

**California Workers' Compensation Medical Treatment Study
Conducted by The RAND Corporation
Task 3, Identifying Potential Medical Treatment Utilization Schedules**

After identifying potential guidelines by formal search, word of mouth, public posting on the California Department of Industrial Relations Website, and other means, RAND will apply the Step 1 Screening Criteria so as to definitively include or eliminate each guideline from consideration. Guidelines must meet ALL of the Step 1 criteria to advance to the Step 2 Technical Evaluation. As part of Step 2, RAND will employ the published AGREE Instrument method to assess the process of guideline development. Assessments will be based on the actual guidelines, developers' summaries of the guideline development process, AND corroborating materials that convincingly demonstrate how each criterion or question has been addressed. **To consider a guideline for evaluation, RAND must have access to guidelines themselves by August 2, 2004 and receive explanations and corroborating materials for both Step 1 and Step 2 criteria and questions by August 9, 2004.**

**Step 1, Screening Criteria to Select Guidelines¹ for Technical Evaluation
Developed with the California Department of Industrial Relations, July 12, 2004**

- **Nationally recognized:** Meaning any of the following:
 - Accepted by National Guidelines Clearinghouse;
 - Published in a peer-reviewed U.S. medical journal;
 - Developed, endorsed, or disseminated by an organization based in two or more U.S. states;
 - Currently used by one or more U.S. state governments; OR
 - In wide use in two or more U.S. states.
- **Current:** Meaning developed, updated, or reviewed during the last three years.
 - When portions of a guideline are considered current but other portions are not, only the portions considered current will be evaluated further.
- **Comprehensive guideline sets are preferred.** Meaning guideline sets that address two or more procedures and modalities performed for musculoskeletal injuries of the spine, the upper extremities, AND the lower extremities.
 - Individual guidelines addressing one type of commonly performed procedure or modality will be included only if a minority of the comprehensive guideline sets meeting the screening criteria address that procedure or modality.

¹ Guidelines are defined as, "...systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances,"¹ except that documents developed to assist payer decisions are also included. IOM, 1990 National Academy Press, <http://books.nap.edu/books/0309043468/html/38.html#pagetop>

- **Evidence-based, peer-reviewed:** Meaning based, at a minimum, on a systematic review of literature published in medical journals included in the National Library of Medicine's MEDLINE.
 - A systematic review is defined as “A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research; and to collect and analyze data from the studies that are included in the review. Statistical methods may or may not be used to analyze and summarize the results of the included studies.”²
 - Convincing evidence of a systematic review of the literature includes lists of search terms, inclusion and exclusion criteria, the number of articles identified by the search and the number meeting the inclusion criteria, a bibliography of literature selected for inclusion, and criteria for appraising the literature selected.
- **Developed by a multidisciplinary clinical team:** Meaning developed or reviewed by a multidisciplinary team including at least three major types of providers that care for injured workers:
 - Family Medicine Physicians,
 - Internal Medicine Physicians,
 - General Practitioners,
 - Occupational Health Specialists,
 - Orthopedic Surgeons,
 - Neurosurgeons,
 - Physical Medicine Specialists,
 - Physical Therapists,
 - Chiropractors,
 - Radiologists,
 - Neurologists,
 - Acupuncturists,
 - And others.
 - Convincing evidence of a multidisciplinary clinical team includes the names and specialties of clinical guideline developers, and the dates on which guideline development meetings were held.
- **Will be kept up to date:** Meaning developers plan to update or review the guideline at least every three years.
 - Convincing evidence includes a written attestation of this plan provided to RAND by August 9, 2004.

² The Cochrane Reviewers' Handbook Glossary, Version 4.1.5, Updated December 2003.

**** FOR PUBLIC POSTING ****

- **Potentially open source**: Meaning the developers are considering making the document available to the public at a cost of less than about \$500 per individual user.
 - **Convincing evidence includes a written attestation of this plan provided to RAND by August 9, 2004.**

Step 2, Technical Guideline Evaluation Questions from the AGREE Instrument³

The technical evaluation of guidelines will be based on the AGREE instrument. There are six domains with 23 questions in the instrument. Each domain is intended to capture a separate dimension of guideline quality. The domains include: ⁴

Scope and purpose (items 1-3) is concerned with the overall aim of the guideline, the specific clinical questions and the target patient population.

Stakeholder involvement (items 4-7) focuses on the extent to which the guideline represents the views of its intended users. Guideline development should involve all stakeholders whose activities are likely to be covered in the proposed guideline. This should also include patient groups.

Rigor of development (items 8-14) relates to the process used to collect and synthesize the evidence, the methods to formulate the recommendations and to update the guideline. This includes information about the literature searches that were carried out, criteria used to select the evidence and the methods used for formulating the recommendations. The recommendations should be explicitly linked to the supporting evidence. A guideline should be reviewed externally before publication and should contain a clear statement about the procedure for updating them.

Clarity and presentation (items 15-18) deals with the language and format of the guideline. Because the main role of guidelines is to help clinicians and patients make better decisions, busy clinicians need simple, patient-specific, user-friendly guidelines that are easy to understand. A good guideline presents clear information about the management options available and the likely consequences of each.

Applicability (items 19-21) pertains to the likely organizational and cost implications of applying the guideline. Guidelines should be feasible to use in the current organization of care and must fit within routine practice and the time constraints of the job. In addition, review criteria should be derived from the key recommendations.

Editorial independence (items 22-23) is concerned with the independence of the recommendations and acknowledgement of possible conflict of interest from the guideline development group. An increasing number of guidelines are funded, directly or indirectly, by external funding. Those who fund guidelines may have a vested interest. There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations.

³ <http://www.agreecollaboration.org/>

⁴ Adapted from AGREE Instrument Training Manual, Jan 2003

To facilitate RAND's evaluation, please provide us with documentation and answers to questions from five of the six domains of the AGREE instrument (RAND will assess the Clarity and Presentation domain so these questions need not be answered by the developers). We have listed individual questions below with accompanying explanatory notes to assist you in answering the questions. If you require more information about the AGREE instrument, please visit their web site: <http://www.agreecollaboration.org/>. As noted above, developers should provide RAND with an explanation AND appropriate corroborating materials that demonstrate convincingly how each question is addressed by August 9, 2004.

Scope and Purpose

1. What is the overall objective of the guideline?

Explanatory Note: This deals with the potential health impact of a guideline on society and populations of patients. The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem. For example specific statements would be:

- Preventing (long term) complications of patients with diabetes mellitus;
- Lowering the risk of subsequent vascular events in patients with previous myocardial infarction;
- Rational prescribing of antidepressants in a cost-effective way.

2. What are the clinical questions covered by the guidelines?

Explanatory Note: A detailed description of the clinical questions covered by the guideline should be provided, particularly for the key recommendations. Following the examples provided in question 1:

- How many times a year should the HbA1c be measured in patients with diabetes mellitus?
- What should the daily aspirin dosage for patients with proven acute myocardial infarction be?
- Are selective serotonin reuptake inhibitors (SSRIs) more cost-effective than tricyclic antidepressants (TCAs) in treatment of patients with depression?

3. What are the patients to whom the guideline is meant to apply?

Explanatory Note: There should be a clear description of the target population to be covered by a guideline. The age range, sex, clinical description, comorbidity may be provided. For example:

- A guideline on the management of diabetes mellitus only includes patients with non-insulin dependent diabetes mellitus and excludes patients with cardiovascular comorbidity.
- A guideline on the management of depression only includes patients with major depression, according to the DSM-IV criteria, and excludes patients with psychotic symptoms and children.

- *A guideline on screening of breast cancer only includes women, aged between 50 and 70 years, with no history of cancer and with no family history of breast cancer.*

Stakeholder involvement

- 4. Does the guideline development group include individuals from all the relevant professional groups (primary care physicians, occupational health specialists, orthopedic surgeons, neurologists, neurosurgeons, physical medicine specialists, physical therapists, chiropractors, radiologists, and others)?**

Explanatory Note: This item refers to the professionals who were involved at some stage of the development process. This may include members of the steering group, the research team involved in selecting and reviewing /rating the evidence and individuals involved in formulating the final recommendations. This item excludes individuals who have externally reviewed the guideline (see Item 13). Information about the composition, discipline and relevant expertise of the guideline development group should be provided.

- 5. Have the patients' views and preferences been sought?**

Explanatory Note: Information about patients' experiences and expectations of health care should inform the development of clinical guidelines. There are various methods for ensuring that patients' perspectives inform guideline development. For example, the development group could involve patients' representatives, information could be obtained from patient interviews, literature reviews of patients' experiences could be considered by the group. There should be evidence that this process has taken place.

- 6. Has the target users of the guidelines been clearly defined?**

Explanatory Note: The target users should be clearly defined in the guideline, so they can immediately determine if the guideline is relevant to them. For example, the target users for a guideline on low back pain may include general practitioners, neurologists, orthopedic surgeons, rheumatologists and physiotherapists.

- 7. Has the guideline been piloted among target users?**

Explanatory Note: A guideline should have been pre-tested for further validation amongst its intended end users prior to publication. For example, a guideline may have been piloted in one or several primary care practices or hospitals. This process should be documented.

Rigor of development

- 8. Were systematic methods used to search for evidence?**

Explanatory Note: Details of the strategy used to search for evidence should be provided including search terms used, sources consulted and dates of the literature covered. Sources may include electronic databases (e.g. MEDLINE, EMBASE, CINAHL), databases of systematic reviews (e.g. the Cochrane Library, DARE), hand-searching journals, reviewing conference proceedings and other guidelines (e.g. the US National Guideline Clearinghouse, the German Guidelines Clearinghouse).

9. What are the criteria for selecting the evidence?

Explanatory Note: Criteria for including /excluding evidence identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. For example, guideline authors may decide to only include evidence from randomized clinical trials and to exclude articles not written in English.

10. What are the methods used for formulating the recommendations?

Explanatory Note: There should be a description of the methods used to formulate the recommendations and how final decisions were arrived at. Methods include for example, a voting system, formal consensus techniques (e.g. Delphi, Glaser techniques). Areas of disagreement and methods of resolving them should be specified.

11. Have the health benefits, side effects, and risks been considered in formulating the recommendation?

Explanatory Note: The guideline should consider health benefits, side effects, and risks of the recommendations. For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes. These may include: survival, quality of life, adverse effects, and symptom management or a discussion comparing one treatment option to another. There should be evidence that these issues have been addressed.

12. Is there an explicit link between the recommendations and the supporting evidence?

Explanatory Note: There should be an explicit link between the recommendations and the evidence on which they are based. Each recommendation should be linked with a list of references on which it is based.

13. Has the guideline been externally reviewed by experts prior to its publication?

Explanatory Note: A guideline should be reviewed externally before it is published. Reviewers should not have been involved in the development group and should include some experts in the clinical area and some methodological experts. Patients' representatives may also be included. A description of the methodology used to conduct the external review should be presented, which may include a list of the reviewers and their affiliation.

14. Is there a procedure for updating the guideline?

Explanatory Note: Guidelines need to reflect current research. There should be a clear statement about the procedure for updating the guideline. For example, a timescale has been given, or a standing panel receives regularly updated literature searches and makes changes as required.

Applicability

19. What are the potential organizational barriers in applying the recommendations?

Explanatory Note: Applying the recommendations may require changes in the current organization of care within a service or a clinic, which may be a barrier to using them in daily practice. Organizational changes that may be needed in order to apply the recommendations should be discussed. For example:

- A guideline on stroke may recommend that care should be coordinated through stroke units and stroke services.
- A guideline on diabetes in primary care may require that patients are seen and followed up in diabetic clinics.

20. What are the potential cost implications of applying the recommendations?

Explanatory Note: The recommendations may require additional resources in order to be applied. For example, there may be a need for more specialized staff, new equipment, and expensive drug treatment. These may have cost implications for health care budgets. There should be a discussion of the potential impact on resources in the guideline.

21. What are the guideline key review criteria for monitoring and review purposes?

Explanatory Note: Measuring the adherence to a guideline can enhance its use. This requires clearly defined review criteria that are derived from the key recommendations in the guideline. These should be presented.

Examples of review criteria are:

- The HbA1c should be < 8.0%.
- The level of diastolic blood pressure should be < 95 mmHg.
- If complaints of acute otitis media lasts longer than three days amoxicillin should be prescribed.

Editorial independence

22. The guideline is editorially independent from the functioning body.

Explanatory Note: Some guidelines are developed with external funding (e.g. Government funding, charity organizations, pharmaceutical companies). Support may be in the form of

financial contribution for the whole development, or for parts of it, e.g. printing of the guidelines. There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations.

23. Are there conflicts of interest among guideline development members?

Explanatory Note: There are circumstances when members of the development group may have conflicts of interest. For example, this would apply to a member of the development group whose research on the topic covered by the guideline is also funded by a pharmaceutical company. There should be an explicit statement that all group members have declared whether they have any conflict of interest.