

# Guideline Summary NGC-5968

#### Guideline Title

Diagnosis and treatment of low back pain: A joint clinical practice guideline from the American College of Physicians and the American Pain Society.

### Bibliographic Source(s)

Chou R, Oaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK, Clinical Efficacy Assessment Subcommittee of the American College of Physicians, American College of Physicians, American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of

Physicians and the American Pain Society. Ann Intern Med 2007 Oct 2;147(7):478-91. PubMed



#### **Guideline Status**

This is the current release of the guideline

### FDA Warning/Regulatory Alert

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

- May 25, 2010 Proton Pump Inhibitors The U.S. Food and Drug Administration (FDA) notified healthcare professionals and patients of revisions to the prescription and over-the-counter [OTC] labels for proton pump inhibitors, which work by reducing the amount of acid in the stomach, to include new safety information about a possible increased risk of fractures of the hip, wrist, and spine with the use of these medications. FDA recommends healthcare professionals, when prescribing proton pump inhibitors, should consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition.
- May 25, 2010 Ultram (tramadol hydrochloride) : Ortho-McNeil-Janssen and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Warnings section of the prescribing information for tramadol, a centrally acting synthetic opioid analgesic indicated for the management of moderate to moderately severe chronic pain. The strengthened Warnings information emphasizes the risk of suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs and also warns of the risk of overdosage.

# Scope

# Disease/Condition(s)

Acute and chronic low back pain not associated with major trauma

# **Guideline Category**

Diagnosis

Management

Treatment

# Clinical Specialty

Chiropractic

Family Practice

Internal Medicine

Neurological Surgery

Neurology

Orthopedic Surgery

Pediatrics

Physical Medicine and Rehabilitation

Radiology

#### Intended Users

Physicians

## Guideline Objective(s)

To present the available evidence for evaluation and management of acute and chronic low back pain in primary care settings

#### **Target Population**

Adults with acute and chronic low back pain not associated with major trauma

**Note**: Children or adolescents with low back pain; pregnant women; patients with low back pain from sources outside the back (nonspinal low back pain); fibromyalgia or other myofascial pain syndromes; and thoracic or cervical back pain are not included.

#### Interventions and Practices Considered

#### **Evaluation**

- 1. History, including assessment psychological risk factors
- 2. Physical examination
- 3. Diagnostic imaging and testing, including magnetic resonance imaging or computed tomography

#### Treatment/Management

- 1. Patient education on back care and self care
- 2. Acetaminophen or nonsteroidal anti-inflammatory drugs
- 3. Intensive interdisciplinary rehabilitation
- 4. Spinal manipulation
- 5. Exercise therapy
- 6. Acupuncture
- 7. Massage therapy
- 8. Yoga
- 9. Cognitive behavioral therapy
- 10. Progressive relaxation

See appendix tables 5 and 6 in the original guideline document for levels of evidence and summary grades for other noninvasive interventions in patients with acute or chronic/subacute low back pain.

#### Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Pain reduction
- · Frequency of side effects from medication
- Cost

# Methodology

# Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

The literature search for this guideline included studies from MEDLINE (1966 through November 2006), the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, and EMBASE. The literature search included all English-language articles reporting on randomized, controlled trials of nonpregnant adults (age >18 years) with low back pain (alone or with leg pain) of any duration that evaluated a target medication and reported at least 1 of the following outcomes: back-specific function, generic health status, pain, work disability, or patient satisfaction.

# **Number of Source Documents**

# Nonpharmacologic

Searches for systematic reviews of low back pain identified 1292 abstracts. Of these, 96 reviews seemed potentially relevant and were retrieved. A total of 40 nonpharmacologic systematic reviews met inclusion criteria; 59 systematic reviews were excluded, most frequently because they met the criteria for outdated reviews or did not report results for patients with low back pain. Five recent, large (>200 patients) trials of acupuncture and spinal manipulation or exercise supplemented the systematic reviews. No systematic reviews were identified for interferential therapy, low-level laser therapy, shortwave diathermy, ultrasonography, or yoga for low back pain. Five (5) searches for randomized trials of these interventions identified 532 citations. Three (3) trials of interferential therapy, 7 trials of low-level laser therapy, 3 trials of shortwave diathermy, 3 trials of ultrasonography, and 3 trials of yoga met inclusion criteria.

# Pharmacologic

Searches for systematic reviews of low back pain identified 1292 abstracts for review. An additional 1586 citations were identified through 8 searches for randomized trials of acetaminophen, celecoxib, aspirin, the serotonin-norepinephrine reuptake inhibitors duloxetine and venlafaxine, antiepileptic drugs, opioids, tramadol, and systemic corticosteroids.

In all, 21 reviews appeared potentially relevant and were retrieved. Seven outdated reviews of nonsteroidal antiinflammatory drugs (NSAIDs), antidepressants, and multiple drugs were excluded. Also excluded were 3 reviews that did not clearly use systematic methods and 4 systematic reviews that evaluated target medications but did not report results specifically for patients with low back pain. Seven systematic reviews of NSAIDs, antidepressants, skeletal muscle relaxants, and benzodiazepines, or multiple medications were included.

# 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

### Grading of Quality of Evidence

High Quality Evidence

Evidence obtained from one or more well-designed and well-executed randomized control trials (RCTs) yielding consistent directly applicable results.

Moderate Quality Evidence

Evidence obtained from RCTs with important limitations. For example, biased assessment of the treatment effect, large loss of follow-up, unblended study, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small N or observed very few events. Evidence from well designed controlled trials without randomization, well-designed cohort or case control analytic studies, multiple time series with or without intervention also fall in this category.

Low Quality Evidence

Evidence obtained from observational studies. However, on very rare occasions, it can be classified as moderate or even high. For example, when they yield extremely large and consistent estimates of the magnitude of a treatment effect or when all plausible biases from observational studies may be working to underestimate an apparent treatment effect.

### 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

Information about study design, population characteristics, interventions, outcomes, and adverse events was abstracted. The Oxman criteria for systematic reviews and the Cochrane Back Review Group criteria for individual trials were used to grade methodological quality.

The primary source of data was systematic reviews. Non-English-language trials were included only if they were included in English-language systematic reviews.

The evidence in this guideline was first evaluated by the American College of Physicians (ACP)/American Pain Society (APS) panel by using a system adopted from the U.S. Preventive Services Task Force for grading strength of evidence, estimating magnitude of benefits, and assigning summary ratings (see Appendix Tables 2, 3, and 4 of the original guideline document). The evidence was independently reviewed by the ACP's Clinical Efficacy Assessment Subcommittee. The ratings for individual low back pain interventions discussed in this guideline are summarized in Appendix Table 5 of the original guideline document for acute low back pain (<4 weeks' duration) and in Appendix Table 6 of the original guideline document for chronic/subacute low back pain (>4 weeks' duration). This guideline considered interventions to have "proven" benefits only when they were supported by at least fair-quality evidence and were associated with at least moderate benefits (or small benefits but no significant harms, costs, or burdens).

See the background papers by Chou & Hoyt Huffman for more details of the methods to analyze the evidence (see "Availability of Companion Documents" field).

#### Methods Used to Formulate the Recommendations

**Expert Consensus** 

## Description of Methods Used to Formulate the Recommendations

The American College of Physicians (ACP) and the American Pain Society (APS) convened a multidisciplinary panel of experts to develop the key questions and scope used to guide the evidence report, review its results, and formulate recommendations.

# Rating Scheme for the Strength of the Recommendations

## Grading of Guideline Recommendations\*

Strong Recommendation

Benefits clearly outweigh risks and burden OR risks and burden clearly outweigh benefits.

Weak Recommendation

Benefits are finely balanced with risks and burden or appreciable uncertainty exists about magnitude of benefits and risks.

I or Insufficient Recommendation

The evidence is insufficient to recommend for or against routinely providing the service. Evidence is conflicting, of poor quality, or lacking and the balance of benefits and harms cannot be determined.

Quality of Evidence	Strength of Recommendation	
	Benefits clearly outweigh risks and burden	Benefits finely balanced with risks and burden
	OR risks and burden clearly outweigh benefits	
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine	I recommendation	
net benefits or risks		

**Note**: Adopted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Workshop.

## Cost Analysis

Published cost analyses were reviewed.

#### Method of Guideline Validation

Peer Review

#### Description of Method of Guideline Validation

This guideline was approved by the American College of Physicians Board of Regents on July 14, 2007 and American Pain Society Board Executive Committee on July 18, 2007.

## Recommendations

## Major Recommendations

The strength of evidence (High, Moderate, Low) and the strength of the recommendations (Strong or Weak) are defined at the end of the "Major Recommendations" field.

#### **Evaluation of Low Back Pain**

**Recommendation 1**: Clinicians should conduct a focused history and physical examination to help place patients with low back pain into 1 of 3 broad categories: nonspecific low back pain, back pain potentially associated with radiculopathy or spinal stenosis, or back pain potentially associated with another specific spinal cause. The history should include assessment of psychosocial risk factors, which predict risk for chronic disabling back pain (*strong recommendation, moderate-quality evidence*).

**Recommendation 2**: Clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain (*strong recommendation, moderate-quality evidence*).

**Recommendation 3**: Clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination (*strong recommendation*, *moderate-quality evidence*).

**Recommendation 4**: Clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy) (*strong recommendation*, *moderate-quality evidence*).

### Treatment of Low Back Pain

**Recommendation 5**: Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options (*strong recommendation, moderate-quality evidence*).

**Recommendation 6**: For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy (strong recommendation, moderate-quality evidence). For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs.

**Recommendation 7**: For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (*weak recommendation, moderate-quality evidence*).

Note: See appendix tables 5 and 6 in the original guideline document for levels of evidence and summary grades for other noninvasive interventions in patients with acute or chronic/subacute low back pain.

# **Definitions**:

# **Grading of Quality of Evidence**

# High Quality Evidence

Evidence obtained from one or more well-designed and well-executed randomized control trials (RCTs) yielding consistent directly applicable results.

## Moderate Quality Evidence

Evidence obtained from RCTs with important limitations. For example, biased assessment of the treatment effect, large

loss of follow-up, unblended study, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small N or observed very few events. Evidence from well designed controlled trials without randomization, well-designed cohort or case control analytic studies, multiple time series with or without intervention also fall in this category.

#### Low Quality Evidence

Evidence obtained from observational studies. However, on very rare occasions, it can be classified as moderate or even high. For example, when they yield extremely large and consistent estimates of the magnitude of a treatment effect or when all plausible biases from observational studies may be working to underestimate an apparent treatment effect.

### Grading of Guideline Recommendations\*

### Strong Recommendation

Benefits clearly outweigh risks and burden OR risks and burden clearly outweigh benefits.

#### Weak Recommendation

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The evidence is insufficient to recommend for or against routinely providing the service. Evidence is conflicting, of poor quality, or lacking and the balance of benefits and harms cannot be determined.

Quality of Evidence	Strength of Recommendation	
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High	Strong	Weak
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Insufficient evidence to determine	I recommendation	
net benefits or risks		

**Note**: Adopted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Workshop.

#### Clinical Algorithm(s)

The original guideline document contains clinical algorithms for:

- Initial evaluation of low back pain
- · Management of low back pain

# Evidence Supporting the Recommendations

# Type of Evidence Supporting the Recommendations

The type of evidence supporting most recommendations is specifically stated (see "Major Recommendations").

# Benefits/Harms of Implementing the Guideline Recommendations

# Potential Benefits

Accurate diagnosis and effective treatment of low back pain

## **Potential Harms**

- Acetaminophen is associated with asymptomatic elevations of aminotransferase levels at dosages of 4 grams per deciliter (g/d) (the upper limit of U.S. Food and Drug Administration-[FDA] approved dosing) even in healthy adults, although the clinical significance of these findings are uncertain. Nonselective nonsteroidal anti-inflammatory drugs (NSAIDs) are more effective for pain relief than is acetaminophen, but they are associated with well-known gastrointestinal and renovascular risks. In addition, there is an association between exposure to cyclooxygenase-2-selective or most nonselective NSAIDs and increased risk for myocardial infarction. Clinicians should therefore assess cardiovascular and gastrointestinal risk factors before prescribing NSAIDs and recommend the lowest effective doses for the shortest periods necessary. Clinicians should also remain alert for new evidence about which NSAIDs are safest and consider strategies for minimizing adverse events in higher-risk patients who are prescribed NSAIDs (such as co-administration with a proton-pump inhibitor).
- Because of substantial risks of opioid analgesics or tramadol, including aberrant drug-related behaviors with long-term use in patients vulnerable or potentially vulnerable to abuse or addiction, potential benefits and harms of opioid analgesics should be carefully weighed before starting therapy.
- Skeletal muscle relaxants are associated with central nervous system adverse effects (primarily sedation). There is no compelling evidence that skeletal muscle relaxants differ in efficacy or safety. Because skeletal muscle relaxants are not pharmacologically related, however, risk-benefit profiles could in theory vary substantially. For example, carisoprodol is metabolized to meprobamate (a medication associated with risks for abuse and overdose), dantrolene carries a black box warning for potentially fatal hepatotoxicity, and both tizanidine and chlorzoxazone are associated with hepatotoxicity that is generally reversible and usually not serious.

• Benzodiazepines seem similarly effective to skeletal muscle relaxants for short-term pain relief but are also associated with risks for abuse, addiction, and tolerance.

# Qualifying Statements

# **Qualifying Statements**

- The authors of this article are responsible for its contents, including any clinical or treatment recommendations. The views and opinions expressed are those of Veterans Affairs/Department of Defense Evidence-Based Practice Workgroup members and do not necessarily reflect official Veterans Health Affairs or Department of Defense positions.
- Clinical practice guidelines are "guides" only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment. All American College of Physicians (ACP) clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

# Implementation of the Guideline

# **Description of Implementation Strategy**

An implementation strategy was not provided

## **Implementation Tools**

Clinical Algorithm

Patient Resources

Personal Digital Assistant (PDA) Downloads

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**

Getting Better

Living with Illness

# **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

# Bibliographic Source(s)

Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK, Clinical Efficacy Assessment Subcommittee of the American College of Physicians, American College of Physicians, American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of

Physicians and the American Pain Society. Ann Intern Med 2007 Oct 2;147(7):478-91. PubMed



#### Adaptation

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

### **Date Released**

2007 Oct 2

# Guideline Developer(s)

American College of Physicians - Medical Specialty Society

American Pain Society - Professional Association

# Source(s) of Funding

American College of Physicians

American Pain Society

### **Guideline Committee**

Clinical Efficacy Assessment Subcommittee of the American College of Physicians/American Pain Society Low Back Pain Guideline Panel

# Composition of Group That Authored the Guideline

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- \*Also a co-chair of the American College of Physicians/American Pain Society Low Back Pain Guidelines Panel
- \*\*Also members of the American College of Physicians/American Pain Society Low Back Pain Guidelines Panel

#### Financial Disclosures/Conflicts of Interest

Honoraria: R. Chou (Bayer Healthcare Pharmaceuticals). Grants received: V. Snow (Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, Novo Nordisk, Pfizer Inc., Merck & Co. Inc., Bristol-Myers Squibb, Atlantic Philanthropics, Sanofi-Pasteur).

### **Guideline Status**

This is the current release of the guideline.

#### **Guideline Availability**

Electronic copies: Available in Portable Document Format (PDF) from the American College of Physicians (ACP) Web site

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

Also available for Personal Digital Assistant (PDA) download from the American College of Physicians (ACP) Web site

# **Availability of Companion Documents**

The following are available:

• Chou R, Huffman LH; American Pain Society; American College of Physicians. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Ann Intern Med. 2007 Oct 2;147(7):492-504. Electronic copies: Available in

Portable Document Format (PDF) from the American College of Physicians (ACP) Web site

• Chou R, Huffman LH; American Pain Society; American College of Physicians. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Ann Intern Med. 2007 Oct 2;147(7):505-14. Available in Portable Document Format (PDF) from the

American College of Physicians (ACP) Web site

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572

A collection of Recommendation Summaries for all current American College of Physicians clinical guidelines is available for Personal Digital Assistant (PDA) download from the American College of Physicians Web site

# **Patient Resources**

The following is available:

• Diagnosis and treatment of low back pain: recommendations from the American College of Physicians/American Pain Society. Ann Int Med 2007 Oct 2;147(7):I-45.

Available in Portable Document Format (PDF) from the Annals of Internal Medicine 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 Institute on December 10, 2007. The information was verified by the guideline developer on December 13, 2007. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on July 20, 2010 following the U.S. Food and Drug Administration advisory on Ultram (tramadol hydrochloride), Ultracet (tramadol hydrochloride/acetaminophen). This summary was updated by ECRI Institute on July 26, 2010 following the U.S. Food and Drug Administration (FDA) advisory on Proton Pump Inhibitors (PPI).

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