ASERNIP-S

Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

Rapid Review

Spinal Surgery for Chronic Low Back Pain: Review of Clinical Evidence and Guidelines

June 2014

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical

The Royal Australasian College of Surgeons

This report has been produced for the Victorian Government Department of Health

June 30, 2014

Please note that this brief report, while broad in some aspects of systematic review methodology, should not be considered a comprehensive systematic review. Rather, this is a rapid review in which the methodology has been limited in one or more of the following areas to shorten the timeline for its completion: search strategy, inclusion criteria, assessment of study quality and data analysis. This report also contains non-systematic elements, such as qualitative information gathered from local surgeons. However, it is considered that these amendments would not significantly alter the overall findings of the rapid review when compared to a full systematic review.

The methodology used for the rapid review is described in detail, including the limits for this particular topic. These limits were applied following the requirements of the specific review topic, in consultation with the requester.

For a more comprehensive understanding of this topic, a broader analysis of the literature may be required. As such, all readers of this document should be aware of the limitations of this review.

This brief was prepared by Ms Lynda McGahan and Dr Ann Scott from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

Declaration of competing interest:

The authors of this publication claim no competing interests.

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Scope of the Report

The objective of this rapid systematic review is to facilitate the appropriate referral of patients with chronic low back pain to surgical specialists in acute hospitals by summarising the evidence base regarding thresholds of pathology for surgical specialist referral, evaluating the comparative clinical effectiveness of surgery versus alternative treatments and identifying the non-surgical therapies available in Victoria for patients with chronic low back pain.

The report was intended to provide a synthesis of the evidence on the following research questions.

1. Does the evidence show a clinical threshold of pathology for chronic low back pain below which referral for surgical opinion is not required?
2. Is there evidence on the clinical effectiveness of alternative treatments compared with surgery for chronic low back pain?
3. Are effective alternative therapies for chronic low back pain accessible throughout Victoria?

Executive Summary

Context and policy issues

Chronic low back pain (CLBP), defined as non-specific low back pain lasting more than 6 weeks, is a highly prevalent, disabling condition associated with significant healthcare resource utilisation. While degenerative lumbar spine disease, herniated or slipped discs, spinal stenosis and musculoskeletal injuries may be associated with CLBP, up to 70 per cent of cases are non-specific or of no known aetiology. Most clinical practice guidelines (CPGs) recommend that low back pain be managed in primary care, with spinal surgery being limited to a minority of patients presenting with severe or progressive CLBP.

Despite the promotion of evidence-based guidelines for managing low back pain, compliance is poor and there is evidence of inappropriate or unnecessary referrals for surgery. In an effort to help reduce inappropriate surgical referrals for CLBP, Health Services in Victoria have introduced three guidelines specifically for the referral and management of back pain by general practitioners (GPs) and other care providers that outline when it is appropriate to refer to a specialist, what information is required in a referral, what diagnostics tests and imaging are required and how to manage a patient's condition when referral is inappropriate. While 80 per cent of patients waiting to see a neurosurgeon are referred with back or neck pain, surgery is indicated in less than 10 per cent of these cases. High referral rates result in longer wait times for initial consultations and limit access to specialists for those who are appropriate candidates for surgery.

Therefore, the objective of this rapid systematic review is to facilitate the appropriate referral of patients with CLBP to surgical specialists in acute hospitals by summarising the evidence base regarding thresholds of pathology for surgical specialist referral, evaluating the comparative clinical effectiveness of surgery versus alternative treatments and identifying the non-surgical therapies available in Victoria for patients with CLBP according to the following research questions.

1. Does the evidence show a clinical threshold of pathology for CLBP below which referral for surgical opinion is not required?
2. Is there evidence on the clinical effectiveness of alternative treatments compared with surgery for CLBP?
3. Are effective alternative therapies for CLBP accessible throughout Victoria?

Methods

A systematic search of MEDLINE, EMBASE, *The Cochrane Library*, the NHS Centre for Reviews and Dissemination databases and the websites of various international health technology assessment agencies and CPG clearinghouses was conducted to identify all relevant systematic reviews, health technology assessments, clinical guidelines and comparative studies published in English from January 2005 (January 2008 for guidelines) to March 2014. A focused internet search was also conducted to identify

relevant grey literature. Randomised and non-randomised comparative studies published after the search end date of the most recent systematic review were later excluded in the interest of timelines. Study selection, data extraction and quality appraisal were undertaken by one reviewer. Two spinal surgeons from Melbourne were surveyed regarding their opinion on the referral mechanism for spine surgery in Victoria and to identify the non-surgical therapies available for CLBP in the state.

Key results

Clinical evidence regarding the threshold of pathology for specialist referral was obtained from a synthesis of guideline recommendations for the assessment and management of low back pain and an American CPG. The comparative effectiveness of surgery versus conservative management for CLBP was reported in an overview of systematic reviews and two systematic reviews. The synthesis of guideline recommendations, CPG, overview of reviews and systematic reviews were based mostly on evidence from systematic reviews and randomised controlled trials. While the quality of the systematic reviews was generally acceptable, the studies included in the reviews showed a high risk of bias and methodological flaws, including poor reporting, heterogeneity, lack of validated outcomes and only short- to mid-term follow-up. In addition, the generalisability of guideline recommendations to the Australian context was limited; some CPGs excluded low back pain with neurological involvement from their scope, even though this group is often targeted for diagnostic imaging or invasive interventions. In addition, delays between completing the literature search and publishing a guideline can result in outdated recommendations. While CPGs recommended that clinicians evaluate the severity of symptoms and functional limitations associated with low back pain, no guidance was provided regarding specific outcome measures. By limiting the scope of this report to systematic reviews, CPGs, overviews and recommendation syntheses, it was not possible to address all possible comparisons between the surgical and non-surgical interventions available in Victoria.

Threshold of pathology for specialist referral

A synthesis of six evidence-based guidelines endorsed by providers in Europe, the United Kingdom and the United States, together with an additional American CPG and expert opinion, informed a threshold of pathology for specialist referral. Guidelines recommended that patients with CLBP undergo assessment to rule out potentially serious spinal pathology and neurological involvement. Education, paracetamol, non-steroidal anti-inflammatory drugs and spinal manipulation were universally recommended for the primary management of CLBP, with the addition of back exercises, behavioural therapy and short-term use of opioids as needed. Secondary care may involve multidisciplinary rehabilitation, adjunctive analgesics, strong opioids or fusion surgery. Diagnostic imaging may be used to determine whether patients with CLBP and neurological involvement that is refractory to conservative management are appropriate candidates for epidural spinal injections or decompression surgery.

One guideline strongly recommended interdisciplinary rehabilitation for non-radicular CLBP—surgery was not generally recommended for CLBP without a radicular component. Good evidence suggested that patients with disabling leg pain due to spinal stenosis, with or without degenerative spondylolisthesis, may benefit from laminectomy, with or without fusion, up to two years after surgery. Patients with CLBP and disabling radiculopathy due to a herniated lumbar disc or spinal stenosis may experience symptom relief after open discectomy or microdiscectomy up to 12 weeks after treatment. However, the benefits of surgery in these patient groups were not sustained one or two years after treatment.

Expert opinion from two surgeons in Melbourne concurred with the recommendations from international CPGs. However, the nuances of surgical cases can sometimes be missed in the general recommendations made by CPGs. Once a pathological cause for persistent low back pain has been excluded, a patient can be managed in primary care indefinitely. While no definitive threshold of pathology for surgical referral could be determined, referral should only occur when pain causes functional limitations that affect a patient's activities of daily living, the condition is amenable to surgery and all non-surgical treatment options have been trialled without success.

Effectiveness of surgery versus conservative management

An overview of seven systematic reviews and two additional systematic reviews provided information on the comparative effectiveness of surgery versus conservative management for the treatment of CLBP. One systematic review showed no detectable difference in effectiveness between lumbar fusion and conservative management for chronic discogenic low back pain. The overview of reviews reported better Zurich Claudication Questionnaire scores in patients with spinal stenosis who received interspinous spacers than in patients who received conservative treatment, but evidence is needed regarding long-term follow-up. Another systematic review found that decompressive surgery was more effective than land-based exercise for the management of lumbar spinal stenosis. However, the review authors still recommended that a trial of conservative management be undertaken prior to considering surgery. In patients with disc herniation and radiculopathy, surgery resulted in greater short-term pain relief than conservative management, but no differences between the treatments were observed at one year follow-up.

Accessibility of effective non-surgical therapies in Victoria

Two surgeons from Melbourne provided expert opinion regarding the accessibility of alternative therapies for CLBP throughout Victoria. The main evidence-based non-surgical interventions available to CLBP patients in Victoria include: analgesics, non-steroidal anti-inflammatory drugs and prescription pain medications; physiotherapy, chiropractic, osteopathic, acupuncture and other needling techniques; facet joint injection; exercise programmes; and pain management programmes in combination with psychological support.

Conclusions and policy implications

While there is evidence to suggest that surgery provides benefit for a select subset of patients with CLBP, there remains a significant demand for specialist assessment for back pain in Victoria. Inappropriate surgical referrals in Victoria were attributed to both patient and GP factors. GPs may need further information regarding the pathophysiology of back and radicular pain, along with information about the facilities and treatments available in Victoria, as there is a tendency for some GPs to refer patients with refractory pain who have not explored all conservative treatment options. Patients often hold inappropriate expectations about surgical outcomes and many GPs may be unaware of which types of back pain are amenable to surgical treatment. Access to physiotherapy in the private system is limited by cost to the patient, and there is a long wait to access publicly funded pain management programmes and physiotherapy-led clinics in Victoria. Consequently, patients may experience a long wait to receive only short periods of treatment. However, anecdotal evidence suggested that physiotherapy-led clinics are reducing over-referral and improving patient outcomes in Victoria by enabling patients to be treated sooner.

Once a GP has ruled out a pathological cause for persistent low back pain, a patient can be managed in primary care indefinitely. Often patients with apparently refractory pain can benefit from continued treatment in the primary care setting after careful re-evaluation of their treatment plan and degree of compliance by an appropriately trained primary care practitioner. Conservative care involves active, long-term management by GPs and significant buy-in from patients to self-manage their condition. A universal guideline or algorithm for the management of patients with CLBP in primary care may support GPs in this role, but there are other barriers to primary care treatment of CLBP including a lack of knowledge among GPs about the range of facilities and non-surgical treatments available and the types of back pain that are amenable to surgery, as well as limited access to physiotherapy-led clinics and multidisciplinary care programmes.

Compliance with guidelines has been relatively poor worldwide; however, there are successful efforts to bridge the guideline implementation gap using structured referral forms, involvement of consultants in educational activities, specialised clinics and financial incentives. A programme in Canada reduced variations in practice patterns by developing a systematic care pathway for the management of low back pain that involved spine surgeons, physicians and chiropractic, physiotherapy and pain clinics. The spinal care pathways significantly reduced the number of unnecessary surgical referrals, with potential cost savings and improved patient care. However, for any CPG or care pathway to be successful, it must have the buy-in of all stakeholders affected by its guidance and be actively supported with appropriate educational initiatives.

Important note:

The information contained in this report is a synthesis of the best available evidence located at the time the searches were completed.

Abbreviations

AGREE	Appraisal of Guidelines for Research and Evaluation
AMSTAR	Assessment of Multiple Systematic Reviews
CI	confidence interval
CLBP	chronic low back pain
CPG	clinical practice guideline
CT	computed tomography
ESI	epidural spinal injection
FU	follow-up
GP	general practitioner
HTA	health technology assessment
LBP	low back pain
MA	meta-analysis
MD	mean difference
MRI	magnetic resonance imaging
NSAIDs	non-steroidal anti-inflammatory drugs
ODI	Oswestry Disability Index
RCT	randomised controlled trial
RR	relative risk
SR	systematic review
TENS	transcutaneous electrical nerve stimulation
TFESI	transforaminal epidural steroid injections
ZCQ	Zurich Claudication Questionnaire

1. Context and Policy Issues

Low back pain (LBP) is a highly prevalent, disabling condition associated with significant healthcare resource utilisation. Approximately 30 per cent of patients with non-specific LBP spontaneously recover within 3 months of pain onset (Morlion 2013). However, close to 65 per cent of patients have persistent or recurrent LBP, defined as non-specific LBP lasting more than 6 weeks but less than 12 months, and are considered to have chronic low back pain (CLBP) (Morlion 2013). In 2001, the lifetime prevalence and incidence of LBP in Australia were 79 per cent and 68 per cent, respectively, and one in ten Australian adults had experienced significant disability due to LBP during the previous six months (WorkCoverSA 2009). LBP was the seventh most common reason Australians visited a general practitioner (GP) in 2007 (Williams et al. 2010). Approximately 70 per cent of acute LBP patients in Australia live in capital cities, 10 per cent are of non-English speaking background and 2 per cent are indigenous Australians (Williams et al. 2010).

Clinical practice guidelines (CPGs) are designed to provide GPs with evidence-based recommendations for patient management that promote treatments with proven benefits and discourage ineffective treatments. There is evidence to suggest that treatment for patients with LBP that is based on best evidence results in better patient outcomes and is cost-effective (Williams et al. 2010). While several CPGs for the management of LBP have been produced worldwide, a comparison of LBP guidelines from 11 countries published between 1994 and 2000 concluded that they provided similar guidance on assessment and management (Koes et al. 2010).

While 70 per cent of acute LBP is managed primarily in general practice, there is evidence of a discrepancy between the usual care provided by GPs and the best practice recommendations in international evidence-based guidelines for managing acute LBP (Williams et al. 2010). Guidelines recommend that primary care should focus on advice and simple analgesics, yet only 21 per cent and 18 per cent of patients receive these aspects of care. Instead, patients with acute LBP are given non-steroidal anti-inflammatory drugs (NSAIDs) (37%) and opioids (20%) (Williams et al. 2010). Although guidelines discourage the use of diagnostic imaging, more than 25 per cent of patients were referred for imaging. Guidelines recommend that LBP typically be managed in primary care and that specialist care is only required for cases of serious disease. However, a survey of GPs in Australia found that these practitioners refer 17 per cent of new cases to allied health practitioners and 1.5 per cent to specialists. Following the release of LBP guidelines, there was no change in the proportion of GP visits to provide advice and referrals for computed tomography (CT) scans increased significantly, while referrals to allied health practitioners, pathology testing and specialists remained unchanged (Williams et al. 2010).

While degenerative lumbar spine disease, herniated or slipped discs, spinal stenosis or musculoskeletal injuries may be associated with CLBP, up to 70 per cent of cases are non-specific, or of no known aetiology (Morlion 2013). Most CPGs recommend that patients with CLBP learn about their condition, stay active, take NSAIDs or weak opioids as needed, exercise, self-manage their pain and undergo spinal manipulation (Morlion 2013). Secondary recommendations include multidisciplinary rehabilitation, adjunctive analgesics, cognitive behavioural therapy and strong opioids (Morlion 2013). Intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation and facet joint denervation are generally not recommended. Spinal surgery for CLBP is limited to a minority of patients presenting with severe or progressive motor weakness or symptoms of cauda equina syndrome (Morlion 2013). There are three main surgical options: decompression surgery, fusion surgery and disc arthroplasty. Spinal decompression surgery involves complete or partial removal of anatomical structures in the lumbar spine that are causing neural impingement, such as large disc herniations and spinal stenosis (Morlion 2013). Decompression surgery includes open discectomy, microdiscectomy and laminectomy. Fusion surgery joins adjacent vertebrae to alleviate symptoms related to excessive movement in an unstable vertebral motion segment due to advanced degenerative changes. Disc arthroplasty involves removing an intervertebral disc and replacing it with an artificial disc to treat degenerative changes that are confined to one vertebral motion segment (Morlion 2013).

Trials comparing intensive rehabilitation with spinal fusion surgery show similar clinical improvements at short- and long-term follow-up for both treatments that diminish with time, yet more complications and lower cost-effectiveness with surgery (Balague et al. 2012). Trials assessing disc replacement surgery show similar clinical outcomes for spinal fusion and intensive rehabilitation. One difficulty with undertaking randomised controlled trials comparing conservative and surgical management is the high rate of treatment group cross over, often resulting from patient preferences and perceptions of the superiority of surgery (Balague et al. 2012). Chronic refractory cases who have undergone multidisciplinary rehabilitation without improvement should be managed by a pain specialist or through multidisciplinary programmes focused on chronic pain management (Balague et al. 2012).

Despite promotion of evidence-based guidelines for managing LBP, compliance is often poor and translation of these recommendations into practice remains limited (Kindrachuk and Fourney 2014). There is growing evidence of inappropriate or unnecessary referrals to surgery for LBP. In Canada, approximately 75 to 80 per cent of patients referred to spine surgeons are not candidates for surgery, and most referrals lack adequate clinical information for triage (Simon et al. 2009). Referral rates for back surgery continue to remain high in Victoria. Consequently, Health Services have introduced three guidelines specifically for the referral and management of back pain by GPs and other care providers that outline when it is appropriate to refer to a specialist, what information is required in a referral, what diagnostics tests and imaging are required and how to manage a patient's condition when referral is inappropriate (AlfredHealth

2006; St Vincent's Hospital 2009; Southern Health 2009). High referral rates can result in waiting times of several months for an initial consultation, limiting access to specialists for those who are appropriate candidates for surgery. Furthermore, while 80 per cent of patients waiting to see a neurosurgeon are referred with back or neck pain, surgery is indicated in less than 10 per cent of these cases (Kindrachuk and Fourney 2014). Between 60 and 75 per cent of referrals to specialists can be managed through alternative care such as physiotherapy-led services (Hourigan and Weatherley 1994). Despite this, the number of patients undergoing any type of spinal surgery in Victorian public hospitals has risen from 1,000 in 2007 to 1,400 in 2012, while the equivalent numbers in private hospitals rose from 2,600 to 4,300. While the rates of discectomy and fusion surgery have increased in public hospitals, the rate of decompression surgery has remained unchanged (Department of Health 2014).

The objective of this rapid systematic review is to facilitate the appropriate referral of patients with CLBP to surgical specialists in acute hospitals by summarising the evidence base regarding thresholds of pathology for surgical specialist referral, evaluating the comparative clinical effectiveness of surgery versus alternative treatments and identifying the non-surgical therapies available in Victoria for patients with CLBP.

Research questions

1. Does the evidence show a clinical threshold of pathology for CLBP below which referral for surgical opinion is not required?
2. Is there evidence on the clinical effectiveness of alternative treatments compared with surgery for CLBP?
3. Are effective alternative therapies for CLBP accessible throughout Victoria?

2. Methodology

Literature review

Literature search strategy

A limited literature search of MEDLINE, EMBASE, *The Cochrane Library* (Issue 3, 2014), the NHS Centre for Reviews and Dissemination databases and the websites of international health technology assessment (HTA) agencies and CPG clearinghouses was conducted to identify relevant research published in English from January 2005 (January 2008 for guidelines) to March 2014. A focused internet search was also conducted to identify grey literature. Filters were applied to limit the retrieval to systematic reviews (SRs), HTAs, meta-analyses, randomised controlled trials (RCTs) and non-randomised comparative studies. Details of the search strategies are provided in Appendix A.

Study selection criteria and methods

One reviewer screened all citations and selected studies. On initial screening, titles and abstracts were reviewed for relevance. Full-text publications were retrieved and assessed for inclusion based on the criteria in Table 1. Only studies conducted in Australia, Canada, Japan, New Zealand, the United States and European countries (except for those with transitional economies) were included for review. These countries, which have developed economies as defined by the United Nations, are likely to have populations whose health status, cultural norms, access to health care and disease burden are comparable to those in Australia (United Nations 2009).

Table 1: Study selection criteria

Population	Adults with persistent or recurrent low back pain, defined as non-specific low back pain lasting more than 6 weeks but less than 12 months, with or without radiculopathy, that is of no known aetiology or is due to degenerative lumbar spine disorders, herniated or slipped discs, spinal stenosis or musculoskeletal injuries
Intervention	Spinal surgery
Comparator	Non-surgical interventions, including, but not limited to, spinal intervention procedures, pharmacological interventions and non-invasive treatments
Outcomes	Long-term clinical benefits and harms, including, but not limited to reduction in pain, functional outcomes, quality of life, return to work, mortality and morbidity
Study design	HTA, SR, MA, RCT, non-randomised comparative study Evidence-based CPGs that provided criteria for or recommendations on surgical management of chronic low back pain

CPG: clinical practice guideline; HTA: health technology assessment; MA: meta-analysis; RCT: randomised controlled trial; SR: systematic review

Exclusion criteria

Studies were excluded if they: did not meet the selection criteria; were included in a selected overview of reviews, SR or synthesis of guidelines; were duplicate or preliminary

results; had incomplete or inappropriate methods; were an ineligible study design; could not be retrieved during the review period; or involved patients with back pain due to malignancy, infection, fracture or ankylosing spondylitis or other inflammatory disorder.

Given the timeline for review, a best available evidence approach was used to select studies. Randomised and non-randomised comparative studies published after the search end date of the most recent SR were later excluded in the interest of timelines.

Data extraction and analysis

One reviewer extracted data on patient characteristics, long-term clinical benefits and harms and guidelines recommendations on the surgical management of CLBP.

Critical appraisal of included studies

One reviewer conducted the methodological quality appraisal. Included SRs were evaluated using the 11-item Assessment of Multiple Systematic Reviews (AMSTAR) checklist (Shea et al. 2007), while the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument was used to appraise clinical practice guidelines (Brouwers et al. 2010). The domains assessed by AMSTAR include design, study selection and data extraction, literature searching, study characteristics, quality assessment, methods used to combine findings, publication bias and conflict of interest. The domains assessed by AGREE II include scope and purpose, stakeholder involvement, rigour of development, clarity and presentation, applicability and editorial independence. Instead of calculating numeric scores, the strengths and weaknesses were described narratively for each study. The evidence presented in the selected studies was classified, where possible, using the levels of evidence defined by the National Health and Medical Research Council (Merlin et al. 2009) (Appendix B).

Data analysis

Study design, heterogeneity of interventions and populations and timelines prevented formal meta-analysis. Study characteristics, quality assessment and results were summarised narratively in relation to the research questions.

Expert opinion

Two surgeons from Melbourne, Victoria who conduct spinal surgery were identified through the Victorian Government Department of Health. The following set of seven questions, developed in consultation with the Victorian Government Department of Health, was emailed to each of the surgeons.

1. What are the main non-surgical interventions available in Victoria to patients with CLBP?
2. Why do you think that some patients with CLBP are incorrectly referred for surgery in Victoria?

3. Do you think that GPs are adequately supported in providing long-term non-surgical treatment to patients with LBP (e.g. adequate access to physiotherapy centres and multidisciplinary care programmes)?
4. Are physiotherapy-led clinics in Victoria helping to reduce over-referral to surgery and improve patient outcomes?
5. How long should a patient with CLBP persist with non-surgical treatments before being referred to a specialist? Are there guidelines available for this?
6. Would a single referral guideline for all of Victoria be useful in ensuring that GPs correctly refer patients for surgery? If not, are there any other ways to achieve this?
7. For patients with CLBP, does the threshold for surgery differ between the public and private health systems in Victoria?

Responses were de-identified, grouped into themes, and reported narratively.

3. Studies Included in the Review

Literature search results

The literature search yielded 1,307 citations. Upon screening titles and abstracts, 22 potentially relevant articles were retrieved for full-text review. Handsearching and searching of grey literature identified another three potentially relevant reports. Of the 25 potentially relevant reports, seven were reported in an overview of SRs or a synthesis of recommendations from CPGs, three contained an irrelevant intervention, four contained an irrelevant population and six were an ineligible study design or were not within the date limits for review. Five studies were included in this review (Bydon et al. 2013; Chou et al. 2009; Dagenais et al. 2010; Jacobs et al. 2013; Jarrett et al. 2012). The study selection process is outlined in Appendix A (Figure A.1) and the excluded studies are listed in Appendix C.

Description of studies

Evidence regarding the threshold of pathology for specialist referral was obtained from a synthesis of guideline recommendations for the assessment and management of LBP (Dagenais et al. 2010) and a CPG by the American Pain Society (Chou et al. 2009). The effectiveness of surgery compared with alternative treatments for CLBP was reported in an overview of SRs (Jacobs et al. 2013) and two SRs (Bydon et al. 2013; Jarrett et al. 2012). The recommendation and evidence grading categories used in the guideline synthesis and CPG are summarised in Appendix D (Table D.1); the characteristics of the included overview of reviews and SRs are summarised in Appendix D (Table D. 4).

No HTAs or RCTs met the inclusion criteria for review. Three non-randomised comparative studies (Choi et al. 2013; Hadzic et al. 2013; Mirza et al. 2013) were excluded from formal review in the interest of time.

Synthesis of guideline recommendations

The synthesis of guideline recommendations for the assessment and management of LBP included ten CPGs: six on acute LBP, seven on CLBP and six on LBP with neurological involvement (Dagenais et al. 2010). CLBP was defined as pain lasting longer than 3 months (Dagenais et al. 2010). The six CLBP guidelines were from Belgium, Europe, Italy, the United Kingdom and the United States. The European guidelines were a joint effort by Denmark, Finland, France, Germany, the Netherlands, Sweden, Switzerland and the United Kingdom. Two guidelines from the United States were from the same group, but one reported on primary interventions while the other reported on secondary interventions. All CPGs included at least one primary care provider and one non-surgical spine specialist among the authors, in addition to a surgical spine specialist, a physiotherapist, an occupational therapist or an osteopath (Dagenais et al. 2010). Of the six guidelines, two were endorsed by national associations of primary care providers, two

by physiotherapists, three by non-surgical spine specialists and one by surgical spine specialists. Evidence for the CPGs was most commonly identified through *The Cochrane Library*, followed by the MEDLINE and EMBASE databases. All seven guidelines included published SRs and RCTs, which were considered the highest level of evidence. Most CPGs assessed study quality using criteria developed by The Cochrane Collaboration. Recommendations were dichotomised to "recommended" if there was strong, moderate or limited evidence of efficacy or "not recommended" if there was insufficient or conflicting evidence, or there was evidence against the intervention (Dagenais et al. 2010).

Clinical practice guidelines

The evidence-based CPG by the American Pain Society was based on a SR conducted by the Oregon Evidence-Based Practice Center (Chou et al. 2009). Evidence from 161 English-language RCTs involving adults with LBP (alone or with leg pain) of any duration that evaluated an interventional therapy or surgery and reported on back-specific function, work disability, patient satisfaction or overall treatment benefit were considered in developing the guideline. The American Pain Society graded the strength of evidence and estimated the magnitude of benefits. Evidence-based recommendations were assigned a grade for strength of recommendation (strong or weak) and for quality of evidence (high, moderate or poor) (Chou et al. 2009) (Appendix D, Table D.1).

Overview of systematic reviews

The overview of evidence on surgical interventions for LBP was based on 13 SRs (level I evidence), of which seven were related to CLBP resulting from disc herniation (n=4), spondylolisthesis (n=1) and degenerative disc disease (n=2) (Jacobs et al. 2013). CLBP was defined as discomfort in the back which may radiate into the legs, hips or buttocks, and which lasts more than three months (Jacobs et al. 2013). Five of seven SRs were rated as being of high quality based on an AMSTAR risk of bias assessment (Shea et al. 2007). The overview summarised SRs on the effectiveness of surgical interventions for CLBP, compared with conservative management, with respect to pain, functional status and recovery up to two years' follow-up (Jacobs et al. 2013). Surgical interventions included thermal coagulation, radiofrequency denervation, decompression surgery and fusion surgery compared with one another or conservative care.

Systematic reviews

Two additional SRs (level I evidence) contained between five and 13 studies involving 707 (Bydon et al. 2013) and 1,098 patients (Bydon et al. 2013; Jarrett et al. 2012). One SR contained a meta-analysis of five RCTs comparing lumbar fusion with conservative management (Bydon et al. 2013), while the other synthesised the results of seven RCTs (level II evidence), one pseudo-randomised trial (level III-1 evidence), two prospective cohort studies (level III-2 evidence) and three before and after studies (level III-3 evidence) comparing decompressive surgery with exercise (Jarrett et al. 2012). The

reviews reported on disability due to back pain measured by the Oswestry Disability Index and patient-reported outcomes, with a follow-up of at least one or two years (Bydon et al. 2013; Jarrett et al. 2012).

Bydon et al. (2014) (level I evidence) evaluated changes in Oswestry Disability Index scores at least one year after lumbar fusion, compared with conservative management, in patients with chronic (>3 months' duration) discogenic LBP. Five RCTs met their inclusion criteria (Brox et al. 2006; Brox et al. 2003; Fairbank et al. 2005; Fritzell et al. 2001; Ohtori et al. 2011). All studies reported on the use of lumbar spine fusion, but the surgical technique varied across the studies. Conservative management included physical therapy, patient education, acupuncture, injections, rehabilitation and hydrotherapy. Three of the five RCTs followed patients for two years, with follow up rates of between 82 and 100 per cent.

Jarrett et al. (2012) (level I evidence) assessed patient-reported functional outcomes and changes in Oswestry Disability Index scores over two years following decompressive surgery or land-based exercise in patients with lumbar spinal stenosis. Studies were only considered if they included patients with degenerative lumbar spinal stenosis as diagnosed by magnetic resonance imaging (MRI) or CT scan and clinical presentation of buttock or lower extremity pain, with or without back pain aggravated by lower lumbar extension and ambulation, that was relieved by lumbar flexion and sitting. Surgical interventions involved decompression of neurovascular structures in the lumbar spinal canal, including laminectomy and minimally invasive approaches. Exercise interventions involved flexibility, range of movement and strengthening and/or conditioning, with or without adjunctive conservative interventions.

Appraisal of study quality

Summaries of the appraisal of the guideline synthesis, CPG, overview of reviews and SRs are provided in Appendix D (Tables D.2 and D. 5).

Synthesis of guideline recommendations

The synthesis of CPG recommendations was based on a comprehensive literature search of electronic databases and grey literature, complemented by internet searching of specific websites, including the National Guideline Clearinghouse, Clinical Evidence and the National Institute for Health and Clinical Excellence (Dagenais et al. 2010). Two reviewers independently selected CPGs using predefined criteria and appraised their quality with the AGREE tool (Dagenais et al. 2010). While one reviewer abstracted data using a piloted data extraction form, another reviewer independently verified the data. Guidelines were excluded if they were not endorsed by a national government agency or professional health provider group, were written in a language other than English, did not cover both assessment and management of LBP or were focused on a single discipline or intervention. These selection criteria may have overly restricted the guidelines eligible for review. Except for the US guideline, all CPGs were sponsored or

funded by their respective national governments, and details of any conflicts of interest were reported in most guidelines (Dagenais et al. 2010).

Clinical practice guidelines

Recommendations in the American Pain Society guideline were supported by a systematic review (Chou et al. 2009). The guideline development group included all relevant professional groups and defined the target audience as all clinicians caring for patients with LBP of any duration with or without leg pain. Health benefits and risks were considered, and the methods used to formulate the recommendations were reported. While patients' views were not systematically sought, each recommendation encouraged shared decision making between the patient and the healthcare provider. The American Pain Society intended to update the CPG by 2012, but no further versions were found. Generally, organisational barriers, cost implications and criteria for monitoring or audit were not reported, and no tools were provided to facilitate implementation.

Overview of systematic reviews

The protocol for the overview of SRs was designed a priori and was registered in the International Prospective Register of Systematic Reviews (Jacobs et al. 2013). The overview was based on a comprehensive literature search using predefined criteria. Two reviewers independently selected reviews according to well-defined criteria and assessed their methodological quality using the AMSTAR tool (Shea et al. 2007). The review had a risk of publication and time lag bias as only Cochrane reviews and non-Cochrane SRs published in peer-reviewed journals were included for study. The authors reported no conflicts of interest.

Systematic reviews

Both SRs reported searching for literature using predefined criteria. However, Bydon et al. (2014) may be susceptible to publication and time lag bias because it did not report searching for grey literature. Jarrett et al. (2012) divided the database searches between two reviewers to screen abstracts, but two reviewers independently reviewed all potentially relevant abstracts and full-text articles that met the inclusion criteria. While Bydon et al. (2014) did not provide a list of excluded studies, Jarrett et al. (2012) reported both the excluded studies and the reasons for exclusion. The authors of Jarrett et al. (2012) collaborated to extract data and assess study quality using the McMaster Critical Review Form for Quantitative Studies (Law et al. 1998). Bydon et al. (2014) conducted duplicate appraisal of the included studies using The Cochrane Collaboration risk of bias tool. Adherence to and duration of exercise programmes were poorly described in trials, and a range of co-interventions were used which may have confounded the results (Jarrett et al. 2012). Also, the included studies may only include patients in whom conservative management has failed, creating a possible bias (Jarrett et al. 2012). All of the studies included in the Bydon et al. (2014) meta-analysis had similar populations and

intervention groups, but there was some heterogeneity in outcomes and concern regarding the methodological rigour of the included studies.

4. Literature Review Results

Threshold of pathology for specialist referral

Synthesis of guideline recommendations

A synthesis of evidence-based recommendations from six CPGs (published between 2005 and 2009), endorsed by providers in Europe, the United Kingdom and the United States suggested a threshold of pathology for specialist referral for CLBP (Dagenais et al. 2010) (Table 2). Recommendations for assessing LBP emphasised ruling out serious spinal pathology, specific causes of LBP and neurological involvement, identifying risk factors for chronicity and measuring severity and function through physical and neurological examination. Education, paracetamol, NSAIDs and spinal manipulation were recommended for the primary management of CLBP by five CPGs. Back exercises, behavioural therapy and short-term use of opioid analgesics may also be added according to five CPGs. Secondary care may involve multidisciplinary rehabilitation, adjunctive analgesics, strong opioids or fusion surgery, as recommended by at least three CPGs. Recommendations for the management of CLBP with neurological involvement included consideration of MRI or CT scans to identify appropriate candidates for epidural spinal injections or decompression surgery among patients who have not improved with conservative management (Dagenais et al. 2010).

Clinical practice guidelines

A CPG by the American Pain Society, based on a SR of 161 RCTs, also suggested a threshold of pathology for specialist referral for CLBP (Chou et al. 2009) (Table 2). The American Pain Society strongly recommended interdisciplinary rehabilitation with a cognitive behavioural emphasis for non-radicular LBP. Interdisciplinary rehabilitation, defined as an integrated intervention with rehabilitation and a psychological and/or social or occupational component, was similar in effectiveness to fusion surgery for non-radicular LBP (Chou et al. 2009).

The American Pain Society strongly recommended that injections not be used for non-radicular LBP as there was no convincing evidence from RCTs that injections were effective for this indication. A weak recommendation was provided regarding the use of epidural spinal injections for persistent radiculopathy due to a herniated lumbar disc; there was no convincing evidence that epidural spinal injections reduced the need for surgery (Chou et al. 2009).

A weak recommendation was provided regarding surgery for non-radicular LBP due to degenerative disc disease (Chou et al. 2009). Fusion surgery was superior to non-surgical therapy without interdisciplinary therapy according to one clinical trial, but it was no more effective than intensive interdisciplinary rehabilitation according to another three

Table 2: Summary of evidence from CPGs on threshold of pathology for specialist referral

Study, Country	Design	Interventions (no. of CPGs recommending use)	Recommendation Details	Conclusions and Limitations
Dagenais et al. (2010) USA	Synthesis of 6 CPGs Endorsed by providers in Europe, the United Kingdom and the United States	**CLBP**: *Primary care*: Education on LBP (n=5), advice on staying active (n=4), back schools (n=4), NSAIDs (n=5), weak opioid analgesics (n=5), back exercises (n=5) and spinal manipulative therapy (n=5) *Secondary care*: Multidisciplinary rehabilitation (n=6), adjunctive analgesics (n=5), strong opioid analgesics (n=4), fusion surgery (n=3), facet injections (n=1), TFESI (n=1), soft tissue injections (n=1) and spinal cord stimulation (n=1) **CLBP with neurological involvement**: *Primary care*: Education on LBP (n=3), advice on staying active (n=3), paracetamol (n=2), muscle relaxants (n=3), NSAIDs (n=3), spinal manipulative therapy (n=2), back schools (n=2) massage (n=2), TENS (n=1), acupuncture (n=1), bed rest (n=1) and autotraction (n=1) *Secondary care*: ESI (n=2), multidisciplinary rehabilitation (n=2), behavioural therapy (n=2), decompression surgery (n=1), TFESI (n=1), strong opioid analgesics (n=2), adjunctive analgesics (n=2), facet injections (n=1), soft-tissue injections (n=1) and spinal cord stimulation (n=1)	• Recommendations for assessment of LBP emphasise importance of ruling out serious spinal pathology, specific causes and neurological involvement. • Recommendations emphasise the importance of identifying risk factors for chronicity and measuring severity and functional limitations through physical and neurological examination. • Recommendations for management of acute LBP emphasise education, paracetamol, NSAIDs or spinal manipulative therapy. • Recommendations for management of CLBP include the addition of back exercises, behavioural therapy and short-term use of opioid analgesics. • Recommendations for management of CLBP with neurological involvement include additional consideration of MRI or CT to identify appropriate candidates willing to undergo ESI or decompression surgery if refractory to conservative management. • No guidelines recommended decompression surgery or intradiscal electrothermal therapy/nucleoplasty for CLBP without neurological involvement.	*Authors' conclusions*: Recommendations for management of CLBP with neurological involvement lend consideration to MRI or CT to identify appropriate candidates willing to undergo ESI or decompression surgery if their condition is refractory to conservative management. Recommendations from several CPGs were similar, and clinicians who care for patients with LBP should adopt these recommendations to improve patient care. *Limitations*: Some CPGs excluded LBP with neurological involvement from their scope even though this group is often targeted for advanced diagnostic imaging or invasive interventions. Temporal classifications of acute versus chronic LBP were somewhat arbitrary given that symptoms fluctuate over time. Delay between completing the literature search and publishing a guideline varied from 10 to 32 months and recommendations could have been outdated by the time of publication. Few details were provided regarding management of potentially serious spinal pathology requiring MRI or CT or urgent surgical evaluation. Future CPGs should provide a synopsis of how serious spinal pathology may be managed. While CPGs recommended that clinicians evaluate the severity of symptoms and functional limitations for LBP, no guidance was provided on specific outcome measures. Only one guideline suggested specific parameters for some recommended interventions for CLBP.

Table 2: Summary of evidence from CPGs on threshold of pathology for specialist referral (cont'd)

Study, Country	Design	Interventions (no. of CPGs recommending use)	Recommendation Details*	Conclusions and Limitations*
American Pain Society Chou et al. (2010) USA	Evidence-based CPG SR of 161 RCTs	**Non-radicular LBP due to**: • Non-specific LBP: intradisciplinary rehabilitation (1) • Degenerative changes: fusion surgery (1) • Single level disc disease: artificial disc replacement (1) **Radicular or symptomatic spinal stenosis**: • Radiculopathy with prolapsed lumbar disc: open discectomy or microdiscectomy (1); chemonucleolysis (1); ESI (1); intradiscal steroid injection (1) • Symptomatic spinal stenosis with or without degenerative spondylolisthesis: laminectomy with or without fusion (1) • One- to two-level symptomatic spinal stenosis relieved with forward flexion: interspinous spacer device (1)	• Good evidence that interdisciplinary rehabilitation provides moderate benefit for non-specific LBP (Grade B recommendation). • Fair evidence that fusion surgery provides moderate benefit for non-radicular LBP with common degenerative changes (Grade B recommendation). • Fair evidence that artificial disc replacement provides no further benefit for single-level degenerative disc disease than fusion at 2 years' follow-up (Grade B recommendation). • Good evidence that open discectomy or microdiscectomy provides moderate 3-month benefit for radiculopathy with prolapsed lumbar disc (Grade B recommendation). • Good evidence that laminectomy, with or without fusion, provides moderate benefit up to 2 years for symptomatic spinal stenosis with or without degenerative spondylolisthesis (Grade B recommendation). • Good evidence that chemonucleolysis provides moderate benefit for radiculopathy with a prolapsed lumbar disc (Grade B recommendation). • Fair evidence that ESI provides moderate 3-month benefit for radiculopathy with prolapsed lumbar disc (Grade B recommendation).	Intensive interdisciplinary rehabilitation with cognitive behavioural emphasis is recommended for non-radicular LBP (strong recommendation, high-quality evidence). Interdisciplinary rehabilitation is similar in effectiveness to fusion surgery for non-radicular LBP. Injections are not recommended for non-radicular LBP (strong recommendation, moderate-quality evidence). Discuss risks and benefits of surgery for non-radicular LBP due to degenerative spinal changes (weak recommendation, moderate-quality evidence). Fusion surgery is superior to non-surgical therapy without interdisciplinary rehabilitation (1 trial), but no more effective than intensive interdisciplinary rehabilitation (3 trials). There was insufficient evidence to assess long-term benefits and harms of vertebral disc replacement for non-radicular LBP due to degenerative spinal changes (insufficient evidence). Discuss risks and benefits of ESI for persistent radiculopathy due to a herniated lumbar disc (weak recommendation, moderate-quality evidence). No convincing evidence that ESI reduces surgery rates. Discuss risks and benefits of surgery for persistent radiculopathy due to herniated lumbar disc or persistent disabling leg pain due to spinal stenosis (strong recommendation, high-quality evidence).

CLBP: chronic low back pain; CPG: clinical practice guideline; CT: computed tomography; ESI: epidural spinal injection; LBP: low back pain; MRI: magnetic resonance imaging; NSAIDs: non-steroidal anti-inflammatory drugs; RCT: randomised controlled trial; SR: systematic review; TENS: transcutaneous electrical nerve stimulation; TFESI: transforaminal epidural steroid injection

*See Table D.1, Appendix D for explanation of evidence and recommendation gradings

trials. Decisions regarding surgery for persistent non-radicular LBP should include discussion of the risks and benefits of fusion versus conservative management, as the benefits of fusion have only been demonstrated in a small subset of patients with moderately severe pain or disability that has been unresponsive to conservative management for at least one year, and who do not have psychiatric or medical comorbidities (Chou et al. 2009). There was insufficient evidence to assess the effects of vertebral disc replacement for non-radicular LBP due to degenerative disc disease. The American Pain Society strongly recommended that clinicians discuss the risks and benefits of surgery as an option for persistent disabling radiculopathy due to a herniated lumbar disc or spinal stenosis (Chou et al. 2009). While open discectomy and microdiscectomy resulted in moderate benefits up to 12 weeks after surgery, compared with non-surgical therapy, the benefits diminished after one or two years. For persistent disabling leg pain due to spinal stenosis, with or without degenerative spondylolisthesis, decompressive laminectomy was associated with moderate benefits, compared with non-surgical therapy, for up to two years. However, the benefits diminished over long-term follow-up (Chou et al. 2009).

Effectiveness of surgery versus conservative management

Overview of systematic reviews

In an overview of 13 SRs, seven reviews compared the effectiveness of surgical interventions with conservative management or another surgical technique in patients with CLBP (Table 3) (Jacobs et al. 2013). The authors of the SRs were unable to identify any statistically significant or clinically relevant differences in effectiveness between most of the interventions for disc herniation with radiculopathy, spondylolisthesis, degenerative disc disease or spinal stenosis. No conclusion could be made regarding the effectiveness of surgery versus conservative management for patients with a herniated disc, based on the results of four SRs.

While surgery may have short-term benefits, a dearth of high-quality trials precluded a definitive statement regarding surgical management. One SR with a high risk of bias showed superior results for posterolateral fusion for low-grade isthmic spondylolisthesis, compared with exercise, at two years' follow-up. Another SR reported that decompressive laminectomy, with or without fusion, in patients with stenosis due to degenerative disc disease was superior to non-surgical therapy up to two years following surgery, but the benefits diminished thereafter. Three high-quality SRs concluded that interspinous spacers produced a statistically and clinically significant improvement in Zurich Claudication Questionnaire scores, compared with conservative management, in patients with spinal stenosis. While the quality of the included reviews was acceptable, studies included in the reviews had a high risk of bias and methodological flaws,

including poor reporting, heterogeneity, a lack of validated outcomes and limited follow-up of between 1 and 2 years.

Systematic reviews

Bydon et al. (2014) analysed the results of five RCTs involving 707 patients with chronic discogenic LBP and found that while lumbar fusion resulted in an overall improvement of Oswestry Disability Index score (-7.39, 95% confidence interval -20.26 to 5.47) from baseline, it was unclear whether this change led to a clinically significant difference compared with conservative management (Table 3). Postoperative complications involving wound infections and bleeding were reported in 9 to 18 per cent of patients. The authors concluded that lumbar fusion and non-surgical management and physical therapy were acceptable treatment options for managing intractable LBP (Bydon et al. 2013).

A second SR of seven RCTs, three prospective cohort studies and three before and after studies involving 1,098 patients demonstrated that decompressive surgery was more effective than exercise for the management of lumbar spinal stenosis (Jarrett et al. 2012). Only one study directly compared the effectiveness of decompressive surgery with exercise in patients with lumbar spinal stenosis. Surgery resulted in statistically significant improvements in patient-reported functional outcomes (Oswestry Disability Index scores) up to two years post-intervention ($P<0.01$). To facilitate comparison, the percentage change in patient-reported functional outcomes from 12 exercise and 10 surgical intervention arms from six RCTs, 3 prospective cohort trials and three before and after studies were compared. While exercise interventions produced initial improvements in function, ranging from 16 to 29 per cent above baseline, decompressive surgical interventions demonstrated greater (range 38% to 67% above baseline), more sustained improvements over two years. Approximately 3 to 14 per cent of surgical patients experienced dural tears. The authors of the SR concluded that a trial of conservative management with land-based exercise should be recommended prior to considering surgical intervention in patients with lumbar spinal stenosis (Jarrett et al. 2012).

Table 3: Summary of evidence from systematic reviews on effectiveness of surgery versus conservative management

Study, Country	Design	Intervention	Comparator	Findings	Conclusions and Limitations
Jacobs et al. (2013) The Netherlands	Overview of reviews 13 SRs Herniated disc (n=4); isthmic spondylolisthesis (n=1); degenerative disc disease without stenosis (n=2) Maximum FU: 2 years	Surgical interventions including thermal coagulation, radiofrequency denervation, decompression and fusion surgery	Conservative management or different surgical technique	• Surgery leads to short-term benefits, but the dearth of high-quality trials precluded a definite choice between conservative management and surgical treatment for disc herniation with sciatica (4 SRs). • Superior clinical outcomes at 2 years following posterolateral fusion compared with exercise for low-grade isthmic spondylolisthesis (1 trial with high risk of bias). • Interspinous spacers produced a statistically and clinically significant improvement in ZCQ scores, compared with conservative treatment, in patients with spinal stenosis (3 SRs). • No difference in effectiveness between interspinous devices or decompressive surgery versus conservative management (2 SRs). • Decompressive laminectomy (with or without fusion) was superior to non-surgical therapy for the first 2 years of FU, but benefits diminished thereafter (1 SR).	*Authors' conclusions*: No conclusion regarding surgery versus conservative management for herniated disc (1 SR). Posterolateral fusion showed superior results for clinical outcome after 2 years, compared with exercise for low-grade isthmic spondylolisthesis (1 SR). Fusion was no more effective than intensive rehabilitation for LBP without stenosis due to degenerative disc disease (2 SRs). Intervertebral process devices were more effective than conservative management in improving ZCQ scores in patients with spinal stenosis (3 SRs). Fusion improved a mixed aggregation of clinical outcomes more than decompression in patients with degenerative spondylolisthesis (1 SR). *Limitations*: Scarcity of high-quality trials for herniated disc. Low-grade isthmic spondylolisthesis study had a high risk of bias and lacked blinding and an intention-to-treat analysis. Inconsistent results for discogenic LBP without stenosis were ascribed to differences in rehabilitation intensity in the non-surgical intervention group. For most comparisons, significant or clinically relevant differences between interventions were not identified in the reviews. While the quality of included reviews was acceptable, the quality of included studies was poor. Reviews included duplication of primary studies.

Table 3: Summary of evidence from systematic reviews on effectiveness of surgery versus conservative management (cont'd)

Study, Country	Design	Intervention	Comparator	Findings	Conclusions and Limitations
Bydon et al. (2014) USA	SR with MA 5 RCTs 707 patients ≥1 year FU	Lumbar fusion	Conservative management	• While pooled ODI from 5 RCTs was in favour of lumbar fusion, compared with conservative management, for chronic low back pain, the difference was not statistically significant. • Postoperative complications involving wound infections and bleeding were observed in 9% to 18% of patients.	*Authors' conclusions*: Despite significant improvement in ODI in lumbar fusion groups in three studies, pooled data revealed no statistically significant difference when compared with non-surgical management. It was unclear whether the change in ODI in favour of lumbar fusion led to a clinically significant difference. *Limitations*: Significant risk of bias as patients, personnel and outcome assessors were not blinded and studies were at high risk of sampling bias due to patient cross over.
Jarrett et al. (2012) Australia	SR of 7 RCTs, 3 prospective cohort studies and 3 before and after studies 1,098 patients Maximum FU: 2 years	Decompressive surgery (8 studies) involving minimally invasive technique, laminectomy, bilateral foraminotomy	Land-based exercise (6 studies) involving physiotherapy-supervised or home exercise (3 to 6 weeks); co-interventions were administered with exercise	• Decompressive surgery produced statistically significant improvements in patient-reported functional outcomes (ODI), compared with exercise, up to 24 months' FU (1 RCT). • Exercise interventions produced improvements of between 16% and 29% above baseline, while decompressive surgery resulted in greater, more sustained improvements over 2 years (range 38% to 67%) (12 exercise and 10 surgical intervention arms). • Dural tears (3% to 14%) were a common surgery-related complication.	*Authors' conclusions*: There was evidence for improvement in patient-reported functional outcomes in patients who underwent decompressive surgery for lumbar spinal stenosis. Studies were consistent across multiple timeframes, with sustained improvement at 2 years. Decompressive surgery was more effective than land-based exercise for management of lumbar spinal stenosis. Land-based interventions are recommended prior to considering surgical interventions. *Limitations*: Heterogeneity of land-based exercise interventions used in included studies prevented formulation of recommendations regarding the most effective forms of exercise.

FU: follow-up; LBP: low back pain; MA: meta-analysis; ODI: Oswestry Disability Index: RCT: randomised controlled trial; SR: systematic review; ZCQ: Zurich Claudication Questionnaire

5. Expert Opinion

Responses were received from two surgeons (one orthopaedic and spine surgeon and one neurosurgeon) from major hospitals in Melbourne, Victoria who were asked to provide their expert opinion on the seven questions below.

Question 1: What are the main non-surgical interventions available in Victoria to patients with CLBP?

- Pharmacological treatments: over-the-counter analgesics, NSAIDs and prescription pain medications.
- Interferential (pain-relieving) modalities: physiotherapy techniques (e.g. massage, manipulation, heat, diathermy, ultrasound and transcutaneous electrical nerve stimulation); chiropractic, osteopathic, acupuncture and other needling techniques; and facet joint injection, medial branch blocks and radiofrequency denervation.
- Management modalities: physiotherapy-taught techniques that promote self-management (e.g. exercise programmes for core strengthening and lumbar stabilisation, stretching and flexibility regimens and hydrotherapy) and gym programmes.
- Multidisciplinary pain management programmes: pain relieving and management modalities in combination with psychological support and training.

N.B. This is a listing of available interventions only; no inference should be made regarding the effectiveness of these treatments.

Question 2: Why do you think that some patients with chronic LBP are incorrectly referred for surgery in Victoria?

The reasons are as follows.

- GP factors:
    - Lack of knowledge of the difference between the pathophysiology of back pain and radicular pain;
    - Desire to refer "difficult" patients who keep re-presenting and who are running out of treatment options.
    - Lack of awareness of the facilities and conservative treatments available for patients with CLBP.
- Patient and GP factors:
    - Incorrect interpretation of imaging results as being not only pathological, but also surgically treatable.
    - Inappropriate expectations of what surgery can achieve (patients) and a lack of knowledge of what is surgically possible (GPs) for back pain. For example, patients with radicular or stenotic pain achieve better surgical outcomes than patients with non-specific LBP.

Question 3: Do you think that GPs are adequately supported in providing long-term non-surgical treatment to patients with LBP (e.g. adequate access to physiotherapy centres and multidisciplinary care programmes)?

GPs and patients need to understand that conservative care is not a cure. It involves long-term pain management and requires significant buy-in from patients to self-manage their condition. The cost of private pain management programs is often a barrier. However, visits to the GP can help by encouraging patients to continue to exercise at the end of treatment and between treatments.

Access to privately funded physiotherapy treatment is limited by cost to the patient, while access to pain management programmes is hindered by the small numbers available. Patients relying on community facilities usually experience long wait times and receive only short periods of treatment.

Question 4: Are physiotherapy-led clinics in Victoria helping to reduce over-referral to surgery and improve patient outcomes?

Both surgeons believed that physiotherapy-led clinics probably help reduce over-referral to surgery and improve patient outcomes. Access to these clinics in the public system allows patients to receive treatment much sooner, thereby potentially preventing the progression to chronic pain that may occur when patients have to wait many months for a specialist appointment. However, one surgeon noted that physiotherapy-led clinics may attract patients who should be treated in community practice rather than at major hospitals.

Question 5: How long should a patient with CLBP persist with non-surgical treatments before being referred to a specialist? Are there guidelines available for this?

A GP can manage a patient with LBP indefinitely once appropriate tests have been ordered to rule out a pathological cause for the pain. The timing of referral is dependent on the patient's symptoms. The patient can be referred to a surgical specialist when all non-surgical options are exhausted, the condition is amenable to surgery and the patient feels that his/her pain is unmanageable with respect to function and ability to perform daily self-care activities. However, this should only be considered after careful re-evaluation of the patient's treatment plan and compliance to date, preferably in consultation with an appropriately trained primary care practitioner, as patients with apparently refractory pain can often benefit from continued, well-managed treatment in the primary care setting.

Question 6: Would a single referral guideline for all of Victoria be useful in ensuring that GPs correctly refer patients for surgery? If not, are there any other ways to achieve this?

There was consensus that a single guideline defining and explaining CLBP and the treatments available would be useful, as would be a management algorithm. However, one surgeon noted that this would need to be properly implemented to ensure correct patient referral, particularly as some GPs may continue to incorrectly refer patients in spite of a universal referral guideline.

Question 7: For patients with CLBP, does the threshold for surgery differ between the public and private health systems in Victoria?

Both surgeons agreed that this was the case and that the threshold also differs between orthopaedic and neurosurgeons. In 2006, spine fusion was over ten times more likely to be done in the private sector than in the public health system in Australia (Harris and Dao 2009). This is, in part, fuelled by financial gain, but also by the budget and resource constraints extant in the public system that limit the number of surgeries performed and result in the characteristically long wait times for surgery. One surgeon felt that this gap will continue to widen in the future.

6. Discussion

Findings

This rapid review summarised the clinical evidence regarding the threshold of pathology for specialist referral, the comparative effectiveness of surgery versus conservative management for CLBP and expert opinion regarding the availability of non-surgical therapies throughout Victoria.

Threshold of pathology for specialist referral

A synthesis of evidence-based guidelines from six CPGs, endorsed by providers in Europe, the United Kingdom and the United States (Dagenais et al. 2010), together with a CPG by the American Pain Society (Chou et al. 2009) and expert opinion informed a threshold of pathology for specialist referral for CLBP (Table 4). The guidelines agreed in recommending that patients with LBP undergo assessment to rule out potentially serious spinal pathology, specific causes of LBP and neurological involvement (Dagenais et al. 2010). Education, paracetamol, NSAIDs and spinal manipulation were universally recommended for the primary management of CLBP, with the possible addition of back exercises, behavioural therapy and short-term use of opioids as needed (Dagenais et al. 2010). Secondary care may involve multidisciplinary rehabilitation, adjunctive analgesics, strong opioids or fusion surgery. For patients who have CLBP with neurological involvement that is refractory to conservative management, diagnostic imaging can be used to identify appropriate candidates for epidural spinal injections or decompression surgery (Dagenais et al. 2010).

The American Pain Society strongly recommended interdisciplinary rehabilitation for non-radicular CLBP. A weak recommendation was made for fusion surgery in patients with non-radicular CLBP who have unresponsive, moderately severe pain due to degenerative disc disease. Good evidence suggested that laminectomy, with or without fusion, provided moderate benefit for symptomatic spinal stenosis, with or without degenerative spondylolisthesis, for up to two years. For persistent, disabling radiculopathy due to a herniated lumbar disc, open discectomy and microdiscectomy provided greater pain relief than nonsurgical therapy between 6 and 12 weeks after treatment, but benefits diminished or were no longer present within one to two years.

Expert opinion from two surgeons in Melbourne concurred with the recommendations from international CPGs. However, the nuances of surgical cases can sometimes be missed in the general recommendations made by CPGs. For example, the longer term outcomes of patients with radiculopathy due to spinal stenosis can be affected by the development of new pathology in the form of re-stenosis, which can limit the gains made by a surgical intervention that successfully relieved the symptoms of the initial condition. In addition, surgery may relieve radicular pain and enable patients to return to work earlier, but they may still have residual back pain. However, CPGs do not always specify

Table 4: Summary of recommendations on clinical threshold for specialist referral (Chou et al. 2009; Dagenais et al. 2010)

Condition	Surgery	Recommendation*
Non-radicular CLBP	Decompression surgery Intradiscal electrothermal therapy or nucleoplasty	Not recommended.
Non-radicular CLBP due to degenerative disc disease	Fusion surgery	Weak recommendation (moderate-quality evidence) Most beneficial for patients who have: • moderately severe pain or disability; • tried conservative management for at least one year without success; • no psychiatric or medical comorbidities.
	Vertebral disc replacement	Insufficient evidence to make a recommendation
Persistent, disabling CLBP with radiculopathy due to herniated lumbar disc or spinal stenosis	Open discectomy Microdiscectomy	High quality evidence (Grade B recommendation) Moderate benefits up to 12 weeks; not sustained one or two years after surgery,
Persistent, disabling leg pain due to spinal stenosis, with or without degenerative spondylolisthesis	Decompressive laminectomy	High quality evidence (Grade B recommendation) Moderate benefits that are not sustained one or two years after surgery

*See Table D.1, Appendix D for explanation of evidence and recommendation gradings

whether the recommended surgical treatments improved the radicular pain, the low back pain, or both.

Once a GP has ruled out a pathological cause for persistent LBP, a patient can be managed in primary care indefinitely. Referral for surgery should only occur when the patient's pain is causing functional limitations that affect his/her ability to perform activities of daily living, the condition is amenable to surgery and a re-evaluation of the patient's clinical management to date indicates that all non-surgical treatment options have been exhausted. Often patients with apparently refractory pain can benefit from continued treatment in the primary care setting after careful re-evaluation of their treatment plan and degree of compliance by an appropriately trained primary care practitioner.

Incorrect referral of patients with CLBP for surgery continues to be a problem. This is partly, but not solely, due to the lack of a unifying, universal guideline or management algorithm for the care of patients with CLBP in primary care that is specifically adapted to the Victorian healthcare context and adequately supports GPs in caring for these patients. Other contributing factors include a lack of knowledge among GPs about the range of non-surgical treatments available and systemic barriers that limit access to physiotherapy-led clinics and multidisciplinary care programmes. There is also published and anecdotal evidence that thresholds for CLBP surgery differ between surgical specialties and the public and private sector of the Australian healthcare system.

Effectiveness of surgery versus conservative management

An overview of seven SRs (Jacobs et al. 2013) and two additional SRs (Bydon et al. 2013;

Jarrett et al. 2012) provided information on the comparative clinical effectiveness of surgical interventions versus conservative management for the treatment of CLBP. The overview reported better Zurich Claudication Questionnaire scores for interspinous process devices than conservative treatment, but evidence is needed regarding long-term follow-up. Individual studies suggested that surgery resulted in greater short-term pain relief than conservative management in patients with disc herniation and radiculopathy, but no differences between treatment were observed at one year follow-up (Jacobs et al. 2013). A SR by Bydon et al. (2014) assessed the comparative effectiveness of lumbar fusion versus conservative management for the treatment of chronic discogenic LBP. While significant improvement in Oswestry Disability Index scores was noted in three studies, pooled data showed no significant difference compared with conservative management (Bydon et al. 2013). Jarret et al. (2012) reported that decompressive surgery was more effective than land-based exercise for the management of lumbar spinal stenosis; however, they recommended that a trial of conservative management be undertaken prior to considering surgery.

Accessibility of effective non-surgical therapies in Victoria

Two surgeons from Melbourne provided expert opinion regarding the accessibility of alternative therapies for CLBP throughout Victoria. The main non-surgical interventions available in Victoria to patients with CLBP include: analgesics, NSAIDs and prescription pain medications; physiotherapy, chiropractic, osteopathic, acupuncture and other needling techniques; facet joint injection; medial branch blocks; radiofrequency denervation; exercise programmes; and pain management programmes in combination with psychological support. Evidence-based CPGs recommend most of these therapies, with the exception of medial branch blocks and radiofrequency denervation (Chou et al. 2009; Dagenais et al. 2010).

Both patient and GP factors were cited as reasons why some patients with CLBP are incorrectly referred for surgery in Victoria. GPs may need further instruction regarding the pathophysiology of back pain and radicular pain, along with information about the facilities and treatments available in the state. In addition, there is a tendency for GPs to refer "difficult" patients whose pain is not improving and who appear to be running out of treatment options. Patients often hold inappropriate expectations of what can be achieved through surgery, and many GPs are unaware of which types of back pain are amenable to surgical treatment. Access to physiotherapy in the private system is limited by cost to the patient, and there is a lack of adequate access to pain management programmes in Victoria. Consequently, patients may experience a long wait to receive only short periods of treatment. It is thought that physiotherapy-led clinics in Victoria are probably helping to reduce over-referral and improve patient outcomes. Access to these clinics in the public system allows patients to receive treatment much sooner, possibly circumventing progression to chronic pain.

Limitations of the evidence

An American CPG (Chou et al. 2009) and a synthesis of recommendations from six CPGs (Dagenais et al. 2010) provided information regarding the threshold for specialist referral. Some CPGs excluded LBP with neurological involvement from their scope, even though this group is often targeted for diagnostic imaging and invasive interventions. Guidelines provided little detail regarding the management of potentially serious spinal pathology that may require imaging or urgent surgical evaluation. While CPGs recommended that clinicians evaluate the severity of symptoms and functional limitations for LBP, no guidance was provided regarding appropriate specific measures. Only one guideline suggested specific parameters regarding alternative treatment options for CLBP. Most notably, the delay between completing the literature search and publishing the guidelines ranged from 10 months to 32 months, during which time recommendations may have become outdated. While guidelines reported benefits in symptoms in relation to some therapies, no details were provided regarding whether benefits were related to back or leg pain. In addition, the generalisability of the guideline recommendations to the Australian context was limited by the fact that none of the CPGs were produced in Australia. Consequently, this synthesis was limited to reporting recommended treatments that are not necessarily available or commonly used in Australia for patients with CLBP and may be silent on treatments that are relevant to the Australian health system.

An overview of seven SRs (Jacobs et al. 2013) and two additional SRs (Bydon et al. 2013; Jarrett et al. 2012) provided information regarding the comparative effectiveness of surgery versus conservative management for the treatment of CLBP. While the quality of reviews included in the overview was acceptable, studies included in the reviews showed a high risk of bias and methodological flaws, including poor reporting, heterogeneity, lack of validated outcomes and only short- to mid-term follow-up. There was also inconsistent use of risk of bias tools to appraise studies in the included reviews. Significant risk of bias was noted in the studies included in the SR by Bydon et al. (2014) as patients, personnel and outcome assessors were not blinded and studies were at high risk of sampling bias due to patient cross over. Jarrett et al. (2012) included four surgical studies that only involved patients who had failed conservative management. Including patients with more disabling cases of lumbar spinal stenosis may skew the results and reduce their external validity.

This report was limited in that only systematic reviews, CPGs, overviews and syntheses of recommendations were reported in the interest of timelines. This limited the scope of comparisons between surgery and non-surgical interventions to only those available in the SRs. Thus, it was not possible to address all possible comparisons between surgery and alternative treatments—more alternative therapies were available in Victoria than were reported in the limited evidence base covered in this report. Also, the inclusion criteria for this review limited studies to those that defined chronic pain as lasting more than 6 weeks, but less than 12 months. However, it is likely that studies included in the

SRs and CPGs enrolled patients who were symptomatic for at least a year on entry, and it is not clear how the outcomes of these patients differ from those had pain of a shorter duration.

Other considerations

Although there is evidence to suggest that surgery provides benefit for only a select subgroup of patients with CLBP, there remains a significant demand for specialist assessment for back pain in Victoria (Department of Health 2014). Compliance with guidelines has been relatively poor worldwide; however, there are successful efforts to bridge the guideline implementation gap. Dissemination with structured referral forms, involvements of consultants in educational activities, specialised clinics and financial incentives have been used to improve adherence to CPGs.

Spine surgeons in the Province of Saskatchewan, Canada worked with referral physicians, chiropractic, physiotherapy and pain clinics to reduce variations in practice patterns by developing a systematic care pathway for the management of LBP (Fourney et al. 2011). The Saskatchewan Spine Pathway is the first province-wide clinical pathway for spine care in Canada. Key aspects of the Pathway include a combination of online and live training completed by primary care providers, online resources for patients and care providers (Government of Saskatchewan 2014), physician billing incentives and access to Saskatchewan Spine Pathway triage clinics for expedited MRI and surgery referrals to help drive compliance (Kindrachuk and Fourney 2014). A retrospective analysis of 87 consecutive patients with LBP who were initially referred to a spine surgeon but were redirected to the Saskatchewan Spine Pathway clinic reported that 71 per cent were discharged after patient education or referral to mechanical therapies. While 29 per cent of patients were directed back to the surgeon, only 13 per cent were offered surgery. MRI utilisation was significantly lower and non-surgeon triage captured red flags detected by the surgeon. The Saskatchewan Spine Pathway significantly reduced the number of unnecessary surgical referrals, offering potential cost savings and improved patient care.

A hospital in the United States implemented a multidimensional spine care pathway using the National Centre for Quality Assurance Back Pain Recognition Program as a foundation (Paskowski et al. 2011). Of 518 consecutive patients, 22 per cent were seen once and triaged to specialty care, 7 per cent received MRI and 83 per cent were treated by a chiropractor (mean 5.2 visits)—95 per cent of patients rated their care as "excellent."

7. Conclusions and Implications for Policy

International evidence-based CPGs recommended that patients with LBP undergo assessment to rule out potentially serious spinal pathology and a specific cause of pain. Once a pathological cause for persistent LBP has been ruled out a GP can manage a patient indefinitely, or until the patient's pain begins to cause functional limitation. There are a number of effective non-surgical care options accessible to patients with CLBP in Victoria, including analgesics, NSAIDs, prescription pain medications, exercise programmes, physiotherapy and multidisciplinary pain management programmes in combination with psychological support and training. Expert opinion concurred with CPGs advice that patients with CLBP and radicular pain who have not benefited from conservative treatment should undergo diagnostic imaging to identify the small subgroup of patients who may benefit from decompression surgery. The American Pain Society strongly recommended interdisciplinary rehabilitation with behavioural therapy for non-radicular LBP and surgery for non-radicular LBP due to degenerative disc disease (weak recommendation). Good evidence suggested that laminectomy, with or without fusion, provided moderate benefit up to two years after treatment in patients with symptomatic spinal stenosis, with or without degenerative spondylolisthesis. It was recommended that clinicians discuss the risks and benefits of surgery versus non-surgical interventions, as surgery offers moderate short-term benefits that are not sustained over the long-term in most patients. While a management algorithm or single guideline explaining CLBP and available treatments may be useful in Victoria, a strong implementation and enforcement plan may be needed to ensure that patients are correctly referred.

An overview of seven SRs and two additional SRs provided evidence on the comparative effectiveness of surgery versus conservative management for CLBP. For the treatment of spinal stenosis, intervertebral process devices were more effective than conservative treatment. While individual studies with a high risk of bias suggested that surgery improved short-term pain relief for disc herniation with radiculopathy, compared with conservative management, no differences were observed at the one-year follow-up. Pooled data showed no statistically significant difference in effectiveness between lumbar fusion and conservative management. Decompressive surgery was reported to be more effective than exercise for the management of lumbar spinal stenosis, based on one SR. While the quality of reviews included in the overview was acceptable, studies included in the reviews showed a high risk of bias and methodological flaws. Evidence from SRs supported the recommendations from the CPGs that surgery only seems to provide long-term benefit in a small subset of patients.

Victorian GPs need further information about the pathophysiology of back pain and the facilities and treatments available in their state. Patients need to be informed about options for self-management, educated and supported in taking a more active role in managing their pain over the long term and apprised of the risks and benefits of surgical interventions. According to experts, access to physiotherapy in the private system is

limited by cost and there is a lack of adequate access to pain management programmes in Victoria. It is thought that physiotherapy-led clinics are helping to reduce over-referral to specialists and improve patient outcomes. Decision makers need to consider that patients may experience long wait times for short periods of treatment and to develop strategies to improve access to care. Spinal care pathways may offer a means of further reducing over-referral to specialists in the manner of the Saskatchewan Spine Pathway, which was effective in reducing MRI utilisation and referrals to surgery.

Acknowledgements

The authors wish to acknowledge the following people for their valuable assistance during the preparation of this report:

- Dr David Tivey, Senior Research Officer, ASERNIP-S, Adelaide, South Australia

These individuals kindly provided comments on this report:

- Senior neurosurgical consultant from a major hospital, Melbourne, Victoria
- Senior orthopaedic and spine surgery consultant from a major hospital, Melbourne, Victoria

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Appendix A: Literature Search and Retrieval

The search was developed and carried out prior to the study selection process.

Databases searched and search terms

The databases and resources searched are shown in Table A.1. Searches were restricted to studies published in English from January 2005 (January 2008 for CPGs) to March 2014. A focused internet search for HTA reports and CPGs on the management of CLBP was also conducted. In addition, the websites of relevant specialist societies were also searched. (Table A.1).

Table A.1: Databases and resources searched

Database	Edition/Date Searched
Ovid MEDLINE	2005 to 2014, 3 March 2014 (RCTs and clinical trials) 2009 to 2014, 3 March 2014 (SRs and meta-analyses)
EMBASE	2005 to 2014, 5 March 2014 (RCTs and clinical trials) 2009 to 2014, 5 March 2014 (SRs and meta-analyses)
The Cochrane Library	Issue 3, March 2014 2005 to 2014, 5 March 2014
NHS Centre for Reviews and Dissemination databases	2005 to 2014, 5 March 2014
HTA agencies	
Agency for Healthcare Research and Quality (AHRQ) http://search.ahrq.gov/	March 6, 2014
BlueCross BlueShield Association http://www.bcbs.com/blueresources/tec/	March 6, 2014
Canadian Agency for Drugs and Technologies in Health (CADTH) http://www.cadth.ca/en/	March 6, 2014
Institute of Health Economics http://www.ihe.ca/	March 6, 2014
MSAC http://www.msac.gov.au/	March 6, 2014
NICE http://www.nice.org.uk/	March 6, 2014
Clinical practice guidelines	
Guidelines International Network (G-I-N) http://www.g-i-n.net/library/international-guidelines-library	March 7, 2014
National Guideline Clearinghouse http://www.guideline.gov/	March 7, 2014
Scottish Intercollegiate Guidelines Network (SIGN) http://www.sign.ac.uk/search.html	March 7, 2014
Clinical Practice Guideline (NHMRC) http://www.clinicalguidelines.gov.au/	March 7, 2014
Canadian Medical Association Infobase http://www.cma.ca/cpgs/	March 7, 2014

Table A.1: Databases and resources searched (cont'd)

Database	Edition/Date Searched
NICE guidance http://guidance.nice.org.uk/	March 7, 2014
Up-to-date http://www.uptodate.com/	March 7, 2014
New Zealand Guidelines Group http://www.health.govt.nz/about-ministry/ministry-health-websites/new-zealand-guidelines-group	March 7, 2014
Targeted internet search	
Medical observer http://www.medicalobserver.com.au/news/investigation-of-low-back-pain	March 12, 2014
Australian Institute of Health and Welfare https://www.aihw.gov.au/back-problems/health-burden/	March 12, 2014
American Family Physician http://www.aafp.org/afp/2011/0815/p437.html	March 12, 2014
World Health Organisation http://www.who.int/medicines/areas/priority_medicines/Ch6_24LBP.pdf	March 12, 2014
Group Health Research Institute https://member.ghc.org/kbase/topic.jhtml?docId=hw56429	March 12, 2014
British Association of Spine Surgeons http://www.spinesurgeons.ac.uk/members/member-news/nice-guidance-on-low-back-pain	March 12, 2014

RCTs: randomised controlled trials; SRs: systematic reviews

Search terms

For MEDLINE, searches on the key concepts of treatment of chronic non-specific LBP are detailed in Table A.2. This search strategy was translated to the EMBASE syntax, with searches again being restricted by language and year. In addition, a NOT MEDLINE limiter was also applied to the EMBASE searches.

Table A.2: Ovid MEDLINE search

Search ID	Key Concept	Search
A	Type of surgery	Laminectomy/ OR diskectomy/ OR diskectomy, percutaneous/ OR Spinal Fusion/ OR (spinal adj fusion).tw. OR laminectomy.tw. OR dis#ectomy.tw. OR spinal decompression.tw. OR *Decompression, Surgical/ OR surgery.mp. OR (nerve adj2 decompress*).mp. OR (root adj2 decompress*).mp. OR (fusion adj2 decompress*).mp. OR back pain surgery.mp. OR spine surgery.mp. OR vertebra* surgery.mp.
B	Low back pain	*back pain/ OR *low back pain/ OR *back injuries/ OR *sciatica/ OR *spine/ OR *coccyx/ OR *intervertebral disc/ OR *lumbar vertebrae/ OR *sacrum/ OR lumbago.tw. OR (lumbar adj pain).tw. OR (back adj pain).tw. OR dorsalgia.tw. OR sciati*.tw. OR (back adj ache).tw. OR backache.mp. OR coccyx.tw. OR coccydynia.tw. OR sacroiliac.tw. OR sacrum.tw. OR (sacral adj pain).tw. OR claudication.mp. OR CNLBP.mp. OR non-specific lower back pain.mp. OR back pains lower.tw. OR low back pain postural.tw. OR (back adj3 pains).tw. OR (low adj back).tw. OR lower back pain.tw. OR backach*.tw.

Table A.2: Ovid MEDLINE search (cont'd)

Search ID	Key Concept	Search
C	Excluded conditions	pregnancy.mp. OR Pain, Referred/ OR (referred adj2 pain).mp. OR *myositis/ OR *myelitis/ OR *arthritis, rheumatoid/ OR *osteoarthritis, spine/ OR *Neuralgia, Postherpetic/ OR *Discitis/ OR *Osteomyelitis/ OR *spondylosis/ OR *spondylolysis/ OR *spondylolisthesis/ OR *Scoliosis/ OR *kyphosis/ OR *scheuermann disease/ OR *bone diseases, metabolic/ OR *bone demineralization, pathologic/ OR *osteoporosis/ OR *female athlete triad syndrome/ OR *osteoporosis, postmenopausal/ OR paget's disease.mp. OR bone neoplasms/ OR *spinal neoplasms/ OR fracture.ti. OR (myositis OR myelitis).tw. OR ((rheumatoid adj arthritis) OR osteoarthritis).tw. OR spondylitis.tw. OR *spondylitis, ankylosing/ OR (Discitis OR diskitis).tw. OR Osteomyelitis.tw. OR (spondylosis OR spondylolysis OR spondylolisthesis).tw. OR Scoliosis.tw. OR (kyphosis OR scheuermann disease).tw. OR (metabolic bone diseases OR bone demineralization OR osteoporosis OR female athlete triad syndrome).tw. OR (bone neoplasms OR spinal neoplasms OR bone cancer).tw.
D	Non-operative interventions (behavioural)	exp Behavior Therapy/ OR conditioning, operant/ OR "Reinforcement (Psychology)"/ OR operant conditioning.mp. OR respondent treatment.mp. OR behavio* therapy.mp. OR cognitive therapy.mp. OR exp Cognitive Therapy/ OR cognitive treatment.mp. OR behavio* treatment.mp. OR Relaxation/ OR Relaxation Therapy/ OR relaxation.mp. OR graded activity.mp. OR pain clinic*.mp. OR Manipulation, Orthopedic/ OR Manipulation, Chiropractic/ OR Manipulation, Spinal/ OR Manipulation, Osteopathic/ OR exp Musculoskeletal Manipulations/ OR acupressure/ OR massage/OR Acupuncture Therapy/ OR Acupuncture/ OR ultrasound.mp. OR Ultrasonic Therapy/ OR acupuncture.mp. OR massage.mp. OR spinal manipulation.mp. OR chiropractic.mp. OR osteopath*.mp. OR orthoped*.mp. OR non-operative.mp. OR conservative management.mp. OR rehab*.mp. OR exercis*.mp. OR core stability.mp. OR back school.mp. OR neuromuscular training.mp. OR walking aids.mp. OR posture correction.mp. OR pilates.mp. OR stretching.mp. OR yoga.mp. OR alexander technique.mp. OR self-management.mp. OR exp Rehabilitation/ OR exp Exercise/ OR Self Care/ OR self care.mp. OR physical fitness/ OR (physical education and training).mp OR "Physical Education and Training"/ OR Walkers/ OR Yoga/
E	Non-operative interventions (pharmaceutical)	nsaids.mp. OR Anti-Inflammatory Agents, Non-Steroidal/ OR Opiate Substitution Treatment/ OR Opiate Alkaloids/ OR opiates.mp. OR exp antidepressive agents/ OR exp antidepressive agents, second-generation/ OR exp Salicylic Acid/ OR salicylic.mp. OR paracetamol.mp. OR Acetaminophen/ OR opiates.mp. OR Neuromuscular Agents/ OR Diazepam/ OR Diazepam.mp. OR Ibuprofen.mp. OR Ibuprofen/ OR adhesiolysis.mp. OR neuroplasty.mp. OR neurolysis.mp. OR Tissue Adhesions/ OR lysis of adhesions.mp. OR papain injectio*.mp. OR enzyme injection.mp. OR Chymopapain.mp. OR Chymopapain/ OR disc lysis.mp. OR disk lysis.mp. OR nerve blocks.mp. OR Nerve Block/ OR electrical stimulation.mp. OR Electric Stimulation/
1	Combined searches (RCTs and clinical trials)	Lower back pain NOT Excluded conditions ([Lower back pain NOT Excluded conditions] and Type of surgery) (Non-operative interventions [behavioural] OR Non-operative interventions [pharmaceutical]) ([Lower back pain NOT Excluded conditions] and Type of surgery) AND (Non-operative interventions [behavioural] OR Non-operative interventions [pharmaceutical])
2	Combined searches	1 with RCT filter Limited to English and past 10yr

Table A.2: Ovid MEDLINE search (cont'd)

Search ID	Key Concept	Search
3	Combined searches (SRs and meta-analysis)	Lower back pain NOT Excluded conditions ([Lower back pain NOT Excluded conditions] and Type of surgery)
4	Combined searches	3 with SR filter Limited to English and past 5yrs

RCT: randomised controlled trial; SR: systematic review

Note: mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier; MEDLINE search was adapted to EMBASE and limited to non-MEDLINE journals

The NHS Centre for Reviews and Dissemination databases and *The Cochrane Library* were searched using the terms listed in Tables A.3 and A.4. HTA and CPG sites were searched for available guidelines and HTAs associated with CLBP.

Table A.3: NHS Centre for Reviews and Dissemination database search terms

Search ID	Key Concept	Search
A	Low back pain	back pain EXPLODE ALL TREES IN DARE,NHSEED,HTA Lumbar Vertebrae EXPLODE ALL TREES IN DARE,NHSEED,HTA (non specific lower back pain) IN DARE, NHSEED, HTA (lumbago) IN DARE, NHSEED, HTA (lumbar) IN DARE, NHSEED, HTA
B	Surgery	Spinal Fusion EXPLODE ALL TREES IN DARE,NHSEED,HTA Laminectomy EXPLODE ALL TREES IN DARE,NHSEED,HTA diskectomy EXPLODE ALL TREES IN DARE,NHSEED,HTA (back surgery) IN DARE, NHSEED, HTA FROM 2004 TO 2014 (lumbar fusion) IN DARE, NHSEED, HTA FROM 2004 TO 2014 (vertebra* surgery) IN DARE, NHSEED, HTA FROM 2004 TO 2014

Note: A handsearch for each key concept was conducted

Table A.4: *The Cochrane Library* search terms

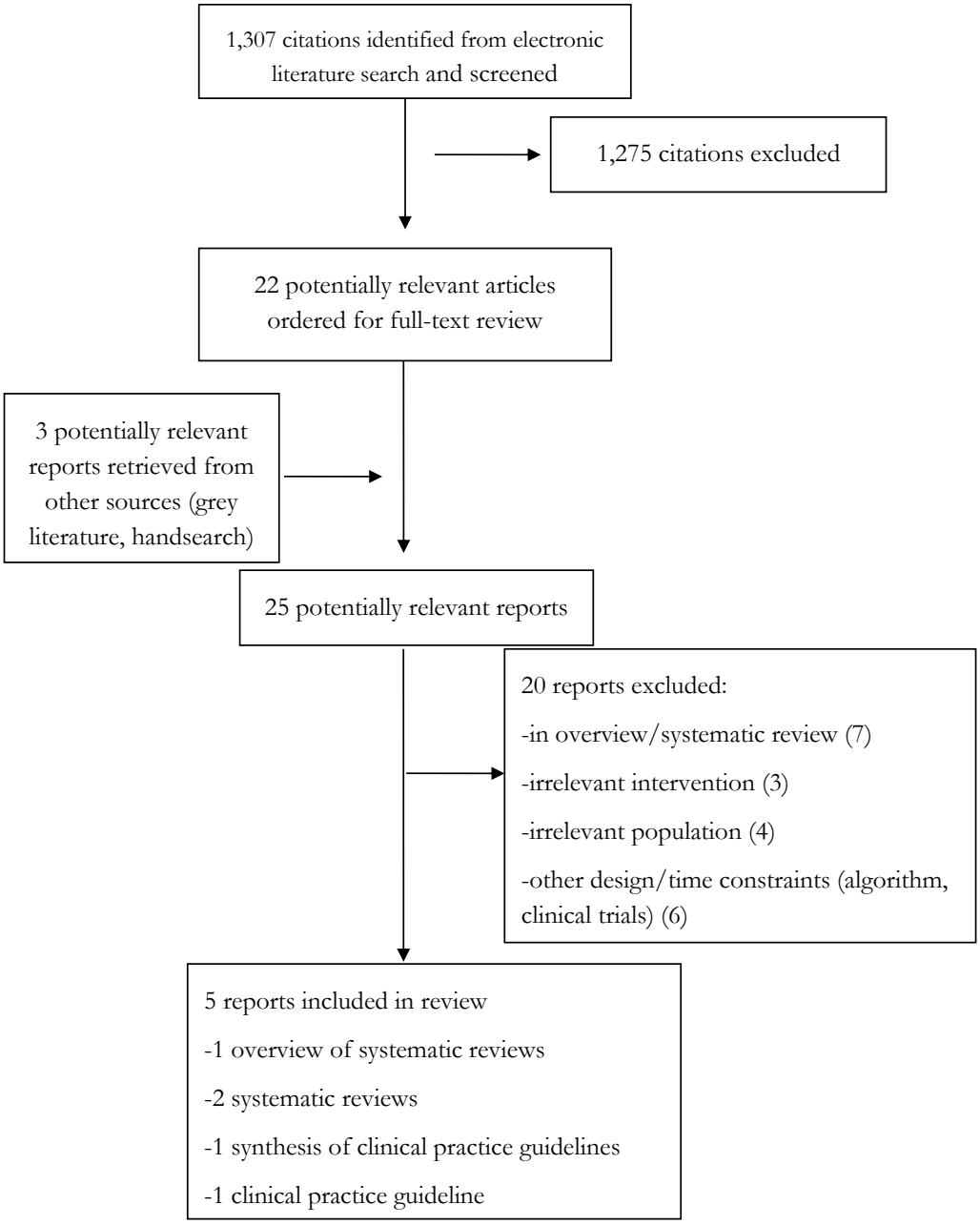
Search ID	Key Concept	Search
A	Low back pain	{Back Pain] explode all trees [Lumbar Vertebrae] explode all trees [Sacrum] explode all trees [Coccyx] explode all trees [Sciatica] explode all trees lumbago:ti,ab,kw (Word variations have been searched) non specific lower back pain:ti,ab,kw (Word variations have been searched) sciati*:ti,ab,kw (Word variations have been searched) Sacrum:ti,ab,kw (Word variations have been searched) "lumbar":ti,ab,kw (Word variations have been searched) coccyx:ti,ab,kw (Word variations have been searched)

Table A.4: *The Cochrane Library* search terms (cont'd)

Search ID	Key Concept	Search
B	Surgery	[Spinal Fusion] explode all trees
		[Diskectomy] explode all trees
		[Laminectomy] explode all trees
		"back surgery":ti,ab,kw (Word variations have been searched)
		"lumbar fusion":ti,ab,kw (Word variations have been searched)
		"vertebra* surgery":ti,ab,kw (Word variations have been searched)
C	Non-surgical (behaviour)	[Behavior Therapy] explode all trees
		[Conditioning, Operant] explode all trees
		[Reinforcement (Psychology)] explode all trees
		[Physical Therapy Modalities] explode all trees
		[Acupuncture] explode all trees
		[Rehabilitation] explode all trees
		[Exercise] explode all trees
		spinal manipulation :ti,ab,kw (Word variations have been searched)
		massage:ti,ab,kw (Word variations have been searched)
		Acupuncture:ti,ab,kw (Word variations have been searched)
		"conservative management":ti,ab,kw (Word variations have been searched)
		"non-operative":ti,ab,kw (Word variations have been searched)
		Rehabilitation:ti,ab,kw (Word variations have been searched)
		Exercise:ti,ab,kw (Word variations have been searched)
D	Non-surgical drugs	[Anti-Inflammatory Agents, Non-Steroidal] explode all trees
		[Opiate Substitution Treatment] explode all trees
		[Antidepressive Agents, Second-Generation] explode all trees
		[Analgesics, Non-Narcotic] explode all trees
		[Neuromuscular Agents] explode all trees
		[Analgesics, Opioid] explode all trees
		[Nerve Block] explode all trees
		Anti-Inflammatory Agents, Non-Steroidal:ti,ab,kw (Word variations have been searched)
		Opiate Substitution Treatment:ti,ab,kw (Word variations have been searched)
		Antidepressive Agents, Second-Generation:ti,ab,kw (Word variations have been searched)
		Analgesics, Non-Narcotic:ti,ab,kw (Word variations have been searched)
		Neuromuscular Agents:ti,ab,kw (Word variations have been searched)
		Analgesics, Opioid:ti,ab,kw (Word variations have been searched)
		Tissue Adhesions:ti,ab,kw (Word variations have been searched)
		Nerve Block:ti,ab,kw (Word variations have been searched)
		Electric Stimulation:ti,ab,kw (Word variations have been searched)
1	Combined searches	A AND (B OR C OR D)

Study selection

Figure A.1: Flow diagram of the study selection process



Appendix B: Evidence Hierarchy

Table B.1: National Health and Medical Research Council evidence hierarchy (Merlin et al. 2009)

Level	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening Intervention
I	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study ▪ Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study
III-3	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study ▪ Interrupted time series without a parallel control group	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Appendix C: Excluded Studies

Included in overview or systematic review

Jacobs, WCH, van Tulder, M, Arts, M, Rubinstein, SM, van Middelkoop, M, Ostelo, R, Verhagen, A, Koes, B & Peul, WC 2011, 'Surgery versus conservative management of sciatica due to a lumbar herniated disc: a systematic review', *European Spine Journal*, vol.20(4), pp. 513-22.

Kovacs, FM, Urrutia, G & Alarcon, JD 2011, 'Surgery versus conservative treatment for symptomatic lumbar spinal stenosis: a systematic review of randomized controlled trials', *Spine*, vol.36(20), pp. E1335-51.

Ohtori, S, Koshi, T, Yamashita, M, Yamauchi, K, Inoue, G, Suzuki, M, Orita, S, Eguchi, Y, Ochiai, N, Kishida, S, Takaso, M, Kuniyoshi, K, Aoki, Y, Ishikawa, T, Arai, G, Miyagi, M, Kamoda, H, Suzuki, M, Nakamura, J, Toyone, T & Takahashi, K 2011, 'Surgical versus nonsurgical treatment of selected patients with discogenic low back pain: a small-sized randomized trial', *Spine*, vol.36(5), pp. 347-54.

Saltychev, M, Eskola, M & Laimi, K 2014, 'Lumbar fusion compared with conservative treatment in patients with chronic low back pain: a meta-analysis', *International Journal of Rehabilitation Research*, vol.37(1), pp. 2-8.

Savigny, P, Kuntze, S, Watson, P, Underwood, M, Ritchie, G, Cotterell, M, Hill, D, Browne, N, Buchanan, E, Coffey, P, Dixon, P, Drummond, C, Flanagan, M, Greenough, C, Griffiths, M, Halliday-Bell, J, Hettinga, D, Vogel, S & Walsh, D 2009, '*Low Back Pain: early management of persistent non-specific low back pain*', National Collaborating Centre for Primary Care and Royal College of General Practitioners, London, United Kingdom, viewed May 2014, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0005442/pdf/TOC.pdf>.

Willems, PC, Staal, JB, Walenkamp, GHIM & de Bie, RA 2013, 'Spinal fusion for chronic low back pain: systematic review on the accuracy of tests for patient selection', *Spine Journal: official journal of the North American Spine Society*, vol.13(2), pp. 99-109.

Wood, KB, Fritzell, P, Dettori, JR, Hashimoto, R, Lund, T & Shaffrey, C 2011, 'Effectiveness of spinal fusion versus structured rehabilitation in chronic low back pain patients with and without isthmic spondylolisthesis: a systematic review', *Spine*, vol.36(21 Suppl), pp. S110-9.

Irrelevant intervention

Manchikanti, L, Abdi, S, Atluri, S, Benyamin, RM, Boswell, MV, Buenaventura, RM, Bryce, DA, Burks, PA, Caraway, DL, Calodney, AK, Cash, KA, Christo, PJ, Cohen, SP, Colson, J, Conn, A, Cordner, H, Coubarous, S, Datta, S, Deer, TR, Diwan, S, Falco, FJ, Fellows, B, Geffert, S, Grider, JS, Gupta, S, Hameed, H, Hameed, M, Hansen, H, Helm, S 2nd, Janata, JW, Justiz, R, Kaye, AD, Lee, M, Manchikanti, KN, McManus, CD, Onyewu, O, Parr, AT, Patel, VB, Racz, GB, Sehgal, N, Sharma, ML, Simopoulos, TT, Singh, V, Smith, HS, Snook, LT,

Swicegood, JR, Vallejo, R, Ward, SP, Wargo, BW, Zhu, J & Hirsch, JA 2013, 'An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations', *Pain Physician*, vol.16(2 Suppl), pp. S49-283.

WorkCoverSA 2009, '*Managing acute-subacute low back pain*', WorkCoverSA, Adelaide, viewed May 2014, <http://www.workcover.com/health-provider/guidelines-by-injury-type/acute-subacute-low-back-pain>.

Work Loss Data Institute 2013, '*Low back - lumbar &thoracic (acute & chronic)* ', Work Loss Data Institute, Encinitas (CA), USA.

Irrelevant population

Daubs, MD, Norvell, DC, McGuire, R, Molinari, R, Hermsmeyer, JT, Fourney, DR, Wolinsky, JP & Brodke, D 2011, 'Fusion versus nonoperative care for chronic low back pain: do psychological factors affect outcomes?', *Spine*, 36(21 Suppl), pp. S96-109.

Hellum, C, Johnsen, LG, Storheim, K, Nygaard, OP, Brox, JI, Rossvoll, I, Rø, M, Sandvik, L, Grundnes, O & Norwegian Spine Study Group 2011, 'Surgery with disc prosthesis versus rehabilitation in patients with low back pain and degenerative disc: two year follow-up of randomised study', *BMJ*, vol.342(d2786), doi: 10.1136/bmj.d2786.

Mannion, AF, Brox, JI & Fairbank, JCT 2013, 'Comparison of spinal fusion and nonoperative treatment in patients with chronic low back pain: long-term follow-up of three randomized controlled trials', *Spine Journal: official journal of the North American Spine Society*, vol.13(11), pp. 1438-48.

Slatis, P, Malmivaara, A, Heliovaara, M, Sainio, P, Herno, A, Kankare, J, Seitsalo, S, Tallroth, K, Turunen, V, Knekt, P & Hurri, H 2011, 'Long-term results of surgery for lumbar spinal stenosis: a randomised controlled trial, [Erratum appears in *European Spine Journal* 2012, vol.21(1), pp. 180]', *European Spine Journal*, vol.20(7), pp. 1174-81.

Other design or time constraint

Choi, HS, Kwak, KW, Kim, SW & Ahn, SH 2013, 'Surgical versus conservative treatment for lumbar disc herniation with motor weakness', *Journal of Korean Neurosurgical Society*, vol.54(3), pp. 183-8.

Hadzic, E, Dizdarevic, K, Hajdarpasic, E, Dzurlic, A & Ahmetspahic, A 2013, 'Low back and lumbar radicular syndrome: comparative study of the operative and non-operative treatment', *Medicinski Glasnik Ljekarske Komore Zenickodobojskog Kantona*, vol.10(2), pp. 309-15.

Mirza, SK, Deyo, RA, Heagerty, PJ, Turner, JA, Martin, BI & Comstock, BA 2013, 'One-year outcomes of surgical versus nonsurgical treatments for discogenic back pain: a community-based prospective cohort study', *Spine Journal: official journal of the North American Spine Society*, vol.13(11), pp. 1421-33.

The Netherlands Organisation for Health Research Development (ZonMw) 2007, '*A classification algorithm for low back pain: matching patients to treatments that they are most likely to benefit from*', ZonMw, The Hague, The Netherlands.

The Netherlands Organisation for Health Research Development (ZonMw) 2001, *'A randomised cost-effectiveness study on the surgical versus conservative treatment of sciatica*', ZonMw, The Hague, The Netherlands.

Weinstein, JN, Lurie, JD, Tosteson, TD, Zhao, W, Blood, EA, Tosteson, ANA, Birkmeyer ,N, Herkowitz, H, Longley, M, Lenke, L, Emery, S & Hu, SS 2009, 'Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts', *The Journal of Bone and Joint Surgery*, vol.91(6), pp.1295-1304.

Appendix D: Summary of Evidence

Table D.1: Grading of recommendations and levels of evidence

Study, Country	Recommendation Grading	Evidence Categories/Grading
Synthesis of CPG recommendations		
Dagenais et al. (2010) USA	Recommendations from CPGs were dichotomised to "recommended" if there was strong, moderate or limited evidence of efficacy or "not recommended" if there was insufficient or conflicting evidence or evidence against a particular intervention. When CPGs contained multiple recommendations regarding management, the one contained in its summary was abstracted.	Recommendations were synthesised according to setting of delivery and type: 1˚ - primary care; 2˚ - secondary care; 3˚ - tertiary care. Acute LBP (<3 months); chronic LBP (>3 months) and LBP with neurological involvement (with moderate, severe or progressive signs or symptoms of neurological dysfunction in lower extremities secondary to neural impingement from spinal stenosis, intervertebral foramen stenosis or mild radiculopathy).
CPGs		
American Pain Society Chou et al. (2009) USA	A. Strong recommendation: good evidence intervention is effective. B. Recommendation: fair evidence intervention is effective. C. No recommendation for or against intervention: fair evidence intervention can improve health outcomes, but concludes that benefits only slightly outweigh harms, or balance benefits and harms. D. Recommendation against: fair evidence the intervention is ineffective or that harms outweigh benefits. E. Insufficient evidence to recommend for or against the intervention: evidence of effectiveness is lacking, of poor quality or conflicting and balance of benefits and harms cannot be determined.	Good: consistent results from well-conducted trials with representative populations that directly assess effects on health outcomes (at least 2 consistent, high-quality trials). Fair: sufficient evidence to determine effects on health outcomes, but strength of evidence is limited by the number, quality, size or consistency of included studies; generalisability to routine practice; or indirect nature of the evidence on outcomes (at least 1 high-quality trial of sufficient sample size; 2 or more high-quality trials with some inconsistency; at least 2 consistent, lower quality trials or multiple consistent observational studies with no significant methodological flaws). Poor: insufficient evidence to asses effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher quality trials, important flaws in trial design or conduct, gaps in chain of evidence or lack of information on important health outcomes.

CPGs: clinical practice guidelines; LBP: low back pain

Table D.2: Summary of critical appraisal of CPG synthesis and the American Pain Society CPG

Study, Country	Strengths	Limitations
Synthesis of CPG recommendations		
Dagenais et al. (2010) USA	Comprehensive literature search of electronic database (1996 to August 2009), internet searching of National Guideline Clearinghouse, Clinical Evidence, National Institute for Health and Care Excellence and other websites, along with grey literature searching. Study selection performed by two independent reviewers based on predefined criteria. Data were abstracted by one reviewer using piloted data extraction forms and independently verified by another reviewer. Two reviewers independently appraised CPGs using the validated AGREE quality assessment tool (Brouwers et al. 2010). All CPGs included at least one primary care provider and one non-surgical spine specialist among their authors, in addition to a surgical spine specialist, occupational therapist, doctor of chiropractic, osteopath or physiotherapist. All CPGs were sponsored or funded by their respective national governments, with the exception of those from the USA.	CPGs were not included if they were not endorsed by a national government agency or professional health provider group, were written in a language other than English, did not include both assessment and management of LBP in their scope or were focused on a single discipline or intervention. Majority of CPGs reported potential conflicts of interest among authors.
CPGs		
American Pain Society Chou et al. (2009) USA	Recommendations were evidence based, supported by a systematic review (searches up to July 2008) conducted at the Oregon Evidence-based Practice Center and commissioned by the American Pain Society. Objective, clinical question and target population were specifically described. Guideline development group included all relevant professional groups and defined the target audience as all clinicians caring for patients with LBP of any duration, with or without leg pain. Methods for formulating recommendations were reported. Health benefits and risks were considered in formulating the recommendations.	While patient's views were not specifically sought, each recommendation encouraged shared decision making between patient and healthcare provider. While the American Pain Society intended to update the CPG and the evidence report used to develop it by 2012, no further versions were found. No tools were provided to facilitate implementation of the CPG. Most potential organisational barriers and cost implications were not reported. Criteria for monitoring and/or audit were not reported.

AGREE: Appraisal of Guidelines for Research and Evaluation; CPGs: clinical practice guidelines; LBP: low back pain

Table D.3: CPG recommendations on treatment for CLBP

Guideline Society, Country, Author, Year	Recommendations
Synthesis of guideline recommendations Dagenais et al. (2010) USA	**Management of CLBP** 6 CPGs from Europe, the United Kingdom and the USA published between 2005 and 2009 (Airaksinen et al. 2005; Chou et al. 2007; Chou et al. 2009; Negrini et al. 2006; Nielens et al. 2006; Savigny et al. 2009) *Primary care interventions recommended*: Brief education (n=5), staying active (n=4), back schools (n=4), NSAIDs (n=5), weak opioid analgesics (n=5), back exercises (n=5) and spinal manipulative therapy (n=5). None recommended bed rest, biofeedback, lumbar supports, heat/cold, traction or ultrasound. *Secondary care interventions recommended*: Multidisciplinary rehabilitation (n=6), adjunctive analgesics (n=5), behavioural therapy (n=5), strong opioid analgesics (n=4) and fusion surgery (n=3). Facet injections, transforaminal epidural steroid injections, soft-tissue injections and spinal cord stimulation were recommended by one CPG. None recommended decompression surgery or intradiscal electrothermal therapy/nucleoplasty. **Management of CLBP with neurological involvement** *Primary care interventions recommended*: Staying active (n=3), brief education about LBP (n=3), paracetamol (n=2), spinal manipulative therapy (n=2), back exercises (n=2), back schools (n=2) and massage (n=2). TENS, acupuncture, bed rest and autotraction were each recommended by one CPG. None recommended biofeedback, lumbar supports, heat/cold or ultrasound. *Secondary care interventions recommended*: Epidural steroid injections (n=2), multidisciplinary rehabilitation (n=2), behavioural therapy (n=2), decompression surgery (n=1), transforaminal epidural steroid injections (n=1), strong opioid analgesics (n=2) and adjunctive analgesics (n=2). Facet injections, soft-tissue injections and spinal cord stimulations were each recommended by one CPG. None recommended fusion surgery or intradiscal electrothermal therapy/nucleoplasty.
American Pain Society CPG Chou et al. (2009) USA	**Patients with non-radicular LBP who do not respond to usual non-interdisciplinary interventions** It is recommended that clinicians consider intensive interdisciplinary rehabilitation with a cognitive /behavioural emphasis (strong recommendation, high-quality evidence). Chronic back pain is complex, involving biologic, psychological and environmental factors. Patients with persistent disabling pain despite recommended non-interdisciplinary therapies should be counselled about interdisciplinary rehabilitation (defined as an integrated intervention with rehabilitation plus a psychological and/or social/occupational component) as a treatment option. - Interdisciplinary rehabilitation was moderately superior to non-interdisciplinary rehabilitation or usual care for improving short- and long-term (up to 60 months) functional status. - Interdisciplinary rehabilitation was similar in effectiveness to fusion surgery for non-radicular LBP. - Most effective programmes involve cognitive/behavioural and supervised exercise components with several sessions a week (>100 total hours). - Barriers to intensive interdisciplinary rehabilitation include relatively high cost, lack of availability and limited insurance coverage. - Insufficient evidence exists to guide recommendations for interdisciplinary rehabilitation for persistent radiculopathy or symptomatic spinal stenosis.

Table D.3: CPG recommendations on treatment for CLBP (cont'd)

Guideline Society, Country, Author, Year	Recommendations
	Patients with persistent non-radicular LBP Facet joint corticosteroid injection, prolotherapy and intradiscal corticosteroid injection are not recommended (strong recommendation, moderate-quality evidence). There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injections, epidural steroid injection, intradiscal electrothermal therapy, therapeutic medical branch block, radiofrequency denervation, sacroiliac joint steroid injection or intrathecal therapy with opioids or other medications for non-radicular LBP. - There was no convincing evidence that injections are effective for non-radicular LBP. - Facet joint steroid injections, prolotherapy and intradiscal steroid injections are not recommended as they were no more effective than sham therapy. - There was insufficient evidence to evaluate benefits of local injections; available trials were small, low-quality with heterogeneous populations and interventions. - Trials of intradiscal electrothermal therapy and radiofrequency denervation reported inconsistent results between small numbers of higher quality trials and technical or methodological shortcomings. - Data were limited to a small placebo-controlled, randomised controlled trial (botulinum toxin injection, epidural steroid injection and sacroiliac joint steroid injection), or there were no placebo-controlled randomised controlled trials (therapeutic medial branch block and intrathecal therapy with opioids or other medications). **Patients with non-radicular LBP, common degenerative spinal changes and persistent and disabling symptoms** Recommended that clinicians discuss the risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence). Shared decision-making regarding surgery for non-specific LBP should include discussion about intensive interdisciplinary rehabilitation as a similarly effective option, the small to moderate average benefit from surgery versus non-interdisciplinary non-surgical therapy and the fact that the majority of patients who undergo surgery do not experience an optimal outcome (minimum or no pain, discontinuation of or occasional pain medication use and return of high-level function). - For persistent non-radicular LBP with degenerative disc disease, fusion surgery was superior to non-surgical therapy without interdisciplinary rehabilitation in one trial, but no more effective than intensive interdisciplinary rehabilitation in three trials. - Compared with non-interdisciplinary rehabilitation, non-surgical therapy average benefits were small for function (5 to 10 points on a 100-point scale) and moderate for improvement in pain (10 to 20 points on a 100-point scale). - Majority of patients who undergo surgery do not experience an "excellent" or "good" outcome (more than sporadic pain, slight restriction of function and occasional analgesics). - Early complications occur in up to 18% of patients who undergo fusion surgery in randomised controlled trials. - Insufficient evidence to recommend a specific fusion method. - Shared decision making regarding surgery for persistent non-radicular pain should include discussion of alternative treatment options (interdisciplinary rehabilitation), average benefits with surgery, potential harms and costs. Benefits of fusion versus non-surgical therapy have only been demonstrated in a narrow group of patients with at least moderately severe pain or disability unresponsive to non-surgical therapy for at least 1 year and without serious psychiatric or medical comorbidities, or other risk factors for poor surgical outcomes. **Patients with non-radicular LBP, common degenerative spinal changes and persistent and disabling symptoms** There was insufficient evidence to adequately evaluate long-term benefits and harms of vertebral disc replacement.

Table D.3: CPG recommendations on treatment for CLBP (cont'd)

Guideline Society, Country, Author, Year	Recommendations
	Patients with persistent radiculopathy due to herniated lumbar disc Recommended that clinicians discuss risks and benefits of epidural steroid injections as an option (weak recommendation, moderate-quality evidence). Shared decision making regarding epidural steroid injections should include discussion about inconsistent evidence showing moderate short-term benefits and lack of long-term benefits. There was insufficient evidence to adequately evaluate benefits and harms of epidural steroid injections for spinal stenosis. - There was no convincing evidence that epidural steroids were associated with long-term benefits and most trials reported no reduction in rates of subsequent surgery. - Insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid infections, use of fluoroscopic guidance or number of injections. - Shared decision making regarding epidural steroid injections should include discussion of inconsistent evidence for short-term benefit, lack of long-term benefit and potential risks and costs. Patient preferences should be considered as epidural steroid injection may offer short-term pain relief in patients who are not optimal surgery candidates due to comorbidities. - Insufficient evidence to guide timing of epidural steroid injection; most trials enrolled patients with subacute (>4 weeks) LBP. - Evidence of efficacy of epidural steroid injection for spinal stenosis was sparse and showed no clear benefit. **Patients with persistent and disabling radiculopathy due to herniated lumbar disc or persistent and disabling leg pain due to spinal stenosis** Recommended that clinicians discuss risks and benefits of surgery as an option (strong recommendation, high-quality evidence). Shared decision making regarding surgery should include discussion about moderate to average benefits, which appear to decrease over time in patients who undergo surgery. - Standard open discectomy and microdiscetomy were associated with moderate short-term (6 to 12 weeks) benefits, compared with non-surgical therapy, though differences in outcomes in some trials were diminished after 1 to 2 years. - Patients tend to improve with or without discectomy and continued non-surgical therapy in patients who have had symptoms for at least 6 weeks did not appear to increase risk for cauda equina syndrome or paralysis. - For spinal stenosis, with or without degenerative spondylolisthesis, decompressive laminectomy is associated with moderate benefits compared with non-surgical therapy for up to 2 years, though effects diminished with long-term follow-up. - Dural tears occurred in 10% of patients undergoing laminectomy and neurological injuries may occur in 2.5%. - Decisions on surgery for radiculopathy due to herniated lumbar disc or leg pain due to spinal stenosis should include discussion of moderate to average benefits that diminish over time, likelihood of improvement with our without surgery and potential risks and costs. Based on a systematic review, there was sufficient evidence from randomised controlled trials to recommend that interdisciplinary rehabilitation, surgery, epidural steroid injection and spinal cord stimulation be considered in certain clinical circumstances. Lumbar discography, prolotherapy, intradiscal steroid injection and facet joint steroid injection were not recommended.

CPG: clinical practice guideline; CLBP: chronic low back pain; LBP: low back pain; NSAIDs: non-steroidal anti-inflammatory drugs; TENS: transcutaneous electrical nerve stimulation

Table D.4: Summary of review characteristics

Study, Country	Study Design	Patient Characteristics	Intervention	Comparator	Outcomes Measured
Overview of systematic reviews					
Jacobs et al. (2013) The Netherlands	Overview of systematic reviews on the effectiveness of surgical interventions for low back disorders Systematic reviews: 13 on surgical interventions; 9 high-quality based on AMSTAR checklist (Shea et al. 2007); 4 on herniated disc, 1 on isthmic spondylolisthesis, 2 on degenerative disc disease without stenosis Literature search: up to May 2012 Follow-up: up to 2 years	Adults with LBP due to lumbar radiculopathy secondary to disc herniation, spondylolisthesis, spinal stenosis and degenerative disc disease	Surgical interventions including thermal coagulation, radiofrequency denervation, decompression or fusion surgery	Conservative care or different surgical technique	Pain, functional status, and recovery
Systematic reviews					
Bydon et al. (2014) USA	Systematic review with meta-analysis (5 RCTs) (Brox et al. 2006; Brox et al. 2003; Fairbank et al. 2005; Fritzell et al. 2001; Ohtori et al. 2011) Participants: 707 patients Literature search: up to August 2013 Follow-up: at least 1 year	Patients at least 18 years of age diagnosed with chronic discogenic LBP (≥3 months)	Lumbar fusion	Conservative management	Change in Oswestry Disability Index score
Jarrett et al. (2012) Australia	SR of 7 RCTs, 3 prospective cohort , 3 before and after studies (Athiviraham and Yen 2007; Cavusoglu et al. 2007; Chopko and Caraway 2010; Goren et al. 2010; Koc et al. 2009; Malmivaara et al. 2007; Pua et al. 2007; Sahin et al. 2009; Sobottke et al. 2010; Thome et al. 2005; Weinstein et al. 2008; Whitman et al. 2006; Yasar et al. 2009) Participants: 1,098 Literature search: January 2000 to June 2011 Follow-up: up to 2 years	Adults with degenerative lumbar spinal stenosis as diagnosed by magnetic resonance or computed tomography imaging and clinical presentation; patients with concurrent diagnosis of spondylolisthesis, foraminal stenosis or non-specific LBP were excluded	Decompressive surgery (8 studies) involving minimally invasive technique, laminectomy, bilateral foraminotomy	Land-based exercise (6 studies) involving physiotherapy-supervised or home-exercise programme ranging from 3 to 6 weeks in duration; co-interventions (analgesics, non-steroidal anti-inflammatory drugs, epidural steroids, manual therapy and electrotherapy) were administered in conjunction with exercise	Patient-reported outcome measures for LBP

AMSTAR: Assessment of Multiple Systematic Reviews; LBP: low back pain; RCT: randomised controlled trial

Table D.5: Summary of critical appraisal of the included reviews

Study, Country	Strengths	Limitations
Overview of systematic reviews		
Jacobs et al. (2013) The Netherlands	Protocol registered in International Prospective Register of Systematic Reviews database; a priori design. Comprehensive literature search based on pre-defined criteria. Study selection and assessment by two independent reviewers according to well-defined criteria. Reasons for exclusion were reported and a list of excluded studies could be obtained on request, though it was not reported in the overview. Methodological quality of systematic reviews was assessed using the AMSTAR checklist (Shea et al. 2007) and results were used appropriately in formulating conclusions. Authors reported no conflicts of interest.	Risk of publication and time lag bias as only Cochrane reviews and non-Cochrane systematic reviews published in peer-reviewed journals were included for study.
Systematic reviews		
Bydon et al. (2014) USA	Literature search based on pre-defined criteria. Studies were selected and assessed by two independent reviewers according to well-defined criteria. Methods of pooling studies were appropriate and publication bias was assessed.	Risk of publication and time lag bias as systematic review failed to report searching for grey literature. A list of excluded studies was not reported. Principal author reported a research grant from DePuy Spine, Inc. (Raynham, MA, USA) and serves on the advisory board of MedImmune, LLC (Gaithersburg, MD, USA).
Jarrett et al. (2012) Australia	Literature search based on pre-defined criteria and protocol. The authors independently reviewed all potentially relevant abstracts and full-text articles that met the inclusion criteria. A list of excluded studies and reasons for exclusion were provided as a supplemental table. Authors declared no competing interests.	Two reviewers divided the database searches and screened abstracts. Only one study compared the effectiveness of exercise and decompression surgery for lumbar spinal stenosis. To facilitate analysis, the percentage change in patient-reported functional outcome measure scores from 12 exercise and 10 surgical intervention arms were compared.

AMSTAR: Assessment of Multiple Systematic Reviews

Table D.6: Summary of findings from systematic reviews

Study, Country	Main Study Findings	Authors' Conclusions
Overview of systematic reviews		
Jacobs et al. (2013) The Netherlands	**Surgical treatment versus conservative management of sciatica due to herniated disc (4 SRs)** (17 RCTs, 9 observational studies, one conference proceeding; 4,052 patients) While heterogeneity prevented meta-analysis, results were consistent that surgery leads to short-term benefits, but the scarcity of high-quality studies did not support a definite choice for conservative or surgical treatment for disc herniation with sciatica. **Surgery versus conservative treatment and surgical techniques compared with one another for low-grade isthmic spondylolisthesis (1 SR)** (8 RCTs, 376 patients; 4 prospective studies, 148 patients; 17 retrospective case series, 648 patients) One study with high risk of bias showed superior results for clinical outcome (74% versus 43% good outcome) at 2 years for posterolateral fusion versus exercise. Studies lacked blinding and intention-to-treat analyses; heterogeneity prevented pooling of results. **Surgery versus conservative treatment for discogenic LBP without stenosis (2 SRs)** One review of 141 patients in 3 studies could not draw conclusions regarding intradiscal electrothermal therapy versus placebo. One review of 4 RCTs reported that fusion was no more effective than intensive rehabilitation, but was associated with small benefits compared to standard non-surgical therapy. **Surgery versus conservative treatment for spinal stenosis with degenerative disc disease (2 SRs)** Both reviews included the same 5 RCTs involving 918 patients Reviews reported no difference in effectiveness between interspinous devices or decompressive surgery versus conservative management. One study found no difference in pooled ODI score (MD -1.57, 95% CI -4.65 to 1.51). Another study found the intention-to-treat analysis not clinically significant. One RCT concluded there was good evidence that decompressive laminectomy (with or without fusion) was superior to non-surgical therapy for the first 2 years of follow-up, but benefits diminish thereafter. Studies varied in the number of patients with spondylolisthesis (0% to100% or unknown) and heterogeneity.	"No overall conclusions could be drawn regarding surgical treatment versus conservative management of sciatica due to a herniated disc." (pp. 1940) "One high-risk of bias study showed superior clinical outcome (74% versus 43% good outcome) at 2 years for posterolateral fusion versus exercise." (pp. 1941) Fusion was no more effective than intensive rehabilitation for LBP without stenosis for degenerative disc disease. "Results were inconsistent and ascribed to differences in rehabilitation intensity in the non-surgical intervention group as fusion was no more effective than intensive rehabilitation, but fusion was associated with small-to-moderate benefits compared to standard non-surgical therapy." (pp. 1943) For the treatment of spinal stenosis, intervertebral process devices were more effective than conservative treatment. "Three reviews concluded that interspinous spacers, both statistically and clinically, significantly improve the ZCQ total score more than conservative treatment." (pp. 1944) "For degenerative spondylolisthesis, fusion showed more favourable results compared to decompression for a mixed aggregation of clinical outcome measures (RR 1.40, 95% CI 1.04 to 1.89) and fusion rate favoured instrumented fusion over non-instrumented fusion (RR 1.37, 95% CI 1.07 to, 1.75)." (pp. 1936) "For most comparisons, the included reviews were not significant and/or clinically relevant differences between interventions were not identified. Although the quality of the reviews was quite acceptable, the quality of the included studies was poor. Future studies are likely to influence our assessment of these interventions." (pp. 1937)

Table D.6: Summary of findings from systematic reviews (cont'd)

Study, Country	Main Study Findings	Authors' Conclusions
	Two SRs compared interspinous process distraction devices with conservative treatment (5 RCTs, 1 controlled observational study, 7 non-controlled observational studies; at least 539 patients) All 3 reviews concluded that interspinous spacers produced a clinically and statistically significant improvement in the ZCQ score, compared with conservative treatment (average improvement in symptom severity and physical function compared to baseline was 23.2% [95% CI 18.5 to 27.8]). Observational studies reported a complication rate of 7%. Quality of evidence was low. These reviews included duplicate publications of primary studies.	
Systematic reviews		
Bydon et al. (2014) USA	Meta-analysis of 5 studies involving 707 patients compared lumbar fusion with non-operative management of CLBP, suggesting moderate benefit for fusion in terms of functional outcomes measured by ODI after 1 and 2 years of follow-up. Pooled MD in ODI (final ODI minus initial ODI) between conservative management and lumbar fusion groups across all studies was -7.39 points (95% CI -20.26 to 5.47) in favour of lumbar fusion, but the difference was not statistically significant (P=0.26) . While ODI is a standardised measure of disability in back patients, there is no consensus on the change in ODI that signifies a clinically important difference. Postoperative complications were observed in 9% to 18% of patients, most commonly wound infections and bleeding. Significant bias was observed as patients, personnel and outcome assessors were not blinded to treatment allocation and studies were at high risk of sampling bias due to patient cross over.	"Despite significant improvement in ODI in the lumbar fusion groups in three studies, pooled data revealed no significant difference when compared to the non-operative group. While there was an overall improvement of 7.39 points in ODI in favour of lumbar fusion, it is unclear that this change leads to a clinically significant difference. Until such time as a prospective RCT comparing a specific surgical technique versus a structured physical therapy improves evidence quality, operative intervention via lumbar fusion or non-operative management and physical therapy remain acceptable treatments for intractable LBP." (pp. 3)

Table D.6: Summary of findings from systematic reviews (cont'd)

Study, Country	Main Study Findings	Authors' Conclusions
Jarrett et al. (2012) Australia	13 studies involving 1,098 patients were included in the SR of decompressive surgery versus exercise for lumbar spinal stenosis. Included studies were of moderate quality. One RCT directly compared decompressive surgery with exercise for lumbar spinal stenosis. Surgery showed statistically significant improvements in patient-reported functional outcomes (ODI) at 6, 12 and 24 months post-intervention (P<0.01). Effect sizes were 0.55 at 6 months, 0.81 at 12 months and 0.56 at 24 months. Results from 12 exercise and 10 surgical intervention arms were compared using percentage change in patient-reported functional outcomes. Exercise interventions showed initial improvements, ranging from 16% to 29% above baseline, while decompressive surgical interventions showed greater, more sustained improvements over 2 years (range 38% to 67%). The most commonly reported surgery-related complications were dural tears (3% to 14%), while adverse effects were lacking in exercise interventions.	"There is strong evidence for improvement in patient-reported functional outcomes in those who undergo decompressive surgery for lumbar spinal stenosis. There is consistency between studies across multiple timeframes with sustained improvements up to 2 years post-surgery." (pp. 7) "Decompressive surgery is more effective in the management of lumbar spinal stenosis than land-based exercise; however, whilst patients wait for surgery and given the risks of surgery, there are potential benefits in functional improvements from land-based exercise interventions. A self-management programme with land-based exercise prior to consideration of surgical intervention for patients with lumbar spinal stenosis is supported. Due to heterogeneity of land-based exercise interventions investigated in the included studies, this systematic review is unable to provide specific recommendations regarding the most effective forms of exercise." (pp. 8)

CI: confidence interval; LBP: low back pain; MD: mean difference; ODI: Oswestry Disability Index; RCT: randomised controlled trial; RR: relative risk; SR: systematic review; ZCQ: Zurich Claudication Questionnaire