Guideline Summary NGC-10536

Guideline Title
VA/DoD clinical practice guideline for the non-surgical management of hip and knee osteoarthritis.

Bibliographic Source(s)

Guideline Status
This is the current release of the guideline.
This guideline meets NGC's 2013 (revised) inclusion criteria.

Scope

Disease/Condition(s)
Osteoarthritis (OA) of the hip and knee

Guideline Category
Counseling
Diagnosis
Evaluation
Management
Rehabilitation
Treatment

Clinical Specialty
Family Practice
Geriatrics
Internal Medicine
Nutrition
Orthopedic Surgery
Physical Medicine and Rehabilitation
Radiology
Rheumatology
Sports Medicine

Intended Users
Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Pharmacists
Guideline Objective(s)
- To provide primary care clinicians with a framework by which to evaluate the individual needs and preferences of patients with osteoarthritis (OA), leading to improved clinical outcomes.
- To assist primary care providers in developing a comprehensive care program for patients with OA in order to achieve maximum functionality and independence, as well as improve patient and family quality of life.

Target Population
Any adult patient eligible for care in the Veterans Health Administration (VHA) or Department of Defense (DoD) healthcare delivery systems who has chronic joint complaints in the absence of acute trauma.

Interventions and Practices Considered

Diagnosis/Evaluation
1. History and physical examination
2. Plain radiography

Management/Treatment
1. Patient education
2. Comprehensive management plan
3. Weight reduction in patients who are overweight or obese
4. Traditional physical therapy and exercise program
5. Manual physical therapy
6. Aquatic therapy
7. Walking aids
8. Pharmacologic therapy
   - Acetaminophen
   - Non-steroidal anti-inflammatory drugs (NSAIDs)
   - Topical capsaicin for the knee
   - Duloxetine
   - Tramadol
   - Non-tramadol opioids
   - Intra-articular injections (corticosteroids and hyaluronic acid)
9. Referral for surgical consultation

Note: The following were considered but not recommended or has insufficient evidence to make a recommendation: magnetic resonance imaging (MRI), routine use of laboratory examination and synovial fluid analysis, dietary supplements, chondroitin sulfate, glucosamine, and/or any combination of the two, topical capsaicin for the hip as first line or adjunctive therapy, intra-articular injection of hyaluronic/hylan for symptomatic osteoarthritis (OA) of the hip, referral for short term trial of needle acupuncture or chiropractic therapy for relief of pain and improved function, joint injections if surgery is anticipated within three months.

Major Outcomes Considered
- Pain
- Function
- Harms

Methodology

Description of Methods Used to Collect/Select the Evidence

Key Question Formulation
Following a series of discussions on the highest priority topics related to Department of Veterans Affairs (VA) and Department of Defense (DoD) populations regarding osteoarthritis (OA), the Champions, in consultation with the Work Group, identified a set of 19 key questions to guide the systematic review of the literature. The key questions followed the industry standard population, intervention, comparison, outcome, timing and setting (PICOTS) framework for evidence questions, as developed by the Agency for Healthcare Research and Quality (AHRQ). Table A-1 in the original guideline document provides a brief overview of the PICOTS typology. Levin described this method in detail during the biweekly...
document provides a brief overview of the ICD-10 coding system. Lewin described this method in detail during the biweekly teleconference held with the Champions and guided them into identifying and prioritizing topics of interest for this Clinical Practice Guideline (CPG).

The key questions, listed in Table A-2 in the original guideline document, cover the following topics:

- Diagnosis and evaluation of OA
- Comparative effectiveness of drugs for OA
- Comparative effectiveness of non-pharmacologic therapies
- Comparative effectiveness of complementary and alternative medicine
- Surgical referral

Evidence Review

The methods guiding this systematic review are described below. In part, these methods follow the guidelines for conducting a systematic review set forth by AHRQ in the Methods Guide for Effectiveness and Comparative Effectiveness Reviews. The methods also follow the guidance set forth by the VA/DoD in the Guideline for Guidelines document (see the "Availability of Companion Documents field.

A systematic review of the literature consists of several distinct steps. ECRI Institute conducted the evidence review for this CPG, by following the process outlined below:

1. Defining the inclusion and exclusion search criteria
2. Developing a search strategy (i.e., search logic using MeSH [Medical Subject Headings] terminology and key words)
3. Screening the results based on abstracts and titles (i.e., identifying relevant studies and excluding duplicate records)
4. Reviewing the full text of remaining studies and abstracting relevant data points (i.e., population, comparator, results, etc.)
5. Assessing the internal and external validity of abstracted studies
6. Summarizing the evidence
7. Interpreting the results

Criteria for Study Inclusion/Exclusion

The inclusion criteria are listed below in separate categories pertaining to the following: general criteria relevant to all studies included in the evidence base; criteria that is specific to studies that address the diagnostic questions; criteria specific to studies that address the pharmacological and non-pharmacological intervention questions; and criteria specific to studies that address the referral questions.

General Criteria

- Clinical studies published on or after January 1, 2002, and systematic reviews published on or after January 1, 2008
- Studies must be published in English
- Publication must be a full-length clinical study or systematic review; abstracts alone were not included. Similarly, letters, editorials, and other publications that are not full-length, clinical studies were not accepted as evidence
- Study must have enrolled a patient population in which at least 85 percent of patients had OA (post-traumatic or idiopathic) of the hips or knees
- Studies must have enrolled adults 18 years or older. In studies that mixed adults and children, at least 85 percent of the enrolled patients must have been 18 years or older
- Study included 50 percent or more of patients at final follow-up
- Studies that enrolled adults with osteonecrosis, rheumatoid arthritis, or other inflammatory joint disease were excluded

Diagnosis/Evaluation Studies

- Studies must have enrolled ≥10 patients
- Studies must have linked use of diagnostic technologies with improvement in clinical outcomes. This ideally requires a study that compares clinical outcomes after diagnostic technology evaluation versus clinical evaluation, or compares clinical outcomes linked to different diagnostic technologies

Intervention Studies

- Study must have evaluated a treatment for OA of the hips or knees
- Study must have been a prospective, randomized or nonrandomized comparative trial with an independent, concurrent control group
- Crossover trials were considered only if data from the first treatment period were reported separately
- Study must have enrolled ≥25 patients per treatment arm
- The study must report data on at least one of the included outcomes
- Study must have followed patients for at least four weeks
- All subjective outcomes (e.g., pain, aspects of patient function) must be measured using validated instruments

Referral Studies

- Study must have enrolled ≥10 patients
- Study must have been a clinical study (comparative or not) that investigated indications for referring patients with OA of the hips or knees for total/partial joint replacement surgery
Off the hips of liners for total joint replacement surgery

- Expert opinion papers were not considered as evidence addressing the referral questions
- Study must have reported on the outcomes associated with indications

Additional Criteria for Key Question 18

- Study must have enrolled at least 100 patients
- Study excluded if it only considered non-modifiable patient risk factors, such as gender or age
- Study excluded if outcomes of pain and function are measured prior to six months follow-up

Search Strategy

MeSH, EMTREE, and Keywords

The search strategies employed combinations of free text keywords as well as controlled vocabulary terms including (but not limited to) the concepts shown in the Topic-specific Search Terms table (see Table A-3 in the original guideline document). The strategies in the original guideline document are presented in OVID syntax; the searches were simultaneously conducted across EMBASE and Medline. Similar strategies were used to search the databases comprising PubMed, and the Cochrane Library (see Tables A-3 through A-12 in the original guideline document). Search sets were structured to address specific key questions and/or groups of key questions (i.e., diagnosis/evaluation, pharmacologic management, non-pharmacologic management, complementary and alternative medicine, and referrals). These search results were further refined to capture specific patient outcomes, study designs and publication types.

Published evidence was identified through extensive searches of the following databases: MEDLINE, PreMEDLINE, EMBASE, (via the OVID SP platform using the one-search and de-duplication features), the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and the Health Technology Assessment Database. Searches were designed to identify unique reviews, trials, and technology assessments. Searches of the World Wide Web were also performed to capture relevant grey literature that has not been indexed to the databases listed above. The searches covered the time period of January 2002 through December 2012.

Search Results

Extensive literature searches identified 6,872 citations potentially addressing the key questions of interest to this evidence review. Of those, 5,315 were excluded upon title review for clearly not meeting inclusion criteria (e.g., not pertinent to the topic, published prior to 2002). Overall, 1,557 abstracts were reviewed with 735 of those being excluded for the following reasons: not a systematic review or clinical study, clearly did not address a Key Question of interest to this review, clearly did not report outcomes of interest to this review, or published prior to 2002 for clinical studies or 2008 for systematic reviews. A total of 822 full-length articles were reviewed. Of those, 459 were excluded at a first pass review for not addressing a key question (mainly because the study did not address a comparison of interest), not reporting on outcomes of interest to the review, not being a full-length systematic review or clinical study, not including the required number of patients, or being a duplicate. A total of 363 full-length articles were thought to address one or more key questions and were further reviewed. Of these, 208 were ultimately excluded. Reasons for their exclusion are presented in Figure A-1 in the original guideline document.

Overall, 155 studies addressed one or more of the Key Questions and were considered as evidence in the review. Table A-13 in the original guideline document indicates the number of studies that addressed each of the questions.

Number of Source Documents

Overall, the evidence base for this guideline consisted of 155 studies.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

The methodological quality of the included systematic reviews and independent clinical studies was assessed using the U.S. Preventive Services Task Force (USPSTF) method. Each study was assigned a rating of Good, Fair, or Poor based on sets of criteria that varied depending on study design. Detailed lists of criteria and definitions of Good, Fair, or Poor ratings for different study designs appear in the USPSTF procedures manual.

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

Assessing the Quality of the Evidence

The strength of the evidence supporting findings for the outcomes of interest under each key question was assessed using the categories listed in the table below. The Working Group considered the evidence for each outcome according to the methodological, as follows: study quality (internal validity), consistency, directness, and precision. Consistency is the similarity in effect sizes or direction of an effect of different studies in an evidence base. An Inconsistent evidence base is one in which the studies report conflicting results. Consistency cannot be assessed when a body of evidence has only a single study (consistency is unknown). Directness refers to whether there is a direct link between the intervention and the ultimate health outcome. An ultimate health outcome (e.g., improved pain) is typically more clinically meaningful than an indirect outcome, and a direct link between outcome and intervention is strongest in head-to-head comparisons. Precision is a measure of the degree of certainty around a single outcome's effect size. In this report, the authors define a "precise" result as one in which the data were informative (e.g., the confidence interval [CI] around the effect size clearly indicated there was a difference between groups) and an "imprecise" result as one in which the data were not.
Clearly indicated there was a difference between groups, and an "impressive" result; as one in which the data were not informative (e.g., the CI was sufficiently wide that an estimate is consistent with either benefit or no benefit in comparison to another intervention).

**Assessment of Evidence Base**

<table>
<thead>
<tr>
<th>Evidence Category</th>
<th>Definition</th>
<th>Example of Assessment of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Quality (Internal Validity or Risk of Bias)</td>
<td>Study Quality takes into account the overall risk of bias rating of all the studies included in the evidence base.</td>
<td>Example: The overall risk of bias was fair. A couple of studies were rated as poor because they did not blind the patients or outcome assessors and did not report the method used to randomize patients.</td>
</tr>
<tr>
<td>Consistency of Results</td>
<td>Consistency of Results considers if the studies demonstrated similar positive or negative results (an inconsistent rating would indicate that the findings across studies were mixed).</td>
<td>Example: The majority of studies (20 out of 25) indicated a statistically positive effect of acetaminophen over placebo in reducing pain and improving function. In five studies, the results were not significant.</td>
</tr>
<tr>
<td>Directness of Evidence</td>
<td>Directness of Evidence considers the link between the interventions and patient outcomes (head-to-head comparisons provide the most direct evidence).</td>
<td>Example: The evidence linking the effects of acetaminophen to patient outcomes of pain and function was direct as it came primarily from head-to-head comparisons of acetaminophen to placebo.</td>
</tr>
<tr>
<td>Precision of Results</td>
<td>Precision estimates the degree of certainty around an outcome’s effect size.</td>
<td>Example: The 95% confidence interval around the between-group difference in pain scores was wide enough to allow the possibility that the treatments were equivalent, treatment A is more effective than treatment B, or treatment B is more effective than treatment A.</td>
</tr>
</tbody>
</table>

**Final Evidence Report**

The evidence review team at ECI Institute synthesized the results of the systematic review and provided a detailed analysis of relevant information for each key question. Some of the key elements discussed in the report include the quality of the evidence base and the magnitude of effect of specific interventions. Furthermore, the synthesis report contained critical information on potential limitations of certain studies, allowing for a better understanding of the certainty of the evidence. The review team produced a comprehensive evidence review report and distributed it to the Champions and Work Group members approximately two weeks prior to the face-to-face meeting.

**Methods Used to Formulate the Recommendations**

Expert Consensus

**Description of Methods Used to Formulate the Recommendations**

**Guideline Development Process**

The methodology used in the development of the clinical practice guideline (CPG) for non-surgical management of osteoarthritis (OA) (Version 1.0 - 2014) follows the Guideline for Guidelines, an internal working document of the Veterans Health Administration (VHA) and Department of Defense (DoD) Evidence-based Practice Working Group (EBPWG). This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (Champions) and other subject matter experts from within the Department of Veterans Affairs (VA) and DoD, known as the Work Group, and ultimately, the submission of a new CPG (see the “Availability of Companion Documents” field).

The Champions and Work Group members for this CPG were charged with developing evidence-based clinical practice recommendations and publishing a guideline document to be used by providers within the VA/DoD healthcare system. Specifically, the Champions for this CPG were responsible for identifying the key evidence questions of greatest clinical relevance, importance, and interest for rehabilitation of a patient with an upper extremity amputation. In addition, Champions assisted in:

a. Conducting the evidence review, including providing direction on inclusion and exclusion criteria
b. Assessing the level and quality of the evidence
c. Identifying appropriate disciplines to be included as part of the Work Group
d. Directing and coordinating the Work Group
e. Participating throughout the guideline development and review processes

The VA Office of Quality, Safety and Value, in collaboration with the DoD, identified four clinical leaders as Champions for the 2014 OA CPG. The Lewin Group (Lewin) and their sub-contractors ECI Institute and Duty First Consulting held the first conference call for this Guideline in August 2012, with participation from the contracting officer's representatives (COR), leaders from the VA and DoD evidence-based guideline development program, and the Champions. During this call, the project team discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing evidence questions for a systematic review on the nonsurgical management of OA. During this call, the team also identified a list, from which the Work Group members were recruited, of clinical specialties and areas of expertise that are important and relevant to OA. The specialties areas included are dietetics, family practice, internal medicine, nursing, orthopedics, primary care, pharmacy and rheumatology.

**Face-to-Face Meeting**

In consultation with the COR, the Champions, and the Work Group, the Lewin Team convened a three and a half day face-to-face meeting of the CPG Champions and Work Group members in May 2013. These experts were gathered in order to review the evidence, develop recommendations, and grade the recommendations in accordance with the U.S. Preventive Services Task Force (USPSTF) methods for assessing and grading the evidence.

**Developing Recommendations**

During the face-to-face meeting, and under the direction of the Champions, the Work Group members were charged with interpreting the results of the evidence review, and asked to review initial recommendations and/or develop new recommendations. In order to accomplish this task, the experts were divided into four smaller subgroups, each of which was led by a Champion. In addition, Work Group members were responsible for assessing the overall strength of evidence for each recommendation, by determining the magnitude and certainty of net benefit.

The recommendations presented in this CPG are based on a systematic appraisal of the published evidence on non-surgical interventions for managing OA. In areas where the evidence is particularly lacking, expert opinion was used on the...
surgical interventions for managing VA in areas where the evidence is particularly lacking, expert opinion served as the basis for the recommendation.

This CPG is the product of many months of diligent effort and consensus building among knowledgeable individuals from the VHA and the DoD. An experienced moderator facilitated the multidisciplinary Working Group. The draft document was discussed in a face-to-face group meeting. The content and validity of each section was thoroughly reviewed in a series of conference calls.

**Grading Recommendations**

The grade of the recommendation is based on a framework that combines the two dimensions, as shown in the table below. The grade depends on both net benefit and certainty. For example, in the USPSTF grading scheme, a grade of A is assigned to a recommendation that is based on a high certainty of a substantial net benefit. Three combinations of certainty and net benefit can yield a grade of B. Note that, in the USPSTF framework, any recommendation associated with low certainty of net benefit results in a recommendation of I, regardless of the magnitude of net benefit.

<table>
<thead>
<tr>
<th>Certainty of Net Benefit</th>
<th>Magnitude of Net Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Substantial Moderate Small Zero/Negative</td>
</tr>
<tr>
<td>Moderate</td>
<td>B C D</td>
</tr>
<tr>
<td>Low</td>
<td>Insufficient</td>
</tr>
</tbody>
</table>

**Grade of EO for Expert Opinion:** To grade the recommendations for the guideline, the Working Group members used a variation of the USPSTF grading framework to provide a grade of EO for "Expert Opinion." Given that evidence-based clinical practice guidelines have to be used in real practice settings for Veterans and Service Members, a grade of I for insufficient evidence may not provide useful guidance for supporting clinical decisions. In particular, we considered certain instances in which evidence suggests a Substantial or Moderate net benefit, but the certainty/strength of that evidence is Low. In those instances, rather than concluding that the evidence is Insufficient to support a clinical decision, we relied on Expert Opinion to support a recommendation. A grade of EO does not imply that the evidence is strong (it is still Low). Rather, it suggests that the magnitude of net benefit (Substantial or Moderate) is of sufficient clinical importance to make a recommendation, even if it is based on low certainty (weak evidence). The final CPG document represents a synthesis of current scientific knowledge and clinical practice regarding the non-surgical management of hip and knee OA. It attempts to be as free as possible of bias toward any theoretical or empirical approach to treatment.

Recommendations with grades A or B typically employ the terms "should" or "should consider," respectively, as it indicates that the certainty of the evidence and magnitude of net benefits is high. Recommendations with a grade C typically use the phrase "may" or "may consider" and recommendations with a grade D use a negative phrase such as "do not." Recommendations with insufficient evidence are stated as such with no positive or negative implication, while expert opinion recommendations may use any of these phrases. It is important to note that these are merely guidelines and should not be accepted as the rule. For example, some recommendations in this CPG with a C grade, may use the term "should" rather than the more common, "may". Careful consideration was given by the Champions regarding the terminology used in each recommendation and may not necessarily follow the guidelines as described above.

**Rating Scheme for the Strength of the Recommendations**

The recommendations in this Clinical Practice guideline are rated according to the U.S. Preventive Services Task Force (USPSTF) rating scheme and are based on two main dimensions: 1) net benefit of an intervention and 2) certainty of evidence associated with that net benefit.

**USPSTF Recommendations**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Grade Definitions</th>
<th>Suggestions for Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is substantial.</td>
<td>Offer or provide this service.</td>
</tr>
<tr>
<td>B</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.</td>
<td>Offer or provide this service.</td>
</tr>
<tr>
<td>C</td>
<td>The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.</td>
<td>Offer or provide this service for selected patients depending on individual circumstances.</td>
</tr>
<tr>
<td>D</td>
<td>The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.</td>
<td>Discourage the use of this service.</td>
</tr>
<tr>
<td>I</td>
<td>Statement: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be measured.</td>
<td>If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.</td>
</tr>
</tbody>
</table>

Grade of EO was added for "Expert Opinion".

**USPSTF Levels of Certainty Regarding Net Benefit**

**Definition:** The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

<table>
<thead>
<tr>
<th>Level of Certainty</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.</td>
</tr>
</tbody>
</table>
| Moderate           | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:  
  - The number, size, or quality of individual studies  
  - Inconsistency of findings across individual studies |

Grade of EO was added for "Expert Opinion".
Cost Analysis

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

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The draft document was discussed in a face-to-face group meeting. The content and validity of each section was thoroughly reviewed in a series of conference calls. The final document is the product of those discussions and has been approved by all members of the Working Group.

Recommendations

Major Recommendations

Note from the Department of Veterans Affairs and the Department of Defense (VA/DoD) and the National Guideline Clearinghouse (NGC): The recommendations for the non-surgical management of hip and knee osteoarthritis (OA) are organized into 6 modules with 1 algorithm. The modules with accompanying recommendations are presented below. See the original guideline document for the algorithm and evidence tables associated with selected recommendations, including level and quality of evidence, strength of recommendation, and supporting evidence citations.

The strength of recommendation rating (A, B, C, D, I, EO) is defined at the end of the "Major Recommendations" field.

Module A: Diagnosis and Evaluation

History and Physical Examination

Recommendation

1. Clinicians should conduct a history and physical examination for all patients, with an emphasis on the musculoskeletal examination. [EO]

Plain Radiography

Recommendation

2. Clinicians may use plain radiography to confirm the clinical diagnosis of hip and knee OA. [C]

Magnetic Resonance Imaging (MRI)

Recommendation

3. Clinicians should not use MRI as an evaluative tool to diagnose, confirm, or manage the treatment of OA. [D]

Routine Use of Laboratories and Synovial Fluid Analysis

Recommendation

4. Clinicians should avoid routine use of laboratory examinations or synovial fluid analysis to diagnose OA of the hip and/or knee. [EO]

Module B: Core Non-surgical Treatment Principles

Patient Education

Recommendation

5. The decision to prescribe any intervention should be based on consideration of assessment findings, risk vs. benefit analysis, pain severity, functional status, patient preference, and resource utilization. [EO]

Comprehensive Management Plan

Recommendations

6. For patients with OA of the hip and/or knee, clinicians should attempt the core non-surgical therapies prior to referral for surgery. [C]

7. For patients with OA of the hip and/or knee, clinicians should refer for physical therapist services early on, as part
Weight Reduction in Patients with Knee or Hip OA and Elevated Body Mass Index (BMI)

**Recommendations**

8. Clinicians should refer overweight or obese patients (defined by a BMI >25 kg/m²) with OA of the knee to a weight management program to lose a minimum of five percent body weight and maintain this new level of weight. [C]

9. Clinicians should refer overweight or obese patients (defined by a BMI >25 kg/m²) with OA of the hip to a weight management program to lose a minimum of five percent body weight and maintain this new level of weight. [E0]

Module C: Physical Therapy Approaches

**Manual Physical Therapy**

**Recommendations**

10. For patients with OA of the knee, the addition of manual physical therapy as an adjunct to traditional physical therapy and supervised exercise can improve pain, function, and walking distance. [B]

11. For patients with OA of the hip, the addition of manual physical therapy as an adjunct to traditional physical therapy and supervised exercise can improve pain, function, and range of motion. [B]

**Aquatic Therapy**

**Recommendation**

12. For adults with OA of the knee who do not tolerate land-based therapeutic exercise, clinicians should consider adjunctive aquatic physical therapy. [C]

**Walking Aids**

**Recommendation**

13. For patients with OA of the knee or hip, the prescription and training of ambulation or walking aids should be carried out by a physical therapist or the referring provider. [E0]

Module D: Pharmacologic Therapies

**Acetaminophen and Non-steroidal Anti-inflammatory Drugs (NSAIDs)**

**Recommendations**

14. In patients with no contraindications to pharmacologic therapy, clinicians should consider acetaminophen or oral NSAIDs as first line treatment. [B]

15. Clinicians should ensure that patients receive no more than four grams of acetaminophen daily from all sources of prescribed and non-prescribed medications. [A]

16. In patients requiring treatment with oral NSAIDs and who are at high risk for serious adverse upper gastrointestinal (GI) events, clinicians should consider the addition of a proton-pump inhibitor (PPI) or misoprostol. [A]

17. Clinicians should consider the balance of benefit and potential harm in prescribing oral NSAIDs in patients at risk for or with known cardiovascular disease or renal injury/disease. [B]

**Topical Capsaicin**

**Recommendations**

18. In patients with mild to moderate pain associated with OA of the knee, topical capsaicin can be considered as first line therapy or adjunctive therapy. [C]

19. There is Insufficient evidence to recommend the use of topical capsaicin for the hip as first line or adjunctive therapy. [I]

**Other Pain Management Pharmacotherapies**

**Recommendations**

20. For patients with persistent moderate or moderately severe OA pain, clinicians may offer duloxetine or tramadol as an alternative or adjunct to oral NSAIDs. [B]

21. For patients with persistent severe OA pain who have contraindications, inadequate response, or intolerable adverse effects with non-opioid therapies and tramadol, clinicians may consider prescribing non-tramadol opioids. [C]

**Intra-articular Injections (Corticosteroids and Hyaluronic Acid)**

**Recommendations**

22. For patients with symptomatic OA of the knee, clinicians may consider intra-articular corticosteroid injection. [C]

23. There is Insufficient evidence to recommend for or against the use of intra-articular hyaluronate/hylan injection in patients with OA of the knee; however it may be considered for patients who have not responded adequately to nonpharmacologic measures and who have an inadequate response, intolerable adverse events, or contraindications to other pharmacologic therapies. [I]

24. For patients with moderate to severe OA of the hip, clinicians may consider imaging/ultrasound directed corticosteroid injection to reduce pain. [C]

25. Intra-articular injection of hyaluronate/hylan is not recommended for patients with symptomatic OA of the hip. [E0]

Module E: Complementary and Alternative Medicine

**Nutritional Supplements/Nutraceuticals/Dietary Supplements**

**Recommendations**
Recommendations

26. In patients with hip and/or knee OA, there is insufficient evidence to recommend for or against the use of dietary supplements for relief of pain and improved function. [I]

27. In patients with hip and/or knee OA, clinicians should not prescribe chondroitin sulfate, glucosamine, and/or any combination of the two, to treat joint pain or improve function. [D]

Acupuncture and Chiropractic Care

Recommendation

28. In patients with hip and/or knee OA, there is insufficient evidence to recommend for or against referral for short term trial of needle acupuncture or chiropractic therapy for relief of pain and improved function. [I]

Module F. Referrals for Surgical Consultation

Recommendations

29. For patients with OA of the hip and/or knee, who experience joint symptoms (such as pain, stiffness, and reduced function) with substantial impact on their quality of life (individualized based upon patient assessment), and who have not benefited from the core non-surgical therapies, clinicians may offer referral for joint replacement surgery. [B]

30. In patients with OA of the hip and/or knee considered for surgical consultations, clinicians should obtain weight-bearing plain radiographs within 6 months prior to the referral to surgical consultation. [B]

31. In candidates for joint replacement of the hip and/or knee, joint injections should not be given into the involved joint if surgery is anticipated within three months. [EO]

Definitions:

The recommendations in this Clinical Practice guideline are rated according to the U.S. Preventive Services Task Force (USPSTF) rating scheme and are based on two main dimensions: 1) net benefit of an intervention and 2) certainty of evidence association with that net benefit.

USPSTF Recommendations

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<tr>
<td>C</td>
<td>The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.</td>
<td>Offer or provide this service for selected patients depending on individual circumstances.</td>
</tr>
<tr>
<td>D</td>
<td>The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.</td>
<td>Discourage the use of this service.</td>
</tr>
<tr>
<td>I</td>
<td>Statement for &quot;Expert Opinion&quot;.</td>
<td>If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.</td>
</tr>
</tbody>
</table>

Grade of EO was added for "Expert Opinion".

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

<table>
<thead>
<tr>
<th>Level of Certainty</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.</td>
</tr>
</tbody>
</table>
| Moderate           | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:  
  - The number, size, or quality of individual studies  
  - Inconsistency of findings across individual studies  
  - Limited generalizability of findings to routine primary care practice and  
  - Lack of coherence in the chain of evidence  
  As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low                | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:  
  - The limited number or size of studies  
  - Important flaws in study design or methods  
  - Inconsistency of findings across individual studies  
  - Gaps in the chain of evidence  
  - Findings not generalizable to routine primary care practice and  
  - A lack of information on important health outcomes  
  More information may allow an estimation of effects on health outcomes. |
Clinical Algorithm(s)

An algorithm for the non-surgical management of hip and knee osteoarthritis is provided in the original guideline document.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified for each recommendation (see the “Major Recommendations” field).

The recommendations are based on a systematic appraisal of the published evidence on non-surgical interventions for managing osteoarthritis. In areas where the evidence is particularly lacking, expert opinion served as the basis for the recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

A comprehensive care program for patients with osteoarthritis (OA) may help them achieve maximum functionality and independence, as well as improve patient and family quality of life.

Potential Harms

- Long-term use of oral non-steroidal anti-inflammatory drugs (NSAIDs) is limited by adverse effects such as increased cardiovascular events, gastrointestinal (GI) perforation, ulceration, and bleeding, and renal impairment. The risks of these complications increase with age, drug-drug and drug-disease interactions, and probably duration of use. These risks are especially important concerning the typically older population affected by osteoarthritis (OA) who often have comorbidities and take multiple medications. Alternative therapies to reduce these risks are limited.

- All NSAIDs have the potential to increase the risk for cardiovascular (CV) events and therefore should be used at the lowest effective dose for the shortest possible duration. Naproxen has a neutral or lowest risk for adverse CV events. Use with caution or avoid use of NSAIDs in patients with renal impairment, history of gastrointestinal bleeding, uncontrolled hypertension, congestive heart failure, advanced liver diseases, known cardiovascular disease, patients receiving anticoagulants, etc.

- Adverse events associated with topical NSAIDs may be due to components of the formulation rather than the NSAID itself (e.g., unpleasant odor from the dimethyl sulfoxide metabolite of dimethylsulfoxide [DMSO] in diclofenac solution).

- Use of nonselective or cyclooxygenase (COX)-2 selective NSAIDs can result in renal papillary necrosis, acute tubular necrosis, renal insufficiency, fluid and electrolyte disturbances, acute renal failure or other renal-related injury in an estimated one to five percent of patients. All available agents approved for use in the U.S. include a warning for such events in their prescribing information. The risk for renal adverse events is increased in patients who are dependent upon a compensatory increase in the production of renal prostaglandins to maintain renal perfusion. Patients at higher risk for renal injury from NSAIDs or COX-2s include those with preexisting renal disease, volume depletion (e.g., diuretics and vomiting), congestive heart failure, liver dysfunction, cirrhosis with ascites, use of angiotensin converting enzyme inhibitors (ACEs) or angiotensin receptor blockers (ARBs) and older patients.

- Although acetaminophen is a relatively safe analgesic when taken in usual doses (up to a maximum of four grams daily), the risk for acute liver injury and liver failure is increased in patients taking doses greater than 4,000 mg daily.

- Duloxetine therapy can be limited by adverse gastrointestinal, central nervous system and other reactions. The most common adverse events in clinical trials were nausea, dry mouth, fatigue, somnolence and constipation. When duloxetine is added on to a NSAID, the incidence of adverse events (i.e., nausea, dry mouth, constipation, fatigue, decreased appetite and dizziness) and withdrawal due to intolerance is slightly to moderately increased relative to those for NSAID therapy alone.

- Some patients may develop physical dependence with regular use and experience withdrawal symptoms typical of opioid withdrawal if tramadol therapy is stopped too quickly. Atypical withdrawal symptoms that may be related to the serotonin–norepinephrine reuptake inhibitor (SNRI) effects (e.g., hallucinations, paranoia, extreme anxiety, panic attacks, confusion and unusual sensory experiences such as numbness and tingling in the extremities) may also occur. If tramadol is discontinued, the dose should be slowly tapered off to avoid withdrawal symptoms. The main safety concern with tramadol is development of seizures. Tramadol should be avoided or used with caution in patients with a history or risk of seizures or those who are taking drugs that reduce the seizure threshold, such as antidepressants, anorectics, selective serotonin reuptake inhibitors (SSRIs), SNRIs, tricyclic antidepressants, tricyclic compounds (such as cyproheptadine, promethazine), other opioids, monoamine oxidase inhibitors (MAOIs), and neuroleptics. Careful attention should be given to recommended dosage adjustments and maximal dosage limits in at-risk populations (e.g., the elderly and patients with renal or hepatic impairment).

- Adverse events such as endocrine dysfunction and sleep-disordered breathing are associated with long-term opioid therapy in chronic pain.

- Results from two studies showed that oral diclofenac has a higher incidence of adverse GI symptoms, whereas topical diclofenac has a higher incidence of local application site reactions, commonly dry skin, rash, and pruritus.

- Adverse events associated with topical capsaicin are limited to temporary burning, stinging and pain at the site of application.

- Local adverse events are the most commonly reported adverse events from steroid injections. These include pain on injection, redness, post injection flare and skin discoloration. The rate of joint infection is considered to be very low when strict aseptic techniques are followed. Systemic effects include rapid suppression of serum cortisol, adrenocorticotropic hormone (ACTH) and inflammatory markers (erythrocyte sedimentation rate [ESR], C-reactive protein [CRP] and cytokines) returning to baseline levels in one to four weeks. In diabetics, a transient, short-term increase in
blood glucose levels has been reported. The evidence for an effect on blood pressure is mixed but facial flushing can occur.

Contraindications

The authors of one study concluded that due to the potential complications from steroid joint injection prior to total hip replacement (THR), their use should be contraindicated in possible candidates for THR.

Qualifying Statements

The Department of Veterans Affairs (VA) and the Department of Defense (DoD) guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision-making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This Clinical Practice Guideline is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendations.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

These guidelines are not intended to represent TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting the appropriate regional TRICARE Managed Care Support Contractor.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards
Quick Reference Guides/Physician Guides
Resources

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

Identifying Information and Availability

Bibliographic Source(s)


Adaptation

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

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Financial Disclosures/Conflicts of Interest
Not stated

Guideline Status
This is the current release of the guideline.
This guideline meets NGC’s 2013 (revised) inclusion criteria.

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:

In addition, various resources, including information on patient history and physical examination and information on pharmacological agents and nutraceuticals and their characteristics, are available in the appendices to the original guideline document.

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:


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

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