State of Oregon Evidence-based Clinical Guidelines Project

Percutaneous Interventions for Low Back Pain

A clinical practice guideline based on the 2009 American Pain Society Guideline (Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain)

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Oregon Health Authority

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Objective

This guideline was developed by a collaborative group of public and private partners to provide up-to-date evidence-based guidance on the role of percutaneous interventions in low back pain. The aim of the guideline is to identify evidence-based, appropriate indications for the use of percutaneous interventions in patients with low back pain of any duration, with and without leg pain. This guideline can then be used to create practice standards and coverage guidelines for use across public and private payers. It does not address patients with back pain associated with major trauma, tumor, metabolic disease, inflammatory back disease, fracture, dislocation, major instability or deformity, progressive or severe neurologic deficits, or back pain in children, adolescents or pregnant women. Percutaneous interventions addressed in this guideline include intradiscal, facet joint, sacroiliac joint and epidural steroid injections, prolotherapy, botulinum toxin injections, local injections, medial branch block, radiofrequency denervation, intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation and coblation nucleoplasty.

Additional evidence concerning other elements of evaluation as well as recommendations for management of low back pain can be found in the State of Oregon Evidence-based Clinical Guidelines:

- Evaluation and Management of Low Back Pain[1]
- Advanced Imaging for Low Back Pain[2]

Background

In June 2009, the Oregon legislature passed health reform legislation HB 2009, which created the Oregon Health Policy Board and charged it with creating a comprehensive health reform plan for our state. In December 2010, the Board released *Oregon's Action Plan for Health*, which lays out "strategies that reflect the urgency of the health care crisis and a timeline for actions that will lead Oregon to a more affordable, world-class health care system." They outlined eight foundational strategies, one of which is to "set standards for safe and effective care." To accomplish this, the plan directs the state to "Identify and develop 10 sets of Oregon-based best practice guidelines and standards that can be uniformly applied across public and private health care to drive down costs and reduce unnecessary care." This work is being conducted by the Oregon Health Services Commission and the Oregon Health Resources Commission in close collaboration with providers, the Center for Evidence-Based Policy, and other key stakeholders.[3]

Development of this guideline:

This guideline was developed by a Guideline Development Group (GDG) consisting of representatives from the State of Oregon Health Authority, the Oregon Healthcare Leadership Council, and the Oregon Corporation for Healthcare Quality with support from clinical evidence specialists from the Center for

[1] Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office for Oregon Health Policy and Research.

[2] Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Vandegriff, S., & Gordon, C. (2012). *State of Oregon Evidence-based Clinical Guidelines Project. Advanced imaging for low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office for Oregon Health Policy & Research.

[3] Effective January 1, 2012, House Bill 2100 (2011) terminates the Health Services Commission and Health Resources Commission and transfers their duties related to evidence-based guideline development to a new Health Evidence Review Commission.

Evidence-based Policy. The Center provided expertise in the process of guideline development and undertook analysis and appraisal to support the development of this guideline.

Methods:
The GDG developed this guideline using the ADAPTÉ[4] framework which is a systematic approach to the endorsement or modification of guideline(s) produced in one cultural context or organizational setting for application in another context. Guideline adaptation is used as an alternative to wholly new guideline development, which can be time consuming, expensive and an inefficient use of resources, when existing quality guidelines are available.

The process for developing this guideline began by searching 17 different databases and other sources for guidelines related to percutaneous interventions for chronic back pain (see appendix A). Candidate guidelines were required to satisfy the following requirements:

- to be evidence-based, that is, guideline recommendations are based on systematic reviews of the literature,
- to address the use of percutaneous interventions in adults with chronic back pain,
- to be published in English and,
- to be freely available to the public.

The GDG required that evidence-based recommendations be made on the basis of both the quality and strength of the underlying evidence from any included guideline's systematic reviews. The initial search identified 10 candidate guidelines which met the above stated criteria (Appendix B). Of the original candidate guidelines, three had been rated as poor quality during the development of a previous guideline and one was excluded because it was not publically available. The six remaining guidelines were then assessed for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II[5] instrument (Appendix C) by two different guideline quality assessors from the Center for Evidence-based Policy. Two of those guidelines were rated good quality, and one was rated fair with good rigor of development of the evidence and recommendations according to the modified AGREE rating tool. These three guidelines were then examined further for scope and clarity of presentation.

Comparison of the APS guideline was made to the other high quality, comprehensive guidelines, which were produced by the National Institute for Health and Clinical Excellence (NICE), and Towards Optimized Practice, Alberta Clinical Guidelines Program. Of the guidelines considered for review, the GDG felt that the APS guideline was the most comprehensive.

After considering guideline scope and specific modalities addressed, the GDG selected the American Pain Society's 2009 guideline "Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society" as the base guideline, primarily because it had recommendations concerning a broader range of interventions than guidelines from the National Institute for Health and Clinical Evidence (NICE) or from Towards Optimized Practice (TOP). (See Appendix E for procedures addressed in the APS guideline.)

[4] http://www.adapte.org/www/
[5] http://www.agreecollaboration.org/

The APS guideline in its entirety can be found at the following link: http://journals.lww.com/spinejournal/Abstract/2009/05010/Interventional_Therapies,_Surgery,_and.14.aspx. The APS guideline is accompanied by a full systematic review on nonsurgical interventional therapies for low back pain in the same journal issue at: http://www.ampainsoc.org/library/pdf/LBPEvidRev.pdf.

The APS guideline panel arrived at treatment recommendations by first evaluating the evidence for treatments according to a system adapted from the US Preventive Services Task Force for grading the evidence, then estimating the magnitude of effects, including whether the benefits of the treatment outweigh the harms. (See Appendix D for the APS criteria for arriving at recommendations.)

Updating:
The APS guideline was published in 2009. The authors of the guideline were contacted in March 2011 and stated that there had been no new published evidence which would change the recommendations of the guideline and that it was considered current. The GDG recommends that this guideline be reevaluated if the APS issues an updated guideline and at least every two years for currency if the original guideline is not updated.

Recommendations

Below are the recommendations of the APS clinical practice guideline followed by discussion of each recommendation.

Table A. State of Oregon Evidence-based Clinical Guideline Recommendations for Percutaneous Injections of the Spine

Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
Non-radicular Low Back Pain				
Non-specific Low Back Pain	• Prolotherapy	No net benefit	In patients with persistent nonradicular low back pain, **clinicians should not** provide prolotherapy.	Recommendation: Strong Grade: High-quality evidence
	• Local injections • Botulinum toxin injection • Epidural steroid injection • Therapeutic medial branch block • Radiofrequency denervation • Sacroiliac joint steroid injection • Coblation nucleoplasty	Unknown	In patients with persistent nonradicular low back pain, there is insufficient evidence to adequately evaluate the benefits of local injections, botulinum toxic injection, epidural steroid injection, therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or coblation nucleoplasty.	Insufficient evidence to determine net benefits or harms

Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
Presumed discogenic pain	• Intradiscal steroid injection	No net benefit	In patients with presumed discogenic pain, **clinicians should not** provide intradiscal steroid injection.	Recommendation: Strong Grade: High quality-evidence
	• Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) • Intradiscal electrothermal therapy (IDET)	Unknown	In patients with presumed discogenic pain, there is insufficient evidence to adequately evaluate the benefits of PIRFT or IDET	Insufficient evidence to determine net benefits or harms
Presumed facet joint pain	• Facet joint steroid injection	No net benefit	In patients with presumed facet joint pain, **clinicians should not** provide facet joint steroid injection.	Recommendation: Strong Grade: Moderate-quality evidence
	• Radiofrequency denervation	Unknown	In patients with presumed facet joint pain, there is insufficient evidence to adequately evaluate the benefits of radiofrequency denervation.	Insufficient evidence to determine net benefits or harms
Presumed sacroiliac joint pain	• Sacroiliac joint steroid injection	Unknown	In patients with presumed sacroiliac joint pain, there is insufficient evidence to adequately evaluate the benefits of sacroiliac joint steroid injection.	Insufficient evidence to determine net benefits or harms
Radiculopathy or Spinal Stenosis				
Radiculopathy with herniated lumbar disc	• Epidural steroid injection	**Moderate benefit (short-term)**	In patients with persistent radiculopathy due to herniated lumbar disc, **clinicians should** discuss the risks and benefits of epidural steroid injections as an option. It is recommended that Shared decision-making regarding epidural steroid injection includes a specific discussion about inconsistent evidence showing moderate short-term benefits and lack of long-term benefits.	Recommendation: Weak Grade: Moderate-quality evidence

Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
Radiculopathy with herniated lumbar disc, cont.	• Coblation nucleoplasty	Unknown	In patients with radiculopathy with herniated lumbar disc, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms
Radiculopathy	• Radiofrequency denervation	Unknown	In patients with radiculopathy, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms
Symptomatic Spinal Stenosis	• Epidural steroid injection	Unknown	In patients with spinal stenosis, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms

***See Appendix D for complete description of APS and ACP evidence grading methods. Chou, et al. (2009) utilize the US Prevent Services Task Force criteria for rating the strength of recommendation and quality of evidence. Recommendations in this table are modified to fit GRADE terminology for consistency among State of Oregon guidelines.**

Recommendation #1[6]:

Epidural Steroid Injection for persistent radiculopathy due to herniated lumbar disc

> *In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injection as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. There is insufficient evidence to adequately evaluate benefits and harms of epidural steroid injection for spinal stenosis.*

For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials (Arden 2005; Bush 1991; Dilke 1973; Wilson-MacDonald 2005) found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others (Carette 1997; Karppinen 2001; Ng 2005) found no differences *versus* placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials (Beliveau 1971; Breivik 1976; Bush 1991; Carette 1997; Cuckler 1985; Karppinen 2001; Klenerman 1984; Ng 2005; Rogers 1992; Snoek 1977; Zahaar 1991) that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials (Arden 2005; Dilke 1973; Helliwell 1985; Mathews 1987; Ridley 1988; Wilson-MacDonald 2005) that compared an epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no

[6] Extracted and modified from Chou, et. al. (2009)

convincing evidence that epidural steroids are associated with long-term benefits and most trials (Arden 2005; Carette 1997; Riew 2000; Wilson-MacDonald 2005) found no reduction in rates of subsequent surgery. Although serious complications following epidural steroid injection are rare in clinical trials, (Arden 2005; Karppinen 2001; Kolsi 2000; Kraemer 1997; Ng 2005) there are case reports of paralysis and infections. (Glaser 2005; Hooten 2006; Huntoon 2004) There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection (Ackerman 2007; Kolsi 2000; Kraemer 1997; McGregor 2001; Thomas 2003) or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though 1 higher-quality trial found that if an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes (Arden 2005).

Epidural steroid injection for the treatment of radiculopathy with herniated lumbar disc is the only percutaneous intervention found to have a net benefit, and the benefit appears to be short-term.

Decisions regarding use of epidural steroid injection should be based on a shared decision-making process that includes a discussion of the inconsistent evidence for short-term benefit, lack of long-term benefit, potential risks, and costs. Patient preferences and individual factors should also be considered. For example, epidural steroid injection may be a reasonable option for short-term pain relief in patients who are less optimal surgery candidates due to comorbidities. There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms.

Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects (Cuckler 1985; Fukusaki 1998; Zahaar 1991). Although chymopapain chemonucleolysis (see glossary, Supplemental Digital Content 1, http://links.lww.com/A840) is effective for radiculopathy due to herniated lumbar disc, (Gibson 2007a, 2007b) it is less effective than discectomy (see glossary, Supplemental Digital Content 1, http://links.lww.com/A840) and is no longer widely available in the United States, in part due to risk of severe allergic reactions.

Recommendation #2[7]:

Facet Joint Injection, Prolotherapy, Intradiscal Corticosteroid Injection

> *In patients with persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection* **are not recommended** *(strong recommendation, moderate-quality evidence).*

Injections and most interventional therapies for nonradicular low back pain target specific areas of the back that are potential sources of pain, including the muscles and soft tissues (botulinum toxin injection, prolotherapy, and local injections [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840]), facet joints (facet joint steroid injection, therapeutic medial branch block, and radiofrequency denervation [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840]), degenerated intervertebral discs (intradiscal steroid injection, IDET, [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840] and related procedures), and sacroiliac joints (sacroiliac joint injection)

[7] Extracted and modified from Chou, et. al. (2009)

There is no convincing evidence from randomized trials that injections and other interventional therapies are effective for nonradicular low back pain. Facet joint steroid injection (Carette 1991; Lilius 1989) prolotherapy (Dagenais 2007) and intradiscal steroid injections (Khot 2004; Simmons 1992) are not recommended because randomized trials consistently found them to be no more effective than sham therapies.

Five randomized, placebo-controlled trials evaluated prolotherapy (Gibson 2007a; Huntoon 2004; Klenerman 1984; Malmivaara 2007; Weber 1983). All were included in a higher quality Cochrane review (Willems 2004). Four trials were rated higher quality (Huntoon 2004; Klenerman 1984; Malmivaara 2007; Weber 1983). For chronic nonspecific low back pain, 3 trials (2 higher quality: Klenerman 1984, Malmivaara 2007) found no difference between prolotherapy and either saline or local anesthetic control injections for short-or long-term (up to 24 months) pain or disability (Malmivaara 2007).

Recommendation #3[8]:
Other Interventional Procedures

> *There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, coblation nucleoplasty, percutaneous intradiscal radiofrequency thermocoagulation …. or other medications for nonradicular low back pain.*

For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions (Collee 1991; Garvey 1989; Hameroff 1981; Sonne 1985). Trials of IDET (Freeman 2005; Pauza 2004) and radiofrequency denervation (Leclaire 2001; Nath 2008; van Kleef 1999; van Wijk 2005) reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings (Hooten 2005), making it difficult to reach conclusions about benefits**.** For other interventional therapies, data are limited to 1-2 small placebo-controlled randomized trials (botulinum toxin injection (Foster 2001), epidural steroid injection for nonradicular low back pain (Serrao 1992), PIRFT (Barendse 2001, Ercelen 2003) and sacroiliac joint steroid injection [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840] (Luukkainen 2002), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty….or other medications).

[8] Extracted and modified from Chou, et. al. (2009)

Appendix A. Sources Searched for Low Back Pain Guidelines

1. British Medical Journal – Clinical Evidence
2. Cochrane Library
3. Agency for Healthcare Research and Quality
4. ECRI
5. Hayes, Inc
6. Veterans Administration – Technology Assessment Program (VA TAP)
7. Blue Cross Blue Shield HTA
8. Centers for Medicare and Medicaid
9. CADTH
10. Washington HTA Program
11. US Preventive Services Task Force
12. ICSI
13. Guidelines.gov
14. American College of Physicians AND American Pain Society
15. American Physical Therapy Association
16. PEDro.org.au (evidence-based physiotherapy database)
17. GIN Guidelines Database

Appendix B. Low Back Pain Guidelines Identified

Methods Summary:
Initially, 17 databases and other sources for guidelines related to percutaneous Interventions for low back pain were searched. Candidate guidelines were required to:

- be evidence-based (recommendations based on a full systematic review)
- be comprehensive
- be published in English
- be freely available to the public

Ten candidate guidelines were identified, of which six were sufficiently comprehensive and were assessed by two clinical epidemiologists for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II[9] instrument.
Candidate guidelines were then assessed considering:

- age
- source
- specific treatment elements addressed
- presentation

The GDG selected the guideline of highest quality and that was most comprehensive. (See guideline text for comprehensive Methods discussion)

Low Back Pain Guidelines Identified in Search – Selected for Quality Assessment

Armon, C., Argoff, C.E., Samuels, J., Backonja, M.M. (2007). Assessment: Use of epidural steroid injections to treat radicular lumbosacral pain: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 68:723-729.
Overall guideline quality rating: Fair

Chou, R., Loesser, J.D., Owens, D.K., Rosenquist, R.W., Atlas, S.J., Baisden, J., Carragee, E.J., Grabois, M., Murphy, D.R., Resnick, D.K., Stanos, S.P., Shaffer, W.O., Wall E.M. (2009) Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. Spine 34:10:1066-1077. – accompanied by:
Chou, R., Atlas, S.J., Stanos, S.P., Rosenquist, R.W. (2009). A review of the evidence for an American Pain Society clinical practice guideline. Spine 34:10:1078-1094.
Overall guideline quality rating: Fair with good rigor of development of evidence and recommendations

Manchikanti, L ., Boswell, M.V., Singh, V., Benyamin, R.M., Fellows, B., Abdi, S., Buenaventura, R.M., Conn, A., Datta, S., Derby, R., Falco, F.J.E., Erhart, S., Diwan, S., Hayek, S.M., Helm II, S., Parr, A.T., Schultz, D.M., Smith, H.S., Wolfer, L. R., Hirsch, J.A. (2009). Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. Pain Physician 12:699-802.
Overall guideline quality rating: Poor

National Health and Medical Research Council. Australian Acute Musculoskeletal Pain Guidelines Group. (2003). Evidence-based management of acute musculoskeletal pain. (Website states that status is "current"). [Chapter 4 of document is on Acute Low Back Pain.]
http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses /cp94.pdf
Overall guideline quality rating: Fair

[9] http://www.agreecollaboration.org/

National Institute for Health and Clinical Excellence (NICE). (2009). Low back pain: Early management of persistent non-specific low back pain. London, UK: National Institute for Health and Clinical Excellence. Retrieved September 30, 2010, from http://www.nice.org.uk/nicemedia/live/11887/44343/44343.pdf
Overall guideline quality rating: Good

Towards Optimized Practice. (2009). Management of low back pain. Edmonton, AB: Towards Optimized Practice Program.
Overall guideline quality rating: Good

Low Back Pain Guidelines Identified in Search– Not Selected for Quality Assessment

American College of Occupational and Environmental Medicine (ACOEM). (2007). Low back disorders. Occupational medicine practice guidelines: Evaluation and management of common health problems and functional recovery in workers. 2nd ed. Elk Grove Village, IL: ACOEM.
Overall guideline quality rating: Fair

Institute for Clinical Systems Improvement (ICSI). (2010). Adult low back pain. Fourteenth edition. Bloomington, MN: ICSI.
Overall guideline quality rating: Poor

Michigan Quality Improvement Consortium. (2008). Management of acute low back pain. Southfield, MI: Michigan Quality Improvement Consortium.
Overall guideline quality rating: Poor

University of Michigan Health System. (2010). Acute low back pain. Ann Arbor, MI: University of Michigan Health System.
Overall guideline quality rating: Poor

Appendix C: Methodology Checklist Adapted from the AGREE II materials

Methodology Checklist: Guidelines			
Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*			
Guideline Topic:			
Checklist completed by:		Date:	
SECTION 1: PRIMARY CRITERIA			
To what extent is there		***Assessment/Comments:***	
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD	FAIR POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD	FAIR POOR
1.3	**EDITORIAL INDEPENDENCE**[10] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD	FAIR POOR
If any of three primary criteria are rated poor, the entire guideline should be rated poor.			
SECTION 2: SECONDARY CRITERIA			
2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD	FAIR POOR

[10] Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

SECTION 2: SECONDARY CRITERIA, Cont.		
2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD FAIR POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available • Updating procedure specified	GOOD FAIR POOR
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered • Monitoring/audit/review criteria presented	GOOD FAIR POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE		
3.1	How well done is this guideline?	GOOD FAIR POOR
3.2	Other reviewer comments:	

Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

Appendix D. APS Guideline Criteria for Treatment Recommendations

The APS guideline panel arrived at treatment recommendations by first evaluating the evidence for treatments according to a system adapted from the US Preventive Services Task Force for grading the evidence, then estimating the magnitude of effects, including whether the benefits of the treatment outweigh the harms.

The underlying strength of the evidence for each intervention was given a rating of good, fair or poor based on factors such as the quality, quantity, consistency, and generalizability of the evidence (Table 1).

Table 1. APS Criteria for Grading the Strength of Evidence

Rating	Strength
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality trials)
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least 1 higher-quality trial of sufficient sample size; 2 or more higher-quality trials with some inconsistency; at least 2 consistent, lower-quality trials, or multiple consistent observational studies with no significant methodologic flaws
Poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Depending on the strength of the evidence for an intervention, the APS used the following criteria for making a recommendation.

Table 2. APS Criteria for making treatment recommendations

Grade	Criteria for making a recommendation
A	The panel strongly recommends that clinicians consider offering the intervention to eligible patients. The panel found good evidence that the intervention improves health outcomes and concludes that benefits substantially outweigh harms.
B	The panel recommends that clinicians consider offering the intervention to eligible patients. The panel found at least fair evidence that the intervention improves health outcomes and concludes that benefits moderately outweigh harms, or that benefits are small but there are no significant harms, costs, or burdens associated with the intervention.
C	The panel makes no recommendation for or against the intervention. The panel found at least fair evidence that the intervention can improve health outcomes, but concludes that benefits only slightly outweigh harms, or the balance of benefits and harms is too close to justify a general recommendation.
D	The panel recommends against offering the intervention. The panel found at least fair evidence that the intervention is ineffective or that harms outweighs benefits.
I	The panel found insufficient evidence to recommend for or against the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

If a recommendation was made, the APS assigned an overall grade of its strength, adapting the grading system of the international Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group. Strong recommendations are required to have clear evidence of benefit or harm. Weak recommendations are based on finely balanced benefits, risks and burdens.

Table 3. ACP Clinical Practice Guidelines Grading System[11]

Quality of Evidence	Strength of Recommendation	
	Benefits Do or Do Not Clearly Outweigh Risks	Benefits and Risks and Burdens Are Finely Balanced
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or harms		

The ACP/APS guideline panel considered interventions to have "proven" benefit if there was at least fair quality evidence of moderate or substantial benefit (or of small benefit with no significant harms, costs or burdens).

[11] Adapted from the system developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) workshop by the American College of Physicians.

Appendix E. Treatments addressed in APS guideline*

Treatment	Definitions Procedures are defined according to APS http://links.lww.com/A840
Prolotherapy (sclerotheraphy) Injections	A procedure involving the repeated injection of an irritant chemical into the soft tissues of the back in order to provoke an inflammatory response that will theoretically subsequently lead to strengthening of the soft tissues with decrease in pain and disability. Also referred to as sclerotherapy
Facet joint corticosteroid injections	Injection of corticosteroid into the facet joints.
Therapeutic medial branch block	Injection of local anesthetic with or without corticosteroid in the area of the medial branch of the posterior primary ramus, the primary nerve innervating the intervertebral facet joint. Usually used as a diagnostic procedure to identify facet joint pain, but has also been used as a therapeutic procedure
Intradiscal corticosteroid injections	Injection of corticosteroid into the intervertebral disc.
Radiofrequency denervation	A procedure involving the destruction of nerves using heat generated by a radiofrequency current.
Intradiscal electrothermal therapy (IDET)	A procedure involving the placement of an electrode or catheter into the intervertebral disc annulus or nucleus and applying electrothermal energy to alter adjacent pain receptors or other structures.
Epidural steroid injection	Injection of corticosteroids via a catheter into the space between the dura and the spine. Common approaches for administering epidural steroid injections are through the interlaminar space, via the neuroforamen under fluoroscopic guidance (transforaminal), and through the sacral hiatus at the sacral canal (caudal).
Local injections	Injection of local anesthetic (with or without corticosteroid) into the muscles or soft tissues of the back. Trigger point injections, a type of local injection, involve an injection performed at a tender area, often with a palpable nodule or band.
Sacroiliac joint steroid Injection	Injection of corticosteroid into or around the sacroiliac joint.
Botulinium toxin injection	Injection of botulinum toxin (an antispasmodic) into the muscles of the back.
Chemonucleolysis	Treatment of herniated discs with intradiscal injections of a proteolysis enzyme, most commonly chymopapain (an extract from papaya). Chymopapain acts by digesting the jelly-like inner portion of the disc known as the nucleus pulposus, while at the same time, leaving the outer portion, the annulus fibrosis, essentially intact.
Adhesiolysis and forceful epidural injection	(not defined)
Coblation® nucleoplasty	A procedure involving the use of a bipolar radiofrequency current in order to create a series of channels in an intervertebral disc and reduce the volume of tissue.
Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)	A procedure involving the placement of an electrode of catheter into the intervertebral disc and applying alternating radiofrequency current. Sometimes classified as a variant of intradiscal electrothermal therapy (IDET).

*Chou, R., Loesser, J.D., Owens, D.K., et al. (2009). Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. *Spine*, 34(10):1066-1077.

Appendix F. List of Peer Reviewers

Invited: Accepted & Reviewed

Susan Bamberger, PT, MPT, DIP MDT
Past President
Oregon Physical Therapy Association

Roger Chou, MD
Scientific Director
Oregon Evidence-based Practice Center
Division of General Internal Medicine and Geriatrics
Oregon Health & Science University

Timothy J. Craven, MD, MPH
Associate Medical Director
Providence Health Plan MCO

Rick Deyo, MD, MPH
Kaiser Permanente Professor of Evidence-Based Family Medicine
Director, KL2 Multidisciplinary Clinical Research Career Development Program
Director, OCTRI Community and Practice-based Research Program
Departments of Family Medicine and Internal Medicine
Oregon Health & Science University

Marc Gosselin, MD
Associate Professor
Director, Thoracic Imaging
Department of Diagnostic Radiology
Oregon Health & Science University

Luci Kovacevic, MD, MPH
Occupational Medicine Physician
Cascade Medical Associates

David Pass, MD
Anesthesiologist
Medical Director
Providence Health Plans

LaVerne A. Saboe, Jr., DC, DACAN, FICC, DABFP, FACO
Chiropractic Physician
Past president, Chiropractic Association of Oregon

Invited: Declined/Did Not Respond/Did Not Review

Fourteen additional reviewers were invited but either declined, did not respond, missed the deadline or did not return the review. Areas of professional expertise for invited reviewers included:

Anesthesiology
Behavioral Health
Complementary and Alternative Medicine
Family Medicine
Internal Medicine
Occupational Medicine
Orthopedic Surgery
Neurosurgery
Pain Advocacy
Pain Medicine
Physical Therapy
Physical Medicine and Rehabilitation
Radiology
Sports Medicine
Worker's Compensation

Appendix G. References

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Chou, R., Loesser, J.D., Owens, D.K., et al. (2009). Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. *Spine*, 34(10):1066-1077.

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