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REVIEW ARTICLE

The Global Spine Care Initiative: a summary of guidelines on invasive interventions for the management of persistent and disabling spinal pain in low- and middle-income communities

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Abstract

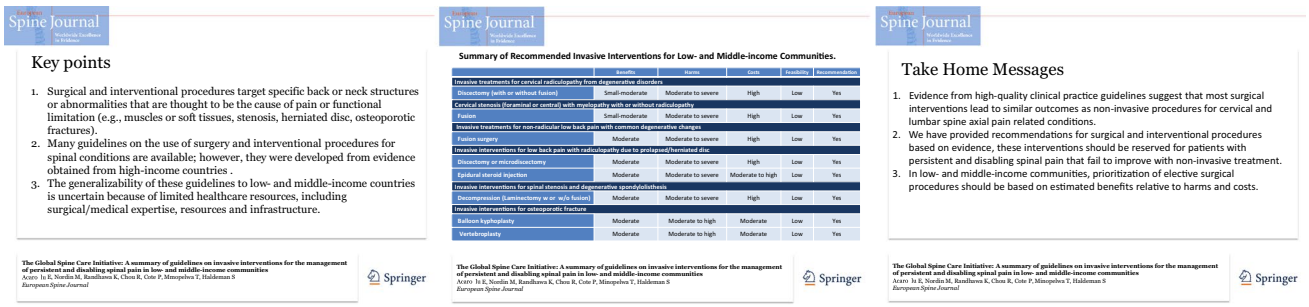
Purpose The purpose of this study was to synthesize recommendations on the use of common elective surgical and interventional procedures for individuals with persistent and disabling non-radicular/axial with or without myelopathy, radicular back pain, cervical myelopathy, symptomatic spinal stenosis, and fractures due to osteoporosis. This review was to inform a clinical care pathway on the patient presentations where surgical interventions could reasonably be considered.

Methods We synthesized recommendations from six evidence-based clinical practice guidelines and one appropriate use criteria guidance for the surgical and interventional management of persistent and disabling spine pain.

Results Lower priority surgery/conditions include fusion for lumbar/non-radicular neck pain and higher priority surgery/conditions include discectomy/decompressive surgery for cervical or lumbar radiculopathy, cervical myelopathy, and lumbar spinal stenosis. Epidural steroid injections are less expensive than most surgeries with fewer harms; however, benefits are small and short lived. Vertebroplasty should be considered over kyphoplasty as an option for patients with severe pain and disability due to osteoporotic vertebral compression fracture.

Conclusion Elective surgery and interventional procedures could be limited in medically underserved areas and low- and middle-income countries due to a lack of resources and surgeons and thus surgical and interventional procedures should be prioritized within these settings. There are non-invasive alternatives that produce similar outcomes and are a recommended option where surgical procedures are not available.

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.



Keywords Spine · Orthopedics · General surgery · Back pain · Neck pain

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Extended author information available on the last page of the article

Introduction

Spinal disorders, including neck and back pain, are a leading source of global disability and place a substantial burden on the healthcare system and society through use of health resources and lost productivity [1–3]. Surgical and interventional procedures target specific back or neck structures or abnormalities that are thought to be the cause of pain or functional limitation (e.g., muscles or soft tissues, stenosis, herniated disc, osteoporotic fractures). Although many cases of spine pain are mild and improve spontaneously, spine pain can also be chronic and recurrent [4–7]. Many patients with acute or chronic low back pain (LBP) improve within the first 6 weeks; however, improvement slows past this point [4]. Furthermore, less than one-third of cases resolve annually, and nearly 30% will experience a recurrence within 6 months [7]. For neck pain, studies show that cases will either resolve within the first few months or it will persist and have a high probably of becoming a chronic complaint [6, 8]. For myelopathy, the natural history varies between individuals, with the evidence suggesting that 20–60% of patients will deteriorate neurologically over time without surgery [9]. Therefore, invasive interventions such as injections or surgery may be considered in patients with persistent and disabling spine pain following unsuccessful non-invasive treatments.

Many guidelines on the use of surgery and interventional procedures for spinal conditions are available. However, they were all developed from evidence obtained from high-income countries and tailored to the needs of these settings [10–15]. In such settings, surgeries and interventional treatments are often performed as elective procedures, and are generally not associated with clearly superior outcomes when compared to non-invasive therapies [10, 16]. The generalizability of these guidelines to low- and middle-income countries is uncertain because of limited healthcare resources, including surgical/medical expertise, resources and infrastructure.

The purpose of this article was to synthesize recommendations on the management of spinal disorders using surgical and interventional procedures for individuals with persistent and disabling spinal pain to inform the Global Spine Care Initiative (GSCI) Care Pathway for patient presentations where surgical interventions could reasonably be considered. This study pertains to "elective" surgical and interventional (i.e., injections) procedures to reduce persistent pain and improve function. Patients with cauda equina, progressive neurological deficits, and serious conditions such as cancer, severe trauma, infection, or other "Red Flag" conditions generally requiring surgical or specialized evaluation were not considered in this review.

Methods

Development of recommendations

We selected spinal disorders associated with persistent pain and loss of function that may be referred to surgery or injections [17]. These conditions are non-radicular/axial neck and back pain, radicular neck pain due to degenerative foraminal stenosis with or without myelopathy, radicular back pain due to herniated disc, and symptomatic spinal stenosis and osteoporotic fracture.

Six evidence-based clinical practice guidelines for the surgical and interventional management of persistent and disabling spine disorders were selected by consensus of the GSCI executives (SH, MN, PC, EH, RC) [10–15]. One guideline focused on low back pain was developed by the American Pain Society (APS) [one of the lead authors of this guideline is an author of this article (RC)] [10]. One guideline focused on percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures and was developed by the National Institutes of Health Care Excellence (NICE) [11]. The other four guidelines were developed by the North American Spine Society (NASS) [12–15].

We appraised the quality of the guidelines using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument [18]. All guidelines met criteria for high-quality guidelines scoring five out of seven (highest score) or higher.

We found no guidelines to inform the management of axial neck pain or cervical myelopathy. These conditions are common indications for surgery for neck pain. For these conditions we used NASS Appropriate Use Criteria [19]. Appropriate use criteria is developed for procedures that are done frequently, consume significant resources, have wide variations in their use, are associated with substantial morbidity and mortality, procedures that are controversial or a combination of these. The objective of NASS Appropriated Use Criteria is to define appropriate (reasonable) care of spinal disorders. The criteria are based on available evidence combined with a rigorous, transparent recommendation process and well-defined scenarios.

Synthesis of recommendations

For each intervention, one reviewer (EA) extracted the available information regarding the clinical benefits and harms of the interventions from the guidelines (see Online Resource Table 1). A second reviewer (KR) checked data extraction for accuracy and completeness.

Through consensus, we categorized the magnitude of benefits and harms, costs and feasibility as uncertain, low/small, moderate, or high based on the categories used in the recent Agency for Healthcare Research and Quality (AHRQ) review on LBP interventions [20] (see Online Resource Table 1).

We classified each recommendation using the system proposed by NICE (see Online Resource Table 2) [21]. Recommendations from the APS guideline [10], the North American Spine Society guidelines [12–15] and the NASS Appropriate Use Criteria [19] were adapted to conform to the NICE wording by taking into consideration the benefits (effectiveness) and harms (adverse events, ineffectiveness). Based on this methodology, we worded our recommendations as:

1. ''offer (recommended)'' (for interventions that are of superior effectiveness compared to other interventions, placebo/sham interventions, or no intervention);
2. ''consider (recommended for consideration)'' (for interventions providing similar effectiveness to other interventions); or
3. ''do not offer (recommended against)'' (for interventions providing no benefit beyond placebo/sham or where harms outweigh benefits) the intervention; or
4. insufficient—insufficient evidence was available to develop a recommendation.

Additional interventions that had insufficient evidence of efficacy or ineffectiveness (insufficient) or were shown to have no benefit (recommended against) are not discussed in the summary of recommendations but are listed in Table 1 for completeness.

After synthesizing recommendations from the guidelines, we developed eight recommendations for the GSCI Care Pathway, taking into consideration possible adaptions for low- and middle-income settings and implementation within these settings.

Summary of recommendations

For patients with persistent (> 3 months) and/or disabling spine pain who do not respond to non-invasive treatments, invasive treatments may be considered. Surgical and injection treatments are elective procedures, and it is important that risks, potential harm and benefits of each intervention are discussed between the healthcare provider and patient. The summary of information is included in Table 1.

Potential harms due to surgical and interventional procedures for spinal disorders

General considerations

Although surgery may be beneficial for certain patients, harms must also be considered. As with most invasive procedures, potential complications of surgical spine procedures may include infection, poor wound healing, dural tears, neural injury, bleeding, thrombosis, acute respiratory distress syndrome, pulmonary edema, heart failure, and pain [22–24].

Cervical spine

Management of cervical axial pain

Recommendation 1: Cervical axial pain is a common spinal disorder. Due to insufficient evidence, surgery is not indicated for the treatment of cervical axial pain.

Management of cervical radiculopathy from degenerative disorders

Discectomy

Recommendation 2: Consider anterior cervical discectomy (commonly with fusion) for patients with persistent cervical radiculopathy secondary to degenerative disorders for more rapid pain relief (one guideline) [12].

Surgery is an option in patients with persistent, moderate to severe cervical radiculopathy who do not respond to a course of non-invasive therapy. In patients with cervical radiculopathy from degenerative disorders, surgery (anterior cervical discectomy, with or without fusion) is associated with more rapid pain relief than non-invasive therapy. However, patients generally experience improvement with or without surgery. Therefore, GSCI recommends that surgery should be reserved for individuals with persistent and moderate to severe symptoms unresponsive to recommended non-invasive interventions.

A anterior cervical discectomy (ACD) and anterior cervical discectomy with fusion (ACDF) are associated with similar short-term clinical outcomes in regard to pain relief. However, adding fusion may result in a more complex surgical procedure with increased risk of complications. Recent literature suggests that ACDF may be associated with better longer term results and cost effectivity

Table 1 Summary of recommendations

	Benefits	Harms	Costs	Feasibility	Recommendation
Invasive treatments for cervical axial pain					
Fusion [19]	No benefit	–	–	–	RA
Invasive treatments for cervical radiculopathy from degenerative disorders					
Discectomy [12] (with or without fusion)	Small to moderate	Moderate to severe	High	Low	RC
Transforaminal epidural steroid injections [12]	No benefit	–	–	–	RA
Interlaminar epidural steroid injections	–	–	–	–	Insufficient
Cervical stenosis (foraminal or central) with myelopathy with or without radiculopathy					
Fusion [19]	Small to moderate	Moderate to severe	High	Low	RC
Invasive treatments for presumed discogenic or facet joint pain					
Facet joint steroid injection [10]	No benefit	–	–	–	RA
Intradiscal steroid injection [10]	No benefit	–	–	–	RA
Coblation nucleoplasty	–	–	–	–	Insufficient
Medial branch block [10]	–	–	–	–	Insufficient
Radiofrequency denervation [10]	–	–		–	Insufficient
Intradiscal electrothermal therapy [10]	–	–	–	–	Insufficient
Percutaneous intradiscal radiofrequency thermocoagulation	–	–	–	–	Insufficient
Invasive treatments for non-specific low back pain					
Prolotherapy [10]	No benefit	–	–	–	RA
Botulinum toxin injection [10]	–	–	–	–	Insufficient
Local injections [10]	–	–	–	–	Insufficient
Epidural steroid injection [10]	–	–	–	–	Insufficient
Spinal cord stimulation [10]	–	–	–	–	Insufficient
Intrathecal therapy [10]	–	–	–	–	Insufficient
Invasive treatments for non-radicular low back pain with common degenerative changes					
Fusion surgery [10]	Moderate±	Moderate to severe	High	Low	RC
Invasive interventions for low back pain with radiculopathy due to prolapsed/herniated disc					
Discectomy or microdiscectomy [10, 13]	Moderate[a]	Moderate to severe	High	Low	RC
Epidural steroid injection [10, 13]	Moderate[a]	Moderate to severe	Moderate to high	Low	RC
Intradiscal steroid injection [10]	No effect	–	–	–	RA
Coblation nucleoplasty [10]	–	–	–	–	Insufficient
Spinal cord stimulation [10]	–	–	–	–	Insufficient
Facetectomy [13]	–	–	–	–	Insufficient
Invasive interventions for spinal stenosis and degenerative spondylolisthesis					
Decompression (laminectomy with or without fusion) [14]	Moderate	Moderate to severe	High	Low	RC
Epidural steroid injection [10, 14]	–	–	–	–	RC
Invasive interventions for osteoporotic fracture					
Balloon kyphoplasty [11]	Moderate	Moderate to high	Moderate	Low	RC
Vertebroplasty [11]	Moderate	Moderate to high	Moderate	Low	RC

± No difference compared to intensive rehabilitation

R recommended, *RC* recommendation for consideration, *RA* recommended against, *Insufficient* not enough data available, – no information available,

[a]Moderate for short-term outcomes (through 3 months)

[25, 26]. Therefore, ACD without fusion (vs ACDF) may only be recommended in very low resource setting in the absence of a clear indication for fusion (e.g., significant instability).

Disc arthroplasty

Disc arthroplasty is comparable to anterior cervical discectomy with fusion for short-term outcomes but may be more

costly and require additional technical skills. In addition, data on long-term outcomes are relatively limited. In addition to general risks of surgery, artificial disc replacement may be associated with additional complications, including prosthesis migration or subsidence (settling or sinking into bone), as well as adjacent level disc degeneration, facet joint arthritis, and need for subsequent artificial disc removal [22]. Therefore, GSCI recommends that discectomy (± fusion) be preferred over arthroplasty in low-resource settings.

Management of cervical stenosis due to spondylosis or disc herniation with myelopathy

Fusion surgery

Recommendation 3: Consider fusion for the management of cervical stenosis due to spondylosis or disc herniation with myelopathy (Table 1) (Appropriate Use Criteria) [19].

There is a lack of evidence for the effectiveness of fusion (anterior and/or posterior) for cervical stenosis due to spondylosis or disc herniation with myelopathy, but based on the Appropriate Use Criteria it may be appropriate to perform fusion if improvement is not evident following non-invasive treatment. In patients with moderate to severe myelopathy, non-invasive treatment may not be effective as myelopathy is typically a progressive disorder with little evidence showing that non-invasive treatment halts or reverses its progression [27].

With cervical fusion there is a risk of pseudoarthritis and risks factors for pseudoarthritis (e.g., smoking, obesity, diabetes, age, vascular abnormalities) should be considered prior to surgery [19].

Lumbar spine

Management of non-radicular low back pain with common degenerative changes

Fusion surgery

Recommendation 4: Consider fusion surgery for non-radicular low back pain with common degenerative changes in individuals with persistent disability in patients who do not improve following recommended non-invasive treatments (Table 1) (one guideline) [10].

Fusion surgery and intensive rehabilitation appear to be similarly effective for persistent non-radicular low back pain thought to be due to degenerative disc diseases and associated with moderate to severe disability. Furthermore, a proportion of patients who undergo fusion surgery do not experience optimal outcomes. Therefore, fusion should be reserved for patients with persistent, or at least severe symptoms not responding to non-invasive therapies. It is recommended that intensive rehabilitation be provided prior to fusion surgery, if available. Elective surgery for axial (non-radicular) LBP is an option, but given the similar effectiveness of non-invasive treatments to fusion and higher costs, the GSCI does not recommend fusion for persistent non-radicular low back pain without instability as a high priority for resource allocation in settings with limited resources [10, 16, 28].

If fusion is considered, the data generally suggest that more complex and costly surgical techniques [e.g., circumferential fusion vs. anterior lumbar interbody fusion or posterior lumbar interbody fusion, instrumentation vs. non-instrumented, bone morphogenetic protein-2 (BMP-2 vs. no BMP-2)] result in no additional benefits or better outcomes, and may result in additional complications.

Disc arthroplasty

Disc arthroplasty is comparable to fusion for short-term outcomes but is generally a more costly surgery requiring additional technical skills and training. In addition to the typical complications of surgery, artificial disc replacement may also result in prosthesis migration or subsidence as well as adjacent level disc degeneration, facet joint arthritis, or require subsequent artificial disc removal [22–24]. Due to the costs and potential additional complications, GSCI recommends that fusion be provided over arthroplasty in low-resource settings.

Management of persistent radiculopathy due to prolapsed/herniated lumbar disc

Epidural steroid injection

Recommendation 5: Consider epidural steroid injection for short-term benefits in patients with persistent radiculopathy due to prolapsed/herniated lumbar disc (Table 1) (one guideline) [10, 13].

Epidural steroid injection should be reserved for patients with persistent symptoms with moderate to severe disability who do not improve with non-invasive interventions. This recommendation is based on trials focused on patients with persistent moderate to severe disability despite non-invasive treatments. The expected benefits from lumbar epidural steroid injections are for short-term small pain relief [10, 13]. Lumbar epidural steroid injections are not associated with a reduction in the risk of subsequent surgery [10]. Epidural lumbar steroid injection could be an option in some low-resource settings for short-term symptomatic relief, but GSCI does not consider this a high-priority intervention given the short-term, relatively small benefits associated with it.

Serious adverse events for epidural injections are rare; minor adverse events include local hematoma, bleeding, and dural puncture [29].

Discectomy

Recommendation 6: Consider discectomy (open discectomy or microdiscectomy) for radiculopathy due to prolapsed/herniated lumbar disc in patients with severe pain and disabling symptoms (Table 1) (two guidelines) [10, 13].

Discectomy may benefit individuals with radiculopathy with severe pain and/or loss of function. On average, patients improve with or without discectomy; however, patients tend to improve more slowly without surgery. In some trials, the medium-term outcomes (1–4 years) are similar for patients who receive discectomy and those who do not. In low-resource settings, GSCI recommends that elective discectomy be considered for patients with persistent radiculopathy due to herniated disc who have severe disabling symptoms that are not improving.

Therefore, the GSCI recommends decompression as a higher priority for resource allocation in low- and middle-income settings, given the benefits, the relatively straightforward procedure, and cost compared to fusion and artificial disc replacement.

Management of lumbar spinal stenosis and degenerative spondylolisthesis

Decompression and fusion

Recommendation 7: Consider decompression surgery (laminectomy) for the management of patients with spinal stenosis (with or without degenerative spondylolisthesis) with moderate to severe symptoms (radiculopathy or pseudoclaudication) (Table 1) (two guidelines) [6, 7].

The evidence indicates that surgery (typically decompressive laminectomy) is associated with small to moderate benefits compared to non-surgical treatment. Therefore, GSCI recommends that decompressive surgery be considered as an option for patients with persistent pain (including radiculopathy/pseudoclaudication due to stenosis) and functional symptoms that do not improve with non-surgical treatment. In most trials, the benefits of decompression surgery for spinal stenosis appear to be longer lasting than for discectomy for herniated disc. Surgery should generally not be considered within the first 3 months, as patients enrolled in RCTs typically had prolonged (often years) symptoms. For patients with mild to moderate symptoms of spinal stenosis or who can adequately function, non-invasive treatment should be considered, such as rehabilitation including exercise and manual therapy.

In the absence of instability, fusion should not be used for the management of stenosis with or without degenerative spondylolisthesis. Fusion with laminectomy is generally not associated with better outcomes than laminectomy alone, and associated with more costs and increased harms [22].

Therefore, the GSCI recommends discectomy and/or laminectomy as a higher priority for resource allocation in low- and middle-income settings, given the benefits, the relatively straightforward procedure, and cost compared to fusion.

Management of osteoporotic fracture

Balloon kyphoplasty and vertebroplasty

Recommendation 8: Consider percutaneous vertebroplasty in patients who have severe ongoing pain after a recent, unhealed vertebral compression fracture despite optimal pain management (Table 1) (one guideline) [11].

Intense and severe pain confirmed at the level of osteoporotic fractures [diagnosed by radiographs, computed tomography (CT) or magnetic resonance imaging (MRI)] may benefit from a percutaneous vertebroplasty or balloon kyphoplasty. In the absence of the need for surgical stabilization, balloon kyphoplasty or vertebroplasty should be considered for patients who did not experience significant pain reduction after a course of conservative treatment.

The effectiveness of balloon kyphoplasty and vertebroplasty are shown similar when compared to each other; however, there are no sham-controlled studies that assess the effectiveness of balloon kyphoplasty. Among three sham-controlled trials of vertebroplasty, it was ineffective in two [30, 31]; one trial that restricted enrollment to people with very acute (< 6 weeks) symptoms found some benefits [32]. If it is used, vertebroplasty should be done in the first 6 weeks [32]. The GSCI recommends vertebroplasty over balloon kyphoplasty as the evidence is stronger for vertebroplasty, which is a technically easier procedure and generally less costly than kyphoplasty. Adverse reactions may occur, as described in the NICE guidelines: "for both vertebroplasty and kyphoplasty, adverse reactions can be caused by: needle insertion (such as local or systemic infection, bleeding, and damage to neural or other structures); leakage of bone cement; displacement of bone marrow and other material by the cement; systemic reactions to the cement (such as hypotension and death); and complications related to anesthesia and patient positioning (such as additional fractures of a rib or the sternum). In addition, there is a small risk that the balloon can rupture in kyphoplasty, which can result in the retention of balloon fragments within the vertebral body" [11].

Discussion

We reviewed and appraised six evidence-based clinical practice guidelines and one appropriate use criteria document to generate eight recommendations and suggestions for prioritization for elective invasive interventions for the management of spinal pain and disabling disorders in lower resource settings [10, 12–15, 19]. Prior recommendations were developed for use in high-resource settings; we adapted and prioritized recommendations on elective invasive interventions to lower resource settings.

The benefits of elective surgical and interventional procedures for cervical and lumbar axial spine pain may be comparable to non-invasive interventions and are associated with additional harms and possible increased costs. Surgery should be reserved for individuals who do not respond to non-invasive interventions and who have progressive, persistent and disabling pain. A shared decision-making approach is warranted. The care providers should provide information regarding potential benefits and harms, and discuss preferences and expectations, values and goals for the patient to play an active role in the decision making process.

Patients with signs of psychological distress, such as somatization, depression, fear avoidance and catastrophizing, have a worse prognosis after surgery than patients without such signs (i.e., slower recovery). An important component of reducing psychological distress is education, reassurance and thorough explanation by the healthcare provider [33]. Patient expectation can also affect the outcomes following surgical or invasive procedures [28, 34–37]. Other important factors that may impact outcomes of surgery and could be used to inform decisions include use of opioids, smoking status, and medical comorbidities (e.g., diabetes).

Based on relatively small benefits relative to harms and costs, lower priority surgery/conditions include fusion for lumbar/non-radicular neck pain; based on greater benefits relative to harms and costs, higher priority surgery/conditions include discectomy/decompressive surgery for cervical or lumbar radiculopathy, cervical myelopathy, and lumbar spinal stenosis. Epidural steroid injections are less expensive than most surgeries with fewer harms; however, benefits are small and short lived. Vertebroplasty should be considered over kyphoplasty as an option for patients with severe pain and disability due to osteoporotic vertebral compression fracture in patients who do not improve following a short course of non-invasive treatment.

Spine surgery may result in complications or adverse events. Knop et al., a Study Group of the German Trauma Association (DGU), analyzed operative complications of 682 spine patients spanning 18 centers in Germany [38]. Overall surgical complication rate for thoraco-lumbar spine was 15%. Anterior spine surgery was associated with a higher complication rate of 30%. Treatment-related mortality was mainly due to pulmonary embolism at 1% [38]. Deep infection was the most common procedure-related complication at 2.2%. Neurological complications occurred in 2% of patients and despite immediate revision, most of them did not improve. Hematoma and wound healing problems occurred in 1.8% of patients. Implant-related complications and cerebrospinal fluid (CSF) leakage were not very common, 1.3 and 0.3%, respectively [38]. There is little information on complication rates from underserved areas.

Limitations

All guidelines and appropriate use criteria were developed in North America and UK and were not developed specifically for low- and middle-income communities. However, we chose these guidelines and criteria because they adhered to methodological standards for developing guidelines. The included guidelines did not provide formal information on cost-effectiveness, but we provided some suggestions for prioritization of resources regarding elective invasive procedures based on estimated relative costs and expected benefits.

Conclusion

Evidence from high-quality clinical practice guidelines suggests that most surgical interventions lead to similar outcomes as non-invasive procedures for cervical and lumbar spine axial pain-related conditions. We have provided recommendations for surgical and interventional procedures based on evidence, these interventions should be reserved for patients with persistent and disabling spinal pain that fail to improve with non-invasive treatment. In low- and middle-income communities, prioritization of elective surgical procedures should be based on estimated benefits relative to harms and costs.

Compliance with ethical standards

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