



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health Technology Assessment of Scheduled Procedures

Surgery for adult degenerative lumbar spine disease

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Safer Better Care

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1.1 Surgery for adult degenerative lumbar spine disease

1.2 Scope of Health Technology Assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral or treatment thresholds for selected scheduled procedures (including discectomy, decompression surgery and spinal fusion) for adults with degenerative lumbar spine disorders provided by the publicly funded healthcare system in Ireland. The effectiveness of these surgeries may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled procedures. Details of the background to the request for the assessments from the Director General of the Health Service Executive (HSE), Mr Tony O'Brien, and the general methodology are included in the separate 'Background and Methods' document.⁽¹⁾

The scope of this HTA is to investigate clinical referral and treatment thresholds for surgery for adults presenting with degenerative lumbar spine disease in Ireland. Inputs from an expert advisory group, along with a review of the clinical and cost-effectiveness literature were used to inform the criteria. Additionally, the budget impact and resource implications were assessed, as appropriate.

1.3 Surgical indication

Degenerative lumbar spine disease is a broad term that encompasses a range of conditions that can occur due to age-related changes in the spine and intervertebral discs and result in back pain and associated neurological symptoms. This review is limited to elective surgery to treat disc herniation, spinal stenosis and instability as a result of chronic degenerative disease. So-called 'red flag' symptoms indicative of conditions that may require urgent review are not covered by the referral and treatment thresholds described in this report. These may include infection, trauma, neoplasia or cauda equine syndrome.

Intervertebral discs help facilitate movement of the spinal column while maintaining stability. As we age these discs begin to lose some of their water and proteoglycan content, making them stiffer and less able to effectively redistribute pressure between adjacent vertebrae during movement. This can result in weakening of the outer layer of the disc wall (annulus fibrosus) causing it to bulge or tear. Inflamed, damaged discs can impinge on nerve roots in the affected area, resulting in pain, weakness or loss of sensation. Nerve compression can also result from narrowing of the spinal canal (lumbar spinal stenosis) as a result of age-related degenerative changes, including facet joint hypertrophy, osteophytosis and spondylolisthesis. In

some cases, these degenerative changes result in spinal instability, where vertebrae are unable to maintain their correct position or limit their relative displacement during movement. While most degenerative conditions of the lumbar spine present as back pain,⁽²⁾ the majority of patients who present in the primary care setting have symptoms of low back pain that cannot reliably be attributed to a specific disease or spinal abnormality. In the US it has been estimated that 85% of patients seen in primary care have non-specific low back pain, with spinal stenosis and symptomatic herniated discs present in about 3% and 4% of patients, respectively.⁽³⁾

1.4 Surgical procedure, potential complications and alternative treatments

Surgical approaches to the management of degenerative lumbar spine disease include discectomy, decompression surgery and spinal fusion. Discectomy involves removal of disc material to relieve pressure on the nerve tissue. Open discectomy is the most common surgical treatment for herniated discs of the lumbar spine and is usually performed under general anaesthesia.⁽⁴⁾ Minimally invasive techniques such as microdiscectomy, performed with the use of a microscope or other magnifying tools, are also available.⁽⁵⁾ Discectomy can be performed on its own or in combination with other procedures designed to relieve pressure on the spinal cord or nerve roots caused by disc herniation or stenosis of the spinal canal. Depending on the clinical circumstances, decompression surgery can include a combination of discectomy, laminectomy, foraminectomy and osteophyte removal. Where degenerative lumbar disease or prior decompression surgery has resulted in spinal instability, fusion of two or more vertebrae may be indicated. This is achieved by the application of a bone graft, synthetic material and/or bone stimulating factors between the affected vertebrae, with or without implantable fixation devices that restrict movement while the bones fuse.

Serious complications from surgery for degenerative lumbar disease are rare,⁽⁶⁾ but can include damage to the spinal cord resulting in some degree of paralysis (0.33% of cases) or death (0.29% in surgery for spinal stenosis and 0.14% in surgery for disc herniation). The most common complication associated with surgery is post-operative wound infection, which occurs in approximately 4% of cases.⁽⁶⁾

Conservative management options for degenerative lumbar disease are generally associated with less risk of serious complications compared to surgery⁽⁷⁾ and are advocated as the initial approach to alleviating symptoms or slowing disease progression.⁽⁸⁾ Non-operative treatment options include analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) to control pain and inflammation, physiotherapy, lifestyle modifications such as weight loss and smoking cessation, intensive interdisciplinary rehabilitation and spinal injections (e.g. epidural steroids, nerve-root

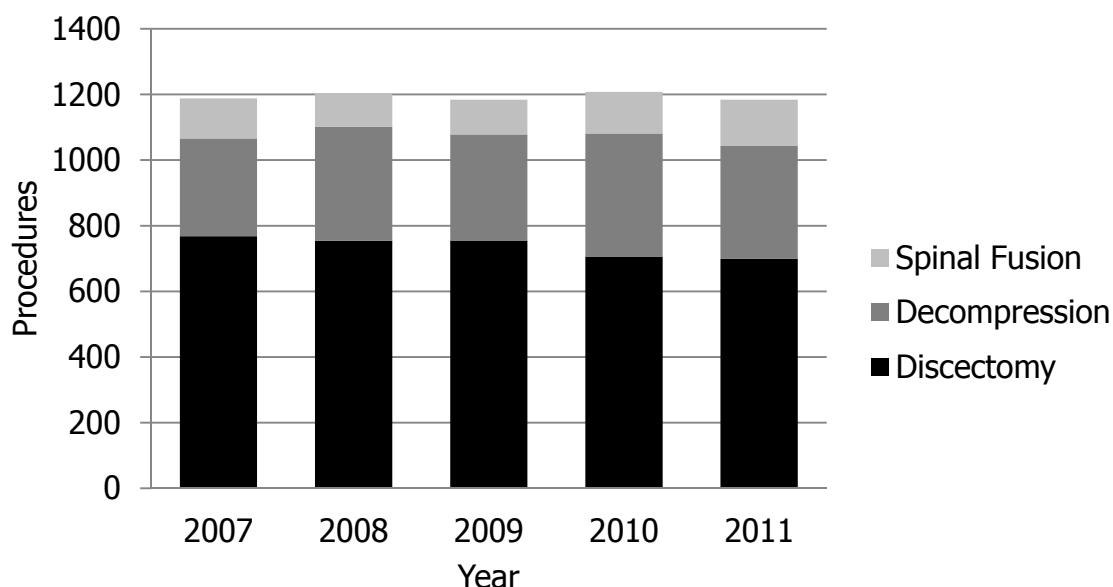
blocks). Clinical guidelines differ in their recommendations regarding initial conservative management and what constitutes an optimal structured conservative management or rehabilitation programme – recommendations in this regard are beyond the scope of this HTA. Separate reports in this series of HTAs on scheduled procedures have been prepared for other interventional procedures for the management of chronic back pain, including spinal injections,⁽⁹⁾ spinal cord stimulation⁽¹⁰⁾ and radiofrequency lesioning.⁽¹¹⁾

1.5 Current practice in Ireland

Degenerative lumbar spine surgery does not constitute a defined group within the Hospital In-Patient Enquiry (HIPE) coding system. Rather, procedures are coded based on either the extent of the surgery (e.g. 1- or 2-level discectomy) or the anatomical location. Surgical activity in this area was therefore estimated by cross referencing discharge data for relevant surgical procedures with patients that had a diagnosis associated with degenerative lumbar spine disease, using the diagnosis and procedure codes specified in Appendix 1.⁽¹²⁾ HIPE data indicate that there were approximately 1,126 procedures performed in public hospitals in 2011 for adult degenerative lumbar disease. An additional 45 discectomies and 84 spinal fusion procedures were procured by the National Treatment Purchase Fund (NTPF) and performed in private hospitals in that year. However, data on the proportion of these that were for degenerative lumbar disease is not available.

The number of discectomies, decompressions and spinal fusions carried out in publicly funded hospitals over the last five years is shown in Figure 1.1.

Figure 1.1. Number of discectomies, decompression surgeries and spinal fusion procedures for degenerative lumbar disease* performed in public hospitals, 2007-2011⁽¹²⁾



* See Appendix 1 for HIPE codes; HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.

Surgery for degenerative spine disease is usually undertaken as an inpatient procedure with an average length of stay in 2011 of 2.9, 6.5 and 9.8 days for lumbar discectomy, lumbar/thoracolumbar decompression surgery and lumbar spinal fusion, respectively. The Health Service Executive (HSE) Elective Surgery Programme has specified target average length of stays (ALOS) for a number of decompression surgeries, including two days for 1-level discectomy (2011 ALOS: 2.8 days) and three days for 1-level decompression of lumbar spine (2011 ALOS: 5.2 days).

Current data do not permit identification of the precise indication for which procedures are performed as intervention, and diagnosis codes are not linked. HIPE data capture the principal and up to 29 secondary diagnoses recorded in the patient medical notes for each episode of care. As noted, surgical activity for degenerative lumbar disease was estimated by cross-referencing discharge data that included a procedure code for discectomy, spinal decompression or spinal fusion with discharges that included a principal diagnosis related to a degenerative lumbar disease (Table 2, Appendix 1). The clinical specialty of consultants undertaking these procedures was mainly either neurosurgery (55%) or orthopaedics (44%).⁽¹²⁾

In 2011, these procedures were carried out in a total of 18 separate centres (17, 15 and 11 separate centres performed discectomy, decompression surgery and spinal fusion, respectively) with a national activity rate of 2.47 per 10,000 population.

Activity for each procedure by proposed hospital group,⁽¹³⁾ including average patient age, average length of stay and total inpatient bed-days, is provided in Tables 1.2, 1.3 and 1.4.

Table 1.1. Discectomy procedures*⁽¹²⁾ per proposed hospital group⁽¹³⁾ (2011)

Hospital group	Total	%	Rate per 10,000	Inpatient bed days	Average age	Average length of stay
Dublin East	56	8.1	0.56	161	41	2.9
Dublin Midlands	52	7.53	0.65	261	41	5
Dublin North East	121	17.51	1.51	447	41	3.7
Midwest	13	1.88	0.33	44	38	3.4
South/South West	392	56.73	4.61	860	44	2.2
West/North West	57	8.25	0.81	242	41	4.2
Total	691	100	1.52	2015	41	3.5

* See Appendix 1 for HIPE diagnosis and procedure codes; HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.

Table 1.2. Decompression procedures*⁽¹²⁾ per proposed hospital group⁽¹³⁾ (2011)

Hospital group	Total	%	Rate per 10,000	Inpatient bed days	Average age	Average length of stay
Dublin East	92	27.71	0.92	744	57	8.1
Dublin Midlands	38	11.45	0.48	357	55.7	9.4
Dublin North East	46	13.86	0.58	283	64.8	6.2
Midwest	6	1.8	0.15	57	68	9.5
South/South West	113	34.04	1.33	415	63	3.7
West/North West	37	11.14	0.53	415	57	11.2
Total	332	100	0.73	2271	60	7.7

* See Appendix 1 for HIPE diagnosis and procedure codes; HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.

Table 1.3. Spinal fusion procedures*⁽¹²⁾ per proposed hospital group⁽¹³⁾ (2011)

Hospital group	Total	%	Rate per 10,000	Inpatient bed days	Average age	Average length of stay
Dublin East	38	27.53	0.38	406	55	10.7
Dublin Midlands	35	25.36	0.44	452	52	12.9
Dublin North East	7	5.07	0.09	78	52	11.1
Midwest	N/R**	N/R	N/R	23	72	5.8
South/South West	24	17.38	0.28	186	52	7.8
West/North West	30	21.74	0.43	299	61	10.0
Total	138	100	0.30	1444	56	9.9

* See Appendix 1 for HIPE diagnosis and procedure codes; HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance;

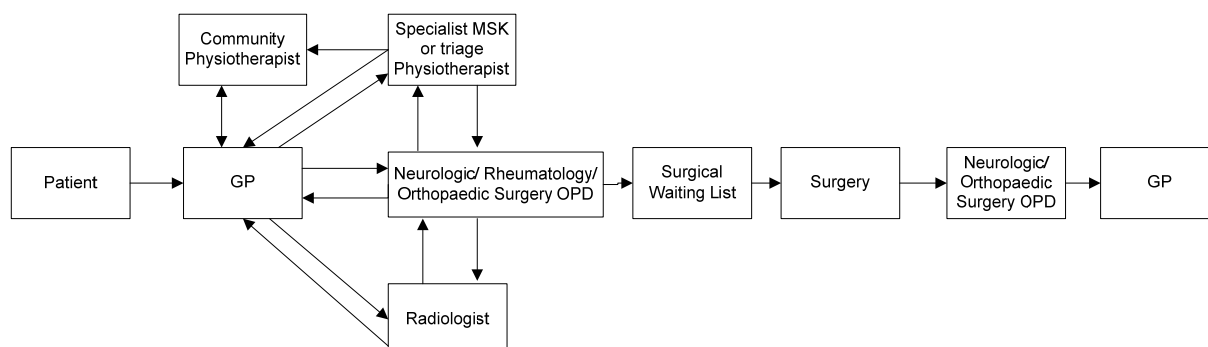
** Data not reported (N/R) as consists of five or fewer cases

Standard practice in the publicly funded healthcare system is that patients must be referred by their general practitioner (GP) or another consultant to obtain a hospital outpatient appointment.⁽¹⁴⁾ Suitability for surgery is based on clinical and radiological criteria.⁽³⁾ The patient may be referred by their GP for radiological imaging prior to attending a hospital outpatient appointment. For example, a lateral X-ray can be used to detect degenerative lumbar spondylolisthesis, with a subsequent magnetic resonance imaging (MRI) used to test for accompanying spinal stenosis.⁽¹⁵⁾ Additional imaging may also be required to detect instability associated with weight bearing and movement. GPs report very limited direct access to MRI in the publicly funded healthcare system. Timely access to MRI can also be problematic as demand, which is increasing with the expansion of the clinical indications for MRI, frequently exceeds capacity leading to long waiting times for MRIs in a number of hospitals.^(14;16) Some

patients choose to procure an MRI privately to expedite care, however, this does not always obviate the need for them to be referred for additional imaging. Documented referral guidelines are already in operation in some centres in Ireland, one example of which is the spinal referral pathway in The Adelaide and Meath Hospital, Dublin Incorporating the National Children's Hospital (see Appendix 2).

Typically, patients with low back pain should have exhausted conservative management, including physiotherapy, prior to referral for surgical review. Access to physiotherapy in the primary care setting is reported to be limited, with the result that it appears that some patients are currently being referred without meeting this criterion. Since March 2012 a triage scheme involving 24 specialist musculoskeletal (MSK) advanced practitioner physiotherapists has been in operation nationally (although not in all hospitals) as a waiting list reduction initiative by the HSE's Orthopaedic and Rheumatology Clinical Care programmes. Under this scheme, referrals to secondary care are initially reviewed by the consultant, who decides which patients are suitable for referral to an MSK physiotherapist for treatment; those whose symptoms persist following physiotherapy are referred back to the consultant for specialist review while those whose symptoms subside may be referred back to primary care.⁽¹⁴⁾ Anecdotal reports indicate that only 20% to 30% of those referred to consultant outpatient clinics are ultimately considered suitable candidates for surgery.⁽¹⁴⁾ This is consistent with a recent Irish study reporting that 85% of patients referred to a spinal triage programme for initial assessment and management by a clinical specialist physiotherapist (without necessarily having first been reviewed by a consultant) were suitable for conservative management, 14% were discharged and only 1% required onward referral for specialist opinion.⁽¹⁷⁾ The percentage of those found suitable for conservative treatment and who subsequently required surgery was not reported. Back pain triage clinics have also been established by some hospitals to facilitate timely access to appropriate services. These use stated referral criteria, standardised referral forms and triage processes for accessing orthopaedic, pain specialist, rheumatology and specialist physiotherapy services. Prior to referral, it is recommended that, unless urgent, patients access physiotherapy within the primary care system prior to referral to the triage clinic. While such stated criteria provide clarity, facilitate timely access and streamline the efficient use of resources, they do not eliminate waiting times if need exceeds available capacity. Urgent cases are seen as soon as possible within a maximum of two weeks, and routine cases are queued according to when their referral letter was added to the appropriate waiting list.⁽¹⁸⁾ The current pathways for the referral, treatment and post-operative follow up of patients undergoing surgery for back pain in the publicly funded healthcare system are illustrated in Figure 1.2.

Figure 1.2. Current referral, treatment and follow-up pathways for publicly funded patients presenting with low back pain as a result of degenerative lumbar spine disease



Key – GP: general practitioner, OPD: Outpatient department

The length of time a patient must wait to be reviewed varies according to the referral pathway and the individual hospital and consultant to which a patient is referred. Patients may be referred to an individual consultant or to a hospital department and reviewed by the next available consultant or, as noted, to dedicated multidisciplinary back pain clinics. Referral to an individual consultant may lead to variability in waiting lists within a hospital and to delays if the consultant does not specialise in the particular procedure. Referral to a hospital department or a dedicated multidisciplinary back pain clinic should optimise efficiency.⁽¹⁹⁾ At the end of August 2013, it was reported that there were 52,455 patients on the Outpatient Waiting List for an orthopaedic appointment, 45% of whom were waiting less than six months, with 67% waiting less than 12 months.⁽²⁰⁾ As of April 2013, 194 people were on surgical waiting lists for discectomy (42% waiting over six months) and 109 people awaiting spinal fusion (16% waiting over six months).⁽²¹⁾ Post-surgery patients generally also require outpatient department (OPD) follow-up appointments at six months and two years.

At present, apart from urgent referral of patients presenting with symptoms suggestive of 'red flag' conditions (including cauda equina syndrome, spinal fracture, malignancy, infection, spondyloarthropathies or visceral disease), there are no standardised national referral criteria that are routinely used to prioritise referrals. This can result in unnecessary outpatient appointments and difficulties in triaging patients according to symptom severity. It is suggested that a significant percentage of those referred to outpatient clinics are not considered appropriate for surgical treatment. Data from the NTPF (2007-2011) indicate that across all specialties, 38% of patients referred for outpatient surgical review are referred back to the primary care system without undergoing surgery or being referred for further diagnostic tests.⁽²²⁾ It is suggested that this rate may be higher for patients referred for

degenerative lumbar spine surgery such as discectomy, with only 20% to 30% considered appropriate for surgical treatment.⁽¹⁴⁾ As noted earlier, it is suggested that among patients referred for first-line outpatient review by a physiotherapist in a spinal triage scheme, only approximately 1% of patients are immediately referred for a specialist opinion,⁽¹⁷⁾ indicating that conservative treatment with physiotherapy is not being exhausted prior to patient referral from primary care.

Initiatives are underway by the HSE to standardise the management of outpatient services and to ensure that there are consistent management processes across all publicly-funded healthcare facilities that provide outpatient services. This includes the publication in January 2013 of a protocol⁽²³⁾ for the management of these services by the NTPF which provides the core guidance for the Outpatient Services Performance Improvement Programme. This specifies that patients should be treated based on clinical urgency, with urgent referrals seen and treated first. It is intended that the definition of clinical urgency and associated maximum wait times is to be developed at specialty or condition level and agreed by the clinical programmes. In January 2013, the NTPF also published a national waiting list management policy⁽²⁴⁾ that outlines the standardised approach to managing scheduled care treatment for inpatient, day case and planned procedures in all publicly-funded hospitals. It outlines a consistent structured approach that must be adopted for the management of the waiting list; monitoring of the implementation of the policy will be routinely undertaken by the NTPF in the form of annual quality assurance reviews.

2 Clinical referral/treatment threshold

2.1 Review of the literature

A literature search was conducted up to July 2013. The approach and general search terms are described in Appendix 1 in the Background and Methods document accompanying this document. A summary of the results of this search is included in Table 2.1. Within the UK's National Health System (NHS), a number of primary care trusts have set their reimbursement policy for spinal surgery through the creation of defined clinical referral criteria. Some examples of these referral thresholds are included in Appendix 2.

Table 2.1. Included evidence sources.

Type of evidence	Number	References
Clinical guidelines	7	(15;25-30)
Literature reviews	12	(5;31-41)
Cost-effectiveness studies	10	(28;35;42-49)

2.2 Clinical evidence

2.2.1 Discectomy

According to published guidelines^(15;25-27) discectomy is recommended for those with radiculopathy due to a herniated disc and those with symptomatic spinal stenosis associated with low-grade degenerative lumbar spondylolisthesis⁽¹⁵⁾ that has failed to respond to conservative treatment. For these patients, where imaging agrees with the clinical examination findings, there seems to be consensus that surgery is indicated.⁽³¹⁾ Four reviews^(31-33;35) concluded that surgical discectomy for patients with sciatica due to lumbar disc prolapse provides an improvement in the short term compared to conservative management. However, any positive or negative effects on the lifetime natural history of the underlying disc disease are still unclear, with differences in outcomes diminished or absent after one to two years. A Cochrane review⁽⁴¹⁾ found evidence that discectomy is beneficial for spinal stenosis, with two thirds of patients experiencing a satisfactory outcome post-surgery. However, evidence was lacking on the clinical or patient characteristics associated with a favourable outcome. It should be noted that as trials of surgery versus conservative management cannot be blinded this could potentially lead to some overestimation of the benefits of surgery.⁽³³⁾ The 2006 SPORT trial⁽⁵⁰⁾ comparing surgical and non-operative treatment for lumbar disc herniation reported that patients in both the surgery and the non-operative treatment groups improved substantially over a two-year period, though the authors were unable to reach definitive conclusions about the superiority or equivalence of the treatments based on the intention to treat analysis. An observational study⁽⁵¹⁾ carried out in parallel with this trial, involving patients who met the inclusion criteria but declined randomisation, found that those who chose operative intervention reported greater improvements than patients who elected for non-operative care. However, as the authors point out, non-randomised comparisons of self-reported outcomes are subject to potential confounding and must be interpreted cautiously.

The optimal timing for referral for surgical review is not clear from the literature.⁽³¹⁾ In the majority of patients with herniated discs, symptoms will improve substantially in the first few weeks either with or without discectomy, and delaying surgery at this point does not appear to increase the risk of cauda equine syndrome or paralysis.⁽³³⁾ There is poor quality evidence that early surgery in patients with sciatica provides for better short-term relief of leg pain as compared to prolonged conservative management.⁽³¹⁾ The criteria developed by the primary care trusts include conservative management for at least four to six weeks.⁽⁵²⁻⁵⁵⁾ When clinical indications are uncertain, postponing surgery to further assess clinical progress has not been shown to lead to long-term harm or affect outcomes.⁽³²⁾

Open and minimally invasive discectomy leads to a substantial and broadly comparable degree of short- and long-term improvement in leg pain, the primary symptom of many patients with lumbar radiculopathy.^(5;34) However, the evidence on other minimally invasive techniques including percutaneous discectomy procedures, endoscopic and laser discectomy remains unclear.^(32;33;56-61) The choice of procedure may be influenced by the surgeon's beliefs about the role of surgery in spinal disorders, and the surgical instrumentation and skills available.⁽⁴¹⁾

2.2.2 Decompression surgery

A consensus statement from the 2011 North American Spine Society (NASS) guidelines⁽³⁰⁾ reported that the natural history of mild to moderate degenerative lumbar stenosis may be favourable for 33% to 50% of patients and that any treatment in this group is unlikely to significantly alter the symptomatic course of the disease. It is estimated that non-surgical management is successful in approximately 33% of people with severe symptoms of lumbar stenosis and 70% of those with mild or moderate symptoms.⁽⁶²⁾

A recently published (2013) overview of systematic reviews of surgical interventions for low back disorders identified two reviews that examined surgery versus conservative treatment for spinal stenosis. The first was a 2011 systematic review⁽³⁹⁾ that identified five randomised controlled trials and concluded that in patients for whom conservative treatment for three to six months has failed to adequately alleviate symptoms, decompressive surgery (with or without fusion) improves pain relief, function, and quality of life to a greater extent than continuing conservative treatment, but does not improve walking ability. The additional benefits of surgery were sustained for up to two to four years, but beyond that the differences were smaller. The other review⁽³³⁾ identified the same five randomised controlled trials and concluded that there was good evidence that decompressive laminectomy (with or without fusion) is superior to non-surgical therapy for the first two years after surgery, but benefits appear to diminish afterwards. A more recent systematic review,⁽³⁸⁾ not included in that overview that compares surgery to physical therapy for lumbar stenosis, also concluded that decompression surgery is more effective, but given the condition's slowly progressing nature and the potential for known surgical complications, recommends that a trial of conservative management with exercise be considered prior to consideration of surgical intervention.

While non-surgical interventions are generally recommended in the initial treatment of degenerative lumbar stenosis, the evidence underpinning conservative treatment is limited.⁽⁴⁰⁾ The 2011 NASS guidelines⁽³⁰⁾ conclude that there is insufficient evidence to make a recommendation for or against the use of pharmacological treatment, physical therapy or exercise (as stand-alone treatments), spinal manipulation,

traction, electrical stimulation, transcutaneous electrical nerve stimulation (TENS) or acupuncture for the treatment of patients with lumbar spinal stenosis.

2.2.3 Spinal fusion

For a spinal fusion to be indicated, a patient should have failed a structured conservative management programme and be clinically suitable for surgery. Four clinical guidelines relating to the adult population were found that specifically mention referral criteria for spinal fusions (Appendix 2).^(3;15;28;29) These guidelines highlight and recommend best practice based on the available evidence base. As previously noted, a number of primary care trusts within the UK's NHS have set their reimbursement policy for spinal fusion through the creation of defined clinical referral criteria. Some examples of these referral thresholds are included in Appendix 2.

There is continued dispute as to whether lumbar fusion is an appropriate and effective method of treating back pain in patients with degenerative lumbar spondylosis. There is a lack of clear evidence on the nature and role of 'instability', and the clinical indications for surgery are not well defined. There is also wide variation in the surgical techniques used, technical success and rate of fusion. Reported satisfactory clinical outcomes range from 16% to 95%.⁽⁴¹⁾

According to the published guidelines,^(15;27-29) spinal fusion is recommended for those with symptomatic spinal stenosis, degenerative spondylolisthesis or non-radicular low back pain with common degenerative changes that has failed to respond to conservative treatment. Two reviews^(41;63) comparing the efficacy of fusion surgery to conservative treatment concluded that the evidence suggests surgical procedures may be more efficacious when compared to continuing what was 'usual' non-operative care at the time the study was conducted in the 1990s, but not when compared to a modern structured rehabilitation programme and cognitive behavioural therapy. It should be noted that as trials comparing surgery to conservative management cannot be blinded this could potentially lead to some overestimation of benefits of surgery.⁽³³⁾

Spinal fusion is usually combined with discectomy, however, discectomy without fusion will lead to a spontaneous fusion in 70% to 80% of cases.⁽⁶³⁾ For patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis, discectomy with fusion can improve clinical outcomes compared to discectomy alone.⁽¹⁵⁾ A meta-analysis reported that decompression without a fusion will give a 69% satisfactory outcome, whereas with fusion, this figure would increase to 90%.⁽⁴¹⁾

Although the specific suggestions about timing of referral are not clear from the literature, benefits of fusion compared with conservative management have only been demonstrated in a relatively narrow group of patients with moderately severe

pain or disability for at least one year, without serious psychiatric or medical comorbidities or other risk factors for poor surgical outcomes.^(3;27;28) There is still limited evidence on the long-term effects of surgical fusion.⁽⁴¹⁾ The criteria developed by the primary care trusts include conservative management of at least six months to two years,^(52;54;55;64-66) with the Bluechoice Healthplan in the US using a shorter conservative management period of three months.⁽⁶⁷⁾ Some primary care trusts have developed a structured referral form, for example, Outer North East London (Appendix 3).⁽⁵⁵⁾ The Catalan health service has developed a priority-setting system that ranks patients on waiting lists from highest to lowest.⁽⁶⁸⁾ Clinical criteria are the most relevant both in relative weight and in number, however, functional and social criteria have an overall weight of 15% and 16%, respectively.⁽⁶⁸⁾ Also, due to the possible evolution of the diagnoses during the waiting period, a periodic reassessment of patients on a waiting list is recommended.⁽⁶⁸⁾

Instrumented fusion is associated with a moderate improvement in fusion rates compared with non-instrumented fusion, but clinical outcomes are similar and additional costs are substantial.^(27;33;41) There is insufficient evidence to recommend an optimal fusion method (anterior, posterolateral, or circumferential), though more technically difficult procedures may be associated with higher rates of complications.^(27;33) Iliac crest autograft performs better (clinically and statistically) than discectomy alone or with a cage. There is no evidence that fusion rates differ between discectomy plus cages or polymethyl methacrylate, discectomy alone, iliac crest autograft plus an anterior plate or iliac crest autograft alone.⁽⁶³⁾ Current evidence on the efficacy of non-rigid stabilisation techniques for the treatment of low back pain shows that these procedures are efficacious for a proportion of patients with intractable back pain.⁽⁶⁹⁾ A 2011 systematic review of guidelines and payer policies for fusion in chronic low back pain⁽³⁶⁾ found that guidelines for the evaluation of lower back pain were more consistent than those for treatment and recommends that more needs to be done to develop high quality treatment guidelines.

2.3 Cost-effectiveness evidence

Four studies^(46;48;49) were found that compared the cost-effectiveness of surgery to conservative management in patients with sciatica due to a herniated intervertebral disc (Appendix 3). Three of these studies^(46;48;49) concluded that early surgery is cost-effective compared to conservative management. However, outcomes were only evaluated in the short term (up to two years), after which point the clinical evidence would suggest little difference between the two management approaches. Two of these studies^(46;48;49) also looked at the cost-effectiveness of surgery when the wider societal costs are included (productivity losses, caregiver time). Both found the

inclusion of these costs resulted in a small or negligible change to the cost-effectiveness. The economic model developed by Lewis et al.⁽³⁵⁾ demonstrated that stepped approaches based on initial treatment with non-opioids represent the most cost-effective regimens for the treatment of sciatica. They conclude that referring patients who fail initial treatments directly to surgery is unlikely to be cost-effective.⁽³⁵⁾

Cost-effectiveness results from a 2010 study comparing surgery and conservative treatment for patients with symptomatic lumbar spinal stenosis studies indicate that surgery is cost-effective at two years.⁽⁴⁴⁾ A 2006 cost-utility analysis of routine spinal surgery⁽⁴⁵⁾ also found that surgery was associated with improved health related quality of life, but that delays in accessing surgery tended to increase costs and reduce quality-adjusted life-year (QALY) gain. A 2011 cost-effectiveness analysis based on data from the SPORT trial⁽⁵⁰⁾ reported large differences in the cost per QALY for surgery for disc herniation, spinal stenosis and spondylolisthesis (USD\$20,600, \$59,400, and \$64,300 respectively).

An economic evaluation⁽⁴²⁾ based on the Medical Research Council (MRC) Spine Stabilisation Trial⁽⁷⁰⁾ calculated the incremental cost-effectiveness ratio for surgical stabilisation versus intensive rehabilitation to be GBP£48,588 per QALY gained (95% CI -£279, 833 to £372,406) with a less than 20% chance that surgery will be cost-effective at two years at a threshold of £30,000 per QALY. The study concluded that stabilisation may not be cost-effective, but emphasised the high levels of uncertainty associated with the estimates. A systematic review of economic studies carried out subsequent to the MRC trial⁽⁴²⁾ identified one additional economic study comparing fusion to non-surgical treatment in chronic back pain. This study,⁽⁷¹⁾ by the Swedish Lumbar Spine Study Group, concluded that 'lumbar fusion in a well-informed and selected group of patients with severe CLBP [chronic lower back pain] can diminish pain and decrease disability more efficiently than commonly used non-surgical treatment.' It also found that the added costs of an additional effect unit (Oswestry Disability Index) amounts to approximately €1,000 when treating the patients surgically compared to conservative management.

2.4 Budget impact and resource implications

Without any clear guidance on referral criteria in place for surgery for back pain in Ireland, there is inevitably variation in referral patterns to outpatient clinics. While no national data is available, regional data indicate that 85% of those referred for initial orthopaedic review by a physiotherapist in a spinal triage scheme were deemed suitable for conservative management.⁽¹⁴⁾ By implementing referral thresholds, patients would attend hospital only when appropriate, and remain under the care of their primary care practitioner until then. This would potentially improve the patient pathway through reducing unnecessary hospital appointments, leading to a reduction

in waiting times for these appointments and improving access for those with the greatest clinical need.

The number of spinal surgeries performed is not expected to reduce with the introduction of thresholds. Instead, it is hoped that introducing clinical referral and treatment thresholds would lead to an improved patient pathway. A reduction in inappropriate referrals would reduce the demand for outpatient appointments; the use of standardised referral criteria would enable better triaging of those referred for review. This should lead to those with a higher clinical need being seen and undergoing surgery earlier, with a potential reduction in waiting times for both outpatient appointments and surgery. Casemix data for the 2011 cohort of patients with a diagnosis associated with degenerative lumbar disease undergoing discectomy, decompression or fusion (see Appendix 1) indicate that the current estimated annual national cost of surgery for this indication is approximately €8.3 million (Table 2.2).

Table 2.2 HSE inpatient and day case acute hospital activity and costs for all spinal surgery summarised by diagnosis-related group (based on 2011 costs and activity)⁽⁷²⁾

AR-DRG	Description	Number carried out	Unit cost (€)	Total cost (€)
801B	OR procedures unrelated to principal diagnosis W severe or moderate CC	2	12,744	25,488
A08B	Autologous bone marrow transplant W/O catastrophic CC	1	22,764	22,764
B03B	Spinal procedures W/O catastrophic or severe CC	15	9,504	142,560
B60A	Acute paraplegia/quadriplegia W or W/O OR Procs W Cat CC	2	43,762	87,524
B60B	Acute paraplegia/quadriplegia W or W/O OR Procs W/O Cat CC	19	15,997	303,943
I02B	Skin graft W/O catastrophic or severe CC; excluding hand	25	11,952	298,800
I06Z	Spinal fusion W deformity	2	32,387	64,774
I09A	Spinal fusion W catastrophic CC	11	31,780	349,580
I09B	Spinal fusion W/O catastrophic CC	121	16,501	1,996,621
I10A	Other back and neck procedures W catastrophic or severe CC	45	15,771	709,695
I10B	Other back and neck procedures W/O catastrophic or severe CC	882	4,917	4,336,794
L07A	Transurethral procedures except prostatectomy W CC	1	5,941	5,941
			Total Cost in 2011	€8,344,484

Key: OR – operating room; W – with; W/O – without; CC – complication or comorbidity; Cat – catastrophic; Procs – procedures.

2.5 Advice on clinical referral/treatment threshold

Evidence suggests that given the natural history of the condition and the risks associated with surgery, referral to secondary care services with a view to surgery for symptoms associated with degenerative lumbar spine disease should only be considered after conservative management has been tried. However, symptoms indicating an increased risk of serious pathology (termed 'red flag' symptoms) and patients with intractable pain despite optimal conservative management should continue to be referred with appropriate urgency. Therefore, the following criteria are advised for adults with chronic low back pain:

The decision to refer a patient for surgery should be based on consideration of their clinical symptoms, and their potential for functional benefits.

Patients presenting with symptoms of focal neurological deficit and/or other symptoms suggestive of any of the so-called 'red flag' conditions (e.g. cauda equina syndrome, spinal fracture, malignancy, infection, spondyloarthropathies or visceral disease) as well as patients with intractable pain despite optimal conservative care should be referred for urgent review.

Patients should not be routinely referred for surgical review if their quality of life or ability to function is not compromised. Patients who are not referred for surgery should remain under the care of their primary care practitioner (general practitioner, physiotherapist) and be reassessed as appropriate.

Referral for surgery of patients without 'red flag' conditions is justified and appropriate in the following situations:

- clinical symptoms and diagnostic imaging compatible with spinal stenosis
- OR
- clinical symptoms and diagnostic imaging compatible with radiculopathy due to a prolapsed disc AND failure of symptoms to improve following at least six weeks of conservative management which includes physiotherapy where appropriate
- OR
- clinical symptoms and diagnostic imaging compatible with spinal instability and/or deformity AND failure of symptoms to improve following at least six weeks of conservative management which may include physiotherapy where appropriate
- OR
- referral for an opinion on spinal fusion may be considered if a patient has severe non-specific axial back pain due to lumbar degenerative disc disease for which they would consider surgery if there has been no improvement in symptoms

following at least one year of structured conservative management.

3 Discussion

Back pain as a result of degenerative lumbar spine disease is a common problem. However, 85% of patients seen in the primary care setting have non-specific low back pain that cannot reliably be attributed to a specific disease or spinal abnormality. Most cases of back pain improve spontaneously within a few weeks, with only a small minority going on to develop chronic back pain. Spinal surgery is performed in patients with a diverse range of conditions. Patients presenting with focal neurological deficit and symptoms suggestive of cauda equina syndrome, spinal fracture, malignancy, infection, spondyloarthropathies or visceral disease should continue to be referred for urgent surgical review.

Clinical evidence suggests most patients with simple degenerative disease will benefit from a structured conservative management programme and a significant proportion of patients will improve spontaneously within a number of weeks. For these patients, undergoing surgery would provide little clinical benefit, but entails all the associated risks and costs. Without any clear referral criteria in place in Ireland for back pain, this has inevitably led to variation in the referral patterns. Referral too early could lead to some patients not availing of either their outpatient appointment or surgery if symptoms have improved or resolved while waiting, particularly if they are obtaining ongoing structured conservative management.

As noted, the number of surgeries for degenerative lumbar spine disease performed in the publicly funded system is not expected to reduce as a result of implementing stated treatment thresholds. The suggested referral criteria reflect existing best practice in Ireland, however, as noted in section 1.4, there is currently some evidence of regional variation in surgical activity which may indicate differences in access or clinical practice - implementing standardised referral and treatment criteria should reduce this variation.

There are a number of caveats to the effective implementation of referral and treatment thresholds. The first is the absence of a definition of what 'structured conservative management' or 'structured rehabilitation' programmes entail in Ireland. In the absence of such definitions, there will continue to be huge variability in what is available and offered to patients. In the interest of clarity, equity of access nationally and efficient use of resources, evidence-based guidelines are required to describe the essential components of this care. It is likely that there will need to be a reallocation of resources to ensure there is timely access to such care in the primary care setting

as a key barrier identified to the implementation of thresholds is the limited access to conservative treatment in the primary care setting. It is reported that there is extremely limited access to physiotherapy and particularly to musculoskeletal (MSK) specialists and multidisciplinary rehabilitation programmes. Waiting lists for general physiotherapy services may exceed six weeks. Therefore, patients may continue to be referred to hospital-based specialists to provide conservative treatment in the absence of adequate primary care services. Of note, initiatives are underway by the orthopaedic and rheumatology clinical care programmes in the Health Service Executive (HSE) to develop interface clinics and consultations between primary and secondary care services in Ireland and to implement agreed national referral guidelines for all patients with musculoskeletal disease.

The aim of standardised referral criteria is to ensure that all patients receive the right care, at the right time and in the right setting. By implementing referral thresholds, patients would attend hospital only when appropriate, and remain under the care of their primary care practitioner until then. This would potentially improve the patient pathway through reducing unnecessary hospital appointments, leading to a reduction in waiting times for these appointments, improving access for those with the greatest clinical need. Given the existing data, it is difficult to estimate what impact, if any, the introduction of formal thresholds would have on outpatient referrals and surgical activity. However, the consistent use of stated thresholds that are integrated into agreed national referral and treatment guidelines should bring greater transparency, ensure equity of access based on clinical need and allow maximal benefit to be gained from existing primary and specialist resources.

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Appendix 1 – Procedure and diagnostic codes used to retrieve HIPE data

App Table 1. Procedure codes related to degenerative lumbar spine disease

	Block	Procedure code	Description
Discectomy	51	40303-00	Discectomy for recurrent disc lesion, 1 level
		40303-01	Discectomy for recurrent disc lesion, ≥ 2 levels
	52	48636-00	Percutaneous lumbar discectomy
		40300-00	Discectomy, 1 level
		40300-01	Discectomy, ≥ 2 levels
Spinal fusion	1389	48660-00	Anterior spinal fusion, 1 level
		48669-00	Anterior spinal fusion, □ 2 levels
		48642-00	Posterior spinal fusion, 1 or 2 levels
		48645-00	Posterior spinal fusion, □ 3 levels
		48648-00	Posterolateral spinal fusion, 1 or 2 levels
		48651-00	Posterolateral spinal fusion, □ 3 levels
		48654-00	Posterior spinal fusion with laminectomy, 1 level
		48657-00	Posterior spinal fusion with laminectomy, □ 2 levels
		48654-01	Posterolateral spinal fusion with laminectomy, 1 level
		48657-01	Posterolateral spinal fusion with laminectomy, □ 2 levels
Decompression	47	40351-00	Anterior decompression of thoracolumbar spinal cord
		90024-00	Decompression of lumbar spinal canal, 1 level
	48	90024-01	Decompression of lumbar spinal canal, □ 2 levels

App Table 2. Diagnosis codes related to degenerative lumbar spine disease

Diagnosis code	Description
M51.1	Lumbar and other intervertebral disc disorders with radiculopathy
M51.2	Other specified intervertebral disc displacement
M43.16	Spondylolisthesis (Lumbar region)
M47	Spondylosis
M48.06	Spinal stenosis (Lumbar region)
M48.07	Spinal stenosis (Lumbosacral region)
M53.2	Spinal instabilities
M54.1	Radiculopathy
M54.3	Sciatica
M54.4	Lumbago with sciatica
M54.5	Low back pain

Appendix 2 – Clinical guidelines, systematic reviews and international thresholds

Clinical guidelines			
Guideline	Scope	Discectomy thresholds	Evidence
NICE CG88 (2009) UK ⁽²⁵⁾	Indications: Non-specific low back pain Population: Adults	Referral for discectomy is not recommended for patients with non-specific low back pain.	Literature review: Systematic Grading system: NICE
ASIPP(The American Society of Interventional Pain Physicians) Interventional Pain Management (IPM) Guidelines (2009) US ⁽²⁶⁾	Indications: Disc prolapse, protrusion or extrusion Population: Adults	Common indications for manual percutaneous disc decompression are as follows: 1) Unilateral leg pain greater than back pain. 2) Radicular symptoms in a specific dermatomal distribution that correlates with MRI findings. 3) Positive straight leg raising test or positive bowstring sign, or both. 4) Neurologic findings or radicular symptoms. 5) No improvement after six weeks of conservative therapy. 6) Imaging studies (CT, MRI, discography) indicating a subligamentous contained disc herniation. 7) Well maintained disc height of 60%.	Literature review: Systematic Grading system: USPSTF Key references: Gibson and Waddell
American Pain Society-Clinical Practice Guideline (2009) US ⁽²⁷⁾	Indications: Radiculopathy due to herniated lumbar disc, persistent and disabling leg pain due to spinal stenosis Population: Adults	In patients with persistent and disabling radiculopathy due to herniated lumbar disc or persistent and disabling leg pain due to spinal stenosis, it is recommended that clinicians discuss risks and benefits of surgery as an option. It is recommended that shared decision-making regarding surgery include a specific discussion about moderate average benefits, which appear to decrease over time in patients who undergo surgery.	Literature review: Systematic Grading system: USPSTF Key references: Peul et al., Weinstein et al.
North American Spine Society (2007) North America ⁽¹⁵⁾	Indications: Spinal stenosis Population: Adults	Direct surgical decompression is recommended for treatment of patients with symptomatic spinal stenosis associated with low-grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment. Surgical decompression with fusion is recommended for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone.	Literature review: Systematic Grading system: Key references: Matsudaira et al. Weinstein et al.
Toward Optimized Practice (2011) Alberta, Canada	Indications: Acute and sub-acute low back pain, chronic low back pain,	Consider referral for an opinion on spinal fusion for patients who: • Have completed an optimal package of care including a combined physical and psychological treatment program (usually six months of care) • Still have severe low back pain for which the patient would consider surgery, particularly if related	Literature review: No guidelines based on expert opinion, after examining other

<p>(29)</p>	<p>acute and sub-acute, sciatica/radiculopathy, chronic sciatica/radiculopathy Population: Adults</p>	<p>to spinal stenosis with leg pain. Offer anyone with significant psychological distress appropriate treatment for this before referral for an opinion on spinal fusion.</p> <p>Exclusions: pregnant women; patients <18 years; diagnosis or treatment of specific causes of low back pain such as: inpatient treatments (surgical treatments); referred pain (from abdomen, kidney, ovary, pelvis, bladder); inflammatory conditions (rheumatoid arthritis, ankylosing spondylitis); infections (neuralgia, discitis, osteomyelitis, epidural abscess); degenerative and structural changes (spondylosis, spondylolisthesis, gross scoliosis and/or kyphosis); fracture; neoplasm; metabolic bone disease (osteoporosis, osteomalacia, Paget's disease).</p>	<p>references nominated by guideline development group members</p>
<p>NICE CG88 (2009) UK⁽²⁸⁾</p>	<p>Indications: Non-specific low back pain Population: Adults with low back pain for >6 weeks and <12 months</p>	<p>Consider referral for an opinion on spinal fusion for people who:</p> <ul style="list-style-type: none"> • have completed an optimal package of care, including a combined physical and psychological treatment programme • still have severe non-specific low back pain for which they would consider surgery. <p>Exclusions: malignancy, infection, osteoporotic collapse, fracture, ankylosing spondylitis or other inflammatory disorders, sciatica and cauda equina syndrome, children <18 years, people with acute low back pain (<6 weeks' duration), people with non-specific low back pain of >12 months' duration.</p>	<p>Literature review: Systematic Grading system: NICE Key references: Ibrahim et al., Mirza et al. Rivero et al.</p>
<p>American Pain Society (2009) US⁽²⁷⁾</p>	<p>Indications: Persistent low back pain Population: Adults</p>	<p>Fusion surgery is recommended for non-radicular low back pain with common degenerative changes.</p> <p>Laminectomy with or without fusion is recommended for symptomatic spinal stenosis with or without degenerative spondylolisthesis</p> <p>The guideline does not cover patients with back pain associated with major trauma, tumour, metabolic disease, inflammatory back disease, fracture, dislocation, major instability, or major deformity; patients with progressive or severe neurologic deficits; children or adolescents with low back pain; pregnant women, patients with low back pain from sources outside the back, and thoracic or cervical spine pain.</p>	<p>Literature review: Systematic Grading system: US Preventive Services Task Force Key references: Brox 2003, Brox 2006, Fairbank, Fritzell</p>
<p>North American Spine Society (2011) US⁽³⁰⁾</p>	<p>Indications: Spinal stenosis Population: Adults</p>	<p>In the absence of reliable evidence, it is the work group's opinion that the natural history of patients with clinically mild to moderately symptomatic degenerative lumbar stenosis can be favourable in about one third to one half of patients. (Work Group Consensus Statement.)</p> <p>In the absence of reliable evidence, it is the work group's opinion that in patients with mild or moderately symptomatic degenerative lumbar stenosis, rapid or catastrophic neurologic decline is rare. (Work Group Consensus Statement.)</p> <p>Decompressive surgery is suggested to improve outcomes in patients with moderate to severe symptoms of lumbar spinal stenosis. Grade of Recommendation: B</p>	<p>Literature review: Systematic Grading system: Levels of Evidence for Primary Research Questions grading scale Key references: See relevant section of report</p>

		<p>In the absence of evidence for or against any specific treatment, it is the work group's recommendation that medical/interventional treatment be considered for patients with mild symptoms of lumbar spinal stenosis. (Work Group Consensus Statement.)</p> <p>There is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis. Grade of Recommendation: I (Insufficient Evidence).</p> <p>Decompression alone is suggested for patients with leg predominant symptoms without instability. Grade of Recommendation: B.</p> <p>Surgical treatment may be considered to provide long-term (four+ years) improvement in patients with degenerative lumbar spinal stenosis and has been shown to improve outcomes in a large percentage of patients. Grade of Recommendation: C.</p>	
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Systematic reviews

Study	Description	Sample	Finding
Gibson, Waddell (2008) ⁽³²⁾	Cochrane review	n = 5197	Surgical discectomy for carefully selected patients with sciatica due to lumbar disc prolapse provides faster relief from the acute attack than conservative management, although any positive or negative effects on the lifetime natural history of the underlying disc disease are still unclear. Forty RCTs and two quasi RCTs were included in the review.
Chou et al. (2009) ⁽³³⁾	Systematic review	24 included studies	Surgery for radiculopathy with herniated lumbar disc and symptomatic spinal stenosis is associated with short-term benefits compared to conservative management, though benefits diminish with long-term follow-up in some trials. Thirty-five trials evaluated surgery for radiculopathy with herniated lumbar disc and 19 trials evaluated surgery for spinal stenosis with or without degenerative spondylolisthesis.
Dasenbrock et al. (2012) ⁽³⁴⁾	Systematic review and meta-analysis	n = 837	The current evidence suggests that both open discectomy (OD) and minimally invasive discectomy (MID) lead to a substantial and equivalent long-term improvement in leg pain. The mean preoperative VAS score for leg pain was 6.9 in patients randomised to MID and 7.2 in those randomised to OD. With long-term follow-up (one to two years postoperatively), the mean VAS score improved to 1.6 in both the MID and OD cohorts. There was no significant difference in relief of leg pain between the two approaches with either short-term follow-up (two to three months postoperatively, 0.81 points on the VAS, 95% CI -4.71 to 6.32) or long-term follow-up (2.64 on the VAS, 95% CI -2.15 to 7.43).

<p>Gibson Waddell (2008)⁽⁴¹⁾</p>	<p>Cochrane review</p>	<p>31 RCTs identified</p>	<p>Thirty one published RCTs of all forms of surgical treatment for degenerative lumbar spondylosis were identified. The trials varied in quality: only the more recent trials used appropriate methods of randomisation, blinding and independent assessment of outcome. Most of the earlier published results were of technical surgical outcomes with some crude ratings of clinical outcome. More of the recent trials also reported patient-centred outcomes of pain or disability, but there is still very little information on occupational outcomes. There was a particular lack of long-term outcomes beyond two to three years. Seven heterogeneous trials on spondylolisthesis, spinal stenosis and nerve compression permitted limited conclusions. Preliminary data from three trials of disc arthroplasty did not permit any firm conclusions.</p>
<p>Jacobs et al. (2012)⁽⁵⁾</p>	<p>Systematic review</p>	<p>16 studies included</p>	<p>The goal of this study was to compare the effect of different surgical techniques for sciatica due to disc herniation. Sixteen studies were included, of which four had a low risk of bias. Studies showed that microscopic discectomy results in a significantly, but not clinically relevant, longer operation time of 12 minutes (95 % CI 2–22) and shorter incision of 24 mm (95 % CI 7–40) compared with open discectomy, but did not find any clinically relevant superiority of either technique on clinical results. There were conflicting results regarding the comparison of tubular discectomy versus microscopic discectomy for back pain and surgical duration. Due to the limited amount and quality of evidence, no firm conclusions can be drawn on effectiveness of the current surgical techniques being open discectomy, microscopic discectomy, and tubular discectomy compared with each other.</p>
<p>Jacobs et al. 2011⁽³¹⁾</p>	<p>Systematic review</p>	<p>five studies included</p>	<p>This study assessed the effects of surgery versus conservative therapy (including epidural injections) for patients with sciatica due to lumbar disc herniation. Five studies were identified, two of which with a low risk of bias. One study compared early surgery with prolonged conservative management followed by surgery if needed; three studies compared surgery with usual conservative management, and one study compared surgery with epidural injections. One large low-risk-of-bias trial demonstrated that early surgery in patients with 6 to 12 weeks of radicular pain leads to faster pain relief when compared to prolonged conservative treatment, but there were no differences after one and two years. Another large low-risk-of-bias trial between surgery and usual conservative management found no statistically significant differences on any of the primary outcome measures after one and two years.</p>
<p>Lewis et al. 2011⁽³⁵⁾</p>	<p>Health technology assessment</p>	<p>12 studies included</p>	<p>This HTA investigated the clinical and cost-effectiveness of different management strategies for sciatica by undertaking a systematic review and an economic evaluation. They found support for the effectiveness of currently used therapies for sciatica, such as non-opioid medication, epidural corticosteroid injections and disc surgery, but also for chemonucleolysis, which is no longer used in the UK NHS. In addition, they did not find support for the clinical effectiveness of opioid analgesia, which is widely used in this patient group. They also suggest that less frequently used treatments, such as acupuncture, and experimental treatments, such as anti-inflammatory biological agents, may be effective. In terms of cost-effectiveness, the argument for stepped approaches based on an initial treatment with non-opioids, as opposed to direct referral for surgery, was apparent.</p>

Cheng et al. 2011 ⁽³⁶⁾	Review of guidelines and payer policies	Three previous reviews and a sample of five clinical guidelines included	There is some consistency across guidelines and policies that are government sponsored with regard to development process and critical evaluation of index studies as well as overall recommendations. There were differences in specialty society recommendations. There is heterogeneity in the medical payer policies reviewed, possibly due to variations in the literature cited and transparency of the development process. A description of how recommendations are formulated and disclosure of any potential bias in policy development is important. Three medical payer policies reviewed are of poor quality, with one rated as good with respect to their development based on the modified Appraisal of Guidelines Research and Evaluation tool.
Jacobs et al. 2013 ⁽³⁷⁾	Overview of systematic reviews	13 systematic reviews identified	For the treatment of spinal stenosis, intervertebral process devices showed more favourable results compared to conservative treatment on the Zurich Claudication Questionnaire [mean difference (MD) 23.2 95% CI 18.5–27.8]. For degenerative spondylolisthesis, fusion showed more favourable results compared to decompression for a mixed aggregation of clinical outcome measures (RR 1.40 95 % CI 1.04–1.89) and fusion rate favoured instrumented fusion over non-instrumented fusion (RR 1.37 95 % CI 1.07–1.75).
Jarrett et al. 2012 ⁽³⁸⁾	Systematic review	One study directly comparing surgery with exercise	Studies were included if one of the intervention arms was a land-based exercise or decompressive surgery. Studies were only included if they specified the exercise type such as flexibility, range of movement, strengthening and/or general conditioning. Aquatic exercises were excluded. Studies that combined other forms of conservative intervention, such as manual therapy, electrotherapy or medication, were included provided an exercise intervention was also undertaken. Surgery demonstrated statistically significant improvements in patient reported functional outcome scores at 6, 12 and 24-months post-intervention ($p < 0.01$).
Kovacs et al. 2011 ⁽³⁹⁾	Systematic review of RCTs	Five RCTs identified	In all the studies, surgery showed better results for pain, disability, and quality of life, although not for walking ability. The advantage of surgery was noticeable at three to six months and remained for up to two to four years, although at the end of that period differences tended to be smaller.
Tran et al. 2010 ⁽⁴⁰⁾	Systematic review of RCTs of non-surgical treatment	13 RCTs identified	'The available evidence suggests that parenteral calcitonin, but not intranasal calcitonin, can transiently decrease pain in patients with LSS. In the setting of epidural blocks, local anaesthetics can improve pain and function, but the benefits seem short lived. The available evidence does not support the addition of steroids to local anaesthetic agents. Based on the limited evidence, passive physical therapy seems to provide minimal benefits in LSS. The optimal regimen for active physiotherapy remains unknown. Although benefits have been reported with gabapentin, limaprost, methylcobalamin, and epidural adhesiolysis, further trials are required to validate these findings.'

Referral and treatment thresholds			
Examples of UK PCT thresholds	Scope	Threshold	Evidence
Bedfordshire and Hertfordshire PCTs (2011) ⁽⁵²⁾	Indications: Sciatica due to lumbar disc prolapse Population: Adults	Discectomy can be recommended in patients with sciatica due to lumbar disc prolapse that fails to resolve with conservative management after four to six weeks. In the majority of patients symptoms will resolve within a month.	Bigos S et al. 1994. Van Tulder et al. 2004 NICE CG88
Berkshire PCTs (2010) ⁽⁵³⁾	Indications: Chronic, non-specific low back pain Population: Adults	It is recommended that the use of discectomy for the treatment of chronic, non-specific low back pain should be low priority, on the grounds of limited evidence of clinical effectiveness. This policy does not cover back pain for which a specific cause is suspected or where there is evidence of impairment of spinal nerves, e.g. malignancy, infection, fracture, ankylosing spondylitis and other inflammatory disorders, radicular pain resulting from nerve root compression (sciatica) and cauda equina syndrome.	NICE CG88
Cambridgeshire and Peterborough PCTs (2011) ⁽⁵⁴⁾	Indications: Sciatica secondary to disc prolapse, severe spinal stenosis, chronic, non-specific low back pain Population: Adults	Patients with lumbar disc conditions including 'acute on chronic' or chronic low back pain (duration of >6 weeks) will only receive non-acute spinal surgery under the following circumstances: 1. Surgical discectomy (standard or microdiscectomy) in selected patients with sciatica secondary to disc prolapse where conservative management has failed for at least four to six weeks; and <ul style="list-style-type: none"> • if radicular pain has not responded to non-invasive treatment after four to six weeks • the patient has been referred to Tier II musculoskeletal assessment service for assessment for spinal surgery or other non-invasive intervention • the patient has lumbar radiculopathy with corresponding intervertebral disc prolapse on MRI. 2. Severe spinal stenosis with symptoms of neurogenic claudication and an MRI shows significant canal stenosis. Low Priority 1. The use of spinal surgery for the treatment of chronic, non-specific low back pain not covered by this policy is a low priority on the grounds of limited evidence of clinical effectiveness. Referral and treatment should only be considered under exceptional circumstances. 2. Endoscopic laser spinal surgery (discectomy, foraminoplasty or endoscopic division of epidural adhesions) for chronic back and leg pain, caused by disc prolapse or adhesions formed around the spinal nerve roots is of unproven benefit and should not be performed. This policy refers to chronic back pain and does not include acute back pain conditions such as fracture, dislocation, complications of tumour or infection and/or nerve root or spinal compression responsible for progressive neurological deficit. This policy does not cover some of the causes of chronic back pain such as osteoporosis and related compression fractures, lumbar spine arthritis, infection, tumour, sagittal imbalance and spinal deformity. GPs should refer to secondary care directly for 'red flag patients', i.e. suspected cancer or cauda equina compression.	Van Tulder M et al. 2004 Gibson JNA, Waddell G. 2005 Fairbank J et al. 2005 Rivero-Arias O, et al. 2005 Airaksinen O et al. 2005 Gamlin G et al NICE IPG365, IPG366, IPG306, CG88, IPG0357, IPG031, IPG061, IPG303, IPG333 Airaksinen O et

<p>Outer North East London PCTs (2011)⁽⁵⁵⁾</p>	<p>Indications: Lumbar prolapse Population: Adults</p>	<p>The following criteria will be in place for eligibility of patients for discectomy:</p> <ul style="list-style-type: none"> • The patient is 18 years or older. • The patient has had MRI, showing disc herniation (protrusion, extrusion, or sequestered fragment) at a level and side corresponding to the clinical symptoms. • The patient has a corresponding neurologic deficit (asymmetrical depressed reflex, decreased sensation in a dermatomal distribution, or weakness in a myotomal distribution, altered bowel or bladder function); OR The patient has radicular pain (below the knee for lower lumbar herniations, into the anterior thigh for upper lumbar herniations) consistent with the level of spinal involvement; OR There is evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise—positive between 30° and 70° or positive femoral tension sign). • Symptoms persist despite some conservative treatment for at least six weeks (e.g. analgesia, physiotherapy, bed rest etc.). <p>When assessing people with acute or chronic low back pain, check for the presence or absence of red flags for serious conditions including cauda equina syndrome, spinal fracture, cancer or infection.</p>	<p>al. 2006 Gibson JNA, Waddell G. 2007 Weber H. 1983 Weinstein JN, et al. 2006 Butterman GR. 2004 Greenfield K, et al. 2003 Hoffman RM et al. 1993 Malter AD et al. 1996</p>
<p>Bedfordshire and Hertfordshire PCTs⁽⁵²⁾</p>	<p>Indications: Non-specific low back pain Population: Adults</p>	<p>Recommendations:</p> <ul style="list-style-type: none"> • The majority of patients with non-specific low back pain can be managed in a primary care setting. Pharmacological recommendations include NSAIDS, weak opioids, noradrenergic or noradrenergic-serotonergic antidepressants and muscle relaxants. • For patients not improving with primary care management, a multidisciplinary approach including physiotherapy and cognitive interventions is recommended in the management of chronic low back pain. • Fusion surgery may be considered in selected patients with severe pain after active rehabilitation programmes (see above) over two years have failed. <p>The recommendations do not apply to patients with neurological claudication or progressive neurological symptoms.</p>	<p>Bigos et al Van der Heijden GJ et al. Van Tulder et al. NICE CG88</p>
<p>Black County Cluster⁽⁶⁴⁾</p>	<p>Indications: Chronic, non-specific low back pain Population: Adults</p>	<p>Unless the following criteria are met spinal fusion will not normally be funded for chronic degenerative low back pain:</p> <ul style="list-style-type: none"> • The patient has been assessed by a clinician trained in the diagnosis and management of chronic low back pain. • The low back pain has lasted >1 year and is documented as significantly interfering with daily life (e.g. loss of function >50% on EuroQoL or BPI tool). • All conservative management functions, undertaken as part of a comprehensive pain management programme, have failed (physiotherapy guided exercise, maximal analgesia and muscle relaxants, psychological therapy). <p>Exceptions: clear cut root compression, spinal stenosis or instability.</p>	<p>NICE CG88</p>
<p>Cambridgeshire and Peterborough⁽⁵⁴⁾</p>	<p>Indications: chronic</p>	<p>Patients presenting mainly with problems of lumbar spondylosis without compromise to the nerve root should be treated conservatively. Access to physiotherapy advice and pain relief should be available to shorten absence</p>	<p>Airaksinen et al den Boer JJ et</p>

	<p>lumbar conditions Population: Adults</p>	<p>from work and usual activities.</p> <p>Patients with lumbar disc conditions including 'acute on chronic' or chronic low back pain (duration >6 weeks), will only receive non-acute spinal surgery under the following circumstances:</p> <ul style="list-style-type: none"> • Spinal fusion may be considered for non-specific back pain if severe pain continues despite two years of active rehabilitation, cognitive intervention combined with exercises where available and the patient has been assessed by a specialist using appropriate scans. <p>The use of spinal surgery for the treatment of chronic, non-specific low back pain not covered by this policy is a low priority on the grounds of limited evidence of clinical effectiveness.</p> <p>This policy does not cover some of the causes of chronic back pain such as osteoporosis and related compression fractures, lumbar spine arthritis, infection, tumour, sagittal imbalance and spinal deformity. GPs should refer to secondary care directly for 'red flag patients', i.e. suspected cancer or cauda inject compression.</p> <p>Surgical management</p> <p>Patients with lumbar disc conditions including 'acute on chronic' or chronic low back pain (duration of over six weeks) will only receive non-acute spinal surgery under the following circumstances:</p> <ol style="list-style-type: none"> 1. Surgical discectomy (standard or microdiscectomy) in selected patients with sciatica secondary to disc prolapse where conservative management has failed for at least four to six weeks; and <ul style="list-style-type: none"> · if radicular pain has not responded to non-invasive treatment after four to six weeks; and <ul style="list-style-type: none"> · the patient has been referred to Tier II musculoskeletal assessment service for assessment for spinal surgery or other non-invasive intervention; and <ul style="list-style-type: none"> · the patient has lumbar radiculopathy with corresponding intervertebral disc prolapse on magnetic resonance imaging (MRI). 2. Severe spinal stenosis with symptoms of neurogenic claudication and the MRI shows significant canal stenosis (IPG 365). 3. Spinal fusion may be considered for non-specific back pain if severe pain continues despite two years of active rehabilitation, cognitive intervention combined with exercises where available and the patient has been assessed by a specialist using appropriate scans (CG88). 	<p>al. Fairbank J et al. Gibson JNA and Waddell G Jacobs et al. 2006 NICE CG88 NICE IPG 365 NICE IPG 843 NICE IPG366 NICE IPG306 NICE IPG321 Rivero-Arias O et al. Savigny et al. Van Tulder et al.</p>
<p>Suffolk PCT⁽⁶⁵⁾</p>	<p>Indications: Non-acute lumbar conditions Population:</p>	<p>Patients will only receive non-acute spinal surgery under the following circumstances:</p> <p>Surgical discectomy (standard or microdiscectomy) in selected patients with sciatica secondary to disc prolapse where conservative management for at least four to six weeks has failed.</p>	<p>NICE CG88 Van Tulder et al. Gibson JNA and</p>

	Adults	<p>It is recommended that primary care referral for assessment for spinal surgery or other invasive intervention should only be considered if radicular pain has not responded to non-invasive treatment after four to six weeks.</p> <p>Fusion surgery for chronic low back pain may be considered if severe pain despite two years of an 'active rehabilitation programme' (cognitive intervention combined with exercises is recommended when available).</p> <p>There is no or insufficient current evidence of effectiveness, and no routine funding available for:</p> <ul style="list-style-type: none"> • newer forms of thermal and laser spinal procedures • trigger point injections • use of epidural and para vertebral injections except in areas where an authorised clinical assessment service exists and provided according to existing clinical protocols • surgery for degenerative lumbar spondylosis/degenerative disc disease/spinal stenosis except in cases of severe spinal stenosis with progressive neurological deficits or severe neurogenic claudication and where an authorised clinical assessment service exists. 	<p>Waddell G. Rivero-Arias O et al. Ibrahim et al. Mirza SK and Deyo RA Gibson JNA and Waddell G.</p>
Derby City and Derbyshire ⁽⁶⁶⁾	<p>Indications: Back Pain Population: Adults</p>	<p>The PCT will fund spinal fusion when there is:</p> <ul style="list-style-type: none"> • unequivocal root compression • spinal stenosis • instability • failure of adequate conservative trial of >6 months duration. 	
Outer North East London ⁽⁵⁵⁾	<p>Indications: Non-acute lumbar conditions Population: Adults</p>	<p>If the referring clinician has the clinical suspicion for one of the following diagnoses then urgent referral to a specialist spinal surgeon is recommended: malignancy, fracture, cauda equina syndrome, infection, ankylosing spondylitis and other inflammatory disorders.</p> <p>Spinal surgery: Consider referral for an opinion on spinal fusion for people who:</p> <ul style="list-style-type: none"> • have completed an optimal package of care, including a combined physical and psychological treatment programme • Still have severe non-specific low back pain for which they would consider surgery. <p>When assessing people with acute or chronic low back pain check for the presence or absence of red flags for serious conditions including: cauda equina syndrome, spinal fracture, cancer or infection.</p>	<p>Gibson JNA and Waddell G NICE CG88 Chou et al 2007</p>

Examples of other national and international thresholds					
AMNCH Spinal Referral Pathway (Ireland) ⁽⁷³⁾	ROUTINE REFERRAL				
	Condition	BPSC	Ortho	Rheum Pain	
	Mechanical back/neck pain lasting > 6-8 weeks and with no improvement in symptoms following a course of appropriate physiotherapy(*see below)	x			
	Nerve root pain without neurological weakness with no improvement after 4-6 weeks (**see below)	x			
	Disc Prolapse	x			
	Sacro-Iliac Joint (SIJ) Pain	x			
	Spinal Stenosis (Lateral/Central)	x			
	Lumbar/Cervical Facet joint pain	x			
	Paget's disease or other bone disease			x	
	Metabolic arthropathy			x	
	Sacroilitis/Inflammatory Spinal Pathology			x	
	Post-surgery failed back syndrome			x	
	Chronic back pain with no neurological abnormalities/ structural damage or systemic illness & having failed a course of appropriate physiotherapy			x	
	<p>*Mechanical Back/Neck Pain lasting > 6- 8 weeks and with no improvement in symptoms following a course of appropriate physiotherapy</p> <ul style="list-style-type: none"> • Presentation: <ul style="list-style-type: none"> ○ 18-55 years ○ mechanical type pain (varies with posture and activity usually better when lies down flat) ○ pain in lower back, buttock or posterior thigh ○ patient otherwise well • These patients can be initially managed in primary care and referral to primary care physiotherapy (where available) is recommended. • These patients should be referred to BPSC after 6-8 weeks in instances of <ul style="list-style-type: none"> ○ problems with pain control or ○ no improvement in symptoms despite a course of appropriate physiotherapy. <p>**Nerve root pain without neurological weakness with no improvement after four to six weeks.</p> <ul style="list-style-type: none"> • Presentation: <ul style="list-style-type: none"> ○ unilateral leg/arm pain that is worse than back/neck pain ○ radiates below knee/elbow ○ numbness or paraesthesia in same distribution ○ straight leg raise increases leg pain • These patients should be referred to BPSC if no improvement after four to six weeks. 				

<p>Catalan health Service (2011) Catalan Region, Spain⁽⁶⁸⁾</p>	<p>Indications: On surgical waiting list for spinal fusion</p>	<p>Priority-setting system for patients on waiting list for spine or spinal fusion elective surgery based on weighted scoring across nine categories, including probability of recovery, neuropathic pain, mechanical pain, neurological deficit, progression of deformity, limitations to activities of daily living, limitations to work or other activities, whether the person has a carer or is caring for someone else.</p> <p>See: http://www.gencat.cat/salut/depsan/units/aatrm/pdf/priority_spine_surgery_summary_aiaqs2011en.pdf for full details including detailed scoring criteria and relative weights.</p>	
<p>Bluechoice Healthplan of South Carolina⁽⁶⁷⁾</p>	<p>Indications: chronic low back pain when conservative treatment options have been unsuccessful</p>	<p>Lumbar Fusion NOTE: the criteria also apply to lumbar fusion performed at an adjacent level to prior lumbar fusion.</p> <p>Lumbar fusion at a single level is considered medically necessary when one or more of the following indications are met:</p> <ol style="list-style-type: none"> 1. The individual has symptomatic spondylolisthesis confirmed on X-ray and a), b), or c) are met: <ol style="list-style-type: none"> a. Age > 18 years with low- or high-grade spondylolisthesis and persistent symptomatic pain or functional impairment, despite at least six months of appropriate conservative treatment; or b. Age <18 years with high-grade (50% or more anterior slippage) spondylolisthesis; or c. The individual has progressive or severe neurologic deficits (for example, bowel or bladder dysfunction); <p style="text-align: center;">OR</p> 2. The individual has symptomatic lumbar spinal stenosis and meets ALL of the following: <ol style="list-style-type: none"> a. The stenosis is moderate to severe; and b. There is clinically significant functional impairment, despite at least three months of conservative medical therapy; and c. The individual meets one or more of the following: <ol style="list-style-type: none"> i. Lumbar spondylolisthesis demonstrated on X-ray; or ii. Spinal instability demonstrated on imaging studies; or iii. Spinal instability is anticipated due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis; <p style="text-align: center;">OR</p> 3. The individual has a spinal fracture and evidence of spinal instability (for example, burst fracture) or neural compression; <p style="text-align: center;">OR</p> <p>The individual is undergoing a spinal repair with fusion for instability due to extensive surgery when performed with other procedures (for example, laminectomy) for neural decompression, fracture, dislocation, infection, abscess, or tumour;</p>	

		<p>OR</p> <ol style="list-style-type: none"> 1. The individual has symptomatic and severe degenerative scoliosis with: <ol style="list-style-type: none"> a. Persistent severe axial pain, persistent weakness with functional impairment, persistent neurogenic claudication, or persistent radicular pain, unresponsive to at least three months of conservative medical therapy; or b. Deformity greater than 50 degrees with functional impairment; <p style="text-align: center;">OR</p> 2. The individual has symptomatic lumbar pseudoarthrosis and it has been at least six months since the initial fusion and ALL of the following: <ol style="list-style-type: none"> a. The pseudoarthrosis is documented radiographically; and b. There is persistent axial pain with clinically significant functional impairment, despite at least three months of conservative medical management; and c. Symptomatic relief had been demonstrated after the initial fusion; <p style="text-align: center;">OR</p> 3. The individual requires disc excision or re-operative discectomy and has radiculopathy secondary to a herniated disc and radiographic evidence of lumbar spinal instability (for example, spondylolisthesis). <p>Not medically necessary:</p> <p>Lumbar fusion is considered not medically necessary when the criteria listed above are not met, including but not limited to:</p> <p>For low back pain due to degenerative disc disease or degenerative lumbar spondylosis without stenosis or spondylolisthesis.</p>	
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Key: BPSC – Back Pain Screening Clinic; CT – computed tomography; GP: general practitioner; MID – micro-discectomy; MRI – magnetic resonance imaging; NICE – National Institute for Health and Care Excellence; OD – open discectomy; Ortho – Orthopaedics; PCT – primary care trust; PT – physiotherapy; RCT – randomised controlled trial; Rheum – Rheumatology; VAS – visual analog scale; QRCT – quasi randomised controlled trial.

Appendix 3 – Cost-effectiveness studies

Study (year)	Type (Country)	Population	Findings
Malter et al. (1996) ⁽⁴⁸⁾	Economic evaluation (US)	n = 126, herniated disc patients	Surgery increased average quality-adjusted life-year (QALY) expectancy by 0.43 years during the decade following treatment. Reimbursements for surgical patients were \$12,550 more than for medical patients. Non-discounted and 5% discounted cost-effectiveness were \$29,200 and \$33,900 per quality-adjusted year of life gained. Direct hospital costs only were included.
Tosteson et al. (2008) ⁽⁴⁶⁾	Economic evaluation (US)	n = 1191, lumbar intervertebral disc herniation	Among patients who underwent surgery and who were treated conservatively, the mean difference in QALYs over two years was 0.21 (95% CI: 0.16–0.25) in favour of surgery. Surgery was more costly than conservative management; the mean difference in cost was USD\$14,137 (95% CI: \$11,737–16,770). The ICER gained for surgery relative to conservative management was USD\$69,403 (95% CI: \$49,523–94,999) using general adult surgery costs and USD\$34,355 (95% CI: \$20,419–52,512) using Medicare population surgery costs. Surgery was moderately cost-effective when evaluated over two years. The estimated economic value of surgery varied considerably according to the method used for assigning surgical costs. Both direct and indirect costs were included.
van den Hout et al. (2008) ⁽⁴⁹⁾	Economic evaluation (Netherlands)	n = 283, sciatica for 6-12 weeks, caused by lumbar disc herniation	Compared to prolonged conservative management, early surgery provided faster recovery, with a gain in QALYs according to the UK EuroQol of 0.044 (95% CI 0.005 to 0.083), the USEuroQol of 0.032 (0.005 to 0.059), the SF-6D of 0.024 (0.003 to 0.046), and the visual analogue scale of 0.032 (–0.003 to 0.066). From the healthcare perspective, early surgery resulted in higher costs (difference €1,819 [£1,449; \$2,832], 95% CI €842 to €2,790), with a cost-utility ratio per QALY of €41,000 (€14,000 to €430,000). From the societal perspective, savings on productivity costs led to a negligible total difference in cost (€–12, €–4,029 to €4,006). Faster recovery from sciatica makes early surgery likely to be cost effective compared to prolonged conservative management. The estimated difference in healthcare costs was acceptable and was compensated for by the difference in absenteeism from work. For a willingness to pay of €40,000 or more per QALY, early surgery need not be withheld for economic reasons.
Lewis et al. 2011 ⁽³⁵⁾	Health technology assessment (HTA)	N/A	This HTA investigated the clinical and cost-effectiveness of different management strategies for sciatica by undertaking a systematic review and an economic evaluation. They found support for the effectiveness of currently used therapies for sciatica, such as non-opioid medication, epidural corticosteroid injections and disc surgery, but also for chemonucleolysis, which is no longer used in the UK NHS. In addition, they did not find support for the clinical effectiveness of opioid analgesia, which is widely used in this patient group. They also suggest that less frequently used treatments, such as acupuncture, and experimental treatments, such as anti-inflammatory biological agents, may be effective. In terms of cost-effectiveness, the argument for stepped approaches based on an initial treatment with non-opioids, as opposed to direct referral for surgery, was apparent.

Rivero et al. 2005 ⁽⁴²⁾	Economic analysis of RCT data	n = 349; 176 randomised to surgery, 173 to intensive rehabilitation	'At two years, 38 patients randomised to rehabilitation had received rehabilitation and surgery whereas just seven surgery patients had received both treatments. The mean total cost per patient was estimated to be GBP£7,830 (SD GBP£5,202) in the surgery group and GBP£4,526 (SD GBP£4,155) in the intensive rehabilitation arm, a significant difference of GBP£3,304 (95% confidence interval GBP£2,317 to GBP£4,291). Mean QALYs over the trial period were 1.004 (SD 0.405) in the surgery group and 0.936 (SD 0.431) in the intensive rehabilitation group, giving a non-significant difference of 0.068 (-0.020 to 0.156). The incremental cost-effectiveness ratio was estimated to be GBP£48,588 per QALY gained (-GBP£279,883 to GBP£372,406).'
Soegaard et al. 2006 ⁽⁴³⁾	Systematic literature review to assess the evidence for cost-effectiveness of various surgical techniques in lumbar spinal fusion	Seven studies identified	'The literature is limited and, in view of the fact that the clinical effects are statistically synonymous, it does not support the use of high-cost techniques. There is a great potential for improvement of methodological quality in economic evaluations of lumbar spinal fusion and further research is imperative.'
Savigny et al. 2009 ⁽²⁸⁾	Clinical guideline with review of cost-effectiveness studies	N/A	Exercise programmes: the analysis suggested that the cost-effectiveness of the included exercise programme, when added to best care had an ICER of £8,300 compared to best care alone. Furthermore, there was about a 60% chance that the estimated ICER was less than £20,000 per QALY. There is health economics evidence that massage is not cost effective compared to normal care or compared to GP advice to exercise. Acupuncture: One NHS-based costs per QALY analysis indicates that we can be 90% certain that acupuncture is cost-effective compared with usual care at 24 months using £20,000/QALY as the threshold of acceptability.
Burnett et al. 2010 ⁽⁴⁴⁾	CEA comparing nonsurgical care, laminectomy, and X-STOP	CEA model, two-year horizon	'Laminectomy was found to be the most effective treatment strategy, followed by X-STOP [an implantable medical device designed to treat spinal stenosis] and then conservative treatment at a two-year time horizon. Both surgical procedures were more costly than conservative treatment. Because laminectomy was both more effective and less costly than X-STOP, it is said to dominate overall. When single level procedures were considered alone, laminectomy was more effective but also more costly than X-STOP.'
Rasanen et al. 2006 ⁽⁴⁵⁾	Cost-utility analysis	Utility data derived from questionnaires from 270 patients	Spinal surgery led to a statistically significant and clinically important improvement in HRQOL (health related quality of life). The cost per QALY gained was reasonable, less than half of that observed, for example, for hip replacement surgery or angioplasty treatment of coronary artery disease; however, a prolonged delay in surgical intervention led to an approximate doubling of the cost per QALY gained by the treatment.
Tosteson et al. 2011 ⁽⁴⁷⁾	CEA based on RCT and observational cohort data	n = 1,594: CEA on outcomes at two and four years	Costs per QALY gained decreased for spinal stenosis from USD\$77,600 at two years to \$59,400 (95% CI: \$37,059, \$125,162) at four years, for degenerative spondylolisthesis from \$115,600 to \$64,300 per QALY (95% CI: \$32,864, \$83,117), and for intervertebral disc herniation from \$34,355 to \$20,600 per QALY (95% CI: \$4,539, \$33,088). Comparative effectiveness evidence for clearly defined diagnostic groups from Spine Patient Outcomes Research Trial shows good value for surgery compared with non-operative care over four years.

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