# AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES

American Association of Neurological Surgeons

A Section of the
American Association of Neurological Surgeons
and
Congress of Neurological Surgeons


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Agenda for Spine Section Executive Committee Meeting

| | |
|---|---|
| 1. Secretary's report | D. Resnick |
| Review and approval of minutes | |
| Review and approval of contact information and EC membership roster | |
| 2. Treasurer's Report | C. Wolfla |
| 3. Committee Reports | |
| a) Annual Meeting | J. Hurlbert/M. McLaughlin |
| b) CPT | R. Johnson |
| c) Exhibits | J. Knightly |
| d) Future sites | I. Kalfas |
| e) World Spine | |
| f) Research and Awards | P. Gerszten |
| g) Education | C. Kuntz |
| h) Guidelines | P. Matz |
| i) Outcomes | M. Kaiser |
| j) Peripheral nerve TF | E. Zager |
| k) Publications | M. Wang |
| l) Public Relations | T. Choudhri |
| m) Membership | Z. Gokaslan |
| n) Washington Committee | R. Heary/C. Branch |
| o) Fellowships | P. Mummaneni |
| p) PAC | S. Ondra |
| q) Web Site | C. Wolfla/ J. Cheng |
| r) CME | E. Mendel |
| s) Nominating Committee | R. Heary |
| t) Rules and Regs | T. Choudhri |
| u) Newsletter | M. Groff |
| 4. Old Business | |
| 1) NREF | |
| 5. New Business | |
| 1) Outcomes Project | Z. Gokowala |
| 2) SANS | G. Rodts |
| 3) Mailing List | J. Alexander |
| 4) SRS Curriculum | S. Ondra |

Minutes of Spine Section Executive Committee Meeting
April 24, 2006

Members Present: Chris Wolfla, Peter Gerszten, Mike Wang, Ehud Mendel, Greg Trost, Joseph Alexander, Charlie Kuntz, William Mitchell, Mike Kaiser, Mike Groff, Steve Ondra, Daniel Resnick, Charlie Branch, Eric Zager, Ian Kalfas, Ziya Gokoslan, Tanvir Choudhri, Chris Shaffrey

Guests: Don Quest, Ron Engelbreit

**Secretary's report:** given by Dr. Resnick. Minutes from March meeting were reviewed and approved.

Dr. Quest visited the section meeting and expressed the welcome of the AANS and support of the AANS for section activities.

**Treasurer's report**: Dr. Wolfla gave the treasurer's report – see page 10 of agenda book. As of March 31, 1.2 million dollars are in the long term investment fund. Overall, we are ahead of budget in terms of the annual meeting- registration fees were less than budgeted but exhibitor fees were increased. The AANSPAC donation was discussed. As it turns out, we cannot contribute due to tax laws. Several alternatives for directed contributions were discussed. Discussion on this issue was tabled. Discussion of annual meeting revenue also ensued. The report was reviewed and approved.

**Annual Meeting**: Drs. Groff and Mclaughlin (written report)

Highlights of the annual meeting were presented. A discussion of what to do with the data derived from the interactive surveys occurred. It was suggested that Dr. McLaughlin collate the collected data and report it at the October executive committee meeting. A decision will be made at that time as to whether or not further dispersal is warranted and in what form.

# Motion:

The AANS/CNS Joint Section on Spinal Disorders and Peripheral Nerves policy on withdrawn abstracts:

**FIRST AUTHORS OF ABSTRACTS (ORAL) ACCEPTED AND ACKNOWLEDGED WHO SUBSEQUENTLY WITHDRAW WILL INCUR A ONE YEAR SUSPENSION OF PRIVILEGES FROM ORAL PRESENTATION AT THE SUBSEQUENT JOINT SPINE ANNUAL MEETING.**

**A STATEMENT REGARDING THIS POLICY WILL BE INCLUDED ON THE AUTHOR ACKNOWLEDGMENT FORM SIGNED BY THE AUTHOR.**

**THE MOTION MADE, SECONDED, DISCUSSED, AND APPROVED.**

It was noted that registration was significantly decreased compared to last year and previous Orlando meetings. Discussion regarding the cause of the lower numbers centered on difficulties with meeting management.

**Exhibits**: no report

**Education:** Dr. Kuntz has been appointed as the new chairman of education. Dr. Groff and Dr. Mendel reported on upcoming activities at the CNS meeting in October. Dr. Groff reported that a paper on hypertonic saline in mouse SCI will receive the Synthes spine award.

**Future Sites:** Dr. Kalfas reported that we are under contract for the next three years. Subsequent negotiations for 2010 and beyond will depend on meeting services arrangements.

**Nominations Committee:** The slate of officers was elected at the annual business meeting on the Friday following the last executive committee meeting. President elect: Joe Alexander, Treasurer: Chris Wolfla, Member at Large: Greg Trost.

**Fellowships:** Dr. Wolfla – nothing new to report.

**Awards:** Dr. Gerszten will be taking over the committee leadership. Drs. Trost, Hurlbert, Kuntz, and Mummanneni volunteered to serve as fellowship reviewers. Dr. Michael Levi will also be asked to participate.

**Website:** Dr. Wolfla – the website has been updated since the meeting. Any new ideas or content should be forwarded to Dr. Wolfla.

**Guidelines:** Dr. Matz- no report.

**Outcomes:** Dr. Kaiser gave a summary report. Dr. Gowhala's proposal was tabled for the present time as he was not available to present.

**Rules and Regs**: Dr. Kuntz – see enclosed addendum. The officers will review the committee grid to determine which committees will be permanent and which are ad hoc. Committee chairman will submit to Dr. Kuntz brief descriptions of their committees for inclusion in the bylaws. Following this process, updating of the voting membership will be proposed.

**A motion was made to change item 6.03 B such that emailing is offered as an alternative to mailing. This was discussed, reviewed, and approved. It was further moved that email was an acceptable alternative to mailing in most circumstances. This was discussed and approved.**

**Washington Committee:** Dr. Alexander discussed participation of section members on the FDA orthopedic devices committee. Dr. Branch encouraged all members to contribute individually to the PAC.
**A motion was made to direct the chairman to investigate the mechanism and merits of a directed contribution to support the Washington Committee.**

**The motion was discussed and approved.**

**Peripheral Nerve Taskforce:** Dr. Zager provided an update on CPT nerve repair survey (see below) and activities at national meetings.

**Public Relations:** Dr. Choudhri reported that the logo contest is underway.

**CPT:** Dr. Mitchell gave an update on code changes for wound infection, TDA, and proposed new codes for the Xstop device. Dr. Zager provided an update on Brachial plexus codes. Dr. Mitchell reminded us that the membership of the section needs to participate in the valuation surveys and to encourage our membership to participate in order to provide data to the coding and reimbursement committee. Dr. Mitchell was asked to communicate directly with the executive committee and to publish announcements in our newsletter and our website in order to notify spinal neurosurgeons about the importance of the surveys. He will also communicate with Dr. Johnson who will be taking over leadership of this committee.

**Membership Committee:** Dr. Gokoslan- eblast scheduled to go out to all residents shortly after the AANS meeting to notify residents about membership policies and to encourage registration.

**Newsletter:** Dr. Groff will be the newsletter chair.

**CME Liason:** Dr. Mendel – no new business.

**Publications:** Dr. Wang – Spine, The Spine Journal, J Neurosurgery, and Neurosurgery have all offered to consider publishing proceedings from our meeting. A decision as to which arrangement best suits the section will be made over the next six months.

**QIW:** Dr. Resnick – no report given

**Meeting Services:** Dr. Branch presented the proposals from Broadwater and the CNS. It was emphasized that the change in meeting services was not a plan to distance ourselves from either of our parent organizations. The change is meant to improve our ability to provide a top quality meeting to our members.

Discussion of the proposals occurred.

**A motion was made to accept the proposal tendered by the Congress of Neurological Surgeons**.

**This motion was approved following discussion. Four voting members present voted to approve the motion. One voting member voted against. One member present and two proxy voted to abstain.**

**Following further discussion, a motion was made to direct the chairman to pursue further negotiations with the Congress with regard to meeting services.**

**This motion was discussed and unanimously approved**.

New Business:

**A motion was made to investigate a spine directed NREF contribution to allow funding of spinal research fellowships. An initial dollar amount of $500,000.00 for research fellowships directed by the spine section.**

**This motion was discussed and approved.**

Announcements:
Dates of the next EC meeting will be distributed once they are available.

Respectfully submitted by Daniel Resnick

Executive Committee

**Officers and Committee Chairs**

**JOINT SECTION ON DISORDERS OF THE SPINE & PERIPHERAL NERVES**

**October, 2006**

| Position | 2003-04 | 2004-05 | 2005-06 | 2006-07 |
|---|---|---|---|---|
| Chair | R.Haid | G. Rodts | R. Heary | C. Branch |
| Chair Elect | G.Rodts | R. Heary | C. Branch | J. Alexander |
| Immediate Past Chair | N.Baldwin | R. Haid | G. Rodts | R. Heary |
| Secretary | C.Branch | C. Branch | D.Resnick | D. Resnick |
| Treasurer | T.Ryken | T. Ryken | T. Ryken | C. Wolfla |
| Members at Large | R.Heary<br>R. Apfelbaum<br>J. Alexander | D. Kim<br>R. Apfelbaum<br>J. Alexander | J. Alexander<br>D. Kim<br>K. Foley | D. Kim<br>K. Foley<br>G. Trost |
| Ex-Officio Members | R. Heary<br>Z. Gokaslan | Z. Gokaslan | Z. Gokaslan | C. Shaffrey<br>G. Rodts |
| Annual Meeting Chair | D.Resnick | C. Shaffrey | M. Groff | M. McLaughlin |
| Scientific Program Chair | C. Shaffrey | M. Groff | M. McLaughlin | J. Hurlbert |
| Exhibit Chair | M.McLaughlin/Knighthly | M.McLaughlin | J. Knightley | J. Knightly |
| Future Sites | J. Alexander | J. Alexander | J. Alexander | I. Kalfas |
| Education Committee Chair | J.Hurlbert | J. Hurlbert | J. Hurlbert | C. Kuntz |
| CME Representative | T.Ryken | T. Ryken | T. Ryken | E. Mendal |
| Newsletter | Hurlbert/Khoo | L. Khoo | J. York | M. Groff |
| Rules and Regulations Chair | D.DiRisio | D. DiRisio | D. DiRisio | T. Choudhri |
| Nominating Committee Chair | N.Baldwin | R. Haid | R. Rodts | R. Heary |
| Research and Awards Committee Chair | | J.Guest | C. Wolfla | P. Gerszten |
| Publications Committee Chair | V.Traynelis | C. Dickman | C. Dickman | M. Wang |
| Web Site Committee Chair | Levi/Wolfla | C. Wolfla | C. Wolfla | C. Wolfla |
| Guidelines Committee Chair | D.Resnick | D. Resnick | P. Matz | P. Matz |
| Membership Committee | G.Trost | G. Trost | G. Trost | Z. Gokoslan |
| Outcomes Committee Chair | P.Gerszten | P. Gerszten | M. Kaiser<br>T. Choudhri | M. Kaiser |
| CPT Committee | W.Mitchell<br>G. Przybylski | W. Mitchell | W. Mitchell<br>R. Johnson | R. Johnson |
| Peripheral Nerve Task Force Chair | R.Midha | R. Midha | E. Zager | E. Zager |
| Washington/FDA | Fessler/McCormick | P. McCormick | R. Rodts | R. Heary |
| Section Rep.,P.A.C. | S.Ondra | S. Ondra | S. Ondra | S. Ondra |
| Public Relations | G. Pait | C. Kuntz<br>T.Choudhri | C. Kuntz<br>T. Choudhri | T. Choudhri |
| Fellowships | | | J. Alexander | P. Mummaneni |

| | | | | |
|---|---|---|---|---|
| NREF Advisory Board | | | | J. Guest |
| AANS PDP Representative | | | | M. Groff |

JOINT SECTION ON DISORDERS OF THE SPINE & PERIPHERAL NERVES

**Committee Membership**

**March 10, 2005**

| | 2002-03 | 2003-04 | 2004-05 | 2005-06 | 2006-07 |
|---|---|---|---|---|---|
| Nominating Committee Mem | N.Epstein | R.Fessler | J. Campbell | V. Traynelis | R. Apfelbaum |
| | R.Fessler | J.Campbell | V. Traynelis | R. Apfelbaum | R. Midha |
| | J.Campbell | V.Traynelis | R. Apfelbaum | R. Midha | G. Trost |
| | | | | | |
| Strategic Planning Committe | N.Baldwin | R.Haid | R. Rodts | R. Heary | C. Branch |
| | P.McCormick | C.Branch | R. Heary | C. Branch | J. Alexander |
| | R.Rodts | R.Rodts | C. Branch | T. Ryken | D. Resnick |
| | C.Branch | T.Ryken | T. Ryken | G. Rodts | C. Wolfla |
| | R.Haid | N. Baldwin | R. Haid | | R. Heary |
| | | | | | |
| | | | | | |
| Research and Awards Comm | C.Wolfla | C.Wolfla | J. Guest | C. Wolfla | |
| | P.Sawin | P.Sawin | C. Wolfla | J. Guest | |
| | | G.Trost | G. Trost | G. Trost | |
| | | | C. Shaffrey | C. Shaffrey | |
| | | | | | |
| Fellowships | | | | J. Alexander<br>S. Ondra<br>C. Shaffrey<br>Z. Gokaslan<br>C. Kuntz | |

heary@umdnj.edu; Cbranch@wfubmc.edu; Resnick@neurosurg.wisc.edu; kfoley@semmes-murphey.com; zgokasl1@jhmi.edu; mgroff@iupui.edu; mclaughlin@princetonbrainandspine.com; jknightly@atlanticneurosurgical.com; jhurlber@ucalgary.ca; cwolfla@neuroscience.mcw.edu; matzpg@yahoo.com; trost@neurosurg.wisc.edu; mgk7@columbia.edu; tanvir.choudhri@msnyuhealth.org; zagere@uphs.upenn.edu; sondra@nmff.org; Charleskuntz@yahoo.com; Kalfas@neus.ccf.org; Rjohnson@neurosurgery.wayne.edu; myw@usc.edu; gersztenpc@upmc.edu; neurokimdaniel@yahoo.com; joseph.cheng@vanderbilt.edu; vmum@aol.com; jtalexan59@yahoo.com CIS8Z@hscmail.mcc.virginia.edu; Gerald_Rodts@emoryhealthcare.org; zoher.ghogawala@yale.edu; ehud.mendel@osumc.edu; neurokimdaniel@yahoo.com

American Association of Neurological Surgeons

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web: www.AANS.org

September 5, 2006

Christopher Wolfla, MD
Department of Neurosurgery
9200 W. Wisconsin Ave.
Milwaukee, WI 53226

Dear Doctor Wolfla:

The enclosed financial statements for the AANS/CNS Section on Disorder of the Spine & Peripheral Nerves are for the Year Ended June 30, 2006, and comparative information for the Year Ended June 30, 2005.

The financials statements have been audited by the auditing firm of RSM McGladrey. Until their final report and opinion are presented, changes to Fiscal Year 2006 are a small possibility. After your review of the financial statements and commentary, if you have any questions, please do not hesitate to contact me at 847-378-0509 or rwe@aans.org.

Sincerely,

Ronald W. Engelbreit, CPA
Deputy Executive Director

Enclosures

Cc: Charles L. Branch, MD
Donald O. Quest, MD
Richard G. Ellenbogen, MD
James R. Bean, MD
Joel D. MacDonald, MD
Laurie Behncke

AANS/CNS Section on Disorders of the Spine
Statement of Financial Position
As of June 30, 2006

| | Current Year 06/30/06 | Prior Year 06/30/05 |
|---|---|---|
| ASSETS | | |
| Checking & Short Term Investments | $854,910 | $703,221 |
| Accounts Receivable, net of Allowance for Uncollectible Accounts | 32,800 | 9,762 |
| Prepaid Expenses | 12,548 | 17,398 |
| Long-Term Investment Pool, at Market | 1,211,422 | 940,545 |
| TOTAL ASSETS | $2,111,680 | $1,670,927 |
| LIABILITIES AND NET ASSETS | | |
| **Liabilities** | | |
| Accounts Payable and Current Liabilities | $46,250 | $25,000 |
| Deferred Contribution Revenue | 41,000 | |
| Deferred Dues | 32,450 | 27,850 |
| **Total Liabilities** | **$119,700** | **$52,850** |
| **Net Assets** | | |
| Unrestricted | $1,618,077 | $1,250,199 |
| Net Revenue (Expense) | 373,903 | 367,878 |
| **Total Net Assets** | **$1,991,980** | **$1,618,077** |
| TOTAL LIABILITIES AND NET ASSETS | $2,111,680 | $1,670,927 |

AANS/CNS Section on Disorders of the Spine
Statement of Activities
For the Twelve Months Ending June 30, 2006

| | FY '04 Final | FY '05 Final | | YTD FY'05 | YTD FY '06 | | FY '06 Budget |
|---|---|---|---|---|---|---|---|
| **REVENUES** | | | | | | | |
| Membership Dues | 52,125 | 55,650 | | 55,650 | 49,488 | | 51,250 |
| Mailing List Sales | 850 | 1,100 | | 1,100 | 1,500 | | |
| Publications Sales Revenue | 50 | | | | | | |
| Fellowship/Award Sponsorship | 45,000 | 50,000 | | 50,000 | 203,000 | | 130,000 |
| Miscellaneous Revenue | 12,398 | | | | | | |
| Contributions for Operating Expenses | 7,679 | 8,363 | | 8,363 | 8,672 | | 8,920 |
| Annual Meeting Revenue | 560,306 | 714,810 | | 714,810 | 730,042 | | 533,570 |
| **TOTAL REVENUES & SUPPORT** | **678,408** | **829,923** | | **829,923** | **992,702** | | **723,740** |
| **EXPENSES** | | | | | | | |
| Audio Visual | 888 | 906 | | 906 | 2,979 | | 1,000 |
| Bank Fee | 352 | 426 | | 426 | 297 | | 400 |
| Contributions & Affiliations | 125,000 | 25,000 | | 25,000 | 25,000 | | 75,000 |
| Decorating | 219 | 271 | | 271 | 504 | | 250 |
| Facility | | | | | | | |
| Food & Beverage | 3,327 | 2,769 | | 2,769 | 1,936 | | 3,500 |
| Fellowships | 131,246 | 131,156 | | 131,156 | 89,491 | | 136,500 |
| Grants | | | | | | | |
| Gifts & Gratuities | | | | | | | |
| Marketing & Advertising | 4,425 | | | | | | 6,000 |
| Legal Services | | | | | | | |
| Office & other Supplies | 266 | 950 | | 950 | 521 | | 400 |
| Photocopy | 116 | 8 | | 8 | 90 | | 200 |
| Postage & Distribution | 1,666 | 1,745 | | 1,745 | 1,182 | | 2,000 |
| Printing/Typesetting | 105 | 324 | | 324 | 36 | | |
| Professional Services | 1,421 | 1,576 | | 1,576 | 538 | | 5,000 |
| Signs | | | | | | | |
| Speaker Expenses | | | | | 5,134 | | |
| Telephone | 60 | 632 | | 632 | 27 | | 1,000 |
| Temporary Personnel | | | | | | | |
| Uncollectable Accounts | | | | | | | |
| Staff Coordination | 8,351 | 8,421 | | 8,421 | 8,781 | | 9,170 |
| Miscellaneous | | (100,000) | | (100,000) | | | |
| Cervical Degenerative Spine Guidelines P | | | | | | | 40,000 |
| Lumbar Fusion Guidelines Project | 13,649 | | | | | | |
| Annual Meeting Expense | 399,405 | 452,030 | | 452,030 | 568,396 | | 504,576 |
| **TOTAL EXPENSES** | **690,496** | **526,214** | | **526,214** | **704,911** | | **784,996** |
| Investment Earnings | 95,637 | 64,169 | | 64,169 | 86,112 | | 51,900 |
| **NET REVENUE** | **83,549** | **367,878** | | **367,878** | **373,903** | | **(9,356)** |

AANS/CNS Section on Disorders of the Spine
Statement of Activities
Annual Meeting
For the Twelve Months Ending June 30, 2006

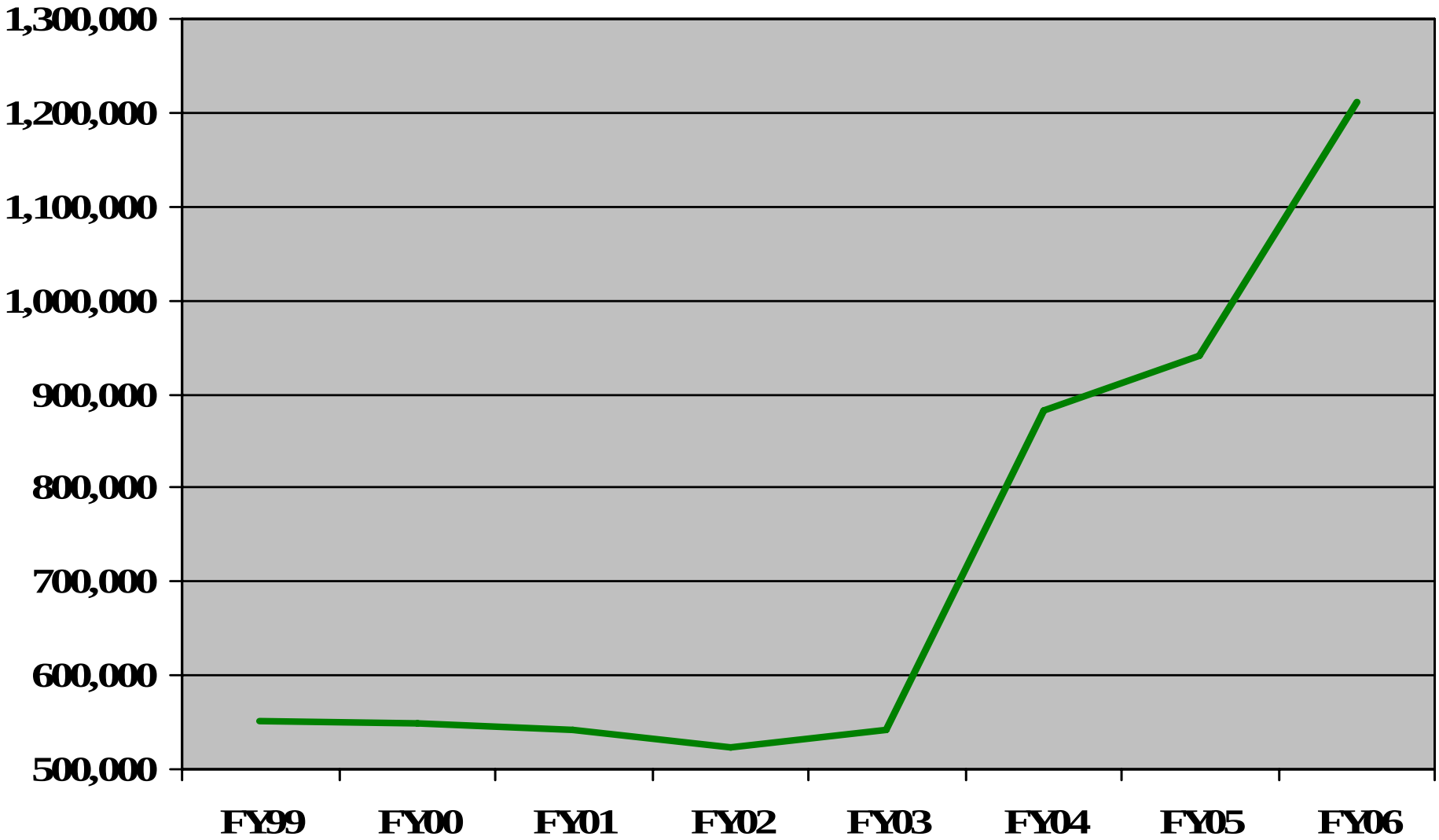
| | FY '04 Final | FY '05 Final | YTD FY'05 | YTD FY '06 | FY '06 Budget |
|---|---|---|---|---|---|
| **REVENUES** | | | | | |
| Registration Fees | 200,465 | 195,820 | 195,820 | 149,680 | 193,050 |
| Exhibitor Fees | 205,275 | 269,725 | 269,725 | 261,900 | 198,400 |
| Contributions/Sponsorships | 134,762 | 229,500 | 229,500 | 282,000 | 118,600 |
| Banquet Revenue | 5,265 | 8,565 | 8,565 | 24,284 | 10,900 |
| Miscellaneous Revenue | 14,539 | 11,200 | 11,200 | 12,178 | 12,620 |
| **TOTAL REVENUES & SUPPORT** | **560,306** | **714,810** | **714,810** | **730,042** | **533,570** |
| **EXPENSES** | | | | | |
| Audio Visual | 35,991 | 42,928 | 42,928 | 67,522 | 69,700 |
| Bank Fee | 9,661 | 9,718 | 9,718 | 7,459 | 10,000 |
| Computer Programing & Supplies | | | | | |
| Decorating | 12,548 | 12,031 | 12,031 | 13,531 | 12,200 |
| Entertainment | 13,944 | 7,516 | 7,516 | 9,958 | 9,550 |
| Facility | 1,575 | 1,034 | 1,034 | | 4,500 |
| Food & Beverage | 146,808 | 191,901 | 191,901 | 203,201 | 185,611 |
| Freight & Shipping | 2,063 | 773 | 773 | 1,581 | 2,500 |
| Gifts & Gratuties | 150 | 920 | 920 | 300 | 1,450 |
| Honoraria & Awards | 36 | 18 | 18 | 1,173 | 4,870 |
| Insurance | 5,606 | 2,688 | 2,688 | 2,754 | 2,800 |
| Marketing & Advertising | 1,347 | 500 | 500 | 150 | 2,250 |
| Outside Labor | 576 | | | | 450 |
| Office & other Supplies | 245 | 443 | 443 | 232 | 600 |
| Photocopy | 404 | 149 | 149 | 986 | 450 |
| Postage & Distribution | 7,814 | 5,229 | 5,229 | 6,499 | 6,675 |
| Printing/Typesetting | 38,637 | 41,914 | 41,914 | 43,627 | 38,350 |
| Professional Services | 9,561 | 13,466 | 13,466 | 14,620 | 16,500 |
| Security | 1,901 | 5,094 | 5,094 | 2,039 | 4,500 |
| Signs | 520 | 1,861 | 1,861 | 2,511 | 3,500 |
| Speaker Expenses | 39,220 | 25,756 | 25,756 | 41,291 | 25,000 |
| Staff Travel | (1,531) | 8,619 | 8,619 | 4,362 | 10,578 |
| Telephone | 4,338 | 10,599 | 10,599 | 6,371 | 9,500 |
| Temporary Personnel | 1,978 | 2,406 | 2,406 | 1,887 | 2,500 |
| Tours & Transportation | 1,014 | | | 633 | 2,500 |
| Volunteer Travel | | 9,824 | 9,824 | 21,488 | 9,792 |
| Uncollectable Accounts | | | | | |
| Staff Coordination | 65,000 | 56,642 | 56,642 | 68,250 | 68,250 |
| Miscellaneous | | | | 45,971 | |
| **TOTAL EXPENSES** | **399,405** | **452,030** | **452,030** | **568,396** | **504,576** |
| **NET REVENUE** | **160,902** | **262,780** | **262,780** | **161,646** | **28,994** |

AANS/CNS Section on Disorders of the Spine
Statement of Activities
For the Twelve Months Ending June 30, 2006

| | FY '04 Final | FY '05 Final | | FY '06 Final | | FY '06 Budget | FY '07 Budget |
|---|---|---|---|---|---|---|---|
| REVENUES | | | | | | | |
| Membership Dues | 52,125 | 55,650 | II | 49,488 | II | 51,250 | 50,750 |
| Mailing List Sales | 850 | 1,100 | II | 1,500 | II | 0 | 0 |
| Publications Sales Revenue | 50 | 0 | II | 0 | II | 0 | 0 |
| Fellowship/Award Sponsorship | 45,000 | 50,000 | II | 203,000 | II | 130,000 | 136,000 |
| Miscellaneous Revenue | 12,398 | 0 | II | 0 | II | 0 | 0 |
| Contributions for Operating Expenses | 7,679 | 8,363 | II | 8,672 | II | 8,920 | 9,368 |
| Annual Meeting Revenue | 560,306 | 714,810 | II | 730,042 | II | 533,570 | 792,376 |
| TOTAL REVENUES & SUPPORT | 678,408 | 829,923 | II | 992,702 | II | 723,740 | 988,494 |
| EXPENSES | | | | | | | |
| Audio Visual | 888 | 906 | II | 2,979 | II | 1,000 | 1,000 |
| Bank Fee | 352 | 426 | II | 297 | II | 400 | 460 |
| Contributions & Affiliations | 125,000 | 25,000 | II | 25,000 | II | 75,000 | 75,000 |
| Decorating | 219 | 271 | II | 504 | II | 250 | 250 |
| Facility | 0 | 0 | II | 0 | II | 0 | 0 |
| Food & Beverage | 3,327 | 2,769 | II | 1,936 | II | 3,500 | 3,500 |
| Fellowships | 131,246 | 131,156 | II | 89,491 | II | 136,500 | 140,800 |
| Grants | 0 | 0 | II | 0 | II | 0 | 500,000 |
| Gifts & Gratuties | 0 | 0 | II | 0 | II | 0 | 0 |
| Marketing & Advertising | 4,425 | 0 | II | 0 | II | 6,000 | 6,000 |
| Legal Services | 0 | 0 | II | 0 | II | 0 | 0 |
| Office & other Supplies | 266 | 950 | II | 521 | II | 400 | 600 |
| Photocopy | 116 | 8 | II | 90 | II | 200 | 200 |
| Postage & Distribution | 1,666 | 1,745 | II | 1,182 | II | 2,000 | 2,000 |
| Printing/Typesetting | 105 | 324 | II | 36 | II | 0 | 0 |
| Professional Services | 1,421 | 1,576 | II | 538 | II | 5,000 | 1,000 |
| Signs | 0 | 0 | II | 0 | II | 0 | 0 |
| Speaker Expenses | 0 | 0 | II | 5,134 | II | 0 | 0 |
| Telephone | 60 | 632 | II | 27 | II | 1,000 | 800 |
| Temporary Personnel | 0 | 0 | II | 0 | II | 0 | 0 |
| Uncollectable Accounts | 0 | 0 | II | 0 | II | 0 | 0 |
| Staff Coordination | 8,351 | 8,421 | II | 8,781 | II | 9,170 | 9,618 |
| Miscellaneous | 0 | (100,000) | II | 0 | II | 0 | 0 |
| Cervical Degenerative Spine Guidelines | 0 | 0 | II | 0 | II | 40,000 | 40,000 |
| Lumbar Fusion Guidelines Project | 13,649 | 0 | II | 0 | II | 0 | 0 |
| Annual Meeting Expense | 399,405 | 452,030 | II | 568,396 | II | 504,576 | 616,053 |
| TOTAL EXPENSES | 690,496 | 526,214 | II | 704,911 | II | 784,996 | 1,397,281 |
| Investment Earnings | 95,637 | 64,169 | II | 86,112 | II | 51,900 | 65,000 |
| NET REVENUE | 83,549 | 367,878 | II | 373,903 | II | (9,356) | (343,787) |

**Long-term Investments of the AANS\CNS Section**

**on Disorder of the Spine & Peripheral Nerves**



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# Investment Account





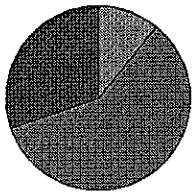
**Account Number:** GS 08240 25

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
CNS SECTION ON DISORDERS OF
THE SPINE
5500 MEADOWBROOK INDSTRL CT
ROLLING MEADOWS IL 60008-3800

## June 2006

## Asset allocation

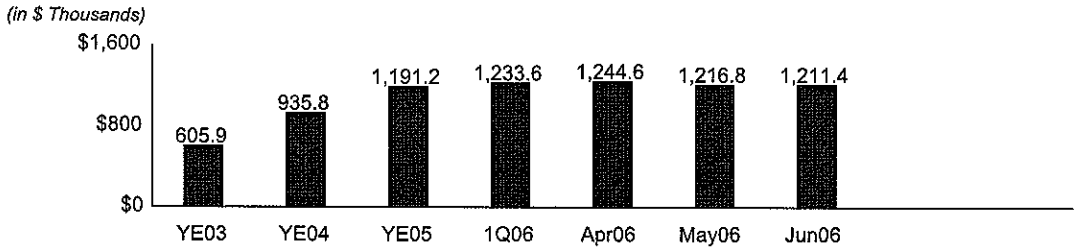
*This graph provides values and/or percentages by asset class. Insurance products, 529 Plans, Private investments, accrued interest and pending return of principal are not included in the asset classification*



| | Total asset value | % of total |
|---|---|---|
| Cash | $ .00 | 0.00 % |
| Cash alternatives | 134,275.83 | 11.08 % |
| Equities | 715,091.18 | 59.03 % |
| Fixed income | 362,067.23 | 29.89 % |
| Balanced | .00 | 0.00 % |
| Alternative strategies | .00 | 0.00 % |
| Other | .00 | 0.00 % |
| **Total** | **$ 1,211,434.24** | **100.00 %** |

## Total value comparison

*This graph includes credits, debits and changes in market value. It does not include Insurance products, 529 Plans, Private investments, accrued interest and pending return of principal.*




**Account instructions**
The account record was signed by your Financial Advisor and approved by a Principal of the Firm.

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*PP3A032174-X6 - 0806 - GS - 0*

# Investment Account

H

*PP3A032174-X6*
*- 000008S*

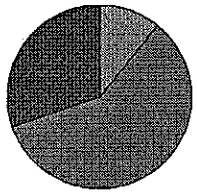
**Account Number:** GS 08240 25

0004235 02 AT 0.545 027PP3A
AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
CNS SECTION ON DISORDERS OF
THE SPINE
5500 MEADOWBROOK INDSTRL CT
ROLLING MEADOWS IL 60008-3800

## *August 2006*

## Asset allocation

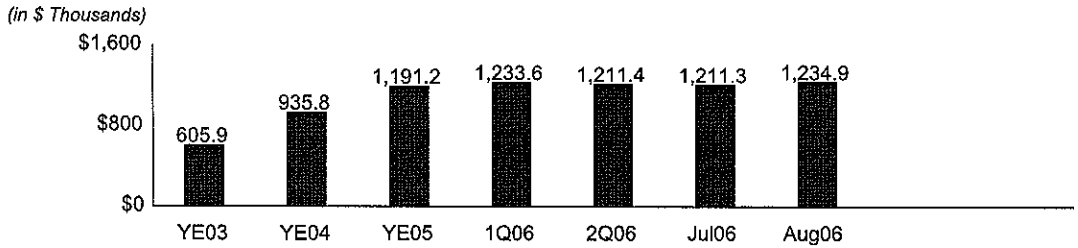
*This graph provides values and/or percentages by asset class. Insurance products, 529 Plans, Private investments, accrued interest and pending return of principal are not included in the asset classification*



| | *Total asset value* | *% of total* |
|---|---|---|
| Cash | $ .00 | 0.00 % |
| Cash alternatives | 134,410.36 | 10.88 % |
| Equities | 727,523.84 | 58.91 % |
| Fixed income | 372,947.11 | 30.21 % |
| Balanced | .00 | 0.00 % |
| Alternative strategies | .00 | 0.00 % |
| Other | .00 | 0.00 % |
| **Total** | **$ 1,234,881.31** | **100.00 %** |

## Total value comparison

*This graph includes credits, debits and changes in market value. It does not include insurance products, 529 Plans, Private investments, accrued interest and pending return of principal.*

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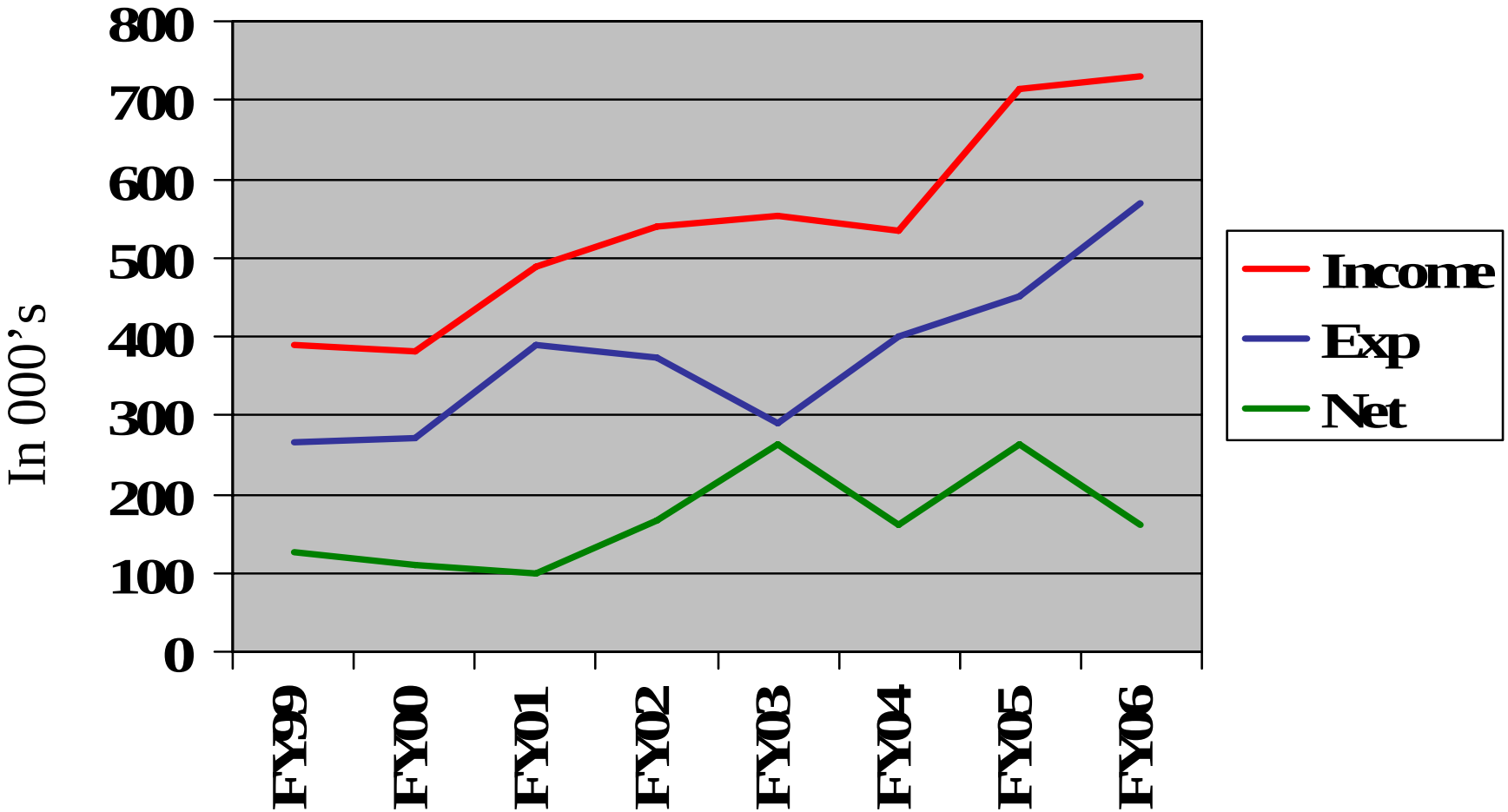
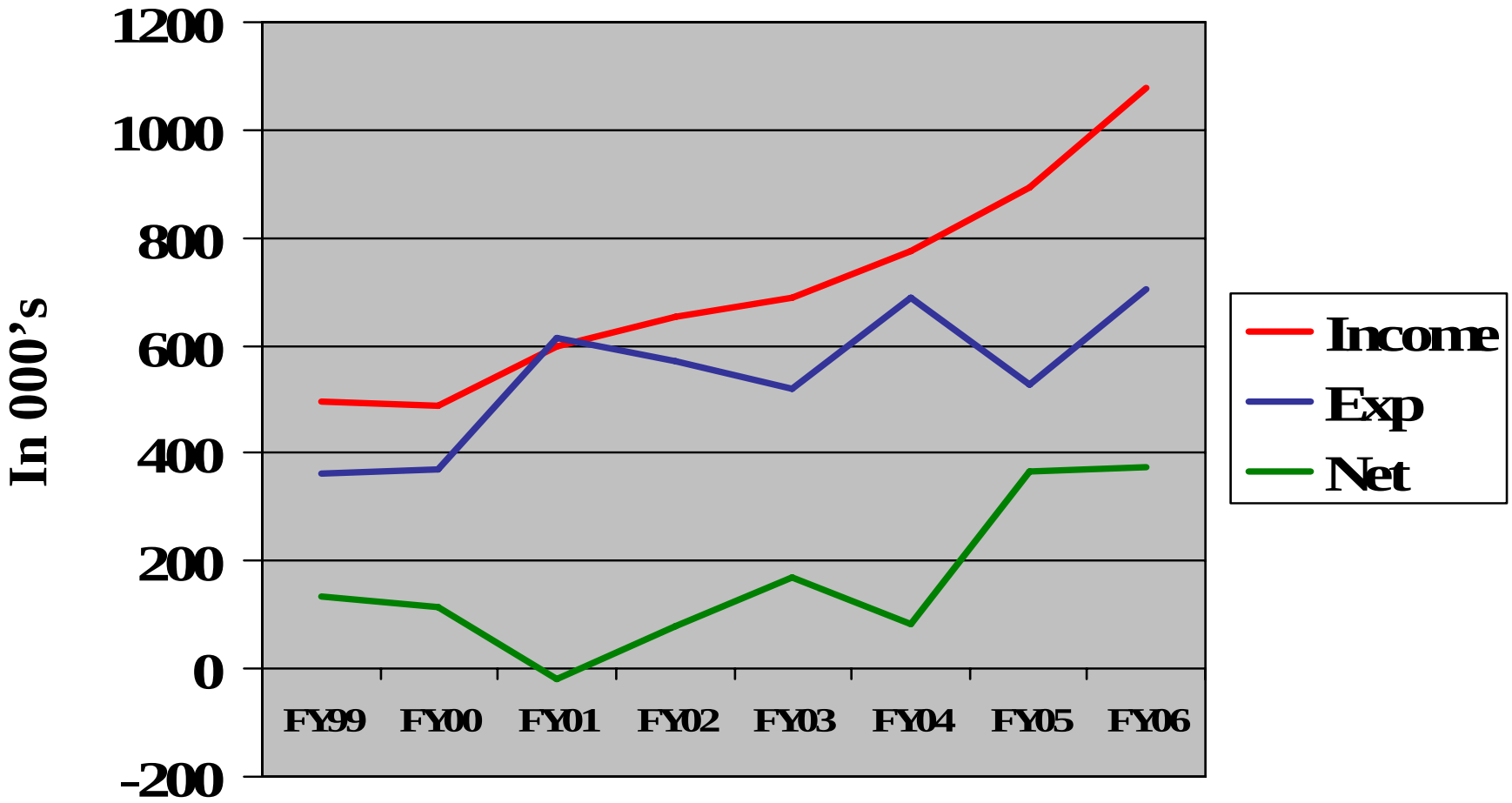
## Annual Meeting Analysis of the AANS\CNS Section on Disorder of the Spine & Peripheral Nerves



# Income Statement Analysis of the AANS\CNS Section on Disorder of the Spine & Peripheral Nerves



American Association of Neurological Surgeons

**5550 Meadowbrook Drive**
**Rolling Meadows, IL 60008**

**member services:** 888.566.AANS
**phone:** 847.378.0500
**fax:** 847.378.0600
**web:** www.AANS.org
www.NeurosurgeryToday.org



August 21, 2006

Charles L. Branch Jr., MD
WFU Baptist Medical Center
Medical Center Blvd/Neurosurgery
Winston Salem, NC 27157

Dear Dr. Branch,

At the recent AANS Executive Committee Meeting, the AANS Annual Meeting dates for 2008 in Chicago were changed from March 29 – April 3 to April 26 – May 1. There was a conflict with another large medical association holding their Annual Meeting over the exact dates as the AANS. Moving the date has the additional beneficial effect of increasing the separation between the AANS Annual Meeting and the Spine Section Meeting.

Should you have any questions, please feel free to contact Patty Anderson, AANS Director of Meetings.

Sincerely,

Donald O. Quest, MD
AANS President

Cc: Joseph T. Alexander, MD
Robert F. Heary, MD
Daniel K. Resnick, MD
Christopher E. Wolfla, MD

**RESEARCH AND AWARDS COMMITTEE**

**Spine Section Executive Committee Meeting**
**CNS Chicago October 9th, 2007**

**1. Current Awards:**

| Award | Vendor Support | Amount |
|---|---|---|
| Larson Award | Depuy Spine | $30,000 |
| Kline Award | Integra | $15,000 |
| Apfelbaum Award | Aesculap | $15,000 |
| Cloward Fellowship | Medtronic | $30,000 |
| Cahill Fellowship | Synthes | $30,000 |
| Sonntag Fellowship | Medtronic | $5,000 |
| Crockard Fellowship | Depuy Spine | $5,000 |
| Outcomes Committee Award | Wallace Fund | $3,000 |
| Mayfield Award (Basic) | Spine Section | $3,000 |
| Mayfield Award (Clinical) | Spine Section | $3,000 |

**2. Deadline will be December 1st, 2006.**

**3. Awards Reviewers:**

Peter C. Gerszten, MD
R. John Hurlbert, MD
Gregory R. Trost, MD
Charles Kuntz, IV, MD
Praveen V. Mummaneni, MD
Allan D. Levi, MD, Ph D

**4.Reviewers for Mayfield Awards?**

**5. 2007 Spine Section Meeting**
15 minutes to announce the 2007 award winners
45 minutes will be allotted to have the 2006 award winners present their work

**6. Other business**
Current status of 1500 word manuscript for the Mayfield Awards

American Association of Neurological Surgeons

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**Rolling Meadows, IL 60008**

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**web:** www.NeurosurgeryToday.org
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July 12, 2006

Daniel K. Resnick, MD
University of Wisconsin-Madison
600 Highland Ave. K4/834 CSC
Madison, WI 53792-0001

Dear Dr. Resnick:

I am writing to the chairs and secretaries of each section to ask for your support of the AANS Case Studies project. This is a new project at the AANS which contains an online repository of neurosurgical case material submitted and reviewed by neurosurgeons for education within our community.

As you may recall, at any stage in practice one encounters cases which differ from the "classic" textbook cases that are often portrayed in our textbooks. In short, there is a great deal to be learned by coming to understand the nuances of how disease presentation and treatment may vary, even within the same diagnosis, when one has seen a large body of case material.

Recognizing this, we set out to create a system whereby neurosurgeons in practice could easily submit cases to an online repository. The system allows one to upload PowerPoint, images, audio, video, word documents and other text files to describe case material that you have seen in practice. The fully searchable database is now available online at MyAANS.org and is organized by disease sections.

You can read more about the features of the index at http://www.aans.org/library/Article.aspx?ArticleId=38185 in our spring 2006 AANS *Bulletin;* or you can view a test drive of the system by logging into MyAANS.org and pointing your browser to https://www.myaans.org/Default.aspx?tabid=131, the online help area for the index.

We are asking if each of the Joint Sections would help us to identify a section member to serve as a reviewer for cases in their subspecialty area. To further your understanding of the initiative, we would very much like to present the Case Studies Project to your executive committee either by conference call or a 10 minute review in person (perhaps at the CNS meeting in Chicago). If you prefer that your volunteer view the demonstration instead, that can be arranged.

We do think this will be a valuable service to your section members. Please contact me at bcarter@partners.org or 617-726-3360 with your thoughts and if it would be possible to present to your committee.

Thank you and best regards,

Bob S. Carter MD PhD
AANS Case Studies Project Leader

cc: Shelley D. Timmons, Chair AANS Information Technology Committee

**AANS 2007 – Joint Section Spine and Peripheral Nerve Afternoon Sessions**

Tuesday

2:45-5:30 Peripheral Nerve

2:45-3:15 (30 minutes)
Guest Lecturer: Treatment Strategies for Upper Extremity Peripheral Nerve Injuries
Christopher Oberlin, M.D.@
Moderator: Robert J. Spinner, M.D.@

3:15-4:30 (75 minutes – 15 minutes each speaker)
Symposium: Peripheral Nerve Debates
Moderator Rajiv Midha, M.D. and John E. McGillicuddy, M.D.@

1) Endoscopic vs Open Carpal and Cubital Tunnel Decompression
   Kartik G. Krishnan, MD vs. Eric L. Zager, M.D.@

2) Lumbar Radiculopathy vs. Lower Extremity Neuropathy
   Allen H. Maniker, M.D. vs. Allan J. Belzberg, M.D.@

3) Questions and Panel Discussion

4:30-5:30 (60 minutes – 10 minutes each abstract)
Oral Abstract Presentations – 6

**Wednesday**

2:45-5:30 Spine

2:45-4:10 (85 minutes – 15 minutes each speaker)
Symposium:
Moderator: Charles Kuntz, IV, M.D. and Michael W. Groff, M.D.

Option 1 Motion Preservation

1) Cervical Arthroplasty: New Horizon – Regis W. Haid, Jr., M.D.@
2) Lumbar Arthroplasty: Success or Failure? – Richard G. Fessler, M.D., Ph.D.
3) Posterior Interspinous Process Distraction/Facet Replacement – Larry T. Khoo, M.D.
4) Posterior Dynamic Stabilization: Preliminary Data – Joseph T. Alexander, M.D.@
5) Minimally Invasive Decompression RCT– Claudius F. C. Thomé. M.D.@
6) Questions and Panel Discussion

Option 2 Spondylolisthesis or Other

1) Primary Repair of Pars Defects
2) Posterolateral Fusion for Degenerative Spondylolisthesis
3) Fusion and Fixation for Degenerative Spondylolisthesis
4) Reduction for High Grade Spondylolisthesis
5) Fusion in Situ for High Grade Spondylolisthesis
6) Questions and Panel Discussion

4:10-5:30 (80 minutes – 10 minutes each abstract)
Oral Abstract Presentations – 8

Dan
Here is a response from the ACP people to Paul's communication.
CB

---

From: Jayne Schablaske [mailto:schablas@ohsu.edu]
Sent: Thu 7/20/2006 2:40 PM
To: pmatz@uabmc.edu
Cc: Roger Chou; timothy-ryken@uiowa.edu; Charles Branch
Subject: Re: Evidence-based Clinical Practice Guidelines for Low back Pain

Dear. Dr. Matz -

Thanks very much for your participation in the peer review - we appreciate your expertise and input.

At the end of July I will send the draft evidence review and peer review form via email, unless you would prefer a hard copy send in the mail.

We will need to have review comments within 3-4 weeks upon receipt. We are making every effort to make the systematic evidence review as concise as possible, but given the scope of the project we anticipate that peer review will require several hours of time. We can provide the evidence electronically or as a hard copy. We anticipate that it will take about 3 months after the systematic evidence review has undergone the peer review process to complete the draft Clinical Practice Guidelines, which would be sent out for peer review in the fall.

If you have any questions, please feel free to ask me or Dr. Chou.

Jayne

---

Jayne Schablaske
Senior Research Assistant

Oregon Evidence-based Practice Center
OHSU - Department of Medical Informatics & Clinical Epidemiology
Mailcode: BICC
3181 SW Sam Jackson Park Road
Portland, OR 97239-3098
503.418.3347 | Fax: 503.494.4551

>>> "Paul Matz" <pmatz@uabmc.edu> 07/17/06 11:14 AM >>>

Dr. Chou,

In reference to your email below, I am volunteering to act as a neurosurgery peer-reviewer in your development of Evidenced-based guidelines for low back pain. I will check with Dr. Ryken on his

status.  Please let me know the details and the time frame.

Paul Matz

---

Gentlemen
It is difficult to know how to process this but we should investigate this.  I will appoint Paul Matz, current Guidelines Committee Chair for

the Section and Tim Ryken, former Section Treasurer/Outcomes expert to understand this intiative and to serve as reviewers.  By way of this email stream, I will ask Paul to communicate with Roger
Chou and express our interest and offer to serve as a resource.  He will report to the Section on this initiative and its potential impact and
what resources we need to direct toward that program and similars ones that will undoubtedly pop up in the future.More to follow.
Charlie Branch

**Peer Review** **August 3, 2006**

Dear Peer Reviewer:

Thank you for agreeing to serve as a peer reviewer for the evidence review for the American Pain Society/American College of Physicians Clinical Guidelines for the Management of Low Back Pain. Included is a brief Peer Review Form to use for your evaluation of the evidence.

As communicated in the invitation sent to you, part of the evidence-based clinical guideline development process is to seek review of the material by external experts and potential users of the guidelines. We plan a 2-stage peer review process for this Guidelines project. The first stage is to review the evidence report, to help insure that the recommendations are based on accurate evidence. The second stage will be to review the actual draft guidelines and recommendations, which we expect to be send out for peer review later this year.

Because of the large volume of evidence to cover for low back pain the evidence report is quite lengthy. We realized that peer reviewers might not have time to provide feedback on every part of the report. Please feel free to focus your comments on those parts of the report where you feel you have the most expertise in. We are particularly interested in knowing if there are important clinical trials that are missing.

Sincerely,

Roger Chou, MD
Director, American Pain Society Clinical Guidelines Development
Oregon Evidence-based Practice Center
Oregon Health & Science University
Portland, OR
503-494-5367
chour@ohsu.edu

| | | | | | |
|---|---|---|---|---|---|
| **Name of Reviewer:** | Paul Matz, MD | | | | |
| **Address:** | Suite 1034 FOT, 510 20th Street South | | | | |
| **City:** | Birmingham | **State:** | **AL** | **Zip code:** | 35294 |
| **Phone:** | 205 975 8872 | | **Fax:** | 205 975 8337 | |
| **Email:** | pmatz@uabmc.edu | | | | |



| | | | | |
|---|---|---|---|---|
| **May we list you as a Peer Reviewer in the final Guidelines?** | **YES** | **x** | **NO** | |

---

**Instructions:**

Please read and review this Draft evidence review with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity and accuracy of the interpretation of the evidence data. If applicable, please specify the draft page and line numbers in your comments.

Given the length of the evidence report, we realize that it would be difficult to provide detailed comments on every part of the report. Please feel free to focus your comments on your particular specialty area/area of expertise as well as on the overall structure and content of the report. We are also particularly interested in knowing of important trials that are missing from the report.

If you need more space than is provided, please attach additional pages.

Return this completed form via email (or mail, if that is the method you received it) by **August 29, 2006** to:

Jayne Schablaske
Oregon Evidence-based Practice Center
Mail code: BICC
Oregon Health Sciences University
3181 SW Sam Jackson Park Road
Portland, OR 97239

For questions, you may contact via email: schablas@ohsu.edu, or phone: 503-418-3347.

| **Specialty Area:** | Neurological Surgery |
|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| 1. Are the methods for identifying relevant systematic reviews and studies adequate? | **YES** | **X** | **No** | | **Not Clear** | |
| 2. Are the methods for exclusion of studies appropriate? | **YES** | **X** | **No** | | **Not Clear** | **X** |
| 3. Are the methods for grading the quality of systematic reviews and individual studies appropriate? | **YES** | **X** | **No** | | **Not Clear** | |
| 4. Is any critical literature, or work in progress, missing? | **YES** | **X** | **No** | | **Not Clear** | |

| | |
|---|---|
| **Comments:** | In the development of these guidelines, the authors undertook a standard review process. For any given question, systematic reviews were obtained along with any RCTs that related to the subject matter. In addition, any case-control studies dealing with the relevant topic were often reviewed. The main drawback of the search process was the shear volume of articles to be found regarding low back pain. Because the subject field was so broad, it appeared difficult to include and review smaller studies. Therefore, emphasis was given to systematic reviews. This approach is acceptable if the original trials and studies contained in a systematic review are re-evaluated. It appeared that sometimes this did not occur.<br><br>Case in point: lines 954-955 state that MRI and CT have similar accuracy in diagnosing herniated discs. This conclusion was drawn from the manuscript: Jarvik J and Deyo R: ***Ann Intern Med 2002;137:586-597.*** However, these authors also state that "Computed tomography can accurately depict the foraminal and extraforaminal nerve root because surrounding fat provides natural contrast …. computed tomography is less effective for evaluating the intrathecal nerve root." This statement is important since most imaging should be undertaken to evaluate nerve root impingement.<br><br>In terms of critical literature missing, the authors (with regard to question 8: surgery and low back pain) did not include any analyses contained in the "Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine." These are included in ***J Neurosurg:Spine 2:636-759, 2005.*** These guidelines review the utility of surgery for lower back pain. |

## Format

| | | | | | | |
|---|---|---|---|---|---|---|
| 1. Is the material organized appropriately and systematically? | **YES** | | **No** | | **Not Clear** | **X** |
| 2. Are the terms adequately defined? | **YES** | **X** | **No** | | | |
| 3. Is the writing style appropriate for health care professionals and patients? | **YES** | **X** | **No** | | | |
| 4. Is the format and structure satisfacotry? | **YES** | | **No** | | **Not Clear** | **X** |

| | |
|---|---|
| **Comments:** | The material was organized systematically. However, the scope of the project was so broad that it appeared detail was missing in the analyses of complex reviews and clinical studies. One might consider two sets of guidelines. One dealing with non-invasive therapy for lower back pain (questions 1-5, 10) and one dealing with invasive therapy (including surgery) for lower back pain (questions 6-9). |

## Overall content

| **The Draft evidence review:** | | | | | | |
|---|---|---|---|---|---|---|
| 1. Has relevant and important Key Questions in the area of LBP | **YES** | **X** | **NO** | | **Not Clear** | |
| 2. Comprehensively covers the Key Questions | **YES** | **X** | **NO** | | **Not Clear** | |
| 3. Is applicable to my patients or area of specialty | **YES** | **X** | **NO** | | **Not Clear** | |
| 4. Has an adequate level of detail | **YES** | | **NO** | | **Not Clear** | **X** |
| 5. Is useful overall to determine LBP recommendations | **YES** | | **NO** | | **Not Clear** | **X** |

| | |
|---|---|
| **Comments:** | Because of the broad scope of the project, it appeared that detail was lacking, especially with regard to in-depth analysis of the appropriate RCTs. In question 1, the authors review the arsenal of diagnostic tests available. The conclusions were sound except for the accuracy of CT and MRI which should be clarified (discussed above). Questions 2-5 address non-invasive management of lower back pain. These cover a broad array of topics in appropriate fashion.<br><br>Question 6: lines 4362 to 4366 review a study comparing fusion for isthmic listhesis to fusion for discogenic back pain. Surgery for the latter was 44% as successful. This is essentially not interpretable since one is comparing "apples to oranges." Accordingly, one should expound about the weaknesses of this study.<br><br>Question 7: deals primarily with injections and seems to show mixed results for different types of injections over the short- and long-term.<br><br>Question 8 addresses the effectiveness of surgery for lower back pain. This question does not review of the analyses undertaken in the "Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine." These are included in ***J Neurosurg:Spine 2:636-759, 2005.***<br><br>Lines 5487 to 5491: The authors state conflicting results regarding fusion for chronic lower back pain with two higher quality trials |

| | |
|---|---|
| | stating surgery was no better and one supporting surgery. Although Fairbank et al. demonstrated improvement with surgery (n=349 study group, $p<0.05$), the authors of this study downplayed these results (***BMJ 2005;330(7502):1233***) for uncertain reasons. Furthermore, in this trial, 48 of 173 patients in the rehabilitation arm crossed over to surgery (28%). Consequently, it is the opinion of this reviewer that few conclusions can be made regarding the efficacy of intensive rehabilitation of 28% of the group has opted to cross over to the alternate therapy. The Fritzell study, though, was a well-controlled trial of 294 patients that supported surgery over a 2-year interval. The Brox studies only included 60-64 patients; in the lumbar fusion guidelines, the small sample size and large confidence intervals noted in the Brox study indicated that the sample size was too small. ***J Neurosurg: Spine 2:670-672, 2005.***<br><br>The authors of these guidelines conclude that the better results observed in the non-surgical group in the Brox and Fairbank studies may be due to improvements from intensive rehabilitation (a result which might be questioned given the small size of the Brox study, Lines 5254 to 5260).<br><br>The authors state that the efficacy of instrumented to non-instrumented fusion is inconsistent though clinical outcomes are similar after excluding two lower-quality trials reporting better outcomes (lines 5492-5495) The authors may be better served undertaking a true meta-analysis and defining inclusion criteria and outcome measure rather than randomly excluding trials as this seemingly introduces bias. The lumbar fusion guidelines ***J Neurosurg: Spine 2:700-706, 2005*** conclude that pedicle screw fixation may be an option for high-risk patients who may have a malunion but that the utilization of pedicle screws does increase cost and complications.<br><br>Lines 5515-5519, “Trials of surgery versus non-surgical management generally included patients who did not have clear indications for surgery, failed to improve after 6 months to 2 years conservative management, and had disease localized to L4-5 or L5-S1.<br>It is my opinion that failure to improve could be construed as a reason to undertake surgery and that there is not an issue with surgery at L4-5 or L5-S1. These points should be clarified.<br><br>Spinal Stenosis: Lines 5520-5526 indicated that standard initial surgical therapy (decompression and/or diskectomy) is associated with improved outcomes after one year compared to initial non-surgical therapy with differences attenuated after 4 years. This |

| | |
|---|---|
| | reviewer concurs. Lines 5532-33 concluded diskectomy superior to chemonucleolysis, a result with which this reviewer concurs.<br><br>Lines 5537-5540 conclude no difference between laminectomy and multiple laminotomy and no difference between decompression with and without posterolateral fusion; this result is in agreement with the lumbar fusion guidelines (***J Neurosurg: Spine 2:686-691, 2005***) which state that fusion is not generally indicated if overt instability is not evident.<br><br>Lines 5541-5543, conclude that no difference exists between patients undergoing fusion alone versus fusion with decompression in the setting of L5-S1 isthmic spondylolisthesis. This conclusion was referenced from the study by E Carragee ***in J Bone Joint Surg Am 79:1175-1180, 1997***. A small group of patients were divided into smokers and nonsmokers. In the nonsmokers, patients underwent non-instrumented PLF ± decompression. In the smokers, patients underwent instrumented PLF ± decompression. It appeared that decompression increased the pseudoarthrosis and pain rates. However, numbers were small and patients were not randomized at all. This author does not believe this represents a "good quality" randomized trial. I would put the strength of data as "poor" not "fair" as these guidelines authors have listed. In addition, the statement should be qualified that this does not extend to patients with neurological deficit (as is stated in the conclusion of the Carragee paper).<br><br>Question 9 addresses the effectiveness of other modalities for treatment of back pain and sciatica. The authors of these guidelines review spinal cord stimulators. They conclude that spinal cord stimulation is beneficial in half of the patients with chronic back/leg pain or failed back surgery syndrome. They report a return-to-work rate of 40%. It is my opinion that they are correct in assessing the quality of supporting data is poor. There do not exist any high quality, randomized controlled trials to support a stronger position. |

GUIDELINE FOR THE
MANAGEMENT OF

# Low Back Pain

## Draft Evidence Review
### Executive Summary

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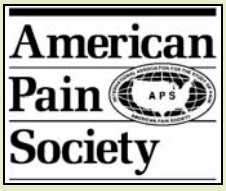
Sponsored by:

The American Pain Society &
The American College of Physicians




CLINICAL GUIDELINE LOW BACK PAIN | AMERICAN PAIN SOCIETY

# EXECUTIVE SUMMARY

## Purpose of this report

This evidence review focuses on evaluation and management of low back pain in adults. The American Pain Society (APS), which commissioned this report, will use it in partnership with the American College of Physicians (ACP) to develop evidence-based recommendations for low back pain.

## Background

Low back pain is an extremely common problem, with a point prevalence in developed countries of up to 33%, one-year prevalence up to 65%, and lifetime prevalence up to 84%, though estimates vary widely. In the US, nonspecific mechanical low back pain is the fifth most common reason for all physician visits, and the second most common symptomatic reason.

Low back pain is costly, with estimates of total annual cost in the U.S. ranging from $20 to $50 billion. In the U.S., low back pain is the most common cause for chronic or permanent impairment in persons under the age of 65, and the most common cause of activity limitations in persons under the age of 45. It has been estimated that between 2% and 8% of the U.S. work force is disabled or compensated for back injuries each year.

Many patients with acute episodes of low back pain do not seek care because symptoms are often brief and self-limited. Among those who do seek medical care, rapid improvements in pain (average improvement of 58% of initial score), disability (average improvement of 58%), and return to work (82% of those initially off work return to work) are seen in the first month. Further improvement generally continues until approximately three months, after which levels for pain, disability, and return to work appear to remain relatively constant. Up to one-third of patients report persistent back pain of at least moderate intensity one year after an acute episode requiring care, and one in five report substantial activity limitations. Recurrences of pain also are common, with 60% to three-quarters of patients experiencing at least one relapse within 12 months. Prolonged disability may be more frequent than previously suspected: in one systematic review of 36 studies on the course of low back pain in the general

population, 16% (range 3% to 40%) of patients were sick-listed 6 months after entry into the study. Factors associated with the development of chronic disability due to low back pain include pre-existing psychological distress, presence of other types of chronic pain, job dissatisfaction or stress, and disputes over compensation issues.

Many options are available for the evaluation and management of acute or chronic low back pain. However, there has been little consensus, either within or between specialties, on appropriate uses of diagnostic tests and interventions. Despite wide variations in practice, several studies have shown that patients experience broadly similar outcomes, though costs of care can differ substantially both between and within specialties. In addition to unexplained practice variations, another historical feature of low back pain management has been the widespread uptake and use of unproven (and sometimes invasive and costly) interventions, some of which have later been shown to be ineffective, or even harmful. Other interventions are widely used despite studies showing only marginal benefits.

## Scope

Target populations for this review are adults (>18 years old), pregnant women, persons with hyperacute, acute, subacute or chronic low back pain, persons with nonspecific low back pain (including discogenic pain, facet joint pain, spondylosis, degenerative disc disease, sacroiliac joint pain, etc.), radicular low back pain (including lumbar disc prolapse), spinal stenosis, and failed back surgery syndrome. Treatment of infection, cauda equina syndrome, cancer, spondyloarthropathies, systemic inflammatory disease, fibromyalgia syndrome, and vertebral compression fracture was excluded from the scope of this review, though evaluation to rule out such conditions was considered within the scope. Evaluation and management of osteoporosis without clear fracture and acute major trauma was also outside our scope. Children and adolescents were excluded because diagnostic and therapeutic considerations are substantially different than in adults. We reviewed evidence on low back pain of any duration.

Target interventions for this review include the following non-invasive interventions: medications, systemic corticosteroids, herbal therapy, brief interventions, back schools, exercise, hydrotherapy, spa therapy, acupuncture, acupressure,

neuroreflexotherapy, spinal manipulation, massage, short wave diathermy, interferential therapy, ultrasound, behavioral intervention, multidisciplinary rehabilitation, physical conditioning programs, traction, and low level laser. Invasive, non-surgical interventions include: epidural steroid injections, intradiscal steroid injections, chemonucleolysis, local injections, facet (zygapophysial) joint injections, prolotherapy, botulinum toxin, adhesiolysis, radiofrequency denervation, intradiscal electrothermal therapy (IDET) and percutaneous intradiscal radiofrequency thermocoagulation. Surgical interventions include: degenerative conditions of the lumbar spine, spinal stenosis, isthmic spondylolisthesis and lumbar disc prolapse.

Target outcomes addressed one of the five core domains for low back pain as suggested in recent recommendations: back specific function, generic health status, pain, work disability, and patient satisfaction.

## Conclusions

**Key Question 1.**

**What features of the history and physical exam are predictive of specific serious underlying conditions ("red flags"), other specific conditions that may be responsive to specific therapies in patients with LBP (such as nerve root compression or spinal stenosis), or high risk for persistent low back pain and associated disability ("yellow flags")?**

***Features of history and physical exam predictive of serious underlying conditions ("red flags"), compression fracture, ankylosing spondylitis, nerve root compression, and spinal stenosis***

- Previous history of cancer (positive likelihood ratio 14.7), unexplained weight loss (positive likelihood ratio 2.7), and failure to improve after 1 month of therapy (positive likelihood ratio 3.0) were associated with a specificity for diagnosing cancer of >0.90 in patients with acute low back pain presenting to primary care in one higher-quality study (level of evidence: fair).
- The presence of any of the following was associated with a high sensitivity (1.00) and moderate specificity (0.60) for diagnosing cancer in one higher-quality study: age >50 years, history of cancer, unexplained weight loss, or failure of conservative therapy (positive likelihood ratio 2.5, negative likelihood ratio 0.0) (level of evidence: fair).

- Few studies have evaluated the accuracy of history and physical exam for diagnosing infection, though history of intravenous drug use, skin infection, or urinary tract infection only had modest sensitivity in one study (level of evidence: poor).
- Older age and history of corticosteroid use were the best predictors of vertebral compression fractures (level of evidence: fair).
- Younger age of onset was sensitive but not specific for diagnosing ankylosing spondylitis. Physical exam findings were generally associated with poor sensitivity and relatively high specificities (level of evidence: fair).
- Describing typical symptoms of sciatica has a relatively high sensitivity but inconsistent specificity for diagnosing radiculopathy. A positive straight leg raise (the best-studied physical exam maneuver) was associated with a pooled sensitivity of 0.91 and specificity of 0.26 in one higher-quality systematic review. A positive crossed straight leg raise was associated with a pooled sensitivity of 0.29 and a specificity of 0.88. The specificity of neurologic deficits consistent with nerve root compression ranges from modest to high (level of evidence: fair).
- In one study, spinal stenosis was less likely in patients younger than 65 years old. A wide-based gait and absence of pain when seated were associated with higher likelihoods of spinal stenosis (level of evidence: fair).

***Features of the history and physical exam associated with development of chronic and disabling low back pain***

- There is consistent evidence from multiple systematic reviews that psychologic distress, job dissatisfaction, high levels of "fear avoidance" beliefs, disputed compensation claims, and somatization are associated with worse low back pain outcomes (level of evidence: good).
- Increased duration or severity of pain and presence of leg pain are modestly associated with poorer outcomes (level of evidence: fair).
- Physical exam findings were inconsistently associated with outcomes and were weaker predictors than psychosocial factors (level of evidence: fair).
- Validated tools or scales for identifying patients likely to have poorer outcomes are lacking, though one study found the Vermont disability questionnaire promising (level of evidence: poor).

**Key Question 1a.**

**Does identification of 'yellow flags' lead to improved outcomes in patients with LBP?**

- Two higher-quality trials found no benefits after 12 months from brief interventions identified at identifying and treating 'yellow flags' relative to usual care or standard physical therapy in unselected patients with acute or subacute back pain (level of evidence: good).
- One lower-quality trial found that an intensive multidisciplinary functional restoration program was more effective than usual care after 12 months in patients with back pain for less than 8 weeks who were identified as being at higher risk for chronic disability using a screening tool (level of evidence: poor).
- One lower-quality trial found fear-avoidance based therapy superior to usual care for back specific functional status after 24 months in patients with persistent activity limitations, though beneficial effects on pain were only short-lived (level of evidence: poor).
- One higher-quality trial found no difference between fear-avoidance therapy and standard physical therapy after 6 months, though fear-avoidance beliefs were decreased in the intervention group (level of evidence: fair).

**Key Question 2.**

**What diagnostic tests should be ordered, and under what circumstances, for patients with LBP?**

**Key Question 2a.**

**What is the diagnostic accuracy of different diagnostic tests for identifying serious underlying conditions (e.g., tumor, infection, compression fracture)?**

- MRI and radionuclide scanning are more sensitive than plain radiography for diagnosing vertebral cancer, though plain radiography is associated with high specificity (level of evidence: good).
- MRI is more accurate than either plain radiography or radionuclide scanning for diagnosing vertebral infection (level of evidence: fair).
- Plain radiography appears sensitive for diagnosing vertebral compression fracture, but is unable to provide information about acuity (level of evidence: fair).
- An elevated erythrocyte sedimentation was associated with moderate sensitivity and specificity for diagnosing vertebral cancer in one higher-quality study (level of evidence: fair).

**Key Question 2b.**

**What is the diagnostic accuracy of different diagnostic tests for identifying other conditions (e.g. nerve root compression, herniated disc, spinal stenosis) that may respond to specific therapies?**

- MRI and CT scan are associated with similar diagnostic accuracy for diagnosing herniated disc or spinal stenosis (level of evidence: good).
- Evidence on the diagnostic accuracy of different imaging methods for diagnosing ankylosing spondylitis is sparse. Plain radiography may have high specificity, but higher-quality studies are needed (level of evidence: fair).
- An elevated ESR was associated with moderate sensitivity and specificity for diagnosing ankylosing spondylitis in patients suspected of having the disease (level of evidence: fair).
- There is no evidence supporting the use of thermography or surface electromyography for diagnosis of low back pain (level of evidence: fair).

**Key Question 2c.**

**In patients with 'red flags,' how does the choice of diagnostic testing affect clinical outcomes**

- There is no direct evidence on the efficacy of diagnostic testing in patients with 'red flags,' though all guidelines recommend prompt and appropriate work-up (including advanced imaging) because delayed diagnosis and treatment can be associated with poorer outcomes

**Key Question 2d.**

**In patients without 'red flags,' how does the choice of diagnostic testing (or no testing) affect clinical outcomes?**

- Routine plain radiography did not identify any additional serious diseases compared to usual care and did not improve outcomes including pain and functional status, though there appeared to be modest beneficial effects on patient satisfaction and psychologic well-being (two trials, one higher-quality) (level of evidence: fair).
- In one lower-quality trial, the combination of delayed selective imaging with a brief educational intervention was not associated with differences in any outcomes relative to routine plain radiography, including patient satisfaction and psychologic distress (level of evidence: poor).

- Routine MRI was associated with only minor benefits on pain and functional status outcomes compared to selective imaging in one higher-quality trial. A lower-quality trial found that in patients who had undergone MRI, disclosure of results was not associated with improved outcomes compared to non-disclosure unless clinically necessary (level of evidence: fair).
- In two higher-quality trials, rapid MRI was not associated with any significant benefits compared to plain radiography in patients in whom imaging was thought indicated (level of evidence: good).

**Key Question 3.**

**What is the effectiveness of different non-invasive interventions for non-specific low back pain, radicular LBP, or spinal stenosis, and under what circumstances?**

## Medications

### *Acetaminophen*

- There is conflicting evidence from lower quality trials regarding the efficacy of acetaminophen versus NSAIDs for acute low back pain, with most showing no difference in outcomes (level of evidence: fair).
- For chronic low back pain, one higher quality trial found acetaminophen inferior to an NSAID on an overall assessment of efficacy (level of evidence: fair).
- Multiple trials of patients with osteoarthritis consistently found acetaminophen inferior to NSAIDs for pain relief (level of evidence: good).
- There is insufficient evidence from single, lower quality trials comparing acetaminophen to other interventions (such as physical therapy, a corset, or spinal manipulation) to accurately judge relative efficacy (level of evidence: poor).
- Acetaminophen is associated with a lower risk of serious GI side effects compared to NSAIDs based primarily on observational data (level of evidence: fair).
- Acetaminophen is better tolerated than NSAIDs (level of evidence: good).
- Additional studies are required to evaluate whether high-dose acetaminophen is associated with increased cardiovascular risk (single observational study) (level of evidence: poor).

### *Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)*

Non-selective, non-steroidal anti-inflammatory drugs

- There is evidence from multiple trials that NSAIDs are associated with modest short-term pain relief compared to placebo in patients with acute low back pain (level of evidence: good).

- A single higher quality trial found that NSAIDs are effective in patients with chronic low back pain (level of evidence: fair).
- NSAIDs have not been shown to be more effective than other medications (opioids, skeletal muscle relaxants) or non-invasive interventions (spinal manipulation, physical therapy, bed rest) (level of evidence: fair).
- There is no evidence that any NSAID is more effective than any other (level of evidence: good).
- NSAIDs are associated with an increased risk of serious GI complications compared to non-use (level of evidence: good).
- NSAIDs other than naproxen were associated with a modest increase in risk of cardiovascular complications relative to non-use in one recent meta-analysis of randomized controlled trials (level of evidence: good).

COX-2 selective NSAIDs

- Systematic reviews of COX-2-selective NSAIDs given for a variety of indications found no clear differences in efficacy (pain relief) relative to non-selective NSAIDs (level of evidence: good).
- Celecoxib is associated with a lower risk of GI complications compared to non-selective NSAIDs, but most of the evidence comes from short-term trials (level of evidence: good).
- Celecoxib appears to be associated with an increased risk of myocardial infarction compared to placebo (level of evidence: good).

### *Aspirin*

- There is insufficient evidence to judge the efficacy of aspirin in patients with low back pain (level of evidence: poor).
- Aspirin is associated with an increased risk of GI bleeding even at low doses (level of evidence: good).
- Aspirin is effective in the primary and secondary prevention of cardiovascular events (level of evidence: good).

## Other medications

### *Antidepressants*

- Tricyclic antidepressants are consistently more effective than placebo for pain relief and other outcomes in higher-quality trials of patients with chronic low back pain, but do not appear to improve functional outcomes (level of evidence: good).
- Several trials suggest that paroxetine and trazodone not effective or marginally effective compared to placebo (level of evidence: fair).

- There is insufficient evidence from head-to-head trials (one lower-quality trial) to judge the relative effectiveness of tricyclic antidepressants and selective serotonin reuptake inhibitors (level of evidence: poor).
- There are no trials on the effectiveness of other antidepressants (such as venlafaxine or duloxetine), and insufficient evidence to judge the efficacy of antidepressants for acute low back pain (level of evidence: poor).
- Although serious adverse events were not reported in the trials, the selected populations evaluated in clinical trials may make it difficult to extrapolate results to general practice (level of evidence: poor).

***Benzodiazepenes***

- There is insufficient evidence to judge the efficacy of benzodiazepines (1 low-quality trial) for acute low back pain (level of evidence: poor).
- Two higher quality trials indicate that benzodiazepines are effective for short-term outcomes in patients with chronic low back pain (level of evidence: fair).
- Diazepam was inferior to carisoprodol (a drug metabolized to meprobamate) in one higher quality trial, but no different than other skeletal muscle relaxants in two other trials (level of evidence: fair).
- Benzodiazepines are associated with increased short-term central nervous system adverse events (level of evidence: good). Risks of addiction, abuse, development of tolerance, and overdose, particularly with long-term use, are unknown.

***Gabapentin***

- Limited evidence from two trials (one higher quality) suggests that gabapentin is associated with modest short-term benefits for pain relief in patients with radiculopathy (level of evidence: fair).
- There are no trials evaluating the efficacy of gabapentin in patients with non-radicular low back pain.

***Muscle relaxants***

- Skeletal muscle relaxants are consistently more effective than placebo for short-term (less than one week) pain relief and global response in patients with acute low back pain (level of evidence: good).
- There is insufficient evidence to judge the efficacy of skeletal muscle relaxants in patients with chronic low back pain or those with sciatica (level of evidence: poor).
- Although there is no evidence proving that one skeletal muscle relaxant is superior to others (level of evidence: fair), the efficacy of cyclobenzaprine is supported by the most evidence.

- Skeletal muscle relaxants are associated with an increased rate of adverse events compared to placebo, though they are usually mild and self-limited (level of evidence: fair).
- Specific safety issues are associated with carisoprodol (metabolism to meprobamate), dantrolene (potentially fatal hepatotoxicity), chlorzoxazone and tizanidine (usually reversible and mild hepatotoxicity).

***Opioid analgesics***

- Multiple trials of patients with various non-cancer pain conditions consistently indicate that opioids are superior to placebo for pain relief in primarily short-term trials (level of evidence: good), though evidence in patients specifically with either acute or chronic low back pain (one higher quality demonstrating benefit) is sparse (level of evidence: fair).
- There is insufficient evidence from single, lower quality trials to judge the efficacy of opioids versus acetaminophen or in addition to NSAIDs (level of evidence: poor).
- Consistent evidence from lower-quality trials found no differences between long- and short-acting opioids on a variety of outcomes in patients with chronic low back pain (level of evidence: fair).
- There were no clear differences between long-acting opioids in two head-to-head trials evaluating different comparisons (level of evidence: fair).
- Although adverse events are common with opioids (level of evidence: fair), there are no reliable estimates for rates of abuse or addiction, overdose, or other serious adverse events (level of evidence: poor).

***Tramadol***

- Tramadol was moderately more effective than placebo for short-term pain and assessment of functional status in one higher-quality trial of patients with chronic low back pain (level of evidence: fair).
- Tramadol was no better than the combination of paracetamol plus codeine in one low-quality trial of patients with chronic low back pain (level of evidence: poor).
- There is insufficient evidence to judge the efficacy of tramadol compared to acetaminophen or opioid analgesics alone or to NSAIDs available in the U.S. (no trials).
- In single trials, tramadol was associated with similar rates of withdrawal due to adverse events (a marker for intolerable or severe adverse events) compared to placebo or the combination of paracetamol + codeine (level of evidence: fair).

### *Systemic corticosteroids*

- Systemic corticosteroids are consistently not associated with a clinically significant benefit in patients with acute sciatica when given parenterally (single injection) or as a short oral taper (three higher-quality trials) (level of evidence: good).
- One trial found no benefit from a single intramuscular injection of corticosteroids in patients with acute non-radicular low back pain, but the level of evidence can't be adequately assessed because it is only available as a conference abstract.
- Serious adverse events after a single large bolus were not reported in one trial (level of evidence: fair). However, systemic corticosteroids are associated with hyperglycemia, systemic infections, bleeding, and osteoporosis, and psychosis, particularly with higher doses and longer courses.

### *Herbal therapy*

- Several higher-quality trials found devil's claw superior to placebo for short-term pain relief in patients with acute exacerbations of chronic low back pain. However all of the trials were led by the same investigator, raising concerns about reproducibility of findings in other settings (level of evidence: fair).
- One higher-quality trial found willow bark superior to placebo for short-term pain relief in patients with acute exacerbations of chronic low back pain (level of evidence: fair)
- Evidence on the efficacy of cayenne was mixed, with three lower-quality trials suggesting short-term benefits compared to placebo for pain relief and other outcomes in patients with acute low back pain or acute exacerbations of chronic low back pain, but one other lower-quality trial showing no benefit compared to a homeopathic gel (level of evidence: fair).
- Serious adverse reactions with herbal therapy appear uncommon (level of evidence: fair).
- No trials evaluated long-term outcomes.

## Acupuncture and related interventions

### *Acupuncture*

- There is consistent evidence from multiple trials that acupuncture is effective for short-term pain relief compared to no treatment or sham acupuncture in patients with chronic low back pain for pain, and superior to no treatment (but not sham) for functional outcomes (level of evidence: good)
- Evidence on longer-term (>6 weeks) outcomes is sparse but suggests that acupuncture is more effective than sham TENs and no treatment in patients with chronic low back pain. One recent, higher-quality trial found that beneficial effects on pain persist for up to 24 months (level of evidence: fair).

- Acupuncture was inferior to spinal manipulation in two trials (one higher quality) (level of evidence: fair)
- There is no evidence that acupuncture is more effective than other active interventions in patients with chronic low back pain (each comparison only evaluated in a small number of trials) (level of evidence: poor to fair).
- There is insufficient evidence to judge the efficacy of acupuncture (small numbers of primarily lower-quality trials) in patients with acute low back pain (level of evidence: poor).
- Dry needling alone was not effective compared to trigger point injections or acupuncture in one trial of patients with acute low back pain (level of evidence: poor), but was more effective than placebo or when added to other interventions in two trials of patients with chronic low back pain (level of evidence: fair).
- Serious adverse events with acupuncture appeared rare in trials and prospective studies, though they were often poorly reported (level of evidence: fair).

***Acupressure***

- There is evidence from two trials (one higher quality) that acupressure is more effective than standard therapy in patients with chronic low back pain for pain and functional outcomes. However, it is not clear if these results can be generalized to other settings because both trials were conducted in Taiwan by the same investigators (level of evidence: fair)
- Acupressure does not appear associated with serious adverse events, but harms were only reported by one trial (level of evidence: fair).
- There is no evidence in patients with acute low back pain

***Neuroreflexotherapy***

- There is consistent evidence (three trials, two higher-quality) that neuroreflexotherapy is superior to sham therapy or usual care for short-term pain relief in patients with chronic low back pain. However, all of the trials were conducted in Spain by the same principal investigator at a specialized center, raising questions about the applicability of results to other settings (level of evidence: fair).
- Evidence on beneficial effects of neuroreflexotherapy relative to sham treatment on functional outcomes is mixed (level of evidence: fair).
- The single lower-quality trial assessing one-year outcomes found lower self-reported sick leave and consumption of health care resources with neuroreflexotherapy relative to usual care (level of evidence: fair).

## Educational interventions

### *Back schools*

- Back schools were superior to placebo in a single lower-quality trial of patients with acute or subacute low back pain for short-term recovery and return to work, but not for pain or long-term recurrences (level of evidence: poor).
- Evidence on the effects of back schools versus placebo or wait list controls for chronic low back pain is inconsistent, though most studies found no beneficial effects (level of evidence: fair).
- There was also mixed evidence on the efficacy of back schools relative to other active interventions in patients with acute low back pain (one higher quality trial finding benefit on sick leave but three other trials finding no benefit), but consistent evidence for modest benefits in patients with chronic low back pain (level of evidence: fair).
- More intensive back school programs based on the original Swedish program and programs in occupational settings appeared more effective (level of evidence: fair).

### *Brief educational interventions*

- In three higher-quality trials, a brief educational intervention was associated with beneficial effects on sick leave in workers with subacute low back pain, though most of the benefits were observed in the first year after the intervention. There were no clear effects on pain or functional status (level of evidence: good).
- A brief intervention was only modestly inferior to the brief intervention plus exercise and manipulation in patients with chronic low back pain (one higher-quality trial) (level of evidence: fair).

## Exercise and related interventions

### *Exercise*

- Exercise is modestly superior to placebo in multiple trials of patients with chronic low back pain for pain relief and work-related outcomes, though the pain relief benefits do not appear to reach pre-defined levels of minimal clinically important differences (level of evidence: good).
- Exercise regimens incorporating features such as individual tailoring, supervision, stretching, and strengthening are associated with the best outcomes in meta-regression analyses (level of evidence: fair).
- Evidence on the efficacy of exercise relative to placebo or no treatment in patients with acute low back pain is somewhat inconsistent, though most trials found no benefit (level of evidence: fair).

- One recent, higher-quality trial found a standardized exercise regimen inferior to physical therapy tailored according to patient signs and symptoms (level of evidence: fair).
- Evidence from numerous trials suggests no clinically significant difference between exercise and other non-invasive interventions for either acute or chronic low back pain (level of evidence: good).

### *Hydrotherapy*

- There is insufficient evidence (one poor-quality trial) to judge the efficacy of hydrotherapy versus delayed hydrotherapy (level of evidence: poor).
- There is consistent evidence from two lower-quality trials that hydrotherapy and land-based therapy are associated with similar outcomes in patients with chronic low back pain (level of evidence: fair).
- There is no evidence on the effects of hydrotherapy in patients with acute low back pain.

### *Yoga*

- Viniyoga was superior to traditional exercises and a self-care education book for back-specific functional status and use of medications in one higher-quality trial (level of evidence: fair).
- There is insufficient evidence to judge the effectiveness of other types of yoga (two small, low quality trials of Hatha yoga) (level of evidence: poor).

## Multidisciplinary interventions

### *Multidisciplinary rehabilitation*

- In two lower-quality trials, multidisciplinary rehabilitation (particularly with a work site visit) in patients with subacute low back pain was associated with quicker return to work, reduced sick leave, and improved disability relative to usual care (level of evidence: fair).
- Intensive multidisciplinary rehabilitation with functional restoration is more effective than usual care or non-multidisciplinary rehabilitation for reducing pain and improving function in patients with chronic low back pain, though effects on work-related outcomes are mixed (four trials, three higher-quality) (level of evidence: good).
- Less intensive (<100 hours) multidisciplinary rehabilitation was not more effective than usual care or non-multidisciplinary rehabilitation (five trials) (level of evidence: good).

- There is insufficient evidence from one, lower-quality RCT to determine the efficacy of multidisciplinary rehabilitation in patients with acute low back pain (level of evidence: poor).

## Physical conditioning programs (work conditioning, work hardening, and functional restoration)

- Evidence of benefits from six heterogeneous trials of physical conditioning programs in patients with acute low back pain is inconsistent, with the majority of studies showing no benefit (level of evidence: fair).
- Physical conditioning programs with a cognitive-behavioral approach are effective for reducing sick leave relative to usual care in two trials (one higher quality) of patients with chronic low back pain (level of evidence: fair). There is no clear benefit from physical conditioning programs without a cognitive-behavioral approach.
- Physical conditioning programs were effective for reducing days lost from work relative to passive physical therapy in patients with chronic low back pain (two high quality trials) (level of evidence: good).

## Physical modalities

### *Interferential therapy*

- One higher-quality trial found no difference between interferential therapy and manipulation in patients with subacute low back pain (level of evidence: fair).
- One lower-quality trial found no difference between interferential therapy and traction in patients with primarily chronic low back pain (level of evidence: poor).
- One lower-quality trial found no clear differences between interferential therapy with electrodes applied in the paraspinal area or to the painful area plus a self-care book versus a self-care book alone (level of evidence: poor).

### *Low-level laser*

- There is conflicting evidence from five trials (four higher quality) on the effectiveness of low-level laser compared to placebo or sham laser in patients with chronic low back pain. Four trials (three higher quality) found laser therapy superior to sham for pain or functional status up to one year following treatment, but one higher-quality trial found no difference between laser and sham in patients also receiving exercise. In addition, interpretation of results is compromised by the use of heterogeneous and non-standardized outcome measures in some studies (level of evidence: fair).
- Low-level laser was equivalent to exercise or the combination of laser plus exercise in one lower-quality trial (level of evidence: poor).
- There is no reliable evidence (one lower-quality trial) on low-level laser therapy in patients with acute low back pain (level of evidence: poor).

- Additional research is needed on optimal doses of low-level laser therapy, number of sessions, and type of laser in patients with chronic low back pain.
- Publication bias from non-English language studies could affect these conclusions.

### *Short-wave diathermy*

- One higher-quality trial found no difference between short-wave diathermy and sham diathermy on pain after 12 weeks in patients with low back pain for at least 2 months (level of evidence: fair).
- In patients with back pain of varying duration, one higher-quality trial found no difference between short-wave diathermy, sham diathermy, exercise, or traction using an unvalidated measure of global effect after 2 weeks (level of evidence: fair).
- One higher-quality trial found no difference between short-wave diathermy and spinal manipulation on pain after 12 weeks in patients with low back pain for at least 2 months (level of evidence: fair).
- In patients with acute low back pain, one small, lower-quality trial found a lower proportion of patients reporting pain relief after 2 weeks in patients randomized to short-wave diathermy compared to spinal manipulation (level of evidence: poor).

### *Traction*

- There is consistent evidence from multiple trials that continuous or intermittent traction are not associated with superior outcomes compared to placebo, sham, or other treatments for patients with low back pain of varying duration, either with or without sciatica (level of evidence: good).
- There is evidence from two lower quality trials that autotraction is superior to placebo or sham therapies and one lower quality trial that autotraction is superior to mechanical traction (level of evidence: fair).
- Adverse events reported in the trials included aggravation of signs and symptoms and subsequent surgery, but were inconsistently and poorly reported (level of evidence: poor).

### *Ultrasound*

- There is insufficient evidence (single low-quality studies) to judge the efficacy of ultrasound for low back pain (level of insufficient: poor).

## Other non-invasive interventions

### *Behavioral interventions*

- There is consistent evidence from four RCTs (one higher quality) that cognitive-behavioral therapy is moderately more effective than wait list control for short-term

pain intensity in patients with chronic low back pain, though there were no significant differences on functional status and other outcomes (level of evidence: good).

- Two lower-quality trials found progressive relaxation associated with large positive benefits relative to wait list control for pain intensity and behavioral outcomes in patients with chronic low back pain (level of evidence: fair).
- Evidence on benefits associated with EMG biofeedback relative to wait list control is mixed, though three out of four trials demonstrated a moderate benefit on pain intensity in patients with chronic low back pain (level of evidence: fair).
- Operant therapy was not associated with any benefits relative to wait list controls in three trials of patients with chronic low back pain (level of evidence: good).
- Behavioral interventions have not clearly been shown to be superior to other active interventions for most outcomes, though one systematic review found moderate benefits for short- and long-term disability (level of evidence: fair).
- There is no clear evidence from head-to-head comparisons that one behavioral intervention is superior to any other (level of evidence: fair to good).

***Massage***

- Massage was superior to sham therapy in one higher quality trial of patients with subacute or chronic non-specific low back pain (level of evidence: fair).
- Massage was consistently inferior to spinal manipulation in three trials (one higher quality) up to one year after a course of treatment in patients with chronic low back pain (level of evidence: fair).
- In single trials comparing massage to other interventions, massage was inferior to transcutaneous electrical stimulation, similar to exercise and corsets, and moderately superior to relaxation, acupuncture, and a self-care education book (level of evidence for each comparison: fair).
- A single trial found acupuncture massage superior to classical (Swedish) massage (level of evidence: fair).
- There is insufficient evidence to judge the efficacy of massage in patients with acute low back pain (one lower-quality trial) or in patients with sciatica (no trials specifically in this population) (level of evidence: poor).

***Modified work***

- There is consistent evidence from one lower-quality trial and observational studies that modified work can decrease time lost from work (level of evidence: fair).

***Spa therapy***

- Spa therapy was consistently and substantially superior to no spa therapy for pain in three lower-quality trials of patients (all conducted in Europe) with chronic low back pain up to nine months after a three-week course of treatment (level of evidence: fair).
- Spa therapy was no better than no spa therapy for pain in one lower-quality RCT of patients with subacute or chronic low back pain, but associated with decreased analgesic use (level of evidence: poor).
- Spa therapy was no better than underwater massage or underwater traction or when added to exercise therapy in patients with subacute or chronic low back pain in two lower-quality trials (level of evidence: poor).
- There is no evidence for spa therapy in patients with acute low back pain.

***Spinal manipulation***

- Pooled evidence from many trials indicates that spinal manipulation is modestly superior to sham, no treatment, or therapies thought to be ineffective or harmful, in patients with either acute or chronic low back pain (level of evidence: good).
- There is also consistent evidence from multiple trials that spinal manipulation is no more effective than other standard conservative interventions (level of evidence: good).
- In patients without severe or progressive neurologic deficits, serious adverse events such as cauda equina syndrome or worsening lumbar disc herniation following lumbar spinal manipulation are very rare (level of evidence: good).

**Key Question 3a.**

**Can decision tools predict which patients are more likely to respond to specific therapies like physical therapy or chiropractic?**

- A decision tool for identifying patients likely to benefit from spinal manipulation has been prospectively validated as highly predictive in a randomized trial. However, evidence of beneficial effects on clinical outcomes from applying the decision tool is not yet available. In addition, the tool may not be practical for use in many primary care settings, and a more pragmatic version has not yet been prospectively validated (level of evidence: fair).
- A decision tool for identifying patients likely to benefit from stabilization exercise has not yet been validated (level of evidence: poor).

**Key Question 4.**

**What is the value of different patient education or patient self-care methods for improving patient outcomes?**

## Self-care advice or education

### *Bed rest*

- In two higher quality trials, advice to rest in bed was consistently associated with small but statistically inferior outcomes compared to advice to remain active in patients with acute nonspecific low back pain (level of evidence: good).
- Advice to rest in bed was consistently associated with similar outcomes compared to physiotherapy/exercise in two higher quality trials of patients with acute nonspecific low back pain (level of evidence: good).
- There is insufficient evidence to accurately judge the efficacy of advice to rest in bed relative to interventions other than exercise (level of evidence: poor).
- In patients with sciatica, one higher quality trial found that physiotherapy was associated with modestly superior functional status outcomes at 3 weeks compared to advice to rest in bed, but this effect was no longer present after 12 weeks (level of evidence: good).
- Longer duration of bed rest was not associated with better outcomes compared to shorter duration, and increased the number of days off work in one higher-quality trial (level of evidence: fair).
- There is no evidence to judge the efficacy of advice to rest in bed in patients with chronic low back pain.

### *Advice for activity*

- Advice to remain active was associated with similar effects on functional status or pain compared to exercise therapy in one higher-quality trial of patients with acute non-specific low back pain and one higher-quality trial of patients with symptoms for more than six weeks, but with slower return from sick leave and more back pain recurrences in one older, lower-quality trial (level of evidence: fair).
- Advice to remain active was not associated with clear benefits in a single, higher-quality trial of patients with acute low back pain with sciatica (level of evidence: fair).
- Advice to exercise was superior to usual care in one lower-quality trial of patients with low back pain for less than 90 days. There were no differences between advice to exercise and a self-care book, and the combination did not improve outcomes (level of evidence: poor).
- See section on bed rest for summary of bed rest versus advice to remain active.

### *Self-care books*

- Four trials (one higher-quality) found no difference between a self-care book and usual care in pain or symptom bothersomeness scores (level of evidence: fair).
- In three higher-quality trials comparing a self-care book to other active interventions (yoga, acupuncture, exercise, massage, or manipulation), there were either no significant differences or the self-care book was modestly inferior on symptom bothersomeness scores and functional status. The largest differences were seen in single trials comparing a self-care book to yoga and a self-care book to massage (level of evidence: good).
- There was no difference between a self-care book and advice to exercise in one lower-quality trial (level of evidence: poor).
- Different methods for providing information in a self-care book were not associated with significant differences in pain or functional status, though a brief nurse education visit increased the proportion of patients who exercised in one higher-quality trial compared to providing the self-care book alone, and an experimental self-care book targeted at changing beliefs and behaviors reduced fear avoidance beliefs more than a traditional self-care book in another higher-quality trial (level of evidence: fair).

### *E-mail discussion groups*

- One lower-quality trial found an e-mail discussion group intervention plus a self-care book and videotape superior to usual care for pain, disability, role function and health distress after one year in patients with chronic low back pain (level of evidence: poor).

### *Self-care exercise videotape*

- One lower quality trial found no differences in functional status between videotaped exercise advice and face-to-face advice through 4 to 6 weeks in patients with back pain of unspecified duration, but videotaped advice was superior for short-term pain (level of evidence: poor).

### *Advice to restrict early morning flexion*

- One lower-quality trial found that patients with chronic low back pain who were given advice to restrict early morning flexion reported better outcomes related to pain intensity and disability compared to those given sham exercise advice, but marked baseline differences make these findings unreliable (level of evidence: poor).

### *Lay-facilitated groups for self-care*

- A four-session lay-led self-care group was associated with greater improvements in functional status (but not pain intensity) compared to usual care after 6 to 12 months in one lower-quality trial of patients with subacute low back pain (level of evidence: poor).

### *Self-help tools for back surgery decisions*

- One higher-quality trial found no differences in function between an interactive video plus self-care book versus a self-care book alone for informing back surgery decisions even though a lower proportion of patients with herniated disc underwent surgery. The video was associated with a lower proportion of patients with severe pain at one year, though there was no difference in rates of resolution of back or leg pain (level of evidence: fair).

## Self-care interventions

### *Lumbar supports*

- There is insufficient evidence from one lower quality trial to determine whether lumbar supports are effective compared to no intervention (level of evidence: poor).
- There is conflicting evidence regarding the effectiveness of lumbar supports compared to other interventions (soft tissue massage, spinal manipulation, advice on lifestyle and bedrest, physiotherapy, acetaminophen, TENS, or usual care). Most comparisons were evaluated in only one lower-quality trial. The trials were mainly conducted in subjects with non-specific low back pain of varying or unspecified duration (level of evidence: poor).
- One higher-quality trial found that a lumbar support with a rigid insert was associated with superior global assessment of outcomes compared to a support without a rigid insert (level of evidence: fair).

### *Mattresses*

- One higher-quality trial found that a firm mattress was less likely to lead to improvement in pain related disability and worsen pain while in bed compared to a medium-firm mattress in patients with chronic low back pain. There were no differences in other pain outcomes (level of evidence: fair).
- There was insufficient evidence to judge the relative effectiveness of other mattress types (level of evidence: poor).

### *Superficial heat or cold*

- There is consistent evidence from three higher-quality trials that heat wrap therapy or a heated blanket is modestly superior to placebo or a non-heated blanket for short-term pain relief and back-specific functional status in patients with acute or subacute low back pain (level of evidence: good).
- Heat wrap therapy was also modestly superior to analgesic medications for short-term pain relief in one higher-quality trial of patients with acute low back pain (level of evidence: fair).

- Heat wrap therapy was superior to a self-care booklet, but not to exercise, in one higher-quality trial of patients with a mix of acute and subacute low back pain (level of evidence: fair).
- There is insufficient evidence (one lower-quality trial) to determine the efficacy of superficial cold (level of evidence: poor).

**Key Question 5.**

**Does referral from primary care providers to back specialty providers affect patient outcomes? What are the outcomes for patients who are managed by different types of care providers or by multidisciplinary or interdisciplinary clinics?**

- There is no direct evidence on the effects of referral from primary care to back specialty providers on patient outcomes, though evidence on the effects of certain interventions offered by specialty providers is reviewed elsewhere.
- One recent large, high-quality trial found medical care and chiropractic care associated with similar patient outcomes. Observational data also suggests no significant differences for back pain episodes managed by different provider types, though patterns of care varied (level of evidence: fair).

**Key Question 6.**

**What is the diagnostic accuracy and potential harms associated with diagnostic tests for identifying patients who will benefit from invasive procedures such as provocative discography, diagnostic nerve blocks, or other similar tests? Does prior use of these tests improve outcomes from invasive procedures?**

## Provocative discography

- Positive responses to provocative discography were uncommon in small series of healthy, asymptomatic volunteers (level of evidence: fair).
- In patients without significant back pain, provocative discography was frequently associated with positive pain responses in small series of patients with chronic pain at other sites, those with somatization, those with previous disc surgery, and those disabled or seeking monetary compensation (level of evidence: fair).
- Incorporating pressure criteria into the definition for a positive response did not eliminate positive results in high-risk sub-groups of patients without significant low back pain in one small study (level of evidence: fair).

- Previous back surgery, chronic pain, and abnormal psychometric testing were also associated with increased rates of positive discography in small series of patients with chronic back pain (level of evidence: fair).
- One higher-quality cohort study found that relative to the rate of successful surgery for single-level isthmic spondylolisthesis, the rate of successful surgery for presumed discogenic back pain (based on provocative discography) was 43-44% in a highly selected population of patients without comorbidities (level of evidence: fair).
- In one lower-quality observational study, surgery outcomes were similar with or without the use of provocative discography to select patients (level of evidence: poor).
- Discitis appears rare with or without antibiotics. Other serious adverse events also appear rare. In one study, persistent pain was reported in patients with somatization or chronic pain at other sites (level of evidence: fair).

## Diagnostic selective nerve root blocks

- There are no studies evaluating the impact of diagnostic selective nerve root blocks on clinical outcomes relative to non-invasive methods alone for evaluating suspected nerve root compression.

## Diagnostic facet joint blocks

- There are no studies evaluating the impact of facet joint blocks on clinical outcomes in patients with prolonged non-specific low back pain.
- Evidence on interventions targeted at facet joint pain is outlined in key question 7. In all trials of facet joint interventions, patients were enrolled based on positive diagnostic facet joint blocks.

**Key Question 7.**

**What is the effectiveness of injections (and different injection interventions) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?**

## Injections

### *Chemonucleolysis*

- Chemonucleolysis with chymopapain was consistently superior to placebo in five higher-quality trials of patients with prolapsed lumbar disc (level of evidence: good).
- There is insufficient evidence to accurately judge the efficacy of chemonucleolysis with collagenase relative to placebo (one lower-quality trial) (level of evidence: poor).

- Chemonucleolysis was consistently associated with trends towards worse outcomes relative to standard discectomy in five lower-quality trials, and led to subsequent surgery in about 30% of cases (level of evidence: fair).
- Chemonucleolysis with chymopapain and intradiscal steroid injections were consistently associated with similar outcomes in three lower-quality trials (level of evidence: fair).
- One lower-quality trial found no differences between chemonucleolysis with chymopapain and spinal manipulation after one year, though manipulation was superior at short-term (through 6 weeks) follow-up (level of evidence: poor).
- Chemonucleolysis with chymopapain and collagenase were associated with similar pain outcomes in two lower-quality trials (one with five year follow-up), but chymopapain was associated with a trend towards reduced rate of subsequent surgery in one trial (level of evidence: fair).
- Chemonucleolysis with chymopapain is associated with mild allergic reactions in up to 12% of patients, though reporting of allergic reactions was suboptimal. Serious complications appear uncommon (level of evidence: poor).

***Epidural steroid injections***

- Evidence of beneficial effects following epidural steroid injections by interlaminar or caudal approaches in patients with sciatica is mixed, with some studies showing short-term benefits, but most trials (including two larger, high-quality trials) reporting no longer-term benefits. Most evidence is in patients with symptoms of at least one month's duration (level of evidence: fair).
- There is insufficient evidence (one lower-quality trial showing no benefit) to accurately judge the efficacy of epidural steroids in patients with low back pain without sciatica (level of evidence: fair).
- One higher-quality trial found that epidural steroids have no sustained effects on walking distance relative to a placebo injection in patients with spinal stenosis (level of evidence: fair).
- In one higher-quality randomized trial, epidural steroid injection was no better than trigger point injections at one month for overall outcomes, though modestly superior at three months. Other trials comparing epidural steroids and local injections were either not randomized or did not clearly inject tender points (level of evidence: fair).
- Epidural steroid injections were not clearly superior to intramuscular steroids for long-term outcomes (level of evidence: fair).
- One higher-quality trial reported inferior outcomes with epidural steroid injection alone versus epidural adhesiolysis in patients with chronic back pain who previously failed an epidural injection, but reported high rates of response in the adhesiolysis group and unusually low rates in the epidural arm (0%) (level of evidence: fair).

- There is insufficient evidence (one lower-quality trial for each comparison) to accurately judge the relative efficacy of epidural steroids compared to dry-needling or discectomy (level of evidence: poor).
- Several trials have found no clear differences between transforaminal and other approaches for administering epidural steroids, but lack of radiologic confirmation of epidural placement for the other approaches limits their interpretation (level of evidence: poor).
- One higher-quality trial found no differences between caudal epidural steroid and targeted steroid placement during spinal endoscopy, with needle placement confirmed by fluoroscopy for both methods (level of evidence: fair).

***Facet (zygapophysial) joint injections***

- Evidence from two randomized trials indicates that facet joint injections are not beneficial for short-term pain relief in patients with chronic low back pain, though there was a trend towards modestly superior sustained pain relief in the single higher-quality trial of patients with chronic low back pain (level of evidence: fair).
- Two trials (one higher-quality) found no difference between facet joint injections and medial branch block.
- There is no evidence on efficacy of facet joint injections for acute low back pain.

***Intradiscal steroid injections***

- There is consistent evidence from three low quality trials that intradiscal steroids are not associated with improved outcomes compared to control injections in patients with chronic low back pain with positive results on provocative discography (level of evidence: fair).
- One low quality trial found that intradiscal steroids are superior to discography alone in a selected subgroup of patients that failed epidural steroid injections and had inflammatory changes on MRI (level of evidence: poor).
- Three lower-quality trials found no differences between intradiscal steroid injection and chemonucleolysis in patients with prolapsed lumbar disc or sciatica (level of evidence: fair).
- None of the trials reported safety outcomes.

***Local injections***

- There is consistent evidence from three lower quality trials that trigger point injection with a local anesthetic is superior to saline injection for short-term pain relief in patients with subacute or chronic low back pain (level of evidence: fair).
- There is no evidence on long-term pain relief.
- One low-quality trial found trigger point injection inferior to a dry needle acupuncture stick (level of evidence: poor).
- Using a steroid in place of a local anesthetic or adding a steroid to a local anesthetic did not result in superior outcomes in one higher-quality trial (level of evidence: fair).

- See section on epidural steroids for comparison between local injections and trigger point injections.

### *Prolotherapy*

- There is conflicting evidence on the efficacy of prolotherapy versus control injections for chronic low back pain from three higher-quality trials (level of evidence: fair).
- There is no evidence in patients with acute low back pain.
- Serious adverse events have not been reported following prolotherapy treatments, though nearly all patients report increases in back pain (level of evidence: fair).

### *Sacroiliac joint injection*

- One higher-quality but very small trial found sacroiliac joint steroid injection superior to local anesthetic injection for short-term pain relief in patients thought to have non-spondylarthropathic sacroiliac pain (level of evidence: poor).

### *Botulinum toxin*

- A single, small, higher-quality trial found botulinum toxin injection superior to saline injection for short-term pain relief and improvement in functional status in patients with chronic low back pain who failed to respond to standard treatments (level of evidence: fair).
- There is no evidence comparing botulinum toxin injection to other interventions.
- There is no evidence on effectiveness of botulinum toxin injection in patients with acute low back pain.
- There is insufficient evidence to judge safety of botulinum toxin in patients with low back pain, though one case of fatal anaphylaxis has been reported.

## Radiofrequency denervation, intradiscal electrothermal therapy, and precutaneous intradiscal radiofrequency thermocoagulation

### *Radiofrequency denervation*

- The evidence on the efficacy of radiofrequency denervation of the medial branch of the primary dorsal ramus in patients with a positive facet joint block is mixed, with two of three higher quality trials showing no benefits compared to sham or control injection, even in highly selected populations (level of evidence: fair).
- Radiofrequency denervation was not effective in one higher quality trial of highly selected patients with chronic radicular pain and a positive nerve block (level of evidence: fair).
- Radiofrequency denervation of the ramus communicans nerve was superior to sham in patients with positive discography in one lower-quality trial (level of evidence: poor).
- Adverse events were poorly reported, but serious adverse events have not yet been observed following radiofrequency denervation.

### *Intradiscal electrothermal therapy (IDET)*

- There is conflicting evidence from two higher-quality trials on the efficacy of IDET relative to sham in patients with chronic low back pain with positive provocative discography. In the one trial reporting benefits from IDET, benefits were modest despite the evaluation of a highly selected population (level of evidence: fair).
- Complications associated with IDET were poorly reported but generally appeared mild or transient, though there are case reports of cauda equina syndrome and vertebral osteonecrosis after IDET (level of evidence: poor).

### *Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)*

- One small, low-quality trial found no differences between percutaneous intradiscal radiofrequency thermocoagulation and sham in patients with a positive response to analgesic discography (level of evidence: poor).
- There is insufficient data to judge the safety of PIRFT.

**Key Question 8.**

**What is the effectiveness of surgery (and different surgical interventions) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?**

## Efficacy of surgery versus non-surgical management

### *Non-specific, degenerative low back pain*

- In patients with chronic low back pain due to other degenerative conditions, two high-quality trials indicate that spinal fusion surgery is no better than intensive rehabilitation plus a cognitive intervention, but a third trial found surgery superior to conventional physical therapy (level of evidence: fair).
- Evidence regarding the efficacy of instrumented versus non-instrumented fusion is inconsistent, though clinical outcomes are similar after excluding two lower-quality trials reporting better outcomes and pooling data from the remaining five trials (level of evidence: fair).
- Evidence regarding the efficacy of anterior, posterior, or combined fusion from four trials is inconsistent and does not permit reliable judgments about relative efficacy (level of evidence: fair).
- Electrical stimulation may improve fusion rates in non-instrumented (but not instrumented) fusion, but didn't have a clear effect on clinical outcomes in three trials (level of evidence: fair).
- Artificial disc replacement with the Charite artificial disc was equivalent to anterior interbody fusion with a stand-alone cage for a combined measure of success at 24

months in the only completed (higher-quality) trial. There were no differences in pain relief, functional status, of employment status at 24 months, though earlier results favored artificial disc replacement (level of evidence: fair).

- Early complications following spine surgery occur in up to about 20% of patients. In-hospitality mortality after spine surgery occurs in about 0.2%, deep wound infection in 1.5%, deep vein thrombosis in 1.6%, pulmonary embolus in 2.2%, and nerve injury in 2.8% for nerve injury (level of evidence: fair).
- Complications from spinal fusion were higher with more technically difficult methods in one trial (level of evidence: fair).
- Rates of complications were similar after artificial disk replacement and fusion in one higher-quality trial (level of evidence: fair).
- Trials of surgery versus non-surgical management generally included patients who did not have clear indications for surgery (such as progressive or severe neurologic deficits or severe, intractable pain), failed to improve after 6 months to 2 years of conservative management, and had disease localized to L4-L5 and/or L5-S1.

***Spinal stenosis, lumbar disc prolapse, and isthmic spondylolisthesis***

- In patients with spinal stenosis and lumbar disc prolapse, consistent evidence from single RCTs and good-quality observational studies indicates that standard initial surgical therapy (decompression or discectomy, respectively) is associated with improved outcomes after one year compared to initial non-surgical therapy (or delayed surgery), but differences in outcomes are attenuated after 4 to 10 years of follow-up (level of evidence: fair).
- There is insufficient evidence from single low quality trials to judge the efficacy of surgery versus non-surgical management for mild isthmic spondylolisthesis (level of evidence: poor).
- There is insufficient evidence from one lower-quality trial to judge the efficacy of an interspinous spacer device for spinal stenosis (level of evidence: poor).
- Standard discectomy was consistently superior to chemonucleolysis in five lower-quality trials (level of evidence: fair).
- There is insufficient evidence (one lower-quality trial) to accurately judge the relative efficacy of epidural steroids compared to discectomy (level of evidence: poor).
- In patients with spinal stenosis, one lower-quality trial found no differences between laminectomy versus multiple laminotomy and three trials found no difference between postero-lateral fusion (with or without instrumentation) versus decompression alone (level of evidence: poor to fair).

- In patients with isthmic L5/S1 spondylolisthesis, one trial found no difference between patients undergoing fusion alone versus fusion plus laminectomy and decompression (level of evidence: fair).
- In patients with lumbar prolapse, there are no clear differences between standard discectomy and microdiscectomy or discectomy using different interposition membranes (level of evidence: fair).
- There is mixed evidence from two trials on the efficacy of automated percutaneous discectomy versus microdiscectomy, with one trial reporting similar outcomes and the other (using different techniques) poorer outcomes (level of evidence: poor).
- There is insufficient evidence to judge the efficacy of laser discectomy relative to other surgical methods (level of evidence: poor).

**Key Question 9.**

**What is the effectiveness of other modalities (such as TENS or spinal cord stimulation) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?**

## Transcutaneous electrical nerve stimulation (TENS)

- There is conflicting evidence regarding the efficacy of TENS versus sham TENS for patients with non-specific chronic low back pain, though the sole higher-quality trial found no benefit (level of evidence: fair).
- There is consistent evidence from four trials that TENS is not superior to acupuncture in patients with chronic low back pain (level of evidence: fair).
- Evidence regarding the efficacy of TENS to other interventions in patients with chronic low back pain is limited to single trials of traction (traction superior), massage (TENS superior), and ice massage (no differences) (level of evidence: poor).
- TENS was no better than sham TENS and inferior to spinal manipulation in two lower-quality trials of patients with subacute low back pain (level of evidence: fair).
- TENS is associated with skin irritation that is usually minor (level of evidence: fair).

## Percutaneous electrical nerve stimulation

- PENS was superior to sham PENS in two lower-quality trials of patients with chronic low back pain for pain outcomes. In the only trial assessing outcomes after the end of treatment, pain benefits were present after two months, but there was no effect on functional outcomes (level of evidence: fair).
- PENS was superior to TENS and a minimal exercise intervention for pain and functional outcomes in one lower-quality trial of patients with chronic low back pain at the end of treatment, but in the only trial evaluating longer-term outcomes, no benefits were present after two months (level of evidence: poor).

- PENS was superior to sham PENS and TENS for pain and functional outcomes in one lower-quality trial of patients with sciatica, but outcomes were only assessed immediately after a two-week course of treatment (level of evidence: poor).
- There is insufficient evidence to accurately judge the safety of PENS.

### Spinal cord stimulation

- Low-quality evidence from multiple case series found that approximately half of patients with chronic back and leg pain or failed back surgery syndrome had decreased pain after spinal cord stimulator implantation, and 40% were returned to work. However, the lack of higher-quality evidence severely limits confidence in these estimates (level of evidence: poor).
- Spinal cord stimulation is associated with frequent complications, especially related to electrode or lead problems. Although most complications appear minor, infections (6% of complications) and cerebrospinal fluid leak (7%) have been reported (level of evidence: poor).

**Key Question 10.**

**Which combinations of therapies are effective for acute low back pain? Chronic low back pain?**

### Combinations of medications

- There is consistent evidence from three higher-quality trials that tizanidine combined with acetaminophen or an NSAID is associated with greater short-term pain relief and decrease of muscle spasm in patients with acute low back pain (level of evidence: good).
- One higher-quality trial found no benefits from adding orphenadrine to acetaminophen in patients with acute low back pain, though the combination was associated with fewer disability days (level of evidence: fair).
- One lower-quality trial found no benefits from adding cyclobenzaprine to an NSAID in patients with acute low back pain (level of evidence: poor).
- There is insufficient evidence from one trial (doses unclear) to judge the efficacy of opioids plus an NSAID versus an NSAID alone (level of evidence: poor).
- Adding a muscle relaxant to acetaminophen or an NSAID was associated with an increased risk of central nervous system adverse effects (level of evidence: good).

### Self-care advice combined with other interventions

- Two trials (one higher-quality) found that a self-care book plus advice plus exercise therapy was superior to the self-care book and advice alone. One trial was in patients with back pain for less than 6 weeks and the other in patients off work for less than one year due to back pain (level of evidence: fair).

- Two trials (one higher-quality) found that adding face-to-face advice to a self-care book did not improve patient outcomes, though one of the trials found that self-reported exercise and patient satisfaction was higher (level of evidence: fair).
- There is insufficient evidence to judge the efficacy of a self-care book plus interferential therapy relative to a self-care book alone (one lower-quality trial) (level of evidence: poor).

### Exercise combined with other interventions

- The addition of exercise to other non-invasive interventions is associated with modest improvements in pain (about 5 points on a 100 point scale) and function (about 2 points on a 100 point scale) in a large meta-regression (level of evidence: good).

### Acupuncture combined with other non-invasive interventions

- In four higher-quality trials, acupuncture was associated with moderate beneficial effects on pain and function through 12 months when combined with a variety of other non-invasive intervention compared to the other intervention alone (level of evidence: good).
- There is insufficient evidence to judge the effects of acupuncture added to other interventions in patients with acute low back pain (one lower-quality trial) (level of evidence: poor).

### Spinal manipulation combined with other interventions

- Compared to exercise therapy alone, the addition of spinal manipulation was not associated with significant benefits in a recent, large, lower-quality trial (level of evidence: fair).
- The combination of spinal manipulation plus exercise and a brief intervention (physician consultation) was associated with modest long-term differences in pain but not function relative to physician consultation alone in one higher-quality trial (level of evidence: fair).

### Massage combined with other interventions

- Compared to exercise and education alone, the addition of massage therapy was associated with moderate short-term benefits for pain and disability in patients with subacute low back pain.

### Behavioral therapy combined with other interventions

- Behavioral interventions were consistently ineffective for improving outcomes when added to a variety of other interventions in six lower-quality trials of patients with chronic low back pain. Diversity in both the behavioral and non-behavioral interventions may limit the generalizability of these findings (level of evidence: fair).

- Behavioral interventions were consistently ineffective for improving outcomes when added to a variety of other interventions in six lower-quality trials of patients with chronic low back pain. Diversity in both the behavioral and non-behavioral interventions may limit the generalizability of these findings (level of evidence: fair).

### Traction combined with other interventions

- Traction plus physical therapy was no better than physical therapy alone in one small, lower-quality trial (level of evidence: poor).

**Key Question 11.**

**What are effective strategies for failed back surgery syndrome?**

### Adhesiolysis

- Although one higher-quality trial found adhesiolysis markedly superior to epidural steroids for pain relief in patients with refractory back pain who failed a previous epidural steroid injection, confirmation of results by other trials is necessary because of the extremely low (0%) response rate in the epidural steroid group (level of evidence: fair).
- There is no clear evidence that use of hypertonic saline or hyaluronidase improves outcomes from adhesiolysis compared to using isotonic saline alone (level of evidence: fair).
- Adverse events were infrequent and usually minor in the trials, but were more common and included suspected infection, subarachnoid puncture, and post-dural headache in up to 9-14% of patients in observational studies (level of evidence: fair).

### Intrathecal therapy

- There is insufficient data to judge the efficacy of intrathecal therapy in patients with failed back surgery syndrome (limited observational studies only) (level of evidence: poor).
- Adverse events with intrathecal therapy appear to be frequent and often require surgery (level of evidence: poor).

### Non-invasive interventions

- One lower-quality trial found no significant differences in immediate post-treatment ODI scores between exercise, physical agents, manipulation, and no treatment in patients with chronic low back pain following L5 laminectomy (level of evidence: poor).

## Spinal cord stimulation

- One small RCT found that spinal cord stimulation was associated with a higher likelihood of pain relief and lower likelihood of increase in opioid use in patients with failed back surgery syndrome, but results are difficult to interpret because of a high rate of crossovers (level of evidence: fair).
- Other evidence (low-quality observational data) is inadequate to make reliable judgments about efficacy.
- Long-term complications after spinal cord stimulation have not been well-studied, but include infection and generator or lead-associated problems.

**Key Question 12.**

**How effective are different methods of integrating and coordinating care in improving outcomes?**

- Coordination of care was superior to usual care for improving functional status and pain after 6 months while reducing use of specialized imaging tests in workers receiving short-term (4 to 8 weeks) compensation for low back pain in one lower quality trial (level of evidence: poor).
- There is insufficient evidence to judge the efficacy of coordination or integration of care in other (primary care) settings (one low quality trial) (level of evidence: poor).

**Key Question 13.**

**What interventions are effective for secondary prevention of LBP in patients who have had an episode of acute LBP, or prevention of flares of LBP in patients with chronic LBP?**

## Back schools

- Evidence on the efficacy of back schools for preventing recurrent episodes of low back pain is mixed, which may be due in part to diversity between populations and interventions evaluated. One higher-quality trial found that an intensive back school intervention decreased recurrent episodes of low back pain more than no back school through three years of follow-up, but another evaluating a ‘mini’ back school found no clear effect. Three shorter-term (1 year) trials (one higher-quality) also found no effect (level of evidence: fair).
- One lower-quality trial found back school inferior to calisthenic exercises for reducing low back pain episodes through 12 months (level of evidence: poor).

### Exercise

- There is consistent evidence from two lower-quality trials that an exercise program is superior to education only for reducing long-term low back pain recurrences (level of evidence: fair).
- There is insufficient evidence (one very low-quality trial) to judge the efficacy of an ongoing exercise program for reducing future episodes of low back pain (level of evidence: poor).

### Lumbar supports

- No trials have evaluated the efficacy of lumbar supports for secondary prevention.

### Advice to stay active

- One higher-quality trial found no difference in long-term (through 3 years) recurrences in patients on sick leave for low back pain randomized to a single spine clinic exam and advice to stay active versus usual care (level of evidence: fair).

### Early occupational medicine intervention

- An early occupational medicine intervention was associated with a greater likelihood of lower back pain recurrences in one higher-quality trial (level of evidence: fair).

### Behavioral interventions, multidisciplinary rehabilitation, spinal manipulation, acupuncture, patient information or education

- There is no evidence on the effects of behavioral interventions, multidisciplinary disciplinary rehabilitation, spinal manipulation, and acupuncture on recurrent back pain episodes

**Key Question 14.**

**What is/are safe and effective strategies for managing low back pain during pregnancy and post-partum?**

### Acupuncture during pregnancy

- Three lower-quality trials found acupuncture more effective than usual care (2 trials) or exercise (1 trial) for improving pain and function in pregnant women with low back pain (level of evidence: fair).

### Physical therapy during pregnancy

- One higher-quality trial found water gymnastics superior to usual care for treating back pain in pregnant women (level of evidence: fair).
- Individualized physiotherapy was superior to usual care in two lower-quality trials (level of evidence: fair).

- Evidence on efficacy of group education and exercise was mixed, with one of three lower-quality trials finding group education and exercise superior to usual care in only one of three lower-quality trials (level of evidence: poor).
- A pelvic tilt exercise was associated with decreased pain in one lower-quality trial of pregnant women with low back pain, but also lower birthweight and earlier (full-term) onset of labor (level of evidence: poor).

### Massage during pregnancy

- Although two lower-quality trials found that massage therapy decreased pain scores in pregnant women, effects appeared modest and it was not clear if the differences were significant relative to usual care or progressive relaxation (level of evidence: poor).

### Supportive devices during pregnancy

- There is insufficient evidence from one lower-quality trial to determine the efficacy of the Ozzlo pillow versus standard pillows in pregnant women with low back pain (level of evidence: poor).

**Key Question 15.**

**What is the cost-effectiveness associated with different interventions or management strategies (such as care provided by different types of providers) for managing low back pain?**

- We identified four recent systematic reviews on cost-effectiveness of different interventions or management strategies in patients with low back pain. All concluded that current economic analyses are insufficient for determining the most cost-effective interventions. Individual cost studies are summarized separately elsewhere for each of the interventions reviewed in this report.

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GUIDELINE FOR THE MANAGEMENT OF

# Low Back Pain

## Draft Evidence Review

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Sponsored by:

The American Pain Society &
The American College of Physicians

American Pain Society

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**TECHNICAL REPORT – EVIDENCE REVIEW**

# Introduction

## Purpose of this report

This evidence review focuses on evaluation and management of low back pain in adults. The American Pain Society (APS), which commissioned this report, will use it in partnership with the American College of Physicians (ACP) to develop evidence-based recommendations for low back pain.

# Background

Low back pain is an extremely common problem, with a point prevalence in developed countries of up to 33%, one-year prevalence up to 65%, and lifetime prevalence up to 84%, though estimates vary widely [1]. In the U.S., nonspecific mechanical low back pain is the fifth most common reason for all physician visits, and the second most common symptomatic reason [2]. In one study, 7.6% of U.S. adults randomly surveyed by telephone had at least one occurrence of severe acute low back pain during a one-year period, with 39% of those seeking medical care for the episode [3].

Low back pain is also very costly, with estimates of total annual cost in the U.S. ranging from $20 to $50 billion [4]. Much of the cost is associated with days lost from work. In the U.S., low back pain is the most common cause for chronic or permanent impairment in persons under the age of 65, and the most common cause of activity limitations in persons under the age of 45 [5]. It has been estimated that between 2% and 8% of the U.S. work force is disabled or compensated for back injuries each year [5, 6]. Treatments costs are also large and growing. Medical treatment for chronic low back pain is estimated to cost $9000 to $19,000 per patient annually, and interventional treatments cost a minimum of $13 billion in 1990 [6].

Many patients with acute episodes of low back pain do not seek care because symptoms are often brief and self-limited. Among those who do seek medical care, rapid improvements in pain (average improvement of 58% of initial score), disability (average improvement of 58%), and return to work (82% of those initially off work return to work) are seen in the first month [7]. Further improvement generally continues until

approximately three months, after which levels for pain, disability, and return to work appear to remain relatively constant. Up to one-third of patients report persistent back pain of at least moderate intensity one year after an acute episode requiring care, and one in five report substantial activity limitations [8]. Recurrences of pain also are common, with 60% to three-quarters of patients experiencing at least one relapse within 12 months [7, 9]. Prolonged disability may be more frequent than previously suspected: in one systematic review of 36 studies on the course of low back pain in the general population, 16% (range 3% to 40%) of patients were sick-listed 6 months after entry into the study [9]. Factors associated with the development of chronic disability due to low back pain include pre-existing psychological distress, presence of other types of chronic pain, job dissatisfaction or stress, and disputes over compensation issues [10].

Many options are available for the evaluation and management of acute or chronic low back pain. However, there has been little consensus, either within or between specialties, on appropriate uses of diagnostic tests [11] and interventions [12]. This is demonstrated by numerous studies showing unexplained variations in use of diagnostic tests and treatment. In an international comparison, for example, the rate of back surgery in the U.S. was over five times higher than the rate in the U.K. [13]. Within Washington State, rates of back surgery varied up to 15-fold among different counties [14]. Despite wide variations in practice, several studies have shown that patients experience broadly similar outcomes, though costs of care can differ substantially both between and within specialties [15, 16]. In addition to unexplained practice variations, another historical feature of low back pain management has been the widespread uptake and use of unproven (and sometimes invasive and costly) interventions, some of which have later been shown to be ineffective, or even harmful [17]. Other interventions are widely used despite studies showing only marginal benefits [18].

## Previous guidelines

The Quebec Task Force on Spinal Disorders published one of the first evidence-based clinical practice guidelines for management of low back pain in 1987 [19]. This early attempt at using an explicit scientific basis for issuing management recommendations found insufficient evidence to support the use of most common diagnostic procedures and treatment modalities. In 1994, a multidisciplinary expert panel convened by the U.S. Agency for Health Care and Policy Research (AHCPR)

issued its recommendations on management of acute low back pain [20]. The approach recommended by the AHCPR guidelines emphasize history taking and physical examination to exclude 'red flag' symptoms suggestive of serious underlying pathology; targeted physical examination focusing on neurologic screening; diagnostic triage into broad categories including nonspecific low back pain, radicular syndrome, or specific pathology (which were felt to be diagnosable in only a small minority of cases); judicious use of diagnostic imaging; and consideration of psychosocial factors when there is no improvement. Despite an exhaustive literature search and review, none of the 40 recommendations made for clinical care were viewed as supported by strong research evidence, and only six were judged as having at least a moderate evidence base. At the time, the AHCPR guidelines were subject to intense criticism and scrutiny, in part because they recommended more conservative initial management for most acute low back problems [21]. Nonetheless, nearly all multidisciplinary guidelines published since 1994 have recommended an approach similar to the AHCPR guidelines [22].

There are now at least 11 international guidelines for management of low back pain. Most of their diagnostic and therapeutic recommendations are similar [22]. However, there are some discrepancies, particularly with regard to recommendations for exercise therapy, spinal manipulation, use of muscle relaxants, and provision of patient information. These differences may in part reflect contextual differences between countries that can affect interpretations of the evidence and how the trade-offs between benefits, side effects, and costs are weighted [23]. In addition, a systematic review of 17 primary care guidelines found areas in which the overall quality of guidelines could be improved, including better descriptions of how the evidence was identified, selected and summarized; more attention to patient preferences; increased consideration of how guidelines could be implemented; better use of external peer review; and more transparent descriptions of editorial oversight and potential conflicts of interests [24].

The effects of evidence-based clinical practice guidelines on outcomes in patients with low back pain are difficult to assess. However, several trials evaluating outcomes associated with the selective imaging approach recommended in nearly all guidelines are now available (see Results, Key Question 2d). In addition, an

observational study from Australia found that back care based on guidelines and provided in multidisciplinary clinics was associated with improved pain scores after 12 months, decreased use of imaging and opioid medications, greater patient satisfaction, and decreased health care costs compared to usual care provided in general practice clinics, though one problem interpreting this study is that the multidisciplinary clinic itself may have had an effect [25]. Another observational study found that a mass-media campaign in the state of Victoria, Australia based on evidence-based guidelines (encouraging normal activities and exercising, remaining at work, and providing positive messages about likelihood of recovery) and aimed at altering back pain beliefs was associated with a decline in the number of claims for back pain, rates of days compensated, and medical payments for low back pain claims compared to a neighboring state without such a campaign [26]. A U.S. trial found that randomization of communities to an educational intervention regarding an evidence-based approach to low back pain as recommended in national guidelines resulted in a decline in the rate of surgery by about 9% compared to usual care [27].

The American Pain Society, in partnership with this American College of Physicians, initiated this project to systematically review the current state of evidence and develop updated recommendations for management of acute and chronic low back pain using an evidence-based, balanced, and multidisciplinary approach. Throughout this evidence report, we highlight previous recommendations and findings from the AHCPR guidelines. We also summarize recommendations from two more recent guidelines from the U.S. and the U.K.: A federally funded U.S. guideline issued by the Veterans Affairs/Department of Defense (VA/DoD) in 1999 [28] and the U.K. Royal College of General Practitioners (RCGP) [29] guideline, which was initially released in 1996 and updated in 1999. The AHCPR, VA/DoD, and UK RCGP guidelines primarily focus on acute low back pain, though some recommendations for evaluation and treatment of persistent low back pain are included. A recent, multinational guideline from Europe issued in 2004 (the European COST B13 guidelines) addresses both acute and chronic low back pain, as well as prevention of back pain [30-32]. Both the AHCPR and VA/DoD guidelines use a letter rating system to grade the strength of evidence for recommendations, ranging from A (strong) to D (no adequate scientific studies). The UK RCGP guidelines use a star rating system, ranging from *** (generally consistent

finding in a majority of multiple acceptable studies) to * (no acceptable studies). The European COST guidelines adopted the AHCPR method for grading evidence, but do not explicitly grade the strength of recommendations.

## Scope of evidence review

### Key Questions

The Key Questions used to guide this evidence review were developed in conjunction with a multidisciplinary expert panel convened by the American Pain Society:

1. What features of the history and physical exam are predictive of specific serious underlying conditions ("red flags"), other specific conditions that may be responsive to specific therapies in patients with LBP (such as nerve root compression or spinal stenosis), or high risk for persistent low back pain and associated disability ("yellow flags")?
    - Does identification of 'yellow flags' lead to improved outcomes in patients with LBP?
2. What diagnostic tests should be ordered, and under what circumstances, for patients with LBP?
    - What is the diagnostic accuracy of different diagnostic tests for identifying serious underlying conditions (e.g., tumor, infection, compression fracture)?
    - What is the diagnostic accuracy of different diagnostic tests for identifying other conditions (e.g. nerve root compression, herniated disc, spinal stenosis) that may respond to specific therapies?
    - In patients with 'red flags,' how does the choice of diagnostic testing affect clinical outcomes?
    - In patients without 'red flags,' how does the choice of diagnostic testing (or no testing) affect clinical outcomes?
3. What is the effectiveness of different non-invasive interventions for non-specific low back pain, radicular LBP, or spinal stenosis, and under what circumstances?
    - Can decision tools predict which patients are more likely to respond to specific therapies like physical therapy or chiropractic?
4. What is the value of different patient education or patient self-care methods for improving patient outcomes?

5. Does referral from primary care providers to specialty providers affect patient outcomes?
    - What are the outcomes for patients who are managed by different types of care providers or by multidisciplinary or interdisciplinary clinics?
6. What is the diagnostic accuracy and potential harms associated with diagnostic tests for identifying patients who will benefit from invasive procedures such as provocative discography and discogram, diagnostic nerve blocks, or other similar tests?
    - Does prior use of these tests improve outcomes from invasive procedures?
7. What is the effectiveness of injections (and different injection interventions) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?
8. What is the effectiveness of surgery (and different surgical interventions) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?
9. What is the effectiveness of other modalities (such as TENS or spinal cord stimulation) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?
10. Which combinations of therapies are effective for acute low back pain? Chronic low back pain?
11. What are effective strategies for failed back surgery syndrome?
12. How effective are different methods of integrating and coordinating care in improving outcomes?
13. What interventions are effective for secondary prevention of LBP in patients who have had an episode of acute LBP, or prevention of flares of LBP in patients with chronic LBP?
14. What is/are safe and effective strategies for managing low back pain during pregnancy and post-partum?
15. What is the cost-effectiveness associated with different interventions or management strategies (such as care provided by different types of providers) for managing low back pain?

**Populations**

Target populations for this review are:

- Adults (>18 years old)
- Pregnant women

- Persons with hyperacute (defined as less than 1 week of symptoms), acute (less than 4 to 6 weeks), subacute (between 4 weeks and 3 months) or chronic (greater than 3 months) low back pain
- Persons with nonspecific low back pain (including discogenic pain, facet joint pain, spondylosis, degenerative disc disease, sacroiliac joint pain, etc.), radicular low back pain (including lumbar disc prolapse), spinal stenosis, and failed back surgery syndrome

Treatment of certain specific conditions (such as infection, cauda equina syndrome, cancer, spondyloarthropathies, systemic inflammatory disease, fibromyalgia syndrome, and vertebral compression fracture) was excluded from the scope of this review, though evaluation to rule out such conditions was considered within the scope. Evaluation and management of osteoporosis without clear fracture and acute major trauma was also outside our scope. Children and adolescents were excluded because diagnostic and therapeutic considerations are substantially different than in adults [33, 34].

Low back pain presents as a continuum ranging from acute (often defined as less than 4 weeks in duration) to chronic (often defined as greater than three months in duration). Patients may present to providers at any stage on this continuum, have mixed presentation (e.g., chronic low back pain with an acute exacerbation), or unclear date of onset. In addition, many trials evaluate mixed populations of patients with different durations of symptoms. Therefore, we reviewed evidence on low back pain of any duration.

## Interventions

Target interventions for this review are:

### *Non-invasive interventions*

#### Medications

Acetaminophen

Non-selective non-steroidal anti-inflammatory drugs (NSAIDs)

Cyclo-oxygenase-2 selective NSAIDs

Aspirin

Skeletal muscle relaxants

Antidepressants

Opioid analgesics

Tramadol

Gabapentin

Systemic corticosteroids

**Other non-invasive interventions**

Herbal therapy

Brief educational interventions

Back schools

Exercise

Hydrotherapy

Spa therapy

Acupuncture

Acupressure

Neuroreflexotherapy

Spinal manipulation

Massage

Short wave diathermy

Interferential therapy

Ultrasound

Behavioral interventions

Multidisciplinary rehabilitation

Physical conditioning programs

Traction

Low-level laser

Self-care interventions (including advice for bed rest or on remaining active and self-care books)

***Invasive, non-surgical interventions***

Epidural steroid injections

Intradiscal steroid injections

Chemonucleolysis

Local injections

Facet (zygapophysial) joint injections

Prolotherapy (sclerosant injections)

Botulinum toxin

Adhesiolysis

Radiofrequency denervation

Intradiscal electrothermal therapy (IDET)

Percutaneous intradiscal radiofrequency thermocoagulation

***Surgical interventions***

Fusion and vertebral disc replacement for degenerative conditions of the lumbar spine

Surgery for spinal stenosis and lumbar isthmic spondylolisthesis

Discectomy for lumbar disc prolapse

**Outcomes**

We selected target outcomes based on the five core domains for low back pain suggested in recent recommendations: back specific function, generic health status, pain, work disability, and patient satisfaction [35, 36]. The two most commonly used measures of back-specific function are the Roland Morris Disability Questionnaire (RDQ) and the Oswestry Disability Index (ODI) [37]. The RDQ is reported on a 0 to 24 scale and the ODI on a 0 to 100 scale. Improvements of 2-3 points on the RDQ and 10 points on the ODI have been proposed as minimal clinically important differences [38].

Studies usually evaluate generic health status with the Medical Outcomes Study Short Form-36 (SF-36) or other multi-question assessments. These questionnaires measure how well an individual functions physically, socially, cognitively, and psychologically. The SF-36 measures 8 dimensions, each on a 0 to 100 scale [39]. The individual dimensions can also be combined into several commonly reported subscales (such as the Physical Component Summary and Mental Component Summary).

Most studies measure pain intensity using either visual analogue or categorical pain scales (using either numbers or a list of adjectives describing different levels of pain intensity) [40]. Visual analogue scales (VAS) usually consist of a line on a piece of paper labeled 0 at one end, indicating no pain, and a maximum number (commonly 10

or 100) at the other, indicating excruciating pain. Patients designate their current pain level on the line. Categorical pain scales, on the other hand, consist of several pain category options from which a patient must choose (e.g., no pain, mild, moderate, or severe for a verbal rating scale, 0 to 10 for a numerical rating scale such as the Brief Pain Inventory). Many studies also report the proportion of patients with "significant" improvement in pain, often defined as at least a 20-point (or 20%) improvement on a VAS[41]. The SF-36 bodily pain scale has been recommended as a preferred method for reporting pain outcomes because it measures both pain intensity and interference with activities [35].

Work status is often measured by employment status, days off work, or time before returning to work. Patient satisfaction is usually assessed using a generic global scale, though more formal methods have been developed. Some studies also report effects of interventions on mood or the preference for one medication over another. Whenever available, we reviewed evidence on adverse events and safety as well as direct and indirect costs.

## Conflict of Interest

The evidence review was conducted at the Oregon Evidence-based Practice Center with funding from APS. None of the investigators conducting this review (RC and LHH) had any known or potential conflicts of interest to disclose.

## Methods

### Literature Search and Strategy

We searched the topic of low back pain using multiple electronic databases. Most searches were conducted from 1966 (the start date of MEDLINE) through July 2005. Periodic updates on the electronic searches were performed through March 2006. Because of the large body of evidence on low back pain, our strategy was to first identify relevant systematic reviews for each Key Question. In addition to MEDLINE, we searched the Cochrane Database of Systematic Reviews and the websites of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), Bandolier, and the NHA Health Technology Assessment Programme. The detailed search strategy for low back pain systematic reviews is presented in Appendix 1.

When high-quality systematic reviews for a particular topic were lacking or required updating, we conducted targeted searches for primary studies using MEDLINE, the Cochrane Central Register of Controlled Trials, EMBASE, PsychoInfo, CINAHL, and PEDro (the latter three for appropriate topics). Examples of detailed search strategies for primary studies are shown in Appendix 2.

Periodic hand searching of relevant medical journals, reviews of reference lists (particularly of relevant guidelines and systematic reviews), and expert suggestions supplemented the electronic searches. Abstracts were not included in systematic searches. Reviews, policy statements, and other papers with contextual value were also obtained.

**Inclusion/exclusion Criteria**

All identified citations were imported into an electronic database (EndNote® 9.0) and considered for inclusion. Papers were selected for full review if they were about low back pain, were relevant to a Key Question, evaluated a target population and intervention, and reported at least one relevant outcome (pain, back-specific functional status, generic health status, work status, patient satisfaction, or harms).

When a systematic review was not available for a particular topic, we included all relevant randomized controlled trials and controlled clinical trials. We also included recently published randomized trials to supplement older systematic reviews for selected topics. We only reviewed controlled observational studies for topics where sufficient clinical trials evidence is not available. Other observational studies (such as uncontrolled case series) were excluded. Studies of cost were included if they were conducted alongside a randomized trial or were a full economic analysis. Foreign language papers were considered if they were clinical trials and an abstract was available in English. Studies of non-human subjects and those without original data were excluded.

**Data Extraction and Synthesis**

We used predefined criteria to assess the internal validity of included systematic reviews and trials. For each systematic review, we abstracted the following information: (1) purpose of the review, (2) databases searched, (3) dates of the searches, (4)

language restrictions, if any, (5) number of studies included, (6) criteria used to include studies, (7) limitations of the included studies, (8) methods for rating the quality of included studies, (9) methods for synthesizing the evidence, (10) the interventions evaluated, (11) main efficacy outcomes, and (12) adverse events. We assessed the internal validity (quality) of systematic reviews using the methods developed by Oxman and Guyatt (Appendix 3) [42]. Each study was scored between 1 and 7 based on the following criteria: comprehensiveness of search strategy; application of pre-defined inclusion criteria to select studies; appropriate assessment of validity; and use of appropriate methods to synthesize the evidence. Using this system, systematic reviews with a score of four or less are considered to have potential major flaws and we classified these as 'lower quality'. Systematic reviews with major flaws have been shown to be more likely to produce positive conclusions about the effectiveness of interventions [43, 44]. Systematic reviews with scores of five or higher were considered 'higher quality'.

For each clinical trial, we abstracted the following information: (1) study design, (2) purpose of study, (3) inclusion and exclusion criteria, (4) number of patients approached, eligible, and randomized, (5) demographics and baseline characteristics, (6) setting, (7) funding source, (8) interventions evaluated, (9) main efficacy results, (10) adverse events (including withdrawal due to adverse events), (11) duration of follow-up, (12) loss to follow-up, and (13) compliance to treatment. We assessed the internal validity of randomized clinical trials using the eleven predefined criteria proposed by the Cochrane Back Review Group (see Appendix 4 for details on how we operationalized the criteria) [45]. We rated the internal validity of each trial based on the methods used for randomization, allocation concealment, and blinding; the similarity of compared groups at baseline; the use of co-interventions; compliance to allocated therapy; adequate reporting of dropouts; loss to follow-up; non-differential timing of outcome assessment; and the use of intention-to-treat analysis. Trials were scored between zero and eleven, according to the number of criteria were met. For certain interventions for which blinding was unfeasible (such as surgery), we removed blinding of patient and providers as quality criteria, so the maximum score was nine. Consistent with most reviews conducted by the Cochrane Back Group [46, 47], we considered trials receiving

more than half of the total possible score 'higher-quality' and those receiving less than half 'lower-quality'.

Several studies evaluating the rate of positive pain responses with discography in patients without serious back pain (see Key Question 6) differed from typical studies of diagnostic test accuracy because they did not compare results of one test to a reference standard (no reference standard is available). We assessed the quality of these studies using nine criteria adapted from methods developed by the U.S. Preventive Services Task Force [48] or based on empiric studies [49, 50] of sources of variation and bias in studies of diagnostic tests. We determined whether each study evaluated a consecutive series of patients or a random subset, was prospective, evaluated patients with a spectrum of symptoms, adequately described the discography technique, used current discography techniques, adequately described criteria for a positive test, used an appropriate definition for a positive test, performed statistical analysis on potential predictors of positive tests, and performed blinded testing. Studies that met at least five of the nine criteria were considered higher-quality.

Two reviewers independently rated the quality of each systematic review and primary study. Any discrepancy was resolved via a consensus process.

**Assessing Research Applicability and Clinical Relevance**

Factors that we considered when assessing the applicability of trials include whether the publication adequately described the study population and interventions, whether the setting or population is so different from typical U.S. settings that the results might not be applicable, whether the differences are clinically (as well as statistically) significant, and whether the treatment received by the control group was reasonably representative of standard practice [51]. We also recorded the funding source and role of the sponsor.

**Rating a Body of Evidence**

We assessed the overall strength of evidence for a body of literature about a particular Key Question using methods adapted from the U.S. Preventive Services Task Force [48]. To assign an overall strength of evidence (good, fair, or poor), we examined the type, number and quality of studies; the strength of association; the consistency of

results within and between study designs; and the possibility for publication bias. For this report, we defined minimum criteria for a body of literature to meet an overall 'good' or 'fair' rating:

**Good quality:** Multiple consistent higher quality RCTs, or 1 definitive RCT

**Fair quality:** 1 higher quality RCT; multiple consistent lower quality RCTs, or multiple consistent higher-quality controlled observational studies

**Poor quality:** Does not meet criteria for fair or good

Consistent results from good-quality studies across a broad range of populations suggest a high degree of certainty that the results of the studies are true (that is, the entire body of evidence would be considered "good-quality"). For a body of fair-quality studies, however, consistent results could indicate that similar biases are operating in all of the studies. For a poor quality body of evidence, reliable conclusions are not possible because of insufficient evidence, of there is low certainty that the results are not due to bias or other methodologic shortcomings in the studies. Inconsistent results from high-quality studies may lower confidence that the results of any particular study are true, or reflect diversity between studies in the populations or interventions evaluated. Large effect sizes on important, patient-centered outcomes can increase the confidence in study findings, particularly when they are reported by higher-quality studies. On the other hand, unvalidated assessment techniques or heterogeneous reporting methods for important outcomes may weaken or downgrade the overall body of evidence for that particular outcome or make it difficult to accurately estimate the true magnitude of benefit or harm.

**Size of literature reviewed**

Investigators reviewed 1312 abstracts identified by searches for systematic reviews. From the searches, 243 full-text articles were reviewed. A list of relevant systematic reviews identified for this report is shown in Appendix 5. A total of 7635 citations were identified in 27 searches for primary studies of selected topics.

# Results

## Key Question 1.

**What features of the history and physical exam are predictive of specific serious underlying conditions ("red flags"), other specific conditions that may be responsive to specific therapies in patients with LBP (such as nerve root compression or spinal stenosis), or high risk for persistent low back pain and associated disability ("yellow flags")?**

### *Features of history and physical exam predictive of serious underlying conditions ("red flags"), compression fracture, ankylosing spondylitis, nerve root compression, and spinal stenosis*

In primary care, about 0.7% of patients will have spinal malignancy (primary or metastatic), 3% ankylosing spondylitis, 4% compression fractures, 0.3% ankylosing spondylitis, and 0.01% spinal infection [52]. Spinal stenosis and symptomatic herniated disc are present in about 3% and 4%, respectively [53]. Up to 90% of patients have non-specific low back pain, for which there is imprecise or no correlation with any specific pathology [53]. Features of history and physical exam that can identify patients more likely to have serious conditions such as cancer or infection ("red flags") or other conditions that may respond to specific treatments (such as nerve root compression from lumbar disc prolapse, spinal stenosis, ankylosing spondylitis, and vertebral compression fracture) are important for guiding diagnosis and therapy.

Results of search: systematic reviews

We identified four systematic reviews (three higher-quality [53, 54, 55], one lower-quality [53]) on the accuracy of history and physical exam for diagnosing various conditions associated with low back pain. We excluded three other reviews that were outdated [56], did not clearly describe systematic methods for identifying or synthesizing the literature [56], did not report diagnostic accuracy [57], or reported duplicate information from another published review [58].

The most recent systematic review was published in 2002 (searches conducted through September 2001) [58]. All of the systematic reviews noted important methodological shortcomings in the primary literature. These included spectrum bias (for example, only

evaluating patients who underwent surgery, patients from referral settings, or those with more severe disease), little attention to inter- or intra-rater reliability, verification bias, non-blinded assessment of the index or reference tests, poor description of the index test, and lack of attention to reproducibility of findings over time. These deficiencies could explain some of the observed variation between studies in reported diagnostic accuracy. Another limitation of the literature is that the specific features of history and physical exam that were assessed varied, and for several features only a single or few studies are available. Only one systematic review (rated higher-quality), on the accuracy of the straight leg raise test for disc herniation, pooled data quantitatively [54].

Results of search: additional studies

We did not search for additional studies.

*Accuracy of history and physical exam features for identifying specific diagnoses associated with low back pain*

Cancer

Two systematic reviews evaluated the diagnostic accuracy of history for identifying patients with cancer [55, 58]. Based on one higher-quality study [52], both systematic reviews found that failure to improve after 1 month of therapy, unexplained weight loss, and previous history of cancer were each associated with high specificity (>0.90). Previous history of cancer was associated with the highest positive likelihood ratio at 14.7. Only age >50 years and no relief with bed rest were associated with sensitivities greater than 0.50 (0.77 and >0.90, respectively). Having any of the following was associated with a sensitivity of 1.0 and specificity of 0.60 for diagnosing vertebral cancer: age >50, history of cancer, unexplained weight loss, or failure of conservative therapy (positive likelihood ratio 2.5). For physical exam findings, one systematic review found that the sensitivity of spinal tenderness for diagnosing vertebral cancer varied widely across four studies (range 0.15 to 0.80), though specificity was relatively consistent (0.60 to 0.78) [55]. Other physical exam findings had poor sensitivity, though certain neuromuscular (weakness, atrophy, reflex changes) or sensory deficits were associated with high specificity in some studies.

Infection

Few studies evaluated the accuracy of history in diagnosing spinal osteomyelitis or other infections causing low back pain. One systematic review found a sensitivity of 0.40 for a history of intravenous drug abuse, urinary tract infection, or skin infection (specificity not reported) [58].

*Compression fracture*

For diagnosis of compression fracture, one systematic review included one unpublished study that found that corticosteroid use had a higher predictive value (positive likelihood ratio 12.0) than age or history of trauma [58]. Age >50 years was associated with a sensitivity of 0.84 and specificity of 0.61 (positive likelihood ratio 2.2 and negative likelihood ratio 0.26) and age >70 years was associated with a sensitivity of 0.22 and specificity of 0.96 (positive likelihood ratio 5.5 and negative likelihood ratio 0.81).

*Ankylosing spondylitis*

Two systematic reviews evaluated the diagnostic accuracy of history for identifying patients with ankylosing spondylitis [53, 55]. Both found younger age of onset associated with high sensitivity but poor specificity (sensitivity and specificity 0.92 and 0.30 for onset <35 years, 1.00 and 0.07 for onset <40 years). Most other historical features had only modest predictive value or gave inconsistent results. For example, the specificity of a history of sacral pressure varied from 0.68 to 0.92 in three studies. Combining historical findings (positive response to 4 of 5 screening questions: onset before age 40, chronic onset, duration >3 months, morning stiffness, and improvement with exercise) did not improve diagnostic accuracy (positive likelihood ratio of 1.3 and negative likelihood ratio of 0.94). All physical exam findings (including Schober's test, degree of chest expansion, reduced lateral mobility, sacral or lumbar pressure) were associated with poor sensitivity. In single studies, chest expansion <=2.5 cm, Schober's sign <4 cm, and restricted anteroposterior compression, lateral compression, or hip extension were associated with relatively high specificities (>0.80).

*Herniated disc or radiculopathy*

For diagnosing a herniated disc or radiculopathy, three systematic reviews found that a history of sciatica had a fairly high (79% to 99%) sensitivity and widely varying specificity (14% to 88%) [59]. One systematic review also found that a typical distribution for radiculopathy on a pain drawing had modest sensitivity (46%) but high

specificity (84%) in one higher-quality study [59]. The best-evaluated physical exam findings for herniated disc are the straight leg raise (Laseague's test) and the crossed straight leg raise tests. In a higher-quality, recent systematic review of 17 studies, the pooled sensitivity and specificity of the straight leg raise test for diagnosing herniated disc were 0.91 (95% CI 0.82 to 0.94) and 0.26 (95% CI 0.16 to 0.38) [54]. The pooled diagnostic odds ratio was 3.74 (95% CI 1.2 to 11.4). For the crossed straight leg raise test, the pooled sensitivity and specificity were 0.29 (95% CI 0.24 to 0.34) and 0.88 (95% CI 0.86 to 0.90), with a pooled diagnostic odds ratio of 4.39 (95% CI 0.74 to 25.9). Three other systematic reviews were consistent with these results [53, 55, 59]. Other physical exam findings (such as decreased reflexes, strength, muscle atrophy, or sensory deficits) have been less well studied. In general, the presence of such neurological deficits is an insensitive finding for diagnosing radiculopathy or herniated disc [53, 55, 59]. Isolated studies found that iliopsoas or tibialis anterior weakness have high (97% and 89%) specificity [59]. The specificity of gastrocnemius weakness, calf atrophy, and depressed ankle or knee jerks for diagnosing herniated disc ranged from modest to high [53, 55, 59].

The accuracy of combined history and physical examination findings for diagnosing herniated disc varied across studies, in part because of inconsistencies in how the clinical findings were defined across studies [59]. For example, the sensitivity and specificity were 27% and 97% in one study that defined a positive "cluster" as two or more positive findings [60], but 98% and 7% in another that defined a positive cluster as "probable diagnosis" based on clinical exam and history [61].

*Spinal stenosis*

One systematic review found that lack of pain when seated and a wide-based gait had the highest positive predictive value for spinal stenosis (6.6 and 14.3 in one study, respectively) [53]. Age greater than 65 years was associated with a negative likelihood ratio of 0.33.

**Summary of evidence**

- Previous history of cancer (positive likelihood ratio 14.7), unexplained weight loss (positive likelihood ratio 2.7), and failure to improve after 1 month of therapy (positive likelihood ratio 3.0) were associated with a specificity for diagnosing

cancer of >0.90 in patients with acute low back pain presenting to primary care in one higher-quality study (level of evidence: fair).

- The presence of any of the following was associated with a high sensitivity (1.00) and moderate specificity (0.60) for diagnosing cancer in one higher-quality study: age >50 years, history of cancer, unexplained weight loss, or failure of conservative therapy (positive likelihood ratio 2.5, negative likelihood ratio 0.0) (level of evidence: fair).
- Few studies have evaluated the accuracy of history and physical exam for diagnosing infection, though history of intravenous drug use, skin infection, or urinary tract infection only had modest sensitivity in one study (level of evidence: poor).
- Older age and history of corticosteroid use were the best predictors of vertebral compression fractures (level of evidence: fair).
- Younger age of onset was sensitive but not specific for diagnosing ankylosing spondylitis. Physical exam findings were generally associated with poor sensitivity and relatively high specificities (level of evidence: fair).
- Describing typical symptoms of sciatica has a relatively high sensitivity but inconsistent specificity for diagnosing radiculopathy. A positive straight leg raise (the best-studied physical exam maneuver) was associated with a pooled sensitivity of 0.91 and specificity of 0.26 in one higher-quality systematic review. A positive crossed straight leg raise was associated with a pooled sensitivity of 0.29 and a specificity of 0.88. The specificity of neurologic deficits consistent with nerve root compression ranges from modest to high (level of evidence: fair).
- In one study, spinal stenosis was less likely in patients younger than 65 years old. A wide-based gait and absence of pain when seated were associated with higher likelihoods of spinal stenosis (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend inquiring about features of the history and clinical exam suggestive of cancer or infection (history of cancer, unexplained weight loss, intravenous drug use, history of urinary infection, pain increased by rest, fever), particularly in patients over the age of 50 (strength of evidence: B).
- The AHCPR guidelines recommend inquiring about features suggestive of cauda equina syndrome such as bladder dysfunction, saddle anesthesia, and major limb motor weakness (strength of evidence: C).
- The AHCPR guidelines recommend inquiring about significant trauma or minor fall or heavy lift in potentially osteoporotic or older patients to avoid delays in diagnosing fractures (strength of evidence: C).

- The AHCPR guidelines recommend straight leg raise testing to assess sciatica in young adults, but notes that it may be normal in older patients with spinal stenosis (strength of evidence: B).
- The AHCPR guidelines recommend a focused neurologic exam emphasizing ankle and knee reflexes, ankle and great toe dorsiflection strength, and distribution of sensory complaints to document the presence of neurologic deficits (strength of evidence: B).
- The VA/DoD and UK RCGP guidelines adopted an approach nearly identical to the one suggested by the AHCPR guidelines (history and physical with focus on identifying red flags and focussed neurologic examination).
- The European COST guidelines also recommend diagnostic triage in patients with acute low back pain as recommended by other guidelines. In patients with chronic low back pain, diagnostic triage is recommended at the first assessment and at reassessment to exclude specific spinal pathology and nerve root pain.

### *Features of the history and physical exam associated with development of chronic and disabling low back pain*

Rapid improvements in low back pain typically occur in the first month after presentation. However, a small proportion of patients develop chronic and disabling back pain. One systematic review found that 82% of those initially off work returned to work within one month, and 93% had returned to work by three to six months, with little subsequent improvement [7]. “Yellow flags” describe features of the history or physical examination that could help identify patients more likely to develop chronic and disabling low back pain in order to provide interventions that might help retain or improve functionality.

Results of search: systematic reviews

We identified nine systematic reviews evaluating features of the history predictive of a high risk for persistent low back pain and related disability [7, 62-69]. Three were rated higher quality [7, 64, 66]. Three lower-quality systematic reviews evaluated features of the physical exam predictive of persistent and disabling low back pain [62, 69, 70]. All of the systematic reviews reported important methodological shortcomings in the primary literature including lack of blinding, small sample sizes, inadequate analyses of confounders, and incomplete follow-up of patients. In addition, the populations and

settings were heterogeneous. Because of these limitations, all of the systematic reviews only qualitatively synthesized the evidence.

Results of search: additional studies

We did not search for additional studies

*Accuracy of history and physical exam features for identifying patients more likely to develop chronic and disabling low back pain*

The most recent, higher-quality systematic review (based on 54 higher-quality studies) found strong evidence that each of the following was a predictor of persistent low back pain, non-return to work, or disability: low back pain associated with increased pain severity, longer duration, associated disability, or leg pain; low back pain-related sickness leave; history of spinal surgery; low job satisfaction; and poor general health [64]. There was moderate evidence that work-related and psychological factors (such as employment status, amount of wages, workers' compensation, and depression) and physical factors (such as time spent lifting per day and work postures) were also associated with worse outcomes. Findings of other systematic reviews were generally concordant. A second higher-quality systematic review of 18 prospective cohort studies (six rated high or acceptable quality), for example, also found increased psychologic distress, somatization, and poorer coping strategies associated with unfavorable outcomes [66]. Several systematic reviews found receipt of benefits or worker's compensation associated with poorer outcomes [62, 65, 69]. Other systematic reviews also found modest evidence for an association between more severe pain [65, 69] or presence of radiating [62, 67] or continuous pain [67] and poorer outcomes. Evidence regarding an association between age or gender and poorer outcomes was mixed and inconsistent [62, 65, 67].

Only a handful of studies assessed the usefulness of specific scales to predict poorer outcomes. One recent higher-quality systematic review found that the Vermont disability prediction questionnaire appeared promising [7]. In one higher quality study, higher scores (>0.48) were associated with a positive likelihood ratio for return to work at 3 months of 5.7 (95% CI 3.9 to 8.5) and a negative likelihood ratio of 0.07 (95% CI 0.01 to 0.50). Fear avoidance (avoidance of activity because of fears that it will worsen symptoms or outcomes) predicted worse outcomes in two [62, 67] of three [66] systematic reviews.

Evidence regarding the prognostic value of physical exam findings for predicting poorer outcomes associated with low back pain is sparser than evidence regarding psychosocial factors. Presence of positive sham tests for pain (such as Waddell's nonorganic signs) consistently predicted disability in one systematic review [67]. Other physical exam findings such as positive straight leg raise tests, absence of neurological signs, and intact range of motion were inconsistently associated with poorer outcomes [62, 70]. One systematic review found that physical exam findings were weaker predictors of outcomes than psychosocial factors [69].

**Summary of evidence**

- There is consistent evidence from multiple systematic reviews that psychologic distress, job dissatisfaction, high levels of "fear avoidance" beliefs, disputed compensation claims, and somatization are associated with worse low back pain outcomes (level of evidence: good).
- Increased duration or severity of pain and presence of leg pain are modestly associated with poorer outcomes (level of evidence: fair).
- Physical exam findings were inconsistently associated with outcomes and were weaker predictors than psychosocial factors (level of evidence: fair).
- Validated tools or scales for identifying patients likely to have poorer outcomes are lacking, though one study found the Vermont disability questionnaire promising (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend inquiring about psychological and socioeconomic problems as nonphysical factors can complicate assessment and treatment (strength of evidence: C).
- The AHCPR guidelines found that social, economic, and psychological factors can significantly alter a patient's response to back symptoms and to treatment of those symptoms (strength of evidence: D).
- The VA/DoD, UK RCGP and European COST guidelines also recommend assessing psychological and socioeconomic factors and reviewing them if there is no improvement.

**<u>Key Question 1a.</u>**

**Does identification of 'yellow flags' lead to improved outcomes in patients with LBP?**

Results of search: systematic reviews

We found no systematic review evaluating the effects of interventions targeted at identification and treatment of yellow flags in patients with acute or subacute low back pain. Although several systematic reviews evaluate interventions addressing psychosocial issues in patients with subacute or mixed duration low back pain, identification and treatment of yellow flags was usually not the main goal of therapy or was included as part of a multidisciplinary biopsychosocial approach [71-75]. See discussions of behavioral interventions, multidisciplinary interventions, and functional restoration/physical conditioning under Key Question 3.

Results of search: trials

We identified two higher-quality trials evaluating brief interventions for identifying and treating 'yellow flags' [76, 77]. A third, lower-quality trial evaluated an intensive, multlidisciplinary intervention [78]. Two other trials (one higher-quality [79]) evaluated the efficacy of fear-avoidance based therapy [79, 80]. All were conducted in patients with acute or subacute low back pain.

Efficacy of interventions for identifying and treating 'yellow flags'

Although several recent trials have assessed interventions for identifying and treating 'yellow flags,' it is difficult to draw general conclusions about their effectiveness because of differences in the treatments (ranging from brief interventions administered by a primary care clinician to intensive, multidisciplinary interventions) and populations studied. Two higher-quality trials found that brief interventions were no more effective than standard practice or conventional physical therapy in patients with back pain of less than 12 weeks' duration (Table 1) [76, 77]. One trial (N=314) found no differences through 12 months between usual care and a minimal (20 minute) intervention aimed at identifying, providing information about, and promoting self-care of psychosocial risk factors for any outcome including back-specific functional status (RDQ score), pain, sick leave, perceived general health (SF-36), or general practitioner visits [77]. The minimal intervention also failed to show a benefit in higher-risk subgroups of patients with increased baseline psychologic distress or recurrent back pain. The second trial (N=402) found no differences on back-specific functional status (ODI score), pain, time off work, depression scores, use of health care resources, or satisfaction with care at either 3 or 12 months among patients randomized to a brief pain management program

(aimed at identifying psychosocial risk factors, emphasizing return to normal activity through functional goal setting, and using educational strategies to overcome psychosocial barriers to recovery as well as a tailored exercise program) versus standard physical therapy (with an emphasis on spinal manipulation), though the number of physical therapy sessions was slightly lower with the brief intervention [76]. In both trials, patients improved regardless of which intervention they were randomized to.

**Table1. Trials of brief interventions for identifying and treating 'yellow flags'**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hay, 2005[76] | N=402<br>12 months | **Brief pain intervention vs. manual physical therapy** (results at 12 months unless otherwise noted)<br>ODI score, mean change from baseline: 7.8 vs. 8.1 at 3 months, p=0.755; 8.8 vs. 8.8 at 12 months, p=0.994<br>Overall assessment 'much better' or 'completely better' at 12 months: 68% vs. 69%<br>Back pain (0 to 100 scale): 78 vs. 70, p=0.401<br>Took time off work in last 12 months: 54% vs. 58%, p=0.45<br>Satisfaction with treatment (0 to 100 scale), median: 93 vs. 93 | 8/11 |
| Jellema, 2005[77] | N=314<br>12 months | **Minimal intervention vs. usual care**<br>(results at 12 months unless otherwise noted)<br>RDQ score (0 to 24 scale): 1 vs. 1, mean difference 0.25 (-0.77 to 1.28)<br>No recovery (rated recovery as slightly improved, no change, slightly worse, much worse, or very much worse): 42/132 (32%) vs. 43/156 (28%), odds ratio 1.16 (0.63 to 2.17)<br>Sick leave due to low back pain: 8/107 (8%) vs. 9/128 (7%), odds ratio 0.69 (0.43 to 1.13)<br>Pain severity: mean difference 0.015 (-0.41 to 0.44) | 6/11 |

Several factors could explain the lack of an effect in these two trials. In one study, patients receiving the intervention were not permitted to receive physical therapy for the first six weeks [77]. In addition, the general practitioners randomized to the minimal intervention arm in that trial were only moderately successful in identifying psychosocial factors, and were no more effective than usual care in improving outcomes measured by psychosocial scales [81]. It's possible that additional training or a more intense intervention could result in more effective treatment. In addition, targeting the intervention to high-risk patients could improve outcomes compared to treating a less selected group of patients [82]. These hypotheses are supported in part by a third, small (N=70), lower-quality trial which found that a more intense (including 3 physician evaluations and a total of 45 physical therapy, biofeedback/pain management, group

747 didactic, and case manager/occupational therapy sessions), multidisciplinary functional
748 restoration intervention was associated with improved pain, and decreased disability
749 after 12 months (Table 2) compared to usual care in patients with acute (<8 weeks) low
750 back pain identified as higher risk for chronic disability using a screening tool [78].

751 **Table 2. Trial of intensive multidisciplinary functional restoration in patients at higher risk**
752 **for chronic disability**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Gatchel, 2003[78] | N=70<br>12 months | **Multidisciplinary functional restoration vs. usual care**<br>Return to work at 12 months: 91% vs. 69% (p=0.027)<br>Average number of healthcare visits: 26 vs. 29 (p=0.004)<br>Average number of healthcare visits related to low back pain: 17 vs. 27, p=0.004<br>Average number of disability days due to back pain: 38 vs. 102, p=0.001<br>Average most 'intense pain" at 12 month follow-up: 46 vs. 67, p=0.001<br>Average self-rated pain over last 3 months: 27 vs. 43, p=0.001<br>Taking opioid analgesics: 27% vs. 44%, p=0.020 | 2/11 |

753

754 Two other trials evaluated interventions for reducing fear avoidance (Table 3). In one
755 lower-quality trial, 240 patients with persistent low back pain and activity limitations 8 to
756 10 weeks after the initial visit were randomized to a four-session individualized fear
757 avoidance intervention with a psychologist and physical therapists versus usual care
758 [79]. The intervention was superior for disability outcomes, with the proportion of
759 patients with greater than one-third reduction in RDQ score 28% vs. 13% at 2 months
760 (p=0.0007) and 49% vs. 37% at 24 months (p=0.08). Average pain intensity was
761 slightly better with the intervention at 2 months, though the difference was no longer
762 significant at 24 months. There was no difference in SF-36 scores or ability to work,
763 though a lower proportion of patients randomized to the fear avoidance intervention
764 reported activity limitation due to back pain for 30 or more days after 24 months (8.5%
765 vs. 14.3%, p=0.04). The patients randomized to the fear avoidance intervention also
766 reported lower scores on fear-avoidance and worry rating scales through 24 months.
767 The second, smaller (N=67), higher-quality trial found no differences on the ODI scale
768 or pain intensity after 6 months between low back pain (less than 8 weeks duration)

patients randomized to fear avoidance-based physical therapy (encouraging patient to take an active role in treatment and to view back pain as common, along with a self-care booklet and graded exercise) and usual physical therapy [80]. The fear avoidance intervention was associated with lower fear avoidance beliefs in the subgroup of patients with high baseline fear avoidance scores.

**Table3. Trials of fear-avoidance based interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Von Korff, 2005[79] | N=240<br>24 months | **Fear avoidance intervention vs. usual care**<br>RDQ score (0 to 24): 10.2 vs. 11.5 at 2 months, p=0.0002; 8.1 vs. 9.1 at 24 months, p=0.0078<br>Proportion of patients with greater than one-third reduction in RDQ score: 28% vs. 13% at 2 months, p=0.0007; 49% vs. 37% at 24 months, p=0.08<br>Fear-avoidance (17-68): 36.4 vs. 39.9 at 2 months, p<0.0001; 34.3 vs. 38.4 at 24 months, p=0.0001<br>Average pain intensity (0 to 10): 4.9 vs. 5.3 at 2 months (p=0.020); 4.3 vs. 4.6 at 24 months (p=0.115)<br>SF-36 social functioning and SF-36 mental health inventory: no differences<br>Unable to work: No differences<br>Unable to carry out usual activities due to back pain for 30 or more days: 24% vs. 26% at 2 months, p=0.06, 8.5% vs. 14.3% at 24 months, p=0.04 | 4/11 |
| George, 2003[80] | N=67<br>6 months | **Fear avoidance vs. standard physical therapy**<br>ODI Score (0 to 100), mean change: 18.0 vs. 17.1 at 4 weeks, (NS), 23.9 vs. 23.0 at 6 months (NS)<br>Present pain intensity (0 to 10), mean change: 2.4 vs. 2.0 at 4 weeks (NS), 2.6 vs. 3.0 at 6 months (NS)<br>Fear Avoidance Beliefs Questionnaire, Physical Activity Scale (0 to 24), mean change: 5.0 vs. 1.8 at 6 months, p=0.037<br>Fear Avoidance Beliefs Questionnaire, Work Scale (0 to 42), mean change: 3.1 vs. 1.9 at 6 months, p=0.352 | 7/11 |

*Safety*

Adverse events were not reported in any of the trials.

*Costs*

A cost-benefit analysis of the trial comparing an intensive, early multidisciplinary intervention in patients identified as higher risk for chronic disability calculated a net gain of $9122, mostly related to a reduction in lost wages in the intervention group [78].

**Summary of evidence**

- Two higher-quality trials found no benefits after 12 months from brief interventions identified at identifying and treating 'yellow flags' relative to usual

786 care or standard physical therapy in unselected patients with acute or subacute
787 back pain (level of evidence: good).

788 • One lower-quality trial found that an intensive multidisciplinary functional
789 restoration program was more effective than usual care after 12 months in
790 patients with back pain for less than 8 weeks who were identified as being at
791 higher risk for chronic disability using a screening tool (level of evidence: poor).

792 • One lower-quality trial found fear-avoidance based therapy superior to usual care
793 for back specific functional status after 24 months in patients with persistent
794 activity limitations, though beneficial effects on pain were only short-lived (level of
795 evidence: poor).

796 • One higher-quality trial found no difference between fear-avoidance therapy and
797 standard physical therapy after 6 months, though fear-avoidance beliefs were
798 decreased in the intervention group (level of evidence: fair).

799 **Recommendations from other guidelines**

800 • No guidelines make specific recommendations about interventions in patients
801 identified as having 'yellow flags'.

802 **Key Question 2.**

803 **What diagnostic tests should be ordered, and under what circumstances, for**
804 **patients with LBP?**

805 Because many anatomic abnormalities are quite common in healthy persons,
806 diagnostic imaging often identifies radiographic abnormalities that are only loosely
807 associated with symptoms. In one systematic review of findings from plain radiography,
808 degenerative changes (disc space narrowing, osteophytes, and sclerosis) were only
809 modestly associated with low back pain (OR 1.2 to 3.3) [83]. Other findings, such as
810 spondylolysis, spondylolisthesis, spina bifida, transitional vertebrae, spondylosis, and
811 Scheuermann's disease did not appear to be associated with symptoms. Another
812 systematic review found that more sophisticated imaging methods were more likely to
813 identify radiologic abnormalities in asymptomatic patients than plain radiography [53].
814 The proportion of asymptomatic patients with herniated disc on MRI, for example,
815 ranged from 9% to 76%, degenerative disc from 46% to 93%, and stenosis from 1% to
816 21%. Greater use of advanced diagnostic imaging could lead to additional testing and
817 interventions. For example, a significant proportion of the geographic variation in spinal
818 surgery rates across the U.S. appears correlated with differential rates of obtaining MRI

[84]. On the other hand, patients and providers may be reassured by obtaining imaging tests, even if the findings don't necessarily alter management.

**Key Question 2a.**

**What is the diagnostic accuracy of different diagnostic tests for identifying serious underlying conditions (e.g., tumor, infection, compression fracture)?**

Results of search: systematic reviews

We identified one recent higher-quality systematic review that evaluated the diagnostic accuracy of plain radiography, magnetic resonance imaging (MRI), computed tomography (CT), or radionuclide scanning for diagnosing serious underlying conditions associated with low back pain [53]. We excluded six other systematic reviews because they were outdated [56, 85-88] or reported duplicate information [58].

The systematic review found numerous flaws in diagnostic studies, with the most common being failure to apply a single reference test to all patients, test review bias (study test was reviewed with knowledge of the final diagnosis), diagnosis review bias (determination of the final diagnosis was affected by the study test), and spectrum bias (only severe cases of disease were evaluated) [53]. Additional limitations of primary studies include heterogeneous populations, small sample sizes, and small numbers of studies. Estimates of diagnostic accuracy were therefore considered imprecise, and ranges rather than pooled estimates were reported.

We also identified one higher-quality systematic review on the accuracy of erythrocyte sedimentation rate testing in patients with low back pain [55], one higher-quality systematic review on the accuracy of thermography for diagnosing lumbar radiculopathy [89], and one lower-quality systematic review on the accuracy of surface electromyogram [90]. One other systematic review of surface electromyogram was excluded because it primarily evaluated whether the test could distinguish patients with low back pain from those without low back pain [91].

*Accuracy of imaging for diagnosing cancer*

The accuracy of diagnostic imaging for diagnosing vertebral cancer is summarized in Table 4. Plain radiography was associated with lower sensitivity for metastatic cancer than MRI or radionuclide scanning (with planar imaging or SPECT), though it was

associated with high specificity [53]. Magnetic resonance imaging and SPECT were associated with similar diagnostic accuracy. Planar imaging was less accurate than SPECT.

**Table 4. Estimated accuracy of different imaging techniques for diagnosing cancer (ranges)**

| Technique | Sensitivity | Specificity | Positive likelihood ratio | Negative likelihood ratio |
|---|---|---|---|---|
| **Plain radiography** | 0.6 | 0.95-0.995 | 12-120 | 0.40-0.42 |
| **MRI** | 0.83-0.93 | 0.90-0.97 | 8.3-31 | 0.07-0.19 |
| **Radionuclide scanning with planar imaging** | 0.74-0.98 | 0.64-0.81 | 3.9 | 0.32 |
| **SPECT** | 0.87-0.93 | 0.91-0.93 | 9.7 | 0.14 |

Source: Jarvik and Deyo, 2002[53]

*Accuracy of imaging for diagnosing vertebral infection*

For diagnosing vertebral infection, plain radiography was less accurate than MRI or radionuclide scanning (Table 5) [53]. MRI was more accurate than either plain radiography or radionuclide scanning.

**Table 5. Estimated accuracy of different imaging techniques for diagnosing vertebral infection (ranges)**

| Technique | Sensitivity | Specificity | Positive likelihood ratio | Negative likelihood ratio |
|---|---|---|---|---|
| **Plain radiography** | 0.82 | 0.57 | 1.9 | 0.32 |
| **MRI** | 0.96 | 0.92 | 12 | 0.04 |
| **Radionuclide scanning** | 0.90 | 0.78 | 4.1 | 0.13 |

Source: Jarvik and Deyo, 2002[53]

*Accuracy of imaging for diagnosing vertebral compression fracture*

For vertebral compression fracture, plain radiography appears sensitive, but its ability to distinguish acute from chronic fracture is poor, and asymptomatic fractures are frequently identified [53]. Although radionuclide scanning is insensitive for diagnosing fractures, it can help distinguish recent from old fractures. MRI can also provide additional information about the acuity of compression fractures.

*Accuracy of elevated erythrocyte sedimentation rate for diagnosing cancer*

One systematic review [55] included a higher-quality study [52] that found that an ESR >=20 mm/hr was associated with a sensitivity of 0.78 and specificity of 0.67 for diagnosing vertebral cancer.

*Costs*

A decision analysis found that for diagnosing cancer in patients with low back pain, a strategy of selectively imaging patients with a positive clinical finding (history of cancer, age >=50 years, weight loss, or failure to improve with conservative therapy) in combination with either an elevated ESR (>=50 mm/hr) or a positive x-ray was associated with the lowest cost-effectiveness ratio ($5283 per case found) [92]. Using a similar strategy but directly imaging patients with a history of cancer resulted in similar estimates of cost-effectiveness. A decision analysis of diagnostic strategies for excluding cancer found that rapid MRI was associated with an incremental cost-effectiveness of nearly $300,000/QALY relative to routine x-ray imaging [93].

**Summary of evidence**

- MRI and radionuclide scanning are more sensitive than plain radiography for diagnosing vertebral cancer, though plain radiography is associated with high specificity (level of evidence: good).
- MRI is more accurate than either plain radiography or radionuclide scanning for diagnosing vertebral infection (level of evidence: fair).
- Plain radiography appears sensitive for diagnosing vertebral compression fracture, but is unable to provide information about acuity (level of evidence: fair).
- An elevated erythrocyte sedimentation was associated with moderate sensitivity and specificity for diagnosing vertebral cancer in one higher-quality study (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines state that plain x-rays in combination with CBC and ESR may be useful for ruling out tumor or infection in patients with acute low back problems when any of the following are present: prior cancer or recent infection, fever over 100 degrees F, IV drug abuse, prolonged steroid use, low back pain worse with rest, unexplained weight loss (strength of evidence: C).
- The AHCPR guidelines recommend prompt CT or MRI in the presence of red flags suggesting cauda equina syndrome or progressive motor weakness, preferably in consultation with a surgeon (level of evidence: C).
- The AHCPR guidelines recommend CT or MRI when clinical findings strongly suggest tumor, infection, fracture, or other space-occupying lesions of the spine (strength of evidence: C).
- The AHCPR guidelines state that in the presence of red flags, especially for tumor or infection, the use of other imaging studies such as bone scan, CT, or

MRI may be clinically indicated even in plain x-rays are negative (strength of evidence: C).

- The AHCPR guidelines recommend against CT-myelography and myelography because they are invasive and have an increased risk of complications, except in special situations for preoperative planning (strength of evidence: D).
- The European COST guidelines recommend MRI in patients with chronic low back pain with serious red flags.

**Key Question 2b.**

**What is the diagnostic accuracy of different diagnostic tests for identifying other conditions (e.g. nerve root compression, herniated disc, spinal stenosis) that may respond to specific therapies?**

Results of search: systematic reviews

We identified the same systematic reviews described for Key Question 2a.

Results of search: trials

We did not search for additional trials

*Accuracy of imaging for diagnosing nerve root compression, herniated disc, and spinal stenosis*

Plain radiography cannot directly visualize intervertebral discs and is therefore insensitive for diagnosing disc herniation [53]. Similarly, facet osteophytes or severe spondylolisthesis on plain radiography can suggest nerve root impingement, but additional imaging is required to confirm the diagnosis. Plain radiography is also unable to detect compromise of the vertebral canal caused by soft tissue.

One recent systematic review evaluated the accuracy of CT and MRI for diagnosing herniated disc and spinal stenosis [53]. It found that magnetic resonance imaging and computed tomography were associated with similar accuracy for diagnosing either condition (Table 6).

**Table 6. Estimated accuracy of different imaging techniques for diagnosing disc herniation and spinal stenosis (ranges reported)**

| Technique | Sensitivity | Specificity | Positive likelihood ratio | Negative likelihood ratio |
|---|---|---|---|---|
| **Herniated disc** | | | | |
| **MRI** | 0.6-1.0 | 0.43-0.97 | 1.1-33 | 0-0.93 |
| **CT** | 0.62-0.9 | 0.7-0.87 | 2.1-6.9 | 0.11-0.54 |
| **Spinal stenosis** | | | | |
| **MRI** | 0.9 | 0.72-1.0 | 3.2-not defined | 0.10-0.14 |
| **CT** | 0.9 | 0.8-0.96 | 4.5-22 | 0.10-0.22 |

Source: Jarvik and Deyo, 2002[]

*Accuracy of imaging for diagnosing ankylosing spondylitis*

Evidence on the diagnostic accuracy of different imaging methods for diagnosing ankylosing spondylitis is sparse. Plain radiography was associated with a sensitivity of 0.26 to 0.45 and specificity of 1, but spectrum bias could have inflated these estimates [53]. Radionuclide scanning with planar imaging was associated with low sensitivity but high specificity in two studies (sensitivity 0.25 and 0.26, specificity 0.95 to 1.0) [94, 95]. In one other study, SPECT increased sensitivity to 0.85 but decreased specificity to 0.90 [94]. MRI was associated with a sensitivity of 0.45 for diagnosing ankylosing spondylitis in one study, but specificity could not be calculated [95].

*Diagnostic accuracy of other (non-imaging) tests*

One higher-quality study found an elevated ESR associated with a sensitivity of 0.69 and specificity of 0.68 for diagnosing ankylosing spondylitis in patients suspected of having the disease [55]. A systematic review on the diagnostic accuracy of thermography found major methodological flaws, inconsistent results, and no clear evidence supporting its use in diagnosis of radiculopathy [89]. Another systematic review found inconclusive and inadequate evidence to support the use of surface electromyography for diagnosis of low back pain [90].

**Summary of evidence**

- MRI and CT scan are associated with similar diagnostic accuracy for diagnosing herniated disc or spinal stenosis (level of evidence: good).
- Evidence on the diagnostic accuracy of different imaging methods for diagnosing ankylosing spondylitis is sparse. Plain radiography may have high specificity, but higher-quality studies are needed (level of evidence: fair).

- An elevated ESR was associated with moderate sensitivity and specificity for diagnosing ankylosing spondylitis in patients suspected of having the disease (level of evidence: fair).
- There is no evidence supporting the use of thermography or surface electromyography for diagnosis of low back pain (level of evidence: fair).

**Recommendations from other guidelines**

- The AHCPR guidelines recommend against thermography for assessing acute low back problems (strength of evidence: C).
- The AHCPR guidelines recommend against electrophysiologic testing when the diagnosis of radiculopathy is obvious and specific on clinical examination (strength of evidence: D).
- The AHCPR guidelines recommend against surface EMG and F-wave tests in patients with acute low back symptoms (strength of evidence: C).
- The AHCPR guidelines found that needle EMG and H-reflex tests of the lower limb may be useful in assessing questionable nerve root dysfunction in patients with leg symptoms for longer than 4 weeks (regardless of presence of back pain) (strength of evidence: C).
- The AHCPR guidelines found that SEPs may be useful in assessing suspected spinal stenosis and spinal cord myelopathy (strength of evidence: C).
- The VA/DoD recommendations for diagnostic imaging are essentially identical to the AHCPR recommendations.
- The European COST guidelines do not recommend electromyography for chronic nonspecific low back pain.
- The European COST guidelines recommend MRI for evaluation of radicular symptoms, and plain radiography for evaluation of structural deformities. They recommend against MRI or CT for the diagnosis of facet joint pain.

**Key Question 2c.**

**In patients with 'red flags,' how does the choice of diagnostic testing affect clinical outcomes?**

Results of search: systematic reviews

We found no systematic reviews addressing this question.

Results of search: trials

No trials are available.

*Efficacy of diagnostic testing in patients with 'red flags'*

We found no studies comparing outcomes associated with the use of different diagnostic tests in patients with low back pain and associated cancer, vertebral infection, or cauda equina syndrome. All guidelines recommend prompt and appropriate work-up (including advanced imaging techniques) and management of patients suspected of having these conditions or with a history of significant vertebral trauma, because delayed diagnosis and treatment can be associated with poorer outcomes [20, 28, 29, 32].

**Summary of evidence**

- There is no direct evidence on the efficacy of diagnostic testing in patients with 'red flags,' though all guidelines recommend prompt and appropriate work-up (including advanced imaging) because delayed diagnosis and treatment can be associated with poorer outcomes.

**Recommendations from other guidelines**

- The AHCPR, VA/DoD, UK RCGP, and European COST guidelines all recommend prompt work-up and immediate action in patients with low back pain suspected of having a red flag condition.
- The European COST guidelines recommend MRI in patients with chronic low back pain with serious red flags.

**Key Question 2d.**

**In patients without 'red flags,' how does the choice of diagnostic testing (or no testing) affect clinical outcomes?**

Results of search: systematic reviews

We found no systematic reviews addressing this question.

Results of search: trials

We identified three randomized controlled trials (one higher-quality [96]) evaluating routine, early plain radiography versus imaging only if clinically necessary (or without improvement) in patients presenting for initial evaluation of low back pain without 'red flags' [96-98]. Routine radiography was compared to usual care in two trials [96, 98] and to a brief educational intervention in the third.[97]. Four other trials evaluated different strategies for using MRI in patients with low back pain. One higher-quality trial (N=782) compared early routine versus delayed selective MRI or CT in patients

presenting to surgical clinics for evaluation of low back pain [99]. A lower-quality trial performed MRI in all patients, and compared results in patients in whom results were routinely given versus those in whom results were disclosed only if clinically indicated [100]. Two higher-quality trials (conducted by the same investigators and using the same study design) evaluated the effects of rapid MRI versus plain radiography in patients with low back pain in whom imaging was clinically felt appropriate [101, 102].

*Efficacy of routine, early plain radiography versus usual care or imaging only if clinically necessary (or without improvement)*

Delayed imaging resulted in no serious missed diagnoses in any of the three trials comparing routine plain radiography to imaging only if clinically necessary (or without improvement) [96-98]. Routine radiography also was not associated with improved patient functioning, time off work, severity of pain, or overall health status in any of the trials (Table 7). The only higher-quality trial (N=153) found routine radiography modestly superior for psychological well-being [96]. In a large (N=421), lower-quality trial, routine radiography was associated with increased physician visits in the 3 months after imaging and a trend towards a higher likelihood of pain at 6 months, but also increased patient satisfaction, though differences were modest [98]. Results of a third, lower-quality trial suggests that patient education might ameliorate any negative effects of delayed imaging, as delayed imaging paired with a brief educational intervention was not associated with increased anxiety, dissatisfaction, or dysfunction or differences in subsequent clinical treatments compared to early routine imaging [97].

**Table 7. Trials of early plain radiography versus imaging only if clinically necessary**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Kerry, 2002[96] | N=153<br>1 year | **Routine plain radiography vs. usual care (1 year data)**<br>SF-36, adjusted difference (not referred - referred): no subscale significant except for mental health -8, p<0.05<br>EuroQol, adjusted difference: 1 (NS)<br>RDQ score (0 to 24), adjusted difference: -0.3 (NS)<br>Consulted for back pain 6 weeks to 1 year: 32% vs. 39%, AOR 0.7 (0.3 to 1.4)<br>Referred to other health professional 6 weeks to 1 year: 45% vs. 46%, AOR 1.1 (0.5 to 2.3)<br>Very satisfied at 6 weeks: 33% vs. 28%, AOR 1.3 (0.6 to 3.0)<br>Days off work, 0-12 months: 8.46 vs. 6.16<br>GP consultations: 1.6 vs. 1.1, p=0.06<br>Other consultations: 5.9 vs. 2.9, p=0.003 | 5/11 |
| Kendrick, 2001[98] | N=421<br>9 month | **Routine plain radiography vs. usual care (9 month data)**<br>Still has pain at 6 months: 65% vs. 57% (p=0.11)<br>Taken time off work: 13% vs. 13% (p=0.87)<br>Median days off work: 11.5 vs. 8.5 (p=0.84)<br>Median RDQ score: 3 vs. 2 (p=0.06)<br>Median pain score: 1 vs. 1 (p=0.17)<br>Median health status score: 80 vs. 80 (p=0.30)<br>Median satisfaction with consultation: 21 vs. 19 (p<0.01, favors routine radiography)<br>>=3 visits to doctor: 5% vs. 5%<br>Visited provider within 3 months: 53% vs. 30% (RR 1.62, 95% CI 1.33 to 1.97) | 6/11 |
| Deyo, 1987[97] | N=101<br>3 months | **Routine plain radiography vs. selective imaging + brief educational intervention**<br>Sickness Impact Profile (0 to 100, higher indicating worse function): 16.6 vs 13.6 at 3 weeks (NS), 12.3 vs. 10.3 at 3 months (NS)<br>Days of work absenteeism: 4.1 vs. 4.4 at 3 weeks (NS)<br>Additional days of work loss: 0.28 vs. 0.05 at 3 months (NS)<br>Self-rated improvement (1 to 6 scale): 2.7 vs. 2.7 at 3 weeks, 2.6 vs. 2.6 at 3 months<br>Duration of pain: 9.4 vs. 10.8 days at 3 weeks (NS), 13.3 vs. 18.4 additional days of pain at 3 months (NS)<br>Total physician visits: 1.07 vs. 0.42 at 3 months<br>Overall satisfaction score (9 to 27 scale): 23.7 vs. 24.0<br>No differences for other measures of patient perceptions and attitudes (including worry that pain is due to serious illness) | 4/11 |

*Efficacy of routine MRI versus MRI only if clinically necessary (or without improvement)*

One higher-quality trial (N=782) found that in patients with low back pain of varying duration (40% with symptoms for >1 year) referred to surgeons with uncertain need for advanced imaging, routine early MRI or CT was associated with statistically significant but modest differences in the Aberdeen Low Back Pain Score, SF-36 Bodily Pain Scale,

and Euro-Qol after 8 and 24 months relative to delayed, selective imaging (Table 8) [99]. Differences on pain scales averaged about 3 points on 0 to100 scales. There were no differences in the proportion of patients undergoing surgery, receiving injections, or other measures of health care use. A lower-quality trial that obtained MRI in all patients with acute low back pain or radiculopathy found that routine disclosure of MRI findings was not associated with greater improvements in RDQ function scores compared to withholding MRI results unless clinically necessary [100]. There were also no differences on any of the SF-36 subscales other than general health, which favored the blinded arm (6.0 vs. 4.2 point improvement at 6 weeks, p=0.008).

**Table 8. Trials of early MRI versus imaging only if clinically necessary**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Modic, 2005[100] | N=246<br>6 weeks | **Unblinded vs. blinded MR results**<br>>50% improvement in RDQ function: 60% vs. 67% (p=0.397)<br>Proportion 'satsified' with condition: 23% vs. 31% (p=0.207)<br>Self-efficacy, fear-avoidance beliefs, and SF-36: similar between arms except for general health subscale of SF-36, mean improvement 4.2 vs. 6.0 at 6 weeks (p=0.008) | 2/11 |
| Gilbert, 2004[99] | N=782<br>2 years | **Early imaging (90% had MRI or CT) vs. delayed (30% had MRI or CT)** (24 month data)<br>Subsequent outpatient appointment: 84% vs. 68%, p<0.001<br>Total number of consultations: 1.91 vs. 1.88 (NS)<br>Hospital admissions: 7.9% vs. 6.7% (NS)<br>Surgical operation: 6.9% vs. 5.1% (NS)<br>Injections: 17.8% vs. 19.3 % (NS)<br><br>Aberdeen Low Back Pain score (0 to 100 scale), adjusted mean difference: -3.62, p=0.002<br>EQ-5D score (-0.59 to +1 scale), adjusted mean difference: 0.057, p=0.01<br>SF-36, bodily pain (0 to 100 scale), adjusted mean difference: 5.14, p=0.004<br>No differences on other SF-36 subscales | 6/11 |

*Efficacy of rapid MRI versus plain radiography in patients with low back pain referred for imaging*

In the larger (N=380) of two higher-quality trials comparing rapid MRI to plain radiography in patients with low back pain referred for imaging, there was no difference in any outcomes including functional status, pain intensity, or rate of spinal surgery

(Table 9) [101]. The smaller (N=62) trial (conducted by the same investigators) reported similar findings [102].

**Table 9. Trials of rapid MRI versus plain radiography in patients referred for imaging**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Jarvik, 2003[101] | N=380<br>6 weeks | **MRI vs. plain radiograph**<br>RDQ Scale score, adjusted (12 month): 9.34 vs. 8.75 (NS) (score better for MRI at 3 months)<br>SF-36: No differences at 12 months for bodily pain, physical functioning, role-physical<br>Pain-bothersomeness: 9.68 vs. 9.75, NS<br>Pain-frequency: 10.09 vs. 10.21, NS<br>Lost work, days past 4 weeks: 1.57 vs. 1.26, NS<br>Patient satisfaction: 7.04 vs. 7.34, NS<br>Patient reassurance score: 3.18 vs. 2.50, p<0.05 favoring MRI<br>Proportion reporting reassurance from imaging: 74% vs. 58% (p=0.002)<br>Lumbar spine surgery: 6% vs. 2% | 8/11 |
| Jarvik, 1997[102] | N=62<br>3 months | **Rapid MRI vs. plain radiography (3 month data)**<br>Modified RDQ score: 12.5 vs. 12.1 (p=0.40)<br>SF-36: No differences<br>Pain bothersomeness (0 to 24): 9.7 vs. 10.0 (p=0.79)<br>Pain frequency (0 to 24): 10.1 vs. 9.9 (p=0.35)<br>Disability days: No differences for number of home days, limited activity days, or bed days<br>Patient satisfaction: Only differences among 12 questions about patient satisfaction were proportion who thought clinicians were concerned (75% vs. 100%, p=0.01) and proportion who felt reassured (72% vs. 37%, p=0.03)<br>Proportion of patients referred to back specialists: 32% vs. 36% | 6/11 |

*Costs*

Several recent RCTs of routine versus selective imaging also conducted cost-effectiveness analysis. In one trial, the cost-effectiveness of routine plain radiography was estimated at £20 per point on a patient satisfaction scale (scored between 9 and 27), the only outcome for which there was a difference in efficacy [103]. The increased cost was mostly related to the direct costs of the imaging procedure itself. In another trial, early MRI or CT imaging was associated with a mean additional QALY of 0.041 during 24 months relative to selective imaging, with an incremental cost-effectiveness of $2,124/QALY [99]. These results are consistent with an older decision analysis that found that the costs associated with routine lumbar radiography in patients with acute low back pain did not appear to justify the small benefits ($2,072 to avert one day of

physical suffering) [104]. Finally, rapid MRI imaging was associated with additional costs of about $300 relative to plain radiography in patients with low back pain referred for imaging, with nearly identical clinical outcomes (essentially a cost-minimization analysis) [101].

**Summary of evidence**

- Routine plain radiography did not identify any additional serious diseases compared to usual care and did not improve outcomes including pain and functional status, though there appeared to be modest beneficial effects on patient satisfaction and psychologic well-being (two trials, one higher-quality) (level of evidence: fair).
- In one lower-quality trial, the combination of delayed selective imaging with a brief educational intervention was not associated with differences in any outcomes relative to routine plain radiography, including patient satisfaction and psychologic distress (level of evidence: poor).
- Routine MRI was associated with only minor benefits on pain and functional status outcomes compared to selective imaging in one higher-quality trial. A lower-quality trial found that in patients who had undergone MRI, disclosure of results was not associated with improved outcomes compared to non-disclosure unless clinically necessary (level of evidence: fair).
- In two higher-quality trials, rapid MRI was not associated with any significant benefits compared to plain radiography in patients in whom imaging was thought indicated (level of evidence: good).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against plain radiography for routine evaluation of patients with acute low back problems within the first month of symptoms, unless a red flag is noted on clinical examination (strength of evidence: B).
- The AHCPR guidelines state that in patients without red flags, after 1 month of symptoms, an imaging test is acceptable when surgery is being considered (or to rule out a suspected serious condition) (strength of evidence: B).
- The UK RCGP guidelines recommend avoidance of unnecessary or repeated x-rays, noting that lumbar spine x-rays involve 150 times the radiation of a chest x-ray (strength of evidence: ***).
- The European COST guidelines recommend against routine diagnostic imaging for acute or chronic nonspecific low back pain.

**Key Question 3.**

**What is the effectiveness of different non-invasive interventions for non-specific low back pain, radicular LBP, or spinal stenosis, and under what circumstances?**

## Medications

### *Acetaminophen*

Search results: systematic reviews

We identified one recent, lower-quality systematic review of medications for low back pain that included trials of acetaminophen [105]. In addition, a higher-quality Cochrane review of NSAIDs for low back pain included trials comparing acetaminophen to NSAIDs [106, 107]. The systematic reviews included three to five short-term (five week or less in duration) trials, only one of which was rated high quality [108]. We excluded two relevant but older systematic reviews [109, 110].

Search results: trials

We identified two lower-quality trials of acetaminophen not included in the systematic reviews [111, 112]. Both compared acetaminophen to other active interventions.

*Efficacy of acetaminophen versus placebo*

We found no trials comparing acetaminophen to placebo in patients with low back pain.

*Efficacy of acetaminophen versus NSAIDs*

The Cochrane review included three lower-quality trials with conflicting evidence on the efficacy of acetaminophen relative to NSAIDs for acute low back pain [106, 107]. Two trials [113, 114] reported no difference in outcomes between acetaminophen and NSAIDs, but a third found that two of four evaluated NSAIDs were superior to acetaminophen [115]. Another trial of patients with back pain of mixed acute and chronic duration found no differences between acetaminophen and flurbiprofen [116].

In patients with chronic low back pain, one higher-quality trial (included in both systematic reviews) found acetaminophen inferior to diflunisal for the proportion of patients reporting good or excellent efficacy after four weeks (10 of 16 vs. 4 of 12, p=0.01), though the proportion reporting no or mild low back pain was similar (13 of 16 vs. 7 of 12) [108]. Although there are no other trials of acetaminophen versus NSAID for chronic low back pain, there is consistent evidence from good-quality systematic

reviews of patients with osteoarthritis that acetaminophen is modestly inferior for pain relief [117-120].

*Efficacy of acetaminophen versus other interventions*

In single, lower-quality trials, acetaminophen was inferior to amitriptyline [121] and electroacupuncture [112]. Other trials found no difference between acetaminophen, codeine, phenylbutazone, or the combination of aspirin plus oxycodone for rates of 'return to work' [114] or between acetaminophen and either physical therapy, a corset, or spinal manipulation for pain or other assessed outcomes [111].

*Safety*

Adverse events associated with acetaminophen were poorly reported in trials of patients with low back pain. In two higher-quality systematic reviews of osteoarthritis patients, acetaminophen was superior to NSAIDs for gastrointestinal tolerability and other GI side effects [118, 120]. However, despite the perceived safety advantages of acetaminophen, data from clinical trials on serious side effects like bleeding, hypertension, and myocardial infarction are sparse. Observational data suggest that acetaminophen is associated with a lower rate of GI bleeding compared to NSAIDs [122, 123], but may be associated with modest increases in blood pressure [124-126] and renal dysfunction [127]. Although requiring further study, one recent analysis from the Nurses' Health Study also suggests that heavy use of acetaminophen may be associated with an increased risk of cardiovascular events similar in magnitude to heavy use of NSAIDs [128]. Although acetaminophen is associated with potentially fatal overdose, use at approved levels does not appear to increase the risk of hepatotoxicity in patients without liver problems.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is conflicting evidence from lower quality trials regarding the efficacy of acetaminophen versus NSAIDs for acute low back pain, with most showing no difference in outcomes (level of evidence: fair).
- For chronic low back pain, one higher quality trial found acetaminophen inferior to an NSAID on an overall assessment of efficacy (level of evidence: fair).

- Multiple trials of patients with osteoarthritis consistently found acetaminophen inferior to NSAIDs for pain relief (level of evidence: good).
- There is insufficient evidence from single, lower quality trials comparing acetaminophen to other interventions (such as physical therapy, a corset, or spinal manipulation) to accurately judge relative efficacy (level of evidence: poor).
- Acetaminophen is associated with a lower risk of serious GI side effects compared to NSAIDs based primarily on observational data (level of evidence: fair).
- Acetaminophen is better tolerated than NSAIDs (level of evidence: good).
- Additional studies are required to evaluate whether high-dose acetaminophen is associated with increased cardiovascular risk (single observational study) (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found acetaminophen reasonably safe and acceptable for treating patients with acute low back problems (strength of evidence: C).
- The VA/DoD guideline recommendations are identical to AHCPR's.
- The UK RCGP guideline found that comparisons of effectiveness between acetaminophen and NSAIDs are inconsistent (strength of evidence: **).
- The European COST guidelines recommend acetaminophen as first choice when needed for pain relief in patients with acute low back pain.

***Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)***

**Non-selective, non-steroidal anti-inflammatory drugs**

Results of search: systematic reviews

We identified two systematic reviews [105-107] evaluating the efficacy of non-selective NSAIDs in patients with non-specific low back pain. One is a higher-quality Cochrane review of 51 trials (16 rated high quality) [106, 107]. A third, fair quality systematic review evaluated the efficacy of NSAIDs in patients with sciatica [129]. We excluded four older systematic reviews [110, 130-132].

Results of search: trials

We did not search for additional trials.

*Efficacy of NSAIDs versus placebo*

The Cochrane review estimated a pooled relative risk (3 trials) for global improvement in patients with acute low back pain of 1.24 (95% CI 1.10 to 1.41) after one week of

NSAID relative to placebo and 1.29 (95% CI 1.05 to 1.57) for not requiring additional analgesics [106, 107]. Qualitatively, two of four higher quality trials included in the Cochrane review reported better pain relief with NSAIDs compared to placebo and two found no differences. In a single trial of patients with chronic low back pain (rated higher-quality), an NSAID (ibuprofen) was superior to placebo [133].

The second, lower-quality systematic review was not as comprehensive (21 trials) as the Cochrane review [105]. It also concluded that NSAIDs are effective for acute low back pain The third systematic review, which focused on a subset of trials evaluating patients with sciatica, found no difference between NSAIDs and placebo (3 trials, OR 0.99, 95% CI 0.6 to 1.7) [129].

*Efficacy of NSAIDs versus other interventions*

The Cochrane review found moderate evidence that NSAIDs are not more effective than opioid analgesics or muscle relaxants (6 trials, 1 higher-quality) [106, 107]. However, small sample sizes (N=19 to 44) could have reduced the ability of some trials to detect differences. The Cochrane review also included two trials that found that NSAIDs are not more effective than physiotherapy or spinal manipulation and two trials that reached discordant conclusions about the efficacy of NSAIDs relative to bed rest in patients with acute low back pain.

*Efficacy of different NSAIDs*

The Cochrane review included multiple (24) trials that provided no evidence suggesting that any one NSAID is superior to others for pain relief [106, 107].

*Safety*

The Cochrane review found that NSAIDs were associated with similar risk of adverse events compared to placebo (RR 0.83, 95% CI 0.64 to 1.08) [106, 107]. However, the trials included in the systematic reviews were not designed to evaluate risks of serious harms such as GI bleeds and CV events. When taken for a variety of indications, NSAIDs are associated with an increased risk for serious GI complications such as bleeding and perforation that increases with age [134, 135]. In a recent, meta-analysis evaluating the cardiovascular safety of NSAIDs, all non-selective NSAIDs other than naproxen were associated with an increased rate of myocardial infarction (about 1 additional myocardial infarction for every 300 patients treated for one year with an

NSAID versus non-use) [136]. Because of concerns about potential cardiovascular risks, the FDA recently required labeling revisions stating additional warnings for all non-selective NSAIDs [137].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is evidence from multiple trials that NSAIDs are associated with modest short-term pain relief compared to placebo in patients with acute low back pain (level of evidence: good).
- A single higher quality trial found that NSAIDs are effective in patients with chronic low back pain (level of evidence: fair).
- NSAIDs have not been shown to be more effective than other medications (opioids, skeletal muscle relaxants) or non-invasive interventions (spinal manipulation, physical therapy, bed rest) (level of evidence: fair).
- There is no evidence that any NSAID is more effective than any other (level of evidence: good).
- NSAIDs are associated with an increased risk of serious GI complications compared to non-use (level of evidence: good).
- NSAIDs other than naproxen were associated with a modest increase in risk of cardiovascular complications relative to non-use in one recent meta-analysis of randomized controlled trials (level of evidence: good).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found NSAIDs acceptable for treating patients with acute low back problems (strength of evidence: B).
- The AHCPR guidelines found that NSAIDs have a number of potential side effects, with the most frequent gastrointestinal irritation. They recommend the decision to use these medications to be guided by comorbidity, side effects, cost, and patient and provider preference (strength of evidence: C).
- The VA/DoD and UK RCGP guidelines for NSAIDs are similar to the AHCPR recommendations.
- Both the VA/DoD (strength of evidence: B) and UK RCGP (strength of evidence: ***) guidelines found that various NSAIDs are equally effective for low back pain.
- The UK RCGP guidelines also found that NSAIDs are less effective for the reduction of nerve root pain (strength of evidence: **).

- The European COST guidelines recommend NSAIDs as second choice (after paracetamol) when needed for pain relief in patients with acute low back pain. They also recommend NSAIDs for pain relief in patients with chronic low back pain, but only for exacerbations or short-term periods (up to 3 months).

**COX-2 selective NSAIDs**

COX-2 selective NSAIDs have a theoretical advantage over non-selective NSAIDs for causing fewer GI complications because they don't block the cyclo-oxygenase-1 enzyme, which helps protect the stomach lining. However, rofecoxib and valdecoxib were both voluntarily withdrawn from the market after the publication of trials indicating an increased risk of myocardial infarction [138, 139]. Celecoxib is currently the only COX-2 selective NSAID available in the U.S.

Results of search: systematic reviews

No trials of COX-2 inhibitors were included in the Cochrane review of NSAIDs [106, 107]. We identified no other systematic reviews evaluating COX-2 inhibitors in patients with low back pain.

Results of search: trials

Although we identified eight trials of COX-2 inhibitors in patients with low back pain [140-147], none evaluated celecoxib, the only drug in this class currently available in the U.S. We did not review these trials further.

*Efficacy of COX-2 inhibitors*

In trials of patients with osteoarthritis and rheumatoid arthritis, there was no clear difference in efficacy or tolerability between celecoxib and non-selective NSAIDs for pain relief, functional outcomes, or other measures of clinical efficacy [148, 149].

*Safety*

Celecoxib was associated with a lower rate of GI complications compared to non-selective NSAIDs in a meta-analysis of primarily short-term randomized trials [149]. In the only long-term study designed to assess ulcer complications (the CLASS trials), celecoxib was associated with fewer gastrointestinal complications after 6 months compared to diclofenac, but not compared to ibuprofen [150]. However, this benefit was no longer present after longer follow-up, in part due to high loss to follow-up [151]. No GI safety advantage was seen with celecoxib in the subgroup of patients taking aspirin.

An increased risk of myocardial infarction in patients randomized to celecoxib compared to placebo was observed in a recently published long-term polyp prevention trial [152]. The most comprehensive meta-analysis also reported an increased risk of myocardial infarction with celecoxib compared to placebo when given for a variety of indications [136]. Other than naproxen, which was associated with a lower risk of myocardial infarction, the risk of MI with selective and non-selective NSAIDs in this meta-analysis was similar.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- Systematic reviews of COX-2-selective NSAIDs given for a variety of indications found no clear differences in efficacy (pain relief) relative to non-selective NSAIDs (level of evidence: good).
- Celecoxib is associated with a lower risk of GI complications compared to non-selective NSAIDs, but most of the evidence comes from short-term trials (level of evidence: good).
- Celecoxib appears to be associated with an increased risk of myocardial infarction compared to placebo (level of evidence: good).

**Aspirin**

Like the non-aspirin NSAIDs, aspirin (acetylsalicylic acid) has anti-inflammatory and analgesic effects. An important distinction between aspirin and non-aspirin NSAIDs, however, is that aspirin also induces long-lasting functional defects in platelets, and is therefore also used for primary and secondary prevention of thrombotic events, though usually in lower doses than those used for pain relief.

Results of search: systematic reviews

We identified no systematic reviews evaluating the efficacy of aspirin for low back pain.

Results of search: trials

We identified one lower-quality trial evaluating the efficacy of aspirin versus multiple comparator drugs in patients with acute low back pain [115].

*Efficacy of aspirin versus other analgesics*

The single relevant trial found that aspirin at 3600 mg/day was associated with a lower mean daily pain index scores (3 point scale, 1.425 vs. 1.713, $p<0.05$) compared to the combination of dextropropoxyphene + acetaminophen, but was not significantly different than indomethacin, mefenamic acid, acetaminophen alone, or phenylbutazone [115]. Aspirin also received the highest patient preference rating, though the difference was only significant compared to mefenamic acid and phenylbutazone (2.37 vs. 1.75 and 1.68, respectively, on a 3-point scale).

*Safety*

Most trials evaluating gastrointestinal bleeding risk and cardioprotective effects with aspirin have been conducted in patients receiving it for prophylaxis and at lower doses (50 mg to 1500 mg/day) than considered effective for full analgesic and anti-inflammatory effects. In a good-quality meta-analysis of 24 such randomized trials with nearly 66,000 participants, the risk of gastrointestinal hemorrhage was 2.47% with aspirin compared with 1.42% with placebo (OR 1.68, 95% CI 1.51 to 1.88), based on an average of 28 months therapy [153]. There was no relation between gastrointestinal hemorrhage and dose, and modified release formulations did not attenuate the risk for bleeding.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is insufficient evidence to judge the efficacy of aspirin in patients with low back pain (level of evidence: poor).
- Aspirin is associated with an increased risk of GI bleeding even at low doses (level of evidence: good).
- Aspirin is effective in the primary and secondary prevention of cardiovascular events (level of evidence: good).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines do not consider aspirin separately from other NSAIDs.

## *Other Medications*

### Antidepressants

Certain antidepressants (particularly those that inhibit norepinephrine uptake) are thought to have potential pain-modulating properties independent from their effects on depression. However, two earlier systematic reviews concluded that in patients with low back pain, there was either insufficient evidence to recommend their use [154] or moderate evidence that they were not effective [110].

Results of search: systematic reviews
We identified four recent systematic reviews evaluating the efficacy of antidepressants for low back pain [105, 155-157]. The two higher-quality systematic reviews included seven [157] and nine [156] placebo-controlled trials ranging from 6 to 16 weeks in duration. One of the other systematic reviews [105] also included one head-to-head trial [158] of antidepressants and one trial [121] comparing an antidepressant to acetaminophen. We excluded four older systematic reviews [110, 154, 159, 160].

Results of search: trials
We did not search for additional trials.

*Efficacy of antidepressants versus placebo*
The overall conclusions of the two higher-quality systematic reviews appeared concordant [156, 157]. One found tricyclic or tetracyclic antidepressants superior to placebo for at least one pain-related outcome measure in four of five trials of patients with chronic low back pain (analgesic effect size 0.43 [161] and 0.69 [162] in the 2 highest quality studies) [157]. Effects on functional outcomes were inconsistently reported and did not suggest a clear benefit. The only tetracyclic antidepressant evaluated was maprotiline, a drug not available in the U.S. [161]. None of the trials evaluated norepinephrine-serotonin reuptake inhibitors such as duloxetine or venlafaxine. There were no beneficial effects seen in three trials of antidepressants without inhibitory effects on norepinephrine uptake (paroxetine and trazodone) compared to placebo.

The second higher-quality systematic review found that all antidepressants pooled together are effective for improving pain severity (standardized mean difference 0.41, 95% CI 0.22 to 0.61), though not for activities of daily living (standardized mean

difference 0.25, 95% CI –0.21 to 0.69) [156]. Although the conclusions were reported as insensitive to antidepressant class (statistics not reported), the point estimates from individual studies suggests that paroxetine and trazodone were associated with the least benefit.

The other two systematic reviews came to similar conclusions regarding the efficacy of antidepressants relative to placebo for chronic low back pain [105, 155]. No trials evaluated the efficacy of antidepressants versus placebo for acute low back pain.

*Efficacy of one antidepressant versus another antidepressant*

Two head-to-head trials provided somewhat conflicting evidence on the relative efficacy of different antidepressant classes: one higher quality trial [162] found maprotiline superior to paroxetine for pain relief in patients with chronic low back pain (-45% vs. –27%, p=0.013), but one lower quality trial [158] found that similar proportions of patients randomized to amitriptyline and fluoxetine reported at least moderate pain relief (82% vs. 77%).

*Efficacy of antidepressants versus other interventions*

There is little evidence regarding the efficacy of antidepressants relative to other medications for low back pain. A single, small (N=39), lower-quality trial included in one of the systematic reviews [105] found amitriptyline superior to acetaminophen for pain relief (p=0.045) in patients with acute low back pain [121].

*Safety*

One systematic review found antidepressants associated with a higher risk for any adverse event compared to placebo (22% vs. 14%, p=0.01), though adverse events were generally not well reported [156]. Drowsiness (7%), dry mouth (9%), dizziness (7%) and constipation (4%) were the most commonly reported events. The trials were not designed to assess the risk of serious adverse events such as overdose, increased suicidality, and arrhythmias associated with antidepressant use.

*Costs*

We found no studies evaluating costs.

### Summary of evidence

- Tricyclic antidepressants are consistently more effective than placebo for pain relief and other outcomes in higher-quality trials of patients with chronic low back pain, but do not appear to improve functional outcomes (level of evidence: good).
- Several trials suggest that paroxetine and trazodone not effective or marginally effective compared to placebo (level of evidence: fair).
- There is insufficient evidence from head-to-head trials (one lower-quality trial) to judge the relative effectiveness of tricyclic antidepressants and selective serotonin reuptake inhibitors (level of evidence: poor).
- There are no trials on the effectiveness of other antidepressants (such as venlafaxine or duloxetine), and insufficient evidence to judge the efficacy of antidepressants for acute low back pain (level of evidence: poor).
- Although serious adverse events were not reported in the trials, the selected populations evaluated in clinical trials may make it difficult to extrapolate results to general practice (level of evidence: poor).

### Recommendations and findings from other guidelines

- The AHCPR guidelines recommend against use of antidepressant medications for acute low back problems (strength of evidence: C).
- The VA/DoD guidelines do not address antidepressant medications, and the UK RCGP guidelines found little evidence on their effectiveness for chronic low back pain, and none for acute low back pain (strength of evidence: *).
- The European COST guidelines recommend consideration of noradrenergic or noradrenergic-serotoninergic antidepressants as co-medications for pain relief in patients with chronic low back pain without renal disease, glaucoma, pregnancy, chronic obstructive pulmonary disease, or heart failure.

## Benzodiazepenes

Results of search: systematic reviews

We identified two systematic reviews evaluating benzodiazepenes for low back pain [105, 163, 164]. Of these, a recent higher-quality Cochrane review was the most comprehensive (8 trials of benzodiazepenes) [163, 164]. We excluded two relevant but older systematic reviews [109, 110].

Results of search: trials

We did not search for additional trials

*Efficacy of benzodiazepines versus placebo*

The Cochrane review included a single, lower-quality placebo-controlled trial of benzodiazepines in patients with acute low back pain. It found diazepam associated with better short-term pain relief and overall improvement [165]. Of three trials in patients with chronic low back pain, two higher-quality trials found that tetrazepam (not available in the U.S.) was associated with better short-term pain relief (RR 0.71, 95% CI 0.54 to 0.93) and overall improvement (RR 0.63, 95% CI 0.42 to 0.97) after 10-14 days [166, 167]. On the other hand, a lower-quality placebo-controlled trial of diazepam found no benefit [168]. Results of a second systematic review were consistent with the Cochrane review [105].

*Efficacy of benzodiazepine versus skeletal muscle relaxant*

There were no differences between diazepam and either tizanidine [169] or cyclobenzaprine [168] in two trials included in the Cochrane review. In a third, high quality trial, diazepam was inferior to carisoprodol for muscle spasm, global efficacy (excellent or very good 70% vs. 45%), and functional status [170].

*Safety*

Central nervous system events such as somnolence, fatigue, and lightheadedness were reported more frequently with benzodiazepines compared to placebo [163, 164]. No trial evaluated risks with long-term use such as addiction, abuse, overdose, or development of tolerance in patients with low back pain.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is insufficient evidence to judge the efficacy of benzodiazepines (1 lower-quality trial) for acute low back pain (level of evidence: poor).
- Two higher quality trials indicate that benzodiazepines are effective for short-term outcomes in patients with chronic low back pain (level of evidence: fair).
- Diazepam was inferior to carisoprodol (a drug metabolized to meprobamate) in one higher quality trial, but no different than other skeletal muscle relaxants in two other trials (level of evidence: fair).
- Benzodiazepines are associated with increased short-term central nervous system adverse events (level of evidence: good). Risks of addiction, abuse,

development of tolerance, and overdose, particularly with long-term use, are unknown.

**Recommendations and findings from other guidelines**

- The UK RCGP guidelines note that benzodiazepines for more than two weeks carry a significant risk of habituation and dependency (strength of evidence: **)
- The European COST guidelines recommendations for muscle relaxants and benzodiazepines are the same.

**Gabapentin**

Gabapentin is an anticonvulsant shown to be effective in patients with neuropathic pain [171, 172]. One advantage of gabapentin over older anticonvulsants is its superior safety profile. However, the efficacy of gabapentin in patients with radicular (or non-radicular) low back pain has not been well studied.

Results of search: systematic reviews

We identified no systematic reviews evaluating the efficacy of gabapentin in patients with low back pain.

Results of search: trials

We identified two short-term (six to eight weeks), randomized, placebo-controlled trials evaluating the efficacy of gabapentin in patients with radiculopathy [173, 174]. One was rated higher quality [173].

*Efficacy of gabapentin versus placebo*

In the higher-quality trial, neither gabapentin nor placebo was associated with an improvement in resting back pain compared to baseline after six weeks (Table 10) [173]. However, gabapentin (but not placebo) was associated with small improvements compared to baseline on assessments of back pain with movement and of leg pain, though it was not clear if between-group differences were significant. In the other, lower-quality trial, patients with radiculopathy had greater improvement in pain at rest with gabapentin versus placebo at the end of treatment [174]

**Table 10. Trials of gabapentin versus placebo in patients with radicular low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Yildirim, 2003[174] | N=50<br>8 weeks | **Gabapentin titrated to 3600 mg/day versus placebo**<br>Back pain at rest (mean change from baseline on 0-3 scale): -1.04 vs. –0.32, p<0.01 | 3/11 |
| McCleane, 2001[173] | N=80<br>6 weeks | **Gabapentin titrated to 1200 mg/day versus placebo**<br>Back pain at rest (mean change from baseline on 0-10 VAS): -0.51 (NS) vs. 0.1 (NS)<br>Back pain with movement (mean change from baseline on 0-10 VAS): -0.47 (p<0.05) vs. +0.01 (NS)<br>Leg pain (mean change from baseline on 0-10 VAS): -0.45 (p<0.05) vs. –0.24 (NS) | 8/11 |

*Safety*

Withdrawal due to adverse events occurred in 2 of 25 patients randomized to gabapentin versus none of 25 randomized to placebo in one trial [174]. No withdrawals due to adverse events occurred in the other trial [173]. However, drowsiness (6%), loss of energy (6%), and dizziness (6%) were reported with gabapentin [173].

*Cost-effectiveness*

We found no studies evaluating cost-effectiveness.

**Summary of evidence**

- Limited evidence from two trials (one higher quality) suggests that gabapentin is associated with modest short-term benefits for pain relief in patients with radiculopathy (level of evidence: fair).
- There are no trials evaluating the efficacy of gabapentin in patients with non-radicular low back pain.

**Recommendations and findings from other guidelines**

- The European COST guidelines found insufficient evidence to recommend gabapentin in patients with chronic nonspecific low back pain.

## Muscle relaxants

Skeletal muscle relaxants are a heterogeneous group of medications used to treat two distinct underlying conditions: spasticity from the upper motor neuron syndrome and pain or spasms from musculoskeletal conditions such as non-specific low back pain. The muscle relaxants carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, and orphenadrine carry FDA-approved indications for

treatment of musculoskeletal conditions. Although the other drugs in this class (baclofen, dantrolene, and tizanidine) are approved only for the treatment of spasticity, there is some overlap in clinical usage. In particular, tizanidine has also been studied in patients with musculoskeletal conditions such as low back pain. Benzodiazepines are commonly used as muscle relaxants, though they are not FDA-approved for this indication (see section on benzodiazepenes).

Results of search: systematic reviews

We identified four systematic reviews evaluating the efficacy and safety of muscle relaxants for low back pain [105, 129, 163, 164, 175]. Of these, a recent higher-quality Cochrane review was the most comprehensive (25 trials of skeletal muscle relaxants) [163, 164]. We excluded two older systematic reviews [109, 110].

Results of search: trials

We found no trials comparing the efficacy of muscle relaxants to acetaminophen or NSAIDs.

*Efficacy of skeletal muscle relaxants versus placebo*

The Cochrane review included eight trials that found skeletal muscle relaxants muscle relaxants superior to placebo for short-term (2 to 4 days) pain relief (at least a two-point or 30% improvement on an 11 point pain rating scale) and global efficacy in patients with acute low back pain [163, 164]. From 3 higher quality trials and one lower quality trial that could be pooled, the relative risk for pain relief was 0.80 (0.71 to 0.89) after 2 to 4 days and 0.58 (0.45 to 0.76) after 5 to 7 days. The relative risk for greater global efficacy was 0.49 (0.25 to 0.95) after 2 to 4 days and 0.68 (0.41 to 1.13) after 5 to 7 days.

The Cochrane review also included three trials of patients with chronic low back pain. Only one—a lower-quality trial of cyclobenzaprine that did not report pain intensity or global efficacy outcomes—evaluated a skeletal muscle relaxant available in the U.S. [168].

Results from three other systematic reviews were concordant with the Cochrane review. A less comprehensive, qualitative systematic review reached similar overall conclusions [105]. Another systematic review focusing on one skeletal muscle relaxant found

cyclobenzaprine modestly superior to placebo (effect size 0.38 to 0.58) for pain, muscle spasm, tenderness to palpation, range of motion, and activities of daily living, with the greatest benefit seen within the first few days of treatment [175]. The third systematic review, focussing on treatments for sciatica, included one trial demonstrating no benefits from tizanidine over placebo [129].

*Efficacy of different muscle relaxants*

The Cochrane review found no clear evidence that any muscle relaxant was superior to others for efficacy or safety in patients with low back pain [163, 164]. A systematic review of muscle relaxants for broader indications came to similar conclusions [176]. However, the amount of supporting evidence for different skeletal muscle relaxants varies widely. Cyclobenzaprine is by far the best-studied drug. One the other hand, there is sparse evidence (two trials) on the effectiveness of the antispasticity drugs dantrolene and baclofen for either chronic or acute low back pain [163, 164].

*Safety*

The Cochrane review found that skeletal muscle relaxants are associated with more total adverse events and central nervous system adverse effects than placebo (RR 1.50, 95% CI 1.14 to 1.98 and 2.04, 95% CI 1.123 to 3.37, respectively), though most are self-limited and serious complications appear rare [163, 164]. Certain skeletal muscle relaxants are associated with specific safety issues. Because of its metabolism in part to meprobamate, a drug removed from the market due to addiction and overdose potential, carisoprodol is a controlled substance in some states (though not federally controlled). Dantrolene carries a black box warning on its label about potentially fatal hepatotoxicity. Chlorzoxazone and tizanidine are also associated with usually self-limited and mild hepatotoxicity [176].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- Skeletal muscle relaxants are consistently more effective than placebo for short-term (less than one week) pain relief and global response in patients with acute low back pain (level of evidence: good).

- There is insufficient evidence to judge the efficacy of skeletal muscle relaxants in patients with chronic low back pain or those with sciatica (level of evidence: poor).
- Although there is no evidence proving that one skeletal muscle relaxant is superior to others (level of evidence: fair), the efficacy of cyclobenzaprine is supported by the most evidence.
- Skeletal muscle relaxants are associated with an increased rate of adverse events compared to placebo, though they are usually mild and self-limited (level of evidence: fair).
- Specific safety issues are associated with carisoprodol (metabolism to meprobamate), dantrolene (potentially fatal hepatotoxicity), chlorzoxazone and tizanidine (usually reversible and mild hepatotoxicity).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend muscle relaxants as an option in the treatment of low back pain problems. While they found muscle relaxants probably more effective than placebo, they also found that muscle relaxants had not been shown to be more effective than NSAIDs (strength of evidence: C).
- The AHCPR guidelines recommend balancing potential side effects (particularly drowsiness) associated with muscle relaxants against a patient's intolerance for other agents when considering the optional use of muscle relaxants (strength of evidence: C).
- The VA/DoD guidelines are identical to the AHCPR guidelines.
- The UK RCGP guidelines are similar to the AHCPR recommendations, but rated evidence on the effectiveness of muscle relaxants for acute back pain more highly (strength of evidence: ***).
- The European COST guidelines recommend adding a short course of muscle relaxants on its own or added to NSAIDs in patients with acute low back pain, if acetaminophen or NSAIDs failed to reduce pain.
- The European COST guidelines recommend considering muscle relaxants for short-term pain relief in chronic low back pain, but to use them cautiously because of side effects and use other pain relieving drugs with fewer side effects first.

**Opioid analgesics**

Opioid analgesics are a class of medications that act on common receptors and are natural derivatives of morphine. They are available in immediate-release and sustained-release formulations, and can be administered via a variety of routes (most

commonly oral or transdermal). Opioids are the most potent medications available for treatment of most types of severe pain. However, they are also associated with a variety of adverse events, including nausea, somnolence, respiratory depression, overdose, abuse, and addiction.

Results of search: systematic reviews

We identified two systematic reviews evaluating the efficacy of medications for low back pain that included trials of opioids [105, 110]. One only included two trials evaluating opioids in combination with another analgesic [105]. The other systematic review [110] included one additional trial [114]. We excluded two other reviews that did not clearly use systematic methods [177, 178] and one older systematic review [109]. None included additional relevant trials. One other recent systematic review evaluated the efficacy and safety of opioids in 15 double-blind, placebo-controlled trials of patients with non-cancer pain, but none specifically evaluated patients with low back pain [179].

Results of search: trials

We identified nine trials (one higher-quality [180]) evaluating the efficacy of opioids in patients with low back pain. Two were placebo-controlled [180, 181]. Two trials compared opioids to either NSAIDs or acetaminophen [114, 182]. The remainder compared different opioid drugs or formulations (long versus short-acting). All of the trials were less than 3 weeks in duration except for two (one 16 weeks [182], the other 13 months [183]).

*Efficacy of opioids versus placebo*

One higher-quality, placebo-controlled trial (N=235) found that long-acting oxymorphone and long-acting oxycodone were both superior to placebo for pain relief after 18 days in patients with chronic low back pain (difference in pain relief about 18 points on a 100 point scale) [180]. The active treatments were also superior to placebo for several outcomes assessing functional status (Table 11). A problem with interpreting these results is that all patients were titrated to stable doses of opioids prior to randomization, so differences between the active treatments and placebo could have been due in part to cessation of opioids and withdrawal.

The other, lower-quality placebo-controlled trial found that in patients with acute or chronic low back pain, the weak opioid propoxyphene was no better than placebo for

improvement in pain scores or assessments of global improvement [181]. In addition, patients on propoxyphene reported greater improvements than placebo in only one of three sleep parameters (difficulty falling asleep).

**Table 11. Trials of an opioid versus placebo in patients with low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hale, 2005[180] | N=235<br>18 days | **Long-acting morphine versus long-acting oxycodone versus placebo**<br>Pain intensity (100 point VAS), mean differences versus placebo: -18.21 vs. –18.55 (p=0.0001 for each comparison)<br>Global assessment at least 'good': 59% vs. 63% vs. 27% | 7/11 |
| Barratta, 1976[181] | N=61<br>14 days | **Propoxyphene versus placebo**<br>Pain on active improvement (mean improvement from baseline): 0.8 vs. 0.4, NS<br>Global improvement at least 'satisfactory': 22% vs. 14% (NS) | 4/11 |

A systematic review of 15 double-blind, placebo-controlled trials of opioids versus placebo for any non-cancer pain condition (most commonly osteoarthritis and neuropathic pain) found that the mean decrease in pain intensity in most trials was at least 30% with opioids and similar for neuropathic and musculoskeletal pain [179].

*Efficacy of opioids versus NSAIDs or acetaminophen*

The relative or added benefits of opioids compared to NSAIDs or acetaminophen have only been evaluated in two lower-quality trials (Table 12). One small trial or patients with chronic low back pain found that adding an opioid to naproxen alone was associated with superior outcomes for average pain, current pain, and anxiety or depression scores after 16 weeks [182]. Differences in pain relief were fairly modest, however, ranging between 5 and 10 points on a 100-point scale. In addition, results are difficult to interpret because doses of naproxen weren't clearly reported. Another trial (N=50) found that the mean number of days before return to work was similar in patients with acute low back pain randomized to codeine or acetaminophen (10.7 vs. 13.0 days) [114].

**Table 12. Trials of an opioid versus an NSAID or acetaminophen**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Jamison, 1998[182] | N=36<br>16 weeks | **Long-acting morphine + short-acting oxycodone (titrated dose) + naproxen versus short-acting oxycodone (set dose) + naproxen versus naproxen alone**<br>Pain intensity (100 point VAS), mean differences versus placebo: -18.21 vs. –18.55 (p=0.0001 for each comparison)<br>Global assessment at least 'good': 59% vs. 63% vs. 27% | 3/11 |
| Wiesel, 1980[114] | N=50<br>14 days | **Codeine versus acetaminophen**<br>Mean number of days before return to work: 10.7 vs. 13.0 (NS) | 1/11 |

*Efficacy of different opioids and opioid formulations*

There was no evidence from five lower-quality trials that long-acting opioid formulations are superior to short-acting formulations in patients with low back pain (Table 13) [182, 184-187].

**Table 13. Trials of a long-acting opioid versus a short-acting opioid**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hale, 1999[186] | N=57<br>4-7 days followed by crossover | **Long-acting versus short-acting oxycodone**<br>No differences for overall pain intensity, mean pain intensity, or rescue drug use | 4/11 |
| Salzman, 1998[187] | N=57<br>10 days | **Long-acting versus short-acting oxycodone**<br>No differences for pain intensity, time to stable pain control, mean number of dose adjustements | 3/11 |
| Jamison, 1998[182] | N=36<br>16 weeks | **Long-acting morphine + short-acting oxycodone (titrated dose) + naproxen versus short-acting oxycodone (set dose) + naproxen**<br>Pain intensity (100 point VAS), mean differences versus placebo: -18.21 vs. –18.55 (NS)<br>Global assessment at least 'good': 59% vs. 63% | 3/11 |
| Hale, 1997[185] | N=104<br>5 days | **Long-acting codeine plus acetaminophen versus short-acting codeine plus acetaminophen**<br>Long-acting codeine superior for pain intensity, but non-equivalent codeine use (200 mg vs. 71 mg) | 5/11 |
| Gostick, 1989[184] | N=61<br>2 weeks followed by crossover | **Long-acting versus short-acting dihydrocodeine**<br>No differences for pain intensity, rescue drug use, global efficacy, patient preference | 5/11 |

In two head to head trials (Table 14), there was no difference in efficacy between long-acting oxymorphone and long-acting oxycodone [180] or transdermal fentanyl and long-

acting morphine [183]. The latter study is the longest (13 months) and largest (N=683) trial available.

**Table 14. Head-to-head trials of long-acting opioids**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hale, 2005[180] | N=235<br>18 days | **Long-acting morphine versus long-acting oxycodone**<br>No differences for pain intensity, pain relief, pain interference with activities, global assessment | 7/11 |
| Allan, 2005[183] | N=683<br>13 months | **Transdermal fentanyl versus long-acting oral morphine**<br>No differences for pain scores, rescue medication use, quality of life, loss of working days | 4/11 |

A systematic review of opioids for all non-cancer pain conditions concluded that no differences have been shown between long- and short-acting opioids or different long-acting opioids [188].

*Safety*

In the single higher quality trial, a large proportion of patients on opioids had adverse events (85%), with constipation and sedation the most commonly reported symptoms [180]. Few "serious" adverse events were reported, and withdrawal due to adverse events was low in all groups, probably due in part to the use of a titration phase. In trials comparing opioids to other analgesics (NSAIDs or acetaminophen), constipation, dry mouth, somnolence, and nausea were all more common in the opioid arms [114, 182]. One lower-quality trial reported a higher rate of constipation with long-acting morphine compared to transdermal fentanyl (52% vs. 65%) [183]. However, long-acting morphine was also associated with a trend towards a lower rate of withdrawal due to adverse events (37% vs. 31%).

In a systematic review of opioids for various non-cancer pain conditions, about 80% of patients experienced at least one adverse event, with constipation (41%), nausea (32%), and somnolence (29%) most common [179]. Opioids were also associated with a higher risk of discontinuation due to adverse events (24% vs. 15%, RR 1.4, 95% CI 1.1 to 1.9). Abuse and addiction were rarely reported, but because of short follow-up and enrollment of highly selected patients, reliable conclusions about risks for these

outcomes was not possible. In trials with longer-term (longer than seven months) open-label follow-up, less than half of patients remained on opioids.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- Multiple trials of patients with various non-cancer pain conditions consistently indicate that opioids are superior to placebo for pain relief in primarily short-term trials (level of evidence: good), though evidence in patients specifically with either acute or chronic low back pain (one higher quality demonstrating benefit) is sparse (level of evidence: fair).
- There is insufficient evidence from single, lower quality trials to judge the efficacy of opioids versus acetaminophen or in addition to NSAIDs (level of evidence: poor).
- Consistent evidence from lower-quality trials found no differences between long- and short-acting opioids on a variety of outcomes in patients with chronic low back pain (level of evidence: fair).
- There were no clear differences between long-acting opioids in two head-to-head trials evaluating different comparisons (level of evidence: fair).
- Although adverse events are common with opioids (level of evidence: fair), there are no reliable estimates for rates of abuse or addiction, overdose, or other serious adverse events (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend opioids as an option for a time-limited course in patients with acute low back problems, with the decision guided by consideration of potential complications (which can lead to discontinuation in as many of 35% of patients) relative to other options (strength of evidence: C).
- The AHCPR guidelines found opioids no more effective in relieving low back symptoms than safer analgesics such as acetaminophen, aspirin, or other NSAIDs (strength of evidence: C).
- The AHCPR guidelines recommend warning patients about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving (strength of evidence: C).
- The VA/DoD and UK RCGP guideline recommendations are essentially identical to the AHCPR recommendations.

- The UK RCGP guidelines also suggest that pain of such severity that it requires opioids for longer than two weeks requires further investigation and assistance with management (strength of evidence: *).
- The UK RCGP guidelines suggest paracetamol-weak opioid combinations as an alterative when paracetamol or NSAIDs alone do not give adequate pain control, though adverse effects include constipation and drowsiness (strength of evidence: **).
- The European COST guidelines recommend weak opioids in patients with nonspecific chronic low back pain who do not respond to other treatment modalities. Due to the risk of addiction, they recommend slow-release over immediate-release formulations and scheduled rather than as needed dosing.

**Tramadol**

Results of search: systematic reviews

We identified one higher-quality systematic review [105] that included three short-term (1 to 4 week) trials (N=55, 127, and 96) [189-191] of tramadol (a synthetic opioid analogue) for low back pain. Two of the trials were rated higher-quality [189, 191].

Results of search: trials

We identified no trials of tramadol in patients with low back pain that met inclusion criteria. Five trials were excluded because they evaluated the efficacy of tramadol in combination with acetaminophen or a long-acting formulation not available in the U.S. (Peloso 2004; Ruoff 2003; Mullican 2001; Raber 1999) [192]. One other trial was excluded because it was only published as an abstract [193].

*Efficacy of tramadol versus placebo*

The systematic review [105] included one higher-quality trial [191] that found tramadol more effective than placebo for mean pain scores at 4 weeks (3.5 vs. 5.1 on 10 point scale, p<=0.001) and also superior on the McGill Pain Questionnaire (p=0.0007) and the RDQ Questionnaire (p=0.0001).

*Efficacy of tramadol versus other interventions*

No trial compared tramadol to opioid analgesics in patients with low back pain. The systematic review included two trials comparing tramadol to other drugs [105]. In one higher-quality trial, tramadol was inferior to dextroprofen-trometamol (an NSAID not available in the U.S.) for pain (p=0.044) and need for rescue medication (p=0.011) in patients with acute low back pain [189]. In a lower-quality trial, tramadol was associated

with similar outcomes compared to the combination of paracetamol + codeine in patients with chronic low back pain [190].

*Safety*

In two trials included in the systematic review [105], tramadol was associated with similar rates of withdrawal due to adverse events compared to placebo [191] or the combination of paracetamol plus codeine [189].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- Tramadol was moderately more effective than placebo for short-term pain and assessment of functional status in one higher-quality trial of patients with chronic low back pain (level of evidence: fair).
- Tramadol was no better than the combination of paracetamol plus codeine in one low-quality trial of patients with chronic low back pain (level of evidence: poor).
- There is insufficient evidence to judge the efficacy of tramadol compared to acetaminophen or opioid analgesics alone or to NSAIDs available in the U.S. (no trials).
- In single trials, tramadol was associated with similar rates of withdrawal due to adverse events (a marker for intolerable or severe adverse events) compared to placebo or the combination of paracetamol + codeine (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend weak opioids (including tramadol) in patients with nonspecific chronic low back pain who do not respond to other treatment modalities. Due to the risk of addiction, they recommend slow-release over immediate-release formulations and scheduled rather than as needed dosing.

**Systemic corticosteroids**

Results of search: systematic reviews

We identified no systematic reviews evaluating the efficacy of systemic corticosteroids in patients with low back pain.

Results of search: trials

We identified three small (N=33 to 65), higher-quality trials evaluating the efficacy of systemic corticosteroids for discogenic sciatica of acute or unspecified duration [194-

196]. One other trial evaluated the efficacy of systematic corticosteroids in patients with acute non-specific low back pain, but is only available as a conference abstract [194-197]. We also excluded one German-language trial [198].

*Efficacy of systemic corticosteroids versus placebo*

In the highest quality trial, a single large (500 mg) bolus of intravenous methylprednisolone was associated with a small (average 6 mm on a 100 mm scale) early improvement in short-term leg pain compared to placebo in patients with acute sciatica, but the benefit was no longer present after the first 3 days (Table 15) [194]. There were no differences in degree of pain relief, improvements in functional disability, the proportion requiring spine surgery within the first month, or medication use. In the two other trials, seven day courses of either oral [195] or intramuscular [196] dexamethasone were not associated with any differences in any outcomes including overall effect (either early or after up to 4 years of follow-up), hospitalization length, or subsequent surgery.

**Table 15. Trials of systemic corticosteroids versus placebo in patients with chronic low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Finckh, 2006[194] | N=65 (acute sciatica)<br>30 days | **Methylprednisolone 500 mg bolus versus placebo**<br>Leg pain, difference between interventions in VAS pain scores (0 to 100 scale): 5.7 (favors methylprednisolone) at day 3, (p=0.04), not significant after 3 days (p=0.22)<br>Proportion with >20 mm improvement in VAS pain score after 1 day: 48% vs. 28% (p=0.097) | 10/11 |
| Haimovic, 1986[195] | N=33 (duration of symptoms unclear)<br>1 to 4 years | **Dexamethasone 1 week oral taper versus placebo**<br>Early improvement: 33% (7/21) vs. 33% (4/12)<br>Sustained improvement (1 to 4 years): 50% (8/16) vs. 64% (7/11) | 6/11 |
| Porsman, 1979[196] | N=52 (duration of symptoms unclear)<br>9 days or longer | **Dexamethasone 1 week intramuscular taper versus placebo**<br>'Positive effect': 52% (13/25) vs. 58% (14/24)<br>Subsequent surgery: 32% (8/25) vs. 25% (6/24) | 6/11 |

The excluded German-language trial also reported no significant difference between a 10-day course of intramuscular steroids and placebo in patients with sciatica (OR for successful outcome 2.0, 95% CI 0.8 to 4.9) [198]. In the only trial of systemic corticosteroids in patients with acute non-specific low back pain (only available as an

abstract), there were no differences in pain relief through one month after a single intramuscular injection of 160 mg of methylprednisolone [197].

*Safety*

A large intravenous methylprednisolone bolus was associated with two cases of transient hyperglycemia and one case of facial flushing in one trial [194]. Adverse events were poorly reported in the other trials.

*Costs*

We found no studies evaluating cost-effectiveness.

**Summary of evidence**

- Systemic corticosteroids are consistently not associated with a clinically significant benefit in patients with acute sciatica when given parenterally (single injection) or as a short oral taper (three higher-quality trials) (level of evidence: good).
- One trial found no benefit from a single intramuscular injection of corticosteroids in patients with acute non-radicular low back pain, but the level of evidence can't be adequately assessed because it is only available as a conference abstract.
- Serious adverse events after a single large bolus were not reported in one trial (level of evidence: fair). However, systemic corticosteroids are associated with hyperglycemia, systemic infections, bleeding, and osteoporosis, and psychosis, particularly with higher doses and longer courses.

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against systemic steroids for acute low back problems (strength of evidence: C).
- The AHCPR guidelines found a potential for severe side effects with extended use of oral steroids or short-term use of high-dose steroids (strength of evidence: D).
- The UK RCGP guidelines on systemic steroids are similar.

**Herbal therapy**

Results of search: systematic reviews

We identified two systematic reviews evaluating the efficacy of herbal therapies for low back pain [105, 199]. The more comprehensive study was a recent, higher-quality Cochrane review of 10 trials evaluating devil's claw, white willow bark, or topical cayenne [199]. Although eight of the ten included trials were rated high quality, they

only assessed short-term (<6 weeks) outcomes and more than half either had authors with potential conflicts of interest or did not report potential conflicts. In addition, the same investigator led half of the trials. The other systematic review was less comprehensive and only included one trial each of willow bark and devil's claw (both included in the Cochrane review) [105]. The Cochrane review was an update of a previous (non-Cochrane) systematic review [200].

Results of search: trials
We did not search for additional trials

*Efficacy of harpagoside (devil's claw) versus placebo*
The Cochrane review included two higher quality trials [201, 202] that found devil's claw (harpagoside) superior to placebo for 'proportion pain-free' (9% to 17% in the active treatment groups versus 2% to 5% with placebo) in patients with acute episodes of chronic non-specific low back pain [199]. However, significant differences were not seen for Arhus Index scores (a measure of physical impairment, disability, and pain) or concomitant analgesic (tramadol) use.

*Efficacy of salix alba (white willow bark) versus placebo*
One higher-quality trial of patients with chronic low back pain found white willow bark superior to placebo for 'proportion pain-free' with a significant dose trend (5.7% with placebo, 21% with low dose willow bark, 39% with high dose) as well as for improvements in Arhus Index scores [203].

*Efficacy of capsicum frutescens (cayenne) versus placebo*
Capsaicin is the main active ingredient in cayenne. In one lower-quality trial of patients with acute low back pain, topical cayenne (in combination with topical salicylate) was superior to placebo cream in one lower-quality trial (improvement of about 3.79 cm on 10 cm VAS after 14 days) [204]. Two other studies of chronic low back pain (both just meeting criteria for classification as higher-quality trials) found that cayenne was associated with a higher likelihood of at least 50% improvement in pain compared to placebo (35% versus 17% in one trial [205] and 45% versus 24% in the other [206]). Arhus Index scores also decreased more in the cayenne groups (33% vs. 22% in one trial [205] and 42% vs. 31% in the other [206]). However, a fourth, lower-quality trial of cayenne versus homeopathic treatment (Spiroflor SLR homeopathic gel) in patients with

back pain of mixed duration found no differences for pain relief, proportion using acetaminophen, proportion unable to work, or assessments of overall efficacy [207].

*Efficacy of herbal therapy versus other interventions*

Two higher-quality trials included in the Cochrane review compared either devil's claw [142] or willow bark [141] to low-dose (12.5 mg) rofecoxib, a COX-2 inhibitor no longer on the market. Both found no statistically or clinically significant differences between herbal therapy and rofecoxib for pain, Arhus Index scores, or other outcomes.

*Safety*

Devil's claw was not consistently associated with a higher rate of adverse events compared to placebo in one systematic review [200]. Serious adverse events were rare in the included trials, though a severe allergic reaction was reported in a study evaluating willow bark [203]. Cayenne is associated with burning or itching upon initial administration that decreases after repeated applications.

*Costs*

We found no studies evaluating cost-effectiveness.

**Summary of evidence**

- Several higher-quality trials found devil's claw superior to placebo for short-term pain relief in patients with acute exacerbations of chronic low back pain. However all of the trials were led by the same investigator, raising concerns about reproducibility of findings in other settings (level of evidence: fair).
- One higher-quality trial found willow bark superior to placebo for short-term pain relief in patients with acute exacerbations of chronic low back pain (level of evidence: fair)
- Evidence on the efficacy of cayenne was mixed, with three lower-quality trials suggesting short-term benefits compared to placebo for pain relief and other outcomes in patients with acute low back pain or acute exacerbations of chronic low back pain, but one other lower-quality trial showing no benefit compared to a homeopathic gel (level of evidence: fair).
- Serious adverse reactions with herbal therapy appear uncommon (level of evidence: fair).
- No trials evaluated long-term outcomes.

**Recommendations and findings from other guidelines**

- The European COST guidelines make no recommendation for herbal therapy for acute low back pain, but note that most of the available trials came from the same research group and primarily involved patients with acute exacerbations of chronic low back pain.
- The European COST guidelines recommend consideration of capsicum pain plasters for short-term symptomatic pain relief in chronic low back pain.

### *Acupuncture and related interventions*

**Acupuncture**

Results of search: systematic reviews

We identified two recent, good-quality systematic reviews (33 and 35 trials) evaluating the efficacy of acupuncture (including electroacupuncture) in patients with primarily chronic low back pain [208-210]. One of these reviews [209, 210] (an update of a previous Cochrane review [211]) also evaluated the efficacy of dry needling (a technique involving the insertion of needles into trigger points). Both reviews found significant methodological shortcomings in the acupuncture literature (10 of 33 and 14 of 35 studies rated as higher quality). In addition, about one third of the trials were conducted in Asian settings, which could limit the generalizability of findings to the U.S. We identified one systematic review on safety of acupuncture in patients with low back pain [212]. We excluded six older systematic reviews [213-220] and one review that didn't clearly use systematic methods [221].

Results of search: trials

We identified one additional recent, higher-quality trial evaluating longer-term (two years) outcomes associated with acupuncture in patients with low back pain [222].

*Efficacy of acupuncture versus placebo or sham treatment*

Both systematic reviews found sparse evidence on the effectiveness of acupuncture in patients with acute low back pain relative to placebo, sham, or no treatment (three RCTs in one systematic review and four in the other) [208-210]. The available evidence was inconclusive because of small sample sizes, methodologic shortcomings, short duration of follow-up, and inconsistent results, with some trials showing no differences.

For chronic low back pain, both systematic reviews found acupuncture more effective than no treatment (SMD 0.69, 95% CI 0.40 to 0.98 [208] and 0.73, 95% CI 0.28 to 1.19

[209, 210]) or sham treatments (acupuncture or TENS) (standardized mean difference 0.54, 95% CI 0.35 to 0.73 and weighted mean difference –17.79, 95% CI –25.5 to –10.7, respectively) for short-term (defined as <6 weeks or <3 months, respectively) pain relief. Both systematic reviews also found acupuncture associated with short-term improvements in functional status compared to no treatment (SMD 0.62, 95% CI 0.30 to 0.95 [208] and 0.63, 95% CI 0.19 to 1.08 [209, 210]), but there were no differences compared to sham therapies. For short- and long-term assessments of "overall" improvement, acupuncture was superior to sham treatments and no treatment.

The systematic reviews found sparse evidence on longer-term (defined as longer than 6 weeks after treatment) benefits. Acupuncture was associated with better long-term pain relief compared to sham TENS in two trials (SMD 0.62, 95% CI 0.03 to 1.22) and to no additional treatment in five trials (SMD 0.74, 95% CI 0.02 to 1.47), though there were no significant differences compared to sham acupuncture (two trials, SMD 0.59, 95% CI –0.10 to 1.29) [208]. One higher-quality trial included in the systematic reviews evaluated outcomes one year after treatment, finding no differences in pain compared to no treatment (SMD 0.35, 95% CI –0.51 to 0.09) [223]. However, a recent high-quality trial not included in the systematic reviews suggests that benefits from acupuncture may extend beyond a year (Table 16) [222]. It found that routinely offering acupuncture (94% of patients offered acupuncture received it) was associated with sustained benefits on SF-36 pain scores after 24 months (mean adjusted difference at 24 months, p=0.032) and use of low back pain medications in the last 4 weeks (60% vs. 41%, p=0.03) compared to usual general practitioner care. However, there were no differences in ODI scores, McGill Present Pain Intensity scores, or other SF-36 dimension scores.

**Table 16. Long-term trial of acupuncture versus usual care**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Thomas, 2005[222] | N=241<br>24 months | **Routinely offering acupuncture versus usual care**<br>SF-36 Pain score, mean adjusted difference between interventions: +5.6 at 12 months (p=0.11), +8.0 at 24 months (p=0.03) (favors acupuncture)<br>McGill Present Pain Intensity: No difference at 12 or 24 months<br>ODI Score: No difference at 12 or 24 months<br>Pain-free in last 12 months: 18% vs. 8% (p=0.06)<br>Use of low back pain medication in last 4 weeks: 60% vs. 41% (p=0.03) | 7/11 |

*Efficacy of acupuncture versus other active interventions*

Both systematic reviews found acupuncture inferior to spinal manipulation for short-term pain relief [208-210]. One of the systematic reviews calculated a standardized mean difference of –1.32 (95% CI –1.87 to –0.77) from two trials [208]. Neither found any evidence that acupuncture is more effective than other active therapies (massage, analgesic medication, or TENS, each comparison evaluated in one to four trials).

*Efficacy of different acupuncture techniques*

The Cochrane review compared the effectiveness of different acupuncture techniques (8 trials, 2 high quality) [209, 210]. In one higher-quality trial, deep stimulation was superior to superficial stimulation immediately after the sessions and at short-term follow-up [224]. In the other high-quality trial, there was no difference between manual acupuncture and electroacupuncture [225]. There was insufficient evidence to judge the comparative efficacy of other acupuncture techniques (single comparisons from flawed trials). There was no difference between manual and electroacupuncture in one trial [225].

*Efficacy of dry needling*

The Cochrane review [209, 210] included one lower-quality trial of patients with acute low back pain that found no difference between one session of dry needling versus trigger point injection with lidocaine and steroid, trigger point injection with lidocaine only, or cooling spray over the trigger point area followed by acupuncture [226]. In patients with chronic low back pain, one higher quality trial found that superficial needling of trigger points was superior to placebo TENS for immediate pain relief [227]

and one lower-quality trial found that dry needling added to a regimen of physiotherapy, occupational therapy, and industrial assessments was superior to the regimen without dry needling [228] for short- and intermediate-term functional status.

*Safety*

The Cochrane review found that only 14 of 35 trials reported any complications or side effects [209, 210]. Minor complications occurred in 5% (13/245) patients receiving acupuncture, 0% (0 of 156) receiving sham, and 10% (21/205) receiving other interventions. None of the complications were fatal or required hospitalization.

Another systematic review of prospective (randomized and non-randomized) studies of acupuncture (over 250,000 acupuncture treatments analyzed) in patients with various conditions found wide variation in rates of adverse events, ranging from 1% to 45% for needle pain, and 0.03% to 38% for bleeding [212]. The wide range in estimates is probably due in part to differences in methods for defining, identifying, and reporting adverse events. Feelings of faintness and syncope were uncommon, with an incidence of 0% to 0.3%. Serious adverse events, which may be more likely to be reported, were rare. Pneumothorax was reported in two patients, and there were no cases of infections.

*Costs*

Only two trials estimated cost-effectiveness for acupuncture. It found that routinely offering acupuncture was associated with an incremental cost-effectiveness of £4241/QALY (95% CI £191 to £28,026) relative to usual care [222]. Another trial found no significant differences in back pain-related HMO costs between patients randomized to acupuncture, massage, and self-care (with massage the most effective therapy) [223].

**Summary of evidence**

- There is consistent evidence from multiple trials that acupuncture is effective for short-term pain relief compared to no treatment or sham acupuncture in patients with chronic low back pain for pain, and superior to no treatment (but not sham) for functional outcomes (level of evidence: good).
- Evidence on longer-term (>6 weeks) outcomes is sparse but suggests that acupuncture is more effective than sham TENs and no treatment in patients with

chronic low back pain. One recent, higher-quality trial found that beneficial effects on pain persist for up to 24 months (level of evidence: fair).

- Acupuncture was inferior to spinal manipulation in two trials (one higher quality) (level of evidence: fair)
- There is no evidence that acupuncture is more effective than other active interventions in patients with chronic low back pain (each comparison only evaluated in a small number of trials) (level of evidence: poor to fair).
- There is insufficient evidence to judge the efficacy of acupuncture (small numbers of primarily lower-quality trials) in patients with acute low back pain (level of evidence: poor).
- Dry needling alone was not effective compared to trigger point injections or acupuncture in one trial of patients with acute low back pain (level of evidence: poor), but was more effective than placebo or when added to other interventions in two trials of patients with chronic low back pain (level of evidence: fair).
- Serious adverse events with acupuncture appeared rare in trials and prospective studies, though they were often poorly reported (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against invasive needle acupuncture and other dry needling techniques for patients with acute low back problems (strength of evidence: D).
- The VA/DoD and UK RCGP guidelines on acupuncture for acute low back pain are similar.
- The European COST guidelines make no recommendations on acupuncture for acute low back pain, and found insufficient evidence to recommend acupuncture for chronic low back pain.

**Acupressure**

Acupressure is a non-invasive method that involves manipulation with the fingers instead of needles on acupuncture points. It has been less well studied than acupuncture.

Results of search: systematic reviews

We found no systematic review evaluating its efficacy.

Results of search: trials

We identified two recent open-label RCTs (one rated higher quality [229]) of acupressure, both conducted in Taiwan by the same group of investigators [229, 230].

*Efficacy of acupressure versus physical therapy*

Both trials found that acupressure was more effective than physical therapy (consisting of multiple techniques at the discretion of the physical therapist) in patients with chronic low back pain (Table 17)[229, 230]. In the one trial reporting functional outcomes, there were modest differences in changes in the RDQ and ODI scores that persisted through the end of follow-up six months (-5.36, 95% CI –7.21 to –3.52 and –7.99, 95% CI –10.8 to –5.17, respectively) [229]. Days off from work/school also improved more in the acupressure group (mean difference compared to baseline –2.79, p<0.0001). In both trials, acupressure was superior to physical therapy for measures of pain relief. The mean difference in changes from baseline pain scores were –27.2 on a 100 point VAS (p<0.0001) and –4.46 on the 0 to 45 Short-form Pain Questionnaire (p=0.0001) after 6 months. The effects on pain relief were about twice as high as seen with most other conventional interventions or acupuncture.

**Table 17. Trials of acupressure versus physical therapy**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hsieh, 2006[229] | N=158<br>6 months | Acupressure versus physical therapy<br>RDQ score, difference in mean change from baseline: -5.36, 95% CI –7.21 to –3.52 (p<0.0001)<br>Modified ODI score, difference in mean change from baseline: -7/99, 95% CI –10.8 to –5.17 (p<0.0001)<br>Pain (VAS, 0 to 100), difference in mean change from baseline between interventions: -27.12 (p<0.0001) | 5/11 |
| Hsieh, 2004[230] | N=146<br>6 months | Acupressure versus physical therapy<br>Short-form Pain questionnaire, mean change from baseline: -8.69 vs. –4.23 (p=0.0001) | 6/11 |

*Safety*

One of the trials reported no adverse events in the acupressure group [230]. The other trial did not report adverse events.

Costs

We found no studies evaluating costs.

**Summary of evidence**

- There is evidence from two trials (one higher quality) that acupressure is more effective than standard therapy in patients with chronic low back pain for pain and functional outcomes. However, it is not clear if these results can be

generalized to other settings because both trials were conducted in Taiwan by the same investigators (level of evidence: fair)

- Acupressure does not appear associated with serious adverse events, but harms were only reported by one trial (level of evidence: fair).
- There is no evidence in patients with acute low back pain.

**Recommendations and findings from other guidelines**

- None of the guidelines address acupressure.

**Neuroreflexotherapy**

Neuroreflexotherapy is a technique from Spain characterized by the temporary implantation of staples superficially into the skin over trigger points in the back and referred tender points in the ear. Like acupuncture, it involves the use of puncture devices in the skin. However, neuroreflexotherapy is believed to stimulate different zones of the skin.

Results of search: systematic reviews

We identified one recent, higher-quality Cochrane review (three trials, two rated higher-quality (Kovacs 1993 and Kovacs 1997) evaluating the effectiveness of neuroreflexotherpay in patients with chronic low back pain [231]. The same principal investigator conducted all three trials in Spain (total number of patients 273).

Results of search: trials

We did not search for additional trials.

*Efficacy of neuroreflexotherapy versus sham neuroreflexotherapy*

The two higher-quality trials [232, 233] found neuroreflexotherapy markedly superior to sham therapy for short-term (up to 45 days) pain relief. In one trial, the proportion of patients with pain relief was 96% with neuroreflexotherapy vs. 2.3% with sham ($p<0.0001$) [232]. In the other, neuroreflexotherapy was associated with an average improvement in spontaneous pain of 3.09 (on a 45 point scale) compared to 0.34 with sham treatment [233]. One [232] of the two trials also found neuroreflexotherapy superior for a variety of functional and work-related outcomes.

*Efficacy of neuroreflexotherapy versus usual care*

The third, lower-quality trial compared neuroreflexotherapy to usual care [234]. It found neuroreflexotherapy superior for short-term (60 days) pain relief (average improvement

5.50 on a 60 point scale versus 1.92, p<0.0005) and functional status (average improvement 8.67 on RDQ scale versus 2.05, p=0.007). Number of days on sick leave and duration of sick leave (average 3.2 vs. 105.2 days, p=0.001) and use of health care services were also lower in the neuroreflexotherapy group after one year. There were no differences in quality of life.

*Costs*

One trial that included a cost-effectiveness analysis found that neuroreflexotherapy dominated (total costs lower and clinical outcomes superior) [234]. Neuroreflexotherapy was associated with median costs of $800 compared to $3800 with usual care, and superior by an average of 5.5 points on the RDQ Scale (0 to 24).

*Safety*

One trial found a higher incidence of adverse effects in the control group (65% vs. 9%), primarily due to gastric discomfort associated with NSAID use [232]. Skin tightness was associated with implantation of staples, but did not require early extraction in any patient. Scarring was not specifically reported in any trial, but is not believed to be an important problem because of the superficial nature of the staple implantations.

**Summary of evidence**

- There is consistent evidence (three trials, two higher-quality) that neuroreflexotherapy is superior to sham therapy or usual care for short-term pain relief in patients with chronic low back pain. However, all of the trials were conducted in Spain by the same principal investigator at a specialized center, raising questions about the applicability of results to other settings (level of evidence: fair).
- Evidence on beneficial effects of neuroreflexotherapy relative to sham treatment on functional outcomes is mixed (level of evidence: fair).
- The single lower-quality trial assessing one-year outcomes found lower self-reported sick leave and consumption of health care resources with neuroreflexotherapy relative to usual care (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend consideration of neuroreflexotherapy for patients with moderate or severe (>3/10 on VAS), chronic low back pain.

## Educational Interventions

### Back schools

The original Swedish back school was introduced in 1969 [235, 236]. The basic elements of back schools consist of an educational and skills program, including exercises, in which all lessons are given to groups of patients and supervised by a therapist or medical specialist. However, the content and intensity of back schools meeting this basic definition can vary widely.

Results of search: systematic reviews

We identified one recent, higher-quality Cochrane review of 19 trials (6 rated higher-quality) of back schools for acute or chronic low back pain [237, 238]. It updated a previous Cochrane review [239]. We also included three other recent systematic reviews, though all were rated lower-quality [240-242]. Another recent, higher-quality systematic review evaluated factors that could predict better outcomes from back schools and multidisciplinary rehabilitation (results not clearly separated for the two interventions) [243]. We excluded ten older systematic reviews [132, 244-252].

Results of search: trials

We did not search for additional trials.

*Efficacy of back schools versus placebo*

The Cochrane review included one lower-quality trial [253] that found back school superior to placebo (short-wave therapy at the lowest intensity) in patients with acute or subacute low back pain for short-term recovery and return to work, but not for short-term pain or long-term recurrences [237, 238]. There was conflicting evidence from eight trials (2 higher-quality [254, 255]) on the effectiveness of back schools versus placebo or wait list controls for chronic low back pain. For short-term outcomes, seven RCTs found no benefit from back schools. For long-term outcomes, one high-quality study [255] found positive effects on functional status and return to work, though two other lower-quality trials [256, 257] found no long-term benefits. Results of back schools were generally more promising in trials conducted in an occupational setting (moderate evidence for improved short- and intermediate-term pain and return to work) and for more intensive (three to five-week stays in specialized centers) programs

consisting of modifications of the original Swedish back school. In general, however, benefits associated with back schools appeared modest.

The systematic review evaluating factors associated with better outcomes after back school or multidisciplinary rehabilitation found consistent evidence that higher baseline pain level was associated with worse outcomes, and that several work-related parameters (such as high satisfaction) and low levels of active coping skills at baseline were associated with better outcomes [243]. Other variables lacked consistent predictive value, in part due to flaws in the studies and because many predictors were only evaluated in one study.

Conclusions of three other recent (lower-quality) systematic reviews were generally consistent with the Cochrane review [240-242].

*Efficacy of back schools versus other interventions*

The Cochrane review [237, 238] included four trials (two higher quality [258-260]) on the effectiveness of back school versus other treatments (physical therapy, usual care, or advice) in patients with acute low back pain. Although one higher-quality trial reported decreased sickness leave after 200 days (30% vs. 60%) and 5 years (19% vs. 34%) [258, 259], the other three trials reported no significant differences [253, 260, 261]. In patients with chronic low back pain, the Cochrane review included 6 trials (four in occupational settings) and found that back schools are superior to other conservative treatments (exercises, spinal manipulation, myofascial therapy, or some kind of advice) for short and intermediate-term pain relief and improvement in functional status, but not for long-term outcomes [237, 238].

*Safety*

No studies assessed safety.

*Cost-effectiveness*

We found no studies evaluating cost-effectiveness.

**Summary of evidence**

- Back schools were superior to placebo in a single lower-quality trial of patients with acute or subacute low back pain for short-term recovery and return to work, but not for pain or long-term recurrences (level of evidence: poor).

- Evidence on the effects of back schools versus placebo or wait list controls for chronic low back pain is inconsistent, though most studies found no beneficial effects (level of evidence: fair).
- There was also mixed evidence on the efficacy of back schools relative to other active interventions in patients with acute low back pain (one higher quality trial finding benefit on sick leave but three other trials finding no benefit), but consistent evidence for modest benefits in patients with chronic low back pain (level of evidence: fair).
- More intensive back school programs based on the original Swedish program and programs in occupational settings appeared more effective (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found that in the workplace, back schools with worksite-specific education may be effective adjuncts to individual education efforts by the clinician the treatment of patients with acute low back problems (strength of evidence: C).
- The AHCPR guidelines found that the efficacy of back schools in nonoccupational settings had not been proven (strength of evidence: C).
- The European COST guidelines recommend considering back schools where information given is consistent with evidence-based recommendations for short-term (<6 weeks) pain relief and improvements in functional status. They do not recommend back schools as a treatment for chronic low back pain when aiming at long-term effects (>12 months).

**Brief educational interventions**

We defined brief interventions as a detailed clinical examination by a physician and/or physiotherapist followed by individualized back education and advice. As we defined them, brief interventions typically require several hours and are usually completed in one or two sessions. Brief interventions differ from back schools because they don't involve group education and exercises. They also are distinct from multidisciplinary rehabilitation, which generally includes a specific psychologic component as well as a supervised rehabilitation program.

Results of search: systematic reviews

We found no systematic reviews of brief interventions.

Results of search: trials

We identified three higher-quality trials (all in workers with low back pain for less than three months) that evaluated brief interventions in workers with subacute low back pain (Table 18) [258, 259, 262-264]. A third higher-quality trial evaluated a brief intervention in patients with chronic low back pain [265, 266].

*Efficacy of brief educational interventions versus usual care*

One trial of patients on sick leave for 8 to 12 weeks due to low back pain found that a single visit to a spine clinic with a detailed examination by a physiatrist and physical therapist and advice to remain active was associated with no differences in the proportion of patients who continued to report low back pain at 6 months or 1 year or the proportion off sick leave at 3 years, though patients randomized to the intervention were more likely to be off sick leave at 1 year (OR 1.60, 95% CI 1.08 to 2.39) [262, 267]. In another trial, which evaluated patients with bothersome low back pain for up to 3 months, the brief intervention was associated with fewer sick days after 1 year (19 versus 41 days, p=0.02) [264] and 2 years (30 versus 62 days, p=0.03) [263]. There were no differences in pain or ODI scores at any time. A smaller proportion of patients reported severe symptoms at 3 months, but not with longer duration of follow-up. The third trial found that compared to usual care, workers with back pain for four to twelve weeks who received a detailed examination and three hours of advice for light activity were less likely to be on sick leave (19% versus 34%, p<0.001) and on permanent disability (49% vs 69%, p<0.03) after five years [258, 259].

**Table 18. Trials of brief educational interventions versus usual care**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Molde Hagen, 2000 and 2003[262, 267] | N=510<br>3 years | **Brief intervention versus usual care**<br>LBP still present at 1 year: 47% vs. 52% (NS)<br>Off sick leave at 1 year: 69% vs. 57% (p<0.05)<br>Off sick leave at 3 years: 64% vs. 62% (NS)<br>New episodes of sick leave due to LBP (through 3 years): 62% (147/237) vs. 61% (135/220) (NS) | 6/11 |
| Karjalainen, 2003[264] | N=170<br>2 years | **Brief intervention versus mini intervention plus work site visit versus usual care**<br>Pain intensity: 3.5 vs. 3.2 vs. 3.4 at 24 months (NS)<br>Very or extremely bothersome symptoms during the past week: 29% vs. 35% vs. 48% at 3 months, 23% vs. 20% vs. 29% at 24 months (p=0.048 for A vs. C at 3 months, NS for B vs. C)<br>ODI: 19 vs. 18 vs. 18 at 24 months (NS)<br>Days on sick leave: 30 vs. 45 vs. 62 (p=0.030 for A vs. C, NS for B vs. C) | 8/11 |
| Indahl, 1995 and 1998[258, 259] | N=489<br>5 years | **Brief intervention vs usual care**<br>On sick leave: 30% vs. 60% at 200 days, 19% vs 34% at 5 years (p<0.001)<br>Long term or permanent disability<br>status after 5 years: 19% vs 34% (p<0.001)<br>Sick listed > 2 x: 49% vs 69% (p<0.03) | 6/11 |

*Efficacy of brief educational interventions versus brief educational interventions plus manipulation and exercise*

One higher-quality trial found a brief intervention (consisting of a physician consultation and individualized reassurance, education, and back advice with a repeat visit at 5 months) modestly inferior to the brief intervention plus manipulation and exercise for pain relief at 12 and 24 months (difference of about 6 points on a 100 point pain scale at 12 months and about 3 points at 24 months) (Table 19) [265, 266]. Effects on disability, health-related quality of life and number of days of sick leave through 1 year (20 vs. 14 days) were similar.

**Table 19. Trial of brief educational intervention versus brief intervention plus exercise and manipulation**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Niemisto, 2003 and 2005[265, 266] | N=204<br>2 years | **Brief intervention versus brief intervention plus manipulation plus exercise**<br>Pain (0 to 100): 32.2 vs. 25.7 at 12 months (p=0.01), 33.1 vs. 30.7 at 24 months<br>ODI: 16.5 vs. 13.7 at 12 months (p=0.20), 14.0 vs. 12.0 at 24 months<br>Health-related Quality of Life (15D): No differences<br>Number of days of work absence through 1 year: 20 vs. 14 | 7/11 |

*Safety*

Neither trial evaluated safety.

*Cost-effectiveness*

The two trials of workers with subacute low back pain found the brief intervention superior to usual care by an average of $3,497 [262] and 4839 Euros [263], largely due to the decreased sick leave in the first year after the intervention (cost-benefit analysis). The third trial estimated an incremental cost-effectiveness of $512 per additional point of improvement on a 100-point pain scale for combined manipulation and exercise plus a brief intervention, versus the brief intervention alone [266].

**Summary of evidence**

- In three higher-quality trials, a brief educational intervention was associated with beneficial effects on sick leave in workers with subacute low back pain, though most of the benefits were observed in the first year after the intervention. There were no clear effects on pain or functional status (level of evidence: good).
- A brief intervention was only modestly inferior to the brief intervention plus exercise and manipulation in patients with chronic low back pain (one higher-quality trial) (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend brief educational interventions that encourage a return to normal activity to reduce sickness absence and disability associated with chronic low back pain.

## *Exercise and Related Interventions*

### Exercise

Results of search: systematic reviews

We identified a recent, good-quality Cochrane review (61 trials) evaluating the effectiveness of exercise therapy for nonspecific low back pain [268, 269]. Most of the evidence was in patients with chronic low back pain (43 trials). Only eight of the 61 trials were rated high quality (met all four quality rating criteria). We included four other recent systematic reviews of exercise therapy; each with a less comprehensive scope than the Cochrane review [270-273]. One was rated higher-quality [270]. We excluded an outdated Cochrane review [274] and 13 other older systematic reviews [110, 132, 249, 250, 275-283].

Results of search: trials

We identified a recent, large, lower-quality trial comparing manipulation, exercise, or both to usual care [284]. We also included a recent, higher-quality trial comparing a standard exercise regimen to an individualized approach using a patient classification scheme [285].

*Efficacy of exercise therapy versus placebo or usual care*

The Cochrane review [268, 269] found that exercise therapy was superior to usual care or no treatment in only two of eleven trials (one higher quality [286] and one lower-quality [287]). Among trials with data that could be pooled, there was no difference between exercise therapy and no exercise for pain relief (3 trials) or functional outcomes (3 trials) at any time period. The Cochrane review also included five trials comparing exercise to usual care or no treatment in patients with subacute low back pain. Although two trials [288, 289] (one higher-quality [289]) found reduced absenteeism with a graded-activity intervention in the workplace compared with usual care and one low-quality trial [290] found improved functioning over usual care with an exercise program combined with behavioral therapy, pooled results suggested no difference on pain scores (5 trials, weighted mean difference 1.89 on a 100 point scale, 95% CI –1.13 to 4.91) or functional outcomes (4 trials, weighted mean difference 1.07, 95% CI –3.18 to 5.32).

By contrast, in patients with chronic low back pain, exercise was modestly superior relative to no treatment for pain relief at the earliest follow-up period (weighted mean improvement 10 points on a 0 to 100 scale, 95% CI 1.31 to 19.09), though not for functional outcomes (weighted mean improvement 3.00, 95% CI –0.53 to 6.48) [268, 269]. Results were similar at later follow-up. The differences were somewhat greater in health care settings (mean improvement 13.3 points on pain, 95% CI 5.5 to 21.1 and 6.9 on function, 95% CI 2.2 to 11.77) than in occupational or general population settings, but still did not meet pre-defined criteria for minimal clinically important differences (20 point improvement for pain and 10 points for function).

Another higher-quality systematic review focusing on work outcomes (14 trials) found that exercise (including exercise as part of a multidisciplinary intervention) reduced sick leave during the first year (effect size –0.24, 95% CI –0.36 to –0.11) and improved the proportion returned to work (RR 0.75 at 1 year, $p<0.05$), though there was no benefit in the severely disabled subgroup (>90 days sick leave under usual care) or in patients receiving disability payments [270].

A lower-quality systematic review [271] focusing on patients with spondylolysis and spondylolisthesis included only two trials (one higher quality [291]), both of which found exercise superior relative to usual care [291] or sham exercise [292].

The recently published, large (N=1334) UK BEAM Trial was consistent with the results of the systematic reviews (Table 21) [284]. In patients with low back pain for at least 28 days, exercise only had small beneficial effects on pain and disability relative to usual care.

**Table 21. Results of the UK BEAM trial**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| UK BEAM Trial, 2004[284] | N=1334<br>12 months | **Manipulation + exercise versus manipulation versus exercise (all results are absolute net benefit relative to usual care at 12 months)**<br>RDQ Questionnaire (0 to 24 scale): 1.30 (95% CI 0.54 to 2.07) vs. 1.01 (95% CI 0.22 to 1.81) vs. 0.39 (95% CI -0.41 to 1.19)<br>Modified Von Korff pain score (0 to 100 scale): 6.71 (95% CI 2.47 to 10.95) vs. 5.87 (95% CI 1.58 to 10.17) vs. 4.90 (95% CI 0.30 to 9.50)<br>Modified Von Korff disability score (0 to 100 scale): 6.71 (95% CI 2.62 to 10.80) vs. 5.65 (95% CI 1.57 to 9.72) vs. 4.56 (95% CI 0.34 to 8.78) | 2 or 3/11 |

*Efficacy of exercise therapy versus other interventions*

The Cochrane review included seven trials of patients with acute low back pain that found no difference between exercise therapy and other conservative treatments (difference in pain relief 0.31 point, 95% CI –0.10 to 0.72) or functional outcomes [268, 269]. In patients with chronic low back pain, exercise was associated with statistically significant but only marginal benefits on pain (5.93 points, 95% CI 2.21 to 9.65) and function (2.37 points, 95% CI 0.74 to 4.0) relative to other conservative interventions.

Another, fair-quality systematic review found that McKenzie exercise therapy (5 trials) was associated with modest short-term improvements in short-term pain and disability compared to other conservative interventions in patients with back pain of mixed duration (pooled effect –8.6, 95% CI –13.7 to –3.5 for pain and –5.4, 95% CI –8.4 to –2.4 for function), but no better for intermediate term disability or work absence [273].

Like the Cochrane review, the UK BEAM Trial [284] found no clear differences between exercise therapy and manipulation (see Table 21 above). Another trial not included in the Cochrane review compared a standardized exercise regimen (low-stress aerobic exercise, general muscle reconditioning, and advice to stay active) with an approach using a classification scheme to match patient signs and symptoms to specific exercises or other treatments (such as manipulation, mobilization, or traction) in workers with back pain for less than three weeks (Table 22) [285]. It found that patients receiving physical therapy according to the classification scheme had greater improvements in ODI scores at 4 weeks (between-group difference 10.9, 95% CI 1.9 to 19.9) and at one year (9.0,

95% CI 0.30 to 17.7), and were less likely to have continued work restrictions (42% vs. 17%, p=0.017). One difficulty in interpreting these results, however, is that the intensity of the standardized exercise regimen was unclear.

**Table 22. Trial comparing standardized exercise therapy to individualized treatment based on a classification scheme**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Fritz, 2003[285] | N=78<br>1 year | **Standard exercise vs. classification-based therapy (mean differences between groups relative to baseline)**<br>ODI: 10.9 (95% CI 1.9 to 19.9) at 4 weeks, 9.0 (0.30 to 17.7) at 1 year<br>SF-36 physical component summary: 5.6 (0.6 to 10.7) at 4 weeks, 3.6 (-2.1 to 9.3) at 1 year<br>SF-36 mental component summary: 5.7 (1.8 to 9.5) at 4 weeks, 3.6 (-1.4 to 8.7) at 1 year<br>Continued work restrictions after four weeks: 42% (15/36) vs. 17% (7/41) | 7/11 |

*Efficacy of different types of exercise regimens*

The authors of the Cochrane review also conducted a meta-regression analysis to evaluated specific features of exercise interventions associated with improved outcomes in patients with chronic low back pain [293]. Compared to home exercises only, improved pain scores were seen with individually designed programs (5.4 point improvement in pain scores, 95% credible interval 1.3 to 9.5), supervised home exercise (6.1 points, credible interval –0.2 to 12.4), group (4.8 points, 95% credible interval 0.2 to 9.4 points), and individually supervised programs (5.9 points, 95% credible interval 2.1 to 9.8 points). High-dose exercise programs (20 or more hours of intervention time) were not superior to low-dose programs. Interventions that included additional conservative care were better (5.1 points, 95% credible interval 1.8 to 8.4 points) than those without additional conservative care. The exercise regimens that were most effective used stretching and strengthening, though there was some overlap with other types (aerobic, mobilizing, or other specific exercise methods). Modelling suggested that an intervention incorporating all of the features of an effective exercise intervention would improve pain scores by 18.1 points (95% credible interval 11.1 to 25.0 points) compared to no treatment and 13.0 points (95% credible interval 6.0 to 19.9 points) compared to other conservative treatment and function by 5.5 points (95%

credible interval 0.5 to 10.5) compared to no treatment and by 2.7 points (95% credible interval –1.7 to 7.1) compared to other conservative interventions, though no trials of such an intervention are available.

*Safety*

None of the systematic reviews assessed adverse events associated with exercise therapy, which were poorly reported in the trials.

*Costs*

Two trials calculated cost-effectiveness ratios for exercise therapies. The UK BEAM trial found the addition of exercise associated with an incremental cost-effectiveness of £8300/QALY relative to best care, though exercise was dominated by the combination of exercise and manipulation (more costly and less effective) [284]. Another British trial estimated an incremental cost-effectiveness of £3010/QALY for physiotherapy relative to physiotherapy advice alone, but a high likelihood of no significant differences between interventions [294].

Two trials compared costs between exercise programs and usual care. One found no significant cost differences related to health services, equipment, and days off work between a progressive exercise program and usual primary care [290]. A cost-minimization analysis from another trial found no differences in total costs (direct and indirect) between either a standard or intensive physical therapy program and usual care [295].

Three other trials included cost-benefit analyses of exercise therapy versus other interventions. One trial found no significant difference between exercise and either bed rest or usual activities in patients with acute low back pain (usual activities associated with more rapid recovery in this trial) [286]. Another trial found exercise associated with greater costs compared to providing a self-care education book ($437 versus $153), and only marginally better outcomes [296]. The trial comparing standardized exercise therapy to classification-based treatment found higher total median costs with the former ($1004 versus $774), though the difference was not significant (p=0.13) [285].

Studies comparing costs between exercise therapy and spinal manipulation are discussed in the spinal manipulation section.

### Summary of evidence

- Exercise is modestly superior to placebo in multiple trials of patients with chronic low back pain for pain relief and work-related outcomes, though the pain relief benefits do not appear to reach pre-defined levels of minimal clinically important differences (level of evidence: good).
- Exercise regimens incorporating features such as individual tailoring, supervision, stretching, and strengthening are associated with the best outcomes in meta-regression analyses (level of evidence: fair).
- Evidence on the efficacy of exercise relative to placebo or no treatment in patients with acute low back pain is somewhat inconsistent, though most trials found no benefit (level of evidence: fair).
- One recent, higher-quality trial found a standardized exercise regimen inferior to physical therapy tailored according to patient signs and symptoms (level of evidence: fair).
- Evidence from numerous trials suggests no clinically significant difference between exercise and other non-invasive interventions for either acute or chronic low back pain (level of evidence: good).

### Recommendations and findings from other guidelines

- The AHCPR guidelines found that low-stress aerobic exercise can prevent debilitation due to inactivity during the first month of symptoms and help patients with acute low back problems return to usual functioning (strength of evidence: C).
- The AHCPR guidelines suggest that low-stress aerobic exercise programs can be started during the first 2 weeks for most patients with acute low back problems (strength of evidence: D).
- The AHCPR guidelines suggest that conditioning exercises for trunk muscles are helpful for patients with acute low back problems, particularly if symptoms persist, but may aggravate symptoms more than aerobic exercise in the first 2 weeks (strength of evidence: C).
- The AHCPR guidelines found no evidence that back-specific exercise machines provide benefit over traditional exercise (strength of evidence: D).
- The AHCPR guidelines found no evidence to support stretching of the back muscles for acute low back problems (strength of evidence: D).
- The AHCPR guidelines suggest that gradually increasing exercise quotas result in better outcomes than telling patients to stop exercising if pain occurs (strength of evidence: C).

- The VA/DoD guideline recommendations for exercise are similar to the AHCPR recommendations.
- The UK RCGP guidelines found that it is doubtful that specific back exercises produce significant improvement in acute low back pain, or that it is possible to select which patients will respond to which exercises (strength of evidence: ***).
- The UK RCGP guidelines found some evidence that exercise programs and physical reconditioning can improve pain and function in patients with chronic low back pain (strength of evidence: **).
- The UK RCGP guidelines found theoretical arguments for starting exercise programs at around 6 weeks after start of symptoms (strength of evidence: *).
- The European COST guidelines recommend against advising specific exercises for acute low back pain.
- The European COST guidelines recommend supervised exercise as a first-line treatment for chronic low back pain. They suggest exercise programs not requiring expensive training machines, the use of a cognitive-behavioral approach with graded exercises, and quotas. Group exercises are considered a low-cost option. The guidelines provide no recommendations on specific types of exercise, and suggest that the patient and therapist could best determine that.

**Hydrotherapy**

Results of search: systematic reviews

We found no systematic reviews evaluating the efficacy of hydrotherapy (water-based exercise) in patients with low back pain.

Results of search: trials

We identified three lower-quality trials of hydrotherapy, all in patients with chronic low back pain [297-299].

*Efficacy of hydrotherapy versus delayed hydrotherapy*

One lower-quality trial (N=109) found hydrotherapy superior to delayed hydrotherapy in patients with chronic low back pain for back-specific functional status, but not for pain (Table 23) [297]. Incomplete and inconsistent reporting of results data makes this trial difficult to interpret.

**Table 23. Trial of hydrotherapy versus delayed hydrotherapy**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| McIlveen, 1998[297] | N=109<br>4 weeks | **Hydrotherapy versus delayed hydrotherapy**<br>ODI, percent improved: 27% vs. 8% (p=0.05)<br>Pain rating index of McGill Pain Questionnaire, percent improved >10 points: 11% vs. 8% (NS)<br>Present pain intensity of McGill Pain Questionnaire, percent improved by >1 point: 33% vs. 22% (NS) | 3/11 |

*Efficacy of hydrotherapy versus land-based therapy*

Two trials (N=60 and N=30) each found no differences between hydrotherapy and land-based therapy for short-term pain or functional status in patients with chronic low back pain (Table 24) [298, 299].

**Table 24. Trials of hydrotherapy versus land-based therapy**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Yozbatiran, 2004[299] | N=30<br>4 weeks | **Hydrotherapy vs. land-based therapy**<br>Pain, mean improvement in VAS (0-10 scale): 3.53 vs. 2.53 (NS)<br>ODI, mean improvement: 19.34 vs. 17.34 (NS) | 2/11 |
| Sjogren, 1997[298] | N=60<br>4 weeks | **Hydrotherapy vs. land-based therapy**<br>Pain, mean improvement in VAS (0-10 scale): 1.35 vs. 0.79 (NS)<br>ODI, mean improvement: 3.25 vs. 2.40 (NS) | 3/11 |

*Safety*

Adverse events were not reported in any of the trials.

*Costs*

We found no studies on costs.

### Summary of evidence

- There is insufficient evidence (one poor-quality trial) to judge the efficacy of hydrotherapy versus delayed hydrotherapy (level of evidence: poor).
- There is consistent evidence from two lower-quality trials that hydrotherapy and land-based therapy are associated with similar outcomes in patients with chronic low back pain (level of evidence: fair).
- There is no evidence on the effects of hydrotherapy in patients with acute low back pain.

**Recommendations and findings from other guidelines**

None of the guidelines address hydrotherapy.

**Yoga**

Yoga can typically be distinguished from traditional exercise by its utilization of specific body positions, breathing techniques, and emphasis on mental focus. One challenge in evaluating the efficacy of yoga is that many styles are practiced, each with different emphases and postures.

Results of search: systematic reviews

We identified no systematic reviews evaluating the efficacy of yoga in patients with low back pain.

Results of search: trials

We identified three trials (one higher quality [300]) evaluating the efficacy of yoga in patients with chronic low back pain (Table 25) [300-302].

*Efficacy of yoga*

In the higher-quality trial (N=101), six weeks of viniyoga (a therapeutically oriented style) was modestly superior to both conventional exercise and a self-care education book for back related function at twelve weeks (mean difference on RDQ score –1.8, 95% DCI –3.5 to –0.1 and mean difference –3.4, 95% CI –5.1 to –1.6, respectively), but only superior to the self-care book at 26 weeks (mean difference –3.6, 95% CI –5.4 to –1.8) [300]. Effects on symptom bothersomeness scores were similar at 12 weeks for all three interventions, though yoga was superior to the self-care book at 26 weeks (mean difference –2.2, 95% CI –3.2 to –1.2). Yoga was also associated with decreased medication use at week 26 (21% vs. 50% vs. 59%, $p<0.05$ for yoga versus either comparator), though there was no significant difference in the proportion of patients visiting health care providers for low back pain.

Two lower-quality, smaller trials (N=60 and 22) evaluated Iyengar yoga, a commonly practiced style of Hatha yoga that makes frequent use of props. The larger trial found yoga more effective than exercise instruction (from a weekly newsletter) for reducing disability [301]. The benefits were sustained for 3 months after the end of a 16-week course of treatment (-8.5 vs. –10.4 on a 70 point scale, $p=0.009$). Differences on pain outcomes were modest and only significant when adjusted for baseline differences in

the intervention groups. In addition, interpreting the results is difficult because nearly a third of the patients did not complete the study or were lost to follow-up. The other trial found no significant differences on measures of back-specific function or depression [302]. Pain outcomes were not assessed.

**Table 25. Trials of yoga versus exercise**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Sherman, 2006[300] | N=101<br>26 weeks | **Viniyoga versus exercise**<br>RDQ Score (0 to 24 scale), mean difference between groups relative to baseline: -1.8 (-3.5 to –0.1) at 12 weeks (p=0.034) and –1.5 (-3.2 to 0.2) at 26 weeks (p=0.092)<br><br>**Viniyoga versus self-care book**<br>RDQ Score, mean difference between groups relative to baseline: -3.4 (-5.1 to –1.6) at 12 weeks (p=0.0002) and –3.6 (-5.4 to –1.8) at 26 weeks (p<0.001) | 8/11 |
| Williams, 2005[301] | N=60<br>7 months | **Iyengar yoga versus exercise education**<br>Present Pain Index, mean change at 7 months (0 to 5 scale): -0.5 vs. –0.9, p=0.140<br>Pain Disability Index, mean change at 7 months (7 to 70 scale): -8.5 vs. –10.4, p=0.009<br>Pain, VAS, mean change at 7 months (0 to 10 scale): 1.2 vs. –1.6, p=0.398 | 4/11 |
| Galantino, 2004[302] | N=22<br>6 weeks | **Iyengar yoga versus usual activities**<br>Oswestry Disabilty Index (change from baseline): 3.83 vs. 2.18<br>Proportion with lower scores on Oswestry: 46% vs. 40% | 3/11 |

*Safety*

No study reported safety outcomes.

*Costs*

We found no studies on costs.

### Summary of evidence

- Viniyoga was superior to traditional exercises and a self-care education book for back-specific functional status and use of medications in one higher-quality trial (level of evidence: fair).
- There is insufficient evidence to judge the effectiveness of other types of yoga (two small, low quality trials of Hatha yoga) (level of evidence: poor).

### Recommendations and findings from other guidelines

None of the guidelines address yoga.

## *Multidisciplinary Interventions*

### Multidisciplinary rehabilitation

Results of search: systematic reviews

We identified higher-quality Cochrane reviews evaluating the efficacy of multidisciplinary rehabilitation in patients with chronic (>3 months) [303, 304] and subacute (defined as >4 weeks and <3 months in duration) [71, 72] low back pain. They included ten (three higher quality) and two (both lower quality) trials, respectively. No systematic review evaluated the effectiveness of multidisciplinary rehabilitation in patients with acute low back pain. We included one other recent systematic review evaluating multidisciplinary rehabilitation and behavioral interventions [305]. Another recent systematic review was excluded because it only included one relevant trial that was already included in the Cochrane review [306]. We also excluded one older systematic review [242].

Results of search: trials

We identified one recent (lower-quality) trial of intensive multidisciplinary rehabilitation in high-risk patients with acute low back pain[78].

*Efficacy of multidisciplinary rehabilitation versus usual care or non-multidisciplinary rehabilitation*

One of the Cochrane reviews found that in patients with subacute low back pain (two lower-quality RCTs, N=103 and 104), multidisciplinary rehabilitation (defined as an intervention consisting of a physician's consultation plus a psychological, social, or vocational intervention, or a combination of these) with a workplace visit is more effective than usual care [71, 72]. In one of the trials, return to work averaged 10 weeks (SD=12.7) with multidisciplinary rehabilitation (including measurement of functional capacity, a work-place visit, back school, and graded exercise with an operant-conditioning approach) versus 15 weeks (SD=15.6) with traditional care (p=0.03 for difference), and there was less sick leave in the multidisciplinary rehabilitation group in the following year (mean difference –7.5 days, 95% CI=-15.06 to 0.06) [289]. Subjective disability was also modestly superior in the intervention group. In the second trial, the duration of absence from work was lower with a combined occupational and clinical intervention (occupational physician consultation and work place visit) and clinical intervention (back school, visit to back specialist, and multidisciplinary work rehabilitation including functional rehabilitation therapy if needed) compared to the

occupational or clinical interventions alone or to usual care (median days off work 60 vs. 67 vs. 131 vs. 120 days, p<0.05) [307]. Return to work was 2.4 times faster in the combined intervention group compared to the usual care group (95% CI 1.19 to 4.89) and 1.91 times faster with any occupational intervention compared to the two groups without the occupational intervention (95% CI 1.18 to 3.1). The combined intervention group also was associated with greater improvements in Oswestry scores after one year compared to usual care (mean difference 10.7, p=0.02).

The other Cochrane review (10 trials) included three trials (two higher quality) [308-310] of patients with chronic low back pain that found intensive (>100 hours), daily multidisciplinary biopsychosocial rehabilitation (defined by the reviewers as an intervention with a physical component plus a psychological and/or social/occupational component meeting pre-defined criteria) with functional restoration superior to non-multidisciplinary rehabilitation or usual care for improving functional status (standardized mean difference –0.40 to –0.90 at 3-4 months and –0.56 to –1.07 at 60 months), and two trials (both higher quality) [308, 309] showing superiority for pain outcomes (standardized mean difference –0.56 and –0.74 at 3-4 months and –0.51 and 0.00 at 60 months) [303, 304]. There was inconsistent evidence regarding vocational outcomes, with one higher-quality trial [309] showing improvements in 'work-readiness' but two other higher-quality trials [310, 311] showing no benefits on sickness leave. In contrast to the intensive interventions, less intensive multidisciplinary rehabilitation was not associated with improvements in pain, function, or vocational outcomes compared to non-multidisciplinary outpatient rehabilitation or usual care (five trials, three higher quality).

The non-Cochrane systematic review found multidisciplinary rehabilitation modestly superior to usual care or non-multidisciplinary rehabilitation for the proportion returned to work (effect size 0.53, 95% CI 0.19 to 0.86 at long-term follow-up), but not for pain intensity [305]. However, it included fewer (five) trials than the Cochrane review, and appeared to combine results of trials evaluating intensive and less intensive multidisciplinary rehabilitation.

One recent, small (N=70) trial found that an intensive multidisciplinary intervention (including 3 physician evaluations and a total of 45 physical therapy, biofeedback/pain

management, group didactic, and case manager/occupational therapy sessions) was associated with improved pain, decreased disability, and decreased costs (mainly related to lost wages) compared to usual care in patients with low back pain of less than 8 weeks duration at higher risk for chronic disability based on a screening tool (Table 26) [78].

**Table 26. Trial of intensive multidisciplinary rehabilitation in patients with low back pain for <8 weeks**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Gatchel, 2005[78] | N=70<br>12 months | **Functional restoration vs. usual care**<br>Return to work at 12 months: 91% vs. 69% (p=0.027<br>Average number of disability days due to back pain: 38 vs. 102, p=0.001<br>Average self-rated pain over last 3 months: 27 vs. 43, p=0.001<br>Taking opioid analgesics: 27% vs. 44%, p=0.020 | 2 or 3/11 |

*Safety*

No study evaluated safety.

*Costs*

In one trial of workers disabled due to low back pain, multidisciplinary rehabilitation with physical conditioning was associated with an average cost-benefit of $18,585 after 6.4 years of follow-up, though the difference was not statistically significant, in part because of skewed distributions [312]. Another trial found a light multidisciplinary intervention associated with an average cost-benefit of about $15,000 after 2 years relative to usual care in workers with chronic low back pain [313]. A cost-benefit analysis of the trial comparing an intensive, early multidisciplinary intervention in patients with acute low back pain identified as higher risk for chronic disability estimated a net gain of $9122, mostly related to a reduction in lost wages in the intervention group [78].

**Summary of evidence**

- In two lower-quality trials, multidisciplinary rehabilitation (particularly with a work site visit) in patients with subacute low back pain was associated with quicker return to work, reduced sick leave, and improved disability relative to usual care (level of evidence: fair).

- Intensive multidisciplinary rehabilitation with functional restoration is more effective than usual care or non-multidisciplinary rehabilitation for reducing pain and improving function in patients with chronic low back pain, though effects on work-related outcomes are mixed (four trials, three higher-quality) (level of evidence: good).
- Less intensive (<100 hours) multidisciplinary rehabilitation was not more effective than usual care or non-multidisciplinary rehabilitation (five trials) (level of evidence: good).
- There is insufficient evidence from one, lower-quality RCT to determine the efficacy of multidisciplinary rehabilitation in patients with acute low back pain (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend considering multidisciplinary treatment programs in occupational settings for workers on sick leave for more than 4-8 weeks and multidisciplinary intervention with functional restoration in patients with chronic low back pain who have failed monodisciplinary treatment options.

### Physical conditioning programs (work conditioning, work hardening, and functional restoration)

Physical conditioning programs (variously referred to as work conditioning, work hardening, and functional restoration/exercise programs) involve simulated or actual work tasks in a supervised environment in order to enhance job performance skills and improve strength, endurance, flexibility, and cardiovascular fitness in injured workers [314]. The goal of such programs is to improve functional and work outcomes. One important challenge in assessing the efficacy of physical conditioning programs, however, is the wide variation in the content (such as the use of behavioral therapy or the type of exercise) and intensity of treatments.

Results of search: systematic reviews

We identified one good-quality Cochrane review (19 trials, 10 rated higher quality) on the efficacy of physical conditioning programs in patients with acute or chronic low back pain [74, 75]. Several of the trials evaluated in this Cochrane review were also included in the Cochrane reviews of multidisciplinary rehabilitation for subacute (2 of 2 trials) [71, 72] and chronic (3 of 10 trials) [303, 304] low back pain. We excluded one older systematic review [314].

Results of search: trials
We identified one additional trial of an intensive multidisciplinary functional restoration intervention in patients with low back pain for less than eight weeks (see discussion in multidisciplinary rehabilitation section) [78].

*Efficacy of physical conditioning programs versus usual care*
In patients with acute low back pain, the Cochrane review found that only one [315] of five included trials (three rated higher quality [286, 315, 316]) found a positive treatment effect from physical conditioning programs on time lost from work, proportion of subjects off work, or functional status [74, 75]. A recent trial not included in the Cochrane review found an intensive, multidisciplinary functional restoration intervention superior to usual care for several outcomes in high-risk patients with acute low back pain (see section on multidisciplinary rehabilitation) [78].

In patients with chronic low back pain (14 trials), physical conditioning programs that included a cognitive-behavioral approach generally appeared effective for reducing time off work. In two relatively homogeneous trials [289, 307] (one higher quality [307]) of physical conditioning programs versus usual care, the number of sick days lost at 12 months follow-up compared to usual care or advice averaged 45 days (95% CI 3 to 88). There was little evidence for or against the efficacy of specific exercises not accompanied by a cognitive behavioral approach.

*Efficacy of physical conditioning programs versus other interventions*
The Cochrane review [74, 75] included two higher-quality trials [317, 318] that found that physical conditioning programs were associated with an average of 112 and 243 fewer lost work days compared to passive physiotherapy in patients with chronic low back pain.

*Safety*
No study evaluated safety.

*Costs*
See the section on multidisciplinary rehabilitation.

**Summary of evidence**

- Evidence of benefits from six heterogeneous trials of physical conditioning programs in patients with acute low back pain is inconsistent, with the majority of studies showing no benefit (level of evidence: fair).
- Physical conditioning programs with a cognitive-behavioral approach are effective for reducing sick leave relative to usual care in two trials (one higher quality) of patients with chronic low back pain (level of evidence: fair). There is no clear benefit from physical conditioning programs without a cognitive-behavioral approach.
- Physical conditioning programs were effective for reducing days lost from work relative to passive physical therapy in patients with chronic low back pain (two high quality trials) (level of evidence: good).

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend considering multidisciplinary treatment programs in occupational settings for workers on sick leave for more than 4-8 weeks and multidisciplinary intervention with functional restoration in patients with chronic low back pain who have failed monodisciplinary treatment options.

## *Physical Modalities*

### Interferential therapy

Interferential therapy involves the application of a medium frequency alternating current modulated to produce low frequencies up to 150 Hz. It is thought to increase blood flow to tissues and provide pain relief, and is more comfortable for patients than transcutaneous electrical nerve stimulation.

Results of search: systematic reviews
We found no systematic reviews of interferential therapy.

Results of search: trials
We identified three trials (one higher-quality [319]) of interferential therapy [319-321]. Two trials evaluated patients with subacute (>4 weeks) back pain and the other evaluated patients with back pain of mixed duration (mainly chronic). Interferential therapy was compared to spinal manipulation, traction, and a back self-care book in one trial each.

*Efficacy of interferential therapy versus spinal manipulation or traction*

One higher-quality trial (N=240) found no difference between an 8-week course of interferential therapy versus spinal manipulation for pain, functional disability, quality of life, work status, or other outcomes after 6 to 12 months in patients with subacute (>4 weeks ) low back pain (Table 27) [319]. A lower-quality trial (N=152) also found no difference between spinal manipulation and traction on pain or the ODI after 3 months in patients with back pain of unspecified duration (primarily >5 years) [320].

**Table 27. Trials of inteferential therapy versus other interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hurley, 2004[319] | N=240<br>12 months | **Interferential therapy versus manipulative therapy versus combination** (mean improvement at 12 months)<br>Pain (0 to 100 VAS): -26.5 vs. -18.2 vs. -25.7 (NS)<br>McGill Pain Questionnaire Pain Rating Index (0 to 78): -8.3 vs. -6.4 vs. -9.2 (NS)<br>RDQ score (0 to 24): -4.9 vs. -4.7 vs. -6.5 (NS)<br>SF-36: No differences<br>Recurrent low back pain: 69% vs. 77% vs. 64% (NS)<br>Absent from work >30 days: 8% vs. 12% vs. 12% | 7/11 |
| Werners, 1999[320] | N=152<br>3 months | **Interferential therapy versus traction** (mean difference from baseline to 3 months)<br>Pain (0 to 100): -9.8 vs. -14.6 (NS)<br>Oswestry (0 to 100): -7.7 vs. -7.4 | 4/11 |

*Efficacy of interferential therapy plus a back self-care book versus a back self-care book alone*

One small (N=60), lower-quality trial in patients with subacute back pain (>4 weeks) found that interferential therapy applied to the paraspinal area (near the target spinal nerve) plus a back self-care book was superior to the back self-care book alone on the RDQ Questionnaire after 3 months, but not on the Pain Rating Index or EQ-5D (Table 28) [321]. However, baseline RDQ Questionnaire scores were higher in the interferential therapy group (median 9.0 vs. 5.0). In fact, median RDQ scores were identical at 3 months in the two groups (1.0 vs. 1.0). This trial also found no differences between interferential therapy applied to the painful area plus a self-care book and the self-care book alone.

**Table 28. Trial of inteferential therapy + self-care book versus a self-care book alone**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hurley, 2001[321] | N=60<br>3 months | **Interferential therapy applied to painful area + self-care book versus interferential therapy applied to area of spinal nerve + self-care book versus self-care book alone** (difference in median scores from baseline to 3 months)<br>McGill Pain Questionnaire Pain Rating Index (0 to 78): +2.2 vs. -2.5 vs. -9.7<br>RDQ Score (0 to 24): -3.5 vs. -8.0 vs. -4.0<br>EQ-5D: No difference<br><br>RDQ Score, median score at 3 months: 2.0 vs. 1.0 vs. 1.0 | 5/11 |

*Safety*

One trial reported no adverse events with interferential therapy or manipulation [319].

The other two trials reported no information on adverse events.

*Costs*

We found no studies evaluating costs.

### Summary of evidence

- One higher-quality trial found no difference between interferential therapy and manipulation in patients with subacute low back pain (level of evidence: fair).
- One lower-quality trial found no difference between interferential therapy and traction in patients with primarily chronic low back pain (level of evidence: poor).
- One lower-quality trial found no clear differences between interferential therapy with electrodes applied in the paraspinal area or to the painful area plus a self-care book versus a self-care book alone (level of evidence: poor).

### Recommendations and findings from other guidelines

- The AHCPR guidelines found physical agents and modalities (including electrical stimulation) of insufficiently proven benefit to justify their cost in patients with acute low back pain (strength of evidence: C).
- The VA/DoD and UK RCGP guidelines reached similar conclusions.
- The European COST guideline made no recommendation for interferential therapy in acute low back pain, and found insufficient evidence to recommend interferential therapy for chronic low back pain.

### *Low-level laser*

Low-level laser therapy involves the application of laser at wavelengths varying from 632 to 904 nm to the skin in order to apply electromagnetic energy to soft tissues.

Results of search: systematic reviews

We identified no systematic reviews evaluating the efficacy of low-level laser in patients with low back pain. One recent systematic review of low-level laser therapy for various musculoskeletal conditions included four trials [322-325] of patients with low back pain [326]. Two older systematic reviews of low-level laser for various musculoskeletal conditions included only one [327] or two [328] trials of patients with low back pain.

Results of search: trials

We identified seven trials (four higher-quality [322-325]) of low-level laser therapy in patients with low back pain [322-325, 329-331]. Four evaluated patients with chronic low back pain, one evaluated patients with acute low back pain, and two did not specify the duration of back pain. Although low-level laser is frequently used in Russia and Asia, we found no non-English language trials. However, studies in those languages are frequently not indexed in English-language electronic databases.

*Effectiveness of low-level laser therapy versus sham therapy or placebo*

Results of six trials evaluating low-level laser in patients with chronic low back pain or low back pain of unspecified duration are difficult to interpret because they used heterogeneous outcome measures and different types of lasers at varying doses. Two [322, 324] of the three [323] higher-quality trials found that laser was superior to placebo or sham laser at the end of treatment for back-specific function (Oswestry score), proportion with pain relief, and ratings of overall response (Table 29). In one trial, these benefits persisted for one month following treatment [322], and in another, relapse of back pain was less likely 6 months following the end of treatment [324]. One other higher-quality trial found laser more ‘effective’ than sham, but used a poorly described and unvalidated outcome measure [325]. One lower-quality trial of patients with back pain of unspecified duration reported similar findings, with decreased relapse through one year following treatment [330]. In the single higher quality trial that found no difference between laser and sham laser, each group also received a standardized home exercise regimen [323].

**Table 29. Trials of low-level laser therapy versus sham laser**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Basford, 1999[322] | N=61<br>1 month after end of treatment | **Nd:YAG laser versus sham** (mean change from baseline)<br>ODI score: -6.3 vs. –2.1<br>Maximal pain in the last 24 hours (0 to 100 VAS): -16.1 vs. –2.3 | 8/11 |
| Soriano, 1998[324] | N=85<br>6 months after end of treatment | **GaAS laser versus sham**<br>Proportion with >60% pain relief at end of treatment: 71% (27/38) vs. 36% (12/33), p<0.007 | 6/11 |
| Toya, 1994[325] | N=41<br>1 day after treatment | **GaAS laser versus sham**<br>Treatment 'effective': 94% (15/16) vs. 48% (12/25) | 10/11 |
| Klein, 1990[323] | N=20<br>1 month after treatment | **GaAS laser + exercise versus sham + exercise** (mean change from baseline)<br>Pain (0 to 7.5 VAS): -1.3 vs. –1.2<br>RDQ Disability score: -1.8 vs. –3.0 | 6/11 |
| Longo, 1988[330] | N=120<br>1 year after treatment | **904 nm laser vs. 10600 nm laser vs. sham**<br>Complete disappearance of pain 1 month after treatment: 95% vs. 82.5% vs. 2.5%<br>Relapse 1 year after treatment: 65% vs. 70% vs. 95% | 5/11 |

A recent systematic review found low level laser effective for a variety of musculoskeletal conditions when the subgroup of trials evaluating higher doses were analyzed [326]. The criteria for adequate doses were pre-defined for various locations in an *a priori* matter. There were too few trials (four) to assess the effects of dose in patients specifically with low back pain.

*Effectiveness of low-level laser therapy versus other interventions: trials*

One trial of low-level laser for acute low back pain was uninterpretable because of poor methodologic quality, unclear reporting of outcomes, and comparison to mesotherapy (an unproven technique involving injections of various substances into fat) (Table 30) [331]. Another lower-quality trial found that laser, exercise, and the combination of laser plus exercise resulted in similar pain and back-specific functional status outcomes in patients with chronic low back pain [329].

**Table 30. Trials of low-level laser therapy versus other interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Monticone, 2004[331] | N=22<br>Up to 12 months after treatment | **Laser versus stabilization (exercise, lumbar therapy, and mesotherapy)**<br>Pain at rest (VAS 0 to 10), mean change from baseline and 12 months following end of treatment: 0 vs. –5; -1 vs. –6<br>Pain with movement (VAS 0 to 10), mean change from baseline and 12 months following end of treatment: -4 vs. –7, -2 vs. –8 | 1/11 |
| Gur, 2003[329] | N=75<br>1 month after treatment | **Laser versus exercise versus laser + exercise (mean change from baseline)**<br>Pain (0 to 10 VAS): -4.2 vs. –3.6 vs. –4.4 (p>0.05)<br>RDQ Score: -9.7 vs. –9.6 vs. –11.5 (p>0.05)<br>Modified ODI: -16.4 vs. –16.9 vs. –17.6 (p>0.05) | 3/11 |

*Safety*

In a systematic review of low-level laser therapy for various musculoskeletal conditions, six of the 11 trials evaluating higher doses reported no adverse events [326]. One other trial reported one transient adverse event in both the laser and sham groups [322].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is conflicting evidence from five trials (four higher quality) on the effectiveness of low-level laser compared to placebo or sham laser in patients with chronic low back pain. Four trials (three higher quality) found laser therapy superior to sham for pain or functional status up to one year following treatment, but one higher-quality trial found no difference between laser and sham in patients also receiving exercise. In addition, interpretation of results is compromised by the use of heterogeneous and non-standardized outcome measures in some studies (level of evidence: fair).
- Low-level laser was equivalent to exercise or the combination of laser plus exercise in one lower-quality trial (level of evidence: poor).
- There is no reliable evidence (one lower-quality trial) on low-level laser therapy in patients with acute low back pain (level of evidence: poor).
- Additional research is needed on optimal doses of low-level laser therapy, number of sessions, and type of laser in patients with chronic low back pain.

- Publication bias from non-English language studies could affect these conclusions.

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found physical agents and modalities (including low-level laser) of insufficiently proven benefit to justify their cost for acute low back pain (strength of evidence: C).
- The VA/DoD guidelines reached similar conclusions.
- The UK RCGP guidelines don't mention low-level laser.
- The European COST guidelines found insufficient evidence to recommend low-level laser for chronic low back pain.

**Short-wave diathermy**

Short wave diathermy involves the application of short wave electromagnetic radiation with a frequency range from 10 to 100 MHz in order to heat the tissues.

Results of search: systematic reviews

We identified no systematic review of short-wave diathermy. However, a good-quality Cochrane review of spinal manipulation [332, 333] included two trials (one higher-quality [334]) comparing short-wave diathermy to sham diathermy or manipulation.

Results of search: trials

We identified one additional higher-quality trial comparing short wave diathermy to exercises, traction, and sham in patients with back pain for longer than one week [335].

*Efficacy of short-wave diathermy versus sham diathermy*

One higher-quality trial included in the Cochrane review found no significant differences in median pain scores after 12 weeks in patients with low back pain for at least two months randomized to short-wave diathermy versus sham diathermy [334]. Another higher-quality trial (not included in the Cochrane review) found no differences in global response (other outcomes not reported) between short-wave diathermy and sham diathermy after 2 weeks in patients with back pain for longer than one week (widely varying durations) (Table 31) [335].

**Table 31. Additional trial of short-wave diathermy in patients with back pain of at least one week in duration**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Sweetman, 1993[335] | N=400 | **Short wave diathermy versus extension exercises versus traction versus sham diathermy**<br>Global effect "better" at 2 weeks: 39% (39/100) vs. 45% (45/100) vs. 49% (49/100) vs. 37% (37/100) (NS) | 6/11 |

*Efficacy of short-wave diathermy versus other interventions*

One higher-quality trial in the Cochrane review of spinal manipulation found no significant differences between short-wave diathermy and spinal manipulation on median pain scores or requirement for analgesics after 12 weeks in patients with low back pain for at least two months [334]. In a small, lower-quality trial (also included in the Cochrane review), the proportion of patients with acute low back pain with continued pain was higher after two weeks with short-wave diathermy (9 of 12) compared to spinal manipulation (1 of 12) [336]. However, no details about the short wave diathermy intervention were provided.

The higher-quality trial not included in the Cochrane review found no difference between short-wave diathermy and either extension exercises or traction after two weeks in patients with low back pain for longer than one week [335].

*Safety*

No studies assessed safety.

*Cost*

We found no studies evaluating costs.

**Summary of evidence**

- One higher-quality trial found no difference between short-wave diathermy and sham diathermy on pain after 12 weeks in patients with low back pain for at least 2 months (level of evidence: fair).
- In patients with back pain of varying duration, one higher-quality trial found no difference between short-wave diathermy, sham diathermy, exercise, or traction using an unvalidated measure of global effect after 2 weeks (level of evidence: fair).

- One higher-quality trial found no difference between short-wave diathermy and spinal manipulation on pain after 12 weeks in patients with low back pain for at least 2 months (level of evidence: fair).
- In patients with acute low back pain, one small, lower-quality trial found a lower proportion of patients reporting pain relief after 2 weeks in patients randomized to short-wave diathermy compared to spinal manipulation (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found physical agents and modalities (including short wave diathermy) of insufficiently proven benefit to justify their cost in patients with acute low back pain (strength of evidence: C).
- The VA/DoD and UK RCGP guidelines reached similar conclusions.
- The European COST guidelines found insufficient evidence to recommend short-wave diathermy for chronic low back pain.

**Traction**

Results of search: systematic reviews

We identified one higher-quality Cochrane review (24 RCTs, 5 rated high-quality) of traction for low back pain [337, 338]. All of the trials evaluated patients with low back pain and sciatica, though seven also included patients without sciatica. We also included three other recent systematic reviews [129, 283, 339]. We excluded three older systematic reviews [110, 277, 340].

Results of search: trials

We did not search for additional trials.

*Efficacy of traction versus placebo, sham, or no treatment*

The Cochrane review [337, 338] included two higher-quality trials [341-343] of patients with low back pain of varying duration (with or without sciatica) that found that traction was no more effective than placebo, sham, or no treatment, for pain, functional status, overall improvement, or work absenteeism. In patients with sciatica of mixed duration, two lower quality trials [344, 345] found autotraction more effective than placebo, sham, or no treatment for pain, global improvement, or work absenteeism, but other forms of traction (continuous or intermittent traction) were not associated with beneficial effects (8 trials, 1 higher-quality [346]).

Three other systematic reviews did not include any trials not in the Cochrane review and either concluded that there is no evidence that traction is effective for low back pain (with [129] or without [283] sciatica), or found insufficient evidence to draw reliable conclusions [339].

*Efficacy of traction versus other active interventions*

Six RCTs (five rated lower-quality) compared various types of traction to other active treatments in patients with sciatica of varying duration. In the lone higher-quality trial, autotraction was superior to abdominal and pelvic floor muscle isometric exercises at the end of treatment [347]. However, the benefits were no longer present after one month. In another trial, intermittent traction was superior to physiotherapy for global well-being after three to five weeks, though no better than patients receiving hot packs only [348]. In the other four trials, no statistically significant differences were seen when traction was compared to spinal manipulation and a corset [349], an infra-red lamp [350, 351], exercise and shortwave diathermy [335], or strengthening and range of motion exercises [352]. In patients with chronic low back pain and sciatica, traction was no more effective than isometric exercise in two trials [352, 353], and superior to TENS in the third [354] (none rated high quality).

In one higher-quality trial of patients with low back pain of varying duration without sciatica, there were no differences on pain or function at three months after treatment in patients randomized to intermittent traction versus interferential treatment [320].

*Efficacy of different types of traction*

One small (N=44) trial found autotraction more effective than mechanical traction for global improvement (but not pain or function) in chronic LBP patients with or without sciatica [355]. In two other small trials, there were no differences between static and intermittent traction [356] or between autotraction and manual traction [357]. One trial found no differences in effects of intermittent or continuous traction using different levels of force [358].

*Safety*

Adverse events were generally reported inconsistently and poorly in the 24 trials included in the Cochrane review [337, 338]. Two trials reported no adverse events [346, 359]. Six other trials reported adverse events including increased pain, increased

rate of subsequent surgery, aggravation of neurological signs, aggravation of symptoms [337, 338]. The other sixteen trials did not mention adverse events.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is consistent evidence from multiple trials that continuous or intermittent traction are not associated with superior outcomes compared to placebo, sham, or other treatments for patients with low back pain of varying duration, either with or without sciatica (level of evidence: good).
- There is evidence from two lower-quality trials that autotraction is superior to placebo or sham therapies and one lower quality trial that autotraction is superior to mechanical traction (level of evidence: fair).
- Adverse events reported in the trials included aggravation of signs and symptoms and subsequent surgery, but were inconsistently and poorly reported (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against traction for treatment of patients with acute low back problems (strength of evidence: B).
- The VA/DoD and UK RCGP also recommend against traction, but rate the strength of evidence differently (strength of evidence: C and ***, respectively).
- The European COST guidelines also recommend against traction for acute low back pain and found insufficient evidence to recommend traction for chronic low back pain.

**Ultrasound**

Results of search: systematic reviews

We identified one higher-quality systematic review evaluating the effectiveness of therapeutic ultrasound in patients with low back pain [283]. It included one randomized trial [360] and one non-randomized study [361] (both rated lower-quality). Four other systematic reviews evaluated ultrasound therapy in patients with a variety of musculoskeletal conditions, but did not include any additional trials of low back pain [277, 362-364].

Results of search: trials

We identified no additional trials of therapeutic ultrasound.

*Efficacy of ultrasound versus sham or placebo*

One non-randomized study found that in patients with acute low back pain from a herniated disc, ultrasound ws superior to sham ultrasound or analgesics for the proportion of patient pain free (41% vs. 12% vs. 6.8%) [361]. Patients in all groups were also prescribed bed rest.

In patients with chronic low back pain, one small (N=36) randomized trial found no difference in pain improvement after one month of therapy [360]. Functional status and other outcomes were not reported.

Three systematic reviews found little evidence of beneficial effects with ultrasound relative to placebo for other musculoskeletal conditions, with the possible exceptions of single trials of lateral epicondylitis, carpal tunnel syndrome, and calcific tendinitis of the shoulder [277, 362, 364]

*Safety*

Adverse events were not reported in the two studies. None of the systematic reviews of therapeutic ultrasound for various musculoskeletal conditions assessed adverse events. There is one report of two patients with a herniated disc who had transiently increased radicular pain after application of therapeutic ultrasound [365].

*Costs*

We found no study evaluating costs.

**Summary of evidence**

- There is insufficient evidence (single low-quality studies) to judge the efficacy of ultrasound for low back pain (level of insufficient: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found physical agents and modalities (including ultrasound) of insufficiently proven benefit to justify their cost in acute low back pain (strength of evidence: C).
- The VA/DoD and UK RCGP guidelines reached similar conclusions.
- The European COST guidelines found insufficient evidence to recommend ultrasound therapy for chronic low back pain.

## *Other Non-invasive Interventions*

### Behavioral interventions

Results of search: systematic reviews

We identified two recent, higher-quality systematic reviews evaluating the efficacy of behavioral interventions in patients with chronic low back pain [73, 305]. One was an update of an older (van Tulder 2000) Cochrane review (21 trials, 7 high quality) [73]. We excluded five other older systematic reviews [110, 132, 249, 251, 366].

Results of search: trials

Several trials investigating interventions for identifying and treating psychosocial risk factors in patients with acute or subacute low back pain are discussed under section Key Question 1a.

*Efficacy of behavioral interventions versus wait list control*

The Cochrane review [73] included four trials (one higher quality [367]) that found combined respondent-cognitive therapy moderately superior to wait list control for short-term pain intensity (pooled effect size 0.59, 95% CI 0.10 to 1.09), but not for functional status (pooled effect size 0.31, 95% CI –0.20 to 0.82). It also included two lower-quality trials that found progressive relaxation associated with a large positive effect on short-term pain (effect size 1.16, 95% CI 0.47 to 1.85) and behavioral outcomes (effect size 1.31, 95% CI 0.61 to 2.01). Evidence regarding the effects of EMG biofeedback relative to wait list control was mixed: although three trials found a positive effect on pain intensity (effect size 0.84, 95% CI 0.32 to 1.35), a fourth trial found no differences. In addition, there were no differences between EMG biofeedback and wait list control for behavioral outcomes. There were also no differences between operant treatment and wait list controls for general functional status (two trials of behavioral outcomes).

The second systematic review (22 trials) also found both cognitive-behavioral and self-regulatory therapy (such as relaxation therapy) superior for pain intensity compared to wait list controls (effect size 0.62, 95% CI 0.25 to 0.98 and 0.75, 95% CI 0.35 to 1.15, respectively) [305]. Self-regulatory therapy was also superior to wait list controls for measures of depression (effect size 0.81, 95% CI 0.11 to 1.52).

*Efficacy of behavioral interventions versus other active interventions*

The Cochrane review [73] included one higher-quality trial [289] that found operant treatment in combination with a graded activity program associated with earlier return to work and reduced long-term sick leave compared to usual care in workers with subacute low back pain [289]. One lower-quality trial found no difference between behavioral treatment and exercise on pain intensity, functional status, and behavioral outcomes through 12 months [368].

The other systematic review found no differences between behavioral therapy (including behavioral therapy as part of multidisciplinary treatment) and other active interventions (including physiotherapy and usual treatments) on pain intensity, pain interference, health care visits, or medication use [305]. However, behavioral therapy was associated with improved short- and long-term disability, with effect sizes of 0.36 (3 trials, 95% CI 0.06 to 0.65) and 0.53 (4 trials, 95% CI 0.19 to 0.86), respectively.

*Comparative efficacy of different behavioral interventions*

Neither systematic review found clear differences in head-to-head comparisons of different types of behavioral therapy [73, 305]. In the Cochrane review, the best-studied comparisons were cognitive-behavioral versus operant therapy (three higher-quality trials [367, 369, 370]) and cognitive versus respondent therapy (three lower-quality trials [371-373]).

*Safety*

Safety was not assessed in any of the systematic reviews.

*Costs*

One trial comparing different operant interventions found no significant differences in costs or utilities [374].

**Summary of evidence**

- There is consistent evidence from four RCTs (one higher quality) that cognitive-behavioral therapy is moderately more effective than wait list control for short-term pain intensity in patients with chronic low back pain, though there were no significant differences on functional status and other outcomes (level of evidence: good).

- Two lower-quality trials found progressive relaxation associated with large positive benefits relative to wait list control for pain intensity and behavioral outcomes in patients with chronic low back pain (level of evidence: fair).
- Evidence on benefits associated with EMG biofeedback relative to wait list control is mixed, though three out of four trials demonstrated a moderate benefit on pain intensity in patients with chronic low back pain (level of evidence: fair).
- Operant therapy was not associated with any benefits relative to wait list controls in three trials of patients with chronic low back pain (level of evidence: good).
- Behavioral interventions have not clearly been shown to be superior to other active interventions for most outcomes, though one systematic review found moderate benefits for short- and long-term disability (level of evidence: fair).
- There is no clear evidence from head-to-head comparisons that one behavioral intervention is superior to any other (level of evidence: fair to good).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against biofeedback in patients with acute low back problems (strength of evidence: C).
- The Va/DoD guideline recommendations are similar.
- The UK RCGP guidelines found conflicting evidence on the effectiveness of biofeedback for chronic low back problems, and no evidence on the effectiveness for acute low back problems (strength of evidence: *).
- The European COST guidelines recommend against behavioural therapy for acute low back pain, but recommend behavioral therapy in patients with chronic low back pain.

**Massage**

Results of search: systematic reviews

We identified one higher-quality Cochrane review of 9 trials (5 high quality) of massage for low back pain [375, 376]. One other recent, higher-quality systematic review came to similar conclusions as the Cochrane review [220]. We excluded two older systematic reviews [283, 377].

Results of search: trials

We did not search for additional trials.

*Efficacy of massage versus placebo or sham massage.*

The Cochrane review [375, 376] included one higher-quality sham-controlled trial of massage [378]. It found that in patients with subacute or chronic low back pain,

massage was superior to sham laser for short- and long-term pain intensity (standardized mean difference –0.80, 95% CI –1.37 to –0.23 and –0.49, 95% CI –1.05 to 0.06, respectively) and functional outcomes (SMD –1.06, 95% CI –1.65 to –0.47 and –0.96, 95% CI –1.58 to –0.35).

*Efficacy of massage versus other active interventions*

The Cochrane review found massage inferior to manipulation in three trials (one higher quality) for immediate (after the first session) relief of pain and improvement in function in patients with chronic low back pain [375, 376]. The superiority of manipulation was maintained during the course of treatment for functional improvements but not for pain, and by the end of treatment through three weeks of follow-up, the effects of manipulation and massage were similar.

In one higher-quality trial, massage was inferior to transcutaneous electrical stimulation for relieving pain and improving range of motion during the course of treatment [379]. In single trials, massage was equivalent to corsets [380, 381] and exercise [378], and moderately superior to relaxation therapy [382], acupuncture [223], and self-care education [223]. Nearly all of the trials only assessed outcomes during or shortly following (within one month) a course of treatment in patients with chronic low back pain. In the single trial (rated higher-quality) with extended follow-up, beneficial effects from massage relative to acupuncture and self-care education persisted for one year [223]. There was insufficient evidence to determine if massage is beneficial in patients with acute low back pain (one lower quality trial [383]), though there was moderate evidence of effectiveness from two trials [378, 380, 381] that included patients with subacute or chronic low back pain.

*Efficacy of different massage techniques*

The Cochrane review found no clear difference between results of trials of manual massage and those that used a mechanical device [375, 376]. One higher quality study [384] found acupuncture massage superior to classical (Swedish) massage for improvements in pain and function. The most significant benefits from massage were seen in trials that used a trained massage therapist with many years of experience or a licensed massage therapist [223, 378, 382]. No conclusions could be drawn regarding

differential effects associated with the number or duration of massage sessions [375, 376].

*Safety*

No study assessed safety.

*Costs*

One trial found no significant differences (p=0.15) between HMO-related costs between massage ($139), acupuncture ($252), and a self-care education booklet ($200) [223].

**Summary of evidence:**

- Massage was superior to sham therapy in one higher quality trial of patients with subacute or chronic non-specific low back pain (level of evidence: fair).
- Massage was consistently inferior to spinal manipulation in three trials (one higher quality) up to one year after a course of treatment in patients with chronic low back pain (level of evidence: fair).
- In single trials comparing massage to other interventions, massage was inferior to transcutaneous electrical stimulation, similar to exercise and corsets, and moderately superior to relaxation, acupuncture, and a self-care education book (level of evidence for each comparison: fair).
- A single trial found acupuncture massage superior to classical (Swedish) massage (level of evidence: fair).
- There is insufficient evidence to judge the efficacy of massage in patients with acute low back pain (one lower-quality trial) or in patients with sciatica (no trials specifically in this population) (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found physical agents and modalities (including massage) of insufficiently proven benefit to justify their cost (strength of evidence: C).
- The VA/DoD and UK RCGP guidelines reached similar conclusions.
- The European COST guidelines recommend against massage for acute low back pain and found insufficient evidence to recommend massage for chronic low back pain.

### Modified work

Results of search: systematic reviews

We identified one lower-quality systematic review on the effects of modified work (light duty) in workers with low back pain [385]. It included one lower-quality randomized trial (also reviewed in the section on multidisciplinary interventions) [307], and 12 higher-quality observational studies.

Results of search: trials

We did not identify any trials not included in the systematic review.

*Efficacy of modified work versus no modified work*

In the only randomized trial included in the systematic review, workers who received an occupational intervention had about half as many lost work days than those without (60 and 67 versus 120 and 131) [307]. The occupational intervention involved a work site visit, ergonomic adjustments, and light duties if necessary. Results from several observational studies were consistent with these findings [385].

*Safety*

We found no studies on safety of modified work.

*Costs*

We found no studies evaluating costs.

#### Summary of evidence

- There is consistent evidence from one lower-quality trial and observational studies that modified work can decrease time lost from work (level of evidence: fair).

#### Recommendations and findings from other guidelines

- The AHCPR guidelines state that activity recommendations for the employed patient with acute low back symptoms need to consider the patient's age and general health, and the physical demands of required job tasks (strength of evidence: D).
- The VA/DoD guidelines are similar.
- The European COST guidelines state that temporary modified work (which may include ergonomic workplace adaptations) can be recommended, when needed, in order to facilitate earlier return to work for workers sicklisted due to low back pain (level B).

## Spa therapy

Results of search: systematic reviews

We identified no systematic reviews evaluating the efficacy of spa therapy (also referred to as spa therapy) in patients with low back pain

Results of search: trials

We identified five lower-quality trials of spa therapy, three in patients with chronic low back pain [386-388] and two in patients with subacute low back pain [359, 389]. All of the trials were conducted in Europe.

*Efficacy of spa therapy versus no spa therapy*

Four trials compared spa therapy to no spa therapy (Table 32) [359, 386-388]. In three trials of patients with chronic low back pain, balneotherapy was substantially superior to no balneotherapy for pain (improved by average of about 20 points compared to no balneotherapy) and analgesic intake at the end of a three-week course of treatment, with persistent benefits for up to 9 months. In two [387, 388] of the three [386] trials, there were also significant differences in measures of functional status or disability.

In the single trial comparing spa therapy to no spa therapy in patients with subacute low back pain, there were no differences in pain outcomes either at the end of therapy or after one year [359]. Daily analgesics use significantly decreased in the spa therapy group but not in the control group.

**Table 32. Trials of balneotherapy versus no balneotherapy**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Constant, 1998[387] (chronic LBP) | N=224<br>3 months | **Balneotherapy vs. no balneotherapy** (mean improvement from baseline at 3 months)<br>Pain, VAS (0 to 100 scale): -37.6 vs. -14.2, p<0.0001<br>Overall patient evaluation (0 to 100 scale): +24.8 vs. +3.9, p<0.0001<br>RDQ Score (0 to 24): -4.0 vs. -1.1, p<0.0001 | 4 or 5/11 |
| Constant, 1995[388] (chronic LBP) | N=126<br>6 months | **Balneotherapy vs. no balneotherapy** (mean improvement from baseline at 6 months)<br>Pain, VAS (0 to 100 scale): -22.4 vs. +1.0, p<0.0001<br>Overall patient evaluation, (0 to 100 scale): +28.7 vs. +1.6, p<0.0001<br>RDQ Score (0 to 24): -5.1 vs. -0.9, p<0.0001 | 5/11 |
| Guillemin, 1994[386] (chronic LBP) | N=104<br>9 months | **Balneotherapy vs. no balneotherapy** (mean improvement from baseline at 9 months)<br>Pain, VAS (0 to 100 scale): -34.4 vs. +7.1, p<0.0001<br>Waddell disability score: +0.09 vs. +0.18, NS | 4/11 |
| Konrad, 1992[359] (subacute or chronic LBP) | N=170<br>1 year | **Balneotherapy vs. no balneotherapy** (mean improvement from baseline at 1 year)<br>Pain, VAS (0 to 100 scale): -13.9 vs. -6.6 (NS) | 3/11 |

*Efficacy of spa therapy versus other interventions*

One trial compared spa therapy plus exercise to exercise alone in patients with subacute or chronic (one to six month duration) low back pain (Table 33) [389]. It found no differences in pain scores through one month after a three-week course of treatment. A second trial compared balneotherapy to either underwater traction or underwater massage [359]. It found no differences in either pain scores or analgesic use through one year after a four-week course of therapy.

**Table 33. Trials of spa therapy versus other interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Yurtkuran, 1997[389] (subacute or chronic LBP) | N=50<br>7 week | **Balneotherapy + exercise versus exercise alone** (mean improvement from baseline at 1 month)<br>Pain, VAS (0 to 10 scale): -2.95 vs. -1.35 (NS) | 3 to 5/11 |
| Konrad, 1992[359] (subacute) | N=170<br>1 year | **Balneotherapy vs. underwater massage vs. underwater traction** (mean improvement from baseline at 1 year)<br>Pain, VAS (0 to 100 scale): -13.9 vs. -10.9 vs. -13.7 (NS) | 3/11 |

*Safety*

None of the trials reported adverse events.

*Costs*

We found no studies on costs.

**Summary of evidence**

- Spa therapy was consistently and substantially superior to no spa therapy for pain in three lower-quality trials of patients (all conducted in Europe) with chronic low back pain up to nine months after a three-week course of treatment (level of evidence: fair).
- Spa therapy was no better than no spa therapy for pain in one lower-quality RCT of patients with subacute or chronic low back pain, but associated with decreased analgesic use (level of evidence: poor).
- Spa therapy was no better than underwater massage or underwater traction or when added to exercise therapy in patients with subacute or chronic low back pain in two lower-quality trials (level of evidence: poor).
- There is no evidence for spa therapy in patients with acute low back pain.

**Recommendations and findings from other guidelines**

- None of the guidelines address spa therapy.

**Spinal manipulation**

Results of search: systematic reviews

We identified a recent, higher-quality Cochrane review of spinal manipulation in patients with low back pain (39 trials, 11 rated higher-quality) [332, 333]. We also identified a recent technology report by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) that reviewed 14 published systematic reviews of spinal manipulation, including the Cochrane review [390]. It also reviewed two new RCTs and two non-randomized studies not in the Cochrane review. Five other recent, higher-quality systematic reviews also evaluated the efficacy of spinal manipulation [129, 220, 391-393]. Six systematic reviews evaluated safety of spinal manipulation in randomized trials and observational studies [220, 394-398]. Because of the large number of systematic reviews, we excluded seven recent, lower-quality systematic reviews [129, 282, 399-403]. We also excluded 23 older systematic reviews [110, 132, 250, 277, 404-422].

Results of search: trials

We included two large (N=681 and N=1334), recently published trials (the UK BEAM Trial [284] and the UCLA Low Back Pain Study [423]) not included in the Cochrane review.

*Efficacy of spinal manipulation versus sham, placebo, or therapies judged ineffective*

The Cochrane review included 14 trials of patients with acute low back pain that found spinal manipulative therapy modestly superior for short-term pain compared to sham therapy (average 10 mm difference on a 100 mm VAS) or therapies judged to be ineffective or harmful (traction, bed rest, home care, topical gel, no treatment, diathermy, and minimal massage) [332, 333]. Differences in functional outcomes did not reach statistical significance (2.8 mm difference on the RDQ Questionnare). In patients with chronic low back pain (11 trials), spinal manipulative therapy was also associated with modest improvements in short- or long-term pain and short-term function compared to sham manipulation (3 trials) or therapies judged to be ineffective or harmful (5 trials). Against sham manipulation, the differences in short- and long-term pain averaged 10 mm and 19 mm on a 100 mm VAS, and the differences for short-term function averaged 3.3 points on the RDQ Questionnaire. The conclusions were insensitive to the presence or absence of radiating pain, study quality, or the profession of the manipulator (chiropractor or other).

A recent technology report by the Canadian Coordinating Office for Health Technology Assessment reviewed 14 published systematic reviews of spinal manipulation [390]. It concluded that the Cochrane review was the best available summary of clinical effectiveness because it received a high quality score, was published recently, and included the largest number of trials. The authors identified two additional randomized trials and two non-randomized trials that did not affect the overall conclusions. Four other recent systematic reviews also reported similar findings compared to the Cochrane review [129, 220, 391, 392]. Another higher-quality systematic review found that trials that allowed manual therapy providers to tailor their techniques to individual patients did not report better outcomes than trials that did not allow therapeutic discretion [393]. In fact, spinal manipulation was associated with better short-term outcomes in trials that didn’t allow discretion, though long-term outcomes were similar.

*Efficacy of spinal manipulation versus usual care or other interventions*

The Cochrane review found that in patients with acute low back pain, spinal manipulative therapy had no clinically or statistically significant advantages over usual general practitioner care or analgesics (3 trials), physical therapy or exercises (5 trials), and back school (2 trials) [332, 333]. In patients with chronic low back pain, there were no differences between manipulation and general practitioner care or analgesics (6 trials), physiotherapy or exercises (4 trials), and back school (3 trials).

Two large, recently published trials reported results consistent with the conclusions of the Cochrane review. In patients with low back pain of unspecified duration, the UCLA Low Back Pain Study (rated higher-quality) found no differences in pain, functional status, or other outcomes between those randomized to chiropractic versus medical care (Table 34) [423]. The other trial found manipulation modestly superior to usual care for back-specific functional status, pain, and disability in patients with subacute or chronic low back pain, though beneficial effects were less after 12 months than after 3 months [284]. There were no significant differences between manipulation and exercise, though trends favored manipulation.

**Table 34. Results of the UK BEAM Trial and the UCLA Low Back Pain Study**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| UK BEAM Trial, 2004[284] | N=1334<br>12 months | **Manipulation + exercise versus manipulation versus exercise (all results are net benefit relative to usual care at 12 months)**<br>RDQ Questionnaire (0 to 24 scale): 1.30 (95% CI 0.54 to 2.07) vs. 1.01 (95% CI 0.22 to 1.81) vs. 0.39 (95% CI -0.41 to 1.19)<br>Modified Von Korff pain score (0 to 100 scale): 6.71 (95% CI 2.47 to 10.95) vs. 5.87 (95% CI 1.58 to 10.17) vs. 4.90 (95% CI 0.30 to 9.50)<br>Modified Von Korff disability score (0 to 100 scale): 6.71 (95% CI 2.62 to 10.80) vs. 5.65 (95% CI 1.57 to 9.72) vs. 4.56 (95% CI 0.34 to 8.78) | 2 or 3/11 |
| Hurwitz, 2002[423] | N=681<br>6 months | **Chiropractic care vs. medical care (between-group difference in improvement from baseline at 6 months)**<br>Most severe pain (0 to 10): 0.27 (95% CI -0.32 to 0.86)<br>Average pain: 0.22 (95% CI -0.25 to 0.69)<br>RDQ score (0 to 24): 0.75 (95% CI -0.29 to 1.79) | 8/11 |

*Safety*

Six systematic reviews consistently found that serious adverse events such as worsening lumbar disc herniation or cauda equina syndrome from lumbar spinal manipulative therapy were very rare [220, 394-398]. One systematic review found no serious complications reported in over 70 controlled clinical trials [398]. Systematic reviews that included data from observational studies estimated risks for serious adverse events as lower than 1 in 1 million patient visits [394, 395]. One of the reasons serious adverse events are so rare may be patient selection: current guidelines recommend against spinal manipulation in patients with severe or progressive neurologic deficits.

*Costs*

In the UCLA Low Back Pain Study, costs were higher with chiropractic care relative to medical care ($560 versus $369, p<0.001) [424]. Because outcomes were very similar for the two interventions, this is essentially a cost-minimization analysis. In the UK BEAM Trial, manipulation was associated with an incremental cost-effectiveness of £4800/QALY relative to best care and £2300/QALY relative to exercise [284]. Two other trials comparing spinal manipulation to exercise therapy found similar costs and outcomes for the two interventions [296, 425, 426]. In one of the trials, chiropractic care was more costly then a self-care booklet ($429 versus $153), with only small differences in patient outcomes [296].

**Summary of evidence**

- Pooled evidence from many trials indicates that spinal manipulation is modestly superior to sham, no treatment, or therapies thought to be ineffective or harmful, in patients with either acute or chronic low back pain (level of evidence: good).
- There is also consistent evidence from multiple trials that spinal manipulation is no more effective than other standard conservative interventions (level of evidence: good).
- In patients without severe or progressive neurologic deficits, serious adverse events such as cauda equina syndrome or worsening lumbar disc herniation following lumbar spinal manipulation are very rare (level of evidence: good).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found that manipulation can be helpful in patients with acute low back problems without radiculopathy when used within the first month of symptoms (strength of evidence: B).

- The AHCPR guidelines found insufficient evidence to recommend manipulation in patients with radiculopathy (strength of evidence: C).
- The AHCPR guidelines found that a trial of manipulation in patients without radiculopathy with symptoms longer than one month is probably safe, but efficacy unproven (strength of evidence: C).
- The AHCPR guidelines recommended an appropriate diagnostic assessment to rule out serious neurologic conditions prior to initiating manipulation therapy when progressive or severe neurologic deficits are present (strength of evidence: D).
- The VA/DoD guidelines for manipulation are essentially identical to the AHCPR guidelines.
- The UK RCGP guidelines found manipulation superior for short-term improvement in pain and activity levels and higher patient satisfaction compared to comparison treatments in patients with acute and subacute back pain (strength of evidence: **).
- The UK RCGP guidelines found that the risks of manipulation for low back pain are very low, provided patients are selected and assessed properly and manipulation is performed by a trained therapist or practitioner (strength of evidence: **).
- The UK RCGP guidelines found no firm evidence regarding what kind of manipulation is most effective, or optimum timing of manipulation (strength of evidence: *).
- The UK RCGP guidelines recommend against manipulation under general anesthesia (strength of evidence: *).
- The European COST guidelines recommend considering referral for spinal manipulation for patients with acute low back pain who are failing to return to normal activities, and a short-course of spinal manipulation/mobilization as a treatment option for chronic low back pain.

**Key Question 3a.**

**Can decision tools predict which patients are more likely to respond to specific therapies like physical therapy or chiropractic?**

Results of search: systematic reviews

We identified no systematic review evaluating the usefulness of decision tools or clinical prediction rules for identifying patients more likely to respond to specific therapies.

However, we found three systematic reviews evaluating the reliability and validity of

physical exam maneuvers used to help determine if manipulative treatments are indicated, though clinical outcomes were not assessed [427-429].

Results of search: trials

We identified one higher-quality randomized trial that prospectively evaluated the usefulness of a clinical prediction rule for identifying patients more likely to respond to spinal manipulation in a randomized trial (Table 35) [430]. The prediction rule was based on a previous study that had identified five factors (symptom duration <15 days, Fear Avoidance Beliefs Questionnaire work subscale score <19, lumbar hypomobility, hip internal rotation range of motion >35 degrees, and no symptoms distal to the knee) associated with greater likelihood of success with spinal manipulation [431]. We also included one recent, small (N=54) observational study that derived a clinical prediction rule for identifying patients likely to benefit from a stabilization exercise program [432].

*Utility of clinical prediction rules for spinal manipulation*

The randomized trial by Childs et al allocated patients (n=131) with a median duration of 27 days of low back pain to spinal manipulation or exercise therapy [430]. It applied a previously derived clinical prediction rule to all patients and prospectively evaluated whether outcomes from spinal manipulation depended on status according to the prediction rule. It found that treatment effects were greatest in the subgroup of patients who were positive on the rule (met at least 4 of 5 criteria) and received manipulation. Relative to patients who were negative on the rule and received exercise, odds of a successful outcome (improvement in Oswestry score at least 50%) in this subgroup was 60.8 (95% CI 5.2 to 704.7), compared to 2.4 (95% CI 0.83 to 6.9) in those negative on the rule who received manipulation and 1.0 (CI 0.28 to 3.6) in those negative on the rule who received exercise. Patients positive on the rule who received manipulation had a 92% chance of a successful outcome, with an associated number needed to treat for one successful outcome (relative to treatment with exercise) of 1.9 (95 % CI 1.4 to 3.5).

**Table 35. Randomized trial evaluating decision tool for predicting success from spinal manipulation**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Childs, 2004[430] | N=131<br>6 months | **Manipulation + exercise vs. exercise alone**<br>"Success" at 4 weeks: 44/70 (63%) vs. 22/61 (36%)<br><br>Likelihood of success at 4 weeks, relative to patients negative on rule who received exercise: Positive on rule and received manipulation OR 60.8 (5.2 to 704.7, p=0.002), negative on rule and received manipulation OR 2.4 (0.83 to 6.91), positive on rule and received exercise OR 1.0, 95% CI 0.28 to 3.6)<br>Positive likelihood ratio for positive rule in manipulation group at predicting success at 1 week: 13.2 (3.4 to 52.1) | 7/11 |

The results of this trial are helpful for confirming the accuracy of the clinical prediction rule in a setting other than the one from which it was originally derived. One classification scheme categorizes clinical prediction rules validated in this manner as level 2 [433]. It does not meet criteria for a level 1 (highest classification) clinical prediction rule, which is defined as one that has been shown to affect clinician behavior and improve outcomes.

Three systematic reviews on the reliability and validity of manual spinal palpatory exam each found suboptimal evidence, poor reproducibility of examination findings, and uncertain validity [427-429]. One potential criticism of the prediction rule evaluated by Childs et al is that it may not be readily applied in everyday practice because it requires the clinician to perform spinal mobility and hip range of motion tests and also requires the patient to fill out a questionnaire (Fear-Avoidance Beliefs Questionnaire). The authors of the trial also developed a 'pragmatic' version of the prediction rule with two factors (duration <16 days and no symptoms extending distal to the knee) that also predicted outcomes with manipulation (positive likelihood ratio 7.2, 95% CI 3.2 to 16.1 in patients meeting both criteria) [434]. However, this variation on the prediction rule was developed retrospectively and needs to be prospectively validated.

*Exercise*

One study (N=54) prospectively derived a clinical prediction rule for determining which patients with low back pain will respond to a stabilization exercise program [435]. It found that presence of three or more of the following factors was associated with a

greater likelihood of treatment success (positive likelihood ratio 4.0, 95% CI 1.6 to 10.0, negative likelihood radio 0.52, 95% CI 0.30 to 0.88): positive prone instability test, presence of aberrant movement, average straight leg raise test >91 degrees, or age <40 years. This prediction rule would be classified as level 4 (derived but not validated) [433].

*Safety*
No study evaluated safety.

**Summary of evidence**

- A decision tool for identifying patients likely to benefit from spinal manipulation has been prospectively validated as highly predictive in a randomized trial. However, evidence of beneficial effects on clinical outcomes from applying the decision tool is not yet available. In addition, the tool may not be practical for use in many primary care settings, and a more pragmatic version has not yet been prospectively validated (level of evidence: fair).
- A decision tool for identifying patients likely to benefit from stabilization exercise has not yet been validated (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The UK RCGP guidelines found no firm evidence that it is possible to select which patients will respond to manipulation (strength of evidence: **).
- The European COST guidelines recommend against the use of spinal palpatory and range of motion tests to identify patients with manipulable lesions.

**Key Question 4.**

**What is the value of different patient education or patient self-care methods for improving patient outcomes?**

Common goals of patient education and patient self-care methods for low back pain are to reduce fear of normal activity, encourage exercise, and promote self-management of pain. A range of interventions have been defined as self-care for low back pain, including individual consultation with a professional or team of professionals, group treatment and/or education by professionals or trained lay leaders, group exercise classes, mini-back school and other approaches. We defined self-care as individual or group educational approaches that involve two sessions or fewer with a professional in a routine clinic visit and are readily implemented independently by

patients. We also review the efficacy of self-care groups led by non-medical lay persons.

### *Self-care advice or education*

#### Bed rest

Search results: systematic reviews

We identified a recently, good-quality Cochrane review (11 trials, 6 meeting all quality criteria) evaluating advice to rest in bed in patients with low back pain [436, 437] that updated a previous Cochrane review [438] We excluded eight older systematic reviews [110, 132, 250, 281, 283, 439-441].

Search results: trials

We did not search for additional trials

*Efficacy of advice to rest in bed versus advice to remain active*

The Cochrane review included two-higher quality trials [286, 442] that found advice to rest in bed associated with inferior outcomes at 3 to 4 weeks (standardized mean difference for pain intensity 0.22, 95% CI 0.02 to 0.41 and for functional status 0.29, 95% CI 0.09 to 0.49) and at 12 weeks (standardized mean difference for pain intensity 0.25, 95% CI 0.05 to 0.45 and for functional status 0.24, 95% CI 0.04 to 0.44) [436, 437]. A standardized mean difference between 0.2 and 0.3 is roughly equivalent to 5 to 7.5 on a 100-mm VAS pain scale and 1.2 to 1.8 points on the 24-point RDQ Questionnaire. Both trials also reported better sick-leave related outcomes in favor of advice to stay active and one trial [286] found no difference in satisfaction with care or costs.

In two higher quality RCTs of patients with sciatica, there was little or no difference between advice to stay active and advice to rest in bed for pain intensity or functional status, and sick leave [443, 444].

*Efficacy of advice to rest in bed versus other interventions*

The Cochrane review [436, 437] included two higher-quality trials that found that no significant differences in pain intensity or functional status between advice to rest in bed and exercises in patients with acute, non-specific low back pain [286, 445]. A third, lower quality trial found no difference on a combined pain, disability, and physical exam

score between bed rest and manipulation, drug therapy, physiotherapy, back school, or placebo [446].

In patients with sciatica, one higher-quality trial found that physiotherapy was modestly superior (weighted mean difference 6.9 points on a 0 to 100 scale) to advice to rest in bed for functional status at four weeks, though the difference was no longer significant at 12 weeks [443]. There were no differences in pain intensity.

*Efficacy of different durations of bed rest*

The Cochrane review [436, 437] included two higher quality trials that found that shorter durations of bed rest (2 or 3 days) were associated with similar pain intensity compared to longer duration (7 days) in patients with acute [447] or mixed duration [448] low back pain. Benefits of shorter bed rest persisted through 12 weeks of follow-up in one trial, which also found shorter bed rest associated with fewer days off work (mean 3.1 days) compared to longer bed rest (mean 5.6 days) at 3 weeks [448].

*Safety*

One recent trial reported one case of pulmonary embolus in patients assigned to bed rest [443].

*Costs*

One trial found no significant differences in costs of health care and home help between bed rest and either exercise or usual activities (usual activities associated with more rapid recovery in this trial) [286].

**Summary of evidence**

- In two higher quality trials, advice to rest in bed was consistently associated with small but statistically inferior outcomes compared to advice to remain active in patients with acute nonspecific low back pain (level of evidence: good).
- Advice to rest in bed was consistently associated with similar outcomes compared to physiotherapy/exercise in two higher quality trials of patients with acute nonspecific low back pain (level of evidence: good).
- There is insufficient evidence to accurately judge the efficacy of advice to rest in bed relative to interventions other than exercise (level of evidence: poor).
- In patients with sciatica, one higher quality trial found that physiotherapy was associated with modestly superior functional status outcomes at 3 weeks

compared to advice to rest in bed, but this effect was no longer present after 12 weeks (level of evidence: good).

- Longer duration of bed rest was not associated with better outcomes compared to shorter duration, and increased the number of days off work in one higher-quality trial (level of evidence: fair).
- There is no evidence to judge the efficacy of advice to rest in bed in patients with chronic low back pain.

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found that a gradual return to normal activities is more effective than prolonged bed rest for treating acute low back problems (strength of evidence: B).
- The AHCPR guidelines found that prolonged bed rest for more than 4 days may lead to debilitation and is not recommended for treating acute low back problems (strength of evidence: B).
- The AHCPR guidelines found that the majority of low back patients will not require bed rest, though bed rest for 2 to 4 days may be an option for patients with severe initial symptoms of primarily leg pain (strength of evidence: D).
- The VA/DoD and UK RCGP guidelines are similar to the AHCPR guidelines, but found stronger evidence that bed rest for 2-7 days is inferior to placebo or ordinary activity (strength of evidence: A and ***, respectively).
- The European COST Guidelines recommend against prescribing bed rest for acute nonspecific low back pain.

**Advice for activity**

In this section, we included trials evaluating advice for self-care given in a typical clinic visit or a clinic session lasting no longer than one hour.

Search results: systematic reviews

We identified one good-quality Cochrane review (4 trials) evaluating the efficacy of advice to stay active (maintaining usual activities as much as possible) [449, 450]. A recently updated Cochrane review of bed rest [436, 437] included two additional trials (both higher-quality) comparing bed rest to active to stay active [442, 443].

Search results: trials

We identified one additional higher-quality trial comparing advice to stay active versus exercise therapy [451]. We also found one lower-quality trial evaluating exercise advice

versus usual care or a self-care book [452], and one lower-quality trial evaluating exercises advice versus exercise [453, 454].

*Efficacy of advice to stay active versus advice to rest in bed*

Results of trials comparing advice to stay active with advice to rest in bed are discussed in the section on bed rest.

*Efficacy of advice to stay active versus other interventions*

The Cochrane review included one higher-quality trial [286] that found advice to stay active associated with similar improvements in pain intensity compared to an exercise program in patients with simple, acute low back pain [449, 450]. Short-term functional status initially favored advice to stay active (weighted mean difference on Oswestry questionnaire –8.6, 95% CI –13.9 to –3.3), but differences were no longer present after 3 weeks. Average length of sick leave was lower in the advice to stay active group, but not statistically significant.

A higher-quality trial not included in the Cochrane review found that in patients with nonspecific low back pain for more than six weeks, there were no differences between advice to stay active and usual physical therapy on pain or functional status through 12 months, though perceived benefit was greater in the physical therapy group (Table 36) [451]. By contrast, one lower quality trial found that in patients with acute low back pain, a single back education session with advice to remain active (45 minutes) was associated with slower return from sick leave (22 vs.12, $p<0.001$), and fewer back pain recurrences in the first year and with longer follow-up (through five years) [453, 454]. A single higher-quality trial of patients with acute sciatica found no differences in pain or functional status between advice to stay active and physical therapy through 6 months of follow-up [443].

**able 36. Trials of advice to stay active vs. exercise therapy not included in Cochrane review**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Frost 2004[451] (nonspecific low back pain) | N=286<br>12 months | **Advice to stay active vs. usual physical therapy**<br>Oswestry score (0 to 100 scale), mean change: -1.33 vs. -2.65 at 2 months, -2.23 vs. -3.27 at 12 months (NS)<br>RDQ Disability score (0 to 24 scale), mean change: -0.56 vs. -1.13 at 2 months, -0.99 vs. -1.36 at 12 months (NS)<br>SF-36: No significant differences<br>Perceived benefit (proportion reporting 'yes'): 60% vs. 77% at 2 months (p=0.002), 50% vs. 65% at 6 months (p=0.007)<br>Perceived benefit (0 to 10 scale): 3.66 vs. 5.42 at 2 months (p<0.001); 4.13 vs. 5.02 at 12 months (p=0.011) | 7/11 |
| Stankovic, 1990, 1995[453, 454] (nonspecific low back pain) | N=100<br>5 years | **Advice to stay active vs. McKenzie exercise**<br>Mean duration of sick leave: 22 vs. 12 days (p<0.001)<br>Pain: decreased in exercise group (p<0.001), data not reported<br>Recurrences: 74% (37/50) vs. 44% (22/50) after 1 year; 88% (37/42) vs. 64% (30/47) between 1 and 5 years (p<0.01)<br>Sick leave between 1 and 5 years: 74% (31/42) vs. 51% (24/47) (p<0.03) | 3/11 |
| Hofstee, 2002[443] (sciatica) | N=167<br>6 months | **Advice to stay active versus physiotherapy**<br>Pain VAS (0 to 100), mean difference in change from baseline: 0.8 (-8.2 to 9.8) at 1 month and –1.0 (-10.0 to 8.0) at 6 months (positive values favor physiotherapy)<br>Quebec Disability Scale (0 to 100), mean difference in change from baseline: -0.5 (-6.3 to 5.3) at 1 month and –0.7 (-8.4 to 6.9) at 6 months | 6/11 |

*Efficacy of exercise advice versus usual care or a self-care book*

One lower-quality trial found advice for regular exercise superior to usual care for pain and function after one week in patients with low back pain for less than 3 months (Table 37) [452]. However, there were no differences after three weeks, when most patients reported resolved pain. Advice to exercise also improved patient satisfaction compared to usual care (p=0.03). There were no differences between advice to exercise and a self-care book. Adding a self-care education book to exercise advice did not improve outcomes compared to either alone.

**Table 37. Trial of exercise advice vs. self-care book vs. usual care**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Little 2001[452] | N=311<br>3 weeks | **Self-care book vs. exercise advice vs. both vs. neither (control) (mean changes versus control)**<br>Pain/function scale (0 to 100): -8.7 vs -7.9 vs -0.1 at 1 week, -6.3 vs -1.4 vs -4.0 at 3 weeks (NS)<br>Aberdeen pain and function scale (0 to 100): -3.8 vs -5.3 vs. -1.9 at 1 week (NS) | 4/11 |

*Safety*

No studies reporting safety associated with advice to stay active.

*Costs*

One of the trials included in the Cochrane review found no significant differences in costs of health care and home help between advice to remain active and either advice to rest in bed or an exercise program [286].

**Summary of evidence**

- Advice to remain active was associated with similar effects on functional status or pain compared to exercise therapy in one higher-quality trial of patients with acute non-specific low back pain and one higher-quality trial of patients with symptoms for more than six weeks, but with slower return from sick leave and more back pain recurrences in one older, lower-quality trial (level of evidence: fair).
- Advice to remain active was not associated with clear benefits in a single, higher-quality trial of patients with acute low back pain with sciatica (level of evidence: fair).
- Advice to exercise was superior to usual care in one lower-quality trial of patients with low back pain for less than 90 days. There were no differences between advice to exercise and a self-care book, and the combination did not improve outcomes (level of evidence: poor).
- See section on bed rest for summary of bed rest versus advice to remain active.

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend providing patients with acute low back pain accurate information about expectations for both rapid recovery and recurrent of symptoms based on the natural history of low back symptoms; safe and effect methods of symptom control; safe and reasonable activity modifications; best means of limiting recurrent low back problems; the lack of need for special

investigations unless red flags are present; and effectiveness and risks of commonly available diagnostic methods and further treatment measures to be considered should symptoms persist (strength of evidence: B).

- The AHCPR guidelines suggest that patients with acute low back problems may be more comfortable if they temporarily limit or avoid specific activities known to increase mechanical stress on the spine, especially prolonged unsupported sitting, heavy lifting, and bending or twisting the back while lifting (strength of evidence: D).
- The AHCPR guidelines suggest considering the patients' age and general health, as well as the physical demands of required job tasks, when considering activity recommendations for employed workers with acute low back problems (strength of evidence: D).
- The VA/DoD and UK RCGP guidelines recommend an approach to patient advice and return to normal activity very similar to the AHCPR guidelines.
- The UK RCGP guidelines found stronger evidence than the AHCPR guidelines for advice to continue ordinary activity (strength of evidence: ***).
- The European COST guidelines recommend providing adequate information and reassurance to patients with acute low back pain. They also recommend advising patients to stay active and continue normal daily activities including work if possible.

**Self-care books**

Results of search: systematic reviews

We identified no systematic reviews on the efficacy of self-care books for patients with low back pain.

Results of search: trials

We included eight trials (five-higher-quality [223, 296, 300, 455, 456]) on the efficacy of reading material (books, booklets, and leaflets) providing education and self-care advice for patients with low back pain) [452, 457, 458]. Although the specific content of self-care books varied, in general they encourage return to normal activity, adoption of a fitness program, and appropriate lifestyle modification, and provide advice on coping strategies and managing flares. Four trials (one rated higher-quality [456]) compared a self-care book to usual care and three trials (all rated higher-quality [223, 296, 300]) compared a self-care book to another intervention. Two other trials compared different methods of providing information from a self-care book [455, 456]. Three trials

evaluating the efficacy of a self-care book alone versus a self-care book combined with other interventions are reviewed for Key Question 10.

*Efficacy of self-care books versus usual care*

Four trials (one rated higher-quality [456]) of patients with low back pain of acute and subacute or unspecified duration found no significant differences in pain or symptom bothersomeness scores with a self-care book versus usual care (Table 38) [452, 456, 458, 459]. There were also no differences in functional status (Little 2001, Cherkin 1996) and time lost from work (Hazard 2000, Cherkin 1996) in the trials that assessed these outcomes. Effects on health care use were mixed: one lower-quality trial found no difference between a self-care book and usual care on number of health care visits [457], but another found that fewer patients receiving a self-care book consulted for back pain over a one-year period [459]. Effects of self-care books on self-reported behaviors was mixed. One trial found that patients randomized to a self-care book were more likely to report recommended back care behaviors [459]. However, another trial found no difference between a self-care book and usual care in the proportion of patients who reported exercising, even though the self-care book group had higher scores on perceived knowledge [456].

**Table 38. Trials of a self-care book versus usual care**

| Author, year<br>Type of LBP | Number of patients<br>Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Roberts, 2002[458]<br>Acute (not defined) | N=64<br>12 months | **Self-care book vs. usual care**:<br>Aberdeen Low Back Pain Scale (0 to 100): 42.7 vs. 42.6 at 2 days, 11.0 vs. 8.1 at 1 year (NS) | 4/11 |
| Hazard, 2000[457]<br>Not specified | N=1108<br>6 months | **Self-care book vs. usual care**<br>Current pain severity, improvement in pain since maximum severity: no differences (data not reported)<br>Number of health care visits: no differences (data not reported)<br>Proportion not working at 6 months: 6.5% vs. 5.9% (p=0.84)<br>Lost work days through 6 months: 19.1 vs. 18.1 | 5/11 |
| Cherkin, 1996[456]<br>Not specified | N=300<br>1 year | **Self-care book vs. nurse education + self-care book vs. usual care (mean change from baseline)**<br>RDQ score (0 to 24 scale): -5.4 vs -5.2 vs -5.3 (NS) at 1 week<br>Symptom bothersomeness score (0 to 10 scale): -3.3 vs -3.3 vs -3.6<br>(NS) at 1 week<br>Health care visits for low back pain: 45% vs. 46% vs. 47% in first 7 weeks after intervention (NS)<br>Work loss days: 24% vs. 36% vs. 29% in first 7 weeks after intervention (NS) | 6/11 |
| Roland, 1989[459]<br>Acute and chronic | N=936<br>1 year | **Self-care book vs. usual care**<br>Patients initiating consultation for back pain: 23% vs 25% (NS) after 2 weeks, over 1 year: 35.6% vs. 42.2% (p<0.05) after 1 year<br>Days certified sickness absence: 10.3 vs 10.1 (NS)<br>Referral to hospital or to physiotherapy: 19.9% vs. 24.7% (p>0.05) | 2/11 |

*Efficacy of self-care books versus other interventions*

Four trials (three higher-quality [223, 296, 300]) compared a self-care book to other treatments (Table 39) [223, 296, 300, 452]. In one trial, patients with chronic low back pain reported lower functional status at 26 weeks with a self-care book compared to either yoga (difference of 3 to 4 points on the RDQ Questionnaire) or exercise therapy (difference of about 2 points on the RDQ) [300]. Yoga (but not exercise) was also associated with greater improvement in symptom bothersomeness scores at 26 weeks (about 2 points on a 0 to 10 scale) relative to the self-care book. Another trial found no significant differences between a self-care book and either chiropractic manipulation or physical therapy on symptom bothersomeness and RDQ scales, though trends favored the chiropractic intervention by about one point on both scales at 4 and 12 weeks [296]. A third higher-quality trial found massage, but not acupuncture, superior to a self-care book and videotapes at 10 weeks in patients with low back pain for at least one week

(difference of about 1 point on a 0 to 10 symptom bothersomeness scale and 2.5 points on the RDQ score), though no differences between the self-care book and the other two interventions were observed after one year [223]. One lower-quality trial of patients with back pain for less than three months found no short-term differences on either a combined pain and function scale or the Aberdeen pain scale between a self-care book and physician advice to exercise [452].

3736 **Table 39. Trials comparing a self-care book to other interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Sherman, 2005[300] | N=101<br>26 weeks | **Yoga vs. self-care book**, mean differences<br>RDQ score (0 to 24 scale): -2.6 (-4.6 to –1.6) at 6 weeks, -3.6 (-5.4 to –1.8) at 26 weeks<br>Symptom bothersomeness score (0 to 10 scale): -1.6 (-2.6 to –0.5) at 6 weeks, and -2.2 (-3.2 to –1.2) at 26 weeks<br><br>**Exercise vs self-care book**, mean differences<br>RDQ score (mean difference): -1.7 (-3.7 to 0.4) at 6 weeks, -2.1 (-4.1 to –0.1) at 26 weeks<br>Symptom bothersomeness score:<br>-0.9 (-1.9 to –0.1) at 6 weeks, -0.8 (-2.1 to 0.5) at 26 weeks<br><br>**Yoga vs. exercise vs. self-care**<br>Visits to health care providers for low back pain: 4/34 (12%) vs 6/32 (19%) vs 9/29 (31%) at 26 weeks (NS)<br>Medication use at week 26: 21% vs. 50% vs. 59% (p<0.05 for yoga vs. exercise or self-care)<br>SF-36: No differences | 7/11 |
| Little, 2001[452] | N=311<br>3 weeks | **Self-care book vs exercise advice vs. both vs. neither (control) (mean changes versus control)**<br>Pain/function scale (0 to 100): -8.7 vs -7.9 vs -0.1 at 1 week, -6.3 vs -1.4 vs -4.0 at 3 weeks (NS)<br>Aberdeen pain and function scale (0 to 100): -3.8 vs -5.3 vs. -1.9 at 1 week (NS) | 4/11 |
| Cherkin, 2001[223] | N=262<br>1 year | **Self care book vs. acupuncture vs. massage**<br>Symptom bothersomeness (0 to 10 scale), mean scores: 4.6 vs. 4.0 vs. 3.6 at 10 weeks (p=0.01 for self care book versus massage, no other significant differences), 3.8 vs. 4.5 vs. 3.2 at 1 year (p=0.002 for acupuncture vs. massage, no other significant differences)<br>RDQ score (0 to 24 scale), mean scores: 8.8 vs. 7.9 vs. 6.3 at 10 weeks (p<0.001 for self care book vs massage, p=0.01 for acupuncture vs. massage, p=0.75 for self care book vs. acupuncture), 6.4 vs. 8.0 vs. 6.8 at 1 year (p=0.05 for acupuncture vs. massage, no other significant differences)<br>Provider visits: 1.5 vs.1.9 vs. 1.0 (p=0.17) | 8/11 |
| Cherkin, 1998[296] | N=323<br>2 years | **Self-care book vs. chiropractic therapy vs. physical therapy**<br>Symptom bothersomeness (0 to 10 scale), mean scores: 3.1 vs. 1.9 vs.2.3 at 4 weeks (NS), 3.2 vs. 2.0 vs. 2.7 at 12 weeks (NS), no differences at 2 years<br>RDQ score (0 to 24 scale), mean scores: 4.9 vs. 3.7 vs. 4.1 at 4 weeks (NS), 4.3 vs. 3.1 vs. 4.1 at 12 weeks (NS), no differences at 2 years<br>Proportion reporting reduced activity in 11 months after intervention: 36% vs. 33% vs. 35%<br>Proportion needing bed rest: 9% vs. 8% vs. 11%<br>Proportion who missed work: 17% vs. 7% vs. 13%<br>Visits for back pain in second year after intervention: 24% vs. 29% vs. 20%<br>Total costs over 2 years: $153 vs. $429 vs. $437 | 7/11 |

*Efficacy of different methods for providing information in self-care books*

One higher-quality trial found no differences in RDQ scores, symptom bothersomeness scores, days lost from work, or number of health care visits between a self-care book alone and a self-care book plus a 15-minute nurse education session and brief telephone follow-up in patients with back pain of unspecified duration (Table 40) [456]. However, patients in the nurse education group perceived themselves to be more knowledgeable and a higher proportion reported they had tried the exercises in the booklet (74% vs. 45%, p<0.001) in the first week after the intervention. A second higher quality trial found no differences in pain or functional status through one year in patients with low back pain of less than three months' duration randomized to an experimental back book (*the Back Book,* developed to accompany the UK's 1996 Royal College of General Practitioners guidelines) aimed at changing beliefs and behaviors, compared to a traditional self-care book mainly targeted at providing factual information [455]. However, patients randomized to the experimental book were more likely to report at least a 4-point reduction on a fear avoidance beliefs scale, and patients with high baseline fear avoidance beliefs were more likely to report improvements of at least three points on the RDQ score.

**Table 40. Trials evaluating different methods of providing information in a self-care book**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Burton, 1999[455] | N=188<br>1 year | **Experimental self-care book vs. traditional self-care book**<br>Pain at worst (0 to 100), mean scores: 53.9 vs. 53.9 at 2 weeks, 50.9 vs. 50.8 at 1 year (NS)<br>RDQ scores: No significant differences, data not reported<br>Fear avoidance beliefs score, >4 point improvement: RR 2.72 (1.57 to 4.72) at 2 weeks, RR 1.47 (1.02 to 2.11) at 1 year | 7/11 |
| Cherkin, 1996[456] | N=300<br>1 year | **Self-care book vs. nurse education + self-care book vs. usual care (mean change from baseline)**<br>RDQ score (0 to 24 scale): -5.4 vs -5.2 vs -5.3 (NS) at 1 week<br>Symptom bothersomeness score (0 to 10 scale): -3.3 vs -3.3 vs -3.6<br>(NS) at 1 week<br>Health care visits for low back pain: 45% vs. 46% vs. 47% in first 7 weeks after intervention (NS)<br>Work loss days: 24% vs. 36% vs. 29% in first 7 weeks after intervention (NS) | 6/11 |

*Safety*

Three trials providing information on adverse events reported none with a self-care book [223, 296, 300].

*Costs*

One trial estimated an average total cost (including the cost of the intervention and health care utilization) lower with a self-care book ($153) compared to either chiropractic therapy or physical therapy (around $430) [296]. Another trial found no significant differences in estimated costs between a self-care book ($200), massage ($139), and acupuncture ($252) [223].

**Summary of evidence**

- Four trials (one higher-quality) found no difference between a self-care book and usual care in pain or symptom bothersomeness scores (level of evidence: fair).
- In three higher-quality trials comparing a self-care book to other active interventions (yoga, acupuncture, exercise, massage, or manipulation), there were either no significant differences or the self-care book was modestly inferior on symptom bothersomeness scores and functional status. The largest differences were seen in single trials comparing a self-care book to yoga and a self-care book to massage (level of evidence: good).
- There was no difference between a self-care book and advice to exercise in one lower-quality trial (level of evidence: poor).
- Different methods for providing information in a self-care book were not associated with significant differences in pain or functional status, though a brief nurse education visit increased the proportion of patients who exercised in one higher-quality trial compared to providing the self-care book alone, and an experimental self care book targeted at changing beliefs and behaviors reduced fear avoidance beliefs more than a traditional self-care book in another higher-quality trial (level of evidence: fair).

**Recommendations and findings from other guidelines**

- None of the other guidelines specifically address self-care books. General recommendations on advice are listed in the bed rest section.

**E-mail discussion groups**

Results of search: systematic reviews

We identified no relevant systematic reviews.

Results of search: trials

We identified one lower-quality trial that compared an e-mail discussion group versus usual care in patients with chronic low back pain [460].

*Efficacy of an e-mail discussion group versus usual care*

The trial found that participation in a closed, moderated e-mail discussion group, along with a self-care book and videotape was associated with greater improvements in pain (p=.045), back-specific functional status (p=.02), role function (p=.007) health distress (p=.001) after 12 months compared to usual care (Table 41) [460]. The differences on back specific functional status average about 1 point on the 24 point RDQ and for pain about 0.5 points on a 10 point scale. There were no differences in physician visits for back pain or average number of hospital days over a 12-month period.

**Table 41. Trial of e-mail discussion group versus usual care**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Lorig, 2002[460] | N=580<br>12 months | **E-mail discussion, book and video vs. usual care**<br>(mean changes from baseline at 12 months)<br>RDQ (0 to 23): -2.77 vs -1.51 (p=.01)<br>Health distress (0 to 5): -0.92 vs -0.57 (p=.001)<br>Pain interference (0 to 10): -1.50 vs -1.02 (p=.05)<br>Role function (0 to 7): -0.830 vs -0.531(p=.007)<br>Physician visits for back in last 6 months: -1.54 vs -0.65 (NS)<br>Chiropractor visits for back in last 6 months: -1.32 vs -0.797 (NS)<br>Physical therapist visits for back in last 6 months: -1.99 vs -1.31 (NS)<br>Hospital days in recent 6 months: -0.198 vs 0.04 (NS) | 2/11 |

*Safety*

Adverse events were not reported

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- One lower-quality trial found an e-mail discussion group intervention plus a self-care book and videotape superior to usual care for pain, disability, role function and health distress after one year in patients with chronic low back pain (level of evidence: poor).

### Recommendations and findings from other guidelines

- None of the other guidelines specifically address e-mail discussion groups. General recommendations on advice are listed in the bed rest section.

## Self-care exercise videotape

Results of search: systematic reviews

We identified no relevant systematic reviews

Results of search: trials

We identified one lower-quality trial comparing a self-care exercise videotape to face-to-face instruction in patients with back pain of unspecified duration [461].

*Efficacy of self-care exercise videotape versus face-to-face advice*

The trial found no differences in RDQ scores after 4 to 6 weeks between a self-care exercise video (featuring either the treating physiotherapist or an anonymous physiotherapist) compared to face-to-face advice (Table 42) [461]. On one subscale of the SF-36 (pain), the self-care video group had greater improvements than the face-to-face advice group (p<0.005, data not reported).

**Table 42. Trial of e-mail discussion group versus usual care**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Miller, 2004[461] | N=550<br>4-6 weeks | **Self-care video with treating physiotherapist vs. self-care video with anonymout physiotherapist vs. face-to-face advice**<br>RDQ score (0 to 24), mean change: -3.58 vs -3.00 vs -2.47. Neither video group improved more than the control (p=.06).<br>SF36 pain subscale: Either video had greater improvement vs. control (p<0.005, data not reported) | 3/11 |

*Safety*

No trials assessed safety

*Costs*

We found no studies evaluating costs.

### Summary of evidence

- One lower quality trial found no differences in functional status between videotaped exercise advice and face-to-face advice through 4 to 6 weeks in

patients with back pain of unspecified duration, but videotaped advice was superior for short-term pain (level of evidence: poor).

### Recommendations and findings from other guidelines

- None of the other guidelines specifically address videotaped exercise advice. General recommendations on advice are listed in the bed rest section.

## Advice to restrict early morning flexion

Results of search: systematic reviews

We identified no relevant systematic reviews.

Results of search: trials

We identified one lower-quality trial comparing advice to restrict early morning lumbar flexion with sham exercise advice in patients with chronic low back pain [462, 463].

*Efficacy of advice to restrict early morning flexion versus sham exercise advice*

The trial found a single 45-minute instructional session on restricting early morning flexion (with supplemental videotape and written instructions) superior to sham exercise advice for mean pain intensity,days with disability as well as medication use (Table 43) [462, 463]. However, large baseline differences between groups (baseline medication use and disability days two times higher in the sham exercise advice group) could invalidate these results.

**Table 43. Trial of advice to restrict early morning flexion versus sham exercise advice**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Snook, 1998[462, 463] | N=85<br>6 months | **Advice to restrict early morning flexion vs. sham exercise advice (mean at 6 months)**<br>Pain intensity (0 to 10): 1.52 vs. 1.36 (p<0.05)<br>Pain days: 102 vs. 150<br>Disability days: 3.0 vs. 10.7<br>Impariment days: 3.0 vs. 10.7<br>Medication days: 16.7 vs. 49.9 | 2/11 |

*Safety*

The trial did not report adverse events.

*Costs*

We found no studies evaluating costs.

### Summary of evidence

- One lower-quality trial found that patients with chronic low back pain who were given advice to restrict early morning flexion reported better outcomes related to pain intensity and disability compared to those given sham exercise advice, but marked baseline differences make these findings unreliable (level of evidence: poor).

### Recommendations and findings from other guidelines

- None of the other guidelines specifically address advice to restrict early morning flexion. General recommendations on advice are listed in the bed rest section.

## Lay-facilitated groups for self-care

We defined lay leaders as non-professionals with or without training in self-care group facilitation or specific self-care approaches for low back pain management.

Results of search: systematic reviews

We identified no systematic reviews evaluating lay-facilitated groups for self-care in patients with low back pain.

Results of search: trials

We identified one lower-quality trial evaluating lay-facilitated self-care groups in patients invited to enroll 6 to 8 weeks after a low back pain visit with their primary care provider [464].

*Efficacy of lay-facilitated groups for self-care versus usual care*

The trial found that a four-session self-care group led by trained lay leaders and supplemented by a self-care book and videotapes was superior to usual care plus a self-care book on function at 6 and 12 months, though not at 3 months (Table 44) [464]. In addition, a higher proportion of patients in the self-care group reported a >50% reduction in RDQ Scores at 6 months. However, there was no difference between the groups in pain intensity.

**Table 44. Trial of lay-led self-care group versus usual care**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Von Korff, 1998[464] | N=255<br>12 months | **Lay-led group + self-care book vs usual care + self-care book**<br>RDQ Questionnaire (0 to 24), mean score: 6.56 vs 7.40 at 3 months (NS), 5.83 vs 7.23 at 6 months (p=0.007), 5.75 vs 6.75 at 12 months (p=0.092).<br>>=50% decrease in RDQ score: 48% vs. 33% (p=0.02) at 6 months<br>Pain intensity (0 to 10), mean score: 3.87 vs. 4.02 at 3 months, 3.22 vs. 3.79 at 12 months (NS) | 5/11 |

*Safety*

No studies assessed safety

*Costs*

A cost analysis based on the trial estimated a mean cost of $9.70 per additional low-impact back day in the low-impact lay-led group relative to usual care [465].

**Summary of evidence**

- A four-session lay-led self-care group was associated with greater improvements in functional status (but not pain intensity) compared to usual care after 6 to 12 months in one lower-quality trial of patients with subacute low back pain (level of evidence: poor).

**Recommendations and findings from other guidelines**

- None of the guidelines addressed lay-led self-care groups.

**Self-help tools for back surgery decisions**

Results of search: systematic reviews

We identified no systematic reviews evaluating tools for helping guide back surgery decisions.

Results of search: trials

We identified one higher-quality trial evaluating patient outcomes associated with a video and a self-care book for informing back surgery decisions versus a self-care book alone [466]. Another higher-quality trial also evaluated a video program for informing surgery decisions, but was excluded because it did not report relevant patient outcomes [467].

*Efficacy of a video plus self-care book for informing back surgery decisions versus a self-care book alone*

The single trial reporting patient outcomes found no difference between an interactive video plus self-care book and a self-care book alone for function at 3 months or 1 year in potential back surgery candidates (Table 45) [466]. The video intervention was superior to the self-care book alone for the proportion of patients reporting 'extreme' or 'quite a bit' of pain (28% versus 37%, p=0.04). However, no difference was found between the interventions for resolution of back or leg pain at 3 months or 1 year. There was no difference in the rate of patients undergoing surgery except for in those diagnosed with herniated disc, who were less likely to have surgery in the video arm (32% vs. 47%, p=0.05).

**Table 45. Trial of interactive video + self-care book versus self-care book alone for informing surgical decisions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Deyo, 2000[466] | N=393<br>1 year | **Videodisc program + booklet vs booklet alone**<br>RDQ Score: no differences between groups at 3 months or 1 year<br>Back pain severity 'extreme' or 'quite a bit' at 1 year: 27.6% vs. 37.2% (p=0.04)<br>Resolution of back or leg pain: no differences between groups at 3 months or 1 year<br>Surgery rate: 26% vs 33% (p=0.08, NS). In those with herniated disks: 32% vs 47% (p=0.05)<br>Health care utilization (Seattle patients only): Except for surgery data reported above, no differences between groups for number of physician visits, physical therapy, spine imaging, overall lab or pharmacy use, hospitizations for back pain.<br>Satisfaction with treatment, decision-making process: no differences<br>Satisfaction with amount of information received: 71.8% vs 57.1% (p=0.005) | 7/11 |

*Safety*

No study assessed safety.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- One higher-quality trial found no differences in function between an interactive video plus self-care book versus a self-care book alone for informing back surgery decisions even though a lower proportion of patients with herniated disc underwent surgery. The video was associated with a lower proportion of patients with severe pain at one year, though there was no difference in rates of resolution of back or leg pain (level of evidence: fair).

**Recommendations and findings from other guidelines**

- None of the other guidelines address tools to help patients with back care decisions.

***Self-care Interventions***

**Lumbar supports**

Results of search: systematic reviews

We identified one higher-quality Cochrane review (6 RCTs, 2 higher quality) evaluating the effectiveness of lumbar supports for the treatment of low back pain [468]. This updated an older Cochrane review [469]. We excluded four other older systematic reviews [249, 282, 440, 470].

Results of search: trials

We did not search for additional trials.

*Effectiveness of lumbar supports versus placebo*

The Cochrane review included one small (N=30), lower-quality trial that found a lumbar support superior to no intervention for improvement in pain in patients with low back pain of unspecified duration after 1 hour, 3 weeks, and 6 weeks [471].

*Effectiveness of lumbar supports versus other interventions*

Four trials [111, 349, 380, 381, 472] included in the Cochrane review found that lumbar supports are not more effective than other interventions in reducing pain, and conflicting evidence on their effects on functional outcomes, return to work, and overall improvement. In the only higher quality trial [380, 381], a lumbar support was superior to soft tissue massage in patients with subacute or chronic low back pain on the RDQ Questionnaire, but there were no significant differences on the ODQ or on outcomes related to pain relief. There were also no differences between a lumbar support and spinal manipulation or transcutaneous muscular stimulation. Two lower-quality trials

also found no differences between lumbar supports and usual care (in patients with chronic low back pain [349]) or either spinal manipulation, physiotherapy, or acetaminophen (in patients with back pain of varying duration [111]). One other lower-quality trial found a lumbar support superior to advice on rest and lifestyle for pain relief, return to work, and overall improvement in patients with acute low back pain [472].

*Comparison of different types of lumbar supports*

The Cochrane review included one higher-quality trial that found that a lumbar support with a rigid insert was associated with significantly more global improvement than a lumbar support without a rigid insert [473].

*Safety*

No studies evaluated safety.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is insufficient evidence from one lower quality trial to determine whether lumbar supports are effective compared to no intervention (level of evidence: poor).
- There is conflicting evidence regarding the effectiveness of lumbar supports compared to other interventions (soft tissue massage, spinal manipulation, advice on lifestyle and bedrest, physiotherapy, acetaminophen, TENS, or usual care). Most comparisons were evaluated in only one lower-quality trial. The trials were mainly conducted in subjects with non-specific low back pain of varying or unspecified duration level of evidence: poor).
- One higher-quality trial found that a lumbar support with a rigid insert was associated with superior global assessment of outcomes compared to a support without a rigid insert (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found that lumbar corset and support belts had not been proven beneficial for treating patients with acute low back problems (strength of evidence: D).
- The VA/DoD and UK RCGP guidelines make similar recommendations.
- The European COST guidelines found insufficient evidence to recommend lumbar supports for nonspecific chronic low back pain.

## Mattresses

Results of search: systematic reviews

We identified no systematic reviews evaluating mattresses in patients with low back pain.

Results of search: trials

We found two randomized [474, 475] and one quasi-randomized trial [476] evaluating effects of different mattresses on chronic low back pain. Only one was rated higher quality [474].

*Efficacy of different mattress types*

In the higher-quality RCT (N=313), patients randomized to a firm mattress were less likely to have improvement in pain related disability compared to those randomized to a medium-firm mattress after 90 days (68% vs. 82%, p=0.005) [474]. There were no differences in the proportion of patients with improvement in pain while lying in bed or on rising (Table 46). One of the other trials compared a soft interior sprung mattress to an isometric mattress [475] and the other compared four different mattresses (orthopedic hard, standard, waterbed, hybrid water-foam). However, we could not reliably interpret their results because of methodological flaws, use of unstandardized outcome measures, and poor reporting of outcomes [475, 476].

**Table 46. Trials of different mattresses in patients with low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Kovacs, 2003[474] | N=313<br>90 days | **Firm versus medium-firm mattress**<br>Proportion with improvement in pain-related disability: 68% vs. 82%, p=0.005<br>Proportion with improvement while lying in bed: 78% vs. 83%, p=0.29<br>Proportion with improvement in pain on rising: 80% vs. 86%, p=0.20 | 11/11 |
| Ahterton, 1983[475] | N=30<br>2 weeks followed by crossover | **Isometric versus soft inferior sprung mattress**<br>Proportion reporting pain 'least': 40% (10/25) vs. 28% (7/25)<br>Proportion reporting comfort 'best': 40% (10/25) vs. 52% (13/25) | 4/11 |
| Garfin, 1981[476] | N=15<br>2 weeks per intervention | **Orthopedic hard mattress versus standard box spring and mattress versus water-filled mattress versus hybrid (combination water-foam) mattress**<br>Results not interpretable | 0/11 |

*Safety*

The higher quality trial found that the firm mattress was associated with a higher proportion of patients with worsening of pain in bed (17% vs. 9.0%) and worsening of disability (24% vs. 9%) compared to the medium-firm mattress [474].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- One higher-quality trial found that a firm mattress was less likely to lead to improvement in pain related disability and worsen pain while in bed compared to a medium-firm mattress in patients with chronic low back pain. There were no differences in other pain outcomes (level of evidence: fair).
- There was insufficient evidence to judge the relative effectiveness of other mattress types (level of evidence: poor).

**Recommendations and findings from other guidelines**

- None of the guidelines address the use of different mattresses.

**Superficial heat or cold**

Results of search: systematic reviews

We identified one recent, good quality Cochrane review (9 trials, five rated higher quality) [477]. The same investigator led three of the trials [478-480]. We excluded one older systematic review that found no studies on superficial hot or cold [283].

Results of search: trials

We did not search for additional trials.

*Efficacy of heat wrap therapy versus placebo*

The Cochrane review [477] included two higher-quality trials [478, 480] that found heat wrap therapy more effective than placebo in patients with acute or subacute low back pain for short-term (5 days) pain relief (WMD 1.06 on a 0 to 5 scale, 95% CI 0.68 to 1.45) and improvement in disability (WMD –2.10 on 0 to 24 RDQ Scale, 95% CI –3.19 to –1.01). Another higher-quality trial [481] found that application of a heated blanket decreased acute low back pain immediately following application compared to a non-heated blanket (WMD –32.20 on a 0 to 100 scale, 95% CI –38.69 to –25.71).

*Efficacy of heat wrap therapy versus other interventions*

The Cochrane review included one higher-quality trial [479] that found heat wrap therapy superior to oral acetaminophen or ibuprofen for short-term pain relief (differences 0.68 and 0.49 points, respectively, on a 0 to 5 scale after 1 day and 0.66 and 0.93 after 3 to 4 days) and improved function (difference 2 and 2.2 points after 4 days) in patients with acute low back pain (p values <0.05 for all differences). Another higher-quality trial [482] found heat wrap therapy superior to an educational booklet for early pain relief (WMD 0.60 on a 0 to 5 scale, 95% CI 0.05 to 1.15 after 2 days and WMD 1.10, 95% CI 0.55 to 1.65 after 4 days) and improved function (WMD 0.40, 95% CI –1.15 to 0.95 after 2 days and WMD 0.30, 95% CI –0.41 to 1.01 after 4 days) in patients with subacute or acute low back pain, though the benefits were no longer present after a week. There were no significant differences between heat wrap therapy and McKenzie exercise.

*Efficacy of superficial cold versus placebo*

There were no trials comparing superficial cold to placebo or no cold.

*Efficacy of superficial cold versus other interventions*

The Cochrane review included one lower quality trial [483] that found found ice massage and transcutaneous electrical stimulation similar effective in reducing pain in patients with chronic low back pain.

*Efficacy of superficial heat versus superficial cold*

Two lower-quality, non-randomized trials [484, 485] included in the Cochrane review reported conflicting results for superficial heat versus cold in patients with back pain of varying duration. One found that hot packs and ice massage were not significantly different in patients with back pain of mixed duration and the other found ice massage superior to hot packs.

*Safety*

No serious adverse events were reported in the trials of heat wrap therapy, and mainly consisted of skin irritation or increased ‘pinkness’ [477].

*Costs*

One decision analysis compared the cost-effectiveness of heat wrap therapy relative to ibuprofen or acetaminophen in patients with acute low back pain [486]. It found that

heat-wrap therapy dominated over both drugs (decreased costs and superior efficacy) and conclusions insensitive to changes in the parameters used. However, these results should be interpreted cautiously since the analysis used outcomes data from a single published trial [479].

**Summary**

- There is consistent evidence from three higher-quality trials that heat wrap therapy or a heated blanket is modestly superior to placebo or a non-heated blanket for short-term pain relief and back-specific functional status in patients with acute or subacute low back pain (level of evidence: good).
- Heat wrap therapy was also modestly superior to analgesic medications for short-term pain relief in one higher-quality trial of patients with acute low back pain (level of evidence: fair).
- Heat wrap therapy was superior to a self-care booklet, but not to exercise, in one higher-quality trial of patients with a mix of acute and subacute low back pain (level of evidence: fair).
- There is insufficient evidence (one lower-quality trial) to determine the efficacy of superficial cold (level of evidence: poor).
- There is conflicting evidence (two lower-quality, non-randomized trials) regarding the efficacy of superficial heat versus superficial cold (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found physical agents and modalities (including superficial heat or cold) of insufficiently proven benefit to justify their cost for acute low back pain (strength of evidence: C). However, they suggested that self-application of heat or cold to the back could be taught to the patient as an option.
- The VA/DoD and UK RCGP guidelines reached similar conclusions.
- The European COST guidelines make no recommendation for superficial heat or cold for acute low back pain, but note that three trials came from one research group with potential conflict of interest.
- The European COST guidelines found insufficient evidence to recommend superficial heat for chronic low back pain.

**Key Question 5.**

**Does referral from primary care providers to back specialty providers affect patient outcomes? What are the outcomes for patients who are managed by different types of care providers or by multidisciplinary or interdisciplinary clinics?**

Results of search: systematic reviews

We found no systematic review evaluating effects of referral by a primary care provider (defined here as a family practitioner, general internist, or general practitioner) to a non-surgical back specialist (defined here as a neurologist, rheumatologist, physiatrist, occupational medicine physician, neurologist, or pain physician) on patient outcomes. The efficacy of multidisciplinary rehabilitation, behavioral interventions, acupuncture, and spinal manipulation is reviewed for Key Question 3 and the efficacy of surgical and non-surgical invasive interventions for Key Questions 7 and 8. In general, trials focused on the intervention rather than the providing managing care, and did not specify whether patients were referred by a primary care provider, managed without a referral, or co-managed by multiple providers.

Results of search: trials

We found no trial evaluating the effects of referral from primary care providers to back specialty providers on patient outcomes. One recent large, higher-quality trial (the UCLA Low Back Pain Study) evaluated chiropractic versus medical care for patients with low back pain of unspecified duration (Table 47) [423]. We also identified one well-designed, prospective cohort study on outcomes of acute low back pain episodes in patients managed by different provider types [15].

*Efficacy of referral to back specialty providers on patient outcomes from low back pain*

The UCLA Low Back Pain Study (N=339) found no significant differences in pain or disability after 6 months in patients randomized to chiropractic care versus medical care without physical therapy, with specific interventions chosen at the discretion of the assigned providers [423]. Adding physical therapy to medical care was associated with a small but statistically significant benefit on disability scores (1.26 point difference on a 0 to 24 scale, 95% CI 0.20 to 2.32).

**Table 47. Results of UCLA Low Back Pain Study**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hurwitz, 2002[423] | N=681<br>6 months | **Chiropractic care vs. medical care (mean difference in improvement from baseline at 6 months)**<br>Most severe pain (0 to 10): 0.27 (95% CI -0.32 to 0.86)<br>Average pain: 0.22 (95% CI -0.25 to 0.69)<br>RDQ score (0 to 24): 0.75 (95% CI -0.29 to 1.79)<br><br>**Medical care + physical thearpy vs. medical care**<br>Most severe pain: 0.27 (95% CI -0.34 to 0.88)<br>Average pain: 0.35 (95% CI -0.12 to 0.82)<br>RDQ score: 1.25 (95% CI 0.20 to 2.32)<br><br>**Chiropractic care + physical modalities vs. chiropractic care**<br>Most severe pain: -0.02 (95% CI -0.63 to 0.59)<br>Average pain: 0.10 (95% CI -0.37 to 0.57)<br>RDQ score: -0.78 (95% CI -1.82 to 0.26) | 8/11 |

A well-designed prospective observational study from North Carolina found little difference in time to functional recovery, return to work, and complete in patients with acute back pain managed by primary care providers, chiropractors, or orthopedic surgeons [15]. Despite similar baseline pain and back-related disability, orthopedists were more likely to order CT or MRI of the spine compared to primary care providers (17% vs. 6-11%). Chiropractors saw patients an average of 9 to 13 visits for the acute back episode, compared to around 2 visits for primary care providers and orthopedists. Satisfaction with care was also greater with chiropractors than with the other providers. The mean cost per episode was higher for orthopedic or chiropractic care ($611 to $783, 1993 dollars) than with primary care providers ($435 to $508). An earlier observational study of 1020 back pain episodes from four states reported similar differences in patterns of care, though it did not assess patient outcomes or satisfaction [16]. A survey of physicians from the early 1990's also found that given the same clinical situations, use of diagnostic tests varied considerably among eight medical specialties (family practice, internal medicine, osteopathic general practice, physical medicine, rheumatology, neurology, orthopedic surgery, neurosurgery) [11]. Neurosurgeons and neurologists were more likely to order imaging studies, physiatrists and neurologists more likely to order electromyograms, and rheumatologists more likely to order laboratory tests.

**Summary of evidence**

- There is no direct evidence on the effects of referral from primary care to back specialty providers on patient outcomes, though evidence on the effects of certain interventions offered by specialty providers is reviewed elsewhere.
- One recent large, high-quality trial found medical care and chiropractic care associated with similar patient outcomes. Observational data also suggests no significant differences for back pain episodes managed by different provider types, though patterns of care varied (level of evidence: fair).

**Recommendations and findings from other guidelines**

- All guidelines recommend considering referral to a back specialist if low back pain is not improving despite non-invasive, usual interventions (strength of evidence: not assessed).
- For active duty personnel who have not improved after 4 to 6 months, the VA/DoD guidelines specifically recommend consideration of referral to the Medical Evaluation Board for possible reclassification or discharge from service (strength of evidence: not assessed).

**Key Question 6.**

**What is the diagnostic accuracy and potential harms associated with diagnostic tests for identifying patients who will benefit from invasive procedures such as provocative discography, diagnostic nerve blocks, or other similar tests? Does prior use of these tests improve outcomes from invasive procedures?**

**Provocative discography**

The usefulness of provocative discography in patients with low back pain remains controversial [487]. Provocative discography, which involves the injection of radiographic contrast material into the nucleus of an intervertebral disc, is most commonly performed in patients with chronic low back pain in whom an invasive procedure for discogenic back pain is being considered. Much of the debate about provocative discography centers on whether it is accurate for identifying painful lumbar discs ('discogenic back pain'), the uncertain natural history of discogram-positive low back pain (in one retrospective study, 68% of un-operated patients improved [488]), and whether use of provocative discography improves patient outcomes or leads to unnecessary and potentially harmful interventions. Many studies show good correlation between results of provocative discography and abnormalities on CT or MRI imaging [489, 490]. However, because the presence of radiographic degeneration or other

abnormalities is not necessarily associated with patient symptoms, imaging is an inadequate reference standard for assessing diagnostic accuracy. However, no other reference standard for 'discogenic pain' has been available.

We focused our review on several specific types of studies of provocative discography. First, we identified studies providing information on populations without serious back pain in which discography provokes a high rate of positive responses. Studies addressing this type of question—"Do test results in patients with the target disorder differ from those in normal people?"—have been categorized as the lowest level (Phase I) on a hierarchy of diagnostic research [491]. Because Phase II ("Are patients with certain test results more likely to have the target disorder than patients with other test results?") and Phase III ("Does the test result distinguish patients with and without the target disorder among patients in whom it is clinically reasonable to suspect that the disease is present?") studies cannot be reliably interpreted in the absence of an appropriate reference standard, we did not review the literature comparing provocative discography with CT or MRI imaging results. However, we searched for studies that evaluated accuracy of provocative discography using alternative reference standards. We also evaluated studies on the impact of provocative discography on patient outcomes. Such evidence addresses the highest level (Phase IV) question in the hierarchy of diagnostic research—"Do patients who undergo this diagnostic test fare better in their ultimate health outcomes than similar patients who are not tested?"

Results of search: systematic reviews

We identified two recent, lower-quality systematic reviews evaluating lumbar discography in patients with low back pain [489, 490]. We also included a systematic review evaluating the risk of discitis following discography [492].

Results of search: additional studies

We found seven studies published since 1990 (when the Walsh criteria were first introduced) evaluating rates of positive pain responses to provocative discography in patients without significant chronic back pain [493-499]. Four other studies evaluated factors associated with a higher likelihood for positive pain responses in patients with chronic low back pain [500-503]. We also found one recent study using a novel

reference standard to assess diagnostic accuracy of discography [504]. Finally, we identified one study comparing surgical outcomes in patients selected by discography versus those in whom discography was not performed [505]. We excluded two studies from the 1960's reporting high rates of positive provocative discography because they used outdated techniques [506, 507].

*Rates of positive pain responses to provocative discography in patients without significant back pain*

A study published by Walsh and colleagues in 1990 found that in ten asymptomatic, healthy young men undergoing provocative discography, none met criteria for a positive test [499]. By contrast, 6 of 7 (86%) of patients with low back pain for more than 6 months had a positive test. A positive test by the 'Walsh criteria' was defined as an abnormal disc in conjunction with pain rated as more severe than moderate and pain-related behavior (at least two of the following: guard/brace/withdraw, rubbing, grimacing, sighing, or verbalizing).

Carragee and colleagues subsequently conducted a series of studies evaluating the proportion of positive pain responses to provocative discography (as defined using Walsh criteria) in patients without serious back pain (or asymptomatic) (Table 48). They found that patients with somatization or abnormal psychometric testing had high rates of positive responses (70% to 83%), as did those who were disabled (86% or 5/6) or had an active worker's compensation or personal injury claim (89% or 8/9) [494, 495]. Patients with pain unrelated to the back also frequently had positive results (50% of 4/8 following iliac crest harvest and 40% or 4/10 in those with neck pain following cervical surgery) [495, 496]. In patients with previous discectomy, positive pain responses were seen in 40% (8/20) of those with good surgical results [494].

More recently, investigators have proposed adding pressure threshold criteria to the requirements for a positive response [508]. With this adaptation, pain that is only provoked with high injection pressures (which occurs in normal discs) is not considered a positive response. In one study, 0% (0/16) of asymptomatic volunteers had a positive response when incorporating pressure criteria, compared to a 35% (100/282) rate of positive discograms in patients with chronic low back pain [498]. In a re-analysis of data reported in earlier studies, Carragee and colleagues also reported no positive pain

responses (0/10) in asymptomatic, low-risk patients without low back pain [497]. However, 36% (5/14) of patients with back pain and either chronic pain or somatization, 25% (5/20) of pain-free patients following disc surgery, and 28% (7/25) of patients with mild low back pain would still be classified as having positive tests.

One limitation of this set of studies is small sample sizes, resulting in imprecise estimates. In addition, asymptomatic subjects in one study mainly consisted of physicians, which could limit the generalizability of results [509].

4257 **Table 48. Rates of positive pain responses to provocative discography in persons**
4258 **without serious back pain**

| Author, year | Definition of positive pain response | Rates of positive pain responses | Quality |
|---|---|---|---|
| Carragee, 2006[497] | Walsh criteria, with added criteria of 'low pressure' response defined as pain provoked with static pressure of less than 22 psi | **A:** No LBP, but with chronic pain or somatization: 36% (5/14); 30% (3/10) in patients with chronic pain and 50% (2/4) in patients with somatization<br>**B:** No LBP, history of prior successful lumbar discectomy (n=20): 25% (5/20)<br>**C:** Mild persistent low back pain but not seeking or receiving treatment for it (also s/p cervical surgery): 28% (7/25); 23% (3/13) in patients with no chronic pain and 33% (4/12) in patients with chronic pain<br>**D:** No LBP, no chronic pain: 0% (0/10) | 8/9 |
| Derby, 2005[498] | Negative discogram= no pain described as 'familiar', no pain >=6/10 at pressures <=50 psi above opening pressure and <=3.5 ml total injected volume | **A:** Asymptomatic volunteers: 0% (0/16)<br>**B:** Chronic low back pain with unremitting pain despite conservative treatment: 35% (100/282) of discs positive | 7/9 |
| Carragee, 2002[493] | Walsh criteria | **A:** Patients with mild persistent low back pain but not seeking or receiving treatment for it and s/p cervical spine surgery: 36% (9/25); 23% (3/13) in patients with good cervical surgery outcomes and 50% (6/12) in patients with worst cervical surgery outcomes<br>**B:** Patients undergoing discography for consideration of surgery: 73% (38/52)<br><br>In group A, 5/5 (100%) of patients with daily opioid had positive discogram vs. 3/17 (18%) without opioids | 9/9 |
| Carragee, 2000[494] | Walsh criteria | **A:** No low back pain 2 to 10 years following successful lumbar disc surgery, no depression: 40% (8/20)<br>**B:** Chronic persistent or recurrent low back and leg problems 14 months to 6 years following posterior discectomy: 63% (17/27); 43% (3/7) in patients with normal psychometric scores and 70% (14/20) in those with abnormal scores | 8/9 |
| Carragee, 2000[495] | Walsh criteria | **A:** No low back pain, status post cervical discectomy and/or fusion 2 to 4 years previously with good surgical outcomes: 10% (1/10)<br>**B:** No low back pain, status post cervical discectomy and/or fusion 2 to 4 years previously with poor surgical outcomes: 40% (4/10)<br>**C:** No low back pain, somatization disorder and chronic pain present: 83% (5/6)<br><br>Disabled: 86% (5/6)<br>Active worker's compensation or personal injury claim: 89% (8/9) | 8/9 |
| Carragee, 1999[496] | Walsh criteria | **A:** No low back pain, status post iliac bone graft harvesting for reasons unrelated to lumbar spine: 50% (4/8) | 7/9 |
| Walsh, 1990[499] | Walsh criteria | **A:** Low back pain >6 months: 86% (6/7)<br>**B:** No low back pain: 0% (0/10) | 6/9 |

*Factors associated with higher rates of positive discography in patients with chronic low back pain*

Two studies of patients with chronic low back pain reported higher rates of positive pain responses to provocative discography in patients with abnormal psychometric testing [500] or abnormal pain drawings (Table 49) [503]. Although one other study found no clear association between presence or absence of somatization disorder and positive pain responses to provocative discography, subjects appeared more highly selected as they had already undergone negative testing for facet joint mediated pain and an epidural steroid injection [502]. Another study reported positive pain responses in 38% (51/136) of un-operated discs in patients with chronic low back pain following lumbar surgery, though the rate was higher in previously operated discs (72% or 73/102) [501].

**Table 49. Trials evaluating predictors of positive pain responses to provocative discography in patients with chronic back pain**

| Author, year | Definition of positive pain response | Rates of positive pain responses | Quality |
|---|---|---|---|
| Manchikanti, 2001[502] | NASS criteria | **A:** Low back pain, negative testing for facet joint mediated pain and epidural steroids, with somatization disorder: 48% (12/25)<br>**B:** Low back pain, negative testing for facet joint mediated pain and epidural steroids, without somatization disorder: 56% (14/25) | 5/9 |
| Heggeness, 1997[501] | Reproduction of patient's typical pain pattern | **A:** Postoperative disks: 72% (73/102)<br>**B:** Unoperated disks: 38% (51/136) | 7/9 |
| Block, 1996[500] | Similar or exact pain reproduction | **A:** Low back pain, with at least 1 nondisrupted disc: 47% (34/72)<br><br>Discordant pain response associated with higher scores on hysteria and hypochondriasis subscales of MMPI | 2/9 |
| Ohnmeiss, 1995[503] | Similar or exact pain reproduction | **A:** Low back pain with abnormal pain drawing: 50% (18/36)<br>**B:** Low back pain with normal pain drawing: 12% (13/105) | 7/9 |

*Accuracy of provocative discography*

One recent, higher-quality prospective cohort study by Carragee and colleagues (2006) attempted to evaluate the positive predictive value of provocative discography by comparing the rate of successful surgical outcomes in patients with presumed discogenic pain by provocative discography relative to patients with single-level, unstable spondylolisthesis (a condition for which surgery is widely considered appropriate) (Table 50) [504]. Patients in the provocative discography group (N=32)

were selected if they met low-pressure criteria for a positive response at a single level, failed conservative therapy, had negative facet joint and sacroiliac joint blocks, and had no other spinal or pelvic pathology or comorbidities associated with poorer surgical outcomes. Patients in the spondylolisthesis group (N=34) also had no comorbidities and had single-level Grade I or II isthmic spondylolisthesis of either L5-S1 or L4-L5 with radiologic segmental instability. Patients appeared well-matched on baseline demographics, pain scores, functional status, and other important covariates.

The rate of highly successful outcomes two years following spinal fusion was 72% (23/32) in the spondylolisthesis group compared to 27% (8/30) in the positive discography group (p=0.0004). The proportion of patients who met criteria for minimal acceptable outcomes was 91% (29/32) in the spondylolisthesis group compared to 43% (13/30) in the positive discography group (assessed by blinded and independent observers). The "positive predictive value" (rate of success in the positive discography group relative to rate of success in the spondylolisthesis group) was 42% to 43% for both outcomes. Using the most favorable assumptions about dropouts (2 dropouts in discogenic pain group considered successes and 2 dropouts in spondylolisthesis group considered failures), the positive predictive value of discography would be 55% to 57%.

**Table 50. Study evaluating rates of successful surgical outcomes in highly selected patients with positive discography relative to patients with isthmic spondylolisthesis**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Carragee, 2006[504] | N=66<br>2 years | **Surgery for presumed discogenic pain (positive discography) vs. unstable single-level isthmic spondylolisthesis**<br>"Success" (pain VAS <=2/10, ODI<=15, no opioid or daily analgesic use, return to full employment): (27% (8/30) vs. 72% (23/32)<br>Minimal acceptable outcome (pain VAS <4/10, ODI <30, no opioid use, return to at least partial employment): 43% (13/30) vs. 91% (29/32 )<br>Pain VAS <2 (0 to 10 scale): 30% (9/30) vs. 84% (27/32)<br>ODI score <15: 33% (10/30) vs. 72% (23/32)<br>No opioid or daily analgesic: 30% (9/30) vs. 88% (28/32)<br>Working in usual occupation: 30% (9/30) vs. 81% (26/32)<br>"Positive predictive value" (positive outcome in discography group relative to spondylolisthesis group: 42% for "success", 43% for minimal acceptable outcome | 6/9 |

Although this study met criteria for a higher-quality prospective cohort study, the reference standard is quite atypical because it involves a comparison to outcomes with the same procedure in another set of patients with a different underlying condition (rather than comparing results to a reference test in the same set of patients). Interpretation of 'positive predictive value' estimates from this study depend on the key assumption that surgery for 'true' discogenic pain should achieve similar outcomes as surgery (in a matched, but different set of patients) for unstable spondylolisthesis. A potential alternative interpretation of study results is that even though surgery for discogenic pain identified by provocative discography is associated with a lower rate of success compared to surgery for unstable spondylolisthesis in highly selected patients without comorbidities, this difference could reflect an imperfect treatment rather than an incorrect diagnosis. On the other hand, it could also be argued that surgical removal of the disc and annulus (the presumed pain generators) should be the definitive treatment for discogenic pain.

*Effects of provocative discography on clinical outcomes*

One lower-quality observational study compared outcomes in patients selected for spinal fusion based on positive discography to those who underwent surgery without discography (Table 51)[505]. It was rated lower-quality because it used a historical control group, did not describe independent or blinded assessment of outcomes, and did not adjust for baseline differences or confounders. It found that after 2.4 to 2.8 years of follow-up, there were no significant differences in rates of satisfactory outcomes (<40 on Oswestry scale), pain, or psychologic testing.

**Table 51. Study of outcomes in patients selected for spinal fusion with or without provocative discography**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Madan, 2002[505] | N=73<br>2.4 to 2.8 years | **Discography vs. no discography**<br>"Excellent" or "good" ODI outcome: 81% vs. 76%<br>"Excellent" ODI outcome: 62% vs. 58%<br>ODI (mean scores): 34 vs. 34<br>Psychologic (mean scores): 22 vs. 15<br>Pain (VAS, 0-10): 4.2 vs. 4.4<br>Core set of surgical outcomes (range 10 to 50): 24 vs. 25 | 6/9 |

Two other retrospective cohort studies were excluded because they didn't compare outcomes in patients who did and did not undergo discography prior to surgery. One found successful surgery more likely in patients with positive discography and an abnormal MRI compared to positive discography and a normal MRI (75% vs. 50%) [510]. The other found success rates higher with abnormal discs and positive pain provocation compared to patients with abnormal discs and no pain provocation (88% vs. 52%) [511]. Both studies failed to report independent or blinded assessment of outcomes and did not adjust for baseline differences or potential confounders.

*Safety*

The most common serious complication following discography is discitis. In one systematic review of observational studies, 12 cases of discitis occurred in 5,091 patients (13,205 disc injections) undergoing discography without prophylactic antibiotics (mean 0.24% using the number of patients as the denominator and 0.09% using the number of disc injections as the denominator) [492]. In the single study of patients who received prophylactic antibiotics (200 patients, 435 discs), no cases were reported [512]. Other rare complications that have been reported after discography include disc herniation after injection, retroperitoneal hemorrhage, and dural penetration [492]. Increased pain following the procedure is frequent but usually transient. However, one small study of patients without back pain who underwent discography reported persistent back pain one year after injection in 20-67% of those with chronic pain at other sites or with somatization [513]. Long-term effects have not been well-studied, though one small study (N=36) found no increase in degenerative disc changes 10 to 20 years after discography [514].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- Positive responses to provocative discography were uncommon in small series of healthy, asymptomatic volunteers (level of evidence: fair).
- In patients without significant back pain, provocative discography was frequently associated with positive pain responses in small series of patients with chronic pain at other sites, those with somatization, those with previous disc surgery, and those disabled or seeking monetary compensation (level of evidence: fair).

- Incorporating pressure criteria into the definition for a positive response did not eliminate positive results in high-risk sub-groups of patients without significant low back pain in one small study (level of evidence: fair).
- Previous back surgery, chronic pain, and abnormal psychometric testing were also associated with increased rates of positive discography in small series of patients with chronic back pain (level of evidence: fair).
- One higher-quality cohort study found that relative to the rate of successful surgery for single-level isthmic spondylolisthesis, the rate of successful surgery for presumed discogenic back pain (based on provocative discography) was 43-44% in a highly selected population of patients without comorbidities (level of evidence: fair).
- In one lower-quality observational study, surgery outcomes were similar with or without the use of provocative discography to select patients (level of evidence: poor).
- Discitis appears rare with or without antibiotics. Other serious adverse events also appear rare. In one study, persistent pain was reported in patients with somatization or chronic pain at other sites (level of evidence: fair).

**Recommendations from other guidelines**

- The AHCPR guidelines recommend against discography in patients with acute low back pain because it is invasive and interpretation is equivocal (strength of evidence: C).
- The AHCPR guidelines recommend against CT-discography over MRI or CT for assessing patients with suspected nerve root compression due to lumbar disc hernia (strength of evidence: C).
- The European COST guidelines recommend against discography for diagnosing discogenic pain.

### Diagnostic selective nerve root blocks

Diagnostic selective nerve root blocks involve the injection of local anesthetic around spinal nerves under fluoroscopy. A positive response requires relief of usual symptoms. Results of selective nerve root blocks correlate well with radiologic or surgical evidence of nerve compression [515]. However, because nerve root compression can usually be assessed with non-invasive imaging, the main purposes of diagnostic nerve root blocks are to evaluate the appropriate target level for interventions when multiple nerve roots are involved and to confirm the diagnosis when imaging is equivocal or when there is discordance between clinical findings and imaging. No

reference standard for evaluating the diagnostic accuracy of selective nerve root blocks for identifying "true" nerve root pain in these situations is available. We therefore focused our review on evidence evaluating whether selective nerve root blocks improve clinical outcomes (Phase 4 on the diagnostic research hierarchy [491]).

Results of search: systematic reviews
We identified one recent systematic review on the diagnostic accuracy of selective nerve root blocks [515]. However, it included no studies evaluating whether diagnostic selective nerve root blocks improve clinical outcomes in patients with suspected nerve root compression compared to relying only on imaging and other non-invasive diagnostic methods.

Results of search: other studies
We identified no relevant studies.

Effects of selective nerve root blocks on clinical outcomes
We could not assess the effects of selective nerve root blocks on clinical outcomes (no evidence).

**Summary of evidence**

- There are no studies evaluating the impact of diagnostic selective nerve root blocks on clinical outcomes relative to non-invasive methods alone for evaluating suspected nerve root compression.

**Recommendations and findings from other guidelines**

- The other guidelines do not address diagnostic selective nerve root blocks.

**Diagnostic facet joint blocks**

Facet joint blocks involve the injection of local anesthetic into facet (zygapophysial) joints or around medial branches of the dorsal rami innervating the target joint under fluoroscopic guidance, in order to determine whether the facet joint is the source of low back pain. Like selective nerve root blocks, a positive response requires the relief of usual symptoms. Positive facet joint blocks have been reported in 15% to 45% of patients in different populations with chronic low back pain [516]. Use of control blocks can reduce the rate of positive responses by up to 50% compared to relying on a single block. However, as in other invasive diagnostic procedures, no reference standard for facet joint pain is available for evaluating the diagnostic accuracy

of facet joint blocks. Furthermore, results of facet joint blocks do not correlate well with findings on imaging studies. We therefore focused our review on evidence regarding the effect of facet joint blocks on clinical outcomes.

Results of search: systematic reviews

We evaluated two recent systematic reviews evaluating the diagnostic utility or accuracy of facet joint blocks [516, 517]. Neither included any study evaluating the effect of facet joint blocks on clinical outcomes.

Results of search: other studies

We identified no relevant studies not included in the systematic reviews.

*Effects of facet joint blocks on clinical outcomes*

We could not assess the effects of facet joint blocks on clinical outcomes (no studies).

**Summary of evidence**

- There are no studies evaluating the impact of facet joint blocks on clinical outcomes in patients with prolonged non-specific low back pain.
- Evidence on interventions targeted at facet joint pain is outlined in Key Question 7. In all trials of facet joint interventions, patients were enrolled based on positive diagnostic facet joint blocks.

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend against facet joint blocks for the diagnosis of facet joint pain.

**Key Question 7.**

**What is the effectiveness of injections (and different injection interventions) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?**

**Injections**

**Chemonucleolysis**

Results of search: systematic reviews

We identified one good-quality Cochrane review on the efficacy of chemonucleolysis (16 trials) in patients with prolapsed lumbar disc [518]. It updated an earlier Cochrane review [519]. We excluded two other older systematic reviews [520, 521]

Results of search: trials

We identified two randomized trials of chemonucleolysis not included in the Cochrane review [455, 522]. One compared chemonucleolysis to spinal manipulation [455], and the other compared long-term outcomes of chemonucleolysis with chymopapain versus chemonucleolysis with collagenase [522].

*Efficacy of chemonucleolysis versus placebo*

The Cochrane review [518] included five generally higher-quality placebo-controlled trials comparing chemonucleolysis using chymopapain with placebo. A total of 446 patients received chemonucleolysis. Chemonucleolysis was superior to placebo as rated by patients (two trials, OR 0.24, 95% CI 0.12 to 0.49) and by surgeons or an independent observer (three trials, OR 0.40, 95% CI 0.21 to 0.75). Fewer patients proceeded to open discectomy following chemonucleolysis relative to placebo (OR 0.41, 95% CI 0.25 to 0.68). One small, lower-quality trial found chemonucleolysis with collagenase superior to placebo [523].

*Efficacy of chemonucleolysis versus standard discectomy*

The Cochrane review also included five generally lower-quality trials (total number of subjects 680) comparing the efficacy of chemonucleolysis using chymopapain to standard surgical discectomy [518]. It found consistent trends towards poorer results with chemonucleolysis, though differences did not reach statistical significance. In addition, some between-study heterogeneity was present, and outcomes were inconsistently reported. At one year, patient-rated outcomes were worse in two trials (OR 0.61, 95% CI 0.30 to 1.24) and surgeon-rated outcomes in three trials (OR 0.37, 95% CI 0.13 to 1.05). About 30% of patients receiving chemonucleolysis subsequently underwent disc surgery within two years (OR 0.07, 95% CI 0.02 to 0.18).

*Efficacy of chemonucleolysis versus other interventions*

One trial not included in the Cochrane review found no significant differences after one year between patients randomized to chymopapain chemonucleolysis or spinal manipulation, though short-term outcomes (through six weeks) favored manipulation (Table 52) [524].

**Table 52. Trial of chemonucleolysis versus other interventions not included in systematic reviews**

| Author, year | Number of | Main results | Quality |
|---|---|---|---|

| | patients Duration of follow-up | | |
|---|---|---|---|
| Burton, 2000[524] | N=40<br>1 year | **Chemonucleolysis vs. manipulation** (mean improvement from baseline at 12 months)<br>Leg pain (0 to 10): -1.38 vs. -1.87 (NS)<br>Back pain (0 to 10): -1.18 vs. -1.52 (NS)<br>RDQ score: -4.68 vs. -6.03 (NS) | 3/11 |

Three lower-quality trials comparing chemonucleolysis and intradiscal steroids were reviewed in the section on intradiscal steroids [525, 526, 527]. None reported any differences between interventions.

*Efficacy of different chemonucleolysis methods*

One trial included in the Cochrane review found no differences in outcomes between low dose and standard dose chymopapain chemonucleolysis [528]. Another trial found no differences between chemonucleolysis with chymopapain versus chemonucleolysis with collagenase [529]. One lower-quality trial not included in the Cochrane review evaluated long-term (five year) outcomes following chemonucleolysis with chymopapain or collagenase [522]. It found a greater proportion of "good" or "excellent" results in the chymopapain group (72% vs. 52%) using the McNab criteria, with much of the difference due to the proportion of patients proceeding to surgery (18% vs. 28%) and considered failures (Table 53). However, improvement in pain scores was similar across the two groups (-7.8 vs. –7.7 on a 10 point scale).

**Table 53. Trials not included in systematic reviews on efficacy of different chemonucleolysis methods**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Wittenberg, 2001[522] | N=66<br>5 years | **Chemonucleolysis with chymopapain vs. collagenase**<br>"Good" or "excellent" result at 5 years (with patients requiring surgery considered poor results): 72% vs. 52%<br>Leg pain score, mean improvement (0 to 10 scale): -7.6 vs. -7.7<br>Required surgery: 18% vs. 28% | 5/11 |

*Safety*

Earlier trials reported allergic reactions in 1.5% to 2% of patients undergoing chemonucleolysis with chymopapain [523, 530, 531]. However, these may be underestimates, depending on how allergic reactions are assessed and defined, as one more recent trial reported that 12% of patient in the chymopapain arm experienced allergic reactions (flushing and itching), including one case of slight anaphylaxis [522].

Rare serious complications that have been reported following chemonucleolysis include lumbar subarachnoid hemorrhage and paraplegia [532, 533].

*Costs*

We identified two studies of costs associated with chemonucleolysis but excluded them because they used unreliable cost and outcomes data from a single observational study [534, 535].

**Summary of evidence**

- Chemonucleolysis with chymopapain was consistently superior to placebo in five higher-quality trials of patients with prolapsed lumbar disc (level of evidence: good).
- There is insufficient evidence to accurately judge the efficacy of chemonucleolysis with collagenase relative to placebo (one lower-quality trial) (level of evidence: poor).
- Chemonucleolysis was consistently associated with trends towards worse outcomes relative to standard discectomy in five lower-quality trials, and led to subsequent surgery in about 30% of cases (level of evidence: fair).
- Chemonucleolysis with chymopapain and intradiscal steroid injections were consistently associated with similar outcomes in three lower-quality trials (level of evidence: fair).
- One lower-quality trial found no differences between chemonucleolysis with chymopapain and spinal manipulation after one year, though manipulation was superior at short-term (through 6 weeks) follow-up (level of evidence: poor).
- Chemonucleolysis with chymopapain and collagenase were associated with similar pain outcomes in two lower-quality trials (one with five year follow-up), but chymopapain was associated with a trend towards reduced rate of subsequent surgery in one trial (level of evidence: fair).
- Chemonucleolysis with chymopapain is associated with mild allergic reactions in up to 12% of patients, though reporting of allergic reactions was suboptimal. Serious complications appear uncommon (level of evidence: poor).

**Recommendations from other guidelines**

- The AHCPR guidelines recommend chymopapain as an acceptable treatment for patients with a herniated disc, severe, disabling sciatica, evidence of nerve root compromise, and persistence after at least one month of therapy, though it is less efficacious than standard or microdiscectomy. Testing patients for

chymopapain allergic sensitivity could reduce the incidence of anaphylaxis (strength of evidence: C).

**Epidural steroid injections**

Results of search: systematic reviews

We identified one higher-quality Cochrane review that included eleven trials (five rated higher quality [350, 536-539]) of epidural steroids in patients with low back pain >1 month and sciatica [540, 541]. We also identified one other recent higher-quality [129] and four lower-quality systematic reviews [542-545]. We excluded seven older systematic reviews [110, 249, 520, 546-549] and another systematic review [550] that has already been updated [542]. We also excluded four reviews that were not clearly systematic [548, 551-553].

Results of search: trials

We identified five recent trials of epidural steroids not included in any of the systematic reviews [554-558]. Four were rated higher-quality [554, 556-558]. One trial compared epidural steroid injection to placebo injection [556], three compared epidural steroid injection to other active interventions (discectomy [554], intrasmuscular steroid injection [557], adhesiolysis [559], and one compared the caudal approach to targeted steroid placement with spinal endoscopy [558].

*Efficacy of interlaminar or caudal epidural steroid versus placebo injection (saline or local anesthetic)*

The Cochrane review [540, 541] included four trials (two higher-quality [538, 560]) that found no differences between epidural steroid and placebo injections for short- (<6 weeks) or longer-term (>6 weeks) pain relief (4 trials, RR 0.93, 95% CI 0.79 to 1.09 and 3 trials, RR 0.92, 95% CI 0.76 to 1.11, respectively) in patients with low back pain and radicular symptoms of more than one month duration. The highest quality and largest (N=158) trial reported results very similar to the pooled estimates [560].

Another systematic review, using different inclusion criteria, came to discordant conclusions [129]. Two [561, 562] of the four [350] trials in this review were not included in the Cochrane review because they evaluated patients with acute low back pain. The non-Cochrane review found epidural steroids superior to placebo injection for 'improvement in symptoms' when restricting the analysis to trials with at least 20 patient in each arm (OR 2.2, 95% CI 1.04 to 4.7), with similar estimates after adding data from

eight smaller trials. However, the results appeared sensitive to the inclusion of one trial of patients with acute low back pain [561] that reported an odds ratio of 6.8 (compared to odds ratios of 1.1 to 2.8 in the others).

A third systematic review that included trials of back pain of any duration, with or without sciatica) found conflicting evidence from 15 trials (14 of patients with sciatica) regarding efficacy of epidural steroids relative to placebo, local anesthetic injection, or other control [544]. Epidural steroids were superior in eight trials but no better (inferior or no significant differences) in seven others. Among the five highest quality trials [350, 536, 538, 560, 562], epidural steroids were superior in two [350, 536]. Two additional trials [563, 564] included in the most recent systematic review [542] both reported positive short-term (<6 weeks) results with epidural steroids, though only one of the trials [563] reported longer-term benefits.

One recent, large (N=228), high-quality trial not included in any of the systematic reviews found no significant short- or long-term (one year) differences in any assessed outcome (functional status, pain, requirement for surgery, and analgesics use) between epidural steroid and epidural saline in patients with subacute or chronic sciatica (Table 54) [556].

**Table 54. Trial of epidural steroid versus epidural saline not included in systematic reviews**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Price, 2005[556] | N=228<br>1 year | **Epidural steroid vs. epidural saline** (all results at 52 weeks unless otherwise noted)<br>Oswestry, proportion with >75% improvement: 12% vs. 4% at 3 weeks (p=0.016), 32%30 at 52 weeks (p=0.64)<br>SF-36: No significant differences<br>Leg pain, >50% improvement: 48% vs. 44% (NS)<br>Back pain (VAS 0 to 100), mean improvement from baseline: -8 vs. –9 (NS)<br>Required surgery: 13% vs. 13%<br>Off work due to sciatica: 24% vs. 22% | 10/11 |

Nearly all of the trials included in the systematic reviews evaluated patients with sciatica. An exception was one lower-quality trial of patients with non-sciatic back pain that found no differences in pain and functional outcomes following epidural steroid injection versus intrathecal midazolam [565]. Another higher-quality trial (not included in

any of the systematic reviews) found that in patients with spinal stenosis, epidural steroid and local anesthetic injections were both associated with improved walking distance at one week compared to epidural saline, though no beneficial effects were present for either at three months (Table 55) [566].

**Table 55. Trial of epidural steroids in patients with spinal stensois**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Fukusaki, , 1988[566] | N=53<br>3 months | **Epidural steroid vs. epidural local anesthetic vs. epidural saline**<br>Mean walking distance (m): 87 vs. 92 vs. 23 at week 1, 10 vs. 13 vs. 11 at 3 months ($p<0.05$ for epidural steroid and epidural local anesthetic vs. saline at week 1 only) | 6/11 |

*Efficacy of transforaminal epidural injection versus placebo injection*

Two recent systematic reviews specifically evaluated the efficacy of the more recently introduced transforaminal approach (using radiographic guidance), rather than the traditional interlaminar or caudal approaches, for administering epidural steroids [542, 543]. Both included one higher-quality trial that found transforaminal epidural steroid injection superior to local anesthetic injection for the proportion of patients proceeding to surgery after a mean of 23 months (71% vs. 33%) [567]. Results were mixed from two other trials: transforaminal steroid injection was superior to saline for 'good' overall response at 3 months (54% vs. 40%) in one lower-quality trial [564], but no better at 12 months in a higher-quality trial [568]. A fourth trial found no differences between transforaminal epidural injection with steroid versus hyaluronidase in patients with failed back surgery syndrome [569].

*Efficacy of epidural steroids versus local injections*

One higher-quality trial [350] included in the Cochrane review [540, 541] found no significant between epidural steroid injection and trigger point injection for the proportion of patients with sciatica who were recovered after one month (67% vs. 56%), though the epidural steroid was superior at three months. In a lower-quality trial included in two non-Cochrane systematic reviews [542, 543], both transforaminal and interlaminar epidural steroid injections were associated with a greater likelihood for a 'good' overall response at 3 months (68% and 53%, respectively) than paravertebral local anesthetic injections (26%), though it was not clear if the local anesthetic was administered at

tender points [564]. Transforaminal epidural steroid injection was also superior to trigger point injection for the proportion of patients with a 'successful' outcome at 12 months in one non-randomized study (84% vs. 48%) [570].

*Efficacy of epidural steroids versus other interventions*

One of the systematic reviews [544] included one small, lower-quality trial that found no differences between epidural steroid injection and dry needling of the interspinous ligament for the proportion of patients improved or cured according to clinician assessment (79% or 15/19 versus 83% or 10/12) [571].

Three other recent trials not included in the systematic reviews also compared epidural steroid injection to other interventions (Table 56). One higher-quality trial found no significant difference in rates of subsequent surgery (41% vs. 31%) two years or longer following epidural steroid versus intramuscular steroid (methylprednisolone 80 mg) plus local anesthetic injection in patients with sciatica for at least six weeks [557]. Pain relief favored the epidural group at 35 days ($p<0.004$, other data not provided) but not at longer follow-up. In patients with a large herniated disc and no improvement for at least six weeks, one lower-quality trial found epidural steroid injection superior to discectomy for most short-term (1-3 months) outcomes, though significant benefits were no longer present for most outcomes by 2-3 years [554]. Results of this trial are difficult to interpret because about one-third of the patients assigned to epidural steroids crossed over to surgery, and no intention-to-treat results were presented. Among patients randomized to epidural steroids who did not cross over to surgery, 42% to 56% considered their treatment a success, compared to 92% to 98% in patients allocated surgery and 82% to 93% in patients who crossed over to surgery. A third trial found epidural steroid alone substantially inferior to adhesiolysis either with or without hypertonic saline for pain relief, functional status, opioid intake, and psychiatric outcome measures in patients with back pain for at least two years and no response to a previous epidural steroid [555]. However, even though this trial was rated higher-quality, its reproducibility needs to be confirmed because of a very low response rate (>50% pain relief at 12 months) in the epidural steroid group (0%) and very high rates in the adhesiolysis groups (72% and 60%).

**Table 56. Additional trials of epidural steroids versus other interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Wilson-MacDonald, 2004[557] | N=93<br>2 years or longer | **Epidural steroid versus intramuscular steroid plus local anesthetic**<br>Proportion of patients undergoing surgery after at least 2 years: 41% vs. 31%, p=0.45 | 7/11 |
| Buttermann, 2004[554] | N=100<br>3 years | **Epidural steroid versus discectomy**<br>Motor deficit: 72% vs. 38% at 1-3 months (p<0.05), 9% vs. 4% at 2-3 years (NS)<br>Back pain, mean score (0 to 10 VAS): 3 vs. 2 at 1-3 months (p<0.05), 1.8 vs. 2.4 at 2-3 years (NS)<br>Leg pain, mean score: 4.1 vs. 1.4 at 1-3 months (p<0.05), 0.8 vs. 1.5 at 2- 3years (NS)<br>Oswestry, mean score: 34 vs. 22 at 1-3 months (p<0.05), 8 vs. 16 at 2-3 years (NS)<br>Much less use of medication: 16% vs. 24% at 1-3 months, 57% vs. 32% at 2-3 years | 3/11 |
| Manchikanti, 2004[555] | N=75<br>12 months | **Epidural steroid vs. adhesiolysis with hypertonic saline vs. adhesiolysis with isotonic saline**<br>Proportion with >50% pain relief at 12 months: 0% vs. 72% vs. 60% (p<0.001)<br>ODI score at 12 months: 32 vs. 23 vs. 24 (p<0.001)<br>VAS pain score (0 to 10) at 12 months: 7.7 vs. 4.6 vs. 5.2<br>Taking opioids: 52% vs. 16% vs. 16% (p<0.001) | 8/11 |

*Efficacy of different approaches for administering epidural steroids*

Four trials (none rated higher-quality) included in the systematic reviews [542, 543] compared different approaches for administering epidural steroids. Two trials [564, 572] found the transforaminal approach modestly superior to the interlaminar approach, but a third reported no differences in outcomes [573]. Radiologic confirmation of epidural placement with the interlaminar approach was either not reported or not performed in any trial. The fourth trial found no differences between the caudal and lumbar interlaminar approaches [574].

One higher-quality trial (not included in the systematic reviews) compared epidural steroid via the caudal approach versus targeted steroid placement during spinal endoscopy in patients with radicular back pain for at least six months, with needle placement confirmed by fluoroscopy for both methods (Table 57) [558]. It found no difference in any outcome between the two approaches.

**Table 57. Trial of epidural steroid via caudal approach versus targeted placement during spinal endoscopy**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Dashfield, 2005[558] | N=60<br>6 months | **Epidural steroid via caudal approach versus targeted placement during spinal endoscopy**<br>Pain (VAS) mean improvement: -1.4 vs. -1.22 (NS)<br>Present pain intensity, mean improvement: -0.8 vs. -1.0 (NS)<br>Short-form McGill Pain Questionnaire (sensory), mean improvement: -2.3 vs. +0.5 (NS)<br>Short-form McGill Pain Questionnaire (affective), mean improvement: 0 vs. 0 (NS)<br>HAD-anxiety and -depression scales: no significant differences between groups | 7/11 |

*Safety*

Serious adverse events were rare in trials of epidural steroid injections, but adverse events were generally not well reported. One systematic review found that four of 15 trials did not report adverse events, and another four reported no adverse events occurred [544]. Adverse events reported in the trials (typically transient and minor) included headache, nausea, irregular periods, pruritus, and increased sciatic pain. A recent, large (N=228), high-quality trial, reported post-injection headache in 3.3% (4/120) receiving epidural steroid, postdural puncture headache in 0.8% (1/120), nausea in 1.7% (2/120), and other adverse events in 4.2% (5/120) [556]. For the newer transforaminal approach, side effects were only reported in three of six trials [543]. One trial reported a 1.9% incidence of headache [564], one trial reported one episode of acute hypertension [573], and another reported one retroperitoneal bleed in a patient on anticoagulation [568]. Another trial found that all patients who underwent targeted placement of steroids during spinal endoscopy reported increased back pain, though no post-spinal headache, dural tap, or infection was observed [558]. Other adverse events associated with systemic corticosteroids include steroid myopathy, hyperglycemia, osteoporosis, avascular necrosis of bone, infection, and fluid retention.

*Costs*

One trial found no significant differences between transforaminal steroid and saline injections for cost per one response ($3740 versus $3629) [568]. However, a subgroup analysis suggested that the transforaminal steroid was more cost-effective for contained

herniations ($4432 versus $17,098 per responder, p=0.0073) than for extrusions ($7165 versus $2484, p=0.0058)

**Summary of evidence**

- Evidence of beneficial effects following epidural steroid injections by interlaminar or caudal approaches in patients with sciatica is mixed, with some studies showing short-term benefits, but most trials (including two larger, high-quality trials) reporting no longer-term benefits. Most evidence is in patients with symptoms of at least one month's duration (level of evidence: fair).
- There is insufficient evidence (one lower-quality trial showing no benefit) to accurately judge the efficacy of epidural steroids in patients with low back pain without sciatica (level of evidence: fair).
- One higher-quality trial found that epidural steroids have no sustained effects on walking distance relative to a placebo injection in patients with spinal stenosis (level of evidence: fair).
- In one higher-quality randomized trial, epidural steroid injection was no better than trigger point injections at one month for overall outcomes, though modestly superior at three months. Other trials comparing epidural steroids and local injections were either not randomized or did not clearly inject tender points (level of evidence: fair).
- Epidural steroid injections were not clearly superior to intramuscular steroids for long-term outcomes (level of evidence: fair).
- One higher-quality trial reported inferior outcomes with epidural steroid injection alone versus epidural adhesiolysis in patients with chronic back pain who previously failed an epidural injection, but reported high rates of response in the adhesiolysis group and unusually low rates in the epidural arm (0%) (level of evidence: fair).
- There is insufficient evidence (one lower-quality trial for each comparison) to accurately judge the relative efficacy of epidural steroids compared to dry-needling or discectomy (level of evidence: poor).
- Several trials have found no clear differences between transforaminal and other approaches for administering epidural steroids, but lack of radiologic confirmation of epidural placement for the other approaches limits their interpretation (level of evidence: poor).
- One higher-quality trial found no differences between caudal epidural steroid and targeted steroid placement during spinal endoscopy, with needle placement confirmed by fluoroscopy for both methods (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found no evidence to support the use of invasive epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculography (strength of evidence: D).
- The AHCPR guidelines recommend epidural steroids as an option for short-term relief of radicular pain after failure of conservative treatment and as a means of avoiding surgery (strength of evidence: C).
- The VA/DoD guidelines found limited evidence to support the use of epidural steroid injections for acute low back pain with nerve root pain and radicular neurologic deficit (strength of evidence: C).
- The UK RCGP guidelines found that epidural steroids with or without local anesthetic appear to produce better short-term relief of acute low back pain with sciatica than comparison treatments (strength of evidence: **).
- The UK RCGP guidelines found limited evidence that epidural injections are not beneficial for acute low back pain without radiculopathy (strength of evidence: *).
- The UK RCGP guidelines found that because of its invasive nature, epidural injections pose rare but serious potential risks (strength of evidence: **).
- The European COST guidelines recommend against epidural steroid injections for acute nonspecific low back pain and found insufficient evidence to recommend epidural injections for chronic, nonspecific low back pain.

**Facet (zygapophysial) joint injections**

Results of search: systematic reviews

One higher-quality Cochrane review (three trials, one higher quality [560]) evaluated the efficacy of facet joint injections in patients with chronic low back pain [540, 541]. We also identified two other recent systematic reviews [575, 576], neither of which identified any randomized trials not included in the Cochrane review, though both also included observational data.

Results of search: trials

We identified one lower-quality randomized trial not included in the systematic reviews that compared facet joint steroid injection versus medial branch block in patients with low back pain (duration of symptoms not specified) [577].

*Efficacy of facet joint injection versus control injection*

The lone high quality trial (N=101) included in the Cochrane review [540, 541] enrolled patients who responded to a single local anesthetic injection into the facet joint with

immediate pain relief [560]. There was no difference in the likelihood of pain relief in patients randomized to steroid or saline either one or three months after the injection (RR 0.89, 95% CI 0.65 to 1.21 and RR 0.90, 95% CI 0.69 to 1.17, respectively). A higher proportion of patients in the corticosteroid injection group had marked or very marked improvement after six months (46% vs. 15%, p=0.002). There is no biologic explanation for a delayed benefit from steroids, which was attenuated after controlling for the increased use of co-interventions in the steroid group. The difference between groups in the proportion of patients with *sustained* improvement (improvement at one, three, and six months) was not significant (22% vs. 10%, p=0.19), as half of the 22 patients with improvement at 6 months had no benefits at earlier time periods. The second, lower-quality trial included in the Cochrane review found no difference in mean pain scores between steroid and/or bupivacaine injection compared to placebo [578]. No diagnostic procedure was used to select patients for enrollment.

The other two systematic reviews included several small (N<100), non-randomized studies (prospective or retrospective), most of which reported that around 50% of patients reported beneficial effects on pain through about three months, and the proportion reporting benefits decreasing with longer-term follow-up [575, 576].

*Efficacy of facet joint injection versus medial branch block*

One higher-quality trial included in the Cochrane review [540, 541] found facet joint injection with a steroid and local anesthetic not associated with superior pain relief compared to medial branch block of the posterior primary ramus after 1 to 3 months [579]. One lower-quality trial not included in the systematic reviews reported no benefit with either facet joint injection or medial branch block, but outcomes were reported using unconventional methods and difficult to interpret (paired sequential analysis) [577].

*Costs*

We found no studies evaluating costs.

*Safety*

No adverse events other than transient local pain at the injection sites were reported in the lone higher quality trial [560].

**Summary of evidence**

- Evidence from two randomized trials indicates that facet joint injections are not beneficial for short-term pain relief in patients with chronic low back pain, though there was a trend towards modestly superior sustained pain relief in the single higher-quality trial of patients with chronic low back pain (level of evidence: fair).
- Two trials (one higher-quality) found no difference between facet joint injections and medial branch block.
- There is no evidence on efficacy of facet joint injections for acute low back pain.

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against facet joint injections in patients with acute low back problems (strength of evidence: C).
- The VA/DoD guideline recommendation is similar.
- The UK RCGP guidelines found that facet joint injection do not produce pain relief or global improvement, with neither the type of agent injected nor the site of injection making a significant difference to outcomes (strength of evidence: *).
- The UK RCGP guidelines also found no evidence on the efficacy of facet injections in acute low back problems (strength of evidence: *).

**Intradiscal steroid injections**

Results of search: systematic reviews

We found no systematic reviews specifically evaluating the efficacy of intradiscal steroid injections for patients with presumed chronic discogenic back pain. However, two RCTs comparing intradiscal steroids to chemonucleolysis with chymopapain were included in a good-quality Cochrane review of surgery for lumbar disc prolapse [519].

Results of search: trials

We identified three lower-quality RCTs and one non-randomized controlled trial evaluating the efficacy of intradiscal steroid in patients with chronic discogenic low back pain [527, 580-582].

Efficacy of intradiscal steroid versus control or no injection

In patients with MRI evidence of degenerative disc disease and positive discography, two trials found no significant difference between intradiscal steroid and control injections with either saline or a local anesthetic for either short- [582] or long-term [581] pain relief or improvement in functional status (Table 58) [581, 582]. In the trial reporting longer-term outcomes, the median pain score was unchanged in both groups

at one year [581]. A third trial found that in patients with degenerative disc disease who failed an epidural steroid injection, intradiscal steroid injection was superior to discography alone only in the subgroup of patients with inflammatory endplate changes on MRI [580]. However, changes in outcome scores and levels of statistical significance were poorly reported in this study. At 1-2 years, rates of 'success' (not clearly defined) in the subgroup with inflammatory endplate changes were 25% in patients randomized to discography plus intradiscal steroid, and 0% in the group randomized to discography alone. The proportion of patients who subsequently underwent fusion in this subgroup was 50% among those randomized to intradiscal steroid compared to 76% among those randomized to discography alone. Intradiscal steroid injection was also superior for functional status (ODI), though not for pain scores.

**Table 58. Trials of intradiscal steroids versus placebo injections**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Khot, 2004[581] | N=120<br>1 year | **Intradiscal methylprednisolone vs. intradiscal saline**<br>ODI, mean improvement (percent): 2.28 vs. 3.42 (p=0.71)<br>VAS pain score (0 to 10), median change: 0 vs. 0 (p=0.72) | 3 or 4/11 |
| Buttermann, 2004[580] | N=171<br>1-2 years | **Discography + intradiscal steroid vs. discography alone (estimated from graphs)**<br>Inflammatory end-plate changes present:<br>Pain, mean improvement in VAS (0 to 10): -0.3 vs. +0.6<br>ODI (0 to 100), mean improvement: -18 vs. +9<br>"Success" (not defined): 10/40 (25%) vs. 0/38 (0%)<br>Underwent fusion: 50% vs. 76%<br><br>No inflammatory end-plate changes present:<br>Pain, mean improvement in VAS: -1.2 vs. +0.6<br>ODI (0 to 100), mean improvement: -1 vs. -1<br>"Success" (not defined): 5/46 (11%) vs. 1/47 (2%)<br>Underwent fusion: 78% vs. 89%<br>Much less use of medication: 16% vs. 24% at 1-3 months, 57% vs. 32% at 2-3 years | 4/11 |
| Simmons, 1992[582] | N=25<br>10-14 days | **Intradiscal methylprednisolone vs. intradiscal bupivicaine**<br>Proportion improved overall: 3/14 (21%) vs. 1/11 (9%) (NS)<br>Proportion improved on VAS pain scale: 43% vs. 36% (NS)<br>Proportion improved on ODI: 36% vs. 27% (NS) | 5 or 6/11 |

*Efficacy of intradiscal steroid versus chemonucleolysis*

Two French-language trials [525, 526] included in the Cochrane review [518] found no differences between intradiscal steroid injection and chemonucleolysis in patients with sciatica (OR for failure or no improvement 1.20, 95% CI 0.61 to 2.38). One additional lower-quality, non-randomized controlled trial also reported similar rates of 'success' (defined as 'virtually pain-free') with intradiscal steroids or chemonucleolysis in patients with long-term back pain and sciatica unresponsive to conservative therapy (Table 59) [527].

**Table 59. Trial of intradiscal steroid versus chemonucleolysis**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Graham, 1975[527] | N=40<br>Not clear | **Intradiscal steroids vs. chemonucleolysis**<br>"Success" (proportion virtually pain-free): 45% vs. 45% | 4 or 5/11 |

*Safety*

None of the trials reported safety.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is consistent evidence from three low quality trials that intradiscal steroids are not associated with improved outcomes compared to control injections in patients with chronic low back pain with positive results on provocative discography (level of evidence: fair).
- One low quality trial found that intradiscal steroids are superior to discography alone in a selected subgroup of patients that failed epidural steroid injections and had inflammatory changes on MRI (level of evidence: poor).
- Three lower-quality trials found no differences between intradiscal steroid injection and chemonucleolysis in patients with prolapsed lumbar disc or sciatica (level of evidence: fair).
- None of the trials reported safety outcomes.

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend against intradiscal steroids for chronic low back pain.

## Local injections

Results of search: systematic reviews

We identified one higher-quality Cochrane review on the efficacy of local or trigger point injections (four relevant trials, one rated higher-quality [350] in patients with low back pain [540, 541]. Two other systematic reviews [542, 543] of epidural steroid injections included two trials (both lower-quality) comparing epidural steroids to local injections [564, 570].

Results of search: trials

We did not search for additional trials.

*Efficacy of trigger point injections versus saline injection*

The Cochrane review included three lower-quality trials that consistently found trigger point injections with a local anesthetic superior to saline injection for short-term pain relief in patients with subacute or chronic low back pain for short-term pain relief. However, the injections evaluated appeared to be heterogeneous: one evaluated an injection over the iliac crest [583], one evaluated injections over the iliolumbar ligament [584], and one evaluated trigger point injections [585]. A fourth trial compared trigger point injection to a single dry acupuncture needlestick, which we considered an active control (see below) [227]. Another trial included in the Cochrane review evaluated the efficacy of prolotherapy and is not discussed further here [586].

Efficacy of trigger point injection versus other interventions

The Cochrane review [540, 541] included one lower-quality trial that found a trigger point injection (with steroid, lidocaine, or both) inferior to a single dry acupuncture needelestick for achieving short-term improvement in pain scores, though the differences were not statistically significant (RR =0.64, 95% CI 0.35 to 1.16) [227]. Evidence on the efficacy of trigger point injections versus epidural steroid injections is reviewed in the section on epidural steroids.

*Efficacy of trigger point injection with a local anesthetic versus a steroid*

The Cochrane reviewed included one higher-quality trial that found no difference between trigger point injection with a local anesthetic versus a local anesthetic plus a steroid [350].

*Safety*

One placebo-controlled trial reported no adverse events [585] and another didn't report adverse events [584]. In two other trials adverse events in patients receiving local injections included pain at the injection site, temporary paresthesia, and nausea (in both active and control injection groups) [227, 583].

*Costs*

We identified no studies evaluating costs.

**Summary of evidence**

- There is consistent evidence from three lower quality trials that trigger point injection with a local anesthetic is superior to saline injection for short-term pain relief in patients with subacute or chronic low back pain (level of evidence: fair).
- There is no evidence on long-term pain relief.
- One low-quality trial found trigger point injection inferior to a dry needle acupuncture stick (level of evidence: poor).
- Using a steroid in place of a local anesthetic or adding a steroid to a local anesthetic did not result in superior outcomes in one higher-quality trial (level of evidence: fair).
- See section on epidural steroids for comparison between local injections and trigger point injections.

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against invasive trigger point injections in the treatment of patients with acute low back problems (strength of evidence=C).
- The VA/DoD guideline recommendations are similar.
- The UK RCGP guidelines found that studies of trigger point injections included patients with chronic low back pain, and findings were equivocal, with little evidence specifically in acute low back pain patients (strength of evidence: *).
- The European COST guidelines found insufficient evidence to recommend trigger point injections for chronic low back pain.

**Prolotherapy**

Prolotherapy (also referred to as sclerotherapy) is a technique involving the repeated injection of irritants into ligaments and tendinous attachments in order to trigger an inflammatory response that will subsequently lead to the strengthening of ligaments and decrease in pain and disability. Prolotherapy injections are often

supplemented by co-interventions such as trigger point injections, manipulation, and exercises that are thought to enhance the effectiveness of treatment. Anti-inflammatories are often discouraged because they are thought to potentially suppress the desired inflammatory response to the irritants.

Results of search: systematic reviews
We identified one recent, higher-quality Cochrane review (four trials, all higher quality) evaluating the efficacy of prolotherapy in patients with chronic low back pain [587].

Results of search: trials
We did not search for additional trials.

*Efficacy of prolotherapy versus control injections*
The Cochrane review included three higher-quality trials that evaluated the efficacy of prolotherapy versus control injections [588-590]. In the only trial to show a significant benefit with prolotherapy for the proportion of patients with short-term improvement in pain or disability (RR 1.47, 95% CI 1.04 to 2.06), both groups also received forceful manipulation, injection of gluteal tender points, flexion and extension exercises, and walking as co-interventions [589]. In the other two trials, there was no difference between prolotherapy and either saline or local anesthetic control injections for short- or long-term (up to 24 months) improvement in pain or disability [588, 590]. A fourth trial was included in the Cochrane review, but the effects of prolotherapy could not be determined because the prolotherapy group received strong manipulation and the control injection group only received light manipulation [586].

*Safety*
In three [586, 589, 590] of the four trials, nearly all participants had temporary increases in back pain and stiffness following injections. Post-injection headaches suggestive of lumbar puncture occurred in two to four percent of patients in two trials [589, 590]. Other adverse events included postmenopausal spotting, leg pain (attributable to herniated disc), diarrhea, and other, generally transient symptoms, but there were no significant differences in any adverse event between treatment and control groups.

*Costs*
We found no studies evaluating costs.

**Summary of evidence**

- There is conflicting evidence on the efficacy of prolotherapy versus control injections for chronic low back pain from three higher-quality trials (level of evidence: fair).
- There is no evidence in patients with acute low back pain.
- Serious adverse events have not been reported following prolotherapy treatments, though nearly all patients report increases in back pain (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against ligamentous and sclerosant injections for patient with acute low back problems (strength of evidence: C).
- The VA/DoD and UK RCGP guideline recommendations are similar.
- The European COST guidelines recommend against injections of sclerosants (prolotherapy) for nonspecific chronic low back pain.

**Sacroiliac joint injection**

Results of search: systematic reviews

We identified one lower-quality systematic review on sacroiliac joint injections [591]. It included only one small (N=24) trial of patients with low back pain not due to spondyloarthritis [592].

Results of search: trials

We identified no additional trials.

*Efficacy of sacroiliac joint injection versus control injection*

One small (N=24), higher-quality trial found a sacroiliac steroid injection superior to control (local anesthetic) injection for improvement in one-month pain scores in patients with chronic pain in the sacroiliac joint area and at least one positive physical exam finding (Table 60) [592].

**able 60. Trial on efficacy of sacroiliac joint injections in patients with suspected sacroiliac joint pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Luukainen, 2002[592] | N=24<br>1 month | **Sacroiliac joint steroid injection vs. control injection**<br>VAS (0 to 100), improvement in median scores: -40 vs. 013, p=0.046<br>Pain index (0 to 12), improvement in median scores: -3 vs. 0, p=0.017 | 6/11 |

*Safety*

Adverse events were not reported in the trial.

*Costs*

We found no trials evaluating costs.

### Summary of evidence

- One higher-quality but very small trial found sacroiliac joint steroid injection superior to local anesthetic injection for short-term pain relief in patients thought to have non-spondylarthropathic sacroiliac pain (level of evidence: poor).

### Recommendations and findings from other guidelines

- The European COST guidelines found insufficient evidence to recommend the use of corticosteroid injections for nonspecific chronic low back pain.

## Botulinum toxin

Results of search: systematic reviews

We identified no systematic review evaluating the effectiveness of botulinum toxin for low back pain.

Results of search: trials

Two small studies (one higher-quality RCT [593] and one lower-quality, non-randomized trial [594]) evaluated botulinum toxin injections for chronic low back pain. We identified no trials evaluating the effectiveness of botulinum toxin for acute or subacute low back pain.

*Efficacy of botulinum toxin versus saline injection or no injection*

A small (N=31), higher-quality RCT found botulinum toxin A superior to saline injection for short-term pain relief (proportion of patients with >50% pain relief 73% vs. 25% at 3 weeks, p=0.012, and 60% vs. 12.5% at 8 weeks, p=0.09), as well as for improvement in

functional impairment (proportion with improvement in ODI score 67% vs. 19%, p=0.011) in patients with chronic low back pain who failed to respond to standard treatments (Table 61) [593]. However, 60% of patients with a response to botulinum toxin responded cessation of benefits after three to four months. A second, lower-quality non-randomized trial (N=19) found botulinum toxin superior to no injection for improvement in pain, though differences in functional status and work outcomes were not significant [594].

**Table 61. Trials of botulinum toxin versus saline injection or no injection**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Subin, 2003[594] (non-randomized study) | N=19<br>6-12 months | **Botulinum toxin A vs. no treatment**<br>Pain, proportion improved on McGill-Melzack score: 78% (7/9) vs. 0% (0/10) (p<0.05)<br>Disability, proportion improved on Oswestry score: 56% (5/9) vs. 10% (1/10) (NS)<br>Proportion that missed work and were disabled: 11% (1/19) vs. 50% (5/10) (NS) | 3/11 |
| Foster, 2001[593] (randomized trial) | N=31<br>8 weeks | **Botulinum toxin A vs. saline injection**<br>Degree of pain relief >50%: 73% (11/15) vs. 25% (4/16) at 3 weeks (p=0.012), 60% (9/15) vs. 12.5% (2/16) at 8 weeks (p=0.009)<br>Oswestry score, proportion with improvement at 8 weeks: 67% (10/15) vs. 19% (3/14) (p=0.011)<br>6/10 responders in botulinum toxin A group reported cessation of analgesic effect after 3 to 4 months | 9/11 |

*Safety*

No side effects were reported in the single RCT [593]. However, a case of fatal anaphylaxis following injection of botulinum toxin A for chronic neck and back pain has been reported [595].

*Costs*

We identified no studies evaluating costs.

**Summary of evidence**

- A single, small, higher-quality trial found botulinum toxin injection superior to saline injection for short-term pain relief and improvement in functional status in patients with chronic low back pain who failed to respond to standard treatments (level of evidence: fair).
- There is no evidence comparing botulinum toxin injection to other interventions.

- There is no evidence on effectiveness of botulinum toxin injection in patients with acute low back pain.
- There is insufficient evidence to judge safety of botulinum toxin in patients with low back pain, though one case of fatal anaphylaxis has been reported.

## Radiofrequency Denervation, Intradiscal Electrothermal Therapy, and Percutaneous Intradiscal Radiofrequency Thermocoaglulation

### Radiofrequency denervation

Results of search: systematic reviews

We identified a recent, higher-quality Cochrane review (seven RCTs, six rated higher-quality) on efficacy of radiofrequency denervation in patients with chronic low back pain [596, 597]. We also identified three other systematic reviews, none of which identified additional trials not included in the Cochrane review [575, 576, 598]. We excluded one systematic review [599] because it has already been updated [575]. Another systematic review was excluded because it focussed on technical aspects and did not evaluate efficacy [600].

Results of search: trials

We identified three recent randomized trials not included in the systematic reviews. Two higher-quality trials evaluated the efficacy of radiofrequency denervation for facet joint [601] or radicular low back pain [602], and one lower-quality trial evaluated the efficacy of radiofrequency denervation for discogenic pain [603].

*Efficacy of radiofrequency denervation of the medial branch of the primary dosal ramus versus sham or placebo for facet joint pain*

The Cochrane review included three small (sample sizes 31 to 70) RCTs of patients with positive responses to facet joint testing (facet joint or dorsal ramus nerve block), all evaluating radiofrequency denervation of the medial branch of the primary dorsal rami [604-606]. The two higher-quality trials reported conflicting results [605, 606]. In one, patients randomized to radiofrequency denervation experienced greater improvement relative to patients randomized to sham on mean VAS pain scores (-2.4 vs. –0.4 on a 0 to 10 scale, $p<0.05$) and Oswestry scores (-11.1 vs. +1.7, $p<0.05$) through 2 months (van Kleef 1999). In addition, a higher proportion of patients randomized to radiofrequency denervation reported at least a 2 point reduction in VAS pain score and greater than 50 percent improvement in global effect (67% vs. 37.5%, $p=0.003$). In the other high quality trial, the radiofrequency denervation group had greater improvement

in RDQ mean scores at four weeks compared to sham (-8.4 vs. –2.2, p=0.05), though not in Oswestry or VAS pain scores [605]. At twelve weeks, the difference in RDQ scores was no longer significant. Results of the third trial could not be reliably interpreted because of low quality, including lack of intention-to-treat analysis [604].

Two of the three non-Cochrane systematic reviews came to similar conclusions about uncertain benefits from radiofrequency denervation [576, 598]. The third systematic review [575] came to more optimistic conclusions regarding benefits of radiofrequency denervation, largely because it excluded the high-quality trial [605] with neutral findings because it used a single block to identify patients with facet joint pain. However, this leaves only a single small trial demonstrating short-term benefits [606]. In addition, even though this systematic review used a liberal definition for a 'positive' response (at least 50% of patients in observational studies reported some pain relief), half of the six observational studies included in this review reported 'negative' results.

One higher-quality trial (N=82) of radiofrequency denervation in patients with positive facet joint testing has been published since the systematic review (Table 62) [601]. It found no differences between radiofrequency denervation and sham intervention for the proportion of patients with success (27.5% vs. 29.3%), VAS pain scores, or other outcomes after three months. About one-fifth of the 462 patients initially approached for possible inclusion were enrolled in this trial.

**Table 62. Additional trial of radiofrequency denervation in patients with positive facet joint testing**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Van Wijk, 2005[601] | N=81<br>3 months | **Radiofrequency denervation vs. sham injection**<br>Clinical success (defined as at least 50% improvement in VAS-leg score, without drop in daily activities score or rise in analgesics rating scale, or improvement of at least 2% in VAS-leg score, daily activities score, and analgesic use score) at 3 months: 28% vs. 29% (p=0.86)<br>Leg pain, change in VAS (0-10) score: -1.1 vs. –0.7 (NS)<br>Back pain, change in VAS (0-10) score: -2.1 vs. 01.6 (NS)<br>Change in daily activities: 1.5 vs. 0.9 (NS)<br>Change in analgesics use: -0.1 vs. –0.2 (NS) | 10/11 |

*Efficacy of radiofrequency denervation of the ramus communicans nerve versus sham or placebo for discogenic*

One lower-quality trial of patients with positive discography who had failed IDET found radiofrequency neurotomy of the ramus communicans nerves associated with better mean VAS pain scores compared to lidocaine injection (3.8 vs. 6.3, p<0.05) as well as SF-36 bodily pain (43.7 vs. 32.4, p<0.05) and physical function (58.9 vs. 46.5, p<0.05) scores at 4 months (Table 63) [603].

**Table 63. Trial of radiofrequency denervation of the ramus communicans nerve**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Oh, 2004[603] | N=49<br>4 months | **Radiofrequency denervation vs. lidocaine injection**<br>Pain, mean VAS (0-10) score at 4 months: 3.8 vs. 6.3 (p<0.05)<br>SF-36 bodily pain subscale: 43.7 vs. 32.4 (p<0.05)<br>SF-36 physical function subscale: 58.9 vs. 46.5 (p<0.05)<br>77% of patients in radiofrequency denervation group decreased analgesics by at least 50% | 5/11 |

*Efficacy of radiofrequency denervation versus sham or placebo for radicular low back pain*

One higher-quality trial of patients with chronic (>6 months) radicular pain and a positive nerve block found no difference between radiofrequency denervation of the dorsal root ganglia and sham treatment for the proportion with clinical success (16% vs. 25%, p=0.43), SF-36 scores, or use of analgesics (Table 64) [602]. There was a trend towards a higher proportion of patients in the sham intervention group reporting >50% reduction in VAS-pain scores for the leg (21% vs. 42%, p=0.051). The population evaluated appeared to be highly selected (1001 approached and only 83 enrolled).

**Table 64. Trial of radiofrequency denervation in patients with chronic radicular pain and positive nerve block**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Geurts, 2003[602] | N=83<br>3 months | **Radiofrequency denervation vs. sham**<br>Clinical success (see definition in van Wijk above): 16% vs. 25% (p=0.43)<br>Leg pain, change in VAS (0-10) score: -0.7 vs. –2.0 (p=0.02)<br>Back pain, change in VAS (0-10) score: -0.6 vs. –1.1 (p=0.32)<br>Change in daily activities: -0.5 vs. –0.4 (p=0.85)<br>Change in analgesics use: 0.1 vs. –0.2 (p=0.23) | 9 or 10/11 |

*Safety*

None of the trials [604-606] included in the systematic reviews reported adverse events [596, 597]. In three other recent trials, adverse events were not reported [601], did not differ between treatment and sham [602], or consisted of one case of subjective mild lower limb weakness that resolved within two weeks [603].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- The evidence on the efficacy of radiofrequency denervation of the medial branch of the primary dorsal ramus in patients with a positive facet joint block is mixed, with two of three higher quality trials showing no benefits compared to sham or control injection, even in highly selected populations (level of evidence: fair).
- Radiofrequency denervation was not effective in one higher quality trial of highly selected patients with chronic radicular pain and a positive nerve block (level of evidence: fair).
- Radiofrequency denervation of the ramus communicans nerve was superior to sham in patients with positive discography in one lower-quality trial (level of evidence: poor).
- Adverse events were poorly reported, but serious adverse events have not yet been observed following radiofrequency denervation.

**Recommendations and findings from other guidelines**

- The European COST guidelines found insufficient evidence to recommend radiofrequency denervation of dorsal root ganglion for chronic low back pain.

**Intradiscal electrothermal therapy (IDET)**

Results of search: systematic reviews

We identified one recent, good-quality Cochrane review (two higher-quality trials [607, 608]) of IDET for chronic low back pain [609, 610]. We also found two other systematic reviews that did not include any trials not included in the Cochrane review, but did review observational data [611, 612]. We considered IDET and a similar procedure, percutaneous intradiscal radiofrequency ablation, separately (see below). We excluded three other review articles that were not clearly systematic [613-615].

Results of search: trials

We did not search for additional trials.

*Efficacy of intradiscal electrothermal therapy versus sham*

The Cochrane review included two higher quality trials of IDET versus sham (N=57 and N=64) in patients with chronic low back pain and positive provocative lumbar discography that reported conflicting results [607, 608]. In one trial, patients randomized to IDET reported modestly superior improvements in mean VAS pain scores (0-10 scale, mean change 2.4 vs. 1.1, p=0.0045) and ODI scores (0 to 100 scale, mean change 11 vs. 4, p=0.050), but no differences in SF-35 bodily pain or physical functioning subscales [608]. The proportion of patients with at least a two-point improvement in VAS pain scores was 56% (18/32) with IDET compared to 38% (9/24) with sham. The trial appeared to evaluate a highly selected subset of patients, as only 64 patients from a potential cohort of 4253 were enrolled. By contrast, in the other trial, there were no differences between IDET and sham on the Low Back Pain Outcome Score, Oswestry Score, SF-36, or Zung Depression Index [607]. A third trial was excluded because it only compared two different durations of thermocoagulation, but found minimal improvement with either intensity of IDET [616].

The two other systematic reviews did not identify any additional trials but also included observational studies. In the only controlled observational study, IDET was associated with better VAS pain scores at 3 months (3.5 vs. 8.0, p<0.0005) and 24 months (3.0 vs. 7.5, p=0.028), as well as a higher proportion pain-free at 24 months (20% or 7/35 vs. 0% or 0/17) [617].

*Safety*

Most studies of IDET reported transient and mild complications ranging in incidence from 0% (0/58) to 15% (5/33) [618]. These included increased radicular pain (5/33), paresthesias and numbness (2/79), and foot drop (1/79). In one study, one patient developed a CSF leak [619]. There have also been case reports of cauda equina syndrome and vertebral osteonecrosis [618].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is conflicting evidence from two higher-quality trials on the efficacy of IDET relative to sham in patients with chronic low back pain with positive provocative

discography. In the one trial reporting benefits from IDET, benefits were modest despite the evaluation of a highly selected population (level of evidence: fair).

- Complications associated with IDET were poorly reported but generally appeared mild or transient, though there are case reports of cauda equina syndrome and vertebral osteonecrosis after IDET (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The European COST guidelines found insufficient evidence to recommend IDET for nonspecific or 'discogenic' chronic low back pain.

**Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)**

Results of search: systematic reviews

One higher-quality Cochrane review (one higher-quality trial [620]) evaluated the efficacy of PIRFT for chronic low back pain [609, 610]. We also identified two other systematic reviews, neither of which identified additional trials not included in the Cochrane review [611, 612].

Results of search: trials

We did not search for additional trials.

*Efficacy of PIRFT versus sham therapy for chronic low back pain*

The Cochrane review included one small (N=28) trial of discogenic low back pain (positive response to analgesic discography) [620]. It found no significant differences between radiofrequency denervation and sham therapy (two treatment successes in active treatment group and one in the sham group).

*Safety*

No adverse events were reported in the single published trial [620].

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- One small, low-quality trial found no differences between PIRFT and sham in patients with a positive response to analgesic discography (level of evidence: poor).
- There is insufficient data to judge the safety of PIRFT.

**Recommendations and findings from other guidelines**

- The European COST guidelines found insufficient evidence to recommend PIRFT for nonspecific or 'discogenic' chronic low back pain.

**Key Question 8.**

**What is the effectiveness of surgery (and different surgical interventions) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?**

Results of search: systematic reviews

We identified a recently updated (2005), higher-quality Cochrane review (31 trials) on the efficacy of surgery for degenerative lumbar spondylosis (defined by the authors of the review as degenerative conditions affecting the intervertebral discs, vertebrae, and/or associated joints, including associated instability, spinal stenosis, and/or degenerative spondylolisthesis) [609, 610]. Another higher-quality Cochrane review (last updated December 1999) evaluated the efficacy of surgery for lumbar disc prolapse (27 trials) [518]. Both Cochrane reviews noted numerous methodological shortcomings in nearly all of the included surgical trials (lack of blinded outcomes assessment, poorly described randomization techniques, poor allocation concealment, short duration of follow-up, absence of standardized clinical outcomes). Seven other systematic reviews addressing surgery for low back pain have been published since 2000 [621-627], but only included one trial (published only as an abstract [628]) not already in the Cochrane reviews. We excluded five older systematic reviews [521, 629-632].

Results of search: trials

We identified one recent randomized trial (not included in the systematic reviews) comparing surgical stabilization with non-surgical management of chronic low back pain [633]. We also included three reports from two randomized trials on artificial disk replacement versus fusion for chronic low back pain [634-636]. Results of the multicenter Spine Patient Outcomes Research Trials (three concurrent randomized trials of patients with sciatica, spinal stenosis, or degenerative spondylolisthesis) have not yet been published [637].

### *Efficacy of surgery versus non-surgical management*

#### Degenerative conditions of the lumbar spine (not including spinal stenosis)

The Cochrane review of surgery for degenerative conditions [609, 610]included two higher quality trials [638-640] comparing surgery to non-surgical management in patients with chronic (>1 year) low back pain without neurological compromise (spinal stenosis or nerve root compression) (Table 65). In the larger (N=294), Swedish trial, independent assessors rated outcomes as 'excellent' or 'good' after 2 years in 46% of patients with chronic back pain randomized to fusion versus 18% in the usual care group ($p<0.0001$), and more of the surgical patients rated their results as 'better' or 'much better' (63% vs. 29%, $p<0.0001$) [640]. The surgical patients also had significantly greater improvements in pain and disability scores, and a higher proportion back to work (36% vs. 13%, $p=0.002$). By contrast, the smaller Norwegian trial found no differences in any of the main outcomes after one year among chronic (>1 year) low back pain patients either with (N=60) or without (N=64) prior discectomy randomized to posterolateral fusion with transpedicular screws versus an educational intervention plus intensive exercise based on cognitive-behavioral principles [638, 639].

A recent, high-quality pragmatic trial compared spinal fusion (technique left to the discretion of the surgeon) to intensive multidisciplinary rehabilitation in patients with chronic low back pain considered candidates for surgical fusion (with or without sciatica) [633]. It found surgery associated with statistically greater improvements in Oswestry scores (mean difference between interventions –4.1, 95% CI –9.1 to –0.1, $p=0.045$) that barely met predefined criteria for minimal clinically important difference. There were no differences in other outcomes, including SF-36 scores and the shuttle walking test.

**Table 65. Trials of surgery versus non-surgical management of chronic low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Fairbank, 2005[633] | N=349<br>2 years | **Surgery versus intensive rehabilitation**<br>ODI score, mean difference between interventions: -4.1 (-9.1 to –0.1, p=0.045)<br>SF-36: no differences | 7/9 |
| Brox, 2006[638] | N=60 (prior discectomy)<br>1 year | **Surgery versus intensive rehabilitation**<br>ODI score, mean difference between interventions: -7.3 (-17.3 to 2.7)<br>Back pain, mean difference between interventions: -5.2 (-18.0 to 7.6)<br>Overall rating 'success': 50% vs. 48%, p=0.91 | 7/9 |
| Brox, 2003[639] | N=64 (no prior discectomy)<br>1 year | **Surgery versus intensive rehabilitation**<br>ODI score, mean difference between interventions: 2.3 (-6.8 to 11.4)<br>Back pain, mean difference between interventions: 8.6 (-3.0 to 20.1)<br>Overall rating 'success': 71% vs. 63%, p=0.59 | 8/9 |
| Fritzell, 2001[640] | N=294<br>2 years | **Surgery versus physical therapy**<br>Back pain VAS score, mean difference compared to baseline (0 to 100 scale): 21.0 vs. 4.3, p=0.0002<br>ODI score, mean: 11.6 vs. 2.8, p=0.015<br>Overall rating 'better' or 'much better': 63% vs. 29%, p<0.0001 | 8/9 |

One potential explanatory factor for the inconsistent results between trials is the non-surgical treatment chosen as the comparator. In the Swedish trial, one of the criteria for enrollment was failure of non-surgical treatment, but the control group appeared to receive similar non-surgical treatments after randomization [640]. In the other trials, by contrast, non-surgical management consisted of intensive rehabilitation interventions incorporating cognitive behavioral components [303, 304], which might explain why they performed better relative to surgery.

### Spinal stenosis

The Cochrane review [609, 610] included a small (N=31), higher quality randomized trial that found that the proportion of patients with an overall outcome rated 'good' was higher in patients randomized to initial surgical treatment (69% vs. 33% at 1 year, 92% vs. 47% at 4 years, 91% vs. 71% at 10 years) (Table 66) [641]. Interpretation of these results, however, is complicated by the fact that 10 of the 18 patients randomized to non-surgical treatment had subsequent surgery (none of the patients randomized to surgery underwent reoperation). In an observational cohort of patients evaluated alongside the randomized trial, the benefits of surgery also became attenuated over

time, with the overall outcome after 1 year judged 'good' in 89% of patients initially receiving surgery vs. 64% initially receiving non-surgical management and 71% vs. 73% after 10 years.

Results of a recent, higher-quality, long-term (8 to 10 years) prospective observational study (N=148) of patients with spinal stenosis (the Maine Lumbar Spine Study) were consistent with the randomized trial [642]. It found that the proportion of patients with improvement in their predominant symptom was greater with initial surgery compared to non-surgical therapy after 1 and 4 years (55% vs. 28%, p=0.003 and 70% vs. 52%, p=0.05, respectively), but not after 8 to 10 years (54% vs. 42%, p=0.3) [642-644]. Satisfaction with current status was also similar with long-term follow-up (55% vs. 49%, p=0.5). However, back-related functional status persistently favored initial surgical treatment (mean change after 8 to 10 years –7.3 vs. –1.2 on modified RDQ scale, p=0.02). Among patients initially undergoing surgery, 23% underwent reoperation, and among patients initially receiving nonsurgical treatment, 39% subsequently underwent surgery.

One other lower-quality RCT found that an interspinous spacer device was superior to non-surgical treatment (epidural injection, NSAIDs, analgesics, physical therapy) for the proportion of patients classified as treatment successes (59% vs. 12%, p<0.05) and on all SF-36 subscales after 1 year [645].

**Table 66. Trials of surgery versus non-surgical treatment for spinal stenosis**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Amundsen, 2000 | N=31<br>10 years | Surgical decompression versus non-surgical treatment<br>Proportion with 'good' results: 9/13 (69%) vs. 6/18 (33%) at 1 year; 11/12 (92%) vs. 8/17 (47%) at 4 years; 10/11 (91%) vs. 12/17 (71%) at 10 years (p values not reported) | 6/9 |
| Zucherman, 2004 | N=200<br>1 year | Interspinous implant versus non-surgical treatment<br>Treatment success: 59% vs. 12% (p<0.05) | 3/9 |

### Isthmic spondylolisthesis

One lower-quality trial included in the Cochrane review compared posterolateral fusion to an exercise program and found that surgery was associated with less pain (mean score 37 vs. 56, p=0.002) and disability (mean Disability Rating Index 29 vs. 44,

p=0.004) and better patient-rated outcomes (74% vs. 43% better or much better) after 2 years in patients with lumbar isthmic spondylolisthesis and low back pain for at least one year, though there were no significant difference in work-related outcomes (46% vs. 45% working) (Table 67) [646]. Outcomes associated with relief of sciatica from foraminal stenosis (the generally accepted indication for surgery in patients with this condition) were not reported.

**Table 67. Trial of surgery versus non-surgical treatment for isthmic spondylolisthesis**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Moller, 2000 | N=114<br>2 years | Posterolateral fusion versus exercise program<br>Disability Rating Index, mean score: 29 vs. 44, p=0.004<br>Pain score, mean: 37 vs. 56, p=0.002<br>Overall outcome 'much better' or 'better': 74% vs. 43% (p not reported) | 4/9 |

## Lumbar disc prolapse

The Cochrane review of surgery for lumber disc prolapse [518] included one lower-quality trial [647] comparing surgery to non-surgical treatment for lumbar disc prolapse in patients without definite indications for surgery that failed to improve with conservative management (Table 68). It found discectomy associated with a lower likelihood of poor results at 1 year (OR 0.38, 95% CI 0.14 to 0.99) but not after 4 or 10 years (OR 1.21, 95% CI 0.42 to 3.45 and OR 1.21, 95% CI 0.29 to 5.10, respectively). However, one-quarter of the patients randomized to conservative management eventually underwent surgery.

**Table 68. Trial of surgery versus non-surgical treatment for lumbar disc prolapse**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Weber, 1983 | N=126<br>10 years | **Surgery versus non-surgical treatment**<br>'Good' result (patient completely satisfied): 36% (24/66) vs. 65% (39/60) at 1 year, 52% (34/66) vs. 70% (40/57) at four years, 56% (37/66) vs. 64% (35/55) at ten years<br>'Poor' or 'bad' result: 21% (14/66) vs. 8% (5/60) at 1 year, 12% (8/66) vs. 14% (8/57) at 4 years, 6% (4/66) vs. 7% (4/55) at 10 years<br>Relapses: 24% (14/58) vs. 15% (8/54) after 0-4 years, 19% (11/58) vs. 27% (13/48) after 4 to 10 years<br>Proportion with no low back pain: 58% (38/66) vs. 60% (36/60) at 4 years, 79% (52/66) vs. 84% (43/51) at 10 years<br>Proportion with no radiating pain: 68% (45/66) vs. 98% (65/66) at 4 years, 76% (45/57) vs. 98% (54/55) at 10 years | 4/10 |

A long-term, higher-quality prospective cohort study (the Maine Lumbar Spine Study) reported results consistent with the randomized trial [648]. Among 507 patients with sciatica due to a herniated disc, initial treatment with surgery was associated with greater likelihood for improvement in the predominant symptom (either back or leg pain) at 1 year compared to initial non-surgical treatment (71% vs. 43%, p<0.001), but the differences were attenuated after 5 years (70% vs. 56%, p<0.001) and no longer significant after 10 years (69% and 61%, p=0.20) [648-650]. Patients initially treated surgically were also more likely to report long-term resolution of low back and leg pain (56% vs. 40%, p=0.006) and greater improvements in the RDQ functional status scores. However, work and disability status were comparable between groups at all follow-up evaluations. About one-quarter of patients in either group underwent additional or subsequent back surgery. Another, lower-quality observational study (did not adjust for baseline differences or confounders) found that fewer patients (N=342) who initially underwent surgery reported their low back condition as unchanged or worse after 13 years (19% vs. 41%), though similar proportions reported sciatica (67% vs. 68%) and being disabled due to a back problem (20% vs. 20%) [651]. There were also no differences in long-term functional status.

### *Efficacy of surgery versus other interventions*

#### Lumbar disc prolapse

The Cochrane review of surgery for lumbar disc prolapse included five lower-quality trials comparing standard surgical discectomy with chemonucleolysis using chymopapain [518]. Results from all trials generally favored surgery, though differences were not always statistically significant. The likelihood of subsequent surgery within two years was about 30% in the two years following chemonucleolysis and substantially more likely than following initial discectomy (5 trials, OR 0.07, 95% CI 0.02 to 0.18). Surgery was also associated with trends towards a lower proportion of patients reporting unchanged or worse condition (two trials, OR=0.61, 95% CI 0.30 to 1.24) and success at one year as rated by the surgeon at one year (three trials, OR=0.37, 95% CI 0.13 to 1.05). By contrast, one lower-quality trial found percutaneous automated endoscopic discectomy associated with a greater likelihood of no success at one year compared to chemonuceolysis with chymopapain (OR 2.26, 95% CI 1.17 to 4.37) [652].

One recent lower-quality trial not included in the systematic reviews compared discectomy to epidural steroid injection [554]. It found discectomy superior for short-term outcomes related to pain relief, functional status, motor deficits, and use of medications, though differences were no longer significant after 2-3 years of follow-up. This study is discussed in more detail in the section on epidural steroid injections. One other small (N=29) randomized trial [628] comparing laser discectomy to epidural steroids was included in a systematic review of laser discectomy [624], but has only been published as a conference abstract. It found no differences between interventions for any outcome.

### *Efficacy of different surgical techniques*

#### Degenerative conditions of the lumbar spine

The Cochrane review included 15 heterogeneous trials evaluating the efficacy of different fusion techniques in patients with mixed degenerative conditions of the lumbar spine [609, 610]. Instrumentation was associated with improved postero-lateral fusion rates after an average of 28 months in eight trials (OR 0.43, 95% CI 0.21 to 0.91). The pooled estimates for clinical outcomes also favored instrumentation (OR 0.49, 95% CI 0.28 to 0.84). However, excluding two lower-quality trials reporting unusually favorable

results (83% [653] and 93% [654]success with instrumented fusion) resulted in marginal and non-significant differences (74% vs. 66%).

The Cochrane review included four trials comparing various combinations of anterior, posterior, or combined fusion that gave conflicting results on relative effectiveness. Four other trials found that electrical stimulation (using heterogeneous methods) increased fusion rates in non-instrumented fusion (OR 0.38, 95% CI 0.22 to 0.64) but not in instrumented fusion (OR 0.59, 95% CI 0.15 to 2.30). In the three trials assessing clinical outcomes, there were no differences in outcomes with or without electrical stimulation [655-657].

**Artificial disk replacement versus fusion**

Three systematic reviews evaluated the efficacy of artificial disk replacement relative to fusion, but only included interim results from ongoing trials [609, 610, 622, 625]. Final results of one equivalence trial comparing the CHARITE Artificial Disc with anterior lumbar interbody fusion using the BAK Interbody Fusion System (a technique no longer commonly used because of frequent failures [658]) for single-level degenerative disc disease from L4-S1 were published after the systematic reviews (Table 69) [634]. It found that total disc replacement was equivalent to fusion for a composite outcome of 'clinical success' (>=25% improvement in ODI, no device failure, no major complications, and no neurologic deterioration) at 24 months in patients with symptomatic disc disease and positive discography who had failed at least six months of non-surgical treatment (57% vs. 46%, $p<0.0001$ for equivalence test). There were no differences in mean improvements in ODI scores (48.5 vs. 42.4, $p=0.27$ for difference) or visual analogue pain scores (40.6 vs. 34.1, $p=0.11$) at 24 months, though disk replacement was statistically superior at earlier evaluations. There were also no differences in rates of employment after 24 months.

**Table 69. Completed trial of total disc replacement versus fusion**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Blumenthal, 2005[634] | N=304<br>24 months | Total disc replacement vs. fusion<br>Clinical success: 117/205 (57%) vs. 46/99 (46%), p<0.0001 for equivalence<br>>=25% improvement in Oswestry: 131/205 (64%) vs. 50/99 (50%)<br>Length of hospitalization: 3.7 vs. 4.2 days, p=0.0039<br>ODI, mean improvement from baseline at 24 months: 49% vs. 42%, p<0.05<br>VAS for pain, mean improvement from baseline (0 to 100 scale): 40.6 vs. 34.1, p<0.05<br>Patient satisfaction rated as 'satisfied': 74% vs. 53%, p=0.0011<br>'Would have same treatment again': 70% vs. 50%, p=0.0062<br>Use of opioids: 148/205 (72%) vs. 85/99 (86%), p=0.0083<br>Employed at 24 months (percent increase): 9.2% vs. 7.4%, NS | 6 or 7/10 |

Two other single center, interim reports from a multicenter trial comparing ProDisc-II artificial disc replacement to anterior discectomy and circumferential fusion have been published [635, 636]. Neither reported significant differences in pain relief or ODI Disability Index scores.

### Spinal stenosis

The Cochrane review included one trial [659] of laminectomy versus multiple laminotomy for spinal stenosis that found no differences in clinical outcomes or spondylolisthesis progression, though confounding factors (including crossovers) may have affected results [609, 610]. Pooled results from three other small trials (total number of participants=139) also suggested no differences between postero-lateral fusion (with or without instrumentation) versus decompression alone for surgeon-rated outcomes (OR 0.44, 95% CI 0.13 to 1.48)

### Isthmic spondylolisthesis

One trial found no difference between patients undergoing fusion alone versus fusion plus laminectomy and decompression for isthmic L5/S1 spondylolisthesis [660]. A systematic review of surgery for isthmic spondylolisthesis that combined data across randomized and non-randomized studies found the posterior approach associated with

poorer success rates compared to anterior or combined approaches (75% versus 90% and 86%) [627].

**Lumbar disc prolapse**

The Cochrane review of surgery for lumbar disc prolapse included two trials [661, 662] that compared microdiscectomy to standard discectomy and reported similar clinical outcomes with either technique [609, 610]. There were also no differences in clinical outcomes in two trials comparing different types of interposition membranes [661, 662]. A third trial reported better clinical outcomes after insertion of an antiadhesion barrier gel, but only published highly selected results [663].

Two trials included in the Cochrane review reported conflicting results for automated percutaneous discectomy versus microdiscectomy, but aren't directly comparable because they evaluated different techniques. In one trial, which used modified forceps and an automated cutter with suction, clinical outcomes were comparable in patients randomized to automated percutaneous discectomy and microdiscectomy, but only 10% to 15% of patients needing surgical treatment were thought to be suitable for the former [664]. In the second trial, percutaneous discectomy using an automated suction nucleotome alone was associated with a lower rate of satisfactory results compared to microdiscectomy (29% vs. 80%) [665].

The Cochrane review found no published trials of laser discectomy. Three other systematic reviews of laser discectomy (with [621] or without endoscopy [624]) and endoscopic laser foraminoplasty [623] identified a single trial [628], published as an abstract only, comparing laser lumbar discectomy versus epidural steroids (see discussion of surgery versus other interventions). No randomized trials evaluating efficacy of laser discectomy with endoscopy or endoscopic laser foraminoplasty were identified.

*Selection of patients for surgery*

Patients enrolled in surgical trials all had chronic pain for at least one year, unresponsive to standard non-surgical treatments. Exclusion criteria generally included any significant psychiatric or somatic illness and often included ongoing compensation issues or other chronic pain. Many of these exclusions are based on uncontrolled

observational studies showing that surgical outcomes are poor in such patients [666, 667]. In a recent randomized trial (the Swedish Lumbar Spine Study) of surgery versus non-surgical management of chronic low back pain, personality features and low disc height both predicted functional improvement after surgery, and low age and short sick leave predicted work resumption after surgery [668]. By contrast, the presence of depressive symptoms predicted functional improvement after non-surgical treatment.

*Safety*

An earlier systematic review that included observational data estimated an in-hospitality mortality rate of 0.2% after spine surgery [632]. Rates of other serious complications included 1.5% for deep wound infection, 1.6% for deep vein thrombosis, 2.2% for pulmonary embolus, and 2.8% for nerve injury (2.8%).

No operative deaths were reported in any of the trials comparing surgery to non-surgical treatment. In two trials, early complication rates in the surgery group were 17% and 18% [639, 640]. One of these studies, which evaluated different fusion techniques, found higher risks of complications with more technically difficult procedures [669]. The total complication rate after two years was 12% with posterolateral fusion, 22% with posterolateral fusion and instrumentation, and 40% with 360 degree fusion.

In the only completed trial comparing total disc replacement to fusion, one death occurred among 205 patients randomized to total disc replacement (none in 99 patients randomized to fusion) [634]. There were no differences in rates of overall complications (p=0.6769). Major complications occurred in 1% with either total disc replacement or fusion.

*Costs*

Two trials of surgery versus non-surgical management of chronic low back pain conducted cost-effectiveness analyses. One study estimated an incremental cost-effectiveness ratio of £48,588/QALY for surgery relative to intensive rehabilitation [670]. This estimate was sensitive to the proportion of patients in the rehabilitation group requiring surgery in the future. The other estimated incremental cost-effectiveness ratios for fusion relative to usual care of 2,600 (600-5,100) Swedish kroners per case of improvement, 5,200 (1,100-11,500) kroners per one point improvement on a 100 point

pain scale, 11,300 (1,300-48,000) kroners per one point improvement on the ODI score, and 4,100 (100-21,400) kroners per patient returned to work [671]. There were no differences in costs associated with three different fusion techniques: posterolateral fusion, instrumented posterolateral fusion, and circumferential fusion with solid autogenous bone grafts.

Another study estimated a cost-effectiveness ratio of $12,000 to 33,900/QALY (depending on the cost of discectomy) for surgery for prolapsed disc relative to continued non-surgical management [672].

A high-quality decision analysis estimated an incremental cost-effectiveness of $56,500/QALY for laminectomy with noninstrumented fusion versus laminectomy without fusion in patients with degenerative spondylolisthesis and spinal stenosis [673]. The cost-effectiveness ratio of instrumented fusion compared with noninstrumented fusion was $3,112,800/QALY. However, this estimate was sensitive to the proportion of patients experiencing symptom relief after surgery, and could be as low as $82,400 if the proportion of patients experiencing symptom relief was 90% with instrumented fusion and 80% with noninstrumented fusion. Estimated costs of laminectomy alone and noninstrumented and instrumented fusion were $12,615, $18,495, and $25,914 in a study published in 1997 [674].

One trial found similar costs for automated percutaneous lumbar discectomy and microdiscectomy for contained lumbar disc herniation (automated percutaneous lumbar discectomy associated with poorer outcomes) [675].

**Summary of evidence**

Non-specific, degenerative low back pain

- In patients with chronic low back pain due to other degenerative conditions, two high-quality trials indicate that spinal fusion surgery is no better than intensive rehabilitation plus a cognitive intervention, but a third trial found surgery superior to conventional physical therapy (level of evidence: fair).
- Evidence regarding the efficacy of instrumented versus non-instrumented fusion is inconsistent, though clinical outcomes are similar after excluding two lower-quality trials reporting better outcomes and pooling data from the remaining five trials (level of evidence: fair).

- Evidence regarding the efficacy of anterior, posterior, or combined fusion from four trials is inconsistent and does not permit reliable judgments about relative efficacy (level of evidence: fair).
- Electrical stimulation may improve fusion rates in non-instrumented (but not instrumented) fusion, but didn't have a clear effect on clinical outcomes in three trials (level of evidence: fair).
- Artificial disc replacement with the Charite artificial disc was equivalent to anterior interbody fusion with a stand-alone cage for a combined measure of success at 24 months in the only completed (higher-quality) trial. There were no differences in pain relief, functional status, of employment status at 24 months, though earlier results favored artificial disc replacement (level of evidence: fair).
- Early complications following spine surgery occur in up to about 20% of patients. In-hospitality mortality after spine surgery occurs in about 0.2%, deep wound infection in 1.5%, deep vein thrombosis in 1.6%, pulmonary embolus in 2.2%, and nerve injury in 2.8% for nerve injury (level of evidence: fair).
- Complications from spinal fusion were higher with more technically difficult methods in one trial (level of evidence: fair).
- Rates of complications were similar after artificial disk replacement and fusion in one higher-quality trial (level of evidence: fair).
- Trials of surgery versus non-surgical management generally included patients who did not have clear indications for surgery (such as progressive or severe neurologic deficits or severe, intractable pain), failed to improve after 6 months to 2 years of conservative management, and had disease localized to L4-L5 and/or L5-S1.

Spinal stenosis, lumbar disc prolapse, and isthmic spondylolisthesis

- In patients with spinal stenosis and lumbar disc prolapse, consistent evidence from single RCTs and good-quality observational studies indicates that standard initial surgical therapy (decompression or discectomy, respectively) is associated with improved outcomes after one year compared to initial non-surgical therapy (or delayed surgery), but differences in outcomes are attenuated after 4 to 10 years of follow-up (level of evidence: fair).
- There is insufficient evidence from single low quality trials to judge the efficacy of surgery versus non-surgical management for mild isthmic spondylolisthesis (level of evidence: poor).
- There is insufficient evidence from one lower-quality trial to judge the efficacy of an interspinous spacer device for spinal stenosis (level of evidence: poor).
- Standard discectomy was consistently superior to chemonucleolysis in five lower-quality trials (level of evidence: fair).

- There is insufficient evidence (one lower-quality trial) to accurately judge the relative efficacy of epidural steroids compared to discectomy (level of evidence: poor).
- In patients with spinal stenosis, one lower-quality trial found no differences between laminectomy versus multiple laminotomy and three trials found no difference between postero-lateral fusion (with or without instrumentation) versus decompression alone (level of evidence: poor to fair).
- In patients with isthmic L5/S1 spondylolisthesis, one trial found no difference between patients undergoing fusion alone versus fusion plus laminectomy and decompression (level of evidence: fair).
- In patients with lumbar prolapse, there are no clear differences between standard discectomy and microdiscectomy or discectomy using different interposition membranes (level of evidence: fair).
- There is mixed evidence from two trials on the efficacy of automated percutaneous discectomy versus microdiscectomy, with one trial reporting similar outcomes and the other (using different techniques) poorer outcomes (level of evidence: poor).
- There is insufficient evidence to judge the efficacy of laser discectomy relative to other surgical methods (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found that patients with acute low back pain who don't have findings suggestive of nerve root compression or positive red flags do not need surgical consultation for possible herniated lumbar disc (strength of evidence: D).
- The AHCPR guidelines recommend against spinal fusion for the treatment of low back problems during the first 3 months of symptoms (strength of evidence: C).
- The AHCPR guidelines recommend that spinal fusion be considered following decompression at a level of increased motion due to degenerative spondylolisthesis (strength of evidence: C).
- The AHCPR guidelines recommend discussion further treatment options after 1 month of conservative therapy in patients with sciatica, and consider referral to a specialist when all of the following are met: 1) sciatica is both severe and disabling, 2) symptoms of sciatic persist without improvement or with progression, 3) there is clinical evidence of nerve root compromise (strength of evidence: B).
- The AHCPR guidelines found standard discectomy or microdiscectomy appropriate for selected patients with herniated discs and nerve root dysfunction (strength of evidence: B).

- The AHCPR guidelines recommended against percutaneous discectomy in patients with lumbar disc herniation because of poor efficacy relative to chymopapain (strength of evidence: C).
- The AHCPR guidelines found that elderly patients with spinal stenosis who can adequately function can be managed without surgery, and surgery should normally not be considered in the first three months of symptoms. Decisions on treatment should take into account patient preferences, lifestyle, surgical risk, and co-morbid medical problems, and should not be based solely on imaging tests, but take into account degree of neurogenic claudication symptoms, associated limitations, and detectable neurologic compromise (strength of evidence: D).
- The European COST guidelines found insufficient evidence to recommend fusion surgery for chronic low back pain unless two years of all other recommended conservative treatments have failed and combined programs of cognitive interventions and exercises are not available in the given geographical area. It strongly recommends that only carefully selected patients with severe pain (and with maximum 2 affected levels) should be considered for fusion.

**Key Question 9.**

**What is the effectiveness of other modalities (such as TENS or spinal cord stimulation) for non-specific low back pain, radicular low back pain, or spinal stenosis, and under what circumstances?**

**Transcutaneous electrical nerve stimulation (TENS)**

Result of search: systematic reviews

We identified one recent, higher-quality Cochrane review (two trials, one higher-quality [676]) on the efficacy of TENS versus sham TENS for chronic (>12 weeks) mechanical low back pain (with or without sciatica) [677]. This updated an earlier Cochrane review [678, 679]. Another higher-quality systematic review included four trials comparing TENS to acupuncture (discussed in the acupuncture section) [208]. We also included a systematic review that included two lower-quality trials of TENS versus other interventions for subacute (6 weeks to 3 months duration) low back pain [282]. We excluded four older systematic reviews [110, 283, 680, 681].

Results of search: trials

Three additional trials of TENS versus ice massage [483], TENS versus massage [379], and TENS versus traction [354] were previously discussed in the sections on massage, superficial heat or cold, and traction.

*Efficacy of TENS versus sham TENS*

The Cochrane review included one higher quality trial (n=145) [676] that found no differences between active and sham TENS for any measured outcome (including pain and functional status) after 4 weeks [677]. A smaller (n=30), fair-quality trial found that active TENS was associated with a greater reduction in pain over the 60-minute treatment session compared to sham TENS (weighted mean difference –33.62, 95% CI –52.27 to –13.97) [682]. Longer-term results and adverse events were not reported.

A systematic review of interventions in subacute low back pain included one lower-quality trial that found that TENS plus acupuncture-like TENS was associated with similar outcomes as sham TENS, with both groups also receiving a rehabilitation intervention [683]. There was a greater likelihood of return to work with TENS at 5 weeks (RR 2.0, 95% CI 0.7 to 5.9) but not at 6 months (RR 0.8, 95% CI 0.6 to 1.1).

*Efficacy of TENS versus other interventions*

A systematic review of acupuncture included four trials in patients with chronic low back pain that found no differences between acupuncture and TENS for short- (four trials, effect size 0.15, 95% CI –0.33 to 0.63) or long-term pain (two trials, effect size 0.32, 95% CI –0.33 to 0.96) [208]. Results of studies comparing TENS to other interventions in patients with chronic low back pain are mixed: one lower-quality trial found traction superior to TENS [354], one higher-quality trial found TENS superior to massage [379], and one lower-quality trial found no differences between TENS and ice massage [483].

A systematic review of interventions in subacute low back pain included one lower-quality trial [380, 381] that found spinal manipulation superior to TENS for pain (effect size 0.5, 95% CI 0.1 to 1.0) and disability (effect size 1.3, 95% CI 0.5 to 2.0) [282].

*Safety*

One third of patients with either active or sham TENS had minor skin irritation, with one patient (sham) discontinuing due to severe dermatitis [677]. The proportion of patients with skin irritation was similar in patients receiving active or sham TENS.

**Summary of evidence**

- There is conflicting evidence regarding the efficacy of TENS versus sham TENS for patients with non-specific chronic low back pain, though the sole higher-quality trial found no benefit (level of evidence: fair).

- There is consistent evidence from four trials that TENS is not superior to acupuncture in patients with chronic low back pain (level of evidence: fair).
- Evidence regarding the efficacy of TENS to other interventions in patients with chronic low back pain is limited to single trials of traction (traction superior), massage (TENS superior), and ice massage (no differences) (level of evidence: poor).
- TENS was no better than sham TENS and inferior to spinal manipulation in two lower-quality trials of patients with subacute low back pain (level of evidence: fair).
- TENS is associated with skin irritation that is usually minor (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines recommend against TENS in patients with acute low back problems (strength of evidence: C).
- The VA/DoD guidelines are identical.
- The UK RCGP found inconclusive evidence on the efficacy of TENS in patients with acute low back problems (strength of evidence: **).
- The European COST guidelines recommend against TENS for chronic low back pain.

### Percutaneous electrical nerve stimulation

Percutaneous electrical nerve stimulation (PENS) involves the insertion of acupuncture-like needles and applying low-level electrical stimulation. It differs from electroacupuncture in that the insertion points target dermatomal levels for local pathology, rather than acupuncture points. However, there is some uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture [684].

Results of search: systematic review

We identified no relevant systematic reviews.

Results of search: trials

We identified three trials of PENS in patients with chronic low back pain [685-687] and one trial in patients with sciatica [688]. All were rated lower quality.

*Efficacy of PENS versus sham PENS*

Two trials compared PENS to sham PENS in patients with chronic low back pain (Table 70) [686, 687]. Both found PENS moderately superior to sham-PENS for pain outcomes at the end of treatment [686] and three months after a course of treatment [687]. One trial also found improvements in functional outcomes and quality of sleep at the end of treatment [686]. The other trial found no benefits on measures of depression or functional status three months after treatment. In both trials, the success of blinding was not assessed.

A third trial compared PENS to sham PENS in patients with sciatica of at least 6 weeks duration. PENS was superior to sham PENS immediately after a two-week course of treatment for pain, functional status, and measures of sleep quality [688].

**Table 70. Trials of PENS versus sham PENS**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Weiner, 2003[687] (non-sciatic low back pain) | N=34<br>3 months after treatment | **PENS + physical therapy versus sham PENS + physical therapy** (mean scores 3 months after treatment)<br>McGill Pain Questionnaire: 6.19 vs. 11.82 (p=0.04)<br>Multidimensional Pain Inventory Pain Inventory score: 2.16 vs. 3.10 (p=0.003)<br>RDQ scale: 9.25 vs. 12.18 (p=0.26) | 3/11 |
| Ghoname, 1999[686] (not-sciatic low back pain) | N=60<br>At end of 2-week course of treatment | **PENS vs. sham PENS** (mean improvement from baseline)<br>Pain (VAS 0 to 10): -2.9 vs. -0.2 (p<0.02 for PENS)<br>Level of activity (0 to 10): -2.3 vs. -0.2 (p<0.02 for PENS)<br>Quality of sleep (0 to 10): -2.4 vs. 0 (p<0.02 for PENS) | 2/11 |
| Ghoname, 1999[688] (sciatica) | N=64<br>At end of 2-week course of treatment | **PENS vs. sham PENS**<br>Pain (VAS 0 to 10): -3.1 vs. -0.5 (p<0.01)<br>Level of activity (0 to 10): -2.4 vs. -0.5 (p<0.01)<br>Quality of sleep (0 to 10): -2.4 vs. -0.3 (p<0.01) | 1/11 |

*Efficacy of PENS versus other interventions*

Two trials compared PENS to TENS [685, 686] in patients with chronic low back pain (Table 71). Both found PENS superior to TENS at the end of treatment for measures of pain and functional status, but the only trial that followed patients after the end of treatment found that benefits were no longer present after 1 to 2 months [685].

One of these trials also compared PENS to a minimal exercise intervention (seated flexion and extension) [686]. PENS was superior to exercise on measures of pain and functional status at the end of a two-week course of treatment.

One trial of patients with sciatica found PENS superior to TENS on measures of pain and functional status at the end of a two-week course of treatment [688].

**Table 71. Trials of PENS versus other interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Yokoyama, 2004[685] (low back pain, presence or absence of sciatica not specified) | N=60<br>2 months after treatment | **PENS vs. TENS**<br>Pain (VAS pain scores): 32 vs. 48 at end of treatment (p<0.01), no differences 2 months after treatment<br>Physical impairment (0 to 4 scale): difference between PENS and TENS significant at end of treatment but not 1 month after treatment (data not reported) | 3/11 |
| Ghoname, 1999[686] (non-sciatic low back pain) | N=60<br>At end of 2-week course of treatment | **PENS vs. TENS vs. exercise**, mean improvement from baseline<br>Pain (VAS 0 to 10): -2.9 vs. -0.6 vs. -0.1 (p<0.02 for PENS vs. other interventions)<br>Level of activity (0 to 10): -2.3 vs. -0.8 vs. 0 (p<0.02 for PENS vs. other interventions)<br>Quality of sleep (0 to 10): -2.4 vs. -0.3 vs. -0.3 (p<0.02 for PENS vs. other interventions) | 2/11 |
| Ghoname, 1999[688] (sciatica) | N=64<br>At end of 2-week course of treatment | **PENS vs. TENS**, mean improvement from baseline<br>Pain (VAS 0 to 10): -3.1 vs. -2.6 (p<0.01)<br>Level of activity (0 to 10): -2.4 vs. -1.3 (p<0.01)<br>Quality of sleep (0 to 10): -2.4 vs. -1.0 (p<0.01) | 1/11 |

*Safety*

None of the trials reported safety outcomes.

Costs

We found no studies evaluating costs.

**Summary of evidence**

- PENS was superior to sham PENS in two lower-quality trials of patients with chronic low back pain for pain outcomes. In the only trial assessing outcomes after the end of treatment, pain benefits were present after two months, but there was no effect on functional outcomes (level of evidence: fair).
- PENS was superior to TENS and a minimal exercise intervention for pain and functional outcomes in one lower-quality trial of patients with chronic low back pain at the end of treatment, but in the only trial evaluating longer-term outcomes, no benefits were present after two months (level of evidence: poor).
- PENS was superior to sham PENS and TENS for pain and functional outcomes in one lower-quality trial of patients with sciatica, but outcomes were only assessed immediately after a two-week course of treatment (level of evidence: poor).

- There is insufficient evidence to accurately judge the safety of PENS.

**Recommendations and findings from other guidelines**

- The European COST guidelines recommend considering PENS for patients with chronic nonspecific low back pain.

**Spinal cord stimulation**

Results of search: systematic reviews

We identified one recent, fair-quality systematic review evaluating the efficacy of spinal cord stimulation in patients with chronic back and leg pain [689]. It found no trials of patients without failed back surgery syndrome, but reviewed 27 case series of patients with chronic back and leg pain (median quality score 1 on a 1 to 7 scale). Two other recent systematic reviews only included studies of patients with failed back surgery syndrome and are discussed in Key Question 11 [690, 691]. We excluded two older systematic reviews [692, 693].

Results of search: trials

We did not search for additional trials

*Efficacy of spinal cord stimulation*

The systematic review included 72 case series (mean duration of pain 6.5 years) reporting outcomes associated with spinal cord stimulation [689]. Twenty-seven studies were in patients with chronic back and leg pain. None of the studies prospectively studied consecutive patients using independently assessed and validated outcomes measures. Results were not reported separately for patients with chronic back and leg pain.

Estimates from pooled case study data of the proportion of patients with greater than 50% pain relief were 62% (95% CI 56-69%) following implantation and 48% (95% CI 43-53%) during follow-up testing. The percentage of patients achieving pain relief was 15 to 20% lower in studies rated higher quality (>3 on a 7 point scale), was reduced by 5% for every additional 10 months of follow-up, was increased by 10% for multicenter compared to single center studies, and was 20% higher for studies in patients with failed back surgery syndrome or chronic leg and back pain. The proportion of patients not requiring an analgesic after implantation was 53% (95% CI 48-56%), the proportion

returned to work 40% (95% CI 28-50%), and the proportion satisfied with the intervention 70% (95% CI 62-85%).

*Safety*

Only 18 of the 72 studies reported usable safety data [689]. Overall, 43% (48/112) of patients with chronic back and leg pain or failed back surgery syndrome experienced at least one complication with spinal cord stimulation. The most frequent complication was related to electrode or lead problems (27%). Other complications included infections (6%), generator problems (6%), extension cable problems (10%) and other issues (such as cerebrospinal fluid leak in 7%). No neurologic-related complications were reported.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- Low-quality evidence from multiple case series found that approximately half of patients with chronic back and leg pain or failed back surgery syndrome had decreased pain after spinal cord stimulator implantation, and 40% were returned to work. However, the lack of higher-quality evidence severely limits confidence in these estimates (level of evidence: poor).
- Spinal cord stimulation is associated with frequent complications, especially related to electrode or lead problems. Although most complications appear minor, infections (6% of complications) and cerebrospinal fluid leak (7%) have been reported (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The European guidelines found insufficient evidence to recommend spinal cord stimulation for chronic nonspecific low back pain.

**Key Question 10.**

**Which combinations of therapies are effective for acute low back pain? Chronic low back pain?**

**Combinations of medications**

Results of search: systematic reviews

A Cochrane review of muscle relaxants included five trials (four higher-quality) evaluating the efficacy of muscle relaxants plus an analgesic versus an analgesic alone

[163, 164]. We found no other systematic reviews evaluating the efficacy of one drug added to another relative to the other drug alone.

Results of search: trials
We identified one lower-quality trial evaluating the efficacy of opioids plus an NSAID versus an NSAID alone [182].

*Efficacy of a muscle relaxant plus an analgesic versus an analgesic alone*
The Cochrane review of muscle relaxants [163, 164] included three higher-quality trials [133, 694, 695] that consistently found tizanidine plus acetaminophen or NSAIDs superior to placebo plus acetaminophen or NSAIDs for short-term (up to one week) pain relief and decrease of muscle spasm in patients with acute low back pain. Another higher-quality trial included in the Cochrane review found no differences in global efficacy between orphenadrine plus acetaminophen compared to placebo plus acetaminophen, but the combination arm was associated with significantly fewer disability days [696]. One lower-quality trial found no difference in pain intensity or global efficacy between cyclobenzaprine plus an NSAID versus an NSAID alone, though effects on muscle spasm were superior [697].

*Efficacy of an opioids plus an NSAID versus an NSAID alone*
Naproxen was inferior to set-dose or titrated-dose opioid plus naproxen in one small N=36) lower-quality trial [182]. However, results are uninterpretable because the dose of naproxen was not specified and average doses not reported.

*Safety*
The Cochrane review found a higher risk of central nervous system adverse effects with the combination of a muscle relaxant plus an analgesic (4 trials, RR 2.44, 95% CI 1.05 to 5.63), but a trend towards a lower risk of gastrointestinal adverse effects (RR 0.54, 95% CI 0.26 to 1.14) [163, 164]. For overall adverse effects there was no significant difference (RR 1.34, 95% CI 0.67 to 2.67).

**Summary of evidence**

- There is consistent evidence from three higher-quality trials that tizanidine combined with acetaminophen or an NSAID is associated with greater short-term pain relief and decrease of muscle spasm in patients with acute low back pain (level of evidence: good).

- One higher-quality trial found no benefits from adding orphenadrine to acetaminophen in patients with acute low back pain, though the combination was associated with fewer disability days (level of evidence: fair).
- One lower-quality trial found no benefits from adding cyclobenzaprine to an NSAID in patients with acute low back pain (level of evidence: poor).
- There is insufficient evidence from one trial (doses unclear) to judge the efficacy of opioids plus an NSAID versus an NSAID alone (level of evidence: poor).
- Adding a muscle relaxant to acetaminophen or an NSAID was associated with an increased risk of central nervous system adverse effects (level of evidence: good).

**Recommendations and findings from other guidelines**

- The AHCPR guidelines found no additional benefit from using muscle relaxants plus NSAIDs over using NSAIDs alone.
- The European COST guidelines recommend adding a short course of muscle relaxants on its own or added to NSAIDs in patients with acute low back pain, if acetaminophen or NSAIDs failed to reduce pain.

**Self-care advice combined with other interventions**

Results of search: systematic reviews

We found no relevant systematic reviews.

Results of search: trials

We identified two trials (one higher-quality [698]) comparing a self-care book plus exercise to a self-care book alone [698, 699]. We also found a lower-quality trial compariing a self-care book plus interferential therapy to a self-care book alone [321]. A fourth trial compared a self-care book plus exercise advice versus either alone [452]. One other trial compared a self-care book to a self-care book plus nurse advice [456].

*Efficacy of a self-care book combined with other interventions*

One higher-quality trial of patients with low back pain for less than 6 weeks found that the a self-care book plus advice and immediate exercise therapy using a biopsychosocial approach was associated with more rapid improvements in function compared to a self-care book plus advice and waiting for 6 weeks to initiate therapy [698]. A lower-quality trial in patients off work for less than one year due to low back pain found that adding a brief exercise intervention to a self-care book and advice was associated with a quicker return to work compared to a self-care book and advice alone

(20 versus 13 days, p=0.034) and greater improvement in pain scores through two months [699].

One lower-quality trial was reviewed in more detail in the section on interferential therapy (Key Question 3) [321]. It found that the addition of interferential therapy applied to the paraspinal area to a self-care book was associated with greater improvement in functional status at three months compared to the self-care book alone, but baseline differences may invalidate these results.

Two other trials evaluating the efficacy of a self-care book plus face-to-face advice with a self-care book alone were reviewed in the section on self-care interventions (Key Question 4). One higher-quality trial found that brief nurse-led education plus a self-care book was associated with a higher proportion of patients exercising and greater patient satisfaction than a self-care book alone [456]. However, there were no differences in pain or functional status. A lower-quality trial found that the combination of a self-care book and advice to exercise was not associated with improved outcomes relative to the self-care book alone [452].

**Summary of evidence**

- Two trials (one higher-quality) found that a self-care book plus advice plus exercise therapy was superior to the self-care book and advice alone. One trial was in patients with back pain for less than 6 weeks and the other in patients off work for less than one year due to back pain (level of evidence: fair).
- Two trials (one higher-quality) found that adding face-to-face advice to a self-care book did not improve patient outcomes, though one of the trials found that self-reported exercise and patient satisfaction was higher (level of evidence: fair).
- There is insufficient evidence to judge the efficacy of a self-care book plus interferential therapy relative to a self-care book alone (one lower-quality trial) (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The other guidelines do not address this issue.

## Exercise combined with other interventions

Results of search: systematic reviews

We identified one good-quality Cochrane review [268, 269] and an associated meta-regression [293] evaluating the efficacy of exercise therapy plus other non-invasive interventions relative to exercise therapy alone in patients with chronic low back pain.

Results of search: trials

One recent, large, lower-quality trial (UK BEAM) not included in the Cochrane review evaluated the effects of exercise plus spinal manipulation versus spinal manipulation alone in patients with subacute or chronic low back pain [284].

*Efficacy of exercise therapy plus non-invasive treatments versus exercise alone*

The meta-regression performed in conjunction with the Cochrane review included 36 groups receiving exercise plus another intervention and 36 groups receiving exercise alone [293]. In multivariate analyses, adding other non-invasive interventions had a modest average additive effect compared to exercise therapy alone of 5.1 points (95% CI 3.6 to 7.1) for pain and 2.1 points (95% CI 0.7 to 3.7) for function (each on 100 point scales).

Results of the recent, large (N=1334) UK BEAM trial were consistent with only modest additive benefits from adding exercise therapy (Table 72) [284]. At 12 months, the combination was associated with slightly greater (but non-significant) net improvements in RDQ scores (0 to 24 scale) than manipulation alone (net improvement relative to usual care 1.30 points, 95% CI 0.54 to 2.07 and 1.01 points, 95% CI 0.22 to 1.81, respectively). The difference between combination therapy and manipulation was similar at three months. There were also no significant differences on the modified Von Korff scale or SF-36, though results on the back beliefs and fear avoidance questionnaires favored combination therapy.

**Table 72. Results of the UK BEAM Trial**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| UK BEAM Trial, 2004 | N=1334<br>12 months | **Manipulation + exercise versus manipulation versus exercise versus usual care (all results are net benefit relative to usual care at 12 months)**<br>RDQ Questionnaire (0 to 24 scale): 1.30 (95% CI 0.54 to 2.07) vs. 1.01 (95% CI 0.22 to 1.81) vs. 0.39 (95% CI -0.41 to 1.19)<br>Modified Von Korff pain score (0 to 100 scale): 6.71 (95% CI 2.47 to 10.95) vs. 5.87 (95% CI 1.58 to 10.17) vs. 4.90 (95% CI 0.30 to 9.50)<br>Modified Von Korff disability score (0 to 100 scale): 6.71 (95% CI 2.62 to 10.80) vs. 5.65 (95% CI 1.57 to 9.72) vs. 4.56 (95% CI 0.34 to 8.78) | 2 or 3/11 |

### Summary of evidence

- The addition of exercise to other non-invasive interventions is associated with modest improvements in pain (about 5 points on a 100 point scale) and function (about 2 points on a 100 point scale) in a large meta-regression (level of evidence: good).

### Recommendations and findings from other guidelines

- The other guidelines don't address this issue.

## Acupuncture combined with other non-invasive interventions

Results of search: systematic reviews

We identified one good-quality Cochrane review of acupuncture for low back pain that evaluated the efficacy of acupuncture added to other non-invasive interventions for acute (one lower-quality trial) or chronic (four higher-quality trials) low back pain [209, 210].

Results of search: trials

We did not search for additional trials

*Efficacy of acupuncture plus other non-invasive treatments versus the other treatment alone*

The Cochrane review included one lower-quality trial (N=100) that found the combination of acupuncture and moxibustion plus Chinese herbal medicine superior to Chinese herbal medicine alone for pain and function at long-term follow-up in patients with acute low back pain [700].

The Cochrane review also included four higher-quality trials (N=289) of patients with chronic low back pain that found the addition of acupuncture to another intervention more effective than the other intervention alone (co-interventions included exercises, NSAIDs, aspirin, non-opioid analgesics, mud packs, infrared heat therapy, back care education, ergonomics, or behavioral modifications). In pooled analyses, the addition of acupuncture was associated with improvements in pain (two trials, standardized mean difference –0.76, 95% CI –1.14 to –0.38) and function (three trials, standardized mean difference –0.55, 955 CI –0.92 to –0.18) that persisted through 3 to 12 months of follow-up [209, 210]. Despite the evaluation of different co-interventions, there was no between-study heterogeneity in the pooled analyses.

**Summary of evidence**

- In four higher-quality trials, acupuncture was associated with moderate beneficial effects on pain and function through 12 months when combined with a variety of other non-invasive intervention compared to the other intervention alone (level of evidence: good).
- There is insufficient evidence to judge the effects of acupuncture added to other interventions in patients with acute low back pain (one lower-quality trial) (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The other guidelines don't address this issue.

**Spinal manipulation combined with other interventions**

Results of search: systematic reviews

A recent, good-quality Cochrane review of spinal manipulation did not evaluate additive benefits of spinal manipulation to other non-invasive interventions [332, 333].

Results of search: trials

One recent, large trial that evaluated exercise therapy plus manipulation versus manipulation alone also evaluated exercise therapy alone [284]

*Efficacy of spinal manipulation plus exercise versus exercise alone*

Relative to usual care, the UK BEAM trial found that patients randomized to manipulation plus exercise improved RDQ scores (0 to 24 scale) after 12 months by an average of 1.30 points (95% CI 0.54 to 2.07) compared to 0.39 (-0.41 to 1.19) with exercise alone (see Table 72 above) [284]. The small difference in average effect

(about one point) was not statistically significant. There were also no significant differences on other outcome measures including the Von Korff scale, back beliefs questionnaire, fear avoidance beliefs questionnaire, or SF-36. Another higher-quality trial found that the combination of manipulation and exercise and a brief intervention (physician consultation) was associated with modest long-term benefits on pain scores (average 6.3 point difference on a 100 point pain scale at 12 months and 2.4 point difference after 24 months) compared to physician consultation only in patients with chronic low back pain [266]. There were no differences on the ODI score or health-related quality of life.

**Summary of evidence:**

- Compared to exercise therapy alone, the addition of spinal manipulation was not associated with significant benefits in a recent, large, lower-quality trial (level of evidence: fair).
- The combination of spinal manipulation plus exercise and a brief intervention (physician consultation) was associated with modest long-term differences in pain but not function relative to physician consultation alone in one higher-quality trial (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The other guidelines don't address this issue.

**Massage combined with other interventions**

Results of search: systematic reviews

We identified one recent, good-quality Cochrane review of massage therapy [375, 376] that included one higher-quality trial [378] of massage plus exercise and education versus exercise and education without massage.

Results of search: trials

We did not search for additional trials.

*Efficacy of massage plus exercise and education versus exercise and education without massage*

In the one relevant trial included in the Cochrane review, combined treatment with massage, exercise and education was superior to exercise and education alone for pain (McGill Present Pain Intensity) and disability (RDQ score) in patients with subacute low back pain at one-month follow-up [378]. Mean Present Pain Intensity scores (0 to 5

scale) were 0.42 (95% CI 0.17 to 0.66) for the combination versus 1.33 (0.97 to 1.7) for exercise and education alone, and mean RDQ scores (0 to 24 scale) 1.54 (95% CI 0.69 to 2.4) versus 5.71 (95% CI 3.5 to 7.9).

**Summary of evidence**

- Compared to exercise and education alone, the addition of massage therapy was associated with moderate short-term benefits for pain and disability in patients with subacute low back pain.

**Recommendations and findings from other guidelines**

- The other guidelines don't address this issue.

**Behavioral therapy combined with other interventions**

Results of search: systematic reviews

We identified one recent, good-quality Cochrane review that included six lower-quality trials comparing behavioral treatment in addition to another treatment versus the other treatment alone [73].

Results of search: trials

We did not search for additional trials

*Efficacy of behavioral therapy in addition to another intervention versus the other intervention alone*

The Cochrane review included six trials that compared behavioral treatment combined with physiotherapy and back education, multidisciplinary treatment, inpatient pain management, various forms of medical treatment (pain medication, nerve blocks, or physical therapy), and exercise therapy [73]. In pooled analyses, adding behavioral therapy to other interventions was not associated with beneficial effects on long-term pain intensity (pooled effect size –0.24, 95% CI –0.64 to 0.16), generic functional status (pooled effect size 0.26, 95% CI –0.06 to 0.57), or behavioral outcomes (pooled effect size 0.32, 95% CI –0.06 to 0.71). There were also no differences on outcomes assessed at the end of treatment. Despite the evaluation of different co-interventions, little between-study heterogeneity was present.

**Summary of evidence**

- Behavioral interventions were consistently ineffective for improving outcomes when added to a variety of other interventions in six lower-quality trials of patients with chronic low back pain. Diversity in both the behavioral and non-behavioral

interventions may limit the generalizability of these findings (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The other guidelines don't address this issue.

**Traction combined with other interventions**

Results of search: systematic reviews

We identified a recent, good-quality Cochrane review [337, 338] that included one lower-quality trial [701] comparing traction plus physical therapy to physical therapy alone.

Results of search: trials

We did not search for additional trials

*Efficacy of traction plus physical therapy versus physical therapy alone*

The small (N=42) trial included in the Cochrane review found no statistically significant differences between traction plus physical therapy and physical therapy alone for pain, functional status, global recovery, or satisfaction in patients with chronic low back pain with or without sciatica [701].

*Costs*

The UK BEAM Trial estimated a cost-effectiveness ratio of £3800/QALY for manipulation plus exercise relative to best care alone [284]. The cost-effectiveness of the combined treatment was superior to either manipulation or exercise alone (L4,800/QALY and 8,3800/QALY respectively, each relative to best care alone).

The UCLA Low Back Pain Study found that the addition of physical modalities to chiropractic care associated with minimal additional average cost ($579 vs. $560) and no differences in outcomes. The addition of physical therapy to usual medical care was associated with substantially increased costs ($760 vs. $369) with clinically negligible benefits [424].

**Summary of evidence**

- Traction plus physical therapy was no better than physical therapy alone in one small, lower-quality trial (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The other guidelines don't address this issue.

**Key Question 11.**

**What are effective strategies for failed back surgery syndrome?**

**Adhesiolysis**

Adhesiolysis (also referred to as lysis of epidural adhesions, epidural neurolysis, and epidural neuroplasty) is a relatively new procedure whose purpose is to improve the application of drugs to target nerves and other tissues by removing scars and adhesions in the epidural space. Adhesiolysis can be performed percutaneously or with endoscopic guidance. It is typically reserved for patients with back pain refractory to other treatments, often in the post-surgical setting.

Results of search: systematic reviews

We identified one recent systematic review evaluating the effectiveness of adhesiolysis [702]. Although the literature search for this systematic review appeared comprehensive, it was rated poor-quality because it used inadequate methods to analyze and synthesize the results of included studies. For example, it classified one study as a randomized trial even though it clearly was non-randomized [703].

Results of search: trials

Because the literature search in the systematic review appeared adequate, we did not conduct a separate search. However, we independently abstracted and analyzed the three studies included in the systematic review [555, 703, 704]. Only one was rated higher-quality [555].

*Efficacy of adhesiolysis with or without hypertonic saline versus other interventions*

One higher quality trial (N=75) randomized patients with chronic back pain who failed to respond to conservative treatment (including epidural steroids) and had negative facet joint block testing to epidural steroid without adhesiolysis, adhesiolysis with normal saline, or adhesiolysis with hypertonic saline [555]. It found adhesiolysis with or without hypertonic saline associated with significantly greater likelihood for >50% pain relief compared to epidural steroid alone (72% and 60% vs. 0%, $p<0.001$) after 12 months. However, even though patients enrolled in this trial had failed a previous injection, the 0% response rate with epidural steroids is still much lower than in other trials. For

example, in a high quality trial of epidural steroids versus saline placebo, rates of improvement in pain were approximately 70% in both groups [537]. A second study comparing adhesiolysis to usual care was classified as a randomized trial by the systematic review [702], but was actually a non-randomized comparative study [703]. Adhesiolysis was superior to usual care on most measured outcomes including pain, measures of functional status, and opioid intake.

**Table 73. Studies of adhesiolysis versus other interventions**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Manchikanti, 2004[555] (randomized controlled trial) | N=75<br>12 months | **Adhesiolysis with hypertonic saline vs. adhesiolysis with isotonic saline vs. epidural steroid**<br>Proportion with >50% pain relief at 12 months: 72% vs. 60% vs. 0% (p<0.001)<br>ODI disability index score at 12 months: 23 vs. 24 vs. 32 (p<0.001)<br>VAS pain score (0 to 10) at 12 months: 4.6 vs. 5.2 vs. 7.7<br>Taking opioids: 52% vs. 16% vs. 16% vs. 52% (p<0.001) | 8/11 |
| Manchikanti, 2001[703] (non-randomized comparative study) | N=45<br>18 months to 3 years | **Adhesiolysis vs. usual care**<br>Average pain (0 to 10): 3.9 vs. 6.9 (p<0.06)<br>Functional status (0 to 10): 5.3 vs. 4.3 (p<0.05)<br>Opioid intake moderate or heavy: 74% vs. 80**%**<br>Employed: 17% vs. 20% | 1/11 |

*Efficacy of adhesiolysis with hypertonic saline versus hyaluronidase versus isotonic saline*

The higher-quality trial found no significant differences in pain relief between patients randomized to adhesiolysis with hypertonic saline compared to adhesiolysis with isotonic saline (Table 73) [555]. One lower-quality trial found no significant differences between patients who underwent adhesiolysis with hypertonic saline alone versus adhesiolysis with hyaluronidase, hyaluronidase alone, or isotonic saline for pain relief or in the proportion of patients requiring additional treatments (Table 74) [704].

**Table 74. Trial of adhesiolysis with hypertonic saline versus hyaluronidase versus isotonic saline**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Heavner, 1999[704] | N=83<br>1 year | **Adhesiolysis with hypertonic saline vs. hypertopnic saline + hyaluronidase vs. isotonic saline vs. isotonic saline + hyaluronidase**<br>No significant differences on McGill Questionnaire, VAS pain score, and percentage requiring additional treatments through 1 year (data only reported in graphs, raw data not provided) | 2/11 |

*Safety*

The single higher-quality trial reported one subarachnoid block among 50 patients undergoing adhesiolysis [555]. One lower-quality trial repored no adverse effects among 59 patients [704]. A non-randomized comparative study reported one suspected infection and minor complications (such as rash and itching) in 10% of patients [703]. In other observational studies, subarachnoid puncture was reported in up to 9% of procedures [705], suspected infection in up to 10% [705], and post dural headache in 14% [706].

*Costs*

We identified no studies evaluating costs.

**Summary of evidence**

- Although one higher-quality trial found adhesiolysis markedly superior to epidural steroids for pain relief in patients with refractory back pain who failed a previous epidural steroid injection, confirmation of results by other trials is necessary because of the extremely low (0%) response rate in the epidural steroid group (level of evidence: fair).
- There is no clear evidence that use of hypertonic saline or hyaluronidase improves outcomes from adhesiolysis compared to using isotonic saline alone (level of evidence: fair).
- Adverse events were infrequent and usually minor in the trials, but were more common and included suspected infection, subarachnoid puncture, and post-dural headache in up to 9-14% of patients in observational studies (level of evidence: fair).

**Recommendations and findings from other guidelines**

- The other guidelines don’t address this issue.

**Intrathecal therapy**

Results of search: systematic reviews

We found no systematic reviews evaluating the efficacy of intrathecal delivery of opioids or other drugs in patients with low back pain.

Results of search: trials

We found no relevant trials.

*Efficacy of intrathecal therapy*

In the only comparative observational study, 27% of patients with failed back surgery syndrome who underwent implantation (N=23) had improvement in the ODI versus 12% in the usual care group (N=44) over a five-year period [707]. One prospective study of 136 patients with chronic low back pain who had an intrathecal device implanted (76% with prior back surgery) found that pain scores had dropped by more than 47% at 12-month follow-up [708]. In addition, more than 65% of implanted patients had improvements in ODI scores. Other data on efficacy of intrathecal therapy primarily comes from small case series of patients with cancer and non-cancer pain, with the proportion of patients with 'good or excellent' results ranging from 50% to close to 100% [709].

*Safety*

Complications with the intrathecal implant appear quite frequent. In one study, there was an average of 0.77 mean complications per implant (N=23). The most common complication was catheter-related and occurred in 26% (6/23). Other complications included pump flipping (22%) and infection (22%). One patient required pump explantation, and another developed late-onset meningitis after catheter replacement [707]. In another study, adverse events occurred in 23 of 136 (17%) patients after intrathecal pump implantation, with 21 (15%) requiring surgical correction [708]. Adverse events included infection (12%), dislodgement or migration (1.5%), and cerebrospinal fluid leak (0.7%).

*Costs*

We identified two cost studies [710, 711]. Both estimated fewer costs with intrathecal morphine relative to medical management, but used poor-quality observational data for generate key parameters.

**Summary of evidence**

- There is insufficient data to judge the efficacy of intrathecal therapy in patients with failed back surgery syndrome (limited observational studies only) (level of evidence: poor).
- Adverse events with intrathecal therapy appear to be frequent and often require surgery (level of evidence: poor).

### Recommendations and findings from other guidelines

- The other guidelines do not address this issue.

## Non-invasive interventions

Results of search: systematic reviews

We found no systematic reviews of non-invasive interventions in patients with failed back surgery syndrome.

Results of search: trials

We identified one lower-quality trial comparing the efficacy of low-tech exercise, hi-tech exercise, physical agents, manipulation, and no treatment in patients with chronic low back pain following L5 laminectomy [712].

*Efficacy of non-invasive interventions for failed back surgery syndrome*

The trial (N=250) found no significant differences in ODI scores at the end of an 8-week course of treatment of high-tech exercise (using specialized exercise equipment), low-tech exercise (using McKenzie and spinal stabilization training exercises), physical agents (hot packs, ultrasound, TENS), joint manipulation, and control, though trends favored the two exercise groups (Table 75) [712].

**Table 75. Trial of efficacy of non-invasive interventions for failed back surgery syndrome**

| Author, year | Number of patients<br>Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Timm, 1994[712] | N=250<br>At end of 8 week course of treatment | **Low-tech exercise vs. high-tech exercise vs. physical agents vs. manipulation vs. no treatment (at end of 8 week treatment session)**<br>ODI (0 to 100), mean improvement: -20.5 vs. -18.1 vs. -0.14 vs. -3.8 vs. -0.18 | 2/11 |

*Safety*

The trial did not assess safety.

*Costs*

No studies evaluated costs.

### Summary of evidence

- One lower-quality trial found no significant differences in immediate post-treatment ODI scores between exercise, physical agents, manipulation, and no treatment in patients with chronic low back pain following L5 laminectomy (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The other guidelines don't address this issue.

**Spinal cord stimulation**

Results of search: systematic reviews

We identified three recent systematic reviews (all rated higher-quality) evaluating spinal cord stimulation for failed back surgery syndrome [689-691]. Only one higher-quality trial [713] and one low-quality, controlled observational study [714] were included in the reviews. Seventy-two other case series of spinal cord stimulation for chronic back and leg pain or failed back surgery syndrome were also included in one of the reviews [689]; results are discussed in Key Question 9.

Results of search: trials

We did not search for additional trials

*Efficacy of spinal cord stimulation*

The single available RCT (N=50) found that patients randomized to spinal cord stimulation were more likely to report >50% pain relief compared to reoperation after 12 months (38% or 9/24 vs. 12% or 3/26, p=0.0475) [713]. Patients randomized to spinal cord stimulation were also less likely to report an increase in opiate analgesia (13% vs. 69%, p=0.0005). However, there was a crossover was high: five of 24 (21%) patients allocated to spinal cord stimulation and 14 of 26 (54%) allocated to reoperation received the other intervention. Analyzed by treatment received, the difference in the proportion of patients with >50% pain relief was not significant (45% or 15/33 vs. 18% or 3/17, p=0.0673). Three-year results were similar.

In the only controlled observational study, patients with failed back surgery syndrome were allocated to spinal cord stimulation if they had persistent symptoms after six months of medical therapy, and continued medical therapy if they were successful [714]. Patients who remained on medical therapy reported similar overall improvements in pain compared to those receiving spinal cord stimulation, but reported superior improvements in disability score (17 versus 3 point improvement, $p<0.05$). However, these results are very difficult to interpret because patients with spinal cord stimulation were selected because of persistent symptoms.

*Safety*

The RCT reported four (17%) and six (26%) complications at 6 and 12 months following spinal cord stimulator implantation [713]. Long-term complications included one infection, two implantation generator pocket-related complications, and one defective lead. Safety results from non-randomized studies are discussed in Key Question 9.

*Costs*

One decision analysis found that the spinal cord stimulation dominated continued medical management over the lifetime of a patient with failed back surgery syndrome [715]. However, this study should be interpreted cautiously because it may have used indirect analyses (combining estimates from one trial of spinal cord stimulation versus surgery and one trial of surgery versus medical management) inappropriately to estimate effectiveness of spinal cord stimulation relative to continued medical management. Specifically, estimates for effectiveness of surgery relative to continued medical management were taken from the only trial showing a benefit from surgery [640]. Other cost studies also used unreliable data to estimates costs and outcomes [707, 716].

**Summary of evidence**

- One small RCT found that spinal cord stimulation was associated with a higher likelihood of pain relief and lower likelihood of increase in opioid use in patients with failed back surgery syndrome, but results are difficult to interpret because of a high rate of crossovers (level of evidence: fair).
- Other evidence (low-quality observational data) is inadequate to make reliable judgments about efficacy.
- Long-term complications after spinal cord stimulation have not been well-studied, but include infection and generator or lead-associated problems.

**Recommendations from other guidelines**

- The European COST guidelines found insufficient evidence to recommend spinal cord stimulation for patients with chronic low back pain.

**Key Question 12.**

**How effective are different methods of integrating and coordinating care in improving outcomes?**

Results of search: systematic reviews

We identified no systematic reviews evaluating the efficacy of different methods of integrating or coordinating care in patients with low back pain.

Results of search: trials

We identified one lower-quality trial evaluating the efficacy of coordination of care relative to usual care in patients with back-pain associated disability [717]. One other low-quality trial evaluated the efficacy of integrated care between primary care and neurology via a psychiatrist liaison versus usual care in patients initially presenting with back pain of unspecified duration [718].

*Efficacy of coordinated or integrated care versus usual care*

One trial found that in workers receiving compensation for low back pain for 4 to 8 weeks, coordination of primary health care was superior to usual care for functional status and disability after 6 months as measured by the ODI scale (average 9 point difference, p=0.02) and the Quebec Back Pain Disability Scale (average twelve point difference, p=0.01) (Table 76) [717]. Coordination of care was also associated with modestly quicker return to work (6.6 days, not significant). Patients randomized to coordinated care also used three times fewer specialized imaging tests ($p<0.01$) and exercised twice as much ($p<0.05$) as controls. Two primary care physicians and a nurse performed the coordination of care intervention, which involved a complete examination, recommendations to the treating physician for clinical management consistent with guidelines, and support to carry out the recommendations.

Another trial, which had numerous methodologic flaws (met 1 of 11 quality criteria) found that integration of care between a neurologist and primary care physician via a psychiatrist did not improve patient outcomes, satisfaction of general practitioners, or affect utilization of healthcare services relative to usual care in patients with low back pain of unspecified duration [718]. The protocol called for the psychiatrist, who did not see the patient, to facilitate communication between the primary care physician and neurologist through structured telephone communication, weekly communication, and

development of a treatment plan of care. However, the protocol was only fully implemented in about one-quarter of the 50 patients randomized to the intervention group.

**Table 76. Trials of coordination of care**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Rossignol, 2000[717] | N=110<br>6 months | **Coordination of care versus usual care**<br>Return to work by 6 months: 78% vs. 73%<br>Time to return to work: average difference 6.6 days (NS)<br>Pain, mean difference from baseline to 6 months: 22.9 vs. 12.8, p=0.1<br>Quebec Back Pain Disability Scale, mean difference from baseline to 6 months: 20.9 vs. 9.1, p=0.01<br>Owestry, mean difference from baseline to 6 months: 17.2 vs. 7.8, p=0.02<br>Dallas Pain Questionnaire, mean difference from baseline to 6 months: 25.9 vs. 11.7 (p=0.01) | 5/11 |
| Meeuwesen, 1996[718] | N=104<br>6 months | **Integrated care versus usual care**<br>SCL-90 subscales, DSM-III-R somatoform disorders (DSM-SOM) scale: No differences between interventions<br>Functional impairment scale (FBI), mean difference from baseline to 6 months: 1.6 vs. 0.9 (NS)<br>General Health Questionnaire-28, mean difference from baseline to 6 months: 2.0 vs. 1.7 (NS)<br>Satisfaction of general practitioners: no differences between interventions<br>Medication use: no differences between interventions<br>Diagnostic imaging: no differences between interventions | 1/11 |

*Safety*

No studies evaluated safety.

### Summary of evidence

- Coordination of care was superior to usual care for improving functional status and pain after 6 months while reducing use of specialized imaging tests in workers receiving short-term (4 to 8 weeks) compensation for low back pain in one lower quality trial (level of evidence: poor).
- There is insufficient evidence to judge the efficacy of coordination or integration of care in other (primary care) settings (one low quality trial) (level of evidence: poor).

### Recommendations and findings of other guidelines

- The other guidelines do not address this issue.

**Key Question 13.**

**What interventions are effective for secondary prevention of LBP in patients who have had an episode of acute LBP, or prevention of flares of LBP in patients with chronic LBP?**

**Back schools**

Results of search: systematic reviews

A recent, good-quality Cochrane review of back schools (19 trials) included five trials (three higher-quality [255, 259, 260]) reporting recurrent low back pain episodes (or sick leave due to low back pain) as an outcome [237, 238]. This updated results from a previous Cochrane review [239]. Another recent, poor-quality systematic review did not include any trials of back schools reporting recurrence rates that weren't included in the Cochrane review [719].

Results of search: trials

We did not identify any additional relevant trials.

*Efficacy of back schools versus no back school, usual care, or placebo for preventing recurrent episodes of low back pain*

The Cochrane review included five trials comparing back schools to no treatment or usual care [237, 238]. Four trials were conducted in occupational settings and the fifth [255] in a mixed setting. Longer-term follow-up [258, 720] is available from two higher-quality trials [255, 259]. One trial of 'mini' back school found no difference in the proportion of patients with subacute low back pain with one or more sick-leave recurrences randomized to back school versus usual care through five years of follow-up (72% or 142/198 versus 74% or 118/160), though the proportion with two or more recurrences was lower in the back school group (35% or 69/198 vs. 46% or 74/160) [258, 259]. The other trial found that in patients with low back pain within the last year who had completed treatment and were no longer on sick leave, the mean number of low back pain recurrences decreased more with an intensive back school program than with no back school through three years (mean decrease 0.9 vs. 0.3 episodes/year, $p<0.05$) [255, 720]. On the other hand, three trials (one higher-quality) with shorter duration of follow-up (one year) reported no difference in low back pain recurrences with back school relative to usual care, placebo treatment, or wait-list control [253, 256, 260].

Two of the trials included patients with back pain for less than three months, and the third [256] included patients with at least three episodes of low back pain annually.

*Efficacy of back schools versus exercise for preventing recurrent episodes of low back pain*

The Cochrane review included one lower-quality trial [256] that found back school associated with a higher incidence of low back pain episodes than biweekly calisthenics through 12 months in workers with frequent (at least three annually) low back pain episodes (mean number of painful months 7.3 vs. 4.5, $p<0.05$).

**Summary of evidence**

- Evidence on the efficacy of back schools for preventing recurrent episodes of low back pain is mixed, which may be due in part to diversity between populations and interventions evaluated. One higher-quality trial found that an intensive back school intervention decreased recurrent episodes of low back pain more than no back school through three years of follow-up, but another evaluating a 'mini' back school found no clear effect. Three shorter-term (1 year) trials (one higher-quality) also found no effect (level of evidence: fair).
- One lower-quality trial found back school inferior to calisthenic exercises for reducing low back pain episodes through 12 months (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The VA/DoD guidelines found inconclusive evidence on the long term benefit of back schools (strength of evidence: A to B).
- The UK RCGP guidelines found that group education based on the Swedish back school approach may be effective in occupational settings (strength of evidence: **).
- The UK RCGP guidelines found that the efficacy of back schools in non-occupational settings has not been demonstrated (strength of evidence: *).
- The European COST guidelines recommend against back schools for acute low back pain.
- The European COST guidelines recommend considering back schools where information is consistent with evidence-based recommendations for short-term (<6 weeks) pain relief and improvements in functional status, but recommend against back schools for chronic low back pain when aiming for long-term effects (>12 months).

## Exercise

Results of search: systematic reviews

A recent, good-quality Cochrane review of exercise for low back pain did not include recurrences as an outcome [268, 269]. We identified one other recent systematic review of exercise that evaluated low back pain recurrences [719]. However, it was rated poor-quality because it did not assess quality of included trials and did not describe methods for synthesizing the evidence.

Results of search: trials

We identified three lower-quality trials that reported effects of exercise on recurrences of low back pain [453, 721, 722].

*Efficacy of exercise versus no exercise for preventing recurrent episodes of low back pain*

One trial found that a weekly, ongoing exercise program reduced the average number of low back pain episodes over a 1 ½ year period by 0.27, compared to an average increase of 0.19 episodes in the no exercise group (Table 77) [721]. However, this study had numerous methodologic shortcomings including unclear randomization and allocation concealment methods, unclear use of blinded outcomes assessment, and lack of intention-to-treat analysis with high loss to follow-up.

**Table 77. Trial of exercise versus no exercise for preventing recurrent episodes of low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Kellett, 1991[721] | N=125<br>1.5 years | **Exercise versus no exercise**<br>Mean episodes of low back pain in 1.5 years prior to intervention minus episodes during 1.5 years during intervention: 0.27 vs. -0.19 ($p<0.05$)<br>Mean sick days in 1.5 years prior to intervention minus episodes during 1.5 years during intervention: 2.86 vs. -1.63 ($p<0.02$) | 1/11 |

*Efficacy of exercise versus education only for preventing recurrent episodes of low back pain*

Two lower-quality trials both found that exercise reduced the number of back pain recurrences (Table 78) [453, 722]. In one trial of patients with a back pain episode who had completed treatment and sick leave, a course of McKenzie extension exercises was associated with fewer low back pain recurrences than back education only through one

year follow-up (44% vs. 74%) [453]. The benefit persisted from one to five years follow-up (proportion of patients with recurrences 64% vs. 88%, p<0.01). In the other trial, a 13-week course of a Mensendieck exercise program (incorporating exercises and education) was associated with fewer recurrences compared to information about the exercise program only during 12 months of follow-up (32% versus 57%, p<0.05) [722].

**Table 78. Trials of exercise versus education for preventing recurrent episodes of low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Soukup, 1999[722] | N=77<br>12 months | **Mensendieck exercise program versus education only**<br>Low back pain recurrences during 12 month follow-up: 32% (11/34) vs. 57% (20/35) (p<0.05)<br>Sick leave (mean days): 30 vs. 38 (NS)<br>Pain, 0 to 100 scale: 26 vs. 32 (p=0.22) | 3/11 |
| Stankovic, 1995[453] | N=100<br>5 years | **McKenzie exercise versus back education**<br>Recurrences: 44% (22/50) vs. 74% (37/50) after 1 year; 64% (30/47) vs. 88% (37/42) between 1 and 5 years (p<0.01)<br>Sick leave between 1 and 5 years: 51% (24/47) vs. 74% (31/42) (p<0.03) | 7/11 |

*Efficacy of exercise versus other interventions for preventing recurrences of low back pain*

One higher-quality trial (reviewed in detail in the section on self-care books) found that approximately 50% of subjects randomized to exercise, manipulation, or a self-care book experienced a recurrence of low back pain during the first year after the intervention, and 70% during the second year [296]. There were no differences in the proportion of patients who sought care for back pain in the second year (20% vs. 29% vs. 24%, p=0.29).

**Summary of evidence**

- There is consistent evidence from two lower-quality trials that an exercise program is superior to education only for reducing long-term low back pain recurrences (level of evidence: fair).
- There is insufficient evidence (one very low-quality trial) to judge the efficacy of an ongoing exercise program for reducing future episodes of low back pain (level of evidence: poor).

**Recommendations and findings from other guidelines**

- The other guidelines don't address this issue.

### Lumbar supports

Results of search: systematic reviews

One recent, good-quality Cochrane review found no trials evaluating the efficacy of lumbar support for secondary prevention of low back pain [469].

Results of search: trials

We found no additional trials.

*Efficacy of lumbar supports for preventing recurrent episodes of low back pain*

There are no trials evaluating the efficacy of lumbar supports for prevention of low back pain recurrences. The Cochrane review found moderate evidence that lumbar supports are not more effective than other interventions or no treatment for primary prevention.

#### Summary of evidence

- No trials have evaluated the efficacy of lumbar supports for secondary prevention.

### Recommendations and findings from other guidelines

- The European COST guidelines recommend against lumbar supports for prevention of low back pain.

### Advice to stay active

Results of search: systematic reviews

One recent, good-quality Cochrane review of advice to stay active included no trials reporting low back pain recurrences as an outcome [450].

Results of search: trials

We identified one higher-quality trial evaluating the effects of a multidisciplinary examination and advice to stay active on recurrent sick leave due to low back pain (Table 79) [262]. It was excluded from the Cochrane review because it didn't evaluate advice to stay active as a single intervention.

*Efficacy of advice to stay active for preventing recurrent episodes of low back pain*

One trial of patients on sick leave for 8 to 12 weeks due to low back pain found that a single visit to a spine clinic with examination by a physiatrist and physical therapist and advice on remaining active was associated with similar rates of recurrent episodes of low back pain compared to usual care through three years (62% vs. 61%, NS) [450].

There were also no differences in the proportion off sick leave at 3 years, though the intervention group was superior at 1 year follow-up (OR 1.60, 95% CI 1.08 to 2.39).

**Table 79. Trial of spine clinic exam and advice to stay active versus usual care for preventing recurrent episodes of low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Hagen, 2003[262] | N=510<br>3 years | **Spine clinic exam and advice to stay active versus usual care**<br>New episodes of sick leave due to LBP (through 3 years): 62% (147/237) vs. 61% (135/220) (NS)<br>LBP still present at 1 year: 47% vs. 52% (NS)<br>On sick leave at 3 years: 64% vs. 62% (NS) | 6/11 |

### Summary of evidence

- One higher-quality trial found no difference in long-term (through 3 years) recurrences in patients on sick leave for low back pain randomized to a single spine clinic exam and advice to stay active versus usual care (level of evidence: fair).

### Recommendations and findings from other guidelines

- Recommendations from other guidelines for advice are summarized in Key Question 4.

## Early occupational medicine intervention

Results of search: systematic reviews

We identified no systematic reviews evaluating the effects of early interventions in preventing future episodes of low back pain.

Results of search: trials

We identified one higher-quality trial evaluating an early evaluation by an occupational physician in workers with low back pain [723].

*Efficacy of an early occupational medicine intervention versus usual care for preventing recurrent episodes of low back pain*

One trial of hospital workers on sick leave for at least 10 days due to low back pain found that early, routine management by occupational physicians trained in recent guidelines was associated with a greater likelihood of recurrent sick leave due to low back pain than usual management by the worker's supervisor for the first three months

(52% vs. 25%, hazard ratio 2.4, 95% CI 1.2 to 4.7) (Table 80) [723]. However, there were no differences in the amount of time until return to work (hazard ratio 1.3, 95% CI 0.90 to 1.90) or other outcomes. A high rate of crossovers (24%) in the usual care group and some deviation from the guidelines by the occupational medicine physicians could have affected the results of this trial.

**Table 80. Trial of early occupational medicine intervention versus usual care for preventing recurrent episodes of low back pain**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Verbeek, 2002[723] | N=120<br>12 months | **Early intervention by an occupational physician versus no early intervention**<br>Time to return to work: 51 vs. 62 days (NS)<br>Recurrence of sick leave in 1 year: 51% (26/51) vs. 25% (12/48) (p<0.05)<br>Pain intensity (mean at 12 months, VAS 0 to 100): 24 vs. 30 (p=0.18)<br>RDQ score (0 to 100): 20 vs. 21 (p=0.57) | 6/11 |

### Summary of evidence

- An early occupational medicine intervention was associated with a greater likelihood of lower back pain recurrences in one higher-quality trial (level of evidence: fair).

### Recommendations and findings from other guidelines

- The other guidelines don't address this issue.

## Behavioral interventions, multidisciplinary rehabilitation, spinal manipulation, acupuncture, patient information or education

Results of search: systematic reviews

Recent, good-quality Cochrane reviews of behavioral interventions [73], multidisciplinary rehabilitation [71, 72, 303, 304], or acupuncture [209, 210] included no other trials reporting rates of low back pain recurrences. One trial of spinal manipulation was discussed in the section on exercise therapy [296]. We found no systematic reviews on the effects of patient information or education on recurrent low back pain.

Results of search: trials

We found no additional relevant trials for any of these interventions.

**Summary of evidence**

- There is no evidence on the effects of behavioral interventions, multidisciplinary disciplinary rehabilitation, and acupuncture on recurrent back pain episodes.

**Key Question 14.**

**What is/are safe and effective strategies for managing low back pain during pregnancy and post-partum?**

We considered low back pain during pregnancy as separate from pelvic girdle pain (defined as pain experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints). The AHCPR, VA/DoD, UK RCGP, and European COST guidelines do not address low back pain in pregnancy, though the latter has developed a guideline on diagnosis and treatment of pelvic girdle pain [724].

**Acupuncture during pregnancy**

Results of search: systematic reviews

A recent, higher-quality Cochrane review [209, 210] of acupuncture (reviewed earlier in this report) included one lower-quality trial [725] of acupuncture versus exercise in pregnant women. This trial was also included in a systematic review of physical therapy for pregnancy-related back pain [726].

Results of search: trials

We identified two lower-quality trials [727, 728] of acupuncture during pregnancy not included in the Cochrane review. Both compared acupuncture to usual care.

*Efficacy of acupuncture versus usual care*

Acupuncture was superior to usual care in pregnant women for pain relief in two lower-quality trials (Table 81) [727, 728]. One found a higher proportion of patients reporting a >50% decrease in average pain intensity in the acupuncture group relative to usual care (78% vs. 15%, $p<0.0001$) [727]. The other reported decreased pain intensity in 60% of patients with acupuncture versus 14% with usual care ($p<0.01$) [728]. Both trials also found greater ability to perform activities with acupuncture, with increased capacity to perform general activities ($p=0.01$) [727] or decreased pain with activity ($p<0.05$) [728]. One trial reported less use of other therapies with acupuncture compared to usual care ($p<0.01$) [728]

**Table 81. Trials of acupuncture versus usual care for low back pain during pregnancy**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Guerreiro da Silva, 2004[727] | N=61<br>8 weeks | **Acupuncture vs. usual care**<br>Average pain (0 to 10), mean difference relative to baseline: -4.8 vs +0.3 (p<0.0001)<br>Average pain intensity decrease by > 50%: 78% (21/27) vs. 15% (5/34) (p<0.0001)<br>Medication use, median number of daily doses between initial and final interviews: 0.0 vs 2.0 (p=0.005)<br>General activities functional status (0 to 10), median difference relative to baseline: -1.0 vs 0.0 (p=0.01)<br>Ability to perform work (0 to 10): 0.0 vs +1.0 (p<0.001)<br>Ability to walk (0 to 10): 0.0 vs +2.0 (p<0.001). | 3/11 |
| Kvorning, 2004[728] | N=72<br>From third trimester to birth | **Acupuncture vs. usual care**<br>Pain intensity decreased: 60% vs. 14% (p<0.01)<br>Decreased pain with activity: 43% vs. 9% (p<0.01)<br>Analgesic drug use: 0% (0/37) vs. 15% (5/34) (p<0.05) | 4/11 |

*Efficacy of acupuncture versus exercise*

Both systematic reviews included one lower-quality trial comparing acupuncture with physiotherapy that found acupuncture superior to exercise for mean pain scores after treatment (difference of about 1.5 to 3 points on a 10 point VAS pain scale) [725]. Acupuncture was also more effective than exercise for improving functional status for various activities as measured by the Disability Rating Index, and a higher proportion of patients reported ‘excellent’ or ‘good’ pain relief with acupuncture (96% or 27/28 versus 178% or 14/18). However, there was a high drop-out rate in the exercise group (12/30) and it is not clear how these patients were handled in the data analysis.

*Safety*

None of the trials reported serious adverse effects in mothers or their infants following acupuncture [725, 727, 728]. In one trial, two women had small bruises, 3 reported ecchymosis at one or two points and one experienced a higher level of pain for a few hours after the first session [727]. In another trial, symptoms were reported in 38% of 37 patients including local pain (n=6), heat or sweating (n=5), local hematoma (n=2), tiredness (n=2), nausea (n=2) and weakness (n=1) [728].

*Costs*

No studies evaluated costs

**Summary of evidence**

- Three lower-quality trials found acupuncture more effective than usual care (2 trials) or exercise (1 trial) for improving pain and function in pregnant women with low back pain (level of evidence: fair).

**Physical therapy during pregnancy**

Results of search: systematic reviews

We identified one higher-quality systematic review of exercise for back pain during pregnancy that included five trials [726]. Only one, a trial comparing water gymnastics to usual care, was rated higher-quality [729].

Results of search: trials

We identified two one additional trial (lower-quality) of a sitting pelvic tilt intervention [730]

*Efficacy of exercise versus usual care*

The systematic review included five trials of physical therapy (exercise, education, advice, or combination of these interventions) for back pain compared to usual care [726]. It did not attempt to pool trials because of diversity in the populations and interventions studied.

In the only higher-quality trial, water gymnastics was associated with decreased pain relative to usual care [729]. Pain intensity was lower in the water gymnastics group relative to the usual care group in the first postpartum week (p=0.034, data not reported). In addition, the water gymnastics group had less absence from work after 32 weeks of pregnancy (OR 0.38, 95% CI 0.16-0.88).

Two trials [731, 732] included in the systematic review [726] found individualized exercise superior to usual care for improving pain intensity. Group education or therapy, however, was superior to usual care in only one [733] of three [732, 734] trials. All of the trials were rated lower-quaity. The only trial with long-term (six years) follow-up found that back pain during pregnancy appeared to return to baseline levels soon after pregnancy [735].

One lower-quality trial not included in the systematic review compared a sitting pelvic tilt exercise to no exercise (Table 82) [730]. Those in the pelvic tilt intervention group had less pain at day 56 versus usual care (2.03 vs. 7.49 on a 10 point VAS, p<0.001).

**Table 82. Trial a sitting pelvic tilt interventions versus usual care for low back pain during pregnancy**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Suputtitada, 2002[730] | N=67<br>56 days | **Sitting pelvic tilt exercise versus no exercise**<br>Pain (0 to 10), mean on day 56: 2.03 vs 7.49 (p<0.05)<br>Labor onset at 37-38 weeks: 56% vs. 20% (p<0.05)<br>Birth weight, mean: 3009g vs 3192g (p=0.018) | 3/11 |

*Efficacy of physical therapy versus other interventions*

One systematic review included a trial comparing physical therapy and acupuncture [725]. We reviewed this trial in the section on efficacy of acupuncture versus other interventions.

*Safety*

In the trial of a sitting pelvic tilt exercise, labor onset was slightly earlier and birth weight slightly lower for those randomized to the pelvic tilt intervention, although there was no preterm labor or low birthweight [730]. Other trials did not report adverse events associated with exercise in pregnancy.

*Costs*

No studies evaluated costs.

**Summary of evidence**

- One higher-quality trial found water gymnastics superior to usual care for treating back pain in pregnant women (level of evidence: fair).
- Individualized physiotherapy was superior to usual care in two lower-quality trials (level of evidence: fair).
- Evidence on efficacy of group education and exercise was mixed, with one of three lower-quality trials finding group education and exercise superior to usual care in only one of three lower-quality trials (level of evidence: poor).
- A pelvic tilt exercise was associated with decreased pain in one lower-quality trial of pregnant women with low back pain, but also with lower birthweight and earlier (full-term) onset of labor (level of evidence: poor)

## Massage during pregnancy

Results of search: systematic reviews

One higher-quality systematic review of physical therapy interventions [726] included one lower-quality trial of massage therapy versus progressive relaxation therapy [736].

Results of search: trials

We identified one lower-quality trial not included in the systematic review that evaluated the same interventions in depressed pregnant women [737].

*Efficacy of massage versus usual care*

In a trial of depressed pregnant women (N=84), mean pain intensity was significantly lower with massage than with usual care at the end of treatment relative to baseline, but the difference was only 0.6 point on a 10-point scale (Table 83) [737]. The pain score was unchanged in the usual care group. The statistical significance of between-group differences was not reported.

**Table 83. Trial a massage versus progressive relaxation and usual care for low back pain in depressed pregnant women**

| Author, year | Number of patients Duration of follow-up | Main results | Quality |
|---|---|---|---|
| Field, 2004[737] | N=84<br>16 weeks | **Massage vs. progressive relaxation vs. usual care**<br>Back pain (0 to 10), mean on last day: 2.9 vs. 4.0 vs. 2.6<br>Anxiety (0 to 80): 42 vs. 45 vs. 35 (between group differences not reported)<br>Mood (0 to 60): 8.2 vs. 9.6 vs. 8.7 (between group differences not reported) | 1/11 |

*Efficacy of massage versus progressive relaxation therapy*

In a small (N=26) trial of non-depressed women included in the systematic review, there was less back pain intensity in the massage therapy group after treatment relative to baseline (4.6 vs. 3.8), but statistical significance of differences compared to the progressive relaxation therapy group (3.8 vs. 3.2) were not reported [736]. In a separate trial of depressed women, mean pain intensity was significantly lower at the end of treatment relative to baseline, but the difference was also small, averaging 0.6 points on a 10-point scale [737]. In the relaxation group, there was no change in pain intensity from baseline to end of treatment. Significance of between-group differences was not reported.

*Safety*

In a trial of depressed pregnant women, scores on the Obstetric Complications Scale were higher (superior) in the massage group relative to the relaxation group (102.1 vs. 91.2), primarily related to decreased prematurity and low birthweight in the massage group [737].

**Summary of evidence**

- Although two lower-quality trials found that massage therapy decreased pain scores in pregnant women, effects appeared modest and it was not clear if the differences were significant relative to usual care or progressive relaxation (level of evidence: poor).

**Supportive devices during pregnancy**

Results of search: systematic reviews

A Cochrane review of interventions during pregnancy [738] included one lower-quality crossover trial (unclear if randomized) of the Ozzlo pillow (a wedge-shaped pillow designed to give support to pregnant women while lying on their side in bed) versus a standard pillow [739].

Results of search: trials

We found no additional trials

*Efficacy of supportive devices versus usual care*

The Ozzlo pillow was superior to a standard pillow for pain at night (median score 14 vs. 19, p=0.002) and during the day (19 vs. 25, p=0.02), though there was no effect on sleeping scores [739]. The pillow was rated as at least moderately useful by 47 of 92 women using it versus 31 of 92 using the standard pillow (OR 0.32, 95% CI 0.18-0.58).

*Safety*

No side effects of the Ozzlo pillow were described.

*Costs*

We found no studies evaluating costs.

**Summary of evidence**

- There is insufficient evidence from one lower-quality trial to determine the efficacy of the Ozzlo pillow versus standard pillows in pregnant women with low back pain (level of evidence: poor).

**Key Question 15.**

**What is the cost-effectiveness associated with different interventions or management strategies (such as care provided by different types of providers) for managing low back pain?**

We identified four recent systematic reviews evaluating cost-effectiveness studies of different interventions or management strategies in patients with low back pain [740-743]. All found few full cost-effectiveness or cost-utility analyses and important methodological deficiencies in the available cost studies, including inadequate methods for identifying, valuing, and analyzing costs, and lack of sensitivity analyses for evaluating the robustness of conclusions. In one systematic review, for example, 12 of the 17 included studies did not mention using the societal perspective to analyze costs [743]. All of the systematic reviews concluded that current economic analyses are insufficient for determining the most cost-effectiveness interventions. Individual cost studies are summarized separately elsewhere for each of the interventions reviewed in this report.

## Summary and Discussion

**Specific findings from this evidence review are reported in the executive summary. We identified several key research gaps:**

- Nearly all trials have been 'efficacy' trials conducted in ideal setting and selected populations, usually with short-term follow-up. More 'effectiveness' studies assessing long-term outcomes in less highly-selected populations are needed to help confirm the usefulness of interventions in real-world settings.
- For most interventions, data on harms are sparse, with disproportionate attention paid to benefits. Better assessment and reporting of harms (adhering to CONSORT recommendations [744]) would help provide a more balanced assessment of net benefits.
- Two higher-quality trials of low-intensity interventions for identifying and treating 'yellow flags' (predictors of chronic disabling back pain) in patients with acute or subacute low back pain have not been shown to be beneficial. More research is needed on effective interventions for treating 'yellow flags' and on methods for identifying patients more likely to benefit from early interventions.
- The optimal use of combinations of medications has not been well studied. In addition, emerging data on potential cardiovascular risks with non-selective NSAIDs (and possibly acetaminophen) may alter risk-benefit assessments

associated with different medications. There is also little evidence on long-term use of opioids for chronic low back pain, and evidence on abuse and addiction remains sparse.

- Decision tools for identifying patients more likely to benefit from certain interventions (such as manipulation or exercise) are promising but still in early stages of development. In addition, available tools include assessment of physical exam findings that many primary care clinicians are unfamiliar with or that have uncertain reliability and reproducibility. More research on decision tools that can be reliably used by most clinicians need to be developed and tested in clinical settings.
- Although concordant pain on provocative discography in selected patients is likely to have some diagnostic value, the use of discography to select patients for surgery or other invasive procedures has not been proven to improve clinical outcomes compared to non-invasive imaging. Clinical trials addressing this issue would be very helpful for resolving this long-standing controversy.
- Additional long-term trials with adequate follow-up and appropriate comparison interventions are required to further clarify the role of surgery in patients with chronic non-specific low back pain.
- Confirmatory trials and trials evaluating long-term outcomes associated with vertebral disc replacement are needed to help clarify its role as an option for surgical management.
- There is no evidence on optimal sequencing of interventions, and limited evidence on optimal combinations of interventions. In many cases, combinations of interventions were not much more effective than monotherapy, but more research is needed to clarify when and how treatments should be combined.
- High quality research on management of failed back surgery syndrome and back pain during pregnancy is lacking and provides little guidance for appropriate management in these populations.
- Few trials specifically evaluated patients with spinal stenosis, and it remains unclear if optimal non-surgical treatments for this condition are different than for patients with non-specific low back pain without spinal stenosis.
- Many interventions for low back pain appear to have similar effects on patient outcomes. Higher quality studies of cost-effectiveness could help clarify optimal choices between such interventions.

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## APPENDIX 1

## SEARCH STRATEGIES

### Systematic Reviews

Database: Ovid MEDLINE(R) <1996 to July Week 2 2005>
Search Strategy:
---
1 ((ache$ or pain$) adj2 (low back or lower back or lumbar)).mp. (6966)
2 lbp.mp. (941)
3 exp Back Pain/ (7424)
4 (1 or 2) and 3 (5305)
5 low back pain/ (5011)
6 4 or 5 (5305)
7 limit 6 to humans (5258)
8 limit 7 to "all adult (19 plus years)" (3381)
9 limit 8 to (guideline or meta analysis or randomized controlled trial) (406)
10 (20021$ or 2003$ or 2004$ or 2005$).ed. (1570361)
11 9 and 10 (157)
12 from 11 keep 1-157 (157)

Database: Ovid MEDLINE(R) <1996 to July Week 2 2005>
Search Strategy:
---
1 ((ache$ or pain$) adj2 (low back or lower back or lumbar)).mp. (6966)
2 lbp.mp. (941)
3 exp Back Pain/ (7424)
4 (1 or 2) and 3 (5305)
5 low back pain/ (5011)
6 4 or 5 (5305)
7 limit 6 to humans (5258)
8 limit 7 to "all adult (19 plus years)" (3381)
9 limit 8 to (guideline or meta analysis or randomized controlled trial) (406)
10 exp Epidemiologic Studies/ (461334)
11 exp Evaluation Studies/ (236763)
12 Comparative Study/ (472223)
13 10 or 11 or 12 (1009798)
14 8 and 13 (1698)
15 14 not 9 (1424)
16 (20021$ or 2003$ or 2004$ or 2005$).ed. (1570361)
17 15 and 16 (571)
18 from 17 keep 1-571 (571)

## APPENDIX 2

## SEARCH STRATEGIES

### Primary Studies: Opioids (Medline)

Database: Ovid MEDLINE(R) <1966 to September Week 3 2005>
Search Strategy:
---
1 randomized controlled trial.pt. (206082)
2 controlled clinical trial.pt. (69290)
3 Randomized Controlled Trials/ (39086)
4 Random Allocation/ (53797)
5 Double-Blind Method/ (83140)
6 Single-Blind Method/ (9273)
7 1 or 2 or 3 or 4 or 5 or 6 (350538)
8 animal/ not human/ (2910356)
9 7 not 8 (330839)
10 clinical trial.pt. (414986)
11 exp clinical trials/ (169622)
12 (clinic$ adj25 trial$).tw. (113509)
13 ((singl$ or doubl$ or trebl$ or tripl$) adj (mask$ or blind$)).tw. (79708)
14 placebos/ (24013)
15 placebo$.tw. (90652)
16 random$.tw. (318251)
17 research design/ (41627)
18 (latin adj square).tw. (2204)
19 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 (744979)
20 19 not 8 (691154)
21 20 not 9 (371148)
22 comparative study/ (1219518)
23 exp evaluation studies/ (532914)
24 follow-up studies/ (305506)
25 prospective studies/ (192151)
26 (control$ or prospective$ or volunteer$).tw. (1568315)
27 cross-over studies/ (16591)
28 22 or 23 or 24 or 25 or 26 or 27 (3129575)
29 28 not 8 (2401820)
30 29 not (9 or 21) (1914642)
31 9 or 21 or 30 (2616629)
32 spine/ or coccyx/ or intervertebral disk/ or lumbar vertebrae/ or sacrum/ or spinal canal/ or exp back/ (52500)
33 (spine or coccyx or intervertebral disk$ or lumbar vertebrae or sacrum or spinal canal or back).tw. (104057)

34 spinal diseases/ or intervertebral disk displacement/ or spinal curvatures/ or kyphosis/ or lordosis/ or scoliosis/ or spinal osteophytosis/ or hyperostosis, diffuse idiopathic skeletal/ or spinal stenosis/ or spondylitis/ or spondylolisthesis/ or spondylolysis/ (39342)
35 (spinal disease$ or spinal curvatur$ or kyphosis or lordosis or scoliosis or spinal osteophytosis or hyperostosis or spinal stenosis or spondyliti$ or spondylolisthesis or spondylolysis).tw. (22739)
36 exp BACK INJURIES/ or ((back or lumbar or sacrum or sacral) adj2 (wound$ or injur$ or trauma$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (12333)
37 34 or 35 or 36 (60094)
38 exp pain/ or pain$.mp. or ache.mp. or aches.mp. or aching.mp. or ached.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (326880)
39 (32 or 33) and 38 (27047)
40 exp back pain/ or ((back or lumbar or sacrum or sacral) adj2 (pain$ or ache$ or aching)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (22849)
41 37 or 39 or 40 (82140)
42 Opioid$.mp. or exp Narcotics/ or narcotic$.mp. (103374)
43 41 and 42 (1117)
44 31 and 43 (568)
45 from 44 keep 1-568 (568)

## SEARCH STRATEGIES

### Primary Studies: Self-care (Cochrane)

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <1st Quarter 2006>
Search Strategy:
---
1 spine/ or coccyx/ or intervertebral disk/ or lumbar vertebrae/ or sacrum/ or spinal canal/ or exp back/ (1443)
2 (spine or coccyx or intervertebral disk$ or lumbar vertebrae or sacrum or spinal canal or back).tw. (5300)
3 spinal diseases/ or intervertebral disk displacement/ or spinal curvatures/ or kyphosis/ or lordosis/ or scoliosis/ or spinal osteophytosis/ or hyperostosis, diffuse idiopathic skeletal/ or spinal stenosis/ or spondylitis/ or spondylolisthesis/ or spondylolysis/ (646)
4 (spinal disease$ or spinal curvatur$ or kyphosis or lordosis or scoliosis or spinal osteophytosis or hyperostosis or spinal stenosis or spondyliti$ or spondylolisthesis or spondylolysis).tw. (617)
5 exp BACK INJURIES/ or ((back or lumbar or sacrum or sacral) adj2 (wound$ or injur$ or trauma$)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (359)
6 3 or 4 or 5 (1421)
7 exp pain/ or pain$.mp. or ache.mp. or aches.mp. or aching.mp. or ached.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (38262)
8 (1 or 2) and 7 (2534)
9 exp back pain/ or ((back or lumbar or sacrum or sacral) adj2 (pain$ or ache$ or aching)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (2248)
10 6 or 8 or 9 (3809)
11 ((self or selves or themsel$) adj3 (care or look after)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (1288)
12 (patient$ adj3 (informed or information or informing or educat$ or teach$ or learn$)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (6090)
13 11 or 12 (6885)
14 10 and 13 (157)
15 from 14 keep 1-157 (157)

## SEARCH STRATEGIES

### Primary Studies: Imaging (Medline)

Database: Ovid MEDLINE(R) <1966 to March Week 3 2006>
Search Strategy:
---
1 spine/ or coccyx/ or intervertebral disk/ or lumbar vertebrae/ or sacrum/ or spinal canal/ or exp back/ (53119)
2 (spine or coccyx or intervertebral disk$ or lumbar vertebrae or sacrum or spinal canal or back).tw. (107146)
3 spinal diseases/ or intervertebral disk displacement/ or spinal curvatures/ or kyphosis/ or lordosis/ or scoliosis/ or spinal osteophytosis/ or hyperostosis, diffuse idiopathic skeletal/ or spinal stenosis/ or spondylitis/ or spondylolisthesis/ or spondylolysis/ (39393)
4 (spinal disease$ or spinal curvatur$ or kyphosis or lordosis or scoliosis or spinal osteophytosis or hyperostosis or spinal stenosis or spondyliti$ or spondylolisthesis or spondylolysis).tw. (22894)
5 exp BACK INJURIES/ or ((back or lumbar or sacrum or sacral) adj2 (wound$ or injur$ or trauma$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (12157)
6 3 or 4 or 5 (60147)
7 exp pain/ or pain$.mp. or ache.mp. or aches.mp. or aching.mp. or ached.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (337357)
8 (1 or 2) and 7 (27925)
9 exp back pain/ or ((back or lumbar or sacrum or sacral) adj2 (pain$ or ache$ or aching)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (22711)
10 6 or 8 or 9 (82897)
11 exp Magnetic Resonance Imaging/ (146646)
12 exp Tomography, X-Ray Computed/ (167684)
13 exp Radiography/ (395689)
14 13 not 12 (228005)
15 exp Myelography/ (7132)
16 11 and 12 (32679)
17 10 and 16 (2109)
18 11 and 14 (7916)
19 10 and 18 (276)
20 11 and 15 (892)
21 10 and 20 (468)
22 12 and 15 (2081)
23 10 and 22 (1014)
24 14 and 15 (5051)
25 10 and 24 (1894)

26 17 or 19 or 21 or 23 or 25 (4825)
27 limit 26 to randomized controlled trial (31)
28 exp "sensitivity and specificity"/ (198840)
29 26 and 28 (159)
30 "reproducibility of results"/ (117278)
31 26 and 30 (40)
32 exp Diagnostic Errors/ (62684)
33 26 and 32 (118)
34 29 or 31 or 33 (284)
35 random$.mp. (443760)
36 26 and 35 (61)
37 27 or 34 or 36 (338)
38 limit 37 to humans (328)
39 limit 38 to english language (265)
40 limit 38 to abstracts (276)
41 39 or 40 (315)
42 from 41 keep 1-315 (315

## APPENDIX 3

## QUALITY RATING SYSTEMS

### Systematic Reviews

| **Criteria for Assessing Scientific Quality of Research Reviews*** | |
|---|---|
| *Criteria* | *Operationalization of Criteria* |
| 1. Were the search methods reported?<br>*Were the search methods used to find evidence (original research) on the primary questions stated?*<br>**"Yes" if the review states the databases used, date of most recent searches, and some mention of search terms.** | The purpose of this index is to evaluate the scientific quality (i.e. adherence to scientific principles) of research overviews (review articles) published in the medical literature. It is not intended to measure literary quality, importance, relevance, originality, or other attributes of overviews.<br><br>The index is for assessing overviews of primary ("original") research on pragmatic questions regarding causation, diagnosis, prognosis, therapy, or prevention. A research overview is a survey of research. The same principles that apply to epidemiological surveys apply to overviews: a question must be clearly specified, a target population identified and accessed, appropriate information obtained from that population in an unbiased fashion, and conclusions derived, sometimes with the help of formal statistical analysis, as is done in "meta-analyses". The fundamental difference between overviews and epidemiological studies is the unit of analysis, not the scientific issues that the questions in this index address.<br><br>Since most published overviews do not include a methods section, it is difficult to answer some of the questions in the index. Base your answers, as much as possible, on information provided in the overview. If the methods that were used are reported incompletely relative to a specific question, score it as "can't tell", unless there is information in the overview to suggest either the criterion was or was not met. |
| 2. Was the search comprehensive?<br>*Was the search for evidence reasonably comprehensive?*<br>**"Yes" if the review searches at least 2 databases and looks at other sources (such as reference lists, hand searches, queries experts).** | |
| 3. Were the inclusion criteria reported?<br>*Were the criteria used for deciding which studies to include in the overview reported?* | |
| 4. Was selection bias avoided?<br>Was bias in the selection of studies avoided?<br>**"Yes" if the review reports how many studies were identified by searches, numbers excluded, and gives appropriate reasons for excluding them (usually because of pre-defined inclusion/exclusion criteria).** | |
| 5. Were the validity criteria reported?<br>*Were the criteria used for assessing the validity of the included studies reported?* | |

<table>
<tr><th colspan="2">Criteria for Assessing Scientific Quality of Research Reviews*</th></tr>
<tr><td>Criteria</td><td>Operationalization of Criteria</td></tr>
<tr><td>6. Was validity assessed appropriately?<br>Was the validity of all the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analyzing the studies that are cited)?<br>"Yes" if the review reports validity assessment and did some type of analysis with it (e.g. sensitivity analysis of results according to quality ratings, excluded low-quality studies, etc.)</td><td></td></tr>
<tr><td>7. Were the methods used to combine studies reported?<br>Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?<br>"Yes" for studies that did qualitative analysis if there is some mention that quantitative analysis was not possible and reasons that it could not be done, or if 'best evidence' or some other grading of evidence scheme used.</td><td rowspan="4">For Question 8, if not attempt has been made to combine findings, and no statement is made regarding the inappropriateness of combining findings, check “No”. if a summary (general ) estimate is given anywhere in the abstract, the discussion, or the summary section of the paper, and it is not reported how that estimate was derived, mark “No” even if there is a statement regarding the limitations of combining the findings of the studies reviewed. If in doubt, mark “Can’t tell”.<br><br>For an overview to be scored as “Yes” in Question 9, data (not just citations) must be reported that support the main conclusions regarding the primary question(s) that the overview addresses.<br><br>The score for Question 10, the overall scientific quality, should be based on your answers to the first nine questions. The following guidelines can be used to assist with deriving a summary score: If the “Can’t tell” option is used one or more times on the preceding questions, a review is likely to have minor flaws at best and it is difficult to rule out major flaws (i.e. a score of 4 or lower). If the “No” option is used on Question 2, 4, 6 or 8, the review is likely to have major flaws (i.e. a score of 3 or less, depending on the number and degree of the flaws).</td></tr>
<tr><td>8. Were the findings combined appropriately?<br>Were the findings of the relevant studies combined appropriately relative to the primary question the overview addresses?<br>"Yes" if the review performs a test for heterogeneity before pooling, does appropriate subgroup testing, appropriate sensitivity analysis, or other such analysis.</td></tr>
<tr><td>9. Were the conclusions supported by the reported data?<br>Were the conclusions made by the author(s) supported by the data and/or analysis reported in the overview?</td></tr>
<tr><td>10. What was the overall scientific quality of the overview?<br>How would you rate the scientific quality of this overview?</td></tr>
<tr><td>Scoring</td><td>Each Question is scored as Yes, Partially/Can’t tell or No</td></tr>
<tr><td colspan="2">Extensive Flaws 1 2 Major Flaws 3 4 Minor Flaws 5 6 Minimal Flaws 7</td></tr>
</table>

*Table created using information from Oxman & Guyatt, J Clin Epidemiol. 1991;44(11):1271-8 and Furlan, Clarke, et al., Spine. 2001 Apr 1;26(7):E155-62.

## APPENDIX 4

## QUALITY RATING SYSTEMS

### Primary Studies

| Criteria List for the Methodological Quality Assessment* | | |
|---|---|---|
| *Criteria* | *Operationalization of Criteria* | **Score** |
| A. Was the method of randomization adequate? | A random (unpredictable) assignment sequence. An example of adequate methods is a computer generated random number table and use of sealed opaque envelopes. Methods of allocation using DOB, date of admission, hospital numbers, or alternation should not be regarded as appropriate. | Yes/No/Don't Know |
| B. Was the treatment allocation concealed? | Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient. | |
| C. Were the groups similar at baseline regarding the most important prognostic factors?<br>"Yes", if at least one of the following:<br>• Age & gender<br>• Description of type of pain<br>• Intensity, duration or severity of pain | In order to receive a "yes", groups have to be similar in baseline regading demographic factors, duration or severity of complaints, percentage of patients with neurologic symptoms, and value of main outcome measure(s). | |
| D. Was the patient blinded to the intervention? | The reviewer determines if enough information about the blinding is given in order to score a "yes":<br>Use the author's statement on blinding, unless there is a differing statement/reason not to (no need for explicit information on blinding). | |
| E. Was the care provider blinded to the intervention? | | |
| F. Was the outcome assessor blinded to the intervention? | | |
| G. Were cointerventions avoided or similar? | Cointerventions should either be avoided in the trial design or similar between the index and control groups. | |
| H. Was the compliance acceptable in all groups? | The reviewer determines if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). | |

| **Criteria List for the Methodological Quality Assessment*** | | |
|---|---|---|
| *Criteria* | *Operationalization of Criteria* | **Score** |
| I. Was the drop-out rate described and acceptable?<br>*>= 85% drop out rate = acceptable.* | The number of participants who are included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 15% and does not lead to substantial bias, a "yes" is scored. | |
| J. Was the timing of the outcome assessment in all groups similar? | Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments. | Yes/No/Don't Know |
| K. Did the analysis include an intention-to-treat analysis?<br>*OK if less than 5% of no-treatment excluded.* | All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and cointerventions. | |
| This list includes only the internal validity criteria (n=11) that refer to characteristics of the study that might be related to selection bias (criteria A and B), performance bias (criteria D, E, G, and H), attrition bias (criteria I and K and detection bias (criteria f and J). The internal validity criteria should be used to define methodologic quality in the meta-analysis. | | |

* Table created using information from van Tulder, Furlan, Bombardier, Bouter, and Editorial Board of the Cochrane Collaboration Back Review Group. Spine. 2003;28(12):121290-9.

## APPENDIX 5

## LIST OF INCLUDED SYSTEMATIC REVIEWS

| |
|---|
| **ACETAMINOPHEN** |
| Schnitzer, 2004<br>A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain |
| **SRs comparing acetaminophen to NSAIDs** |
| Van Tulder, 2000<br>Nonsteroidal anti-inflammatory drugs for low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group (also published as a Cochrane review) |
| **ACUPUNCTURE** |
| Furlan, 2005<br>Acupuncture and dry-needling for low back pain: An updated systematic review within the framework of the Cochrane collaboration |
| Manheimer, 2005<br>Meta-analysis: Acupuncture for low back pain |
| **ANTIDEPRESSANTS** |
| Fishbain, 2000<br>Evidence-based data on pain relief with antidepressants |
| Salerno, 2002<br>The effect of antidepressant treatment on chronic back pain |
| Schnitzer, 2004<br>A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain |
| Staiger, 2003<br>Systematic review of antidepressants in the treatment of chronic low back pain |
| **BACK SCHOOLS** |
| DiFabio, 1995<br>Efficacy of comprehensive rehabilitation programs and back school for patients with low back pain: A meta-analysis |
| Elders, 2000<br>Return to work after sickness absence due to back disorders--a systematic review on intervention strategies |
| Heymans, 2005 (update of van Tulder,1999)<br>Back schools for non-specific low-back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group<br>(also published as a Cochrane review). |
| Linton, 2001<br>Preventive interventions for back and neck pain problems. What is the evidence? |
| Maier-Riehle, 2001<br>The effects of back schools - a meta-analysis |
| **BED REST** |
| Hagen, 2002<br>The Cochrane review of advice to stay active as a single treatment for low back pain and sciatica |
| Hagen, 2004<br>Bed rest for acute low-back pain and sciatica |
| Hagen, 2005<br>The Updated Cochrane review of bed rest for low back pain and sciatica |

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| **BEHAVIORAL** |
| Assendelft, 2003<br>Spinal manipulative therapy for low back pain. A meta-analysis of effectiveness relative to other therapies |
| Assendelft, 2004<br>Spinal manipulative therapy for low-back pain |
| Furlan, 2005<br>Acupuncture and dry-needling for low back pain |
| Furlan, 2005<br>Acupuncture and dry-needling for low back pain: an updated systematic review within the framework of the cochrane collaboration |
| Guzman, 2001<br>Multidisciplinary rehabilitation for chronic low back pain: systematic review |
| Guzman, 2002<br>Multidisciplinary bio-psycho-social rehabilitation for chronic low-back pain |
| Hoffman, 2006 (in press)<br>Meta-analysis of psychological interventions for chronic low back pain |
| Karjalainen, 2001<br>Multidisciplinary biopsychosocial rehabilitation for subacute low-back pain among working age adults |
| Karjalainen, 2003<br>Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults (update) |
| Ostelo, 2005<br>Behavioural treatment for chronic low-back pain<br>*Previously published in Spine (van Tulder et al 2000)* |
| **BENZODIAZEPENES** |
| Schnitzer, 2004<br>A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain |
| van Tulder, 2003 (#198)<br>Muscle relaxants for non-specific low-back pain |
| **COST EFFECTIVENESS/MANAGEMENT STRATEGIES** |
| Baldwin, 2001<br>Cost-effectiveness studies of medical and chiropractic care for occupational low back pain. A critical review of the literature |
| Thomsen, 2001<br>Economic evaluation of multidisciplinary pain management in chronic pain patients: A qualitative systematic review |
| Uhlig, 2003<br>Effectiveness and cost-effectiveness of comprehensive rehabilitation programs |
| van der Roer, 2005<br>What is the most cost-effective treatment for patients with low back pain? A systematic review |
| **DECISION TOOLS**<br>We identified no systematic review evaluating the usefulness of decision tools or clinical prediction rules for identifying patients more likely to respond to specific therapies. However, we found three systematic reviews evaluating the reliability and validity of physical exam maneuvers used to help determine if manipulative treatments are indicated, though clinical outcomes were not assessed. |
| Hestbrook, 2000<br>Are chiropractic tests for the lumbo-pelvic spine reliable and valid? A systematic critical literary review |
| Najm, 2003<br>Content validity of manual spinal palpatory exams - a systematic review |
| Seffinger, 2004 #262<br>Reliability of spinal palpation for diagnosis of back and neck pain |

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| **DIAGNOSIS—INVASIVE TESTING** |
| **Diagnostic Nerve Blocks** |
| Everett, 2005<br>A Systematic Review of Diagnostic Utility of Selective Nerve Root Blocks |
| **DISCOGRAPHY** |
| Cohen, 2005<br>Lumbar discography: A comprehensive review of outcome studies, diagnostic accuracy, and principles |
| Shah, 2005<br>Discography as a Diagnostic Test for Spinal Pain: A Systematic and Narrative Review |
| Willems, 2004<br>Lumbar discography: should we use prophylactic antibiotics? A study of 435 consecutive discograms and a systematic review of the literature |
| **EXERCISE** |
| Clare, 2004 #3441<br>A systematic review of efficacy of McKenzie therapy for spinal pain |
| Hayden, 2005<br>Exercise therapy for low-back pain |
| Hayden, 2005<br>Meta-analysis: exercise therapy for nonspecific low back pain |
| Hayden, 2005 (303)<br>Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain |
| Kool, 2004<br>Exercise reduces sick leave in patients with non-acute non-specific low back pain: a meta-analysis |
| Liddle, 2004 #354<br>Exercise and chronic low back pain: what works? |
| Linton, 2001<br>Occupational psychological factors increase the risk for back pain: a systematic review |
| McNeely, 2003 #3173<br>A systematic review of physiotherapy for spondylolysis and spondylolisthesis |
| **FAILED SUREGERY SYNDROMES** |
| **Adhesiolysis** |
| Chopra 2005<br>Role of adhesiolysis in the management of chronic spinal pain: a systematic review of effectiveness and complications |
| **Spincal Cord Stimulation** |
| Maillis-Gagnon, 2004<br>Spinal cord stimulation for chronic pain |
| Taylor, 2005<br>Spinal cord stimulation for chronic back pain and leg pain and failed back surgery syndrome: a systematic review and analysis of progressive factors |
| Turner, 2004<br>Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications |
| **HERBAL THERAPY** |
| Gagnier, 2006<br>Herbal medicine for low back pain |
| Schnitzer, 2004<br>A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain |
| **IDET** |
| Gibson, 2005<br>Surgery for degenerative lumbar spondylosis |

| |
|---|
| Surgery for Degenerative Lumbar Spondylosis: Updated Cochrane Review |
| NICE, 2004 #3749<br>Interventional procedures overview of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain |
| Samson, 2004<br>Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain |
| IMAGING |
| ***Plain Radiography*** |
| Jarvik, 2002<br>Diagnostic evaluation of low back pain with emphasis on imaging |
| Lurie, 2003<br>Rates of advanced spinal imaging and spine surgery |
| van Tulder, 1997<br>Spinal radiographic findings and nonspecific low back pain: a systematic review of observational studies |
| **INJECTIONS** |
| Chemonucleolysis |
| Gibson, 2000<br>Surgery for lumbar disc prolapse |
| ***Epidural steroid injections*** |
| Abdi, 2005<br>role of epidural steroids in the management of chronic spinal pain: a systematic Review of effectiveness and complications - a systematic review |
| DePalma, 2005<br>A critical appraisal of the evidence for selective nerve root injection in the treatment of lumbosacral radiculopathy |
| Koes, 1999<br>Epidural steroid injections for low back pain and sciatica: an updated systematic review of randomized clinical trials |
| Nelemans, 1999<br>Injection therapy for subacute and chronic benign low-back pain |
| Nelemans, 2001<br>Injection therapy for subacute and chronic benign low back pain (update) |
| Tonkovich-Quaranta, 2000<br>Use of epidural corticosteroids in low back pain |
| Vroomen, 2000<br>Conservative treatment of sciatica: a systematic review |
| Facet (zygapophysial) joint injections |
| Boswell, 2005<br>Therapeutic facet joint interventions in chronic spinal pain: A systematic review of their role in chronic spinal pain management and complications |
| Nelemans, 1999<br>Injection therapy for subacute and chronic benign low-back pain |
| Nelemans, 2001<br>Injection therapy for subacute and chronic benign low back pain (update) |
| Slipman, 2003<br>A critical review of the evidence for the use of zygapophysial injections and radiofrequency denervation in the treatment of low back pain |
| Intradiscal steroid injections |
| We found no systematic reviews specifically evaluating the efficacy of intradiscal steroid injections for patients with presumed chronic discogenic back pain, however, two RCTs comparing intradiscal steroids to chemonucleolysis with chymopapain were included in a good-quality Cochrane review of surgery for lumbar disc prolapse. |
| Gibson, 1999 |

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| The Cochrane review of surgery for lumbar disc prolapse and degenerative lumbar spondylosis |
| Local Injections |
| Kraemer, 1997<br>Lumbar epidural perineural injection: a new technique |
| Nelemans, 1999<br>Injection therapy for subacute and chronic benign low-back pain |
| Nelemans, 2001<br>Injection therapy for subacute and chronic benign low back pain (update) |
| Prolotherapy |
| Yelland, 2004<br>Prolotherapy injections for chronic low-back pain |
| Sacroiliac joint injections |
| McKenzie-Brown, 2005<br>A systematic review of sacroiliac joint interventions |
| **MASSAGE** |
| Furlan, 2002<br>Massage for low-back pain |
| Furlan, 2002<br>Massage for low-back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group |
| **MODIFIED WORK** |
| Krause, 1998<br>Modified work and return to work: a review of the literature |
| **MULTIDISCIPLINARY** |
| **Multidisciplinary rehabilitation** |
| Guzman, 2001<br>Multidisciplinary rehabilitation for chronic low back pain: systematic review |
| Guzman, 2002<br>Multidisciplinary bio-psycho-social rehabilitation for chronic low-back pain |
| Hoffman, 2006<br>Meta-analysis of psychological interventions for chronic low back pain |
| Karjalainen, 2001<br>Multidisciplinary biopsychosocial rehabilitation for subacute low-back pain among working age adults |
| Karjalainen, 2003<br>Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults (update) |
| **Physical conditioning** |
| Schonstein, 2003<br>Physical conditioning programs for workers with back and neck pain: a cochrane systematic review |
| Schonstein, 2003<br>Work conditioning, work hardening and functional restoration for workers with back and neck pain |
| **MUSCLE RELAXANTS** |
| Browning, 2001<br>Cyclobenzaprine and back pain: a meta-analysis |
| Schnitzer, 2004<br>A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain |
| Van Tulder, 2003<br>Muscle relaxants for nonspecific low back pain: a systematic review within the framework of the Cochrane collaboration |
| Van Tulder, 2003<br>Muscle relaxants for non-specific low-back pain |
| Vroomen, 2000 |

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| Conservative treatment of sciatica: a systematic review |
| NEUROREFLEXOTHERAPY |
| Urrutia, 2004<br>Neuroreflexotherapy for non-specific low-back pain |
| **NSAIDS** |
| **Non-steroidal NSAIDs** |
| Schnitzer, 2004<br>A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain |
| Van Tulder, 2000<br>Non-steroidal anti-inflammatory drugs for low-back pain |
| Van Tulder, 2000<br>Nonsteroidal anti-inflammatory drugs for low back pain: a systematic review within the framework of the Cochrane Collaboration back review group |
| Vroomen, 2000<br>Conservative treatment of sciatica: a systematic review |
| **OPIOIDS** |
| Schnitzer, 2004<br>A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain |
| van Tulder, 1997<br>Conservative treatment of acute and chronic nonspecific low back pain: a systematic review of randomized controlled trials of the most common interventions |
| **Percutaneous intradiscal radiofrequency thermocoagulation (PENS)** |
| Gibson, 2005<br>The cochrane review of surgery for lumbar disc prolapse and degenerative lumbar spondylosis<br>surgery for degenerative lumbar spondylosis: updated cochrane review |
| NICE, 2004 3749<br>Interventional procedures overview of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain |
| Samson, 2004<br>Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain |
| **PREGNANCY** |
| Stuge, 2003<br>Physical therapy for pregnancy-related low back and pelvic pain: a systematic review |
| Young, 2005<br>Interventions for preventing and treating pelvic and back pain in pregnancy |
| **RADIOFREQUENCY DENERVATION** |
| Boswell, 2005<br>Therapeutic facet joint interventions in chronic spinal pain: A systematic review of their role in chronic spinal pain management and complications |
| Geurts, 2001<br>Efficacy of radiofrequency procedures for the treatment of spinal pain: a systematic review of randomized clinical trials |
| Niemisto, 2003<br>Radiofrequency denervation for neck and back pain. a systematic review of randomized controlled trials<br>Radiofrequency denervation for neck and back pain: a systematic review within the framework of the Cochrane collaboration back review group |
| Slipman, 2003<br>A critical review of the evidence for the use of zygapophysial injections and radiofrequency denervation in the treatment of low back pain |
| **RED FLAGS** |
| Crook, 2002 |

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| Determinants of occupational disability following a low back Injury: a critical review of the literature |
| Devillé, 2000<br>The test of Lasegue: systematic review of the accuracy of diagnosing herniated discs |
| Dionne, 2001<br>Formal education and back pain: a review |
| Fayad, 2004<br>Chronicity, recuurence, and return to work in low back pain: common prognostic factors |
| Jarvik, 2002<br>Diagnostic evaluation of low back pain with emphasis on imaging |
| Linton, 2000<br>A review of psycholocial risk factors in back and neck pain |
| McIntosh, 2000<br>Low back pain prognosis: structured review of the literature |
| Pengel, 2003<br>Acute low back pain: systematic review of its prognosis |
| Pincus, 2002<br>A systematic review of psychological factors as predictors of chronicity/disability in prospective cohorts of low back pain |
| Shaw, 2001<br>Early prognosis for low back disability: intervention strategies for health care providers |
| Truchon, 2000<br>Biopsychosocial determinants of chronic disability and low-back pain: a review |
| van den Hoogen, 1995<br>On the accuracy of history, physical examination, and erythrocyte sedimentation rate in diagnosing low back pain in general practice. A criteria-based review of the literature |
| **SELF-CARE** |
| **Advice for activity** |
| Hagen, 2002<br>The Cochrane review of advice to stay active as a single treatment for low back pain and sciatica |
| Hilde, 2002<br>Advice to stay active as a single treatment for low-back pain and sciatica |
| **Bed Rest** |
| Hagen, 2004<br>Bed rest for acute low-back pain and sciatica (update) |
| **Self-care interventions** |
| van Tulder, 2000<br>Bed rest for acute low-back pain and sciatica |
| Superficial heat or cold |
| French, 2006<br>Superficial heat or cold for low back pain |
| **SHORT WAVE DIATHERMY**<br>We identified no systematic review of short-wave diathermy, however, a good-quality Cochrane review of spinal manipulation: Assendelft, 2003 and Assendelft, 2004 (update) included two trials comparing short-wave diathermy to sham diathermy or manipulation. |
| **SPINAL CORD STIMULATION** |
| Maillis-Gagnon, 2004<br>Spinal cord stimulation for chronic pain |
| Taylor, 2005<br>Spinal cord stimulation for failed back surgery syndrome: A decision-analytic model and cost-effectiveness analysis |
| Turner, 2004 #269<br>Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications |

| **SPINAL MANIPULATION** |
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| Assendelft, 1996<br>Complications of spinal manipulation: a comprehensive review of the literature |
| Assendelft, 2003<br>Spinal manipulative therapy for low back pain. A meta-analysis of effectiveness relative to other therapies |
| Assendelft, 2004<br>Spinal manipulative therapy for low-back pain |
| Brown, 2005<br>Costs and outcomes of chiropractic treatment for low back pain - Technology Report No 56 |
| Cherkin, 2003<br>A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy, and spinal manipulation for back pain |
| Ernst, 2001<br>Prospective investigations into the safey of spinal manipulation |
| Ferreira, 2002<br>Does spinal manipulative therapy help people with chronic low back pain? |
| Ferreira, 2003<br>Efficacy of spinal manipulative therapy for low back pain of less than three months duration |
| Kent, 2005<br>Clinical rule predicts patients likely to benefit from spinal manipulation |
| Meeker, 2002<br>Chiropractic: A profession at the crossroads of mainstream and alternative medicine |
| Oliphant, 2004<br>Safety of spinal manipulation in the treatment of lumbar disk herniations: a systematic review and risk assessment |
| Stevenson, 2002<br>Risks associated with spinal manipulation |
| Vroomen, 2000<br>Conservative treatment of sciatica: a systematic review |
| **SURGERY** |
| Bono, 2004<br>Critical analysis of trends in fusion for degenerative disc disease over the past 20 years: influence of technique on fusion rate and clinical outcome |
| Boult, 2000<br>Percutaneous endoscopic laser discectomy |
| de Kleuver, 2003<br>Total disc replacement for chronic low back pain: background and a systematic review of the literature |
| Gibson, 2000<br>Surgery for lumbar disc prolapse |
| Gibson, 2005<br>Surgery for degenerative lumbar spondylosis<br>Surgery for degenerative lumbar spondylosis: updated cochrane review |
| Kwon, 2005 #3164<br>A critical analysis of the literature regarding surgical approach and outcome for adult low-grade isthmic spondylolisthesis |
| NICE, 2003<br>Endoscopic laser foraminoplasty |
| NICE, 2003<br>Laser lumbar discectomy |
| NICE, 2004<br>Prosthetic intervertebral disc replacement |

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| **TENS** |
| Khadilkar, 2005<br>Transcutaneous electrical nerve stimulation (TENS) for chronic low-back pain |
| Manheimer, 2005<br>Meta-analysis: acupuncture for low back pain |
| Pengel, 2002<br>Systematic review of conservative interventions for subacute low back pain |
| **TRACTION** |
| Clarke, 2006<br>Traction for low back pain with or without sciatica: an updated systematic review within the framework of the Cochrane Collaboration |
| Clarke, 2005<br>Traction for low-back pain with or without sciatica |
| **ULTRASOUND** |
| Beckerman, 1993<br>Efficacy of physiotherapy for musculoskeletal disorders: what can we learn from research? |
| Gam, 1995<br>Ultrasound therapy in musculoskeletal disorders: a meta-analysis |
| Philadelphia Panel, 2001<br>Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for low back pain |
| Robertson, 2001<br>A review of therapeutic ultrasound: effectiveness studies |
| van der Windt, 1999<br>Ultrasound therapy for musculoskeletal disorders: a systematic review |
| **YELLOW FLAGS**<br>No systematic reviews evaluated the effects of interventions targeted at identification and treatment of yellow flags; several evaluated interventions addressing psychological issues, identification of yellow flags was not the main goal of therapy. |
| Karjalainen, 2001<br>Multidisciplinary biopsychosocial rehabilitation for subacute low-back pain among working age adults |
| Karjalainen, 2003<br>Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults (update) |
| Ostelo, 2005<br>Behavioural treatment for chronic low-back pain |
| Schonstein, 2003<br>Work conditioning, work hardening and functional restoration for workers with back and neck pain |
| Schonstein, 2003<br>Physical conditioning programs for workers with back and neck pain: a cochrane systematic review |

NORTH AMERICAN SPINE SOCIETY
8320 St. Moritz Dr., Spring Grove, IL 60081 877-SpineDr (815) 675-0021 Fax (815) 675-3137 www.spine.org

August 14, 2006

Richard Ellenbogen, MD
President
Congress of Neurological Surgeons
10 North Martingale Rd., Ste. 190
Schaumburg, IL 60173

**Subject: Spine Clinical Guideline Collaboration Invitation**

Dear Dr. Ellenbogen:

Per previous correspondence, NASS would like to invite the Congress of Neurological Surgeons to join us in the collaborative development of evidence-based clinical guidelines and performance measures. As a multidisciplinary society, it is our sincere belief that multispecialty collaborative efforts to develop these tools can only lead to stronger documents and measures, better patient care and stronger bonds between specialties relative to quality of care. Currently six societies have expressed interest in this project: American Academy of Physical Medicine and Rehabilitation, American Academy of Orthopaedic Surgeons, America Academy of Family Physicians, American Society of Spine Radiology, International Spinal Injection Society and the American Academy of Pain Medicine. It is anticipated that any clinical guidelines written will be followed by the development of corresponding performance measures through the AMA Physician Consortium for Performance Improvement. Since all affected specialties will come to the table for the development of spine-related performance measures at the Consortium, it can only be beneficial to be in agreement in advance.

A planning meeting is scheduled for October 13, 2006 in Chicago, Illinois to discuss this project and begin negotiation of the project terms. The terms are to be determined in a democratic manner with equal representation by each group. All terms (development methodology, publication and ownership) will be decided by the group, with each society (at a later date) being given the opportunity to opt-in or out. Terms will not be determined in advance. However, we are providing you with some of our previously used guidelines' materials for reference and a meeting agenda.

Each society is invited to send two physician representatives and one staff representative to this meeting at their own expense. Further details regarding the meeting (location, time, local hotels, etc.) will be forwarded in the near future. In the interest of strong collaborative medicine, we would invite you to consider our invitation and RSVP with your participation and representatives' names by September 1, 2006 to Pam Hayden, Director of Research at 815.675.0021 or hayden@spine.org. We look forward to working with you on the advancement of spine care in the best interests of all our patients.

Best wishes,

Joel Press, MD
2006 NASS President

Richard Guyer, MD
2007 NASS President

cc. Dan Resnick, MD
Paul Matz, MD
Charlie Branch, MD
Katie Orrico

NORTH AMERICAN SPINE SOCIETY
8320 ST. MORITZ DR., SPRING GROVE, IL 60081 877-SPINEDR (815) 675-0021 FAX (815) 675-3137 WWW.SPINE.ORG

**Agenda**
**Spine Clinical Guideline Collaborative Project**
**October 13, 2006**

**Attendees:**

**Vision:** NASS envisions collaborative, broad spectrum spine guidelines that will be widely accepted due to their multispecialty and evidence-based nature.

**Belief:** Multispecialty collaborative efforts to develop guidelines lead to stronger documents and performance measures, better patient care and stronger bonds between specialties.

**Belief:** All issues regarding collaboration should be negotiated and agreed upon upfront by all participating societies.

**Belief:** Up until the collaborative project terms are finalized and signed off on by all groups, anyone can opt out.

# Collaboration Terms and Issues for Discussion

I. General Issues Relative to Collaborative Works
   A. All organizations must be prepared to deal with the politics inherent in working with multiple organizations with differing expectations.
   B. Process/terms will be outlined in advance and agreed upon in writing by participating societies.
   C. Transparent negotiations with clear expectations and written agreements.
   D. Any work products/text/etc. brought to the collaborative are shared with the understanding that they may become a part of the clinical guideline developed and submitted with the understanding that the item is shared without condition.

II. Development Process
   A. Broad multidisciplinary representation, with equal representation from each society.
   B. Thorough & realistic timeframe
   C. Scope: primary care, musculoskeletal care and spine specialists
   D. Transparency
   E. Topics
   F. Methodology
      1. Input by all participating societies on methodology
      2. All societies are responsible for ensuring compliance to chosen methodology
      3. Evidence-based, with rated literature and graded recommendations
      4. Agreed upon levels of evidence and grades of recommendation
      5. Clearly identified expert consensus where literature is lacking
      6. Agreement on literature search protocol and inclusion/exclusion criteria
      7. EBM training of representatives
   G. Format
   H. Openly stated and documented disclosure

III. Resource Allocation/Commitment
   A. Since guideline development will be a long-term proposition (potentially several years for multiple topics), resource allocation issues must be addressed in advance. All resource allocations shall be for the guideline development only.
      1. Indirect costs
         a. Volunteer time
         b. Staff time
      2. Direct Costs
         a. Travel expenses
         b. Literature searches/article retrieval
         c. Meetings expense
         d. Volunteer training
         e. Promotion
      3. Walk-Away Terms
         If any society chooses to walk away after agreeing in writing to the terms of collaboration and prior to the completion of any guideline, any resources allocated will be forfeited and they shall give up any right to the publication.
   B. Multi-year commitments from all participating societies
      1. Support guideline's evidence-based conclusions & recommendations
      2. Acknowledge & support changes in practices supported by strong evidence even if the evidence doesn't support current practice or trends.

IV. Approval/Endorsement

A. All societies will be given an opportunity for review and formal endorsement prior to publication.

B. No revision of content by individual society boards or committees; more evidence or comments may be submitted to the collaborative for review. Comments and responses will be documented. If changes are made based on comments, guidelines will be resubmitted for final review/endorsement.

V. Publication, Use, Distribution, Copyright, Recognition and Revenue

A. All participating societies should:

1. Have joint copyright permanently? Or for a predetermined timeframe?
2. Be recognized as authors in an equitable manner
3. Be provided with a final electronic copy of the guideline in a standard publishing software to be published, distributed and marketed at their own expense, in a format of their choosing
4. Not make any changes to the document and should represent it as work of the collaborative at all times
5. Be invited to participate in any revision process
6. Recognize that all terms apply on guideline by guideline basis and agreements will be signed on a guideline by guideline basis

B. Marketing/Distribution

1. Participating societies may distribute and use the guidelines as they see fit, at their own expense, retaining their own profits. Derivative products are acceptable at individual society expense as long as they accurately represent the content of the guideline and are acknowledged as the work of the authoring society, not the collaborative.
2. The collaborative shall predetermine some mutually beneficial venues for promotion and submission of the guidelines (eg, National Guidelines Clearinghouse) to eliminate any duplication of effort between societies. In the event that new opportunities for same types of promotion arise, the collaborative should submit the guidelines jointly.
3. Standard, agreed upon marketing verbiage and appearance shall be provided to all the participating societies in order encourage promotion of a consistent message about the guidelines and represent the collaborative well.
4. All societies should agree on pricing.
    a. Same price for all?
    b. One copy free to members and charge for additional copies to members, with all nonmembers being charged?
    c. Will guidelines be available on members' only sides of web sites? Read-only or in electronically downloadable form?

C. Performance Measures

All societies should agree that the guidelines will be used to develop performance measures using appropriately qualified methodologists. Optimally, it is proposed that the collaborative will approach the AMA Physician Consortium for Performance Improvement enmasse in this endeavor.

# Tentative Timeline for Collaborative Guideline Development-Topic 1

**We recognize this timetable makes certain assumptions and is somewhat aggressive. It is based on a desire to complete a collaborative guideline by December 2007, as well as our most recent experiences in guideline development. Times can be adjusted as necessary.*

| | |
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| August 2006 | Invitations Sent to All Organizations |
| October 2006 | Meeting With All Interested Organizations To Discuss/Negotiate Terms and Process (October 13, 2006)<br><br>Documentation Of Agreed Upon Terms From The Meeting Is Distributed To All Organizations For Review |
| November 2006 | All Organizations Sign Off on Project Terms and Opt-in or Out (Including Topic Selection)<br><br>Identification of All Guideline Development Participants (Content Participants and Staff) |
| By December 15, 2006 | Identified Content Participants Signed Up for EBM Training |
| February 15, 2007 | All Participants Complete EBM Training |
| February 28, 2007 | Conference Call to Identify Clinical Questions and Discuss Work Group Formations |
| March 15, 2007 | Master List of Clinical Questions Completed<br><br>Work Group Chairs Identified and Member Assignments Finalized |
| March 30, 2007 | Identification of Search Terms and Parameters |
| April 15, 2007 | Searches Conducted |
| May 1, 2007 | Review of Search Results/Identification of Literature To Review |
| June 1, 2007 | Evidence Analysis Begins<br><br>Creation of Guideline Template (Staff) |
| August 1, 2007 | Meeting to Formulate Evidence-based Recommendations and Incorporation of Expert Consensus |
| September 1, 2007 | Submission of Draft Guidelines for Review/Comment to Each Organization |
| October 1, 2007 | Re-Submission to Each Organization of Any Necessary Revisions |
| November 1, 2007 | Formal Endorsement or Opt-Out by All Organizations Due |
| November 30, 2007 | Distribution of Finalized Guideline to All Organizations |
| December 2007 | Presentation of Guideline to the AMA Consortium for Development of Performance Measures<br><br>(NASS, AAOS, AANS serve as co-joint lead organizations in the development of any spine measures at the Consortium). |


# EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

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## NASS GUIDELINE DEVELOPMENT METHODOLOGY

2006

# GUIDELINE DEVELOPMENT METHODOLOGY
2006

## BACKGROUND

Through objective evaluation of the evidence and transparency in the process of making recommendations, it is NASS' goal to develop evidence-based clinical practice guidelines for the diagnosis and treatment of adult patients with back pain. These guidelines are developed for educational purposes to assist practitioners in their clinical decision-making processes. It is anticipated that where evidence is very strong in support of recommendations, these recommendations will be operationalized into performance measures.

### Levels of Evidence and Grades of Recommendation

NASS has adopted standardized levels of evidence and grades of recommendation (*Attachments 1 and 2*) to assist practitioners in easily understanding the strength of the evidence and recommendations within the guidelines. These levels of evidence and grades of recommendation have also been adopted by the Journal of Bone and Joint Surgery, the American Academy of Orthopaedic Surgeons, Clinical Orthopaedics and Related Research and the Pediatric Orthopaedic Society of North America.

### Evidence Analysis Training of All NASS Guideline Developers

NASS has initiated, in conjunction with the University of Alberta's Centre for Health Evidence, an online training program geared towards educating guideline developers about evidence analysis and guideline development. All volunteers participating in guideline development for NASS must complete the training prior to participating in the guideline development program at NASS. This training includes a series of readings and exercises, or interactivities, to prepare guideline developers for systematically evaluating literature and developing evidence-based guidelines. The online course takes approximately 15-30 hours to complete, and participants are awarded CME credit upon completion of the course.

### Disclosure of Potential Conflicts of Interest

All participants involved in guideline development will disclose potential conflicts of interest to their colleagues and their potential conflicts will be documented for future reference. They will not be published in any guideline, but kept on file in the case a question arises. Participants will be requested to update their disclosures regularly throughout the guideline development process.

### Multidisciplinary Collaboration

With the goal of ensuring the best possible care for adult patients suffering with back pain, NASS is committed to multidisciplinary involvement in the process of guideline and performance measure development. To this end, NASS will ensure that representatives from medical, interventional and surgical spine specialties participate in the development and review of all NASS guidelines. It is also important that primary care providers and musculoskeletal specialists who care for patients with back pain are represented in the development and review of guidelines that address treatment by first contact physicians. To ensure broad-based representation, NASS has invited and welcomes input from other societies and specialties.

Any societies who wish to collaborate in guideline development with NASS must identify qualified representatives who are willing to complete the online training program in evidence analysis and guideline development prior to participating in the development process. NASS acknowledges that many issues will need to be discussed with societies interested in collaboration prior to embarking upon a collaborative effort. Agreements will need to be negotiated about financial support and resource allocation, the development process, the review and approval process, copyright issues, publication and use of the guidelines, etc. As societies agree to become involved, their designated representatives will be rolled into the training component, and once the training is completed they will be full participants in the guideline development project.

With broad-based representation and buy-in on the development of evidence-based guidelines for the diagnosis and treatment of back pain, the goal of increasing the implementation of evidence-based recommendations can be realized. With the push for development of performance measures to meet the prospect of pay-for-performance programs, it is becoming increasing important that providers develop the measures upon which they will be held accountable. Once the guidelines are completed, it is anticipated that all specialties will work together, in collaboration with either the AMA Physician's Consortium for Performance Improvement or others appropriately trained in evidence-based performance measure development, to develop evidence-based performance measures for the diagnosis and treatment of back pain. If all those who care for patients with back pain can collaborate on the development of evidence-based guidelines, and then upon the resulting performance measures, eventual implementation of any pay-for-performance or quality improvement program will be greatly facilitated.

## METHODOLOGY

Once a topic has been identified, the following steps are implemented:

❖ Step 1: Identification of Clinical Questions

Trained guideline participants are asked to submit a list of clinical questions that the guideline should address. The list is compiled into a master list, which is then circulated to each member with a request that they independently rank the questions in order of importance for consideration in the guideline. The most highly ranked questions, as determined by the participants, will serve to focus the guideline.

❖ Step 2: Identification of Work Groups

Multidisciplinary teams are assigned to work groups and assigned specific clinical questions to address. Because NASS is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross-section of NASS membership is represented on each group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations are minimized.

❖ Step 3: Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol (*Attachment 3*) which will be followed to identify literature for evaluation in guideline development. In keeping with the Literature Search Protocol, work group members will identify appropriate search terms and parameters to direct the literature search.

❖ Step 4: Completion of the Literature Search

Once each work group identifies search terms/parameters, the literature search will be implemented by a medical/research librarian, consistent with the Literature Search Protocol.

❖ Step 5: Review of Search Results/Identification of Literature to Review

It is at this point that members will review abstracts yielded from the literature search and identify the literature they will review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members will strive to identify the best research evidence available to answer the targeted clinical questions. That is, if Level I, II, and/or III literature is available to answer specific questions, the work group will not be required to review Level IV or V studies.

❖ Step 6: Evidence Analysis

Each member will develop their own evidentiary table summarizing study conclusions, strengths and weaknesses, and identifying levels of evidence. In order to systematically control for potential biases, two work group members will review each article selected, and independently assign levels of evidence to the literature using the NASS levels of evidence (*Attachment 1*). Any discrepancies in scoring will be addressed by the two reviewers, and where consensus cannot be reached by two reviewers, another work group member will be assigned to review the article and assign a level of evidence (without knowledge of the other scores identified).Gaps in the evidence should also be documented to educate guideline readers about where evidence is lacking and help guide further needed research by NASS and other societies.

❖ Step 7: Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Two- or three-day meetings of the work groups will be scheduled to discuss the evidence-based answers to the clinical questions, the grades of recommendations (*Attachment 2*), and the incorporation of expert consensus. Expert consensus will be used only where evidence is lacking and the work group deems a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and any consensus-based recommendations made in the guidelines will very clearly indicate that the evidence is insufficient to make a recommendation and that the recommendation is based only on expert consensus. The work groups will develop a preliminary draft of their guidelines.

❖ Step 8: Submission of the Draft Guidelines for Review/Comment

Guidelines will be submitted to the full Guidelines Committee, the Clinical Care Council Director and, later, the Advisory Panel for review and comment. The Advisory Panel is comprised of representatives from physical medicine and rehab, pain medicine/management, orthopedic surgery, neurosurgery, anesthesiology, rheumatology, psychology/psychiatry and family practice. In addition, the guidelines will be submitted to participating societies for review and comment. ***Revisions to recommendations will be considered for incorporation only when substantiated by a preponderance of appropriate level evidence.***

❖ Step 9: Submission for Board Approval

Once any evidence-based revisions are incorporated, the drafts will be prepared for NASS Board review and approval. ***Edits and revisions to recommendations and any other content will be considered for incorporation only when substantiated by a preponderance of appropriate level evidence.***

❖ Step 10: Submission for Endorsement, Publication and NGC Inclusion

Once approved by the NASS Board, the guidelines will be published, submitted for endorsement to all appropriate societies, and submitted for inclusion in the National Guidelines Clearinghouse (NGC). Given that societies participating in the development of guidelines will have had an opportunity to review/comment, the final society review is for endorsement of the guidelines as submitted for consideration. No revisions will be made at this point in the process, but comments will be saved for the next iterations.

❖ Step 11: Identification and Development of Performance Measures

Once the guidelines are finalized, the recommendations will be reviewed by a group experienced in performance measure development (eg, the AMA Physician's Consortium for Performance Improvement) to identify those recommendations rigorous enough for measure development. All relevant medical specialties involved in the guideline development and at the Consortium will be invited to collaborate in the development of evidence-based performance measures related to spine care.

## Levels of Evidence For Primary Research Question[1]

| | Types of Studies | | | |
|---|---|---|---|---|
| | Therapeutic Studies – Investigating the results of treatment | Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease | Diagnostic Studies – Investigating a diagnostic test | Economic and Decision Analyses – Developing an economic or decision model |
| Level I | • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals<br>• Systematic Review[2] of Level I RCTs (and study results were homogenous[3]) | • High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients)<br>• Systematic review[2] of Level I studies | • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level I studies | • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level I studies |
| Level II | • Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization)<br>• Prospective[4] comparative study[5]<br>• Systematic review[2] of Level II studies or Level 1 studies with inconsistent results | • Retrospective[6] study<br>• Untreated controls from an RCT<br>• Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.)<br>• Systematic review[2] of Level II studies | • Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level II studies | • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level II studies |
| Level III | • Case control study[7]<br>• Retrospective[6] comparative study[5]<br>• Systematic review[2] of Level III studies | • Case control study[7] | • Study of non-consecutive patients; without consistently applied reference "gold" standard<br>• Systematic review[2] of Level III studies | • Analyses based on limited alternatives and costs; and poor estimates<br>• Systematic review[2] of Level III studies |
| Level IV | Case Series[8] | Case series | • Case-control study<br>• Poor reference standard | • Analyses with no sensitivity analyses |
| Level V | Expert Opinion | Expert Opinion | Expert Opinion | Expert Opinion |

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g. failed total arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

## Grades of Recommendation
## for Summaries or Reviews of Studies

A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.

B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V Studies) for or against recommending intervention.

I: There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

# Protocol for NASS Literature Searches

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care or use of new technologies is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence, which will be instrumental to these activities.

## Background

It has become apparent that the number of literature searches being conducted at NASS is increasing and that they are not necessarily conducted in a consistent manner between committees/projects. Since the quality of a literature search directly affects the quality of recommendations made, a comparative literature search was undertaken to help NASS refine the process and make recommendations about how to conduct future literature searches on a NASS-wide basis.

In November-December 2004, NASS conducted a trial-run at new technology assessment. As part of the analysis of that pilot process, the same literature searches were conducted by both an experienced NASS member and a medical librarian for comparison purposes. After reviewing the results of that experiment and the different strategies employed for both searches, it was the recommendation of NASS Research staff that a protocol be developed to ensure that all future NASS searches be conducted consistently to yield the most comprehensive results. While it is recognized that some searches occur outside the Research and Clinical Care Councils, it is important that all searches conducted at NASS employ a solid search strategy, regardless of the source of the request. To this end, this protocol has been developed and NASS-wide implementation is recommended.

## Protocol for NASS Literature Searches

The NASS Research Department has a relationship with Northwestern University's Galter Health Sciences Library. When it is determined that a literature search is needed, NASS research staff will work with the requesting parties and Galter to run a comprehensive search employing *at a minimum* the following search techniques:

1. A preliminary search of the evidence will be conducted using the following clearly defined search parameters (as determined by the content experts). The following parameters are to be provided to research staff to facilitate this search.

    - Time frames for search;
    - Foreign and/or English language;
    - Order of results (chronological, by journal, etc.);
    - Key search terms and connectors, with or without MeSH terms to be employed;
    - Age range;

    Must answer the following questions:

    - Should duplicates be eliminated between searches?
    - Should searches be separated by term or as one large package?
    - Should human studies, animal studies or cadaver studies be included?

This preliminary search should encompass a search of the Cochrane database when access is available.

2. Search results with abstracts will be compiled by Galter in Endnote software. Galter typically responds to requests and completes the searches within 2-5 days. Results will be forwarded to the Research staff, who will share it with the appropriate NASS staff member or requesting party(ies). (Research staff has access to Endnote software and will maintain a database of search results for future use/documentation.)

3. NASS staff shares the search results with an appropriate content expert (NASS Committee member or other) to assess relevance of articles and identify appropriate articles to review and on which to run a "related articles" search.

4. Based on content expert's review, NASS Research staff will then coordinate with the Galter medical librarian the second level searching to identify relevant "related articles."

5. Galter will forward results to Research staff to again share with appropriate NASS staff member.

6. NASS staff shares related articles search results with an appropriate content expert (NASS Committee member or other) to assess relevance of this second set of articles, and identify appropriate articles to review and on which to run a second "related articles" search.

7. NASS Research staff will work with Galter library to obtain the 2nd related articles search results and any necessary full-text articles for review.

8. NASS members reviewing full-text articles should also review the references at the end of each article to identify additional articles which should be reviewed, but may have been missed in the search.

**Protocol for Expedited Searches**

Numbers 1,2 and 3 should minimally be followed for any necessary expedited search. Following #3, depending on the time frame allowed, deeper searching may be conducted as described by the full protocol or request of full-text articles may occur. If full-text articles are requested, #8 should also be included. Use of the expedited protocol or any deviation from the full protocol should be documented with explanation.

Following these protocols will help ensure that NASS recommendations are (1) based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. Research staff will maintain a search history in Endnote, for future use or reference.

Dear Colleague,
On behalf of the AANS/CNS Joint Section on Spine & Peripheral Nerves we would like to thank you for presenting your research at the annual meeting in Orlando, Florida. The 2006 meeting was a great success, due in large part to the outstanding quality of your podium presentation.

Following the 2005 meeting last year, solicitations were made for oral presenters to submit manuscripts to the *Journal of Neurosurgery: Spine.* This resulted in the expeditious publication of many high-quality papers. This year we would like to again invite authors of oral presentations to submit their manuscripts for possible publication to the *Journal of Neurosurgery: Spine.*

As you know, the *Journal of Neurosurgery: Spine* is a peer-reviewed monthly publication, and all papers submitted must undergo a rigorous peer-review process. However, based on the high quality of the presentations at the 2006 Section Meeting we encourage you to submit your work. Author guidelines can be found on the Journal's website http://manuscript.thejns-net.org under View instructions & Forms. Please include a statement in your cover letter this material was presented at the 2006 Spine Section meeting.

Thank you once again for your participation in Orlando, and we look forward to seeing you in Phoenix in 2007!

Sincerely,

Robert Heary, MD
Immediate Past-Chairman

Michael Groff, MD
Annual Meeting Chairman

Mark McLaughlin, MD
Scientific Program Chairman

Michael Y Wang, MD
Publications Committee Chairman

# SP Section Membership Report

*sjmtember 18, 2006*

| SP Member Type | | Count |
|---|---|---|
| **Current Members** | | |
| SP01S | Spine Section Active Member | 1,041 |
| SP15D | Spine Section Associate Member | 9 |
| SP25S | Spine Section Senior Member | 198 |
| SP40S | Spine Section International Member | 46 |
| SP45D | Spine Section Honorary Member | 1 |
| SP60D | Spine Section Adjunct Member | 21 |
| SP60P | Spine Section Pending Adjunct Member | 3 |
| SP65R | Spine Section Resident Member | 120 |
| | | **1,439** |
| **Resigned, Deceased, or Suspended Members - 2006** | | |
| SP96S | Spine Section Suspended Member | 21 |
| SP97S | Spine Section Resigned Member | 10 |
| SP98S | Spine Section Deceased Member | 9 |
| | | **40** |

# Outstanding Section Dues



| Member ID | Name | AANS Member Type | CNS Member Type | Inv # | Batch | Inv Amt | Amt Paid | Amt Due |
|---|---|---|---|---|---|---|---|---|
| **Section: Spine Section** | | | | | | | | |
| 59709 | Moustapha Abou-Samra MD | A01S | CN01S | | | | | |
| | | | | 5-000130393 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 121910 | Bret B. Abshire MD | A01S | | | | | | |
| | | | | 5-000130066 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 96107 | Maged Lotfy Abu-Assal MD | A01S | | | | | | |
| | | | | 5-000130007 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 117649 | Mark S. Adams MD | A01S | | | | | | |
| | | | | 5-000130061 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 103026 | James M. Alvis MD FACS | A01S | CN01S | | | | | |
| | | | | 5-000130663 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 102033 | Ely Ashkenazi MD | C99S | CN05S | | | | | |
| | | | | 5-000130985 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 120391 | Koang Hum Bak MD | A40S | | | | | | |
| | | | | 5-000111729 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130108 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 104371 | William B. Betts MD | A01S | | | | | | |
| | | | | 5-000111662 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130033 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 136815 | Kenneth C. Brewington II MD | A01S | CN01S | | | | | |
| | | | | 5-000130876 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 59022 | Leonard A. Bruno MD | A01S | CN01S | | | | | |
| | | | | 5-000130375 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 50611 | Kim J. Burchiel MD FACS | A01S | CN01S | | | | | |
| | | | | 5-000111941 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130304 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 50807 | Carlos A. Carrion MD | C99S | CN01S | | | | | |
| | | | | 5-000130941 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 96156 | Richard L. Carter MD FACS | A01S | CN01S | | | | | |
| | | | | 5-000130582 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 98017 | W. Bruce Cherny MD | A01S | CN01S | | | | | |
| | | | | 5-000112242 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130591 | SP051219DU01 | 50.00 | 0.00 | 50.00 |

# Outstanding Section Dues



| Member ID | Name | AANS Member Type | CNS Member Type | Inv # | Batch | Inv Amt | Amt Paid | Amt Due |
|---|---|---|---|---|---|---|---|---|
| 415100 | Bo-Young Cho | X99D | | | | | | |
| | | | | 5-000131010 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 106551 | Kyung Gi Cho MD | A40S | | | | | | |
| | | | | 5-000130105 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 105968 | Tanvir F. Choudhri MD | A60S | | | | | | |
| | | | | 5-000111737 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130116 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 96164 | Geoffrey P. Cole MD | A01S | CN01S | | | | | |
| | | | | 5-000112234 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130583 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 90092 | George R. Cybulski MD FAC | A01S | CN01S | | | | | |
| | | | | 5-000112067 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130420 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 3202 | David F. Dean MD | A01S | CN97S | | | | | |
| | | | | 5-000111786 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130156 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 105038 | Mohamed Nagy El Wany MD | C99S | CN05S | | | | | |
| | | | | 5-000112609 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130987 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 161845 | Ghasem E. Eshaghi MD | C99S | CN01S | | | | | |
| | | | | 5-000130836 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 123026 | Frank Feigenbaum MD | A01S | | | | | | |
| | | | | 5-000130069 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 90934 | Aaron G. Filler MD PhD | A01S | CN01S | | | | | |
| | | | | 5-000130544 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 10216 | S. Sam Finn MD | A01S | CN97S | | | | | |
| | | | | 5-000111820 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130189 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 419676 | Shee Yan Fong FRCS | X99D | | | | | | |
| | | | | 5-000131012 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 22 | Modesto Fontanez MD JD FA | A01S | CN01S | | | | | |
| | | | | 5-000130128 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 97345 | Joel Ira Franck MD PA | A01S | CN01S | | | | | |
| | | | | 5-000130588 | SP051219DU01 | 50.00 | 0.00 | 50.00 |

# Outstanding Section Dues



| Member ID | Name | AANS Member Type | CNS Member Type | Inv # | Batch | Inv Amt | Amt Paid | Amt Due |
|---|---|---|---|---|---|---|---|---|
| 130218 | Bruce M. Frankel MD | A60S | CN01S | | | | | |
| | | | | 5-000130871 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 90575 | Marvin E. Friedlander MD FA | A01S | CN01S | | | | | |
| | | | | 5-000112138 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000131046 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 95126 | Paul A. Grabb MD | A01S | CN01S | | | | | |
| | | | | 5-000130570 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 90082 | John Peter Gruen MD | A01S | CN01S | | | | | |
| | | | | 5-000130416 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 52431 | L. N. Hopkins III MD | A01S | CN01S | | | | | |
| | | | | 5-000130324 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 6429 | Herman Hugenholtz MD | C99S | CN01S | | | | | |
| | | | | 5-000130975 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 52589 | Abelardo D. Inoa MD | C99S | CN01S | | | | | |
| | | | | 5-000112567 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130947 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 130258 | Terrence D. Julien MD | C99S | CN65T | | | | | |
| | | | | 5-000130972 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 401601 | Dimitrios Kafritsas | X99D | | | | | | |
| | | | | 5-000131008 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 98236 | Phillip Kissel MD | A01S | CN01S | | | | | |
| | | | | 5-000130619 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 119015 | Joseph L. Koen MD | A01S | | | | | | |
| | | | | 5-000111743 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130064 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 101140 | Tadashi Kojima MD | C99S | CN05S | | | | | |
| | | | | 5-000112606 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130984 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 7708 | Vijay S. Kumar MD | A40S | CN01S | | | | | |
| | | | | 5-000112387 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130838 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 106784 | Giuseppe Lanzino MD | A60S | CN01S | | | | | |
| | | | | 5-000130852 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 51111 | Bothwell Graves Lee MD | A01S | CN01S | | | | | |

# Outstanding Section Dues



| Member ID | Name | AANS Member Type | CNS Member Type | Inv # | Batch | Inv Amt | Amt Paid | Amt Due |
|---|---|---|---|---|---|---|---|---|
| | | | | 5-000131043 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 90836 | Sean Raymond Logan MD | A01S | CN01S | | | | | |
| | | | | 5-000130530 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 150202 | Rafael A. Lopez MD | X99D | | | | | | |
| | | | | 5-000131006 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 53157 | Gary J. Lustgarten MD | C99S | CN01S | | | | | |
| | | | | 5-000112669 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130948 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 101376 | Philip J. Marra MD | A01S | CN97S | | | | | |
| | | | | 5-000130630 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 53462 | Jay D. Miller MD | A01S | | | | | | |
| | | | | 5-000111593 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000129966 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 50293 | Daniel W. Moore MD FACS | A01S | CN01S | | | | | |
| | | | | 5-000130293 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 16585 | John Innis Moseley MD | A01S | | | | | | |
| | | | | 5-000129955 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 152306 | Jaime H. Nieto MD | C99S | CN01S | | | | | |
| | | | | 5-000112594 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130974 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 135940 | Robert T. Numoto MD | C99S | CN05S | | | | | |
| | | | | 5-000130995 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 62389 | Hirohisa Ono MD | A01S | | | | | | |
| | | | | 5-000129972 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 97980 | Jeffrey H. Oppenheimer MD | A01S | CN01S | | | | | |
| | | | | 5-000130589 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 59279 | A. E. Oygar MD | A01S | CN01S | | | | | |
| | | | | 5-000130380 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 113664 | Jung Yul Park MD PhD | A40S | CN05S | | | | | |
| | | | | 5-000130843 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 102513 | John Bruce Payne DO | A01S | | | | | | |
| | | | | 5-000111652 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130023 | SP051219DU01 | 50.00 | 0.00 | 50.00 |

# Outstanding Section Dues



| Member ID | Name | AANS Member Type | CNS Member Type | Inv # | Batch | Inv Amt | Amt Paid | Amt Due |
|---|---|---|---|---|---|---|---|---|
| 58776 | David Buenor O. Puplampu M | T01S | CN01S | | | | | |
| | | | | 5-000112666 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000131063 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 154784 | Alfredo Quinones-Hinojosa M | A60S | CN65R | | | | | |
| | | | | 5-000130851 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 102935 | Paul K. Ratzker MD | A01S | | | | | | |
| | | | | 5-000130026 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 117630 | Michael J. Rauzzino MD | A01S | | | | | | |
| | | | | 5-000111740 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130060 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 50073 | Gary L. Rea MD | A01S | CN01S | | | | | |
| | | | | 5-000130271 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 101367 | Robert L. Remondino MD | A01S | | | | | | |
| | | | | 5-000111649 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130020 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 161534 | Ayman M. Salem MD | A60S | CN65T | | | | | |
| | | | | 5-000130922 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 407325 | Dino Samartzis BS | C99S | CN20S | | | | | |
| | | | | 5-000112622 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000131001 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 152106 | Alan M. Scarrow MD JD | A60S | CN01S | | | | | |
| | | | | 5-000130909 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 91770 | Itzhack Shacked MD | A40S | | | | | | |
| | | | | 5-000111724 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000131054 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 90553 | Bryson Swain Smith MD | A01S | CN01S | | | | | |
| | | | | 5-000130486 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 95102 | Richard A. Stea MD | A01P | | | | | | |
| | | | | 5-000131018 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 50318 | Mark Stern MD | A01S | CN01S | | | | | |
| | | | | 5-000130298 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 100806 | Jung-Keun Suh MD PhD | A40S | | | | | | |
| | | | | 5-000130104 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 102795 | Mitchell L. Supler MD | A01S | CN01S | | | | | |

# Outstanding Section Dues



| Member ID | Name | AANS Member Type | CNS Member Type | Inv # | Batch | Inv Amt | Amt Paid | Amt Due |
|---|---|---|---|---|---|---|---|---|
| | | | | 5-000130641 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 161272 | Leonello Tacconi MD FRCS | A40S | CN05S | | | | | |
| | | | | 5-000130849 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 130182 | Richard J. Teff MD | A06S | CN01S | | | | | |
| | | | | 5-000112396 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000130773 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 98260 | Larry L. Teuber MD | X99S | CN01S | | | | | |
| | | | | 5-000131058 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 135968 | Robert E. Tibbs Jr. MD | A01S | CN01S | | | | | |
| | | | | 5-000130753 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 105055 | Robert L. Tiel MD | A01S | CN01S | | | | | |
| | | | | 5-000130681 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 157292 | Daniel J. Tomes MD | A60S | CN65T | | | | | |
| | | | | 5-000130915 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 55327 | Raul A. Vernal MD | C99S | CN01S | | | | | |
| | | | | 5-000130954 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 120085 | Beverly C. Walters MD | A01S | CN01S | | | | | |
| | | | | 5-000130718 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 50172 | Melvin D. Whitfield MD FAC | A01S | CN01S | | | | | |
| | | | | 5-000111917 | SP041220DU01 | 50.00 | 0.00 | 50.00 |
| | | | | 5-000131042 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 408696 | Diana B. Wiseman MD | A06S | | | | | | |
| | | | | 5-000130085 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 102927 | Peter A. Zahos MD FACS | A01S | CN01S | | | | | |
| | | | | 5-000130655 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 98285 | Luis Manuel Zavala MD | A01S | | | | | | |
| | | | | 5-000130016 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| 104034 | Christian G. Zimmerman MD | A01S | CN01S | | | | | |
| | | | | 5-000130675 | SP051219DU01 | 50.00 | 0.00 | 50.00 |
| **Totals for Section: Spine Section** | | | | | | **111** | **$5,550.00** | **$0.00** | **$5,550.00** |
| **Grand Totals** | | | | | | **111** | **$5,550.00** | **$0.00** | **$5,550.00** |

American Association of Neurological Surgeons

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**Rolling Meadows, IL 60008**

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**web:** www.AANS.org
www.NeurosurgeryToday.org



August 31, 2006

Debbie Katsarelis
Staff Liaison
Society of Interventional Radiology
3975 Fair Ridge Drive
Suite 400 North
Fairfax, Virginia 22033

RE: Vertebroplasty Position Statement

Dear Ms. Katsarelis,

Thank you for giving the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) the opportunity to review the draft "Position Statement on Percutaneous Vertebral Augmentation". We have circulated this among our spine and endovascular neurosurgeons, and reached consensus that this is a very well written document that generally arrives at the appropriate conclusions.

The AANS/CNS Cerebrovascular Section and the AANS/CNS Joint Section on Diseases on Disorders of the Spine and Peripheral Nerves have recommended that the AANS endorse this position statement subject to you making several editorial changes that we believe would strengthen the document.

- There are a number of places in the document that seem to inappropriately favor vertebroplasty over kyphoplasty, primarily because of the increased costs associated with kyphoplasty. While we appreciate that kyphoplasty may be more expensive, the AANS and CNS believe that both procedures are equally beneficial for those patients in need of this therapy and both should be fully covered by Medicare. The document should therefore be edited to eliminate any potential bias against kyphoplasty.

- The introductory comments on pages 3-4 of the attached .pdf file should describe the procedure as percutaneous vertebral augmentation, regardless of whether vertebroplasty or kyphoplasty is performed.

- Using the introductory paragraphs to establish the position that percutaneous vertebral augmentation is a valid, safe, and beneficial therapy, in a generic, non-technique specific way, is a much stronger introduction. Since this is the message conveyed at the conclusion of the document, it seems appropriate to state this conclusion at the beginning of the document as well.

- The description of the differences between vertebroplasty and kyphoplasty should appear later in the document. Since the description of kyphoplasty appears on page 12 of the attached .pdf file, perhaps this would be a more appropriate position for the statements of comparison or contrast that are currently expressed in the introductory paragraphs on pages 3-4.

Again, thank you for soliciting our feedback. We hope you will consider making our suggested changes so the AANS can be listed as an endorsing organization. Please let me know if you need additional information or clarification on any of our suggestions.

Sincerely,

Donald O. Quest, MD
President

cc: J. Kevin McGraw, MD
Charles Branch, MD
Gregory Thompson, MD

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September 19, 2006

FDA Panel on Orthopedic and Rehabilitation Devices

Gaithersburg, Maryland

Dr. Mabrey,

Ladies and Gentlemen:

Good morning. Thank you for this opportunity to speak. I will begin with an introduction and disclosure. My name is Charles L. Branch, Jr. and I am neurosurgeon certified by the American Board of Neurological Surgery and licensed by and practicing in the State of North Carolina where I am the Professor and Chair of the Department of Neurosurgery at the Wake Forest University School of Medicine in Winston-Salem. I have a long standing subspecialty interest in the field of spinal surgery. This morning I represent the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) as the Chair of the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves. I disclose that my travel expense to this presentation is funded by the AANS and CNS. I also disclose that I am a consultant to Medtronic and receive compensation for consulting service but will not personally benefit financially from any decision made by this panel today. I have not participated as an investigator or reviewer of the device being considered today. Neither I nor my family directly own stock in Medtronic nor are we directors on any of its Boards.

The American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS) and the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves support the FDA Orthopaedic and Rehabilitation Devices Panel's serious and favorable consideration of cervical disc arthroplasty technology.

During the most recent 4-5 years, the concept of cervical disc arthroplasty has been presented and debated in a variety of scientific forums sponsored by the AANS and CNS and the Section on Spinal Disorders including the Annual Scientific Meetings. In these same forums, the distinct difference or uniqueness of the cervical spine as opposed to the lumbar spine has been articulated and deliberated. Conceptually, cervical disc arthroplasty or disc replacement technology has been embraced as a potential advance in patient care pending further experience and understanding of the safety and long term effectiveness of this technology to preserve normal or near normal motion in one or multiple segments of the cervical spine. For the treatment of symptomatic cervical disc degeneration, this technology would appear to have value in the relief of symptoms and added value in the prevention of adjacent level degeneration.

In our scientific forums, reported experience with cervical artificial disc technology both domestic and international has shown this to be safe, durable, and effective both with respect to preservation of motion and relief of radicular symptoms, at least comparable to the currently standard treatment of anterior cervical discectomy and fusion.

Should the Panel find that the PMA study data validates that the device under review is in fact safe and effective, then Neurosurgery strongly supports a recommendation for approval by the FDA so that as physicians we may gain a greater experience and we anticipate that our patients may benefit from a broader application of this technology.

Again, thank you for considering our views on this issue.

Charles L. Branch, Jr. MD

Chair

AANS/CNS Section on Disorders of the Spine and Peripheral Nerves

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*President*
RICHARD G. ELLENBOGEN, MD
University of Washington
Seattle, Washington

May 5, 2006

Food and Drug Administration
Division of Dockets Management
HFA-305
5630 Fishers Lane, Room 1601
Rockville, MD 20852

Dear Sir or Madame:

RE: Orthopedic Devices: Reclassification of the Intervertebral Body Fusion Device.
Docket No. 2006N--0019

On behalf of the American Association of Neurological Surgeons (AANS), we appreciate the opportunity to comment on the above referenced notice, which was published in the *Federal Register* on February 9, 2006.

We support the FDA proposal to reclassify intervertebral body fusion devices that contain bone grafting material from class III to class II. We believe that these devices are safe and effective when implanted by appropriately trained surgeons in carefully selected patients.

With regard to the proposal to retain intervertebral body fusion devices containing therapeutic biologic (e.g. bone morphogenic protein) in class III, we would suggest that the device itself is not substantially different than the device used for the bone grafting material and would recommend de-linking the device from the material placed in the device. In other words, we feel the "cage" itself should be reclassified to class II even if the FDA believes that the therapeutic biologic should remain in class III.

Thank you for your time and attention.

Sincerely,

Donald O. Quest, MD, President
American Association of Neurological Surgeons

Richard G. Ellenbogen, MD, President
Congress of Neurological Surgeons

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*President*
RICHARD G. ELLENBOGEN, MD
University of Washington
Seattle, Washington

September 8, 2006

Mark Melkerson, Deputy Director
Division of General, Restorative, and Neurological Devices
FDA Center for Devices and Radiological Health
Room 350C, Mail stop HFZ 410
Rockville, MD 20850

RE: September 19, 2006, Orthopaedic and Rehabilitation Panel Consideration of Cervical Disc Prosthesis

Dear Mr. Melkerson:

The American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS) and the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves support the FDA Orthopaedic and Rehabilitation Devices Panel Panel's serious and favorable consideration of cervical disc arthroplasty technology.

The potential for treatment of pathology with preservation of motion in symptomatic cervical disc degeneration appears to have value in the relief of symptoms and in the prevention of adjacent level degeneration. Reported experience with the cervical artificial disc has shown this to be safe, durable, and effective both with respect to preservation of motion and relief of radicular symptoms, at least comparable to the currently standard treatment of anterior cervical discectomy and fusion. Should the Panel find that the IDE study data validates that the device under review is in fact safe and effective, then Neurosurgery strongly supports its approval by the FDA so that patients may benefit from a broader application of this technology.

The AANS and CNS intend to have a representative present our views at the September 19 panel meeting and we will inform you who that individual is as soon as possible.

In the meantime, thank you for considering our views on this issue.

Sincerely,

Donald O. Quest, MD, President
American Association of Neurological Surgeons

Richard G. Ellenbogen, MD, President
Congress of Neurological Surgeons

**Staff Contact**
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August 7, 2006

Thomas A. Marshal
Executive Director
American Association of Neurological Surgeons
5550 Meadowbrook Drive
Rolling Meadows, Illinois 60008-3852

RE: Vertebroplasty Position Statement

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Dear Mr. Marshal,

The Society of Interventional Radiology would like to know if AANS would like to endorse this position statement: "**Position Statement on Percutaneous Vertebral Augmentation".**

This statement is an adaptation of a position statement sent to the Medicare Coverage Advisory Committee on May 3, 2005 with supporting information on the issues surrounding percutaneous vertebroplasty and kyphoplasty in the treatment of painful vertebral body compression fractures. Vertebroplasty is a medically appropriate therapy for treatment of painful vertebral compression fractures refractory to medical therapy and it is the recommendation of the ASITN, ASNR, and SIR that CMS continue to cover the procedure for the medical indications outlined in the published standards.

CMS communicated back that the available evidence was not sufficient to permit conclusions of the effect of percutaneous vertebroplasty (PVP) on health outcomes. The published evidence describing the outcomes of vertebroplasty consisted mostly of uncontrolled studies. These uncontrolled studies were mostly retrospective and enrolled heterogeneous patient populations. Such studies could not eliminate placebo and natural history effects as explanations for the apparent effectiveness of PVP.

The purpose of the enclosed statement is to give members useful information should they need to appeal an insurer's denial of payment for vertebral augmentation procedures. With your endorsement, we can strengthen consensus and make the position statement even stronger.

Enclosed is a **Confidential Draft** for your review. **Please acknowledge intent by August 31, 2006.**

If you have any questions please do not hesitate to email debbie@sirweb.org. Thank you in advance for your immediate reply.

Sincerely,

Debbie Katsarelis
SIR Staff Liaison

# Position Statement on Percutaneous Vertebral Augmentation: A consensus statement developed by the American Society of Interventional and Therapeutic Neuroradiology

American Society of Neuroradiology

Society of Interventional Radiology

Mary E. Jensen, MD, J. Kevin McGraw, MD, John F. Cardella, MD, Joshua A. Hirsch, MD, Patrick A. Turski, MD

It is the position of the Societies that percutaneous vertebroplasty is a safe, efficacious and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures, when performed in a manner in accordance with published standards[1,2]. This procedure is offered only when traditional medical therapy has not provided pain relief or pain is significantly altering the patient's lifestyle. Multiple case series[3-17], retrospective[18,19] and prospective non-randomized studies[20-23] have shown statistically significant improvement in pain and function, particularly ambulation, and these results have been confirmed in a prospective study using a control group[24], and a prospective randomized control study[25]. The benefits of vertebroplasty far outweigh its risks and the risks of conservative therapy, and the success rate is consistently high. This procedure is cost effective by producing immediate improvement in a patient's quality of life, primarily through the alleviation of pain and rapid return to ambulation. In addition to reducing the need for costly skilled care, expensive drugs, or orthopedic devices, a return to ambulation is known to reduce adverse outcomes in elderly patients confined to bed[26]. It is the opinion of the ASITN, ASNR, and SIR that vertebroplasty is a medically appropriate therapy for treatment of painful vertebral compression fractures refractory to medical therapy when performed for the medical indications outlined in the published standards[1,2].

Kyphoplasty has been introduced as an alternative approach[27]. It is quite similar to vertebroplasty, and has been referred to as "balloon-assisted vertebroplasty." Kyphoplasty entails the inflation of a percutaneously delivered balloon in the vertebral body, followed by the percutaneous injection of bone cement into the cavity created by the balloon. The balloon is intended to restore the vertebral body height in addition to creating the cavity[27].

After reviewing the published literature on kyphoplasty, the Societies have determined that the clinical response rate in individuals treated with kyphoplasty is equivalent to that seen in patients treated with vertebroplasty. There is no proven advantage of kyphoplasty relative to vertebroplasty with regard to pain relief, vertebral height restoration, and complication rate[27-44]. Because of additional equipment, anesthesia, and hospital costs, kyphoplasty is approximately 2.5 times more expensive than vertebroplasty. It is possible that certain subgroups of patients may derive more benefit from one particular procedure[45]. Features that might affect choice of procedure include degree of compression deformity, age of the fracture, and the presence of neoplastic involvement, but the benefits of kyphoplasty relative to vertebroplasty in such subgroups currently remain totally undefined. With the considerable added financial expense of kyphoplasty, a significant clinical benefit over vertebroplasty would have to be proven to justify this cost. A convincing benefit to kyphoplasty relative to vertebroplasty can only be proven by comparing outcomes from both procedures in a prospective, randomized study. The Societies recognize, however, that performance of kyphoplasty instead of

vertebroplasty may be due to operator experience or preference. Since the clinical outcomes studies show the same benefit as vertebroplasty in patient pain relief and mobility at similar complication rates, it is the Societies' position that kyphoplasty should be considered an alternative procedure to vertebroplasty.

## RATIONALE

### Vertebral Augmentation versus Traditional Conservative Management

Although "conservative" implies "safe," conservative therapy is neither benign nor risk-free, and its complications are well documented[46-48]. Conservative treatment of painful vertebral compression fractures usually consists of bed rest, bracing and narcotic analgesia. In a recent prospective study of 498 hospitalized patients age 70 or older, low mobility (defined as bed rest or ability to transfer to chair) or intermediate mobility (defined as ambulation one to two times with total assistance) were independent predictors of the following poor hospital outcomes at discharge: a) decline in activities of daily living (ADLs), b) new institutionalization, and c) death when compared to high mobility (defined as ambulation two or more times with partial or no assistance)[26]. The contribution of low mobility to these outcomes remained statistically significant in multivariate analyses even after controlling for multiple variables including age, sex, severity of illness and comorbitidies. In short, conservative treatment leads to adverse outcomes associated with low

mobility and bed rest, which may be viewed as iatrogenic events leading to complications such as functional decline.

As previously mentioned, conservative treatment often includes immobilization with bed rest. During bed rest virtually every organ system is adversely affected and these effects tend to be more pronounced in older patients who have less reserve than younger patients. Bone density declines approximately 2% per week, a serious concern in patients already suffering from osteoporosis and these patients are unlikely to ever regain the lost bone mass[49]. Bone loss tends to occur in stages with the most dramatic changes occurring in the first twelve weeks of immobilization.

Muscle strength declines 1-3% per day or 10-15% per week[46]. Nearly half of normal strength is lost within 3 to 5 weeks of immobilization and the rate of recovery from disuse weakness is slower than the rate of loss. Complete rest results in decreased endurance, which leads to a sense of fatigue and reduced patient motivation, setting up a vicious circle of greater inactivity. Ligament complexes are also affected by immobilization, leading to contractures, which are more prone to occur in frail, elderly individuals. Muscles that cross two joints, such as the back muscles, are particularly at risk of shortening during immobilization. There is abundant evidence that shows early active mobilization after initial stabilization—a benefit of vertebral augmentation-- is the key to contracture prevention.

Early mobilization also leads to the prevention of pressure sores, the prevalence of which tends to increase significantly with age. Patients older than

70 years have more than 70% of all pressure sores and get them within two weeks of admission to the hospital. Once decubitus ulcers occur, nursing costs can increase by as much as 50% with the total cost of treatment per ulcer estimated between $15,000 and $20,000. Complications often develop with pressure sores. Infection is the most common complication and leads to septicemia, osteomyelitis, anemia and protein loss through chronic discharge.

Cardiovascular effects include increased heart rate, shorter diastolic times and reduced coronary blood flow. Cardiac output, stroke volume and left ventricular function decline overall. In the elderly, orthostatic hypotension occurs within the first three weeks of bed rest. This, along with the elevated heart rate, leads to diminished diastolic ventricular filling and a decline in cerebral perfusion. Depending on the length of bed rest it may take 20-72 days to restore pre-bed rest cardiac function[46].

In patients at bed rest the incidence of deep vein thrombosis is 61% with proximal DVT occurring in 29%. Pulmonary embolism is seen in 2-12% of patients and is fatal in 0.5-10%[49]. A restrictive impairment, an overall decrease in muscle strength, deconditioning of respiratory muscles, and failure to fully expand the chest wall results in a 25% to 50% decrease in respiratory capacity[47]. The lungs also suffer from decreased ciliary clearance, less effective coughing, atelectasis, and a predilection for pneumonia. Gastrointestinal effects include reduced appetite, constipation, and fecal impaction, all exacerbated by the concomitant use of narcotics. Glucose intolerance is a frequent but often overlooked complication of bed rest and can mimic brittle

diabetes[47]. Patients are at increased risk of genitourinary calculus formation, incontinence, urinary tract infections and urosepsis. Even the central nervous system is not immune; patients at bed rest exhibit higher levels of anxiety, depression, insomnia, pain intolerance, sensory deprivation and balance problems.

Narcotic analgesia is commonly used in conjunction with bed rest in the treatment of acute and chronic non-malignant musculoskeletal pain[48,50]. Adverse drug reactions (ADRs) have been seen in over 70% of individuals treated with opioids[48], and although the majority of side effects are minor, the elderly are more likely to suffer severe ADR such as confusion. In one study[48], severe ADRs occurred in over 10% of patients. A multivariate analysis of the findings showed that the only factor associated with severe ADRs was advancing age.

Vertebroplasty has consistently shown immediate and considerable improvement in pain and patient mobility following treatment[3-25]. In a recent study of 79 consecutive patients with osteoporotic compression fractures[24], of whom 55 (70%) were treated with vertebroplasty and 24 (30%) were treated with conservative therapy, the vertebroplasty group showed statistically significant reduction in pain and improvement in physical functioning at 24 hours over the conservative treatment group. In addition, 24% of the vertebroplasty patients were able to cease all analgesia after 24 hours compared to none in the conservative treatment group. These markedly different clinical

outcomes at 24 hours to one week represent the enormous benefit of vertebroplasty over conservative therapy in terms of early mobilization, even though at 6 weeks, 6 months and 12 months the clinical outcomes were the same in the two groups.

In a trial of vertebroplasty versus best medical therapy[25], 40 patients with acute (symptomatic for six weeks or less) osteoporotic compression fractures were randomized to vertebroplasty or conservative therapy, with crossover for the medically treated group allowed at six weeks. The vertebroplasty group showed statistically significant improvement in pain and mobility and reduction in medication use immediately after vertebroplasty. None of the patients randomized to medical therapy showed significant improvement, and 16 of the 19 patients were offered vertebroplasty. This post-medical therapy vertebroplasty group also showed statistically significant improvement in all three parameters immediately following the procedure. At 12 weeks, both groups showed statistically significant durability of the therapeutic response.[25]

It is well documented that the natural history of healing compression fractures is comprised of gradual improvement in pain over two to twelve weeks with variable return of function[51,52]. What is not described as "natural history" is sudden improvement in pain and return in function-- the hallmark picture of a positive therapeutic response with vertebroplasty. Most of the patients enrolled in the initial vertebroplasty studies did not undergo treatment until all non-invasive therapies had been exhausted. These patients acted as

their own internal controls, as vertebroplasty was performed at a point in their clinical course where if improvement associated with healing were to occur it should have happened. It is therefore unlikely that the rapid, marked improvement in clinical findings following vertebroplasty was associated with the natural course of the disease.

It may also be argued that patients treated medically are just as likely to have a long-term positive outcome similar to that of the vertebroplasty treated population, a finding noted in the Diamond study[24]. However, equality in long-term outcomes does not negate the early positive effects of a successful vertebroplasty. The potential complications associated with conservative therapy are most likely to happen early in the course of a patient's immobilization, leading to physiological losses from which the patient may not recover, or resulting in adverse outcomes as seen in the Brown study[26].

Another consideration is that the positive outcomes seen in vertebroplasty are due to the placebo effect. Vertebroplasty reports have consistently shown positive responses in the 80% to 90% range for osteoporotic fractures, regardless of cohort demographics, etiology of osteoporosis, geographic location, or type of institution (community practice versus academic setting). The question would be laid to rest with the completion of a sham trial. A feasibility study reported in an abstract by Kallmes et al.[53] showed that patients could be successfully randomized to vertebroplasty or a sham procedure, but no meaningful clinical information was obtained. This small study was used to obtain NIH funding for a multi-center vertebroplasty versus

sham procedure trial. A total of 150 patients are to be studied, but the trial has been hampered by enrollment difficulties.

Over 450 papers concerning vertebroplasty have been published in the last 20 years. Among these papers, about one hundred studies address the clinical outcomes of patients treated with percutaneous vertebroplasty. Without exception, these reports describe vertebroplasty as a successful therapy for the relief of the pain associated with vertebral compression fractures caused by either osteoporosis or tumor involvement. The earliest literature consisted of small, retrospective, uncontrolled case series introducing the technique, and described excellent results for the patients involved[3-8]. Since that time, larger case series have been published[9-19]. Literature reviews on the efficacy of vertebroplasty have concluded that the procedure, when used in the setting of osteroporotic compression fractures, results in substantial and immediate pain relief, improved functional status, and minimal short-term complications[54-57]. Prospective reports[20-23], including unrandomized and randomized controlled studies[24,25] also show overwhelming positive responses. The Societies conclude that the evidence supports the statement that vertebroplasty is efficacious in the relief of pain and improvement of mobility associated with acute and subacute compression fractures. Two studies[17,58] show similar results in chronic fractures up to two years in age.

Given the currently available scientific data, the Societies believe that vertebroplasty has been shown to be more effective than continued medical

treatment in patients with painful VCFs who have failed conservative therapy. To deny a patient vertebroplasty in favor of "more of the same" increases the chance of an adverse outcome associated with low mobility and complications associated with bed rest and narcotic analgesia.

As vertebroplasty utilization became widespread, kyphoplasty was introduced as an alternative approach. Kyphoplasty entails inflation of a percutaneously delivered balloon in the vertebral body, followed by the percutaneous injection of bone cement into the cavity created by the balloon. Kyphoplasty is quite similar to vertebroplasty, differing only in the use of the balloon. Indeed, kyphoplasty has been referred to as "balloon assisted vertebroplasty". The balloon ,in theory, is intended to restore the vertebral body height while creating a cavity to be filled with bone cement[27]. The balloon, the KyphX Inflatable Bone Tamp, is manufactured by Kyphon, Inc. (Sunnyvale, CA), and has been approved by the United States Food and Drug Administration for use as a bone tamp for the reduction of fractures, and/or the creation of a void in cancellous bone.

The clinical outcomes data is not as extensive as vertebroplasty. However, the available data[27-40] describes treatment of osteoporotic and some neoplastic[38] fractures and has some prospective non-randomized data[27,28,34] with one report including a control group of patients given conservative therapy[31]. Currently, there has been no comparison of kyphoplasty to vertebroplasty. As with vertebroplasty, the kyphoplasty reports show substantial pain relief and improved mobility in the great majority of patients who have failed

conservative therapy. Given the similarity of the two techniques and their outcomes, the Societies are confident that kyphoplasty is effective in substantially reducing pain and improving mobility in affected patients who have failed conservative therapy.

**Quality of Life**

Not only has vertebroplasty been shown to decrease pain and improve mobility, it also has a positive impact on patients' quality of life. In a recent study, forty-six consecutive patients underwent vertebropasty. At the time of enrollment, all patients completed the Osteoporosis Quality of Life Questionnaire, a validated thirty-item, five domain, 7-point response-option instrument. All five domains of the questionnaire were improved at two weeks post procedure and remained improved at each evaluation point through six months[59]. Similar quality of life improvements have been shown for kyphoplasty[68].

**Complications**

The complication rate for Vertebroplasty is exceeding low but complications nevertheless do occur. The primary cause of a symptomatic vertebroplasty complication is leakage of polymethylmethacrylate (PMMA) into adjacent structures, although the vast majority of such leaks are completely asymptomatic.. This leakage can occur through fracture lines, areas of cortical destruction, along the needle track, or into the epidural and paravertebral

venous complexes[9,60]. Acrylic material that has leaked from the vertebral body may cause spinal cord or nerve root compression, with resultant worsening pain and/or neurological dysfunction. Migration of small amounts of PMMA through the epidural or paravertebral venous system to the pulmonary vasculature is virtually always clinically insignificant, but rare cases of symptomatic pulmonary embolus have been reported[61].

Perivertebral acrylic is usually asymptomatic, although dysphagia from esophageal compression after a cervical vertebroplasty has occurred[10]. Other complications that have occurred, as reported in the literature or through personal knowledge, include fracture of the transverse process or pedicle, paravertebral hematoma, epidural abscess, pneumothrax, CSF leak, seizure or respiratory arrest from oversedation, and death. Severely osteoporotic patients may sustain rib fractures[11] or sternal fractures from lying prone on the procedure table.

Hemodynamic compromise has been associated with packing of the acetabulum with PMMA during hip replacement surgery. Transient systemic hypotension during acrylic injection in vertebroplasty has been reported[62], but a large retrospective study of the cardiovascular effects of PMMA in vertebroplasty patients found no generalized association between acrylic injection and systemic cardiovascular derangement[63].

One theoretical complication is thermal injury to adjacent neurological structures during acrylic polymerization. There have been no clinical reports of

this phenomenon and its possibility appears unlikely based upon in vitro tests, which showed no significant temperature rise in the spinal canal with vertebroplasty[64], and in vivo animal experiments, which showed no spinal cord damage from PMMA located adjacent to the dural sac in dogs[65].

More often than not, PMMA leakage is asymptomatic, even in malignant lesions. Cotten et al[9] demonstrated acrylic leaks by computed tomography, both venous and cortical, in 29 out of 40 patients with osteolytic metastases or myeloma. Most of these leaks were asymptomatic, but two of eight foraminal leaks produced nerve root compression that required decompressive surgery. In a later series, Cotten et al[13] reported one patient out of 258 treated who experienced spinal cord compression that required surgery. Of 13 patients with radicular pain, only three required surgical decompression, while ten responded to local anesthetic infiltration or medical therapy. Deramond et al[12] noted a single transient neurologic complication in 80 patients with osteoporotic fractures. Review of all major vertebroplasty series shows that the complication rate ranges from 1% to 10%; Murphy and Deramond[66] divide it further into 1.3% for osteoporosis, 2.5% for hemangiomas and 10% for neoplastic disease. Fortunately, most patients with radicular symptoms respond to anti-inflammatory or narcotic analgesics or local anesthetic infiltration, while surgical intervention is required only in a minority of cases. Complications are most likely to occur during or immediately after treatment. In two long-term studies, no complications were found in patients followed at 48 months[19] and 5

years[67]. A difference in complication rates between acute and chronic fractures has not been reported.

The issue of increased risk for fracture at an adjacent level has been raised in the literature. Grados and colleagues[19] found a slight, but statistically significant, increased risk of vertebral fracture in the vicinity of a cemented vertebra when compared to a vertebral fracture in the vicinity of an uncemented fracture. However, new fractures following vertebroplasty may actually represent the natural history of osteoporosis rather than a complication of the procedure and further study is necessary.

Complications associated with kyphoplasty are similar to those seen in vertebroplasty. Six major complications in 531 patients (1.1%) treated with kyphoplasty were reported in a multicenter collection of patients, four of which were neurological complications[40]. This complication rate is similar to the 1.3% complication rate seen in vertebroplasty for osteoporotic fractures[66].

In summary, clinically significant complications for vertebroplasty remain small and are most significant in the treatment of malignant disease. Most respond to short-term medical therapy and surgery is usually not required. The societies recommends that all practitioners incorporate indicator thresholds into one's quality improvement program to identify potential problems. As serious complications of vertebroplasty are infrequent, a review is recommended for all instances of death, infection, and symptomatic pulmonary embolus. Recommended thresholds for complications can be found in The American College of Radiology's "Standards for the Performance of

Percutaneous Vertebroplasty" document[1] and the Society of Interventional Radiology's "Quality Improvement Guidelines for Percutaneous Vertebroplasty" document[2]. The Societies are very confident in the validity of the abovementioned complication data.

## CONCLUSION

It is the position of the ASITN, ASNR, and SIR that vertebral augmentation with Vertebroplasty or Kyphoplasty is a medically appropriate therapy for treatment of painful vertebral compression fractures refractory to medical therapy when performed for the medical indications outlined in the published standards[1,2]. We believe vertebral augmentation with vertebroplasty or kyphoplasty is established therapy and should be reimbursed by payors as a safe and effective treatment for painful compression fractures.

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# NREF-AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves
# Young Clinician Investigator Award (SS-YCI)

**The Joint Section on Disorders of the Spine and Peripheral Nerves** (the "Section") wishes to provide the **Neurosurgery Research and Education Foundation (NREF)** (the "Institution") with an endowment totaling $500,000, which should be apportioned as follows: $400,000 in a permanent endowment and $100,000 to be distributed over five (5) years in order to bring the income generated from the endowment to a full YCI award of $40,000 (the "Grant").

It is understood that at the end of five (5) years, if funds are available, the Section will replenish the $100,000 portion of this Grant, which will be distributed over the next five (5) years pursuant to this Agreement.

The purpose of this agreement is to set forth the terms and conditions pursuant to which the Section shall provide the Grant to the Institution.

Scope of Grant Support

1. Potential grant recipients will apply to the Institution between July 1st and June 30th of said year.

1.2 The Scientific Advisory Committee of NREF will review all applications and will render its recommendations to the NREF Executive Council (EC). The NREF EC will make the decision and will forward its selection(s) onto the Section.

1.3 The Section's designated grant will be available only for applications dealing with topics related to spine and/or peripheral nerve. For the AANS/CNS Joint Spine Section Young Clinician Investigator Award (SS-YCI), the NREF SAC shall review, score and rank only those applications that meet the aforementioned requirements.

Terms and Conditions

1. The Grant shall be used by the Institution to support an endowment and an annual AANS/CNS Joint Spine Section Young Clinician Investigator Award (SS-YCI).

2. The Institution and Section acknowledge and agree that the Institution shall have sole and complete control over the review and selection process for the Grant (see 1.1 to 1.4 above for more detail).

3. The Institution shall remit to the Section a detailed accounting of the manner in which the Grant proceeds were disseminated to the beneficiaries and otherwise expended. Additionally, as requested by the Section, the Institution shall permit the Section to review accounting records, which are related to the Grant.

4. The Institution and Section acknowledge and agree that the Grant has not been determined in a manner which takes into account the volume or value of business otherwise generated between the Institution and the Section and shall not obligate the Institution to purchase, use, recommend, or arrange for the use of any product of or service provided by the Section.

5. The Institution or the Section in the event of a material breach may immediately terminate this agreement by the other, which breach is not cured by said party within thirty (30) days after written notice thereof from the other. In the event that this agreement is terminated by the Section for cause, as provided in this paragraph, and the termination is approved by the Section's two parent organizations (AANS and CNS), the Institution shall immediately return

to the Section the endowment funds and any remaining funds in the pay-down portion of the grant that has not been expended as of the effective date of the termination.

6. The Institution and Section agree that this agreement shall be governed by and interpreted under the laws of the State of Illinois. Any controversy or claim arising out of or relating to this agreement or the validity, inducement in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining. The Institution and Section hereby consent to the jurisdiction of the federal district court for the Northern District of Illinois and the entry of judgment on any award rendered hereunder. The Institution and Section further agree that this agreement sets forth the entire understanding regarding the subject matter hereof, supercedes all prior agreements or understandings, whether written or oral, between the Institution and Section, and can only be modified upon the prior mutual written agreement of the Institution and Section.

If the terms of this agreement are acceptable to the Section, please acknowledge the Section's agreement to the terms of this agreement by countersigning the attached three (3) copies and returning one (2) copies to AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves c/o Michele S. Gregory, Director of Development, AANS, 5550 Meadowbrook Drive, Rolling Meadows, IL 60008. Should there be any questions or a need for clarification, please contact the AANS at (847) 378-0500.

**AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves**

By: _____
Thomas A. Marshall, AANS Executive Director

Date: _____

Agreed and acknowledged this _____ day of _____.

_____
(Signature)

By: _____
Laurie Behncke, CNS Executive Director

Date: _____

Agreed and acknowledged this _____ day of _____.

_____
(Signature)

By: _____
Ronald W. Engelbreit, CPA

Date: _____

Agreed and acknowledged this _____ day of _____.

_____
(Signature)

Results of Spine executive Committee Vote on NREF Contribution

Total Votes: 14

Yes: 11
No: 2
Abstain: 3

September 23, 2006

Dr. Marty Weiss
Chair
NREF Executive Council

Dear Marty,

I am delighted to report to you that the Executive Committee of the Section on Disorders of the Spine and Peripheral Nerves has voted to approve the establishment and funding of the Young Clinician Investigator Award for Spine through the NREF.

The details of this proposal are described in the revised document from Michele Gregory dated July 14, 2006, also attached to the electronic transmission of this document. We understand that upon this directive that appropriate signatures from the parent organizations will memorialize this decision and initiate the transfer of funds from the long term investment pool of the Section, the details of which will be determined by Mr. Engelbreit, AANS Treasurer and Dr. Wolfla, Section Treasurer.

It is our pleasure to participate in this very significant way in the NREF. We appreciate and understand that the NREF Executive Council will receive nominations from the Section and include a qualified member or members of our Section on the Council so that the true breadth of Neurosurgery will be represented in this important research enterprise. We also appreciate and understand that the NREF Scientific Advisory Committee has accepted our nomination of Dr. Jim Guest to that committee and will maintain a qualified member or members of the Section on that committee as well.

The Section leadership recognizes the great value of a Neurosurgery research initiative, and the great value of the subspecialty area of Spine to Neurosurgery and visa versa. We also recognize that in some areas, spinal research in Neurosurgery has been limited and it is our intent with this and other initiatives to grow our research base and our participation in Neurosurgery research leadership.

Thank you and Michele for your efforts to make this particular iniative successful. I personally look forward to continuing our work together in the future.

With kindest regards,

Charles L. Branch, Jr., M.D.
Chairperson
AANS/CNS Section on disorders of the Spine and Peripheral Nerves

Cc: Michele Gregory
Don Quest
Tom Marshall
Rich Ellenbogen
Laurie Behncke
Joe Alexander
Dan Resnick
Chris Wolfla

# Clinical Trials Committee Proposal

## Problem:

There are many questions in spine surgery for which good-quality clinical trial evidence is not available, and too few investigator-initiated clinical trials in spine surgery; most current trials are industry sponsored. Most spine surgeons recognize that we need more class I evidence on many questions, but few neurosurgeons are trained in clinical trial methods or design. Compounding these problems, funding clinical trials is becoming an increasingly difficult challenge. Failure to correct these problems, however, will result in industry driving the field as opposed to spine surgeons, who should be in the saddle to push the field forward (with help from industrial partners as necessary).

## **Objectives:**

1) **To encourage more investigator-initiated clinical trials in spine and develop strategies for team building and funding.**

2) **To increase appreciation and disseminate information on ongoing clinical trials.**

## Background:

I have personally designed 2 multicenter clinical trials in spine surgery. The SLIP study is a multi-center prospective randomized clinical trial which tests whether adding fusion to a decompressive laminectomy improves outcomes for the surgical management of spinal stenosis with a grade I spondylolisthesis. Preliminary data for the trial has been published in *JNS (Spine)*. We have 80 patients accrued to date from 5 centers. Grant support for this trial is $250,000, of which $185,000 has been disbursed to date. The second study, the CSM trial, is just getting off the ground. This study tests whether anterior or posterior approaches for decompression of cervical spondylotic myelopathy will provide better results. This study is funded to date at $ 470,000. Preliminary results from the design process of the CSM trial have included a survey of the CSRS membership to define entry criteria for the trial; a manuscript on the analysis of the survey has been resubmitted after revision to *Spine*.

Specific Goals:

## 1) To encourage more investigator-initiated clinical trials in spine and develop strategies for team building and funding.

- Provide guidelines on the section website for designing a clinical trial including NIH-guidelines (http://www.clinicaltrials.gov/ct/show/NCT00109213 – the SLIP study, for example, is registered with the NIH site)
- Keep an interactive forum on the website for potential investigators to join with those at other centers to create multi-center collaborative efforts. Provide useful information on the section website or as a newsletter to section members on funding mechanisms (such as the newly created NIH R34 mechanism) and resources for designing clinical trials (i.e. dates of American College of Surgeons Clinical Trials courses, relevant papers, books, etc).
- Work closely with the Outcomes Committee (Mike Kaiser, MD, Chairman – where I am also a member) to help trialists to identify appropriate outcomes measures when designing their trials.

## 2) To increase appreciation and disseminate information on ongoing clinical trials

- To create a team award for the best clinical trial proposal that would by design involve at least 3 centers. This would be a great lesson in team building and we would reward all who collaborated (up to 5 people). I am certain I can create support for this from Foundations that support my work. I'd target $ 750/ resident.
- To organize a time at the AANS, Congress, or spine section meeting for getting '2 minute updates' on current trials including those ongoing in Europe. The tumor section is doing this at the April AANS meeting and it allows investigators the opportunity to 'advertise' their trials in a national forum and gain recognition for being involved in long-term projects. In addition, we could have guest speakers address funding mechanisms for neurosurgical research. For example, the tumor section held a roundtable discussion with invited NIH speakers at the Congress '05 meeting regarding funding opportunities.

Thanks,

Zo Ghogawala

Charlie, Dan and Chris:

Bill Krauss and Brad Currier are at Mayo and are putting together a meeting--see below. Do we have a policy about our section mailing list for activities like this--I can't recall if we do. If not, I would suggest that legitimate educational meetings run by true non-profits like universities (not companies, or company-sponsored entities or meetings) could use our list for free. Profit-based entities, or meetings with major corporate support, could potentially use it for a fee that we could establish. Either type would have to be for activities that would not conflict with our section's annual meeting or significant activities of our parent organizations.

If such a policy does not exist, I would suggest that we allow Mayo to use the list for this purpose. I would further suggest that we put this on the agenda for the Exec Committee next month. Requests could be handled by the education committee person based on guidelines that we set up, with uncertain cases referred for wider ex-comm input.

Joe

Dan,

As the liason member to and from the SRS from the Spine Section Exec, I have two items that the SRS has asked for review and possible support from the Section.

1. From the SRS Education Committee:
The SRS has developed a suggested curriculum for spinal deformity fellowship. This is not meant as a mandate or to suggest practice restriction. It is also not intended to be a step into sub specialty certification. It is simply meant to be a recommendation of what should be included in any fellowship that is to train fellows in spinal deformity surgery as a primary goal. If supported by other societies, such as ours that train spine surgeons for all types of spine practice, the SRS will send the curriculum to all of those societies for distribution.

My assistant will attach the curriculum document and cover letter from it's Chair, Jim Olgilvie.

I strongly encourage the Section to issue a letter in support of this and send it along to the AANS, CNS and SNS executive coimmittees. This document will provide a template to optimize and codify training in fellowships dealing with spinal deformity. It can also serve as a model for other fellowships. All to often, the curriculum and quality of fellowship training is poorly defined. Developing nonrestrictive fellowship curriculum guidelines would go a long way to standardizing acceptable education parameters. This is in the interest of our specialty, it's fellows and society. Standardized curriculum development is fast becoming a norm and it would be good to get ahead of the curve on this one.

The SRS has reached out to work with organized neurosurgery as colleagues. They are the first to change by-laws to allow both specialties to belong to one organization (NASS is a big tent by definition). They included neurosurgical input on the education committee to draft the curriculum. I believe that the Section's cooperation will help foster collaborative work in spine education between organized neurosurgery and orthopedic surgery. This will improve training and education for all.

2. From the SRS Advocacy Committee
The SRS asks for a letter of support from the Spine Section to allow spine surgeons to practice in their area of training regardless of specialty.

This seemingly straight forward issue arises from an issue of professional discrimination in Turkey. In Turkey, there is an SRS member, Dr. Aydinli, who is an Orthopedic surgeon who is extensively trained in spine surgery. This includes deformity, degenerative reconstruction and decompression. He is being prevented from performing decompressive and degenerative spine procedures by the Department of neurosurgery at his hospital as this is the "purvue" of neurosurgery and orthopedics should not perform them. This of course is blatant prejudice based on turf and practice protection, not qualification. It is the type of behavior that is unprofessional and embarrassing to our field. Fortunately, it is rapidly evaporating in the U.S. While the Section cannot dictate a hospital policy in Turkey, we can make the stance a bit less tenable by joining the SRS in condemming restrictive behavior that arises from specialty self interest rather than training and education. If we fail to do this, we will fail to stand for the high road principles of justice. On the low road of self interest, failure to do this could re-ignite inter specialty rivalry and organized orthopedics taking the stance that they are the only ones qualified to do reconstruction and deformity. That neurosurgery is for decompression alone. I strongly recommend that we join the SRS on the high road. They have demonstrated their willingness to support neurosurgeons as spine surgeons. We should return this favor.

Please let me know if there are any questions or additional documentation needed from me.

See you at the CNS.

Sincerely,
Steve Ondra

# Spine Deformity Educational Curriculum

**Definition:** Spine deformity is any condition in which the posture and/or spinal contour is the primary abnormality determining the treatment strategy.

**Educational curriculum:** The Spinal Deformity Educational Curriculum is a suggested ideal format for educational planning. It is recognized that some educational programs/fellowships may not incorporate all aspects of the curriculum.

I. Suggested Topics for Didactic Presentation:
- Clinical biomechanics of the spine
- Pain management
- Nutritional
- Spinal radiology
- Spine embryology, growth, development and genetics
- Pediatric and adult reading list – (determined by each site)
- Principles of evidence-based medicine

II. The fellowship curriculum for spine deformity should include exposure to and familiarity with the pathogenesis, treatment principles, and surgical decision making, but not necessarily a comprehensive surgical experience in the following diagnoses:

a. Scoliosis: idiopathic, neuromuscular (cerebral palsy, muscular dystrophies, myelodysplasia, etc), congenital, degenerative, syndromic (neurofibromatosis, osteogenesis imperfecta, mucopolysaccharidoses, Down, etc.), pathologic, traumatic, iatrogenic, post-infectious, metabolic, and other etiologies
b. Sagittal plane deformity: Scheuermann's, post-laminectomy, neuromuscular, degenerative, traumatic, pathologic, congenital, neoplastic, and other etiologies
c. Spondylolisthesis

III. The fellowship curriculum for spine deformity should include exposure to and familiarity with the following non-operative spinal deformity evaluation and treatment methods:

a. Orthotic and cast treatment options for spinal deformity
b. Awareness of long term consequences of treatment and non-treatment options
c. Knowledge of appropriate referral patterns for specialized care in ICU, nephrology, metabolic disorders, developmental pediatrics, pulmonology, genetics, and other specialties that relate to spinal deformity care.
d. Knowledge of appropriate diagnostic evaluations for patients with spinal deformity

IV. The fellowship curriculum for spine deformity should include exposure to and/or familiarity with the surgical approaches listed below, performed either with an attending spinal deformity surgeon or access surgeon:

a. Anterior, including extracavitary
    i. cervical including cervicothoracic junction
    ii. thoracic
    iii. lumbar
b. Posterior
    i. midline including cervico-occipital
    ii. transpedicular
    iii. posterior lateral (TLIF, costotransversectomy)

iv. sacropelvic exposure

c. Techniques of bone graft harvesting

d. Techniques of thoracoplasty

V. The fellowship curriculum for spine deformity should include exposure to and/or familiarity with the following surgical intra-operative spinal deformity correction techniques, decision making and post operative management:

a. Instrumentation

i. spinal fixation with hook, screw and wire anchorage for the posterior occipital, cervical, thoracic, lumbar regions of the spine

ii. sacral and iliac fixation

iii. anterior fixation with plate and/or rod systems – cervical, thoracic and lumbar regions of the spine

iv. anterior column structural support, intradiscal and corpectomy

v. Techniques appropriate for the immature, deformed spine (growth rods, VEPTR, stapling, etc.)

b. Osteotomies

i. Smith-Petersen

ii. Pedicle subtraction

iii. Vertebral body resection

c. Principles of and indication for neuromonitoring

i. SSEP

ii. MEP

iii. Evoked EMG