CHIROPRACTIC MANAGEMENT OF LOW BACK PAIN AND LOW BACK RELATED LEG COMPLAINTS

A Literature Synthesis by the Research Commission of the Council on Chiropractic Guidelines and Practice Parameters

A literature synthesis is an academically rigorous analysis of all the available scientific literature on a specific topic. Reviewers use internationally accepted tools to rate each article according to specific criteria. These include the type of study (randomized controlled trial, case series, etc), the quality of the study, size of the study and many other factors that influence the credibility and strength of the study's conclusions. Each reviewer independently rates all the available articles, and the ratings are compared among the members of the review team. When there is disagreement among the reviewers regarding the conclusions, a formal consensus process is followed to arrive at an overall conclusion upon which all reviewers can agree. The resulting conclusions do not represent the reviewers' own beliefs but rather what the literature actually supports. A literature synthesis is a starting point. It indicates only what we can conclude with supportable, scientific evidence. Appropriate therapeutic approaches will consider the literature synthesis as well as clinical experience, coupled with patient preferences in determining the most appropriate course of care for a specific patient.

This document is solely a survey of existing studies, and only expresses the opinion of CCGPP. It is not intended to, nor does it establish a standard of care in specific communities, specific cases, or as to the care of any particular individual or condition. Each case must be determined on the basis of a careful clinical examination and diagnosis of the patient, giving due consideration to the specific condition presented and the individual's informed choice as to care and treatment. No part of this document is intended to support any litigation or proceeding involving the standard of care, medical necessity or reimbursement eligibility.

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Preface to Final Version

After posting of the draft version of this chapter, there were 313 responses to the question, “Within the scope of this chapter, are there any related disorders/conditions or diagnostic procedures commonly used by doctors of chiropractic that were not included in this review?” In the case of 31 of these, the topic mentioned had actually been addressed in the document. Fifty-six comments concerned topics which had already been scheduled to be covered in other chapters.

The 226 comments requesting additional information on modalities, radiology and diagnostics led the CCGPP to develop two new chapters addressing 1) diagnostics, including radiology and 2) modalities. The revised Low Back chapter reflects solely information pertaining directly to the use of manual methods and exercise as a treatment for LBP, as well as manual diagnostic procedures and patient-reported outcome assessments.

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***Scope*:**

- Low back pain and low back related leg pain.
- Chronicity range: acute, subacute, chronic and recurrent
- Applicable IDC CD codes include but are not limited to: 720.0, 720.2, 721.5, 722.1, 722.2, 722.52, 722.73, 722.83, 724.02, 724.2, 724.3, 724.4, 724.5, 724.71, 724.6, 724.8, 724.9, 728.85, 737.30, 738.4, 739.3, 756.12, 782.0, 729.1, 739.4, 846.0

***Objectives*:**

1. To implement an interactive process that will create and successively build a consolidation for systematic summary of various types of evidence on the effectiveness of chiropractic management for low back and related disorders including their quantity, quality and summary of conclusions.
2. Types of evidence ultimately to be rated include: Guidelines, meta-analyses, systematic reviews, randomized controlled trials, cohort studies, case series.
3. Initiation of the iterative process will begin by team review of the literature and determination of the most common clinical disorders and treatments involving chiropractors.

Intended audience:

- Chiropractors
- Chiropractic students and prospective students
- Chiropractic educators/educational institutions
- Chiropractic organizations/agencies
- Third-party payers
- Governmental agencies
- Patients and prospective patients

***Practices and interventions considered*:**

- Therapeutic
  - Assurance and advice
  - High-velocity, low-amplitude manipulation, mobilization and massage
  - Exercise

Methods used to select/collect evidence:

- *Selection:* Topics were selected based on the most common disorders seen, and most common classifications of treatments used by chiropractors based on the literature.
- *Collection* - Hand-searches of Published Literature (Primary Sources)
- Searches of Electronic Databases

Number of source documents:

- 887 source documents were identified
- Conclusions were drawn from 64 RCTs, 12 guidelines and 13 systematic reviews and 11 cohort studies

Methods to assess the quality and strength of the evidence:

- Weighting according to a rating scheme (scheme given)
- Standardized and validated instruments were used for rating evidence

Methods to analyze the evidence and formulate conclusions:

- Two strategies were used in consolidating and rating the literature: 1) Rate and accept /reject existing published reviews (including guidelines), independently reviewing the underlying literature if the rating was considered substandard and 2) independently review and rate newer or previously unrated literature as appropriate.
- Divergence in team member opinions triggered a modified Delphi consensus process.

Summary of Conclusions:
(Conclusions exclude patients with RED flag findings)

Topic	Conclusion and Strength of Evidence Rating
Acute low back pain (< 6 weeks duration)	
Manipulation	**RATING A**, Supported by good evidence from relevant studies.
Exercise	**RATING I,** no recommendation can be made because of insufficient evidence
Specific exercise	**RATING C**, Supported by limited evidence from studies or reviews.
Subacute low back pain (6-12 weeks)	
Assurance and advice to stay active	**RATING B,** Supported by fair evidence from relevant studies
Manipulation	**RATING A**, Supported by good evidence from relevant studies.
Customizable exercise programs	**RATING B**, Supported by fair evidence from relevant studies.
Intensive training for severe pain	**RATING C**, Supported by limited evidence from relevant studies.
Chronic low back pain (>12 weeks)	
Assurance and advice to stay active in activities of daily living (ADL)	**RATING B**, Supported by fair evidence from relevant studies
Manipulation	**RATING A**, Supported by good evidence from relevant studies.
Exercise	**RATING A**, Supported by good evidence from relevant studies. Multi-disciplinary rehabilitation for severe back pain with functional loss and for post-surgical rehabilitation
Post-surgical rehabilitation	
Exercise	**RATING C**, Supported by limited evidence from relevant studies.
Sciatica/radicular/radiating leg pain	
Assurance and advice to stay active in Activities of daily living (ADL)	**RATING B**, Supported by fair evidence from relevant studies
Manipulation	**RATING C**, Supported by limited evidence from studies or reviews.

Process Description

Process development was guided by experience of Commission members with the RAND consensus process (1), Cochrane collaboration, AHCPR (2) and published recommendations (3) modified to the needs of the Council.

The objective and purpose motivating this work:

The purpose of the work presented here is to provide an informed and balanced interpretation of the literature for appropriate treatment of the low back and related disorders by chiropractors, attempting to be patient centered yet responsive to evidence based values.

The methods used for this work:

Balancing patient-centered and evidence-based values imparts similar internal tensions with tendency for the best intent of individuals to succumb to training biases and personal preferences (Table 1). Four strategies were used to minimize this problem while empowering legitimate and informed interpretation of the literature. They were:

1. Review of the literature by a panel of experts including those who do use and those who do not use the methods under review.
2. Standardized and validated, structured instruments for rating the quality of and results from the literature.
3. Formal consensus process to adjudicate differences in professional opinion on the literature or to address important areas where literature is weak or lacking.
4. Wide stakeholder review with opportunity for critical comment offered to all stakeholder groups including patients, professionals, policymakers and third party payers.

Topic Selection:

Patients having many clinical descriptions seek care from chiropractors based upon the generally recognized reputation and the individual doctor's practice focus. Some providers center specifically on subluxation and its manifestations while others limit their practice to treating patients with spinal disorders or musculoskeletal complaints. Others may address more general health problems, prevention and special populations (4). The diversity of professional practice makes the review of all related literature to conclude evidence on Best Practices an impossible task. To accommodate the need for substantive review of the most relevant and informative literature, an interactive process was developed.

The Council on Chiropractic Guidelines and Practice Parameters (CCGPP) and its organizational structure are described elsewhere. Representing its constituent member organizations, the Council approved a listing of disorders by ICD9-CM codes (Table 2) that would form the scope of the investigations. CCGPP teams have been identified consisting of content experts from within the profession and involving consultants that are cross-trained or external to the profession in select areas. .

The practice of chiropractic was divided into general areas based on anatomical regions and the list was given to the CCGPP Research Commission who used it to bind the literature searches within each domain. The domain for this report is that of low back

Table 1: Sources of interpretation bias in the literature.

Type of Bias	Source of Bias	Definition of Bias
Experimental	Sampling	Biased selection of subjects
	Allocation	Biased method of assigning subjects or creating groups
	Measurement	Systematic or random measure error or interpretation of measure by subject or investigator
	Analysis	Inappropriate statistical methods and interpretation
Publication	Favored outcome	Author / Editor preference or expectation for a given result
Interpretive	Confirmation bias	Evaluating evidence that matches preconceptions differently from that evidence that challenges convictions
	Rescue bias	Discounting data by finding selective faults in the experiment
	Auxiliary hypothesis bias	Introducing ad hoc modifications to imply that an unanticipated finding would have been otherwise had the experimental conditions changed
	Mechanism bias	Reduced skepticism when underlying science furnishes credibility for the data
	Watchful wait bias	Different amounts of time confirmatory evidence needed for different reviewers
	Orientation bias	The hypothesis itself introduces prejudices and errors and becomes a determinate of outcome

pain and low back-related leg symptoms. Using surveys of the profession (4-6) and publications on practice audits (7-9), the team selected the topics for review by this iteration. The criteria used was based on the team's determination of the most common disorders seen, and most common classifications of treatments used by chiropractors based on the literature.

Table 2: Applicable ICD9-CM codes used as boundaries for disorders to be addressed, as set by the CCGPP Council. ***(The following should be considered a representative but not exclusive list.)***

720.0	Ankylosing spondylitis
720.2	Sacroiliitis, not elsewhere classified
721.5	Spondylosis and allied disorders, kissing spine
722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
722.73	Intervertebral disc disorder with myelopathy – lumbar region
722.83	Post-laminectomy syndrome – lumbar region
724.02	Spinal stenosis – lumbar region
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.71	Hypermobility of coccyx
724.6	Disorders or sacrum
724.8	Other symptoms referable to back
724.9	Other unspecified back disorders
728.85	Spasm of muscle
737.30	Scoliosis (and kyphoscoliosis), idiopathic
738.4	Acquired spondylolisthesis
739.3	Nonallopathic lesions, not elsewhere classified – lumbar region
756.12	Spondylolisthesis
782.0	Disturbance of skin sensation
729.1	Myalgia and myositis, unspecified
739.4	Non-allopathic lesions, not elsewhere classified – sacral region
846.0	Low back sprain/strain

Team selection and orientation training of team leaders:

The CCGPP Council appointed 2 co-chairs for the Research Commission, each having experience in practice, structured literature review and formal consensus processes, either having been involved with one or more of original clinical and educational research, the Agency for Health Care Policy and Research acute low back pain guidelines, the RAND corporation task forces on appropriateness for use of spinal manipulation and earlier CCGPP Mercy Center chiropractic guidelines. Team leaders were nominated by the Commission co-chairs and recommended to the Council for approval. Selection was based upon identification of individuals with clinical experience, additional cross-training in the content area of their assigned domain and/or scholarly work. Team members were selected from a multidisciplinary list of practitioners and content experts that had been solicited from the Council stakeholders and colleges. Additional nominees were identified to serve as consultants based on content expertise. Once a team leader accepted members for his/her team, no changes were permitted in the team composition without being initiated by the team lead to add or replace

members as necessary. All changes were submitted to the Council for agreement before implementation. All Commission member services were uncompensated.

A team lead packet of information setting out motivation and methodology, including standardized instruments, with example formats for the final report was distributed. An orientation meeting was convened with all team leads and available consultants at the 2004 Association of Chiropractic Colleges Research Agenda Conference held in Las Vegas. Survey of the literature, rating and interpretation of evidence commenced in July of 2004, leading to this report.

Identifying the Question, Selecting and Reviewing the Evidence

Identifying the Question:

Because this is a literature synthesis, designed to address the practical problem of care for individual patients, it was necessary to cast a wider net for literature collection than used in pure guideline documents. Based on the extent and volume of the literature as well as specific study of the practice of chiropractic from the National Board of Chiropractic Examiners Job Analysis and other focused references, the topics for specific review were selected. The results apply to conditions that may be listed under various diagnostic terms.

The central question for management of low back and related lower extremity symptoms was: what is the extent and quality of the evidence for or against the use of spinal manipulation/mobilization, physical activity and exercise for treatment of low back pain?

Searching the literature and selecting the evidence:

Material for review was obtained through formal hand-searches of published literature and of electronic databases. A search strategy to identify papers related to the topic areas was developed, based upon the Cochrane Working Group for Low Back Pain (10), but was modified to accommodate the needs of CCGPP (See ***Appendix 1***). Basic science or mechanistic information was included if directly relevant in foundation to the central questions listed above. Search materials, regardless of source, were routed to the team leader. Notices were extended to the profession by way of publications in widely distributed professional news and association media with invitation to submit relevant scientific and clinical articles. Searches focused on identifying existing guidelines, meta-analyses, systematic reviews, randomized clinical trials, cohort studies and case series. A professional librarian from one of the Association of Chiropractic Colleges was available both to assist the team in literature search and obtaining copies of articles not available electronically.

See Appendix 1 for details of search strategy.

Forming Conclusions from the Evidence:

Two strategies were used in consolidating and rating the literature: 1)rate and accept /reject existing published reviews of the various types, independently reviewing

the underlying literature if the rating was considered substandard and 2)independently review and rate newer or previously unrated appropriate literature. The search strategy can be found below.

A total of 887 source documents were obtained as a result. Search results were sorted into related topic groups: randomized trials of low back pain and manipulation; randomized trials of other interventions for low back pain; guidelines; systematic reviews and meta-analyses; basic science; diagnostic-related papers[djl1]; methodology; cognitive therapy and psychosocial issues; cohort and outcome studies, etc. Each group was subdivided by topic so that team members received approximately equal numbers of papers from each group, chosen randomly for distribution. Based on the CCGPP formation of an iterative process and the volume of work available, the team elected to limit consideration in this first iteration to guidelines, systematic reviews, meta analyses, randomized controlled trials (RCT's) and cohort studies. This yielded a total of 12 guidelines, 64 RCTs and 13 systematic reviews/meta analyses and 11 cohort studies.

Evidence rating:

Rating and interpretation of the literature is a complex task that often leads to divergent opinions based on a number of sources of bias (Table 1). Experimental bias arises from uncontrolled variables within the conduct of research that is reported. Publication bias occurs when, by advertent or inadvertent effort, a journal's editorial board policy or practice favors articles that are positive or negative with respect to a specific topic. The last form is interpretation bias that favors or disputes results based on weighting consideration of intrinsic or extrinsic factors of the work under review. Standardized ratings were accomplished by first matching the type of literature to the appropriate scoring system before random distribution to the team members.

Selection of rating instruments to minimize interpretation bias was accomplished by combing the literature on the rating of evidence. Standardized tools and checklists to guide evaluator review of individual pieces of literature were identified for each category of evidence and made available to the team.

One feature of the team's efforts for evaluating the evidence for low back and related lower extremity symptoms warrants closer examination. The initial effort used the Bronfort tool to assess RCTs, taking advantage of the presence on the team of a clinical scientist highly experienced in conducting team ratings of literature through his own work (12) and by way of participation as an author with the Cochrane collaboration (10) and other international efforts. As work progressed, a subgroup of the Commission (Adams, Bronfort, Meeker, Triano) considered the generalizability of effort for the entire CCGPP project of best practices development and recommended a change to the SIGN (13) system that contained a number of different instruments for evaluating the various types of studies and reports. While there is significant overlap in concerns for biasing factors, the SIGN advantage, it was felt, was a consistent development and application

of rating across the literature. A brief review of the features for each of the methods used to rate RCTs follows.

The Bronfort method consists of 8 items, each with 3 choices: yes (+), partial (P), or no (-). One point is given for a yes, half a point for a partial, and 0 points for a no. Criteria for scoring accompany each entry. The point total is divided by 8 and then multiplied by 100 to create a 100-point scale. The 8 items contained in the instrument include:

- Similarity of baseline characteristics to adjusted effects reported
- Concealment of treatment allocation
- Blinding of patients
- Blinding of provider/attention bias
- Blinding of assessor/unbiased outcome assessment
- Dropouts reported and accounted for in the analysis
- Missing data reported and accounted for in the analysis
- Intention-to-treat analysis/balanced co-intervention

In the SIGN approach, there are 11 questions, separated into 2 parts: Part 1 has 10 questions and examines elements of internal validity, while Part 2 has a single question concerning overall assessment of the study. For Part 1, each question has 6 possible choices: well covered, adequately addressed, poorly addressed, not addressed, not reported, not applicable. Criteria for evaluating the overall study in Part 2 is defined by three options: + (strong, most criteria fulfilled), n (neutral), or – (weak, few or no criteria fulfilled). The Part 1 considerations include:

- The study addresses an appropriate and clearly focused question;
- The assignment of subjects to treatment groups is randomized;
- An adequate concealment method is used;
- Subjects and investigators are kept “blind” about treatment allocation;
- The treatment and control groups are similar at the start of the trial;
- Only difference between groups is the treatment under consideration;
- All relevant outcomes are measured in a standard, valid and reliable way;
- The percentage of dropouts is given for each treatment arm of the study.
- Multisite studies have comparable reporting methods at all sites.
- All the subjects are analyzed using an intention to treat analysis.

There are 3 points where the study may be categorically rejected: if there is no indication of randomization; if the groups were not treated equally; and if the outcome measures are not stated or if the study bases its conclusions on secondary outcomes.

In summary, the 2 methods compare favorably including concern for concealment of allocation, randomization, blinding of patients and/or investigators, drop out rates, intention-to-treat analysis and use of appropriate outcomes. The two distinguishing characteristics are that Bronfort asks about missing data, while SIGN asks about replicability across many sites.

For other literature types, the scoring tools included the AGREE (14) instrument for rating guidelines and MOOSE rating system for systematic reviews/meta analyses (15). The AGREE examines 6 domains:

- Scope and purpose (items 1-3)
- Stakeholder involvement (items 4-7)
- Rigor of development (items 8-14)
- Clarity and presentation (items 15-18)
- Applicability (items 19-21)
- Editorial independence (items 22-23)

Scores are not aggregated across domains but are assessed individually. The MOOSE checklist (15) evaluates 34 elements across 6 categories of reporting including: search strategy, methods, results, discussion, and conclusion.

Definitions for evidence ratings:

GRADE A: Supported by good evidence from relevant studies.

Explanation

- The evidence consists of results from studies based on appropriate research designs of sufficient strength to answer the questions addressed.
- The results are both clinically important and consistent with minor exceptions at most.
- The results are free of any significant doubts about generalizability, bias, and flaws in research design.
- Studies with negative results have sufficiently large sample sizes to have adequate statistical power.

Examples

- Supporting evidence may consist of a systematic review of randomized controlled trials (RCT's) with comparable methodology and consistent results or the preponderance of evidence from several relevant RCT's with consistent results.
- For the question of natural history of a disorder, in the absence of evidence to the contrary, the evidence might be results from a single well done prospective cohort study.

GRADE B: Supported by fair evidence from relevant studies.

Explanation

- The evidence consists of results from studies based on appropriate research designs of sufficient strength to answer the questions addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies, or because of minor doubts about generalizability, bias, and research design flaws, or adequacy of sample size.
- Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Examples

- Supporting evidence might consist of a several RCT's with differing results although overall the results support the conclusion.

- The evidence might also be the result of a single randomized controlled trial with a clinically significant conclusion but doubtful generalizability.
- Alternatively, the evidence might come from a systematic review of RCT's with similar methodologies but differing results.

GRADE C: **Supported by limited evidence from studies or reviews.**
Explanation
- The evidence consists of results from studies of appropriate design for answering the question addressed, but there is substantial uncertainty attached to the conclusions because of inconsistencies among the results from different studies, or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size.
- Alternatively, the evidence consists solely of results from a limited number of studies or because of weak design for answering the question addressed.

Examples
- For a question of treatment efficacy or effectiveness, the evidence might consist of systematic or narrative reviews or RCT's with contradictory results and/or serious methodological flaws.
- From relevant cohort, case control, ecological studies, and outcomes research.
- Alternately, the evidence might consist of individual case series.

GRADE D: Supported by expert opinion, and usual and customary clinical practice.
Explanation
- The evidence consists of expert opinion. Research studies cannot be or have not been performed.

Examples
- The literature cited might consist of a consensus report, a consensus opinion based on practice guidelines, an editorial, and a position statement from a national body without citations of the results of research studies.

GRADE I: No recommendation can be made because of insufficient or non-relevant evidence.
Explanation
- There is no evidence that directly pertains to the addressed question because either the studies have not been performed or published, or are non-relevant.

Examples
- No studies could be identified using optimal search strategies of appropriate databases or by hand searching. Alternately, the literature cited does not have direct bearing on the question being addressed.

Use of evidence tables:

Evidence tables for RCTs rated by the team were constructed using categorical information shown reliable (16) in other studies. Templates were provided to each team member for recording this information during the course of their review. The team leader consolidated results and tables themselves are present in the ***Appendix 2***.

Literature Summary

The approach of this work:

The embrace of policy makers for the concepts and principles of evidence-based care drive the goal of managing access to and the empowerment of today's healthcare delivery. Implementation of these principles is the shared task primarily involving 3 parties: providers, patients and third-party payers. After nearly 2 decades of experience, evidence now shows that many individuals within these constituent groups are ill equipped, by nature of education, training, experience or content expertise, in the rigors of the necessary clinical and scientific disciplines to interpret the application of the literature base for evidence-based care (EBC). Moreover, as stakeholders in the process of healthcare delivery, individuals often are required to make judgments based on competing priorities and pressures.

The individual most at risk to sense being placed in adverse, even adversarial, disadvantage is the patient. The patient, and his or her care, becomes buffeted by dueling interpretations of the literature. Individual providers' perspectives are sometimes bolstered by parochial or *ad hoc* and selective use of literature and countered by agents of third-party payers quoting proprietary undisclosed databases, misapplied or misunderstood literature generalized beyond rational bounds to specific patient care circumstance.

Brief review of methods used for this work: *(see Methods document posted separately for details)*

Balancing patient-centered and evidence-based values imparts similar internal tensions with tendency for the best intent of individuals to succumb to training biases and personal preferences. Several strategies were used to minimize this problem while empowering legitimate and informed interpretation of the literature. They were:

1. Review of the literature by a panel of experts including those who do use and those who do not use the methods under review.
2. Standardized, validated and structured instruments for rating the quality of and results from the literature.
3. Wide stakeholder review with opportunity for critical comment offered to all stakeholder groups including patients, professionals, policymakers and third-party payers.

Finally, a patient-centered focus requires consideration of individual patient care as a process, not a statistic. Taken as a whole, the evidence clearly demonstrates that it is the process of care and how the individual needs are matched to available resources that matters most to good outcome. Guidance has been sought from the literature for providing care that can enhance quality of life using patient values and outcome parameters for which there is evidence.

An ongoing work in progress:

This is a second iteration in what is designed as a cyclical process. The scope of all care delivery is too dynamic and too broad a process to accomplish a review in one pass.

Literature on assurance and advice:

The search strategy employed by the team was that developed by van Tulder et al (17). Eleven trials met inclusion criteria. The review found that there is strong evidence that those with acute LBP and who are advised to have bed rest have slightly more pain and slightly less functional recovery than those who stay active. There is no difference in pain and functional status between those who get bed rest and those who are given exercises. For those with sciatica, there is moderate evidence of no real difference in pain and functional status between bed rest and staying active. There is moderate evidence of no difference in pain intensity between bed rest and physiotherapy, but small improvements in functional status. And finally, there is little difference in pain intensity or functional status between shorter-term or longer-term bed rest.

Hagen et al (18) completed a Cochrane review of nine studies. Comparisons made were bed rest vs. advice to stay active, bed rest vs. other treatments, and shorter periods of bed rest (2-4 days) vs. longer periods of bed rest (>4 days). Three of the studies demonstrated small advantages in the short and long term for continuing activity over bed rest.

The most recent work surveying the effectiveness of assurance and advice on bed rest found was that performed by the Danish Society of Chiropractic and Clinical Biomechanics (19). The review was considered to be of high quality and was recommended by the team.

The Danish work found 4 systematic reviews [including Hagen (18)] and four additional randomized trials and 6 sets of guidelines. The conditions for which evidence was available included acute low back pain and sciatica. The Cochrane review by Hilde et al (20) based its conclusions on four trials and concluded a small beneficial effect for staying active in cases of acute, uncomplicated low back pain but without benefit for patients with sciatica. The studies, only one of high quality, all compared recommendations to stay active with bed rest. Eight studies (two overlapping with Hilde) on advice to remain active were included in an analysis by Waddell's group (21). Several forms of therapy were coupled with advice to stay active and include analgesic medication, pt, back school and behavioral counseling. Some, to enforce counsel to remain active, used graded home activity program. An additional ten studies of bed rest were also examined. Bed rest for acute low back pain was similar in effect to no treatment and placebo and less effective than alternative treatment. Outcomes considered across the studies were rate of recovery, pain, activity levels and work time loss. Continuing activity, on the other hand, was found to have favorable effect.

The 6 guidelines included in the Danish review (19) (Finnish, Swedish, Australian, British, Paris Task Force and earlier Danish guidelines) all were in

consensus noting that recommendations to stay active are beneficial and bed rest is counter productive for acute low back pain. A short course (2–3 days) might be helpful for acute radiating leg pain.

The review of 4 studies not covered by any of the guidelines or other systematic reviews assessed the use of brochures/booklets to inform patients about back problems and to recommend remaining active versus activity avoidance or 'usual' care and vs. manipulation or McKenzie exercise. One study coupled the pamphlet with other therapy (e.g. medical or osteopathic management, nurse education visit, usual care). While patient knowledge was notably increased when given information, the trend was for no differences in outcome for pamphlets with medical or osteopathic management, nurse educational visits, or usual care versus alternative care for pain or function early on. One exception was noted that those who received manipulation had less bothersome symptoms at 4 weeks and significantly less disability at 3 months for those who received a booklet encouraging staying active.

In summary, patient assurance that they are likely to do well and recommendation to stay active and avoid bed rest is the best practice for management of acute low back pain (Grade level C*). Bed rest for short intervals may be beneficial for patients who are intolerant of weight bearing and have radiating leg pain.

Literature on treatment with adjustment / manipulation / mobilization versus multiple modalities:

Studies that clearly differentiated by scientific means, the different clinical manual procedures were unavailable. There are numerous named systems. For purposes of this review, the literature was considered with respect to high velocity, low amplitude (HVLA) procedures, often termed adjustment or manipulation, and mobilization. HVLA procedures are considered those that utilize thrusting maneuvers applied quickly and mobilization methods are applied cyclically. Where applicable, HVLA and mobilization may be mechanically assisted. On that basis, mechanical impulse devices are considered with HVLA and flexion-distraction methods and continuous passive motion methods are within mobilization.

The team found that the recent systematic review by Bronfort et al (19) (Quality score 88), which covered literature up to the year 2002, and its findings should be adopted. The team elected to separately rate 52 papers published since 2002 and including a number not captured within Bronfort's criteria.

Bronfort's review covered 31 randomized trials (25 addressed manipulation alone, 3 mobilization and 3 addressed them together) from a cull of an original 46. The contrasts included a variety of treatments including: exercise, heat, injection, back school acupuncture, bed rest, ultrasound or other physiotherapeutic modalities, sham adjusting, etc. Study reports were scored using the Bronfort system and were grouped according to a) acute, b) chronic or c) mixed (acute and chronic) pain based on sample characteristics. Conclusions are summarized here by sample groups.

For acute LBP, there was moderate evidence that HVLA has better short-term efficacy than either mobilization or diathermy, and limited evidence that is has better short-term efficacy than diathermy, exercise and ergonomic modifications.

In patients treated for chronic LBP, several observations were made. There was better evidence that HVLA combined with strengthening exercise was as effective as NSAIDs used with exercise for providing pain relief. Moderate evidence was presented that manipulation is better than physical therapy and home exercise for reducing disability. Similarly, there is moderate evidence that manipulation is better than general medical care or placebo in the short term and to physical therapy in the long term for patient improvement. HVLA had better outcomes than home exercise, TENS, traction, exercise, placebo and sham manipulation or chemonucleolysis for disc herniation.

With regard to groups with mixed (acute and chronic) pain, the conclusions were complex, with 16 trials involved. Hurwitz (22) found that HVLA was the same as medical care for pain and disability, and that adding physical therapy to manipulation did not improve outcomes. Hsieh (23) found that no real significant value for HVLA over back school or myofascial therapy. A short-term value of manipulation over a pamphlet, and no difference between manipulation and McKenzie technique were reported by Cherkin et al. (24). Meade (25,26)- contrasted manipulation and hospital care, finding greater benefit for the manipulation group over both short and long term periods. Finally, Doran and Newell (27) treated a mixed pain group and found that SMT resulted in greater improvement than physical therapy or corsets.

The randomized clinical trials (RCTs), systematic reviews and guidelines rated independently, their reference numbers and quality scores are presented in Appendix 2. The results for each are summarized in the paragraphs that follow. Some of these RCTs overlap with those considered by Bronfort et al. (12). For convenience, the team has grouped the literature by chronicity and body region.

Acute low back pain

Sick list comparisons:

Seferlis (28) found that patients sick listed with acute low back pain, whether accompanied by sciatica, were significantly improved symptomatically after one month regardless of the intervention studied, including manipulation. Patients were more satisfied, and felt that they were provided better explanations about their pain from practitioners who utilized manual therapy (Quality score- 62.5). Wand et al. (29) examined the effects of sick listing itself and noted that a group receiving assessment, advice and treatment improved better than did a group getting assessment, advice and who were put on a wait list for a 6-week period. Improvements were observed in disability, general health, quality of life and mood, though pain and disability were not different at long-term follow-up (Quality score- 68.75).

Physiological therapeutic modality and exercise comparisons:

Hurley and colleagues (30) tested the effects of manipulation combined with interferential therapy compared to either modality alone. Their results showed all 3 groups improved function to the same degree, both at six months and at 12 months follow-up (Quality score- 81.25). Using a single-blind experimental design to compare manipulation to massage and low-level electrostimulation, Godfrey et al. (31) found no differences between groups at the 2-3 week observation time frame (Quality score- 19). In the study by Rasmussen (32), results showed that 94% of the patients treated with manipulation were symptom free within 14 days, compared to 25% in the group that received short wave diathermy. Sample size was small, however, and the study was not strongly powered (Quality score- 18).

The Danish systematic review (19) examined 12 international sets of guidelines, 12 systematic reviews and 10 randomized clinical trials on exercise. They found no specific exercises, regardless of type that were useful for the treatment of acute low back pain with the exception of McKenzie maneuvers (Quality Score- TBC).

Sham and alternate manual method comparisons:

Hadler's study (33) balanced for effects of provider attention and physical contact with a first effort at a manipulation sham procedure. Patients were reported to have benefit from the manipulation for the group that entered the trial with greater prolonged illness at the outset. Similarly, they improved faster and to a greater degree (Quality score- 62.5). Continuing that work, Hadler (33,34) demonstrated that there was a benefit for a single session of manipulation compared to a session of mobilization (Quality score- 69). Erhard (35) reported that the rate of positive response to manual treatment with a hand-heel rocking motion was greater than with extension exercises (Quality score- 25). von Buerger (36) examined the use of manipulation for acute low back pain, comparing rotational manipulation to soft-tissue massage. He found that the manipulation group responded better than the soft-tissue group, but the effects occurred in the short-term, and results were hampered by the nature of the forced multiple choice selections on the data forms (Quality score- 31). Gemmell (37) compared 2 different forms of manipulation for low back pain of less than 6 weeks duration, Meric style adjusting (a form of HVLA manipulation) and Activator technique (a form of mechanically assisted HVLA adjusting). No difference was observed and both helped to reduce pain intensity (Quality score- 37.5). A short-term benefit in disability measures was noted within the first 1-2 weeks of starting therapy for the manipulation that disappeared by 4 weeks in a control group reported by MacDonald's (38) (Quality score- 38). Hoehler's work, while containing mixed data for both acute and chronic low back pain patients, is included here because of larger proportion of acute patients were involved in the study (39). Patients who underwent manipulation reported immediate relief far more often than the group that did not receive manipulation. However at discharge, there were no differences between the groups (Quality score- 25).

Medication comparisons:

Several studies have contrasted manipulation with medication use in the acute patient. In an early paper by Coyer (40), in the group receiving manipulation 50% were

symptom-free within 1 week and 87% were discharged symptom-free in 3 weeks, while only 27% of the control group (bed rest and analgesics) were symptom-free in 1 week, and 60% in 3 weeks. (Quality score- 37.5). Doran and Newell involved a combination of individuals with pain of less than 1 week and more than 4 weeks (27). The treatment arms included manipulation, physiotherapy, corset or analgesic medication, and the outcomes examined pain and mobility. There were no real differences among the groups over time, save that manipulation seemed to produce an immediate beneficial effect in a few patients (Quality score- 25). Waterworth (41) compared manipulation to conservative physiotherapy and 500mg of diflunisal twice per day for 10 days. They did not find that spinal manipulation had any benefit for the rate of recovery (Quality score- 62.5). Manipulation has been compared with steroid injections by Blomberg (42) and to a control group receiving conventional activating therapy. After 4 months the manipulation group suffered from less restricted motion in extension, less restriction in side-bending to both sides, less local pain on extension and right side-bending, less radiating pain and less pain when performing a straight leg raise (Quality score- 56.25). Finally, in a small-scale study, Bronfort (43) found no outcome differences between a group receiving chiropractic care compared to a group receiving medical care at one month of treatment, but did find more notable improvements in the chiropractic group at both 3 and 6 month follow-up (Quality score- 31).

Subacute back pain

Staying active comparisons:

Staying active appears to have some benefit for acute back pain sufferers, and it is reasonable to evaluate its effects in subacute patients. Grunnesjo (44) looked at the combined effects of manual therapy with advice to stay active compared to advise alone in a mixed population of acute and subacute back pain patients. The addition of manual therapy appeared to reduce pain and disability more effectively than the “stay active” concept alone (Quality score- 68.75).

Physiological therapeutic modality and exercise comparisons:

Pope and colleagues (45) demonstrated that manipulation offered better pain improvement than did transcutaneous electrical nerve stimulation (Quality score- 38). Two papers by Sims-Williams give comparison of manipulation to “physiotherapy”(46,47). Results demonstrated a short-term benefit for the manipulation group on outcomes of pain and ability to do light work. Differences between groups waned at 3 and 12 month follow-ups (Quality scores- 43.75, 35). Skargren et al. (48) compared chiropractic to physiotherapy for patients with back pain who had no treatment over the prior month. No differences in health improvements, costs or recurrence rates were noted between the 2 groups. However, based on Oswestry scores, chiropractic performed better for patients who had pain for less than 1 week, while the physiotherapy seemed to be better for those who had pain for more than 4 weeks (Quality score- 50).

The Danish systematic review (19) examined 12 international sets of guidelines, 12 systematic reviews and 10 randomized clinical trials on exercise (Quality Score

TBC). Results suggested that exercise, in general, benefits patients with subacute back pain. No clear superior method is known. Use of a basic program that can be readily modified to meet individual patient needs is recommended. Issues of strength, endurance, stabilization and coordination without excessive loading can all be addressed without the use of high tech equipment. Intensive training consisting of greater than 30 and less than 100 hours of training are most effective.

Sham and alternate manual method comparisons:

Kathryn Hoiriis (49) compared the relative efficacy of chiropractic manipulation to placebo/sham for subacute LBP. All groups improved on measures of pain, disability, depression and Global Impression of Severity. Chiropractic manipulation scored better than placebo in reducing pain and Global Impression of Severity scores (Quality score- 75). Andersson and colleagues (50) compared osteopathic manipulation to standard care to patients with subacute low back pain, finding that both groups improved over a 12-week period at about the same rate (Quality score- 50).

Medication comparisons:

In a separate treatment arm of the Hoiriis (49) study, the relative efficacy of chiropractic manipulation to muscle relaxants for subacute LBP was studied. In all groups, pain, disability, depression and Global Impression of Severity decreased. Chiropractic manipulation was more effective than muscle relaxants in reducing Global Impression of Severity scores (Quality score- 75).

Chronic Low Back Pain

Staying active comparisons:

Aure (51) compared manual therapy to exercise in patients with chronic low back pain who were also sick listed. While both groups showed improvements in pain intensity, functional disability, general health and return to work, the manual therapy group showed significantly greater improvements than did the exercise group for all outcomes. Results were consistent for both the short term and the long term (Quality score- 81.25).

Physician consult / medical care / education comparisons:

In the paper by Niemisto and colleagues (52), the effectiveness of combined manipulation, stabilization exercise and physician consultation were compared to consultation alone. The combined intervention was more effective in reducing pain intensity and disability (Quality score- 81.25). Koes (53) studied treatment by a general practitioner compared to the effectiveness of manipulation, physiotherapy, and a placebo of detuned ultrasound. Assessments were made at 3, 6, and 12 weeks. The manipulation group had a quicker and larger improvement in physical function capacity compared to the other therapies. Changes in spinal mobility in the groups were small and without a consistent pattern (Quality score- 68). In a follow-up report, Koes found during subgroup analysis that improvement in pain was greater for the manipulation group than for other treatment arms at 12 months when considered both for patients with chronic conditions and for those who were under 40 years of age (54) (Quality

Score- 43). Further work by the same group (55) showed that many patients in the non-manipulation treatment arms had received additional care during follow-up. Yet, improvement in the main complaints and in physical functioning remained better in the manipulation group than in the physical therapy group (Quality score- 50). Meade and associates (25) observed that chiropractic treatment was more effective than hospital outpatient care, as assessed using the Oswestry scale (Quality score- 31). Rupert (56) performed an RCT in Egypt that compared 3 treatment arms, including chiropractic manipulation, after medical and chiropractic evaluation. In this study, pain, forward flexion, active and passive leg raise all improved to a greater degree in the chiropractic group; however, the description of main alternate treatments and outcomes was ambiguous (Quality score- 50).

Triano and colleagues looked at comparing manual therapy to educational programs for chronic low back pain (57). They found greater improvement in pain and activity tolerance in the manipulation group, which continued beyond the 2-week treatment period. There were similar improvements in function (Quality score- 31).

Physiological therapeutic modality comparisons:

A negative trial for manipulation was reported by Gibson (58) (Quality score- 38). Detuned diathermy was reported to achieve better results over manipulation, although there were baseline differences between groups initially. Koes (53) studied the effectiveness of manipulation, physiotherapy, treatment by a general practitioner and a placebo of detuned ultrasound. Assessments were made at 3, 6, and 12 weeks. The manipulation group showed a quicker and better improvement in physical function capacity compared to the other therapies. Flexibility differences between groups were not significant (Quality score- 68). In a follow-up report, Koes found that a subgroup analysis demonstrated that improvement in pain was greater for those treated with manipulation both for younger (<40) patients and those with chronic conditions at 12 month follow-up (54) (Quality Score- 43). Despite the fact that many patients in the non-manipulation groups received additional care (55) during follow-up, improvements remained better in the manipulation group than in the physical therapy group (Quality score- 50). In a separate report by the same group (59) there were improvements in both the physiotherapy and manual therapy groups with regard to severity of complaints and global perceived effect compared to general practitioner care; however, the differences between the two groups was not significant (Quality score-50). Mathews et al. (60) found that manipulation hastened recovery from low back pain more than the control did (SIGN rating- no).

Exercise modality comparisons:

Hemilla (61) observed that spinal manipulation led to better long and short-term disability reduction compared to physical therapy or home exercise (Quality score-63). A second paper by the same group (62) found that neither bone-setting nor exercise differed significantly from physical therapy for symptom control, though bone-setting was associated with improved lateral and forward bending of the spine more than exercise (Quality score- 75). Coxhead (63) reported that HVLA provided better outcomes when compared to either exercise, corsets, traction or no exercise when

studied in the short term (Quality score- 25). Conversely, Herzog (64) found no differences between manipulation, exercise or back education in reducing either pain or disability (Quality score- 6). Aure (51) compared manual therapy to exercise in patients with chronic low back pain who were also sick listed. While both groups showed improvements in pain intensity, functional disability, and general health and returned to work, the manual therapy group showed significantly greater improvements than did the exercise group for all outcomes. This result persisted for both the short term and the long term (Quality score- 81.25). In the paper by Niemisto and colleagues (52), the effectiveness of combined manipulation, exercise (stabilizing forms) and physician consultation compared to consultation alone was investigated. The combined intervention was more effective in reducing pain intensity and disability (Quality score- 81.25). The UK Beam study (65) found that manipulation followed by exercise achieved a moderate benefit at 3 months and a small benefit at 12 months. Likewise, manipulation achieved a small to moderate benefit at 3 months and a small benefit at 12 months. Exercise alone had a small benefit at 3 months but no benefit at 12 months (SIGN rating- yes). Lewis et al. (66) found improvement occurred when patients were treated by combined manipulation and spinal stabilization exercises versus use of a 10-station exercise class (SIGN rating- yes).

The Danish systematic review (19) examined 12 international sets of guidelines, 12 systematic reviews and 10 randomized clinical trials on exercise (Quality Score TBC). Results suggested that exercise, in general, benefits patients with chronic low back pain. No clear superior method is known. Use of a basic program that can be readily modified to meet individual patient needs is recommended. Issues of strength, endurance, stabilization and coordination without excessive loading can all be addressed without the use of high tech equipment. Intensive training consisting of greater than 30 and less than 100 hours of training are most effective. Patients with severe chronic low back pain, including those off work, are treated more effectively with a multidisciplinary rehabilitation program. For post-surgical rehabilitation, patients starting 4-6 weeks after disc surgery under intensive training receive greater benefit than with light exercise programs.

Sham and alternate manual method comparisons:

Triano (57) found that actual spinal manipulation produced significantly better results in terms of pain and disability relief for the short-term, than did sham manipulation (Quality score- 31). Cote (67) found no difference over time or for comparisons within or between the manipulation and mobilization groups (Quality score- 37.5). The authors posed that failure to observe differences may have been due to low responsiveness to change in the instruments used for algometry, coupled with a small sample size. Hsieh (23)- found that no real significant value for HVLA over back school or myofascial therapy (Quality score- 63). In the study by Licciardone (68), a comparison was made between osteopathic manipulation, sham manipulation, and a no-intervention control for patients with chronic low back pain. All groups showed improvement. Sham and osteopathic manipulation were associated with greater improvements than seen in the no manipulation group, but no difference was observed between the sham and manipulation groups (Quality score- 62.5). Both subjective and

objective measures showed greater improvements in the manipulation group compared to a sham control in a report by Waagen (69) (Quality score- 44). In the work of Kinalski (70), manual therapy reduced the time of treatment of patients with low back pain associated with intervertebral disc lesions. When disc lesions were not advanced, a decreased muscular hypertonia, and increased mobility was noted. This paper, however, was limited by a poor description of patients and methods (Quality score- 0).

Haas and colleagues examined the dose-response patterns of manipulation for chronic low back pain (71). Patients were randomly allocated to groups receiving 1, 2, 3 or 4 visits per week for 3 weeks, with outcomes recorded for pain intensity and functional disability. A positive and clinically important effect of the number of chiropractic treatments on pain intensity and disability at 4 weeks was associated with the groups receiving the higher rates of care (Quality score- 62.5).

Medication comparisons:

Burton and colleagues (72) demonstrated that HVLA led to greater short-term improvements in pain and disability than did chemonucleolysis for managing disc herniation (Quality score- 38). Bronfort (73) studied spinal manipulation combined with exercise versus a combination of NSAIDS and exercise. Similar results were obtained for both groups (Quality score- 81). Forceful manipulation coupled with sclerosant therapy (injection of a proliferant solution comprised of dextrose-glycerine-phenol) was compared to lower force manipulation combined with saline injections by Ongley (74). The group receiving forceful manipulation with sclerosant fared better than the alternate group but effects cannot be separated between manual procedure and the sclerosant (Quality score- 87.5).

Sciatica / Radicular / Radiating Leg Pain

Staying active / bed rest comparisons:

Postacchini studied a mixed group of low back pain patients with and without radiating leg pain (75). Patients could be either acute or chronic, and were evaluated at 3 weeks, 2 months and 6 months post onset. Treatments included manipulation, drug therapy, physiotherapy, placebo and bed rest; Acute back pain without radiation and chronic back pain responded well to manipulation; however, in none of the other groups did manipulation fare as well as other interventions (Quality score- 6).

Physician consult / medical care / education comparisons:

Arkuszewski looked at patients with lumbosacral pain or sciatica (76). One group received drugs, physiotherapy and manual examination, while the second added manipulation. The group receiving manipulation had a shorter treatment time and a more marked improvement. At 6-month follow-up, the manipulation group showed better neuromotor system function and a better ability to continue employment. Disability was lower in the manipulation group (Quality score- 18.75).

Physiological therapeutic modality comparisons:

Physiotherapy combined with manual manipulation and medication was examined by Arkuszewski, in contrast to the same scheme with manipulation added, as noted above (76). Outcomes from manipulation were better for neurological and motor function as well as disability (Quality score- 18.75). Postacchini (75) looked at patients with acute or chronic symptoms evaluated at 3 weeks, 2 months and 6 months post onset. Manipulation was not as effective for managing the patients with radiating leg pain as the other treatment arms (Quality score- 6). Mathews and colleagues (60) examined multiple treatments including manipulation, traction, sclerosant use and epidural injections for back pain with sciatica. For patients with low back pain and restricted straight leg raise test, manipulation conferred highly significant relief more so than alternate interventions (Quality score- 19). Coxhead et al. included among their subjects, patients who had radiating pain at least to the buttocks (63). Interventions included traction, manipulation, exercise and corset, using a factorial design. After 4 weeks of care, manipulation showed a significant degree of benefit on one of the scales used to assess progress. There were no real differences between groups at 4 months and 16 months post-therapy (Quality score- 25).

Exercise modality comparisons:

In the case of low back pain following laminectomy, Timm (77) reported that exercises conferred benefit both in terms of pain relief and cost effectiveness (Quality Score – TBC). Manipulation had only a small influence on improvement on either symptoms or function (Quality score- 25). Radiating pain at least as far as the buttocks in the study by Coxhead et al. (63) was better after 4 weeks of care for manipulation in contrast to other treatments which disappeared 4 months and 16 months follow-up post-therapy (Quality score- 25)

Sham and alternate manual method comparisons:

Siehl (78) looked at the use of manipulation under general anesthesia for patients with low back pain with unilateral or bilateral radiating leg pain. Only temporary clinical improvement was noted when traditional electromyographic evidence of nerve root involvement was present. With negative electromyography, manipulation was reported to provide lasting improvement (Quality score- 31.25)

Medication comparisons:

Mixed acute and chronic back pain with radiation treated in a study using multiple treatment arms were evaluated at 3 weeks, 2 months and 6 months post onset by Postacchini's group (75). Medication management fared better than did manipulation when radiating leg pain was present (Quality score- 6). Conversely, for the work of Mathews and colleagues (60) the group of patients with low back pain and limited straight leg raise test responded more to manipulation than to epidural steroid or scelerosants (Quality score- 19).

Disc herniation:

Nwuga (79) studied 51 subjects who were suffering from a diagnosis of prolapsed intervertebral disc and who had been referred for physical therapy.

Manipulation was reported to be superior to conventional therapy (Quality score- 12.5). Zylbergold (80) found that there were no statistical differences between 3 treatments; lumbar flexion exercises, home care and manipulation. Short term follow-up and a small sample size were posed by the author as a basis for failing to reject the null hypothesis (Quality score- 38).

Summary of conclusions on Adjustment / manipulation / mobilization

1. As much or more evidence exists for the use of spinal manipulation to reduce symptoms and improve function in patients with chronic low back pain as for use in acute and subacute low back pain. – Evidence grade A.
2. Use of exercise in conjunction with manipulation is likely to speed and improve outcomes as well as minimize episodic recurrence. – Evidence grades A, B, C.
3. There was less evidence for the use of manipulation for patients with low back pain and radiating leg pain, sciatica or radiculopathy (Rating: AB).
4. Cases with high severity of symptoms may benefit by referral for co-management of symptoms with medication. – B,C.
5. There was little evidence for the use of manipulation for other conditions affecting the low back, and very few papers to support a higher rating (Rating: C).

Exercise

Exercise is one of the most well studied forms of treatment for low back disorders. There are many different approaches to exercise. For purposes of this report, it is important only to differentiate multidisciplinary rehabilitation. These programs are designed for especially long term chronic patients with significant psychosocial problems. They involve trunk exercise, functional task training including work simulation/vocational training, and psychological counseling.

In a recent Cochrane review on exercise for the treatment of non-specific low back pain (81) (Quality Score- 82) effectiveness of exercise therapy in acute, sub-acute, and chronic patients was compared to no treatment and alternate treatments. Outcomes included the assessment of pain, function, return to work, absenteeism, and/or global improvements. In the review, 61 trials met the inclusion criteria, the majority of which dealt with chronic (N=43), while smaller numbers addressed acute (N=11) and sub-acute (N=6) pain. The general conclusions were:

- Exercise is not effective as a treatment for acute LBP.
- Evidence that exercise was effective in chronic populations relative to comparisons made at follow up periods.
- Mean improvements of 13.3 points for pain, and 6.9 points were observed for function.
- There is some evidence that graded-activity exercise is effective for sub-acute LBP, but only in the occupational setting

The review examined population and intervention characteristics and outcomes (Table 3) to reach its conclusions.

Table 3: Characteristics examined by Cochrane systematic review of exercise.

- Population characteristics
  - source or setting
  - inclusion criteria
  - duration of back pain episode
  - patient age
- Intervention characteristics
  - description and type of exercise
  - duration and number of treatment sessions
  - intervention delivery type
  - co-interventions
- Outcome data
- Overall conclusion about effectiveness

Extracting data on return to work, absenteeism and global improvement proved so difficult that only pain and function could be quantitatively described. Levels of evidence used in the exercise ratings for review of exercise included:

- Strong evidence-findings seen in multiple high-quality studies
- Moderate evidence- consistent findings in multiple low-quality studies or one high-quality study
- Limited evidence- one low quality study
- Conflicting evidence- inconsistent findings across trials
- No evidence- no randomized trials available

The authors separated the population sources into *healthcare* (primary, secondary, or tertiary care centers), *occupational*, or *general/mixed* and subgroup analysis was performed for comparisons.

Eight studies scored positively on key validity criteria. With regard to clinical relevance, many of the trials presented inadequate information, with 90% reporting the study population but only 54% adequately describing the exercise intervention. Relevant outcomes were reported in 70% of the trials.

Exercise for acute low back pain:

Ten of the 11 trials (total N=1192) had non-exercise comparison groups. The trials presented conflicting evidence. Eight low-quality trials showed no differences between exercise and usual care or no treatment. Pooled data showed that there was no difference in short-term pain relief between exercise and no treatment, no difference in early follow-up for pain when compared to other interventions, and no positive effect of exercise on functional outcomes.

Sub-acute low back pain:

In six studies (total N=881), 7 exercise groups had a non-exercise comparison group. The trials offered mixed results with regard to evidence of effectiveness, with

the only notable finding that there was moderate evidence of effectiveness for a graded-exercise activity program. Pooled data did not show evidence to either support or refute the use of exercise for sub-acute low back pain either for decreasing pain or improving function.

Chronic low back pain:

There were 43 trials included in this group (total N=3907). Thirty-three of the studies had non-exercise comparison groups. Exercise was at least as effective as other conservative interventions for low back pain; 2 high-quality studies and nine lower-quality studies found exercise to be more effective. These studies used individualized exercise programs, focusing mainly on strengthening or trunk stabilization. There were 14 trials that found no difference between exercise and other conservative interventions; of these, 2 were rated highly and 12 rated lower. Pooling the data showed a mean improvement of 10.2 (95% CI: 1.31-19.09) points for exercise compared to no treatment, and 5.93 points (95% CI: 2.21-9.65) points compared to other conservative treatments. Functional outcomes also showed improvements: 3.0 points at earliest follow-up compared to no treatment (95% CI: -0.53-6.48) and 2.37 points (95% CI: 1.04-3.94) compared to other conservative treatments.

Indirect subgroup analysis found that trials examining healthcare study populations had higher mean improvements in pain and physical functioning compared to their comparison groups or to trials set in occupational or general populations.

The review authors offered the following conclusions:

1. In acute low-back pain, there is evidence that exercises are not more effective than other conservative interventions. Meta-analysis showed no advantage over no treatment for pain and functional outcomes over the short or long-term.
2. There is moderate evidence of effectiveness of a graded-activity exercise program in subacute low-back pain in occupational settings. The effectiveness for other types of exercise therapy in other populations is unclear.
3. In chronic low-back pain, there is strong evidence that exercise is at least as effective as other conservative treatments. Individually designed strengthening or stabilizing programs appear to be effective in healthcare settings. Meta-analysis found functional outcomes significantly improved, however, the effects were very small, with a less than 3-point (out of 100) difference between the exercise and comparison groups at earliest follow-up. Pain outcomes were also significantly improved in groups receiving exercises relative to other comparisons, with a mean of approximately 7 points. Effects were similar over longer follow-up though confidence intervals increased. Mean improvements in pain and functioning may be clinically meaningful in studies from healthcare populations in which improvements were significantly greater than those observed in studies from general or mixed populations.

The Danish (19) group review of exercise was able to identify 5 systematic reviews and 12 guidelines that discussed exercise for acute low back pain, 1 systematic review and 12 guidelines for subacute, and 7 systematic reviews and 11 guidelines for chronic. Further, they identified 1 systematic review that selectively evaluated for post-surgical cases. Conclusions were essentially the same as the Cochrane review with the exceptions that there was limited support for McKinsey maneuvers for acute patients and for intensive rehabilitation programs for 4-6 weeks after disc surgery over light exercise programs.

Table 4 presents the number of sources rated by the review team for formulating recommendations.

Table 4. Number of sources rated by the interdisciplinary team of reviewers and used in formulating conclusions.

	LBP<2	LBP 2-6	LBP >6	LBP w/radiculopathy	Other
Number of RCTs reported	17	7	32	6	2
Number rated as high	1	1	5	0	0
Number rated as moderate	11	6	22	1	1
Number rated as low	5	0	5	5	1
Number of meta-analyses reported	0	0	3	0	0
Number rated as high	0	0	1	0	0
Number rated as moderate	0	0	1	0	0
Number rated as low	0	0	0	0	0
Number of clinical trials not included in the meta-analysis	6	5	11	1	0
Number of Systematic Reviews	6	1	10	0	0
Number rated as high*	3	1	5	1	1
Number rated as moderate	4	1	4	0	0
Number rated as low	0	0	2	0	0
Number of case series	1	0	7	0	0
Number rated as high	1	0	5	0	0
Number rated as low	0	0	2	0	0
Number of case-control/cohort studies	4	1	7	0	0
Number rated as +	2		3	0	0
Number rated as N	2		3	0	0
Number rated as -	0		1		
Nominal group process	NA	NA	NA	NA	NA

* Includes Danish Society of Chiropractic and Clinical Biomechanics

Natural and Treatment History for Low Back Pain:

Most studies have demonstrated that nearly half of low back pain will improve within 1 week, while nearly 90% of it will be gone by 12 weeks (91). Even more, Dixon demonstrated that perhaps as much as 90% of low back pain will resolve on its own, without any intervention whatsoever. (92). Von Korff (93) demonstrated that a significant amount of acute low back pain patients will have persistent pain if they are followed out to two years.

Phillips (94) found that nearly 4 out of 10 people will have low back pain after an episode at 6 months from onset, even if the original pain has disappeared, because over 6 in 10 will have at least 1 relapse during the first year following an episode. These initial relapses occur within 8 weeks most commonly and may reoccur over time, though in decreasing percentages.

Worker Compensation injury patients were followed for one year to examine symptom severity and work status (95). Half of those studied lost no work time in the first month after injury, but 30% did lose time from work due to their injury over the course of one year. Of those who missed work in the first month due to their injury and had already been able to return to work, an additional nearly 20% had absence later in that same year. This implies that assessing return to work at one month after injury will fail to give an honest depiction of the chronic, episodic nature of low back pain. Even though many patients have returned to work, they will later experience continuing problems and work-related absences. Impairment present at more than 12 weeks post injury may be far higher than has been previously reported in the literature, where rates of 10% are common. In fact, the rates may up to three to four times that high.

In a study by Schiotzz-Christensen and colleagues (96), the following was noted: In relation to sick leave, low back pain has a favorable prognosis, with a 50% return to work within the first eight days and only 2% on sick leave after one year. However, 15% had been on sick leave during the following year and about half continued to complain of discomfort. This suggested that an acute episode of low back pain significant enough to cause the patient to seek a visit to a GP is followed by a longer period of low-grade disability than had been previously found. Also, even for those who returned to work, up to 16% indicated that they were not functionally improved. In another study looking at outcomes after four weeks following initial diagnosis and treatment (97), only 28% of patients did not experience any pain; more strikingly, the persistence of pain differed between groups that had radiating pain and those that did not, with 65% of the former feeling improvement at four weeks, versus 82% of the latter. The general findings from this paper differ from other studies in that 72% of patients still experienced pain four weeks after initial diagnosis.

Hestbaek and colleagues reviewed a number of papers in a systematic review (98). The results showed that the reported proportion of patients who still experienced pain after 12 months following onset was 62% on average, with 16% sick-listed six months following onset, and with 60% experiencing relapse of work absence. Also, they

found that the mean reported prevalence of low back pain in patients who had past episodes of LBP was 56%, compared to just 22% for those who had no such history. Croft and colleagues (99) performed a prospective study looking at the outcomes of LBP in general practice, finding that 90% of patients with low back pain in primary care have stopped consulting with symptoms within three months; however, most will still be experiencing LBP and disability one year after the initial visit. Only 25% had fully recovered within that same year.

There are even different results in the study by Wahlgren et al. (100). Here, a considerable majority of the patients continued to experience pain at both six and 12 months (78 and 72% respectively). Only 20% of the sample had fully recovered by six months and only 22% by 12 months.

Von Korff (101) has provided a lengthy list of data he considers relevant to assessing the clinical course of back pain: age, sex, race/ethnicity, years of education, occupation, change in occupation, employment status, disability insurance status, litigation status, recency/age at first onset of back pain, recency/age when care was sought, recency of back pain episode, duration of current/most recent episode of back pain, number of back pain days, current pain intensity, average pain intensity, worst pain intensity, ratings of interference with activities, activity limitation days, clinical diagnosis for this episode, bed rest days, work loss days, recency of back pain flare-up and duration of the most recent flare-up.

The variability noted in these and many other studies can be explained in part by the difficulty in making an adequate diagnosis, by the different classification schemes used in classifying low back pain, by the different outcome tools used in each study and by many other factors. It also points up the extreme difficulty in getting a handle on the day-to-day reality for those who suffer from LBP.

Common Markers and Rating Complexity for Low Back Pain:

What are the relevant benchmarks for evaluating process of care?

One benchmark is described above, that being natural history. Complexity and risk stratification are important, as are cost issues; however, cost effectiveness is beyond the scope of this report.

It is understood that patients with uncomplicated low back pain improve faster than those with various complications, the most notable of which is radiating pain. (102). Many factors may influence the course of back pain, including comorbidity, ergonomic factors, age, the level of fitness of the patient, environmental factors, and psychosocial factors. The latter is receiving a great deal of attention in the literature, though as noted elsewhere in this book, such consideration may not be justified. Any of these factors, alone or in combination, may hamper or retard the recovery period following injury.

It seems that biomechanical factors play an important role in the incidence of first-time episodes of low back pain and its attendant problems such as work loss;

psychosocial factors come in to play more in subsequent episodes of low back pain. The biomechanical factors can lead to tissue tearing, which then create pain and limited ability for years to follow (103). This tissue damage cannot be seen on standard imaging and may only be apparent upon dissection or surgery.

Risk factors for low back pain include:

- Age, gender, severity of symptoms
- Increased spinal flexibility, decreased muscle endurance
- Prior recent injury or surgery
- Abnormal joint motion or decreased body mechanics
- Prolonged static posture or poor motor control
- Work-related: vehicle operation, sustained loads, materials handling
- Employment history and satisfaction
- Wage status

IJzelenberg and Burdorf A investigated whether demographic, work-related physical or psychosocial risk factors involved in the occurrence of musculoskeletal conditions determine subsequent health care use and sick leave (104). They found that within 6 months, nearly one-third of industrial workers with LBP (or neck and upper extremity problems) had a recurrence of sick leave for that same problem and a 40% recurrence of health care use. Work-related factors associated with MS symptoms were similar to those associated with health care use and sick leave; but, for LBP, older age and living alone strongly determined whether patients with these problems took any sick leave. The 12-month prevalence of LBP was 52%, and of those with symptoms at baseline, 68% had a recurrence of the LBP. Jarvik and colleagues add depression as an important predictor of new LBP (105). They found the use of MRI to be a less important predictor of LBP than depression.

What are the relevant outcome measures?

The Clinical Practice Guidelines (CPG) formulated by the Canadian Chiropractic Associatation and the Canadian Federation of Chiropractic Regulatory Boards (106) note that there are a number of outcomes that may be used to demonstrate change as a result of treatment. These should be both reliable and valid. According to the Canadian guidelines, appropriate standards are useful in chiropractic practice because they are able to:

- Consistently evaluate the effects of care over time
- Help indicate the point of maximum therapeutic improvement
- Uncover problems related to care such as noncompliance
- Document improvement to the patient, doctor and third parties
- Suggest modifications of the goals of treatment if necessary
- Quantify the clinical experience of the doctor
- Justify the type, dose and duration of care
- Help provide a data-base for research
- Assist in establishing standards of treatment for specific conditions.

The broad general classes of outcomes include functional outcomes, patient perception outcomes, physiological outcomes, general health assessments and subluxation syndrome outcomes. This chapter addresses only functional and patient

perception outcomes assessed by questionnaires and functional outcomes assessed by manual procedures.

Functional Outcomes: These are outcomes that measure the patient's limitations in going about his or her normal daily activities. What is being looked at is the effect of a condition or disorder (i.e., low back pain, for which a specific diagnosis may not be present or possible) and its outcome of care. Many such outcome tools exist. Some of the better known include:

- Roland Morris Disability Questionnaire
- Oswestry Disability Questionnaire
- Pain Disability Index
- Neck Disability Index
- Waddell Disability Index
- Million Disability Questionnaire

These are only some of the existing tools for assessing function.

In the existing RCT literature for LBP, functional outcomes have been shown to be the outcome that demonstrates the greatest change and improvement with spinal manipulation. Activities of daily living, along with patient self-reporting of pain, were the two most notable outcomes to show such improvement. Other outcomes fared less well, including trunk motion ROM and straight leg raise.

In the chiropractic literature, the outcome inventories used most frequently for low back pain are the Roland Morris Disability Questionnaire and the Oswestry Questionnaire. In a study in 1991, John Hsieh found that both tools provided consistent results over the course of his trial, but that the results from the two questionnaires differed (107) Thus, it seems that either will report meaningful and reliable information when used in trials of manipulation for low back pain.

Patient Perception Outcome:
Another important set of outcomes is those involving patient perception of pain and of their satisfaction with care. The first involves measuring changes in pain perception over time of pain intensity, duration and frequency. There are a number of different tools that can do so. These include:

***Visual Analogue Scale*:** This is a 10-cm line which has pain descriptions noted at both ends of that line representing no pain to intolerable pain; the patient is asked to mark a point on that line that they feel demonstrates their perception of pain intensity. There are a number of variants for this outcome, including the use of the Numerical Rating Scale (where the patient provides a number between 0-10 to represent the amount of pain they have) and the use of pain levels from 0-11 depicted pictorially in boxes, which the patient may check. All of these appear to be equally reliable, but for ease of use either the standard VAS or NRS are often used.

***Pain Diary*:** These may be used to help monitor a variety of different pain variables (for example, frequency, which the VAS cannot measure). Different forms may be used to collect this information, but it is typically completed on a daily basis.

***McGill Pain Questionnaire*:** This scale helps to quantify several psychological components of pain: cognitive-evaluative, motivational-affective, and sensory-discriminative. In this instrument, there are 20 categories of words that describe the quality of pain. From the results, 6 different pain variables can be determined.

***Borg Pain Scale*:** This is a VAS that can be used at intake and at follow-up examinations.

All of the above instruments have been used at various times to monitor the progress of treatment for back pain with spinal manipulation.

Patient satisfaction addresses both the effectiveness of care as well the method of receiving that care. There are numerous methods of assessing patient satisfaction, and not all of them were designed to be specifically used for low back pain or for manipulation. However, Richard Deyo did develop one for use with low back pain (108). His instrument examines the effectiveness of care, information, and caring. There is also the Patient Satisfaction Questionnaire, which assesses eight separate indices (such as efficacy/outcomes or professional skill, for example). (109). Dan Cherkin noted that the Visit Specific Satisfaction Questionnaire can be used for chiropractic outcome assessment (110).

General Health Outcome Measures:
This has traditionally been a difficult outcome to effectively measure but a number of more recent instruments are demonstrating that it can be done reliably. The two major instruments for doing so are the Sickness Impact Profile and the SF36. The first assesses dimensions such as mobility, ambulation, rest, work, social interaction and so on; the second looks primarily at well being, functional status and overall health as well as eight other health concepts to ultimately determine eight indices which can be used to determine overall health status. Items here include physical functioning, social functioning, mental health, etc. This tool has been used in many settings and has also been adapted into shorter forms as well.

Physiological Outcome Measures:
The chiropractic profession has a number of physiological outcomes that are used with regard to the decision-making process regarding treatment. These include such procedures as range of motion testing, muscle function testing, palpation, radiography and other less common procedures (leg length analysis, thermography, etc.). This chapter addresses only the physiological outcomes assessed manually.

***Range of Motion*:** This examination procedure is used by nearly every chiropractor and is used to assess impairment since it is related to spinal function. It is possible to use range of motion (ROM) as a means to monitor improvement in function over time, and therefore improvement as it relates to the use of spinal manipulative therapy. One can assess regional and global lumbar motion, for example, and use that as one marker for improvement.

ROM can be measured via a number of different means. One can use standard goniometers, inclinometers, and more sophisticated tools that require the use of specialized equipment and computers. When doing so, it is important to keep mindful of the reliability of each individual method. A number of studies have assessed various devices:

- Zachman (111) found the use of the rangiometer moderately reliable
- Nansel (112) found that using five repeated measures of cervical spine motion with an inclinometer to be reliable
- Liebenson (113) found that the modified Schrober technique, along with inclinometers and flexible spinal rulers had the best support from the literature
- Triano and Schultz (114) found that ROM for the trunk, along with trunk strength ratios and myoelectrical activity, were good indicators for low back pain disability
- A number of studies found that the kinematic measurement of ROM for spinal mobility is reliable (69,79,113,115)

***Muscle Function*:** Evaluating muscle function may be done using an automated system or by manual means. While manual muscle testing has been a common diagnostic practice within the chiropractic profession, there are few studies demonstrating clinical reliability for the procedure, and they are not believed to be particularly accurate (23,116,117).

Automated systems are more reliable and are capable of assessing muscle parameters such as strength, power, endurance and work, as well as assess different modes of muscle contraction (isotonic, isometric, isokinetic). Hsieh found that a patient initiated method worked well for specific muscles (23), and other studies have shown the dynamometer to have good reliability (118).

***Posture*:** In a small number of studies, posture has been used as an outcome for changes following manipulation (119,120). Harrison has developed a model of the ideal spine using postural means along with engineering and mathematical principles, however this awaits further testing in clinical trials (121-126).

***Leg Length Inequality*:** Very few studies of leg length have shown any reliability; most have been unable to do so. The best methods for assessing reliability of leg length involve radiographic means and are therefore subject to exposure to ionizing radiation. Finally, the procedure has not been studied as to validity, making the use of this as an outcome questionable (127).

***Soft Tissue Compliance*:** Compliance is assessed by both manual and mechanical means, by use of the hand alone or by use of a device such as an algometer. By assessing compliance, the chiropractor is looking to assess muscle tone as well.

Early tests of compliance by Lawson demonstrated that the procedure had good reliability (135). Fisher found increases in tissue compliance with subjects involved in physical therapy (136). Waldorf looked at prone segmental tissue compliance and found that the procedure had a good test/retest variation of less than 10% (137).

Pain tolerance can also be assessed using these means. The procedure has been found reliable for doing so (134,138) and Vernon found it was a useful measure in assessing the cervical paraspinal musculature after adjusting (139). The guidelines group from the Canadian Chiropractic Association and the Canadian Federation of Chiropractic Regulatory Boards concluded, “the assessments are safe and inexpensive and appear to be responsive to conditions and treatments commonly seen in chiropractic practice.” (106)

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Appendix 1:
Search Strategies

Search strategies.

The Cochrane Group used the following strategies for locating studies for inclusion.

MEDLINE

1. exp Exercise Movement Techniques/
2. Exercise Therapy/
3. Physical Fitness/
4. exp EXERTION/
5. RECREATION/
6. exercise$.mp.
7. McKenzie$.mp.
8. Alexander.mp.
9. William$.mp.
10. Feldenkrais.mp.
11. or/1-10
12. limit 11 to randomized controlled trial
13. Randomized Controlled Trials/
14. double blind method/ or single blind method/
15. Random Allocation/
16. PLACEBOS/
17. Research Design/
18. ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).mp.
19. placebo$.mp.
20. random$.mp.
21. volunteer$.mp.
22. or/13-21
23. exp Back Pain/ or back pain.mp.
24. backache.mp.
25. (lumbar adj pain).mp.
26. (lumbar adj trauma).mp.
27. lumbosacral.mp.
28. dorsalgia.mp.
29. sciatica.mp.
30. or/23-29
31. 11 and 22
32. 12 or 31
33. 31 and 30.
34. limit 33 to (human)

EMBASE

1. clinical article/
2. clinical study/
3. clinical trial/
4. controlled study/
5. randomized controlled study/
6. major clinical study/
7. double blind procedure/
8. multicenter study/
9. single blind procedure/
10. placebo/
11. or/1-10
12. allocate$.mp.
13. assign$.mp.

14. blind$.mp.
15. (clinic$ adj25 (study or trial)).mp.
16. compare$.mp.
17. control.mp.
18. cross?over.mp.
19. factorial$.mp.
20. follow?up.mp.
21. placebo$.mp.
22. random$.mp.
23. ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).mp.
24. trial$.mp.
25. (versus or vs.).mp.
26. or/12-25
27. low back pain/
28. backache/
29. back pain.mp.
30. backache.mp.
31. or/27-30
32. kinesiotherapy/
33. exp Physical Activity/
34. exp EXERCISE/
35. REHABILITATION/
36. exercise$.mp.
37. McKenzie$.mp.
38. Alexander$.mp.
39. William$.mp.
40. Feldenkrais$.mp.
41. yoga.mp.
42. or/32-41
43. 11 or 26
44. 31 and 42 and 43
45. limit 44 to (human and yr=1999-2002)
46. limit 45 to yr=1999
47. limit 45 to yr=2000
48. limit 45 to yr=2001
49. from 48 keep 1-144
50. 45 not (46 or 47 or 48)
51. from 50 keep 1-58
52. 44
53. limit 52 to (human)

The search strategy used to locate information for this Cochrane review was:
TENS:

1. Exp electric stimulation therapy/
2. (electric$ adj nerve) or therapy).tw
3. electrostimulation.tw
4. electroanalgesia.tw
5. (tens or altens).tw
6. electroacupuncture.tw
7. (high volt or pulsed or current).tw
8. (electromagnetic or electrotherapy$).tw

Back Pain:

9. exp back/
10. exp back injury/
11. exp back pain/
12. back.hw.tw
13. (spine or spinal).tw
14. sacrococcygeal.tw
15. lumbar.tw
16. sciatica/ or sciatic$.tw
17. lumbosacral.tw
18. cauda equina.tw
19. backache.tw

Low back pain

Summarize the search strategy

In specific, the project used the search strategy as implemented by the Cochrane Back Group (21). The strategy is as follows:

• For MEDLINE, CINAHL, MANTIS

Part A: Generic search for RCTs and CCTs

1. randomized controlled trial.pt
2. controlled clinical trial.pt
3. Randomized Controlled Trials/
4. Random Allocation/
5. Double-Blind Method/
6. Single-Blind Method/
7. or/1-6
8. Animal/not Human/
9. 7 not 8
10. clinical trial.pt
11. deep Clinical Trials/
12. (clin$ adj25 trial$).tw
13. ((singl$ or doubl$ or trebl$ or tripl$) adj 25 (blind$ or mask$)).tw
14. Placebos/
15. placebo$.tw
16. random$.tw
17. Research Design/
18. (latin adj square).tw
19. or/10-18
20. 19 not 18
21.20 not 9
22. Comparative Study/
23. exp Evaluation Studies/
24. Follow-Up Studies/
25. Prospective Studies?
26. (control$ or prospective$ or Volunteer$).tw
27. Cross-Over Studies/

28. or/22-27
29. 28 not 8
30. 29 not (9 or 21)
31. 9 or 21 or 30

Part B: Specific search for thoracic, low back, sacrum and coccyx problems

32. dorsalgia.ti,ab
33. exp back pain
34. back pain.sh
35. low back pain.sh
36. backache.ti,ab
37. exp back/
38. (lumbar adj trauma).ti,ab
39. (lumbar adj pain).ti,ab
40. lumbosacral.ti,ab
41. sacrum.ti,ab
42. sacroiliac.ti,ab
43. coccyx.ti,ab
44. coccydynia.ti,ab
45. sciatica.ti,ab
46. (cauda adj equine).ti,ab
47. spondylolisthesis.ti,ab
48. spondylosis.ti,ab
49. lumbago.ti,ab
50. trunk.ti,ab
51. or 32-50

Part C: Other spinal disorders

52. exp spine
53. spinal.ti,ab
54. exp spondylitis
55. discitis.ti,ab
56. exp spinal diseases
57. (disc adj degeneration).ti,ab
58. (disc adj prolapse).ti,ab
59. (disc adj herniation).ti,ab
60. spinal canal.sh
61. exp spinal curvatures
62. exp spinal dysraphism
63. exp spinal injuries
64. spinal fusion.sh
65. spinal neoplasms.sh
66. exp spinal nerve roots
67. exp spinal nerves
68. exp spinal osteophytosis
69. spinal stenosis.sh
70. (facet adj joints).ti,ab
71. intervertebral disk.sh
72. intervertebral disk displacement.sh
73. scoliosis.ti,ab
74. kyphosis.ti,ab
75. lordosis.ti,ab
76. nerve root.ti,ab
77. paraspinal.ti,ab
78. intradural.ti,ab
79. intraspinal.ti,ab
80. myelopathy.ti,ab
81. (spinal adj cord).ti,ab

82. postlaminectomy.ti,ab
83. arachnoiditis.ti,ab
84. (failed adj back).ti,ab
85. or 52-84

Part D: Specific outcome measurements related to spinal disorders

86. Oswestry.ti,ab
87. Roland-Morris.ti,ab
88. or 86-87

Results (all RCTs and CCTs for spinal disorders)

89. 51 or 85 or 88
90. 31 and 89

• For EMBASE (OVID)

Part A: Generic search for RCTs and CCTs

1. clinical article/
2. clinical study/
3. clinical trial/
4. controlled study/
5. randomized controlled trial/
6. major clinical study/
7. double blind procedure/
8. multicenter study/
9. single blind procedure/
10. phase 3 clinical study/
11. phase 4 clinical study/
12. crossover procedure/
13. placebo/
14. or/1-13
15. allocate$.ti,ab
16. assign$.ti,ab
17. blind$.ti,ab
18. ((clinic$ adj25 (study or trial)).ti,ab
19. compare$.ti,ab
20. control$.ti,ab
21. cross?over.ti,ab
22. factorial$.ti,ab
23. follow?up.ti,ab
24. placebo$.ti,ab
25. prospective$.ti,ab
26. random$.ti,ab
27. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab
28. trial.ti,ab
29. (versus or vs).ti,ab
30. or/15-29
31. 14 or 30
32. human/
33. nonhuman/
34. animal/
35. animal experiment/
36. 33 or 34 or 35
37. 32 not 36
38. 31 not 36
39. 31 and 37
40. 38 not 39

Part B: Specific search for back pain

41. backache/

42. low back pain/
43. back pain/
44. backache.ti,ab
45. or/41-44

Part C: Other spinal problems

46. spine/
47. spinal disorders/
48. vertebrae/
49. scoliosis.ti,ab
50. kyphosis.ti,ab
51. lordosis.ti,ab
52. or/46-50

Results (all RCTs and CCTs for spinal disorders)

53. 45 or 52
54. 40 and 53

Search Strategy for CENTRAL (Cochrane Library)

Part A: Specific search for back pain

1. back*.ky
2. buttock*.ky
3. leg*.ky
4. (back near pain*.ky)
5. (back near injury*.ky)
6. (low near back near pain*.ky)
7. (low near back near pain)
8. lbp
9. sciatica*.ky
10. (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9)

Part B: Other spinal disease

11. spine*.ky
12. (spinal near disease*.ky)
13. (#11 or #12)

Results (all RCTs and CCTs for spinal disorders)

14. (#10 or #13)

APPENDIX 2:
Summary of evidence from the rated references.
Evaluation of methodological rigor is separately embodied in the ratings tables and is not included in the evidence tables themselves. Additional evidence tables can be found in Bronfort (12) and are adopted herein by reference.

Note: the evidence table does not reflect all papers described in the text of this chapter, and will be updated in a future iteration.

Definitions/Descriptions of Evidence Table Headings.

• **Author**: Principal author and code number

• **Duration of Pain**: Was the duration of pain of subjects described? If so, please describe. Answers could include responses such as acute, less than 14 days; acute, less than one month; chronic, greater than 6 months; pain of 1-3 months duration, etc.

• **Sciatic pain**: Were patients with sciatic pain included in the study? Answers here could include present, absent or excluded, unclear or not disclosed.

• **Minor neurologic findings**: Were patients with minor neurological findings included in the study? If so, were the findings described? Answers could include not disclosed, unclear, present, absent or excluded, none reported. If present, a short description of the finding could be listed (i.e., “leg pain in some participants”).

• **Palpatory findings**: Were palpatory findings described? Answers could include not reported, unclear, undefined/undetermined. If present, the findings were to be described (i.e., “tender trigger points” or “decreased range of motion”).

• **Manipulation defined (Type):** What form of manipulation was used? Was it described in terms such as high-velocity, low amplitude (HVLA), low-velocity, variable amplitude (LVVA)? Was a specific named form of manipulation used? Was a side posture procedure used, or a different posture?

• **# manipulated/total sample (and # of manipulations provided):** How many people in the study received manipulation, how many people were in the total sample, and how many manipulations were provided to the participants is recorded here.

• **Results**: Summarize only the significant findings from the study

Evidence Tables: Summary of evidence from the rated references. Evaluation of methodological rigor is separately embodied in the ratings tables and is not included in the evidence tables themselves.

Author	Duration of Pain	Sciatic Pain	Minor Neuro Findings	Palp. Findings	Manip defined (type)	# Manip/Total sample	Results
Hemmila (61)	Acute < 1 mo	Not stated	Pain / none	Decreased ROM	Bone setting- Gentle mobilization NOT forceful chiropractic	45 manipulated / 114 total. 9.9 rxs for physiotherapy 8.1 for bone setting 4.5 for exercise	Bone setting and physiotherapy provided increased mobility as compared to exercise. Manual therapy may be useful for chronic pain.
Hadler (33)	Acute < 1 mo	"Some" had signs of radiculopathy	None reported	Not reported	Short arc, high velocity OR long lever arm moves	Mobilization of 28 / total 54	In the 1st week, those receiving manipulation improved more rapidly and to a greater degree than those receiving mobilization.

Author	Duration of Pain	Sciatic Pain	Minor Neuro Findings	Palp. Findings	Manip defined (type)	# Manip/Total sample	Results
Erhard (35)	< 3 months	Yes, n of 2	Leg pain in some participants	Lumbar and SI ROM	Supine rotational thrust	12 / 24 total. 1-2 rx's per pt	Rate of positive response greater in manipulation / hand-heel group than in extension group.
Blomberg (42)	Acute / subacute < 3 mo	13% had true radicular pain	Pos. SLR / pain	Tender SI & spine. Decreased ROM	Thrust technique or specific mobilization to spine. Kubis technique for SI.	53 received SMT / 101 total. 2.8 Ave. Rx	Manual Rx with (cortisone injection) was superior to conventional treatment.

Author	Duration of Pain	Sciatic Pain	Minor Neuro Findings	Palp. Findings	Manipulation defined (type)	# Manip/Total sample	Results
Cote (67)	Chronic 74 months	Excluded	Sclerotomal Pain	Trigger points at: 1) erector spinae muscles at L5 level; 2) posterior sacroiliac ligament; 3) gluteus muscle group.	Side posture manipulation Short lever, high velocity side thrust.	16/30 Total 1 treatment	Neither CMT nor mobilization produced significant changes in trigger point pain/pressure thresholds.

Author	Duration of Pain	Sciatic Pain	Minor Neuro Findings	Palp. Findings	Manipulation defined (type))	# Manip/Total sample	Results
Seferlis (28)	LBP up to 2 weeks duration	Included	Included	Tenderness to palp of L/S	Manip of L/S & SIJs; mobilization of L/S; muscle energy techniques	Mean = 10 per subject	Dextrose-glycerine-phenol proliferant therapy superior to xylocaine-glycerine-phenol proliferant
Haas (71)	LBP of at least 3 months duration	Excluded	Not disclosed	Not described	HVLA manip determined by clinical findings; also added physiotherapy	Dose response-patients received 1, 2, 3 or 4 visits per week for 3 weeks	Intensive isotonic exercise plus resistance was superior to isotonic exercise or isometric exercises
Wand (29)	Acute LBP of less than 6 weeks duration	Excluded	Excluded	Not described	Maitland technique, combing LV joint mobilization with HVLA manipulation.	Not described	Intensive isotonic exercise plus resistance was superior to isotonic exercise or isometric exercises
Grunnesjo (44)	Acute or subacute LBP of 3 months or less	Excluded	Included	Not described	Lumbar and thoracic thrust techniques	2.6 (2.1-2.5 95% CI) treatments with physician; 5.4 treatments (4.6-6.3 95% CI) with pts	Mineral bath, underwater traction and underwater massage superior to control group
Hurley (30)	Acute low back pain of 4-12 weeks duration	Included	Included	Joint dysfunction noted but not described	Maitland mobilization and manipulatory oscillatory and glide techniques, and Cyriax manipulations; both using short and long arm manipulations	Each subject received 5 treatments over a period of 5 weeks	Z joint on side of manip gapped more than side posture alone when measured by MR
Hoiriis (49)	Subacute LBP of 2-6 weeks duration	Excluded	Excluded	Not described	HVLA adjusting, Grostic instrumented adjusting	8 visits over a 2 week period, with a 9th 2 weeks later. 50 in chiropractic	After 1 month and long term follow up all groups improved (man ther, exercise, and MD care); pts more satisfied with manual care and exercise; more satisfied with explanation of care in manual ther

						group.	group
Ongley (74)	"chronic" (inclusion criteria of duration not specified)	unknown	unknown	unknown	G1 forceful manipulation=modified sacroiliac lumbar roll; G2 manipulation component=pressure applied from behind to torso and buttocks simultaneously (no torsion)	40/ 81	At 4 weeks, there was a substantial linear effect of visits favoring a larger number of visits. There was no effect of treatment regimen. At 12 weeks data suggested a potential for similar effects of visit on patients with combined manip and pt.
Aure (51)	8 weeks to 6 months	included in study	unknown	unknown	HVLA SMT, mobilization, and stretching techniques; 16 treatments (2 per week for 8 weeks), each lasting 45 minutes	27 / 49	At 6 weeks, the assess/advise/treat group showed greater improvements in disability, mood, general health and quality of life than in the assess/advise/wait group
Licciardone (68)	>3 months	excluded if radiating leg pain into distal extremity	excluded if history of persistent numbness or weakness in lower extremities	osteopathic structural evaluation	osteopathic manipulative therapy, including myofascial release, strain-counterstrain, muscle energy, soft tissue, HVLA thrust, and cranio-sacral; 7 visits over 5 months.	48 / 91	At both 5 and 10 weeks, the experimental group had less pain and lower disability than the reference control group.
Niemisto (52)	>3 months	with or without	unknown	unknown	muscle-energy technique (voluntary contraction of the patient's muscles against a distinctly controlled counterforce from a precise position and in a specific direction; 4 treatments over 4 weeks	102 / 204	No differences between the effects of a combined manipulation therapy and interferential therapy and either manipulation or interferential alone; all therapies significantly reduced functional disability and pain.
Von Buerger (36)	Sudden onset, recent	Not clear	Not included	Palpation of paravertebral	Rotational manipulation (included	83/1649 randomly	All patients received 10mg diazepam prior to treatment: G1

	onset of 2-3 weeks duration (no more specific)			tissues	rotational thrust to stretch muscles), soft-tissue massage	selected for rotational manipulation and soft tissue massage, 892/1649 selected for spinal manipulative therapy	(n=40) >10ml 0.5% lignocaine injections+ forceful manipulation; G2 (n=41) <10ml 0.5% lignocaine injections+ non-torsion manipulation. Significant improvement in pain (VAS) and disability (Roland scale) for G1 post treatment, month 3 and 6; no differences in physical clinical signs.
Tobis (147)	Not clear	Not clear	Not clear	Not clear	Rotational manipulation of the lumbosacral spine	Unclear	G1 manipulation (n=16). G2 mobilization (n=14), 1 treatment of an assisted supine knee to chest maneuver held for 3 seconds. Pain/ pressure threshold of L5, SI ligament, and gluteus measured at -15, 0, +15, and +30 minutes from treatment; no statistically significant differences between SMT and mobilization.
Koes (53)	> 6 wks	Not clear	Not included	Not included	Not clear	65/256	G1 manual therapy (n=27). G2 exercise therapy (n=22), 16 sessions in 8 weeks including strengthening, stretching, mobilizing, coordination, and stabilization of abs, back, pelvis, and leg muscles. Primary outcomes measured at baseline, post-treatment, week 4, month 6 and 12: sig improvements in pain (VAS), general health (COOP), and disability (Oswestry) post-treatment and month 12; significant differences between groups at all time points in pain, general heath, and disability in favor of MT; MT showing significantly larger improvement at post- treatment for ROM

Koes (54)	>6 wks	Not clear	Not included	Not included	According to Dutch Society for Manual Therapy and the Royal Dutch Society for Physiotherapy	65/256	G1 osteopathic manipulation (n=48). G2 sham manipulation (n=23), 7 visits over 5 months, including range of motion activities, light touch, and simulated OMT. G3 no intervention control (n=20), postal questionnaires in lieu of clinic visits. Primary outcomes measured at baseline, month 1, 3, and 6: at 1 month, OMT reported more improvement in physical functioning than control (p=0.03); at month 3 and 6, only sham manipulation improved more than control (p=0.01 and p=0.03 respectively); OMT and sham reported statistically significant improvement in VAS at months 1,3,6; no sig differences in Roland-Morris disability scores, medication use, or lost work time.
Kinalski (70)	Not clear	Not clear	Not included	Not included	Rotational mobilization of spine, mobilization in way of postisometric muscle relaxation, Stoddard's cross catch, manipulation in way of Kubis	Not clear	G1 manipulation + consultation (n=102). G2 consultation (n=102), 2 one-hour sessions over 5 months, including an educational booklet, ergonomic recommendations, and instructions for exercise. Primary outcomes measured at baseline, month 5, and month 12: Pain measured with VAS (0-100), at baseline for manipulation 59.5(21.2) and consultation (control) 53.3(21.2); Frequency of LBP experienced, percent experiencing daily LBP at baseline for manipulation 58% and consultation (control) 62%; Disability measured with the Oswestry Low Back Pain Disability Questionnaire (0-100), at baseline for manipulation 29.5(9.7) and consultation (control) 28.8(9.7). Significant improvement in VAS at month 12 for manipulation 25.7(23.3) and consultation (control) 32.2(23.3), with statistically significant difference between groups (p<0.001) in favor of manipulation group. A

							decrease in the percent of subjects reporting daily LBP at month 12 for manipulation 37% (p=0.001) and consultation (control) 39% (p<0.001) with no statistically significant differences between groups.
Rasmussen (32)	< 3 wks	Not clear	Not included	Not included	Rotational manipulation in the pain-free direction	12/24	G1 flexion distraction (n=123). G2 exercise (n=112) 2-4 times per week for 4 weeks, including McKenzie, flexibility and cardiovascular exercise, ultrasound and cryotherapy, extremity weight training, and lumbar extension. Primary outcomes measured at baseline and week 4: Pain measured with VAS (0-100), at baseline for manipulation 38.00(2.01) and exercise (control) 35.70(1.96); Health status measured with SF-36, analyzing each of the 10 sub-scales. Overall, a strong effect for pre- to post-intervention VAS scores F=40.43(p=0.0000) and a statistically significant difference between groups at week 4 F=6.20 (p=0.0136) favoring the manipulation group. No statistically significant differences between groups at week 4 on SF-36, a trend favoring manipulation t=0.90 (p=0.19) for the physical function scale and a trend favoring exercise t=1.48 (p=0.07) for the bodily pain scale is noted.

APPENDIX 2. Rating the literature.

- **Quality Scores for RCTs.**

Author	Reference Number	Quality Score
Andersson	50	50
Arkuszewski	76	18.75
Aure	51	81.25
Blomberg	42	56.25
Bronfort	43	31
Bronfort	73	81
Burton	72	38
Cherkin	24	50
Cote	67	50
Coxhead	63	25
Coyer	40	37.5
Doran	27	25
Erhard	35	25
Evans	140	19
Farrell	141	25
Gemmell	37	37.5
Gibson	58	38
Gilbert	142	37.5
Giles	143	31
Glover	144	50
Godfrey	31	19
Grunnesjo	44	50
Haas	71	62.5
Haas	145	93.75
Hadler	33	69
Hemila	61	75
Hemila	62	63
Herzog	64	6
Hoehler	39	25
Hoiriis	49	75
Hsieh	23	63
Hurley	30	81.25
Hurwitz	22	63
Kinalski	70	0
Koes	55	50
Koes	54	68
Koes	53	43
Koes	146	62
Koes	59	50
Licciardone	68	62.5
MacDonald	38	38
Mathews	60	19
Meade	25	31
Niemisto	52	81.25
Nwuga	79	12.5
Ongley	74	87.5
Pope	45	38
Postacchini	75	6
Rasmussen	32	18

Rupert	56	50
Seferlis	28	62.5
Siehl	78	31.25
Sims-William	46	43.75
Sims-William	47	37.5
Skargren	48	50
Timm	77	25
Tobis	147	0
Triano	57	31
von Buerger	36	31
Waagen	69	44
Wand	29	68.75
Waterworth	41	62.5
Wreje	148	13
Zylbergold	80	38

- **AGREE scores rating of guidelines.**

Name	Reference	D1	D2	D3	D4	D5	D6	Status
Philadelphia Panel	149	66.67	33.33	61.9	50	0	33.33	Rec
Koes	150	33.33	33.33	57.14	41.66	0	50	Rec
Occupational Medicine	151	66.67	58.33	61.9	83.33	55.55	50	Rec
Waddell	152	100	83.33	95.24	83.33	22.22	16.67	Rec
New Zealand	153	55.56	66.67	66.67	66.67	22.22	0	Rec
Minnesota	154	11.11	8.33	7	25	0	0	Not Rec
CCA/CFCRB (Canadian) Guidelines	107	77.78	75	66.67	58.33	33.33	16.67	Rec
New Jersey	155	0	83.33	0	83.33	0	0	Not Rec
Waddell and Burton	156	66	16	57	83.33	44	50	Rec
European Commission	157	33.33	41	38	0	0	0	Not Rec
Danish Institute	19	100	50	42	100	44	33	Rec
Royal College	158	100	75	80	75	0	16	Rec

• MOOSE scores for rating systematic reviews/meta-analyses.

Principal Author	Reference	Score
Anderson	159	91
Bronfort	160	88
Ernst	161	50
Ferreira	162	62
Furlan	163	50
Guzman	164	79.41
Koes	165	68
Malone	166	23.52
Oliphant	167	44.11
Ottenbacher	168	59
Pengel	169	53
van Tulder	170	76.47
Vernon	171	26