



AMERICAN COLLEGE OF  
OCCUPATIONAL AND  
ENVIRONMENTAL MEDICINE

Chapter 6: CHRONIC PAIN

Focus on Opioids  
January 2008

# ACOEEM: Chronic Pain

- Purpose, sponsorship, medical perspective, target audience
- Evidence Search
- Evidence Selection
- Evidence Review
- Review Panel
- Funding
- Miscellaneous

**ACOEM Evidence-Based  
Practice Panel  
ABBREVIATED  
Methodology Training**

Methodology, JOEM 2008, in press

# EBM Rationale

- Variance in practice
  - Small area, regional
  - Among health care financing systems
- Cost variation and escalation
  - No outcome improvement
  - Dissociation of care from outcomes

# Evidence-Based Medicine

- “...the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.
- ...means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”

Sackett DL, et al. *BMJ*. 1996;312:71-80.

# Evidence-Based Medicine

## **IS NOT:**

- Selecting an article to support a viewpoint
- Selecting a few articles for support
- Reprinting abstracts without critical appraisal

## **IS:**

- An **objective, graded** assessment of the **ENTIRE** body of **high quality** literature on that topic

# Clinical Practice Guidelines

- “Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”
  - National Institute of Medicine, 1990
- **Types of Guidelines**
  - **Evidence-based**
  - **Consensus based**

# Characteristics of Excellent Practice Guidelines

- Validity
- Reliability/  
reproducibility
- Clinical applicability
- Clinical flexibility
- Clarity
- Multidisciplinary  
process
- Scheduled review
- Documentation
- Transparency
- Approval

# AGREE Domains

<u>Domain</u>	<u>Area</u>
<b>I Scope, Purpose</b>	<ol style="list-style-type: none"><li>1. The overall objectives of the guidelines are specifically documented.</li><li>2. The clinical questions covered by the guidelines are specifically described</li><li>3. The patients to whom the guideline is meant to apply are specifically described.</li></ol>
<b>II Stakeholder Involvement</b>	<ol style="list-style-type: none"><li>1. The guideline development group includes individuals from all relevant Involvement professional groups.</li><li>2. The patients' views and preferences have been sought.</li><li>3. The target users of the guidelines are clearly defined.</li><li>4. The guidelines have been piloted among target users.</li></ol>

# AGREE Domains

## Domain

## Area

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### III Rigor of Development

1. Systematic methods were used to search for evidence.
2. The criteria for selecting the evidence are clearly described.
3. The methods used for formulating the recommendations are clearly described.
4. The health benefits, side effects and risks have been considered in formulating the recommendations.
5. There is an explicit link between the recommendations the supporting evidence.
6. The guideline has been externally reviewed by experts prior to its publication.
7. A procedure for updating the guidelines is provided

# AGREE Domains

## Domain

## Area

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### IV. Clarity, Presentation

1. The recommendations are specific and unambiguous.
2. Different options for management of the condition are clearly presented.
3. Key recommendations are easily identifiable.
4. The guideline is supported by tools for application.

# AGREE Domains

<u>Domain</u>	<u>Area</u>
V. Applicability	<ol style="list-style-type: none"><li>1. The potential organizational barriers in applying the recommendations have been discussed.</li><li>2. The potential cost implications of applying the recommendation have been considered.</li><li>3. The guideline presents key review criteria for monitoring and/or audit purposes.</li></ol>
VI. Editorial Independence	<ol style="list-style-type: none"><li>1. The guideline is editorially independent from the funding body.</li><li>2. Conflicts of interest of guideline development members have been recorded</li></ol>

# First Principles

## Application Principle

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Ethics

Clinicians should adhere to ACOEM's Code of Ethics

Clinicians should disclose any conflicts of interest (including ownership or other financial arrangements) they may have with any of the testing or treatment methods.

Diagnostic testing

Tests should be performed only if the results will affect the course of treatment.

Imaging or testing should generally be done to confirm a clinical impression prior to surgery or other major, invasive treatment

# First Principles

## Application Principle

Treatment Treatments should improve on the natural history of the disorder, which in many cases is recovery without treatment.

When there are options for testing or treatment available, choose the option supported by clinical and statistical significance

Treatment should be in accordance with evidence based practice as described in the Methodology, particularly with respect to prioritization of treatment modalities

# First Principles

<u>Application</u>	<u>Principle</u>
Use of High Quality Evidence	Recommendations should be evidence-based with evidence of efficacy balanced with evidence of benefits and harms.
Management	<p>Treatment should, in almost all cases, be preceded by adequate conservative treatment</p> <p>Treatment should have specific, objective goals and should be monitored for achievement of those goals within a reasonable time.</p> <p>Failure to achieve a goal does not change the risk/benefit calculation for a subsequent treatment.</p>

# First Principles

<u>Application</u>	<u>Principle</u>
Invasive treatment	<p>Invasive treatment may be performed if conservative treatment does not improve the health problem and there is evidence of effectiveness for a specific diagnosis, indication, and situation</p> <p>The more invasive and permanent, the more caution should be exercised in considering invasive tests or treatments and the stronger the evidence of efficacy should be.</p>
Disability	Treatment should not create dependence or functional Management disability
Shared Decision Making	Testing and treatment decisions should be the result of collaboration between the clinician and the patient with full disclosure of benefits and risks.

# First Principles

<u>Application</u>	<u>Principle</u>
Shared Decision Making	<p>The best treatment strategy should be recommended.</p> <p>In cases where the patient cedes that judgment to the clinician, the clinician's judgment as to the best treatment strategy should be implemented.</p>
Cost Effectiveness	<p>The more costly the test or intervention, the more caution should be generally exercised prior to ordering the test or treatment and the stronger the evidence of efficacy should be</p> <p>When two treatment methods appear equivalent, the most cost-effective method is preferred.</p>

# ACOEM Guideline Development Process

# Steps in the EBM Process

## *Methodology Development*

- Create, review and publish a detailed methodology for answering basic and clinical questions.
  - Review texts and studies on the EBM process
    - Cochrane methodology, GRADE
    - McMaster, Oxford groups, others
  - Outline and explain the steps in the process
  - Provide tools
    - Criteria, tables, training
  - Review the methodological quality of the above by a separate independent methodology group (option).

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# Creating and Updating *Guidelines*

<b>Step</b>	<b>Purpose</b>	<b>Individual(s) Responsible</b>	<b>Educational Credentials</b>
<b>Literature Search</b>	-Comprehensive search of the literature -Pull articles	Research Assistant(s)	Undergrad/ MS/MPH/MD
<b>Article Abstraction/ Preliminary Evidence Table Development</b>	-Read articles -Initial construction of evidence tables for topic	Research Assistant(s)  Study Coordinator(s)	MS/MPH/PhD
<b>Article Abstraction/ Semi-Final Development of Evidence Tables</b>	-Read articles -Semi-final construction of evidence tables for topic, including critiquing of study design and data.	Study Coordinator(s),  Research Associate	MS/MPH/PhD
<b>Evidence Table Review and Finalization</b>	-Over-read evidence tables to ensure that all important aspects of articles are included -QA/QC	Physician(s)	MD/DO with MPH (or equivalent)

# Creating and Updating *Guidelines*

<b>Rating of Articles</b>	<ul style="list-style-type: none"><li>-Rate the articles based on defined criteria</li><li>-Determine strength of evidence rating for topic based on the quality of the articles</li></ul>	Physician(s)	MD/DO with MPH (or equivalent)
<b>Panel Process</b>	<ul style="list-style-type: none"><li>-Review evidence tables and strength of evidence ratings</li><li>-Revise recommendations based on new evidence</li></ul>	Multi-disciplinary health professionals	MD/DO/MPH, MS, PT, DC, PhD, etc.
<b>Guideline Review</b>	<ul style="list-style-type: none"><li>-Review/oversight of final guidelines to ensure consistency</li><li>-QA/QC</li></ul>	Physicians	MD/DO

# Steps in the EBM Process

## *Stakeholder Input-Market Research*

### ■ Stakeholders

- Clinicians
- Health-care systems
- Workers/patients
- Employers
- Utilization reviewers, case managers
- Insurers and third part administrators
- Attorneys
- Regulators and policy makers

### ■ Stakeholder meetings, interviews, surveys

# Steps in the EBM Process

## *Devising Clinical Questions*

- Pose an answerable clinical question
  - Most recommend using the PICO format
    - Patient
      - Disease entity, risk, population
    - Intervention
      - Test, maneuver, prevention or treatment
      - Single intervention preferred
    - Comparison group
      - True control group preferred
    - Outcomes
      - Function, harms, objective, subjective findings

# Domains of Evidence Questions

- Etiology
- Harms
- Prognosis
- Clinical assessment  
(diagnosis/testing)
- **Treatment**
- Symptoms, prevalence
- Cost-effectiveness
- Disability management
- Quality of life

# Question Formulation: Low Back

PICO: Patient, Comparison, Intervention, Outcome

- **Patients:** Working age adults with low back pain greater than 3 months
- **Intervention:**
  - Disc replacement
- **Comparisons:**
  - Usual care/medications
  - Multi-disciplinary rehab
  - Physiotherapy
  - Exercise
- **Outcomes:**
  - Pain
  - Medication use
  - Functional recovery/improvement

# Steps in the EBM Process

## *Literature Search and Screening*

- Perform a search of the medical literature for original studies relevant to the question asked. May also include high-quality systematic reviews and meta-analyses of studies.
  - Search terms
  - Strategy
- Screen the abstracts located for relevance and apparently high-quality design and reporting.
  - Two screeners
  - Screening tool

# Literature Searches

- The National Library of Medicine's MEDLARS Database (Medline) ([www.nlm.nih.gov](http://www.nlm.nih.gov))
- The Cochrane Central Register of Controlled Trials
- CINAHL (Nursing, allied health, physical therapy, occupational therapy, social services)
- EMBASE
- PEDro
- EMB Online ([www.bmjournals.com](http://www.bmjournals.com))
- TRIP Database ([www.tripdatabase.com](http://www.tripdatabase.com))

# Inclusion/Exclusion Criteria (for Evaluation of Treatments)

- Be a **Randomized Controlled Trial (RCT) or Crossover Trial** evaluating clinical outcomes in a group receiving the intervention compared to a comparison group receiving either no intervention and/or a different intervention.
- Be published in English in a peer-reviewed scientific publication.
- Evaluate a clinical method currently used by providers in the U.S.
- Evaluate subjects similar to the general population of working age adults
- Evaluate at least 10 subjects in each group studied.

# Steps in the EBM Process

## *Getting Full Information*

- Obtain the full text of apparently high-quality studies
  - “Hand search” the literature following leads in high quality studies to find reviews or studies missed in computerized searches
- Contact study authors if needed to obtain further information if the published study contains inadequate or ambiguous information about design or results

# Article Abstraction

- Detailed abstraction performed for included articles
- Generally abstracted as follows:
  - **Research Assistant** begins abstraction
  - **Masters trained epi/biostats** completes initial abstraction
  - Summary table compiled
  - **MD/DO** oversight of the summary table/rate studies
  - **Other MDs/DOs** on the Panel review articles as part of the development of the guideline

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# Notes on Study Design

- Iterative process for article's references
- Panel will consider only “adequate” evidence
  - Must be original research
  - Must have description of cases, controls or randomization process for inclusion
  - Note that most, but not all, MSD treatments are difficult if not impossible to completely blind.
- Lower quality studies are far too frequently overturned by subsequent studies
- Study design is not necessarily correctly stated in the article

# Steps in the EBM Process

## *Critical Assessment*

- Analyze and rate the methodological quality (design and execution) of each screened study or review
- Create evidence tables for each study
- Combined tables for high quality evidence
  - Visually compare the design issues, direction and magnitude of study results

# RCT Article Grading (0-11 points)

1. Randomization (0, 0.5, 1.0 pts.)
2. Allocation concealed (0, 0.5, 1.0)
3. Baseline comparability of groups
4. Blinding of patients
5. Blinding of provider
6. Blinding of assessor
7. Avoid co-interventions

# RCT Article Grading (0-11 points)

8. Compliance Rate
9. Dropout Rate
10. Timing of Assessments
11. Intention to Treat Analysis

Note Bias rating (0, 0.5, 1.0) is also included, but not in the 0-11 point grade

(Also developed related ratings for diagnostic test)

# Strength of a Study

Low Quality:	0-3.5 points
Moderate Quality:	4.0-7.5 points
High Quality:	8.0+ points

# Strength of Evidence

- A: Strong evidence-base:** Two or more high-quality studies.
- B: Moderate evidence-base:** At least one high-quality study, or multiple lower-quality studies relevant to the topic and working population.
- C: Limited evidence-base:** At least one study of intermediate quality.
- I: Insufficient Evidence:** Evidence is insufficient or irreconcilable.

# Evidence-Based Recommendations

<b>Strongly For</b>	<b>A</b>	<b>Strong Evidence improves outcomes</b>
<b>Moderately for</b>	<b>B</b>	<b>Moderate Evidence benefits outweigh harms and costs</b>
<b>Recommended</b>	<b>C</b>	<b>Limited evidence of improved outcomes</b>
<b>Insuff. For</b>	<b>I</b>	<b>Felt to be appropriate, or nominal costs (Consensus)</b>
<b>Insufficient</b>	<b>I</b>	<b>No recommendation (Consensus)</b>
<b>Insuf Against</b>	<b>I</b>	<b>Not rec: high costs or potential for harms (Consensus)</b>
<b>Recommend Against</b>	<b>C</b>	<b>Limited evidence harms and costs exceed benefits</b>
<b>Mod Against</b>	<b>B</b>	<b>Moderate evidence ineffective or harms outweigh costs</b>
<b>Strongly Against</b>	<b>A</b>	<b>High quality evidence ineffective or harms outweigh costs</b>

# Critiquing: Case Definition

- Precision of definition
  - Symptoms?
  - Signs?
    - Require patient response?
    - Reproducible?
  - Test results?
    - Anatomy v pathophysiology
- Time from apparent cause
  - Duration
- Prior treatment
- Prior episodes

# Critiquing: Population Definition Cohort/subgroup

- Time frame in case
- Demographics
  - Age, gender
- Co-morbidity
- Prior treatment
- Occupation
  - Work exposures
- Workers' compensation cases
  - Litigation/representation

# Steps in the EBM Process

## *Expert Panels*

- Select and vet an expert panel independent of the funding source with experience in EBM and the relevant content area to review the above work
- Train the panel(s) in the specifics of the scientifically valid methodology in use

# Steps in the EBM Process

## *Panel Process: Evidence Review*

- Develops introductory information
- Receives the summary tables of evidence, original articles, and draft summary evidence paragraph(s) from the research team
- Reviews evidence tables & original articles
- Revises summary tables of evidence if needed
- Revises the strength of evidence as necessary
- Votes on ratings of the evidence (if not unanimous)
- If no consensus, discuss and vote again

# Steps in the EBM Process

## *Panel Process: Recommendations*

- Convene initial panel meeting
  - Review the data
  - Rank the technical quality of the body of high quality evidence
- Draft recommendations, considering
  - Costs
  - Benefits
  - Harms
  - First principles
- Discuss the recommendations to answer the clinical question
- Revise the recommendations and supporting material as needed

# Roles of Panel Members (short list)

- Review assigned topic
  - Articles
  - Summary Draft Text
- Use clinical knowledge
- Address if significant article is not included
- Critique evidence
- Address accuracy of the strength of evidence rating
- Revise, Edit and Finalize chapter update text on the topic

# Recommendations Will State

- Diagnoses for which test or treatment recommendation
- Specific indications for test or treatment
- Point in time course when appropriate
- Appropriate prior conservative treatment
- Relative and absolute contraindications
- Number of tests and procedures recommended

# Recommendations Will State

- Potential benefits and harms
- **Includes sentences prior to the final recommendation that give an overview & leads to the conclusion:**
  - There was/not quality evidence
  - Treatment option is/not costly, invasive, and has high/low risks or side effects
  - Studies examined acute (<1 mo), subacute (1-3 mo), and/or chronic (>3 mo) patients

# Process for Filling Gaps

- Gaps exist in literature
- Especially common regarding details of treatment (length, numbers of appointments, etc.)
- Also applies for all areas without moderate or high quality evidence
- Panel will **develop consensus**
- Text should note that such statements are consensus or otherwise are not evidence-based (e.g., “Insufficient evidence, Recommended”)

# Process for Filling the Gaps

- Use the Panels already empanelled for each body part/system as a consensus panel.
- Each Panel should be supplemented, as needed, with representatives of relevant and appropriate specialties which are not already represented on the Panel for the given problem or body area (e.g., chiropractic, osteopathy, OT, PT, orthopedics, neurology, neurosurgery, physical medicine and rehabilitation, and psychology or psychiatry).

# Updating Issues

- How frequently to update?
  - “Seismic” change articles are extremely rare
  - Most change is incremental
  - Frequent changes in text result in endless rulemaking and confusion
  - What is the balance? Q 3 years for updates.
- Current proposed solution to major changes
  - Monitor the literature
  - Press releases for seismic/major changes

# ACOEEM: Chronic Pain

- ✓ Purpose, sponsorship, medical perspective, target audience
- ✓ Evidence Search
- ✓ Evidence Selection
- ✓ Evidence Review
- ✓ Review Panel
- ✓ Funding
- ✓ Miscellaneous

# ACOEEM: Chronic Pain

- ✓ Literature Review
- ✓ Critique and Grading of Articles
- ✓ Indications for Initiation (by Diagnosis)
- ✓ Frequency and Dose
- ✓ Indications for Discontinuation

# ACOEM: Chronic Pain

- ✓ Abuse and Tolerance issues
- ✓ Risks of Addiction and Tolerance
- ✓ Psychological Evaluations
- ✓ Opioid Agreements
- ✓ Opioid Weaning