, 1998; Cohen et al., 1992; Gan et al., 1997; Pitkanen et al., 1997; Wang, Ho, & Hu, 1996)

For sedation: Quality of Evidence = I; Overall Quality = Fair; Strength of Recommendation = B (Passik & Weinreb, 2000; Canadian Pain Society Task Force, 1998; Jacox, Carr, & Payne, 1994; Cherny et al., 2001)

For itching: Quality of Evidence = I; Overall Quality = Fair, Strength of Recommendation = B (Cherny et al., 2001)

For hallucination/dysphoria: Quality of Evidence = I; Overall Quality = Fair; Strength of Recommendation = B (Cherny et al., 2001)

For sexual dysfunction: Quality of Evidence = I; Overall Quality = Fair; Strength of Recommendation = B (Daniell, 2002)

R3. Titrate Dosage or Agent to Achieve Stable Pain Relief

Objective

Adjust dosage or agent in an attempt to achieve therapeutic goals.

Recommendations

1. Documentation is essential and should demonstrate the evaluation process, including consultation, prescriptions, and periodic review of patient status.
2. Consider one or more of the following adjustments in therapy:
    - Increase dose titration. Increase dose by 25 to 100%. An increase of less than 25% is not appropriate.
    - To ensure that the full effect from a dosage change has been manifest and to avoid potential toxicity due to rapid accumulation of a drug, do not increase the dose more frequently than every 5 half-lives
    - If possible, titrate only one drug at a time, while observing the patient for additive effects. Inappropriate medications should be tapered while initiating an appropriate pharmacologic regimen.
    - Medication may be increased until limited by adverse effects or clear evidence of lack of efficacy.
    - Rotate to another agent based on equianalgesic table and titrate as in 1-4 above.
    - Provide a drug holiday.
    - In some patients receiving long-term opioid therapy, rotation between opioids may help to improve efficacy and reduce dose escalation.

3. For a patient with continuous pain, an agent with a long duration of action, such as controlled-release morphine or methadone, is recommended.
4. Maintain patients on as few medications as possible. Drug interactions and adverse events increase as the number of medications in a regimen increases. Discontinue medications, especially adjuvant medications, which do not add substantially to patient function or comfort.

Evidence

Documentation of evaluation process and any consultations: Quality of Evidence = III; Overall Quality = Poor Strength of Recommendation = I (Working Group Consensus)

Consultation to demonstrate compliance with controlled substance legislation: Quality of Evidence = III; Overall Quality

= Poor; Strength of Recommendation = I (Canadian Pain Society Task Force, 1998)

In cases of non-efficacy: Quality of Evidence = I, II; Overall Quality = Fair, Good; Strength of Recommendation = A, B (Roth et al., 2000; Caldwell et al., 2002; Thomsen, Becker, & Eriksen, 1999)

Long-acting agents are effective for continuous, chronic pain: Quality of Evidence = I; Overall Quality = Good; Strength of Recommendation = A (Caldwell et al., 1999; Caldwell et al., 2002; Hale et al., 1999; Peat et al., 1999; Salzman et al., 1999)

S. Follow-up at Appropriate Intervals

Objective

Evaluate pain as a guide to further intervention.

Recommendations

1. At each visit, assessment should address:
    - Comfort (degree of analgesia)
    - Opioid-related side-effects
    - Functional status (physical and psychosocial)
    - Adherence to opioid therapy contract and other aspects of treatment plan

2. Use of self-report instruments (diary, opioid log) may be helpful but should not be required.
3. Documentation is essential, and the medical record for each encounter should specifically address comfort, function, adverse-effects, and treatment plan adherence.
4. Visits should be scheduled at least every 2 to 4 weeks for the first 1 to 2 months of the trial (titration phase), and then at least once every 1 to 6 months for the duration of the therapy (maintenance).
5. A consultation should be requested if:
    - The patient requires doses of opioids beyond what is usually required for his condition, or beyond what the provider is comfortable prescribing.
    - Pain and functional status have not substantially improved after 3 months of opioid treatment.
    - A patient has a new or recurrent substance use disorder, or is at high risk for relapse to a substance use disorder (substance use disorder specialist consultation).
    - A patient appears to have significant problems with depression, anxiety, or irritability (a

psychiatric consultation may be indicated in such cases).

6. Laboratory studies (especially liver or kidney function screens), and/or drug screens should be ordered as indicated.

Evidence

Evaluate and document comfort, adverse effects, functional status, and aberrant behaviors at each visit: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (The College of Physicians and Surgeons of Ontario Task Force, 2000)

See the patient every 2 to 4 weeks for first 1 to 2 months, then every 6 to 8 weeks: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (The College of Physicians and Surgeons of Ontario Task Force, 2000)

Request a consultation, as indicated: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Laboratory studies and/or drug screens, as indicated: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (The College of Physicians and Surgeons of Ontario Task Force, 2000)

T. Indication to Discontinue Opioid Therapy

At this point the clinician will have reached the decision to discontinue opioid therapy for one of the following reasons: (1) uncontrolled adverse effects; (2) serious non-adherence to the treatment plan or unsafe behaviors; (3) lack of effectiveness of therapy or a desire on the part of the patient to discontinue therapy.

The patient may not understand or agree with the decision to withdraw the opioid therapy. This may lead to a variety of unwanted behaviors. The patient may seek to take advantage of the provider's desire to help and may therefore engage in a prolonged debate about continuing the therapy. The provider should keep in mind the reasons that led to the decision; another provider's support can be very helpful in this situation. In other cases, the patient may resort to threats and intimidation in an effort to obtain a prescription. All providers have a right to work in a safe and secure place. If a provider anticipates a threatening response, a system that summons security should be in place, the provider should avoid situations where it might be difficult to escape an unsafe situation and

should consider asking additional staff members to be present while seeing the patient. In fact, acts of violence are rare but do occur, and the provider should never act based on intimidation.

U. Is There Evidence of Illegal or Unsafe Behavior; Stop Opioid Therapy; Apply Legal Mandates; Document in Medical Record

Objective

Discontinue opioid therapy in situations in which patients engage in illegal activities.

If the clinician has a reason to believe the patient engaged in prescription fraud or diversion, it will be necessary to discontinue opioid therapy. Opioid prescription is regulated by the Controlled Substances Act (see Appendix D in the original guideline document). Serious variations are those that jeopardize the safety of the patient or society or are illegal. Active diversion, forgery, theft, or assaultive behaviors are illegal and mandate prompt documentation and notification of authorities.

Recommendations

1. Opioid therapy should be discontinued immediately in the following cases:

   <u>Predictors of Opioid Misuse</u>

   Illegal or Criminal Behavior

   - Diversion (sale or provision of opioids to others)
   - Prescription forgery
   - Stealing or "borrowing" drugs from others

   Dangerous Behavior

   - Motor vehicle crash/arrest related to opioid or illicit drug or alcohol intoxication or effects
   - Intentional overdose or suicide attempts
   - Aggressive/threatening/belligerent behavior in the clinic

2. Consider notifying law enforcement authorities about patients who are suspected of prescription fraud or diversion (e.g., VA police, risk manager, and/or regional counsel).
3. Carefully document the details of the situation.

4. Document and refer to mental health specialists those patients demonstrating behaviors suggestive of suicide.

V. Addiction Behavior: Refer to Substance Use Disorder Specialist

Objective

Safe termination of opioid therapy

Recommendations

Patients manifesting behaviors characteristic of compulsive drug use (addiction) to either opioids or other drugs or alcohol should be referred to a substance use disorder specialist. If there are clearly unsafe or illegal behaviors, opioid prescribing should stop immediately and withdrawal addressed.

In other circumstances, a decision might be made to either taper and discontinue opioid prescribing or wait until after consultation has been obtained.

If opioid agonist therapy for opioid addiction (e.g., methadone maintenance) is being considered, it may be helpful to wait to taper the prescribed opioids until the diagnosis is clarified and opioid agonist therapy induction begun.

Patients with complex conditions with multiple comorbidities, including other psychiatric disorders, should be referred to an addiction medicine or addiction psychiatry specialist for the management of opioid discontinuation. See Table 4b of the original guideline document for Case Examples.

W. Address Safety and Misuse; Begin Process to Discontinue Opioid Use

Objective

Safe termination of opioid therapy

Recommendations

1. Maintain contact with any patient who withdraws from treatment due to a disagreement.
2. Refer patients with comorbid psychiatric disorders to appropriate mental health providers.

Evidence

Do not abandon a patient under any circumstances: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Maintain contact with any patient who withdraws from treatment due to a disagreement: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Refer patients with comorbid psychiatric disorders to appropriate mental health providers: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

X. Discontinue Opioid Therapy; Taper Medication

Objective

Provide medication to help maintain patient safety and comfort during the initial phase of opioid abstinence.

Recommendations

1. Opioid detoxification in a primary care setting followed by ongoing substance use treatment may be appropriate for selected opioid-dependent patients.
2. Decisions regarding tapering schedule should be made on an individual basis. Sometimes faster or slower tapering may be warranted.

Y. Educate on Withdrawal Symptoms; Taper Medications

Objective

Prepare the patient to discontinue opioids with a minimum of withdrawal symptoms.

Recommendations

1. Complete evaluation of treatment, comorbidity, psychological condition, and other relevant factors should be completed prior to the initiation of the taper.
2. Clear, written instructions should be given to patients/family to educate them about the slow taper protocol that will minimize abstinence (withdrawal) syndromes.
3. Patients who are unable to tolerate the taper as described should be considered for referral to or consultation with a pain specialist, substance use specialist, or other expert.

4. Detoxification for addicted patients is not part of this guideline. Refer to the VA/DoD Guideline for the Management of Substance Use Disorders.

Protocol for Tapering:

- Taper by 20 to 50% per week (of original dose) for patients who are not addicted. The goal is to minimize adverse/withdrawal effects.
- The rapid detoxification literature indicates that a patient needs 20% of the previous day's dose to prevent withdrawal symptoms.
- Decisions regarding tapering schedule should be made on an individual basis. Sometimes faster or slower tapering may be warranted.
- Some experts suggest that the longer the person has been on opioids, the slower the taper should be.
- Remain engaged with the patient through the tapering process, and provide psychosocial support as needed.

Z. Follow-up as Indicated

Objective

Provide appropriate long-term surveillance.

Recommendations

1. Do not abandon a patient under any circumstances.
2. Maintain contact with any patient who withdraws from treatment due to a disagreement.
3. Refer patients with comorbid psychiatric disorders to appropriate mental health providers.
4. Discontinue opioid therapy using a safe tapering protocol

Evidence

Do not abandon a patient under any circumstances: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Maintain contact with any patient who withdraws from treatment due to a disagreement: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Refer patients with comorbid psychiatric disorders to appropriate mental health providers: Quality of Evidence = III; Overall Quality = Poor; Strength of Recommendation = I (Working Group Consensus)

Definitions:

Strength of Recommendation

A. A strong recommendation that the intervention is always indicated and acceptable

B. A recommendation that the intervention may be useful/effective

C. A recommendation that the intervention may be considered

D. A recommendation that a procedure may be considered not useful/effective, or may be harmful

I. Insufficient evidence to recommend for or against – the clinician will use clinical judgment

Quality of Evidence

I: At least one properly done randomized controlled trial (RCT)

II-1: Well designed controlled trial without randomization

II-2: Well designed cohort or case-control analytical study

II-3: Multiple time series, dramatic results of uncontrolled experiment

III: Opinion of respected authorities, case reports; and expert committees

Overall Quality of Evidence

Good
High grade evidence (I or II-1) directly linked to health outcomes

Fair
High grade evidence (I or II-1) linked to intermediate outcome; or Moderate grade evidence (II-2 or II-3) directly linked to health outcome

Poor
Level III evidence or no linkage or evidence to health outcome

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for Management of Opioid Therapy for Chronic Pain.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The quality and strength of evidence are provided for selected recommendations (see "Major Recommendations" field). Where evidence was ambiguous or conflicting or scientific data were lacking, the clinical experience within the multidisciplinary group guided the development of consensus-based recommendations.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved use of opioids to treat chronic non-cancer pain

POTENTIAL HARMS

- Typical opioid adverse effects are common. They include constipation, nausea, vomiting, somnolence, headache, dyspepsia, hyperalgesia, sexual dysfunction, pruritus, dizziness, tiredness, dry mouth, sweating, and sedation.
- Opioids may also cause adverse cognitive effects (e.g., confusion, deterioration of cognitive function) and perceptual or affective adverse effects (e.g., hallucinations, depression).

See Appendix E of the original guideline for more information regarding potential harms of specific opioid drugs used to manage chronic pain.

Subgroups Most Likely to be Harmed

Older patients are more likely to experience difficulty with common adverse effects of opioids such as constipation and respiratory depression.

CONTRAINDICATIONS

CONTRAINDICATIONS

Opioid therapy should not be used in the following situations (absolute contraindications):

- Allergy to opioid agents (may be resolved by switching agents)

- Co-administration of drug capable of inducing life-limiting drug-drug interaction
- Active diversion of controlled substances

Opioid therapy should be used only after careful consideration of the risks and benefits (relative contraindications) in the following situations:

- Acute psychiatric instability
- Intolerance, serious adverse effects, or history of inadequate clinical response to opioids (lack of efficacy)
- Meets Diagnostic and Statistical Manual - Version IVR (DSM-IVR) criteria for current substance use disorder other than nicotine dependence
- Inability to manage opioid therapy responsibly
- Unwillingness or inability to comply with treatment plan
- Unwillingness to adjust at-risk activities resulting in serious re-injury
- Social instability
- Patient with sleep apnea not on continuous positive airway pressure (CPAP)
- Elderly patients
- Chronic obstructive pulmonary disease (COPD) patients

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Clinical practice guidelines, which are increasingly being used in health care, are seen by many as a potential solution to inefficiency and inappropriate variations in care. Guidelines should be evidenced-based as well as based upon explicit criteria to ensure consensus regarding their internal validity. However, it must be remembered that the use of guidelines must always be in the context of a health care provider's clinical judgment in the care of a particular patient. For that reason, the guidelines may be viewed as an educational tool analogous to textbooks and journals, but in a more user-friendly format.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar. various p. [51 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar

GUIDELINE DEVELOPER(S)

Department of Defense - Federal Government Agency [U.S.]
Department of Veterans Affairs - Federal Government Agency [U.S.]
Veterans Health Administration - Federal Government Agency [U.S.]

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United States Government

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The Management of Opioid Therapy for Chronic Pain Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Department of Veterans Affairs Web site.

Print copies: Available from the Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guideline for Guidelines. Draft. Washington (DC): Veterans Health Administration, Department of Veterans Affairs. Available from the: VHA Web site.
- Various other companion documents are available from the Veterans Health Administration (VHA) Web site.
- The VHA Web site also provides references to related guidelines, performance measures, and other resources.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

PATIENT RESOURCES

The following is available:

- Appendix B. Patient education. In: Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar. Various p.

Electronic copies: Available from the Department of Veterans Affairs Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on August 2, 2004. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on July 15, 2005 following the FDA advisory on Duragesic.

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