European guidelines for the management of low back pain

European Commission COST B13 Management Committee*

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Low back pain is a tremendous health care and socioeconomic problem (van Tulder et al. 1995). Utilization of limited resources available at an early point in time may prevent the development of unnecessary suffering and related costs. Several approaches to the prevention of back pain have been reported in the literature, but there still is a lack of clarity regarding which types of interventions are employed as well as the effectiveness of them (Linton and van Tulder 2001). Prevention of the occurrence of low back pain and prevention of chronic low back pain and disability are major challenges.

Non-specific low back pain represents a large majority of cases (Deyo and Weinstein 2001) and there is great variability in its clinical management. Low back pain is most commonly treated in primary health care settings. The diagnostic and therapeutic management of patients with acute as well as chronic low back pain seems to vary substantially among health care providers (e.g., general practitioners, medical specialists, physical therapists, chiropractors, osteopaths, manual therapists) within European countries. However, there are also considerable discrepancies in the management of low back pain between countries in Europe and elsewhere, so there is a need to increase consistency in the management of low back pain across professions and countries.

At present, there is an increasing international trend towards evidence-based health care in Europe. Within the framework of evidence-based health care, clinicians should conscientiously, explicitly and judiciously use the current best evidence in making decisions about care of individual patients (Sackett et al. 1997). In choosing the optimal management for an individual low back pain patient, health care providers should integrate clinical expertise with patient's preferences and expectations.

The field of LBP research in primary care is an excellent example of evidence-based health care. At present, more than 500 randomised controlled trials have been published evaluating all types of conservative and alternative treatments for low back pain that are commonly used in primary care. The establishment of the Cochrane Back Review Group in 1997 was an important step forward to promoting systematic collection, review, and synthesis of the low back pain literature (Bombardier et al. 1997). Within the framework of the Cochrane Back Review Group method guidelines have been developed and published to improve the quality of reviews in this field and to facilitate comparison across reviews and enhance consistency among reviewers (van Tulder et al. 1997). During the last two decades, there has been a vast increase in the number of systematic reviews evaluating the effec-

tiveness of various conservative treatments for low back pain. Subsequently, since 1994 a number of clinical guidelines for the management of low back pain in primary care have been developed in various countries worldwide in which the evidence from trials and reviews has been translated into clinically relevant recommendations.

Since the available evidence is international, one would expect that each country's guidelines would give more or less similar recommendations regarding diagnosis and treatment. Comparison of clinical guidelines for the management of low back pain in primary care from 11 different countries showed that the content of the guidelines regarding the diagnostic classification (diagnostic triage) and the use of diagnostic and therapeutic interventions is quite similar. However, there were also some discrepancies in recommendations across guidelines. (Koes et al. 2001) Differences in recommendations between guidelines may be due to incompleteness of the evidence, different levels of evidence, magnitude of effects, side effects and costs, differences in health care systems (organisation / financial), or differences in membership of guidelines committees. More recent guidelines may have included more recently published trials and, therefore, may end up with slightly different recommendations. Also, guidelines may have been based on systematic reviews that included trials in different languages; the majority of existing reviews have considered only studies published in a few languages, and several, only those published in English. Some authors have reported that exclusion of trials published in other languages than English might be associated with bias (Grégoire 1995; Egger et al. 1997), while others found that language bias has little impact on the overall treatment effect related to some specific topics (Moher 1996; Jüni et al. 2002). Although inclusion in a systematic review of studies published in other languages than English is recommended, it may not always be feasible and may depend on the time and resources available (van Tulder et al. 1997).

Recommendations in guidelines are not only based on scientific evidence, but also on consensus. Guideline committees may consider various arguments differently, such as the magnitude of the effects, potential side effects, cost-effectiveness, and current routine practice and available resources in their country. Especially as we know that effects in the field of low back pain, if any, are usually small and short-term effects only, interpretation of effects may vary among guideline committees. Also, guideline committees may differently weigh other aspects such as side effects and costs. The constitution of the guideline committee and the professional bodies they represent, may introduce bias – either for or against a particular treatment. This does not necessarily mean that one guideline is better than the other or that one is right and the other is wrong. It merely shows that when translating the evidence into clinically relevant recommendations more aspects play a role, and that these aspects may vary locally or nationally.

The development of clinical guidelines should ensure that patients are treated according to the best available evidence and should lead to optimal patient outcomes. Recently, the AGREE (Appraisal of Guidelines, Research, and Evaluation in Europe) collaboration developed and published an instrument for the appraisal of the quality of guidelines that can also be used as framework for the guidelines developers (www.agreecollaboration.org; the AGREE group 2000). The AGREE instrument consists of 23 items in six domains. (see Table 1)

However, good guidelines are no guarantee for ensuring their use in daily practice. Changing health-related behaviour is very complex and involves enhancing knowledge; changing values, beliefs, attributes, and perception; providing necessary skills and resources; and providing support and feedback (Grimshaw et al. 2001). Development, publication and dissemination of guidelines are not enough to change behaviour of health care providers. Development of effective implementation strategies is needed. Implementation of clinical guidelines will be a major challenge for the near future.

Objectives

To increase consistency in the management of non-specific low back pain across countries in Europe, the European Commission has approved a program for the development of European guidelines for the management of low back pain, called "COST B13". The main objectives of this COST

Table 1. The AGREE instrument.

1) Scope and purpose of the guideline:
- a. The overall objective of the guideline is specifically described
- b. The clinical question covered by the guideline is specifically described
- c. The patients to whom the guideline is meant to apply are specifically described

2) Stakeholder involvement:
- a. The guideline development group includes individuals from all the relevant professional groups
- b. The patients' views and preferences have been sought
- c. The target users of the guideline are clearly defined
- d. The guideline has been piloted among target users

3) Rigour of development:
- a. Systematic methods were used to search for evidence
- b. The criteria for selecting the evidence are clearly described
- c. The methods used for formulating the recommendations are clearly described
- d. The health benefits, side effects and risks have been considered in formulating the recommendations
- e. There is an explicit link between the recommendations and the supporting evidence
- f. The guidelines has been externally reviewed by experts prior to its publication
- g. A procedure for updating the guideline is provided

4) Clarity and presentation:
- a. The recommendations are specific and unambiguous
- b. The different options for the management of the condition are clearly presented
- c. Key recommendations are easily identifiable
- d. The guideline is supported with tools for application

5) Applicability:
- a. The potential organisational barriers in applying the recommendations have been discussed
- b. The potential cost implications of applying the recommendations have been considered
- c. The guideline presents key review criteria for monitoring and/or audit purposes

6) Editorial independence:
- a. The guideline is editorially independent from the funding body
- b. Conflicts of interest of guideline development members have been recorded

action are:

1. Developing European guidelines for the prevention, diagnosis and treatment of non-specific low back pain.
2. Ensuring an evidence-based approach through the use of systematic reviews and existing clinical guidelines.
3. Enabling a multidisciplinary approach; stimulating collaboration between primary health care providers and promoting consistency across providers and countries in Europe.
4. Promoting implementation of these guidelines across Europe.

To ensure an evidence-based approach, recommendations will be based on Cochrane and other systematic reviews and on existing evidence-based national guidelines. The European guidelines should be the basis for future national guidelines or future updates of existing national guidelines. National guideline committees should also take other aspects into account that may vary among countries, such as availability and costs. The European guidelines should also help health care providers to make evidence-based decisions, should improve the quality and outcome of health care, should lead to a more rational and efficient use of resources, and should identify gaps in the existing scientific evidence in order to prioritise future research.

Target population

The target population of the guidelines consists of health care providers who are reached through individuals or groups that are going to develop new guidelines or update existing guidelines, and their professional associations that will disseminate and implement these guidelines. Indirectly, these guidelines also aim to inform the general public, low back pain patients, and policy makers in Europe.

Structure of COST B13

The COST program of the European Committee stimulates and co-ordinates European collaboration in the field of scientific and technical research with the aim to establish networks of researchers across Europe. A bottom-up approach is used in which every member state can submit proposals for the so-called COST actions. Every COST action typically has a scientific secretariat located at the EC offices, a Management Committee that is responsible for the action, and several Working Groups.

Management committee

The Management Committee consists of researchers and clinical experts designated by the governments of the 13 participating countries. The members of the Management Committee have a number of tasks:

- To introduce this COST action to the relevant professional associations within their own country.
- To gather any scientific evidence from languages not in the existing reviews, to help translate it together with existing national guidelines, and to feed that information to the Working Groups.
- To explore possible sources of additional funding.

Furthermore, the Management Committee acts as an advisory and editorial board for the guidelines produced by the Working Groups. All members of the Management Committee can submit evidence or suggestions to the Working Groups. The Management Committee will comment on the first draft of guidelines produced by the Working Groups and will have final responsibility for approval of the guidelines.

Members of the Management Committee are responsible for dissemination of the guidelines to national health organisations, policy makers, and patient organizations in their own country. If resources are available, national or local meetings may be organised. The guidelines also will be published on a specific web-site 'www.backpaineurope.org'. National representatives participating in the Management Committee of COST B13 have the intention to stimulate implementation of the guidelines on a national level. However, resources are lacking to actively plan implementation in every country.

Working groups

Four Working Groups have been initiated within this COST B13 action that produce the final guidelines. National representatives participating in the working groups are also responsible for dissemination of the guidelines and also have the intention to stimulate implementation of the guidelines on a national level. WG1 on the diagnosis and treatment of acute low back pain (less than 12 weeks) consists of 15 experts from 11 countries; WG2 on the diagnosis and treatment of chronic low back pain (12 weeks or more) consists of 18 experts from 12 countries; WG3 on prevention (general population, workforce and schoolchildren) consists of 9 experts from 8 countries; WG4 on pelvic pain consists of 5 experts from 4 countries. The experts in the groups represent all countries that have issued guidelines for low back pain and all relevant health professions in the field of low back pain: anatomy, anaesthesiology, chiropractic, epidemiology, ergonomy, general practice, occupational care, orthopaedic surgery, pathology, physiology, physiotherapy, psychology, public health care, rehabilitation, and rheumatology.

Methods

Evidence

To ensure an evidence-based approach, the recommendations are based on Cochrane and other systematic reviews and on existing national guidelines if available, and original studies if not. A search for clinical guidelines was first performed in Medline. Since guidelines are only infrequently published in medical journals we extended the search on the Internet (using search terms 'back pain' and 'guidelines', and searching national health professional association and consumers websites) and identified guidelines by personal communication with experts in the field. The systematic reviews and original studies are identified using the results of validated search strategies (Dickersin et al. 1991; Haynes et al. 1994) in various databases: Medline, Embase, Cochrane Library, CINAHL, HealthStar, Pascal, PEDRO, Psyclit, Biosis, Lilacs and IME (Índice Médico Español).

Firstly, evidence is derived from systematic reviews. If there are no systematic reviews or if additional studies including those published in other languages are identified, these original studies are included. Secondly, existing national guidelines are compared and recommendations from these guidelines summarised. Thirdly, the members of the Working Groups discuss the evidence and recommendations of guidelines.

The methodological quality of systematic reviews is assessed in case they provide conflicting findings using a criteria list (Oxman & Guyatt, 1991) The methodological quality of additional trials will be assessed using relevant criteria

Table 2. Levels of evidence.

1. Therapy and prevention

Level A:
Generally consistent findings provided by (a systematic review of) multiple high quality randomised controlled trials (RCTs).

Level B:
Generally consistent findings provided by (a systematic review of) multiple low quality RCTs or non-randomised controlled trials (CCTs).

Level C:
One RCT (either high or low quality) or inconsistent findings from (a systematic review of) multiple RCTs or CCTs.

Level D:
No RCTs or CCTs.

Systematic review: systematic methods of selection and inclusion of studies, methodological quality assessment, data extraction and analysis.

2. Prognosis

Level A:
Generally consistent findings provided by (a systematic review of) multiple high quality prospective cohort studies.

Level B:
Generally consistent findings provided by (a systematic review of) multiple low quality prospective cohort studies or other low quality prognostic studies.

Level C:
One prognostic study (either high or low quality) or inconsistent findings from (a systematic review of) multiple prognostic studies.

Level D, no evidence:
No prognostic studies.

High quality prognostic studies: prospective cohort studies

Low quality prognostic studies: retrospective cohort studies, follow-up of untreated control patients in a RCT, case-series

3. Diagnosis

Level A:
Generally consistent findings provided by (a systematic review of) multiple high quality diagnostic studies.

Level B:
Generally consistent findings provided by (a systematic review of) multiple low quality diagnostic studies.

Level C:
One diagnostic study (either high or low quality) or inconsistent findings from (a systematic review of) multiple diagnostic studies.

Level D, no evidence:
No diagnostic studies.

High quality diagnostic study: Independent blind comparison of patients from an appropriate spectrum of patients, all of whom have undergone both the diagnostic test and the reference standard. (An appropriate spectrum is a cohort of patients who would normally be tested for the target disorder. An inappropriate spectrum compares patients already known to have the target disorder with patients diagnosed with another condition)

Low quality diagnostic study: Study performed in a set of non-consecutive patients, or confined to a narrow spectrum of study individuals (or both) all of who have undergone both the diagnostic test and the reference standard, or if the reference standard was unobjective, unblinded or not independent, or if positive and negative tests were verified using separate reference standards, or if the study was performed in an inappropriate spectrum of patients, or if the reference standard was not applied to all study patients.

related to the internal validity of trials.(van Tulder et al. 1997) High quality reviews and trials are less likely to be associated with biased results than low quality reviews and trials. As experts involved in this COST action conduct the quality assessment, it is not feasible to blind studies. Criteria are scored as positive, negative or unclear, and it is clearly defined when criteria are scored positive or negative. A consensus method is used to resolve disagreements and a third reviewer is consulted if disagreements persist.

The strength of the evidence is based on a four-level rating system used in best evidence syntheses of systematic reviews. This grading system is simple and easy to apply, and shows a large degree of consistency between the grading of therapeutic and preventive, prognostic and diagnostic studies (see Table 2).

Each Working Group summarizes the available evidence from systematic reviews, summarizes the recommendations of existing guidelines, and discusses these evidence and recommendations to develop the final recommendation for the European guideline.

Current status

The Management Committee had its first meeting in December 1999 at the offices of the European Commission in Brussels, Belgium. Five subsequent meetings were held in Brussels in February 2000 and December 2000, in Amsterdam, The Netherlands, in May 2001, in Liège, Belgium, in December 2001, and in Palma de Mallorca, Spain, in April, 2002.

The Working group on acute low back pain already has produced guidelines. The Working Groups on chronic low back pain, prevention and pelvic pain are in the process of analysing the available information, and expect to have a first draft by the end of 2002. An update of the guidelines is planned every two to three years, if new evidence is available. Further details on current status and on workgroup composition can be found at www.backpaineurope.org.

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