Eur Spine J (2006) 15 (Suppl. 2): S169–S191
DOI 10.1007/s00586-006-1071-2

Maurits van Tulder
Annette Becker
Trudy Bekkering
Alan Breen
Maria Teresa Gil del Real
Allen Hutchinson
Bart Koes
Even Laerum
Antti Malmivaara

On behalf of the COST B13 Working Group on Guidelines for the Management of Acute Low Back Pain in Primary Care

Chapter 3
European guidelines for the management of acute nonspecific low back pain in primary care

Contributors

Maurits van Tulder (chairman)	Epidemiologist	(NL)
Annette Becker	General practitioner	(GER)
Trudy Bekkering	Physiotherapist	(NL)
Alan Breen	Chiropractor	(UK)
Tim Carter	Occupational physician	(UK)
Maria Teresa Gil del Real	Epidemiologist	(ESP)
Allen Hutchinson	Public Health Physician	(UK)
Bart Koes	Epidemiologist	(NL)
Peter Kryger-Baggesen	Chiropractor	(DK)
Even Laerum	General practitioner	(NO)
Antti Malmivaara	Rehabilitation physician	(FIN)
Alf Nachemson	Orthopaedic surgeon	(SWE)
Wolfgang Niehus	Orthopaedic / anesthesiologist	(Aus)
Etienne Roux	Rheumatologist	(SUI)
Sylvie Rozenberg	Rheumatologist	(FR)

GUIDELINES FOR ACUTE NONSPECIFIC LOW BACK PAIN – Abstract

Based on systematic reviews and existing clinical guidelines

Summary of recommendations for diagnosis of acute nonspecific low back pain:

- Case history and brief examination should be carried out
- If history taking indicates possible serious spinal pathology or nerve root syndrome, carry out more extensive physical examination including neurological screening when appropriate
- Undertake diagnostic triage at the first assessment as basis for management decisions
- Be aware of psychosocial factors, and review them in detail if there is no improvement
- Diagnostic imaging tests (including X-rays, CT and MRI) are not routinely indicated for nonspecific low back pain
- Reassess those patients who are not resolving within a few weeks after the first visit, or those who are following a worsening course

Summary of recommendations for treatment of acute nonspecific low back pain:

- Give adequate information and reassure the patient
- Do not prescribe bed rest as a treatment
- Advise patients to stay active and continue normal daily activities including work if possible
- Prescribe medication, if necessary for pain relief; preferably to be taken at regular intervals; first choice paracetamol, second choice NSAIDs
- Consider adding a short course of muscle relaxants on its own or added to NSAIDs, if paracetamol or NSAIDs have failed to reduce pain
- Consider (referral for) spinal manipulation for patients who are failing to return to normal activities
- Multidisciplinary treatment programmes in occupational settings may be an option for workers with subacute low back pain and sick leave for more than 4–8 weeks

Objectives

The primary objective of these European evidence-based guidelines is to provide a set of recommendations that can support existing and future national and international guidelines or future updates of existing guidelines.

These guidelines intend to improve the primary care management of acute nonspecific low back pain for adult patients in Europe, by:

1. Providing recommendations on the clinical management of acute nonspecific low back pain in primary care.
2. Ensuring an evidence-based approach through the use of systematic reviews and existing clinical guidelines.
3. Providing recommendations that are generally acceptable by all health professions in all participating countries.
4. Enabling a multidisciplinary approach; stimulating collaboration between primary health care providers and promoting consistency across providers and countries in Europe.

Target population

The target population of the guidelines consists of 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, patients with low back pain, health care providers (for example, general practitioners, physiotherapists, chiropractors, manual therapists, occupational physicians, orthopaedic surgeons, rheumatologists, rehabilitation physicians, neurologists, anaesthesiologists and other health care providers dealing with patients suffering from acute nonspecific low back pain), and policy makers in Europe.

Guidelines working group

The guidelines were developed within the framework of the COST ACTION B13 ‘Low back pain: guidelines for its management’, issued by the European Commission, Research Directorate-General, department of Policy, Coordination and Strategy. The guidelines working group consisted of experts in the field of low back pain research in primary care who have been involved in the develop-

ment of national guidelines for low back pain in their countries. Members were invited to participate, taking into account that all relevant health professions should be represented. The group consisted of 10 men and 4 women with various professional backgrounds. All countries that had already issued national guidelines were represented [NL: Bekkering, Koes, Van Tulder; Fra: Rozenberg; Ger: Becker; UK: Breen, Carter, Hutchinson; DK: Kryger-Baggesen; Fin: Malmivaara; Sui: Roux; Swe: Nachemson]. Because the United Kingdom and the Netherlands have produced most of the systematic reviews and clinical guidelines, these two countries were represented by more than one participant.

The guidelines working group had its first meeting in November 2000. In December 2000, the first draft of the guidelines was prepared. Three subsequent meetings in February, April and May 2001 were used to discuss this draft. The draft was circulated through email among the members of the working group for their final comments and approval. Finally, the final draft was sent for peer review to the members of the Management Committee of COST B13 and discussed at two subsequent meetings in December 2001 and April 2002. Two meetings in December 2003 and March 2004 were used to update the evidence review and guideline recommendations. An update of the guidelines is recommended within three years, when new evidence has become available.

Evidence

The main evidence was not systematically reviewed again for the purpose of this guideline, because 1) there already is a large amount of evidence on diagnosis and treatment of acute nonspecific low back pain, 2) this evidence has already been summarised in many systematic reviews, and 3) this evidence has already been translated into clinical recommendations in various national clinical guidelines. To ensure an evidence-based approach, the recommendations were based on Cochrane reviews (and on other systematic reviews if a Cochrane review was not available), additional trials published after the Cochrane reviews, and existing national guidelines. The authors of this guideline had no financial conflict of interest and were not involved in quality assessment or discussion of their own papers.

The systematic reviews were identified using the results of validated search strategies in the Cochrane Library, Medline, Embase and, if relevant, other electronic databases, performed for Clinical Evidence, a monthly, updated directory of evidence on the effects of common clinical interventions, published by the BMJ Publishing Group (www.evidence.org). The literature search covered the period from 1966 to October 2003. 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.

A three-stage development process was undertaken. First, recommendations were derived from systematic reviews. Secondly, existing national guidelines were compared and recommendations from these guidelines summarised. Thirdly, the recommendations from the systematic (Cochrane) reviews and guidelines were discussed by the group. A section was added to the guidelines in which the main points of debate are described. The recommendations are put in a clinically relevant order; recommendations regarding diagnosis have a letter D, treatment T.

A grading system was used for the strength of the evidence (Appendix 1). 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. The system is based on the original ratings of the AHCPR Guidelines (1994) and levels of evidence recommended in the method guidelines of the Cochrane Back Review group [1,2]. The strength of the recommendations was not graded.

Several of the existing systematic reviews have included non-English language literature, usually publications in French, German, and Dutch language and sometimes also Danish, Norwegian, Finnish and Swedish. All existing national guidelines included studies published in their own language. Consequently, the non-English literature is covered for countries that already have developed guidelines. The group additionally included the Spanish literature, because this evidence was not covered by existing reviews and guidelines (see Appendix IV).

The Working Group aimed to identify gaps in the literature and included recommendations for future research.

Introduction

Definitions

Low back pain is defined as pain and discomfort, localised below the costal margin and above the inferior gluteal folds, with or without leg pain.

Acute low back pain is usually defined as the duration of an episode of low back pain persisting for less than 6 weeks; sub-acute low back pain as low back pain persisting between 6 and 12 weeks; chronic low back pain as low back pain persisting for 12 weeks or more. In this guideline, recommendations are related to both acute and subacute low back pain unless specifically stated otherwise. Recurrent low back pain is defined as a new episode after a symptom-free period of 6 months, but not an exacerbation of chronic low back pain.

nonspecific low back pain is defined as low back pain not attributed to recognisable, known specific pathology (e.g. infection, tumour, osteoporosis, ankylosing spondyli-

tis, fracture, inflammatory process, radicular syndrome or cauda equina syndrome).

'Red flags'

The initial clinical history taking should aim at identifying 'red flags' of possible serious spinal pathology.[3] **'**Red flags' are risk factors detected in low back pain patients' past medical history and symptomatology and are associated with a higher risk of serious disorders causing low back pain compared to patients without these characteristics. If any of these are present, further investigation (according to the suspected underlying pathology) may be required to exclude a serious underlying condition, e.g. infection, inflammatory rheumatic disease or cancer.

'Red flags' are signs in addition to low back pain. These include:[3]

- Age of onset less than 20 years or more than 55 years
- Recent history of violent trauma
- Constant progressive, non mechanical pain (no relief with bed rest)
- Thoracic pain
- Past medical history of malignant tumour
- Prolonged use of corticosteroids
- Drug abuse, immunosuppression, HIV
- Systemically unwell
- Unexplained weight loss
- Widespread neurological symptoms (including cauda equina syndrome)
- Structural deformity
- Fever

Cauda equina syndrome is likely to be present when patients describe bladder dysfunction (usually urinary retention, occasionally overflow incontinence), sphincter disturbance, saddle anaesthesia, global or progressive weakness in the lower limbs, or gait disturbance. This requires urgent referral.

'Yellow flags'

Psychosocial 'yellow flags' are factors that increase the risk of developing, or perpetuating chronic pain and long-term disability (including) work-loss associated with low back pain.[4] Identification of 'yellow flags' should lead to appropriate cognitive and behavioural management. However, there is no evidence on the effectiveness of psychosocial assessment or intervention in acute low back pain.

Examples of 'yellow flags' are:[4]

1. Inappropriate attitudes and beliefs about back pain (for example, belief that back pain is harmful or potentially severely disabling or high expectation of passive treatments rather than a belief that active participation will help),
2. Inappropriate pain behaviour (for example, fear-avoidance behaviour and reduced activity levels),
3. Work related problems or compensation issues (for example, poor work satisfaction)
4. Emotional problems (such as depression, anxiety, stress, tendency to low mood and withdrawal from social interaction).

Epidemiology

The lifetime prevalence of low back pain is reported as over 70% in industrialised countries (one-year prevalence 15% to 45%, adult incidence 5% per year). Peak prevalence occurs between ages 35 and 55.[5]

Symptoms, pathology and radiological appearances are poorly correlated. Pain is not attributable to pathology or neurological encroachment in about 85% of people. About 4% of people seen with low back pain in primary care have compression fractures and about 1% has a neoplasm. Ankylosing spondylitis and spinal infections are rarer. The prevalence of prolapsed intervertebral disc is about 1% to 3%.[6]

Risk factors are poorly understood. The most frequently reported are heavy physical work, frequent bending, twisting, lifting, pulling and pushing, repetitive work, static postures and vibrations.[5] Psychosocial risk factors include stress, distress, anxiety, depression, cognitive dysfunction, pain behaviour, job dissatisfaction, and mental stress at work.[5,7,8]

Acute low back pain is usually self-limiting (recovery rate 90% within 6 weeks) but 2%–7% of people develop chronic pain. Recurrent and chronic pain account for 75% to 85% of total workers' absenteeism.[5,9]

Outcomes

The aims of treatment for acute low back pain are to relieve pain, to improve functional ability, and to prevent recurrence and chronicity. Relevant outcomes for acute low back pain are pain intensity, overall improvement, back pain specific functional status, impact on employment, generic functional status, and medication use. [10] Intervention-specific outcomes may also be relevant, for example coping and pain behaviour for behavioural treatment, strength and flexibility for exercise therapy, depression for antidepressants, and muscle spasm for muscle relaxants.

Structure of the guideline

The guideline includes recommendations on diagnosis and treatment. We have included these as separate chapters starting with diagnosis. However, there will be some overlap between the diagnosis and treatment sections because in clinical practice diagnosis at the first visit will probably lead to treatment. If patients fail to recover and require reassessment, this will probably lead to review of the management plan. We have included the reassessment section in the chapter on diagnosis for practical reasons.

Diagnosis of acute low back pain

For most patients with acute low back pain a thorough history taking and brief clinical examination is sufficient. The primary purpose of the initial examination is to attempt to identify any 'red flags' and to make a specific diagnosis. It is, however, well-accepted that in most cases of acute low back pain it is not possible to arrive at a diagnosis based on detectable pathological changes. Because of that several systems of diagnosis have been suggested, in which low back pain is categorised based on pain distribution, pain behaviour, functional disability, clinical signs etc. However, none of these systems of classification have been critically validated.

A simple and practical classification, which has gained international acceptance, is by dividing acute low back pain into three categories – the so-called 'diagnostic triage':

- Serious spinal pathology
- Nerve root pain / radicular pain
- nonspecific low back pain

The priority in the examination procedure follows this line of clinical reasoning. The first priority is to make sure that the problem is of musculoskeletal origin and to rule out non-spinal pathology. The next step is to exclude the presence of serious spinal pathology. Suspicion therefore is awakened by the history and/or the clinical examination and can be confirmed by further investigations. The next priority is to decide whether the patient has nerve root pain. The patient's pain distribution and pattern will indicate that, and the clinical examination will often support it. If that is not the case, the pain is classified as nonspecific low back pain.

The initial examination serves other important purposes besides reaching a 'diagnosis'. Through a thorough history taking and physical examination, it is possible to evaluate the degree of pain and functional disability. This enables the health care professional to outline a management strategy that matches the magnitude of the problem. Finally, the careful initial examination serves as a basis for credible information to the patient regarding diagnosis, management and prognosis and may help in reassuring the patient.

D1 Diagnostic triage

Evidence D1

Although there is general consensus on the importance and basic principles of differential diagnosis, there is little scientific evidence on the diagnostic triage (level D).

History taking

One systematic review of 9 studies evaluated the accuracy of history in diagnosing low back pain in general practice.[11] The review found that history taking does not have a high sensitivity and high specificity for radiculopathy and ankylosing spondylitis. The combination of history and erythrocyte sedimentation rate had a relatively high diagnostic accuracy in vertebral cancer (level A).

Physical examination

One systematic review of 17 studies found that the pooled diagnostic Odds Ratio for straight leg raising for nerve root pain was 3.74 (95% CI 1.2 – 11.4); sensitivity for nerve root pain was high (1.0 – 0.88), but specificity was low (0.44 – 0.11).[12] All included studies were surgical case-series at non-primary care level. Most studies evaluated the diagnostic value of SLR for disc prolapse. The pooled diagnostic Odds Ratio for the crossed straight leg raising test was 4.39 (95% CI 0.74 – 25.9); with low sensitivity (0.44 – 0.23) and high specificity ((0.95 – 0.86). The authors concluded that the studies do not enable a valid evaluation of diagnostic accuracy of the straight leg raising test (level A).[12]

Clinical guidelines D1

All guidelines propose some form of diagnostic triage in which patients are classified as having (1) possible serious spinal pathology; 'red flag' conditions such as tumour, infection, inflammatory disorder, fracture, cauda equina syndrome, (2) nerve root pain, and (3) nonspecific low back pain. All guidelines are consistent in their recommendations that diagnostic procedures should focus on the identification of 'red flags' and the exclusion of specific diseases (sometimes including radicular syndrome). 'Red flags' are signs in addition to low back pain and include, for example, age of onset less than 20 years or more than 55 years, significant trauma, thoracic pain, weight loss, and widespread neurological symptoms. The types of physical examination and physical tests that are recommended show some variation. Neurological screening, which is largely based on the straight leg raising test (SLR), plays an important role in most guidelines.

Discussion / commentary D1

Diagnostic triage is essential to further management of the patient even though the level of evidence is not strong. Individual 'red flags' do not necessarily link to specific pathology but indicate a higher probability of a serious underlying condition that may require further investigation. Multiple 'red flags' need further investigation.

The aim of history taking and physical examination is contributing to the diagnosis, exclude serious pathology, and identify risk factors for poor outcomes. The group agrees that extensive physical examination is not always necessary for patients without any indication of serious spinal pathology or nerve root pain. It is considered that a brief physical examination is always an essential part of the management of acute low back pain. A properly conducted straight leg raising test is the most accurate test to

identify nerve root pain. The group strongly agrees that history taking and physical examination should be carried out by a health professional with competent skills. Competence will depend on appropriate training.

Recommendation D1
Undertake diagnostic triage consisting of appropriate history taking and physical examination at the first assessment to exclude serious spinal pathology and nerve root pain. If serious spinal pathology and nerve root pain are excluded, manage the low back pain as nonspecific.

D2 Psychosocial risk factors

Evidence D2
One systematic review was found of 11 cohort and 2 case-control studies evaluating psychosocial risk factors for the occurrence of low back pain.[7] Strong evidence was found for low social support in the workplace and low job satisfaction as risk factors for low back pain (level A). There was moderate evidence that psychosocial factors in private life are risk factors for low back pain (level B). There was also strong evidence that low job content had no effect on the occurrence of low back pain (level A). Conflicting evidence was found for a high work pace, high qualitative demands, and low job content (level C).

Another systematic review found that there is strong evidence that psychosocial factors play an important role in chronic low back pain and disability, and moderate evidence that they are important at a much earlier stage than previously believed (level A).[8]

Clinical guidelines D2
All guidelines, with varying emphasis, mention the importance of considering psychosocial factors as risk factors for the development of chronic disability. There is, however, considerable variation in the amount of detail given about how to assess psychosocial factors or the optimal timing of the assessment, and specific tools for identifying these factors are scarce. The UK guideline [3] gives a list describing four main groups of psychosocial risk factors, whilst the New Zealand guideline [4,13] gives by far the most attention towards explicit screening of psychosocial factors, using a standardised questionnaire.[14]

Discussion / consensus D2
The group strongly agrees that there should be awareness of psychosocial factors from the first visit in primary care to identify patients with an increased risk of developing chronic disability. The group suggests considering it useful information for later management. Explicit screening of psychosocial factors (for example by using specific questionnaires or instruments) may be performed when there are recurrent episodes or no improvement.

Recommendation D2
Assess for psychosocial factors and review them in detail if there is no improvement.

D3 Diagnostic imaging

Evidence D3
One systematic review was found that included 31 studies on the association between X-ray findings of the lumbar spine and nonspecific low back pain.[15] The results showed that degeneration, defined by the presence of disc space narrowing, osteophytes and sclerosis, is consistently and positively associated with nonspecific low back pain with Odds Ratios ranging from 1.2 (95% CI 0.7 – 2.2) to 3.3 (95% CI 1.8 – 6.0). Spondylolysis/listhesis, spina bifida, transitional vertebrae, spondylosis and Scheuermann's disease did not appear to be associated with low back pain (level A). There is no evidence on the association between degenerative signs at the acute stage and the transition to chronic symptoms.

A recent review of the diagnostic imaging literature (magnetic resonance imaging, radionuclide scanning, computed tomography, radiography) concluded that for adults younger than 50 years of age with no signs or symptoms of systemic disease, diagnostic imaging does not improve treatment of low back pain. For patients 50 years of age and older or those whose findings suggest systemic disease, plain radiography and simple laboratory tests can almost completely rule out underlying systemic diseases. The authors concluded that advanced imaging should be reserved for patients who are considering surgery or those in whom systemic disease is strongly suspected (level A).[16]

A recent RCT of 380 patients aged 18 years or older whose primary physicians had ordered that their low back pain be evaluated by radiographs determined the clinical and economic consequences of replacing spine radiographs with rapid MRI.[17] Although physicians and patients preferred the rapid MRI, there was no difference between rapid MRIs and radiographs in outcomes for primary care patients with low back pain. The authors concluded that substituting rapid MRI for radiographic evaluations in the primary care setting may offer little additional benefit to patients, and it may increase the costs of care because of the increased number of spine operations that patients are likely to undergo.

Clinical guidelines D3
The guidelines are consistent in the recommendation that plain X-rays are not useful in acute nonspecific low back pain and that X-rays should be restricted to cases suspected of specific underlying pathology (based on 'red flags'). In some guidelines X-rays are suggested as optional in case of low back pain persisting for more than 4 to 6 weeks).[1,3,18,19] None of the guidelines recommend any

form of radiological imaging for acute, nonspecific low back pain while the US and UK guidelines overtly advise against.[1,3]

Discussion / consensus D3

Although there is some evidence for an association between severe degeneration and nonspecific low back pain, the group agrees that the association is only weak and that it does not have any implications for further management. If a patient with low back pain but no 'red flags' shows signs of disc space narrowing, this has no implications for the choice of therapy or the chances of recovery. The risks of the high doses of radiation in X-rays of the lumbar spine do not justify routine use.

The group strongly agrees that diagnostic imaging tests should not be used if there are no clear indications of possible serious pathology or radicular syndrome. The type of imaging test that may be used in such cases is outside the scope of this guideline. Although X-rays are commonly used for reassurance, there is no evidence to support this. A randomised trial even showed that radiography of the lumbar spine was not associated with improved clinical outcomes, but with increased workload of the general practitioners.[20]

Recommendation D3

Diagnostic imaging tests (including X-rays, CT and MRI) are not routinely indicated for acute nonspecific low back pain.

D4 Reassessment of patients whose symptoms fail to resolve

Evidence D4

There is no scientific evidence on the reassessment of patients (level D).

Clinical guidelines D4

Most guidelines do not specifically address reassessment. The New Zealand guidelines stated that 'A reasonable approach for most patients is a review by the end of the first week, unless symptoms have completely resolved.[13] It may be appropriate to arrange an earlier review, to reinforce the message to keep active and avoid prolonged bed rest.' The Dutch guidelines advise reassessment at follow-up visits after 1 week if severe pain does not subside, after 3 weeks if the symptoms are not diminishing, and after 6 weeks if there is still disability or if there is no progress in function, or if pain does not decline.[21] The Danish guidelines recommend re-evaluation after 2 and 4 weeks if low back pain is unchanged or worsened.[19]

Discussion / consensus D4

The group feels that the thresholds for reassessment of 4–6 weeks used in most existing guidelines are arbitrary and suggests using them flexibly, because the interval between onset and first visit to a primary health care provider is variable.

Reassessment should include psychosocial factors. The group agrees that diagnostic imaging at this stage still does not add anything to the management strategy if there are no red flags.

Recommendation D4

Reassess those patients who are not resolving within a few weeks after the first visit or those who are following a worsening course. Exclude serious pathology and nerve root pain. If identified, consider further appropriate management. Identify psychosocial factors and manage appropriately.

Treatment for acute low back pain

Various health care providers may be involved in the treatment of acute low back pain in primary care. Although there may be some variations between European countries, general practitioners, physiotherapists, manual therapists, chiropractors, exercise therapists (e.g., Alexander, Feldenkrais, Mendendieck, Cesar therapists), McKenzie therapists, orthopaedic surgeons, rheumatologists, physiatrists (specialists in physical medicine and rehabilitation) and others, may all be involved in providing primary care for people with acute low back pain. It is important that information and treatment are consistent across professions, and that all health care providers closely collaborate with each other.

Treatment of acute low back pain in primary care aims at: 1) providing adequate information, reassuring the patient that low back pain is usually not a serious disease and that rapid recovery is expected in most patients; 2) providing adequate symptom control, if necessary; and 3) recommending the patient to stay as active as possible and to return early to normal activities, including work. An active approach is the best treatment option for acute low back pain. Passive treatment modalities (for example bed rest, massage, ultrasound, electrotherapy, laser and traction) should be avoided as mono-therapy and not routinely be used, because they may increase the risk of illness behaviour and chronicity.

Recommendations included in these guidelines relate mainly to pain causing activity limitations or to patients seeking care.

Referral to secondary health care should usually be limited to patients in whom there is a suspicion of serious spinal pathology or nerve root pain (see diagnostic triage).

Recommendations for treatment are only included if there is evidence from systematic reviews or high quality RCTs on acute nonspecific low back pain. No RCTs have been identified on various commonly used interventions for acute low back pain, for example acupuncture, heat/cold, electrotherapy, ultrasound, trigger point and facet

joint injections, and physiotherapy (defined by a combination of information, exercise therapy and physical modalities (e.g, massage, ultrasound, electrotherapy)).

T1 Information and reassurance

Evidence T1

One non-systematic review evaluated the effectiveness of educational interventions for back pain in primary care.[22] One study showed that an educational booklet decreased the number of visits to a general practitioner for back pain. Another study showed that a 15-minute session with a primary care nurse plus an educational booklet and a follow-up phone call resulted in greater short-term patient satisfaction and perceived knowledge compared with usual care, but symptoms, physical functioning and health care utilisation were not different (level C). In another trial published after the review, patients were given either an experimental booklet (the 'Back Book') or a traditional booklet.[23] Patients receiving the experimental booklet showed greater early improvement in beliefs and functional status but there was no effect on pain (level C).

The review is not systematic and trials included in the review have various controls and outcomes. A Cochrane review is currently being conducted.

Guidelines T1

Most guidelines recommend reassuring patients. The UK, US, Swiss, Finnish and Dutch guidelines recommend providing reassurance by explaining that there is nothing dangerous and that a rapid recovery can be expected.[1,3,21,24-26] The US guidelines also stated that patients who do not recover within a few weeks may need more extensive education about back problems and told that special studies may be considered if recovery is slow.[1] The Swiss guidelines added that it is important to reassure patients through adequate information instead of making them insecure by stating that 'nothing was found'.[24,25] The New Zealand guidelines stated that 'it is important to let the patient know that, if a full history and examination have uncovered no suggestion of serious problems, no further investigations are needed.'[13]

Discussion T1

The group recommends reassuring the patient by acknowledging the pain of the patient, being supportive and avoiding negative messages. It is important to give a full explanation in terms that the patient understands, for example, back pain is very common; although back pain is often recurrent, usually the outlook is very good; hurting does not mean harm; it could arise from various structures, such as muscles, discs, joints or ligaments. Cover the points discussed elsewhere in this guideline as appropriate.

Core items of adequate information should be: good prognosis, no need for x-rays, no underlying serious pathology, and stay active. Consistency across professions is very important.

Give adequate information and reassure the patient.

T2 Bed rest

Evidence T2

Six systematic reviews (10 RCTs, no statistical pooling) evaluated the effect of bed rest for acute low back pain.[1,27-31] Five RCTs (n=921) compared bed rest to alternative treatments, e.g., exercises, physiotherapy, spinal manipulation, or NSAIDs. They found either no differences or that bed rest was worse using outcomes of pain, recovery rate, time to return to daily activities and sick leave (level A). Five RCTs (n=663) found that bed rest was no different or worse than no treatment or placebo (level A). Two RCTs (n=254) found that seven days of bed rest was no different from 2 to 4 days bed rest.

Clinical guidelines T2

There now appears to be broad consensus that bed rest should be discouraged as treatment for low back pain.[24-26,32,33] Some guidelines state that if bed rest is indicated (because of severity of pain), it should not be advised for more than 2 days.[13,18,19,21,34] The UK guideline suggests that some patients may be confined to bed for a few days but that should be regarded as a consequence of their pain and should not be considered a treatment.[3] The US guidelines stated that the majority of back pain patients will not require bed rest, and that prolonged bed rest for more than 4 days may lead to debilitation and is not recommended.[1]

Discussion / consensus T2

The group agrees that bed rest does not promote recovery. Adverse effects of bed rest are joint stiffness, muscle wasting, loss of bone mineral density, and venous thrombo-embolism.[1] Prolonged bed rest may lead to chronic disability and may impair rehabilitation.

Recommendation T2

Do not prescribe bed rest as a treatment.

T3 Advice to stay active

Evidence T3

Two systematic reviews found that advice to stay active (with or without other treatments) reduced disability, pain, and time spent off work compared with bed rest (with or without other treatments).[31,35]

One systematic review of eight RCTs found that there is strong evidence that advice to stay active is associated with equivalent or faster symptomatic recovery, and leads to less chronic disability and less time off work than bed

rest or usual care (level A).[31] Advice to stay active was either provided as single treatment or in combination with other interventions such as back schools, a graded activity programme or behavioural counselling. Two RCTs (n=228) found faster rates of recovery, less pain and less disability in the group advised to stay active than in the bed rest group. Five RCTs (n=1500) found that advice to stay active led to less sick leave and less chronic disability compared to traditional medical treatment (analgesics as required, advice to rest and 'let pain be your guide').

The other systematic review included four trials with a total of 491 patients.[35] Advice to stay active was compared to advice to rest in bed in all trials. The results were inconclusive. Results from one high quality trial of patients with acute simple LBP found small differences in functional status and length of sick leave in favour of staying active compared to advice to stay in bed for two days. One of the high quality trials also compared advice to stay active with exercises for patients with acute simple LBP, and found improvement in functional status and reduction in sick leave in favour of advice to stay active.

Two subsequent RCTs do not change the conclusion [36,37].

Clinical guidelines T3

Guidelines in the Netherlands, New Zealand, Finland, Norway, United Kingdom, Australia, Germany, Switzerland and Sweden all recommend advice to stay active.[3,13,21,24-26,32-34,38,39] Other guidelines made no explicit statement regarding advice to stay active.

Discussion / consensus T3

The recommendation in this guideline is based on additional evidence from one Cochrane review and two subsequent RCTs that were not included in earlier national guidelines. The group feels that advice to continue normal activities if possible is important. There is also consensus that advice to stay at work or return to work if possible is important. Observational studies indicate that a longer duration of work absenteeism is associated with poor recovery (lower chance of ever returning to work) [see also appendix II 'Back pain and work'].

Recommendation T3

Advise patients to stay active and continue normal daily activities including work if possible.

T4 Exercise therapy

Evidence T4

Five systematic reviews and 12 additional RCTs (39 RCTs in total, no statistical pooling) evaluated the effect of exercise therapy for low back pain.[1,27,30,40,41] Results for acute and chronic low back pain were not reported separately in three trials.

Twelve RCTs (n=1894) reported on acute low back pain. Eight trials compared exercises with other conservative treatments (usual care by the general practitioner, continuation of ordinary activities, bed rest, manipulation, NSAIDs, mini back school or short-wave diathermy). Seven of these found no differences or even mildly worse outcomes (pain intensity and disability) for the exercise group (level A). Only one trial reported better outcomes for the exercise therapy group on pain and return to work compared to a mini back school. Four trials (n=1234) compared exercises with 'inactive' treatment (i.e., bed rest, educational booklet, and placebo ultrasound) and found no differences in pain, global improvement or functional status (level A). Two small studies (n=86) compared flexion to extension exercises, and found a significantly larger decrease of pain and a better improvement in functional status with extension exercises.

Clinical guidelines T4

Recommendations regarding exercise therapy also show some variation. In several guidelines, back-specific exercises (e.g., strengthening, flexion, extension, stretching) are considered not useful during the first weeks of an episode.[3,21,26,38,39] Other guidelines state that low stress aerobic exercises are a therapeutic option in acute low back pain.[1] The Danish guidelines specifically mention McKenzie exercise therapy as a therapeutic option in some patients with acute low back pain.[19] The Australian guidelines state that therapeutic exercises are not indicated in acute low back pain, but that general exercises for maintaining mobility and avoiding sick role may be considered.[33] The Finnish recommend guided exercises as part of multidisciplinary rehabilitation for subacute low back pain.[26] Guidelines from Switzerland consider exercises (active therapy, mobilising, relaxation, strengthening) optional in the first 4 weeks, and useful after 4 weeks as training programmes within an activating approach.[24,25]

Discussion / consensus T4

The group agrees that the advice to stay active or to get active should be promoted, and that increase in fitness will improve general health. However, the current scientific evidence does not support the use of specific strengthening or flexibility exercises as a treatment for acute nonspecific low back pain.

Recommendation T4

Do not advise specific exercises (for example strengthening, stretching, flexion, and extension exercises) for acute low back pain.

T5 Analgesia (paracetamol, nsaids, muscle relaxants)

Evidence T5

Paracetamol

Two systematic reviews found strong evidence that paracetamol is not more effective than NSAIDs.[1,30] There is strong evidence from a systematic review in other situations that analgesics (paracetamol and weak opioids) provide short-term pain relief.[42] Six RCTs (total n=329) reported on acute low back pain. Three compared analgesics with NSAIDs. Two of these (n=110) found that meptazinol, paracetamol and diflunisal (a NSAID) reduced pain equally. The third trial found that mefenemic acid reduced pain more than paracetamol, but that aspirin and indomethacin were equally effective.

NSAIDs

Two systematic reviews found strong evidence that regular NSAIDs relieve pain but have no effect on return to work, natural history or chronicity.[43,44] NSAIDs do not relieve radicular pain. Different NSAIDs are equally effective. Statistical pooling was only performed for NSAIDs *v* placebo in acute low back pain.

Versus placebo: Nine RCTs (n=1135) found that NSAIDs increased the number of patients experiencing global improvement (pooled OR after 1 week 2.00, 95% CI 1.35 to 3.00) and reduced the number needing additional analgesic use (pooled OR 0.64, 95% CI 0.45 to 0.91). Four RCTs (n=313) found that NSAIDs do not relieve radicular pain.

Versus paracetamol: Three trials (n=153) found conflicting results. Two RCTs (n=93) found no differences in recovery, and one RCT (n=60) found more pain reduction with mefenamic acid than paracetamol.

Versus muscle relaxants and opioid analgesics: Five out of six RCTs (n=399 out of 459) found no differences in pain and overall improvement. One RCT (n=60) reported more pain reduction with mefenamic acid than with dextropropoxyphene plus paracetamol.

Versus non-drug treatments: Three trials (n=461). One RCT (n=110) found that NSAIDs improved range-of-motion more than bed rest and led to lesser need for treatment. One trial (n=241) found no statistically significant difference. Two studies (n=354) found no differences between NSAIDs and physiotherapy or spinal manipulation in pain and mobility.

Versus each other: 15 RCTs (n=1490) found no difference in efficacy. One recent trial (n=104) found somewhat better improvement of funcioning with nimesulide, a COX-2 inhibitor, compared with ibuprofen 600 mg, but no differences on pain relief.[45]

Muscle relaxants

Three systematic reviews (24 RCTs; n=1662) found strong evidence that muscle relaxants reduce pain and that different types are equally effective.[1,30,46]

Twenty-four trials on acute low back pain were identified. Results showed that there is strong evidence that any of these muscle relaxants (tizanidine, cyclobenzaprine, dantrolene, carisoprodol, baclofen, orphenadrine, diazepam) are more effective than placebo for patients with acute LBP on short-term pain relief. The one low quality trial on benzodiazepines for acute LBP showed that there is limited evidence (1 trial; 50 people) that an intramuscular injection of diazepam followed by oral diazepam for 5 days is more effective than placebo on short-term pain relief and better overall improvement (level C). The pooled RR for non-benzodiazepines versus placebo after two to four days was 0.80 [95% CI; 0.71 to 0.89] for pain relief and 0.49 [95% CI; 0.25 to 0.95] for global efficacy (level A). The various muscle relaxants were found to be similar in performance.

Clinical guidelines T5

Guidelines of the USA, New Zealand, Switzerland, Denmark, Finland, the Netherlands, UK, Germany and Australia all recommend paracetamol and NSAIDs, in that order.[1,3,13,19,21,24-26,33,34] The Israeli guidelines only recommend NSAIDs.[18] Guidelines of the Netherlands, UK and Sweden explicitly recommend a time-contingent prescription, while the other guidelines do not mention this.[3,21,32]

The Danish, Dutch, New Zealand guidelines clearly state that muscle relaxants should not be used in the treatment of low back pain, because of the risk of physical and psychological dependency.[13,19,21] The German and Swiss guidelines state that muscle relaxants may be an option if muscle spasms play an important role.[24,25,34] The US guidelines state that muscle relaxants are an option in the treatment of acute low back pain, but that they have potential side effects.[1] The UK guidelines recommend considering to add a short course (less than 1 week) if paracetamol, NSAIDs or paracetamol-weak opioid compounds failed to provide adequate pain control.[3]

Discussion / consensus T5

Adverse effects of paracetamol are usually mild. Combinations of paracetamol and weak opioids slightly increase the risk of adverse effects with OR 1.1 (95% CI 0.8 to 1.5) for single dose studies and OR 2.5 (95% CI 1.5 to 4.2) for multiple dose studies.[42] Adverse effects of NSAIDs (particularly at high doses and in the elderly) may be serious.[1,47] Effects include gastritis and other gastro-intestinal complaints (affect 10% of people). Ibuprofen and diclofenac have the lowest gastrointestinal complication rate, mainly due to the low doses used in practice (pooled OR for adverse effects compared to placebo 1.27 95% CI 0.91 to 1.78). [47]. Adverse effects of

muscle relaxants include drowsiness and dizziness in up to about 70% of patients, and a risk of dependency even after one week of treatment.[1,44] Adverse effects were significantly more prevalent in patients receiving muscle relaxants compared to placebo with a relative risk of 1.50 [95% CI; 1.14 to 1.98], and especially the central nervous system adverse effects (RR 2.04; 95% CI; 1.23 to 3.37).

There was consensus among the group that paracetamol is to be preferred as first choice medication for acute low back pain, because of the evidence of effectiveness from other studies outside the field of low back pain and because of the low risk of side effects. If the patient is already taking an adequate doses of paracetamol, NSAIDs may be started. If the patient already takes an NSAID, a combination of NSAIDs and mild opiates, a combination of paracetamol and mild opiates or a combination of NSAIDs and muscle relaxants may be used. The group acknowledges the disagreement that exists among the various guidelines regarding muscle relaxants and suggests very limited use of (if any) and only a short course of muscle relaxants due to the high risk of side effects and the danger of habituation. The group points out that there is no evidence for a time-contingent prescription of drugs, but that it reflects the way it has been used in RCTs and that it is consistent with advice to stay active and encouragement to continue ordinary activities.

Recommendation T5
Prescribe medication, if necessary, for pain relief. Preferably to be taken at regular intervals. First choice paracetamol, second choice NSAIDs. Only consider adding a short course of muscle relaxants on its own or added to NSAIDs, if paracetamol or NSAIDs have failed to reduce pain.

T6 Epidural steroids

Evidence T6
Four systematic reviews included two small RCTs on acute low back pain.[1,30,48-50] The second trial (n=63, epidural steroids *v* epidural saline, epidural bupivacaine and dry needling) found no difference in number of patients improved or cured. We found conflicting evidence on the effectiveness of epidural steroids.

Clinical guidelines T6
The German, Norwegian and Danish guidelines do not recommend epidural injections for acute nonspecific low back pain.[19,34,39] The other guidelines do not include any recommendations regarding epidural steroids for acute low back pain.

Discussion / consensus T6
General consensus. The group concludes that there is a lack of sufficient evidence on epidural steroid injections for acute nonspecific low back pain. Adverse effects are infrequent and include headache, fever, subdural penetration and more rarely epidural abscess and ventilatory depression.[1]

Recommendation T6
Do not use epidural steroid injections for acute nonspecific low back pain.

T7 Spinal manipulation

Evidence T7
We found six systematic reviews [1,27,30,51-53] and one recent Cochrane review [54] (search date 2000). The Cochrane review included 17 RCTs on acute low back pain.

Versus placebo/Sham: Patients receiving manipulation showed clinically important short-term (less than 6 weeks) improvements in pain (10-mm difference in pain (95% CI, 2-17 mm) on a 100-mm visual analogue scale) and functional status (2.8 points difference on the Roland-Morris Scale (95% CI, -0.1 to 5.6)) compared to sham therapy or therapies judged to be ineffective or even harmful. After 6 months follow up there were no significant differences.

Versus other treatments: Spinal manipulative treatment had no statistically or clinically significant advantage on pain and functional status over general practitioner care, analgesics, physical therapy, exercises, or back school.

Clinical guidelines T7
Recommendations regarding spinal manipulation for acute low back pain show some variation. In most guidelines spinal manipulation is considered to be a therapeutic option in the first weeks of a low back pain episode. The US, UK, New Zealand and Danish guidelines consider spinal manipulation a useful treatment for acute low back pain.[1,3,13,19] In the Dutch, Australian and Israeli guidelines spinal manipulation is not recommended for acute low back pain, although the Dutch advocate its consideration after 6 weeks.[18,21,33]

Discussion / consensus T7
We do not know for which subgroup of patients spinal manipulation is most effective. Future studies should focus on identifying these subgroups. Spinal manipulation should be provided by professionals with competent skills. Risk of serious complication after spinal manupulation is low (estimated risk: cauda equina syndrome <1 in 1 000 000).[55] Current guidelines contraindicate manipulation in people with severe or progressive neurological deficit.

Recommendation T7
Consider (referral for) spinal manipulation for patients who are failing to return to normal activities.

T8 Back schools

Evidence T8
A systematic review of three RCTs found conflicting evidence that back schools are effective for acute low back pain.[56] Two RCTs (n=242) compared back schools with other conservative treatments (McKenzie exercises and physical therapy). They found no difference in pain, recovery rate, and sick leave. One trial (n=100, physical therapy (McKenzie exercises) *v* back school) found that exercises improved pain and reduced sick leave more than back school up to five years, but the back school in this study consisted of one 45 minute-session while exercises were ongoing. The other trial (n=145) compared back schools with short-wave diathermy at lowest intensity, and found that back schools are better at aiding recovery and reducing sick leave in the short-term.

Clinical guidelines T8
The US guidelines state that workplace back schools may be effective in addition to individual education efforts by a clinician.[1] The New Zealand guidelines state that there is insufficient evidence for back schools.[13] The Swiss and German guidelines recommend back schools for secondary prevention of chronicity and recurrences in patients with resolved acute low back pain.[24,25,34] The Danish guidelines recommended 'modern' back schools ("teaching focuses upon ignoring the pain as much as possible") for patients with low back pain if there is a clear need for rehabilitation, or when prevention at the workplace is being considered.[19] The other guidelines do not include recommendations on back schools for treatment of acute low back pain.

Discussion / consensus T8
The recommendations in favour of back schools in some of the national guidelines seem related to treatment of subacute low back pain or secondary prevention of chronic low back pain, but not to treatment of acute low back pain.

Recommendation T8
We do ot recommend back schools for treatment of acute low back pain.

T9 Behavioural therapy

Evidence T9
Five systematic reviews were identified on behavioural therapy for low back pain.[1,22,27,30,57] However, there was only one RCT on acute nonspecific low back pain. There is limited evidence (one RCT; n=107) that behavioural treatment reduced pain and perceived disability more than traditional care (analgesics and exercise until pain had subsided) at 9 to 12 months.

Clinical guidelines T9
None of the international guidelines on acute low back pain included recommendations on behavioural treatment.

Discussion / consensus T9
A behavioural approach may become more important in treatment of sub-acute low back pain or in the prevention of chronicity and recurrences. One small trial was published approximately 30 years ago. There is consensus that randomised trials evaluating a behavioural approach in primary care settings are needed.
None of the guidelines, (with the exception of some general principles in the New Zealand 'Yellow Flags') give any specific advice on what to do about psychosocial risk factors that are identified, and there are no randomised trials directly linking an intervention to psychosocial risk factors for acute low back pain.

Recommendation T9
We do not recommend behavioural therapy for treatment of acute low back pain.

T10 Traction

Evidence T10
Three systematic reviews [27,30,58] included two RCTs that reported on acute low back pain (total n=225, traction *v* bed rest + corset, traction *v* infrared). One trial found that traction significantly increased overall improvement compared with both other treatments after 1 and 3 weeks. But the second trial found no significant difference in overall improvement after 2 weeks.

Clinical guidelines T10
The UK guidelines state that traction does not appear to be effective for low back pain.[3] The New Zealand guidelines state that traction should not be used for acute low back pain.[13] The Danish and US guidelines do not recommend traction.[1,19] Other guidelines made no explicit statement regarding traction.

Discussion / consensus T10
General consensus.

Recommendation T10
Do not use traction.

T11 Massage therapy

Evidence T11
One systematic review found insufficient evidence to recommend massage as a stand-alone treatment for acute nonspecific low back pain.[59] Two low quality RCTs investigated the use of manual massage as a treatment for acute nonspecific low back pain. In both studies massage was the control intervention in evaluating spinal manipulation. There is limited evidence showing that massage is less effective than manipulation immediately after the first session. At the completion of treatment and at 3 weeks after discharge there is no difference between massage and manipulation.

Clinical guidelines T11
The Danish guidelines do not generally recommend massage, but state that it may be considered for pain relief for localised muscle pain or for initial pain relief prior to using, for example, manipulation or exercise therapy.[19] The New Zealand, US and UK guidelines do not recommend massage due to insufficient evidence or due to lack of any effect on clinical outcomes.[1,3,13] Other guidelines made no explicit statement regarding massage.

Discussion / consensus T11
General consensus.

Recommendation T11
We do not recommend massage as a treatment for acute nonspecific low back pain.

T12 TENS

Evidence T12
Two systematic reviews of two RCTs found insufficient evidence.[1,30]
One study (n=58) compared a rehabilitation program with TENS to the rehabilitation program alone in an occupational setting and found no differences on pain and functional status. The other low quality study (n=40) compared TENS with paracetamol and reported significantly better improvement in the TENS group after 6 weeks regarding pain and mobility.

Clinical guidelines T12
The US, Swiss and Danish guidelines do not recommend TENS.[1,19,24,25] The New Zealand guidelines state that there is at least moderate evidence of no improvement in clinical outcomes with TENS.[13] The UK guidelines state that there is inconclusive evidence on the efficacy of TENS.[3] Other guidelines made no explicit statement regarding TENS.

Discussion / consensus T12
General consensus.

Recommendation T12
We do not recommend transcutaneous electrical nerve stimulation (TENS) for acute nonspecific low back pain.

T13 Multidisciplinary treatment programmes

Evidence T13
One systematic review of two RCTs (n=233) found that multidisciplinary treatment leads to faster return to work and less sick leave than usual care.[60] In one study in patients who had been absent from work for eight weeks the multidisciplinary 'graded activity' programme consisted of 1) measurement of functional capacity, 2) a workplace visit, 3) back school education, and 4) an individual, submaximal, gradually increased exercise programme, with an operant-conditioning behavioural approach. In the other study in patients who had been absent from work for more than four weeks, the comprehensive multidisciplinary programme consisted of a combination of clinical intervention (by a back pain specialist, back school, functional rehabilitation therapy, and therapeutic return to work), and occupational intervention (visit to an occupational physician and participatory ergonomics evaluation conducted by an ergonomist, including a work-site evaluation).

Clinical guidelines T13
The Finnish guidelines recommend active multidisciplinary rehabilitation after 6 weeks.[26] The Swiss and Dutch guidelines recommend multidisciplinary treatment for chronic low back pain only, not for acute or sub-acute low back pain.[21,24,25,38] The German guidelines recommend multidisciplinary treatment for patients with a high risk of chronicity and sick leave of three months or more [34].

Discussion / consensus T13
Evidence from trials is related to multidisciplinary programmes which typically include a variety of interventions, such as exercises, back school education, workplace visit, ergonomic advise and behavioural treatment. It is unclear what the effectiveness of the various components of these programmes is.

Recommendation T13
Consider multidisciplinary treatment programmes in occupational settings for workers with sick leave for more than 4 - 8 weeks.

Other treatments

Several RCTs were identified on treatments for acute low back pain that were not included in the guidelines: four trials on acupuncture [61-64], six trials on herbal medicine [65-70], one trial on interferential therapy [71], and three

trials on low-level heatwrap therapy [72-74]. These interventions were not included in the guidelines, because they were not summarized in a systematic review, involve alternative therapy, or are not commonly used throughout Europe for the treatment of acute low back pain. Note that all three trials on low-level heatwrap therapy came from one research group and that there was a strong conflict of interest in these trials. Also note that most of the trials on herbal medicine came from one research group and that most patients included in these trials had acute exacerbations of chronic back pain. References are provided for readers who are interested in these trials.

RCTs on neuroreflexotherapy included patients with subacute and chronic low back pain and will be summarized in the chronic guideline.

Recommendations for future research:

There is an urgent need for validated instruments to assess psychosocial risk factors.

There is a need to identify the relative effect of specific types of or components of behavioural treatment.

There is a need to identify relevant sub-groups of patients with a high risk of psychosocial factors or a high risk of chronicity.

Future RCTs concerning therapeutic strategies should focus primarily on interventions with an activating approach and the prevention of chronicity as one of the main outcomes.

There is a need to identify effective implementation strategies for low back pain guidelines.

References

1. Bigos S, Bowyer O, Braen G et al. Acute low back problems in adults. Clinical practice guideline no. 14. AHCPR publication no. 95-0642. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of health and Human Services. December 1994. [**USA**]
2. Van Tulder MW, Furlan A, Bouter LM, Bombardier C and the Editorial Board of the Cochrane Back Review Group. Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. *Spine* 2003; 28: 1290-9.
3. Royal College of General Practitioners. Clinical Guidelines for the Management of Acute Low Back Pain. London, Royal College of General Practitioners, 1996 and 1999. [**UK**]
4. Kendall NAS, Linton SJ, Main CJ. Guide to assessing psychosocial yellow flags in acute low back pain: risk factors for long-term disability and work loss. Accident Rehabilitation & Compensation Insurance Corporation of New Zealand and the National Health Committee. Wellington, New Zealand, 1997. [**New Zealand**]
5. Andersson GBJ. The epidemiology of spinal disorders. In: Frymoyer JW, ed. The adult spine: principles and practice. 2nd ed. New York: Raven Press, 1997: 93-141.
6. Deyo RA, Rainville J, Kent DL. What can the history and physical examination tell us about low back pain? *JAMA* 1992; 268: 760-5.
7. Hoogendoorn WE, van Poppel MNM, Bongers PM, Koes BW, Bouter LM. Systemic review of psychosocial factors at work and private life as risk factors for back pain. *Spine* 2000; 25: 2114-25.
8. Linton SJ. A review of psychological risk factors in back and neck pain. *Spine* 2000; 25: 1148-56.
9. Frymoyer JW. Back pain and sciatica. *N Engl J Med* 1988; 318: 291-300.
10. Deyo RA, Battie M, Beurskens AJ, Bombardier C, Croft P, Koes B, Malmivaara A, Roland M, Von Korff M, Waddell G. Outcome measures for low back pain research. A proposal for standardized use. *Spine* 1998; 23: 2003-13.
11. Van den Hoogen HMM, Koes BW, van Eijk JThM, Bouter LM. On the accuracy of history, physical examination and erythrocyte sedimentation rate in diagnosing low back pain in general practice. A criteria-based review of the literature. *Spine* 1995; 20: 318-27.
12. Deville WL, van der Windt DA, Dzaferagic A, Bezemer PD, Bouter LM. The test of Lasegue: systematic review of the accuracy in diagnosing herniated discs. *Spine* 2000; 25: 1140-7.
13. ACC and the National Health Committee. New Zealand Acute Low Back Pain Guide. Wellington, New Zealand, 1997. [**New Zealand**]
14. Linton SJ, Hallden K. Can we screen for problematic back pain? A screening questionnaire for predicting outcome in acute and subacute back pain. *Clin J Pain* 1998; 14: 209-15.
15. Van Tulder MW, Assendelft WJJ, Koes BW, Bouter LM. Spinal radiographic findings and nonspecific low back pain: a systematic review of observational studies. *Spine* 1997; 22: 427-34.
16. Jarvik JG, Deyo RA. Diagnostic evaluation of low back pain with emphasis on imaging. *Ann Intern Med* 2002; 137: 586-97.
17. Jarvik JG, Hollingworth W, Martin B, Emerson SS, Gray DT, Overman S, Robinson D, Staiger T, Wessbecher F, Sullivan SD, Kreuter W, Deyo RA. Rapid magnetic resonance imaging vs radiographs for patients with low back pain: a randomized controlled trial. *JAMA* 2003; 289: 2810-8.
18. Borkan J, Reis S, Werner S, Ribak J, Prath A. Guidelines for treating low back pain in primary care (Hebrew; available in English). The Israeli Low Back Pain Guideline Group. *Harfuah* 1996; 130: 145-151. [**Israel**]
19. Danish Institute for Health Technology Assessment: Low back pain. Frequency, management and prevention from an HTA perspective. Danish Health Technology Assessment 1999. [**Denmark**]
20. Kendrick D, Fielding K, Bentley E, Kerslake R, Miller P, Pringle M. Radiography of the lumbar spine in primary care patients with low back pain: randomised controlled trial. *Br Med J* 2001; 322: 400-5.
21. Faas A, Chavannes AW, Koes BW, Van den Hoogen JMM, Mens JMA, Smeele IJM, Romeijnders ACM, Van der Laan JR. Clinical practice guidelines for low back pain. (Dutch, available in English). *Huisarts Wet* 1996;39:18-31. [**the Netherlands**]
22. Turner JA. Educational and behavioral interventions for back pain in primary care. *Spine* 1996; 21: 2851-9.

23. Burton AK, Waddell G, Tillotson KM, Summerton N. Information and advice to patients with back pain can have a positive effect. A randomized controlled trial of a novel educational booklet in primary care. *Spine* 1999; 24: 2484-91.
24. Keel P, Perini Ch, Schutz-Petitjean D, et al Chronicisation des douleurs du dos: problematique, issues. Rapport final du Programme National de Recherche No 26B. Bale: Editions EULAR 1996. [**Switzerland**]
25. Keel P, Weber M, Roux E, et al. Kreuzschmerzen: Hintergründe, prävention, behandlung. Basisdokumentation. Verbindung der Schweizer Ärzte (FMH), Bern, 1998. [**Switzerland**]
26. Malmivaara A, Kotilainen E, Laasonen E, Poussa M, Rasmussen M, Clinical Practice Guidelines: diseases of the low back. (Finnish, available in English) The Finnish Medical Association Duodecim 1999. [**Finland**]
27. Evans G, Richards S. Low back pain: an evaluation of therapeutic interventions. Bristol: Health Care Evaluation Unit, University of Bristol, 1996.
28. Hagen KB, Hilde G, Jamtvedt G, Winnem M. Bed rest for acute low back pain and sciatica (Cochrane Review). In: The Cochrane Library, Issue 4, 2000. Oxford: Update Software.
29. Koes BW, van den Hoogen HMM. Efficacy of bed rest and orthoses of low back pain. A review of randomized clinical trials. *Eur J Phys Med Rehabil* 1994; 4: 86-93.
30. Van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain: a systematic review of randomized controlled trials of the most common interventions. *Spine* 1997; 22: 2128-56.
31. Waddell G, Feder G, Lewis M. Systematic reviews of bed rest and advice to stay active for acute low back pain. *Br J Gen Pract* 1997; 47: 647-52.
32. Nachemson AL, Jonsson E. (Eds.) Neck and back pain: the scientific evidence of causes, diagnosis, and treatment. Lippincott Williams & Wilkins, Philadelphia, 2000. [**Sweden**]
33. Victorian Workcover Authority. Guidelines for the management of employees with compensable low back pain. Melbourne, Victorian Workcover Authority. 1993 and revised edition 1996. [**Australia**]
34. Handlungsleitlinie – Rueckenschmerzen. Empfehlungen zur Therapie von Rückenschmerzen, Artzneimittelkommission der deutschen Ärzteschaft. (Treatment guideline - backache. Drug committee of the German Medical Society). Zeitschrift fur Artzliche Fortbildung und Qualitatssicherung Aug 1997; 91(5): 457-460. [**Germany**]
35. Hilde G, Hagen KB, Jamtvedt G, Winnem M. Advice to stay active as a single treatment for low back pain and sciatica (Cochrane Review). In: The Cochrane Library, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd.
36. Hagen EM, Eriksen HR, Ursin H. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? *Spine* 2000; 25: 1973-6.
37. Rozenberg S, Delval C, Rezvani Y, et al. Bed rest or normal activity for patients with acute low back pain: a randomized controlled trial. *Spine* 2002; 27: 1487-93.
38. Bekkering GE, van Tulder MW, Hendriks HJM, Oostendorp RAB, Koes BW, Ostelo RWJG, Thomassen J. Dutch physiotherapy guideline for low back pain. (KNGF richtlijn lage rugpijn) *Ned Tijdschr Fysiother* 2001;111 (Suppl. 3): 1-24. [**the Netherlands**]
39. Nasjonalt ryggnettverk – Formidlingsenheten. Akutte korsryggsmerter. Tverrfaglige, kliniske retningslinjer. Oslo, 2002: Nasjonalt ryggnettverk. [**Norway**]
40. Abenhaim L, Rossignol M, Valat JP, Nordin M, Avouac B, Blotman F, Charlot J, Dreiser RL, Legrand E, Rozenberg S, Vautravers P. The role of activity in the therapeutic management of back pain. Report of the International Paris Task Force on Back Pain. *Spine* 2000; 25 (Suppl):1S-33S.
41. Van Tulder MW, Malmivaara A, Esmail R, Koes BW. Exercise therapy for nonspecific low back pain (Cochrane Review). In: The Cochrane Library, Issue 4, 2000. Oxford: Update Software.
41. De Craen AJM, Di Giulio G, Lampe-Schoenmaeckers AJEM, Kessels AGH, Kleijnen J. Analgesic efficacy and safety of paracetamol-codeine combinations versus paracetamol alone: a systematic review. *Br Med J* 1996; 313: 321-325.
42. Koes BW, Scholten RJPM, Mens JMA, Bouter LM. Efficacy of non-steroidal anti-inflammatory drugs for low back pain: a systematic review of randomised clinical trials. *Ann Rheum Dis* 1997; 56: 214-23.
43. Van Tulder MW, Scholten RJPM, Koes BW, Deyo RA. Non-steroidal anti-inflammatory drugs (NSAIDs) for nonspecific low back pain (Cochrane Review). In: The Cochrane Library, Issue 4, 2000. Oxford: Update Software.
44. Pohjalainen T, Jekunen A, Autio L, Vuorela H. Treatment of acute low back pain with the COX-2-selective anti-inflammatory drug Nimesulide: results of a randomized, double-blind comparative trial versus ibuprofen. *Spine* 2000; 25: 1579-85.
45. Van Tulder MW, Touray T, Furlan AD, Solway S, Bouter LM. Muscle relaxants for nonspecific low back pain (Cochrane Review). In: The Cochrane Library, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd.
46. Henry D, Lim LLY, Rodriguez LAG, et al. Variability in risk of gastrointestinal complications with individual non-steroidal anti-inflammatory drugs: results of a collaborative meta-analysis. *Br Med J* 1996; 312: 1563-6.
47. Koes BW, Scholten RJPM, Mens JMA, Bouter LM. Epidural steroid injections for low back pain and sciatica: an updated systematic review of randomized clinical trials. *Pain Digest* 1999; 9: 241-7.
48. Nelemans PJ, de Bie RA, de Vet HCW, Sturmans F. Injection therapy for subacute and chronic benign low back pain. In: The Cochrane Library, Issue 4, 2001. Oxford: Update Software.
49. Watts RW, Silagy CA. A meta-analysis on the efficacy of epidural corticosteroids in the treatment of sciatica. *Anaesth Intensive Care* 1995; 23: 564-9.
50. Koes BW, Assendelft WJJ, van der Heijden GJMG, Bouter LM. Spinal manipulation for low back pain. An updated systematic review of randomized clinical trials. *Spine* 1996; 21: 2860-71.
51. Shekelle PG, Adams AH, Chassin MR, Hurwitz EL, Brook RH. Spinal manipulation for low back pain. *Ann Intern Med* 1992; 117: 590-8.
52. Bronfort G. Spinal manipulation: current state of research and its indications. *Neurol Clin* 1999; 17: 91-111.
53. Assendelft WJJ, Morton SC, Yu Emily I, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low back pain (Cochrane Review). In: The Cochrane Library, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd.
54. Assendelft WJJ, Bouter LM, Knipschild PG. Complications of spinal manipulation: a comprehensive review of the literature. *J Fam Pract* 1996; 42: 475-80.
55. Van Tulder MW, Esmail R, Bombardier C, Koes BW. Back schools for nonspecific low back pain (Cochrane Review). In: The Cochrane Library, Issue 4, 2000. Oxford: Update Software.

56. Van Tulder MW, Ostelo RWJG, Vlaeyen JWS, Linton SJ, Morley SJ, Assendelft WJJ. Behavioural treatment for chronic low back pain (Cochrane Review). In: The Cochrane Library, Issue 4, 2000. Oxford: Update Software.
57. Van der Heijden GJMG, Beurskens AJHM, Koes BW, de Vet HCW, Bouter LM. The efficacy of traction for back and neck pain: a systematic, blinded review of randomized clinical trial methods. *Phys Ther* 1996; 75: 93-103.
58. Furlan AD, Brosseau L, Welch V, Wong J,. Massage for low back pain (Updated Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Oxford: Update Software.
59. Karjalainen K, Malmivaara A, van Tulder M, Roine R, Jauhiainen M, Hurri H, Koes B. Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults. (Cochrane Review). In: The Cochrane Library, Issue 4, 2000. Oxford: Update Software.
60. Araki S, Kawamura O, Mataka T, et al. RCT ni yoru kyusei yotsu-sho ni taisuru shishin-gun to gishin-gun no tiryou koka [Randomized controlled trial comparing manual acupuncture and sham acupuncture for acute low back pain]. *J Japan Soc Acupuncture Moxibustion* 2001; 51: 382.
61. He RY. The effect of acupuncture with moxibustion plus herb on lumbago. *Chinese Acupuncture* 1997; 5: 279-80.
62. Kittang G, Melvaer T, Baerheim A. [Acupuncture contra antiphlogistics in acute lumbago]. *Tidsskr Nor Laegeforen* 2001; 121: 1207-10.
63. Wu YC ea. Acupuncture for 150 cases of acute lumbago. *Shanghai J Acupuncture Moxibustion* 1991; 10: 18-9.
64. Chrubasik S, Zimpfer C, Schtt U, Ziegler R. Effectiveness of Harpagophytum procumbens in treatment of acute low back pain. *Phytomedicine* 1996; 3: 1-10.
65. Chrubasik S, Junck H, Breitschwerdt H, Conradt C, Zappe H. Effectiveness of Harpagophytum extract WS 1531 in the treatment of exacerbation of low back pain: a randomized, placebo-controlled, double- blind study. *Eur J Anaesthesiol* 1999; 16: 118-29.
66. Chrubasik S, Eisenberg E, Balan E, Weinberger T, Luzzati R, Conradt C. Treatment of low back pain exacerbations with willow bark extract: a randomized double-blind study. *Am J Med* 2000; 109: 9-14.
67. Chrubasik S, Kunzel O, Model A, Conradt C, Black A. Treatment of low back pain with a herbal or synthetic anti-rheumatic: a randomized controlled study. Willow bark extract for low back pain. *Rheumatology* (Oxford) 2001; 40: 1388-93.
68. Ginsberg F, Mingard P, Weber T. Double-blind study on antitissue immunoglobulin injections versus placebo in the treatment of acute lumbar pain with muscular spasms. *Int J Clin Pharmacol Res* 1987; 7: 401-5.
69. Stam C, Bonnet MS, van Haselen RA. The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multi-centre, randomised, double-blind comparative clinical trial. *Br Homeopath J* 2001; 90: 21-28.
70. Hurley DA, Minder PM, McDonough SM, Walsh DM, Moore AP, Baxter DG. Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation. *Arch Phys Med Rehabil* 2001; 82: 485-93.
71. Nadler SF, Steiner DJ, Erasala GN, Hengehold DA, Abeln SB, Weingand KW. Continuous low-level heatwrap therapy for treating acute nonspecific low back pain. *Arch Phys Med Rehabil* 2003a; 84: 329-34.
72. Nadler SF, Steiner DJ, Petty SR, Erasala GN, Hengehold DA, Weingand KW. Overnight use of continuous low-level heatwrap therapy for relief of low back pain. *Arch Phys Med Rehabil* 2003b; 84: 335-42.
73. Nadler SF, Steiner DJ, Erasala GN, Hengehold DA, Hinkle RT, Goodale MB, Abeln SB, Weingand KW. Continuous low-level heatwrap therapy provides more efficacy than ibuprofen and acetaminophen for acute low back pain. *Spine* 2002; 27: 1012-7.

Appendix I: Methodological quality of studies and levels of evidence

A grading system was used for the strength of the evidence. 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. The system is based on the original ratings of the AHCPR Guidelines (1994) and levels of evidence used in systematic (Cochrane) reviews on low back pain.

Level 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.

The methodological quality of additional studies will only be assessed in areas that have not been covered yet by a systematic review or of the non-English literature.

The methodological quality of trials is usually assessed using relevant criteria related to the internal validity of trials. High quality trials are less likely to be associated with biased results than low quality trials. Various criteria lists exist, but differences between the lists are subtle.

Quality assessment should ideally be done by at least two reviewers, independently, and blinded with regard to the authors, institution and journal. However, as experts are usually involved in quality assessment it may often not be feasible to blind studies. Criteria should be scored as positive, negative or unclear, and it should be clearly defined when criteria are scored positive or negative. Quality assessment should be pilot tested on two or more similar trials that are not included in the systematic review. A consensus method should be used to resolve disagreements and a third reviewer was consulted if disagreements persisted. If the article does not contain information on the methodological criteria (score 'unclear'), the authors should be contacted for additional information. This also gives authors the opportunity to respond to negative or positive scores.

The following checklists are recommended:

Checklist for methodological quality of therapy / prevention studies

Items:

1) Adequate method of randomisation,
2) Concealment of treatment allocation,
3) Withdrawal / drop-out rate described and acceptable,
4) Co-interventions avoided or equal,
5) Blinding of patients,
6) Blinding of observer,
7) Blinding of care provider
8) Intention-to-treat analysis,
9) Compliance,
10) Similarity of baseline characteristics.

Checklist for methodological quality of prognosis (observational) studies

Items:

1) Adequate selection of study population,
2) Description of in- and exclusion criteria,
   Description of potential prognostic factors,
4) Prospective study design,
5) Adequate study size (> 100 patient-years),
6) Adequate follow-up (> 12 months),
7) Adequate loss to follow-up (< 20%),
8) Relevant outcome measures,
9) Appropriate statistical analysis.

Checklist for methodological quality of diagnostic studies

Items:

1) Was at least one valid reference test used?
   Was the reference test applied in a standardised manner?
   Was each patient submitted to at least one valid reference test?
4) Were the interpretations of the index test and reference test performed independently of each other?
5) Was the choice of patients who were assessed by the reference test independent of the results of the index test?
6) When different index tests are compared in the study: were the index tests compared in a valid design?
7) Was the study design prospective?
   Was a description included regarding missing data?
   Were data adequately presented in enough detail to calculate test characteristics (sensitivity and specificity)?

Appendix II: Back pain and work by Tim Carter

These guidelines are directed at the management of back pain in primary health care settings. Effective collaboration with those providing occupational health services, managers responsible for defining the tasks undertaken at work and social security administrations may be required whenever back pain occurs in people of working age. This appendix outlines the contributions which good occupational health practice can make to back pain management and identifies where the evidence base for such practice can be found. Detailed guidelines are not presented as these will vary considerably between member states depending on the provisions for occupational health and social security.

Low back pain is a very common problem in people of working age. The physical demands of work can precipitate individual attacks of low back pain and the risks are higher in jobs where there is:

- Heavy manual labour
- Manual material handling
- Awkward postures
- Whole body vibration

The demands of work may also influence the ease of return after an episode of pain (1).

However although work may be a contributory cause, it is not responsible for a large proportion of episodes of pain. Back pain is common in all occupations and is a major cause of absence from work and one of the leading reasons for long term incapacity and medical retirement. Thus employers and social security administrations should have a strong incentive to ensure that disability from back pain is minimised and to collaborate with primary care providers to secure effective case management.

Good occupational health practice for back pain management has been addressed in guidelines produced in the Netherlands (2), UK (3, 4, 5), Australia (6, 7), Japan (8), USA (9), Canada [10] and New Zealand [11, 12].

The key evidence based principles for back pain management in the occupational health setting are:

- Recognising that selection at recruitment will not reduce incidence significantly. There is no evidence that clinical examination or diagnostic tests such as X-rays are valid predictors of future risk. Hence they have no place in routine pre-placement screening or selection.
- Understanding that while ergonomic measures will bring some benefits there are no well-validated preventative techniques. This means that some incidents of back pain in any workforce are inevitable
- Ensuring that the need for an active approach to case management is understood by employees and employers and planning for this in anticipation of future incidents. The educational element in this would include a shared understanding that active management reduces pain and disability and that return to work before the person is pain free will often be the best way of speeding resolution of the discomfort.
- Securing a collaborative approach to case management with primary care providers as soon as possible after an incident of back pain in order to plan an early and effective return to work, with temporary modification to tasks or working arrangements if this is likely to hasten recovery.
- Arranging access to rehabilitation for anyone who has been away from work for more than four weeks.

Implications for primary care providers

Giving a patient entitlement to absence from work because of nonspecific back pain should be avoided where possible as it is likely to delay rather than hasten recovery.

Where there is an occupational health professional available, the primary care provider is recommended to secure consent from the patient to initiate a shared plan for case management. This should include arrangements for referral for rehabilitation if the pain persists and for prevention of return to work within four weeks.

Where there is no occupational health service available, the primary care provider is recommended to review the options for collaboration on occupational aspects with the patient and ensure that the principles outlined above are followed.

If the patient is of working age but not in employment liaison with the social security, administration as specified in national regulations will be required. It will often be to the benefit of the patient to propose a treatment plan to the administration and obtain their support for it, especially in relation to access to rehabilitation services and retraining should this be needed.

References:

1. Research on work related low back disorders. Luxembourg Office for Official Publications of the European Union (2000), ISBN 92 95007 02 6.
2. Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde. Handelen van de bedrijfsarts bij werknemers met lage rugklachten. Geautoriseerde richtlijn, 2 april 1999. / Dutch Association for Occupational Medicine. Management by the occupational physician of employees with low back pain. Authorised Guidelines, April 2, 1999, ISBN 90 76721 01 7. [**the Netherlands**]
3. Carter JT, Birrell LN. Occupational Health Guidelines for the Management of Low Back Pain at Work: recommendations. Faculty of Occupational Medicine, London 2000, ISBN 1 86016 131 6 (also on **www.facoccmed.ac.uk**) [**UK**]

4. Waddell G, Burton AK. Occupational Health Guidelines for the Management of Low Back Pain at Work: evidence review. Faculty of Occupational Medicine, London 2000, ISBN 1 86016 131 6 (also on **www.facoccmed.ac.uk**) [**UK**]
5. Waddell G, Burton AK. Occupational Health Guidelines for the Management of Low Back Pain at Work: evidence review. Occup Med 2001; 51: 124-35. [**UK**]
6. Steven ID (Ed) Guidelines for the management of back-injured employees. Adelaide: South Australia Workcover Corporation. 1993 [**Australia**]
7. Victorian Workcover Authority.. Guidelines for the management of employees with compensable low back pain. Melbourne, Victorian Workcover Authority. 1993 and revised Edition 1996 [**Australia**]
8. Yamamoto S. Guidelines on Worksite Prevention of Low Back Pain Labour Standards Bureau Notification No.57. Industrial Health 1997; 35:143-172. [**Japan**]
9. Fordyce WE (Ed). Back Pain in the Workplace: Management of Disability in Nonspecific Conditions. Seattle, IASP Press. 1995 [**US – International**]
10. Spitzer WO, Leblanc FE, Dupuis M. Scientific approach to the assessment and management of activity-related spinal disorders. A monograph for clinicians. Report of the Quebec Task force on Spinal disorders. Spine 1987;12(Suppl.7S):1-59. [**Canada**]
11. Accident Compensation Corporation and National Health Committee. Active and working! Managing acute low back pain in the workplace. Wellington, New Zealand, 2000. [**New Zealand**]
12. Accident Compensation Corporation and National Health Committee, Ministry of Health. Patient guide to acute low back pain management. Wellington, New Zealand, 1998. [**New Zealand**]

Appendix III: Dissemination and implementation by Even Laerum

Clinical guidelines are usually defined as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care' as a vehicle for assisting health care providers in grasping new evidence and bring it into daily clinical routines for improving practice and for diminishing costs (1).

Implementation of guidelines means putting something (e.g. a plan or an innovation) into use. The process of spreading clinical guidelines implies diffusion, active dissemination and implementation. Diffusion is a passive concept while dissemination is a more active process including launching of targeted and tailored information for the intended audience. Implementation often involves identifying and assisting in overcoming barriers to the use of the knowledge obtained from a tailored message. Normally implementation procedures mean a multi-disciplinary enterprise.

Effectiveness of interventions

Success in the implementation process requires knowledge about important factors behind general positive and negative attitudes towards guidelines related to usefulness, reliability, practicality and availability of the guidelines. Also the overall individual, team and organisational competence to follow recommended procedures seem to be vital.

Systematic reviews of the effectiveness of interventions to promote professional behaviour or change have shown (2):

Consistently effective are
- Educational outreach visits (for prescribing in North American settings)
- Reminders (manual or computerised)
- Multifaceted interventions
  – A combination that includes two or more of the following: audit and feedback, reminders, local consensus process and marketing
- *Interactive educational meetings*
  – *Participation of health care providers in workshops that include discussions of practice*

Mixed effects
- Audit and feedback
  – Any summary of clinical performance
- Local opinion leaders
  – Use of providers nominated by their colleagues as 'educationally influential'
- Local consensus process
  – Inclusion of participating providers in discussion to ensure that they agreed that chosen clinical problem was important and the approach to managing the problem was appropriate
- Patient mediated interventions
  – Any intervention aimed at changing the performance of health care providers where specific information was sought from or given to patients

Little or no effect
- Educational materials
  – Distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications
- Didactic educational meetings
  – Lectures

Barriers and facilitators
A successful implementation of guidelines requires thoroughly performed planning and monitoring of the implementation whereof addressing barriers and facilitators appear to be of vital importance to enhance the implementation process. Before starting the implementation such barriers and facilitators should be systematically recorded among target groups for applying the clinical guidelines.

Potential barriers to change may include (3):

Practice environment
- Limitations of time
- Practice organisation, e.g. lack of disease registers or mechanisms to monitor repeat prescribing

Educational environment
- Inappropriate continuing education and failure to link up with programmes to promote quality of care
- Lack of incentives to participate in effective educational activities

Health care environment
- Lack of financial resources
- Lack of defined practice populations
- Health policies which promote ineffective or unproven activities
- Failure to provide practitioners with access to appropriate information

Social environment
- Influence of media on patients in creating demands/beliefs
- Impact of disadvantage on patients' access to care

Practitioner factors
- Obsolete knowledge
- Influence of opinion leaders
- Beliefs and attitudes (for example, related to previous adverse experience of innovation)

Patient factors
- Demands for care
- Perceptions/cultural beliefs about appropriate care

Implementation strategies should be tailored according to recorded identified barriers and facilitators. How to do this is described in detail in *Evidence Based Practice in Primary Care* (4).

Evaluation
In general it is also recommended to evaluate outcome and result of the implementation process. Outcome measures related to low back pain will often be before and after status of use of health services, for instance x-ray, sickness absence and back related health status of the patient population (e.g. pain, function/quality of life). Types of evaluation may include RCTs, cross-over and semi-experimental trials, before-after study and interrupted time series analyses (4). An economic evaluation is also required on both the course and the benefits of implementation (5).

Oxman *et al.* (6) reviewed 102 randomised controlled trials in which changes in physician behaviour were attempted through means such as continuing medical education workshops and seminars, educational materials, academic detailing and audit and feedback. Each produced some change but the authors concluded that a multifaceted strategy was called for using a combination of methods and that there can be no "magic bullet" for a successful implementation.

References

1. Thorsen T, Mäkelä M. Changing Professional Practice. Theory and Practice of Clinical Guidelines Implementation. Copenhagen: Danish Institute for Health Services Research and Development, 1999:13.
2. Haines A, Donald A, eds. Getting Research Findings into Practice. London: BMJ Books, 1998: 31.
3. Haines A, Donald A, eds. Getting Research Findings into Practice. London: BMJ Books, 1998: 6.
4. Silagy C, Haines A. Evidence Based Practice in Primary Care. London: BMJ Books, 1998.
5. Thorsen T, Mäkelä M. Changing Professional Practice. Theory and Practice of Clinical Guidelines Implementation. Copenhagen: Danish Institute for Health Services Research and Development, 1999.
6. Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. Can Med Assoc J 1995; 153: 1423-31.

Appendix IV: Inclusion of non-English language literature by Maria Teresa Gil del Real

Background

There is still an ongoing debate about inclusion in systematic reviews of studies published in other languages than English. Although inclusion of non-English literature is often recommended, it may not always be feasible and may depend on the time and resources available. Some authors suggested that there is empirical evidence that exclusion of trials published in other languages than English might be associated with bias. Grégoire et al. (1995) suggested that positive results by authors from non-English speaking countries are more likely to be published in English and negative results in the authors' language. They found an example of a meta-analysis where inclusion of a non-English language trial changed the results and conclusion. Egger et al. (1997) found that authors of German-speaking countries in Europe were more likely to publish RCTs in an English-language journal if the results were statistically significant. On the other hand, Moher et al. (1996) evaluated the quality of reporting of RCTs published in English, French, German, Italian and Spanish between 1989 and 1993 and did not find significant differences. Vickers et al (1998) found that trials published in some non-English languages (Chinese, Japanese, Russian and Taiwanese) had an unusually high proportion of positive results. However, Jüni et al (2002) found that excluding trials published in other languages than English generally has little impact on the overall treatment effect.

Although the evidence seems to be inconclusive, most authors concluded that all trials should be included in a systematic review regardless of the language in which they were published, to increase precision and reduce bias. The Cochrane Back Review Group recommended in its method guidelines for reviews on low back pain that if RCTs published in other languages are excluded from a review, the reason for this decision should be given. (van Tulder et al 2003) Especially on topics where there are likely to be a significant number of non-English language publications (for example, the Asian literature on acupuncture) it may be wise to consider involvement of a collaborator with relevant language skills. The members of the Working Group acknowledged that a different literature search should be performed for non-English literature than for the English literature. Databases do not exist for most other languages, the reliability and coverage of the databases that do exist is unclear, and sensitive search strategies for these databases may not have been developed.

Most of the systematic reviews used in the European guidelines included trials published in English and some other languages (mostly German, French, Dutch and sometimes Swedish, Danish, Norwegian and Finnish). Obviously, the national guidelines that we have used as basis for our recommendations have included studies published in their respective languages. National committees that developed guidelines in these languages have considered Danish, Dutch, Finnish, French, German, Norwegian and Swedish language studies. Only Italian and Spanish trials have yet not been considered, because guidelines in these countries do not exist. Because there was no Italian member participating in the WG, we only considered the Spanish literature.

Objectives

To summarise the evidence from the Spanish literature and evaluate if it supports the evidence review and recommendations of the guidelines.

Methods

Literature search

Relevant trials were identified in existing databases: Literatura Latino Americana e do Caribe em Ciencias da Saude (LILACS) and Índice Médico Español (IME). The Iberoamerican Cochrane Centre (Centro Iberoamericano de la Colaboración Cochrane) was contacted for additional trials.

Inclusion criteria are: 1) randomised controlled trials, 2) acute and subacute low back pain (less than 12 weeks), and 3) any intervention.

Quality Appraisal

The abstracts with no English version have been translated from Spanish by a native English speaker. Some papers had an English version of their abstracts. In these cases, the translator has just done a linguistic review of them and, in those cases in which the Spanish and English versions did not match, a translation of the Spanish abstract has been done. Some Spanish journals publish only short reports of the studies (similar to abstracts). In these cases, the entire report has been considered as the abstract. Other Spanish journals have a mandatory structure for the abstracts they publish, which may have changed over time, but most do not. Therefore, there is a considerable difference in the amount of information provided by different abstracts. Two reviewers assessed the quality of the trials using the checklist for methodological quality of therapy/prevention studies (see Appendix 1).

Data extraction

Data were extracted regarding characteristics of patients, interventions and outcomes (pain, functional status, global improvement, return to work, patient satisfaction, quality of life, generic functional status and intervention-specific outcomes) and the final results of the study for each outcome measure at each follow-up moment.

Data analysis
The results of the Spanish literature (quality, data and results) were considered by the members of the WG to see if the results do or do not support the recommendations. If not, reasons for these inconsistencies were explored.

Results

Study selection.
From over 25,000 entries in IME and LILACS databases, 9 randomized controlled trials on back pain were selected from 112 available controlled trials on all subjects. Seven trials were identified through contacting the Iberoamerican Cochrane Centre. So, a total of 16 back pain RCTs were identified. Six of these were excluded because the study population consisted of chronic pain patients (Gonzalez et al 1992; Kovacs et al 1993; Llop 1993; Kovacs et al 1996; Ortiz et al 1997; Kovacs et al 2001), and three because patients had specific low back pain (Mota et al 1989; Ferrer et al 1992; Marquez et al 1998). One study had already been included in a Cochrane review on muscle relaxants (Corts Giner 1989). Consequently, the evidence of six Spanish trials was summarised.

Muscle relaxant plus vitamin B12 vs. muscle relaxant alone or vit B12 alone.
One low quality study compared the therapeutic effect of the combination of a muscle relaxant plus vitamin B12 (tiocolchicoside + dibencozide; n=40) with the muscle relaxant alone (tiocolchicoside 4 mg; n=30) for patients with acute low back pain (Portugal 1987). Both therapies were administered as i.m. injections one-a-day for 10 days. The drug combination was found to be significantly better in improving pain and function. The overall tolerance was excellent with the drug combination and good with tiocolchicoside alone.

Another low quality study compared the effect of of the combination of a muscle relaxant plus vitamin B12 (dibencozide + tiocolchicoside; n=40) with the vitamin B12 alone (dibencozide 20 mg; n=30) for patients with acute low back pain and exacerbations of chronic low back pain (Sanchez 1987). At baseline, patients in both groups were comparable with regard to age and severity of symptoms. Patients receiving dibencozide+tiocolchicoside had a statistically significant better improvement in pain and functioning when compared to those receiving only dibencozide. Tolerance was excellent in the group receiving dibencozide + tiocolchicoside and very good in the one receiving dibencozide alone.

The group agrees that the evidence from these relatively small trials does not change the recommendations based on systematic reviews.

Nsaids vs. nsaids.
One low quality study including 50 adults of either sex with low back pain compared sodium diclofenac 75 mg intramuscular (n=25), and triapophenic acid 200 mg bid (n = 25) (Uriegas MA 1987). The study was double-blind. A verbal analogue scale, a visual analogue scale, and parameters of pain and analgesia were assessed. In addition, the overall subjective feeling of improvement was asked of both the researcher and the patient. On comparing the different variables at the start, during and at the end of treatment, all the variables were significantly ($p<0,05$) favourable to sodium diclofenac. This was in accordance with the general observation of the researcher. Tolerance was similar for both products.

Another double blind study of low methodological quality was designed to assess the safety and efficacy of piroxicam and sulindac in the treatment of acute low back pain (Castro 1992). Thirty patients received piroxicam 40 mg IM for 2 days, and 20 mg oral daily for 4 days, and 30 patients received 200 mg of sulindac twice a day for 6 days. Muscle contracture, straight leg raising test, Schober's test and antalgic gait showed more improvement in the piroxicam group. Pain and disability were not considered in this trial. Gastritis was the only side effect reported in both groups. There was no significant incidence of adverse reactions in any of the study groups.

A double-blind, high quality trial was carried out to evaluate the efficacy of etodolac versus piroxicam for the treatment of acute low back pain (Arriagada & Arinoviche 1992). Two homogenous groups (in terms of age, sex, time since last crisis and duration of current episode) were treated during one week with either etodolac 300 mg b.i.d. (n=30) or piroxicam 20 mg/day (n=31). All 61 patients completed the study. Several clinical parameters were assessed prior to and after treatment, and adverse drug reactions were registered at the final visit. Compared to baseline, statistically significant ($p<0.005$) relief of symptoms was achieved in both groups for pain intensity, sleep quality, paravertebral muscle spasm and spinal range of motion. No significant differences were established between groups in relation to efficacy. Patients treated with etodolac had significantly less adverse reactions than those on piroxicam ($p<0.025$).

The group agrees that these trials do not change the recommendations of the guideline.

Corticosteroid vs. nsaids.
One low quality study compared the effectiveness of oral corticosteroid therapy vs. conventional NSAIDs in the treatment of acute low back pain (Rivera et al 1993). Twenty-seven patients who visited the emergency room were included. They were randomized into two groups, one treated with indomethacin 25/8 hr and the other with deflazacort 15 mg/day, during 14 days. There were no statistical differences at the beginning of the trial in patient characteristics, pain intensity, leg radiated pain or neuro-

logical involvement. Pain, subjective improvement, functional status, return to work, and side effects were assessed at days 0, 3, 7, and 14. Both treatments showed a significant improvement in all the parameters analyzed, but no differences between groups were found. However, 66% of patients in the corticosteroid group and none in the nsaid group had returned to work by the end of the trial. More gastrointestinal side effects were found in the indomethacin group ($p < 0.05$).

This small, low quality trial does not change the recommendations of the guideline.

References

1. Grégoire G, Derderian F, Le Lorier J. Selecting the language of the publications included in a meta-analysis: is there a tower of Babel bias? J Clin Epidemiol 1995; 48: 159-63.
2. Jüni P, Holenstein F, Sterne J, Bartlett C, Egger M. Direction and impact of language bias in meta-analysis of controlled trials: empirical study. Int J Epidemiol 2002; 31: 115-23.
3. Moher D, Fortin P, Jadad AR, Jüni P, Klassen T, Le Lorier J, Liberati A, Linde K, Penna A. Completeness of reporting of trials published in languages other than English: implications for conduct and reporting of systematic reviews. Lancet 1996; 347: 363-6.
4. Van Tulder MW, Furlan A, Bouter LM, Bombardier C and the Editorial Board of the Cochrane Back Review Group. Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. Spine 2003; 28: 1290-1299
5. Portugal J. A clinical trial of tiocolchicoside dibencozide vs. tiocolchicoside 4 mg in the treatment of acute low back pain. Folha Med 1987; 4 (95): 285-7.
6. Sanchez L. A clinical trial of tiocolchicoside dibencozide vs. dibencozide 20 mg in the treatment of acute low back pain. Arq Bras Med 1987; 5 (61): 365-7.
7. Uriegas MA. A double blind study for comparing efficacy and speed of action of two analgesics for the treatment of acute low back pain. Invest Med Int 1987; 3 (14): 161-7.
8. Corts Giner JR. Muscle relaxant in the treatment of acute low back pain: A double blind study of tizanidine+paracetmol vs. placebo+paracetamol. Rev Esp Cir Osteoart 1989; 24 (140): 119-123.
9. Mota A, De Antonio P, Huertas G, Márquez C, Torres E, Noval R, Pajuelo A, Torres LM. Single-dose spinal anesthesia in the pre-surgical course of discal herniation. Rev Esp Anest y Reanim 1989; 36: 56.
10. Castro LA. A clinical trial of piroxicam versus sulindac in the treatment of acute low back pain. (Estudio abierto comparativo entre piroxicam y sulindac en el tratamiento de la lumbalgia aguda). Rev Med Costa Rica 1992; 519 (59): 75-9.
11. Arriagada M, Arinoviche R. A double blind study of etodolac versus piroxicam in the treatment of acute low back pain. (Etodolaco versus piroxicam en el tratamiento del lumbago agudo: estudio doble ciego). Rev Med Chile 1992; 120 (1): 54-8.
12. Ferrer MD, Ortiz JC, Alcón A, Escolano F, Castaño J, Carbonell J. Epidural corticosteroids for treating low back pain with sciatica. (Corticoides epidurales en el tratamiento de la lumbociatalgia). Rev Esp Anest y Reanim 1992; 39: 56.
13. González JL, Portuondo S, Molina JR. Interferential electrical current in the treatment of chronic low back pain. (Las corrientes interferenciales en el tratamiento del dolor lumbosacro crónico). Rev Cuba Ortop Traumatol 1992; 6 (19): 54-60.
14. Kovacs FM, Abraira V, López Abente G, Pozo F. Neuroreflexotherapy in the treatment of subacute and chronic low back pain. A double blind, controlled, randomized trial. (La intervención neurorreflejoterápica en el tratamiento de la lumbalgia inespecífica subaguda y crónica: un ensayo clínico controlado, aleatorizado, a doble ciego). Med Clin 1993; 101 (15): 570-75.
15. Rivera J, Ariza A, García A. Oral corticosteroid therapy versus NSAIDs in acute low back pain. (Terapia corticosteroidea oral versus NSAID en el dolor agudo de la baja espalda). Rev Esp Reum 1993; 20: 409.
16. Llop MT. Relaxation and spine neurostimulation in chronic low back pain with sciatica. (Relajación y neuroestimulación medular en las lumbociatalgias crónicas). Psicothema 1993; 5: 229-39.
17. Kovacs FM, Abraira V, Pozo F, Kleinbaum DG, Beltrán J, Zea A, González-Lanza M, Peña A, Mateo I, Morrilas L, Pérez de Ayala C. Neurorreflexotherapy in the treatment of chronic low back pain. A multicenter, randomized, double-blind, controlled trial. (La intervención neurreflejoterápica en la lumbalgia inespecífica). Rev Esp Reum 1996; 5: 206.
18. Ortiz M, Mazo V, Rodriguez R, Domingo V, Vidal F. Evaluation of pain during corticosteroid caudal epidural injection in patients with chronic low back pain. (Valoración del dolor durante la inyección epidural de corticoides via caudal en pacientes con dolor lumbar crónico). Rev Soc Esp Dolor 1997; 4: 397-401.
19. Márquez A, Cañas A, Peramo F, Serrano M, Caballero J, Bejar MP. A study of the treatment of lumbar spondylolysthesis using superoxide dismutase versus triamcinolone. (Estudio comparativo del tratamiento de la espondilolistesis lumbar mediante superóxido dismutasa versus acetónido de triamcinolona). Rev Soc Esp Dolor 1998; 5: 418-21.
20. Kovacs FM, Llobera J, Abraira V, Aguilar MD, Gestoso M, Lázaro P, Grupo Kap. Economic evaluation of Neuroreflexotherapy for the treatment of subacute and chronic low back pain. (Evaluación económica de la Neurorreflejoterapia en el tratamiento de la lumbalgia inespecífica). E. González, B. González. R. Meneu, J. Ventura, eds. Asociación Economía de la Salud, Barcelona, 2001: 529.