CHIROPRACTIC BEST PRACTICES:
A Systematic Review by the Research Commission of the Council on Chiropractic Guidelines and Practice Parameters

- DRAFT FOR STAKEHOLDER REVIEW AND COMMENTARY -

Quality health care delivery enhances satisfaction and value for patients, caregivers and society.

[Note to reader: This stakeholder review draft holds several formats for references that occurred as source documents were consolidated. The final draft may include additional references submitted by stakeholders. Thus, final formatting and listing of references will be deferred until the stakeholder comments have been received.]

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What Constitutes Evidence for Best Practice?

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Introduction

Health care in the United States is broken. The Institute of Medicine published its report, *Crossing the Quality Chasm* [1]in 2001 noting the critical need to address organizational support process, evidence-based practice infrastructure, effective use of information technology, and alignment of payment incentives to support quality. None of the stakeholders in the health care system are satisfied with today's bureaucratic and adversarial system. Although the American system is number one in emergency care, it ranks number 37 in overall quality of care. Appropriateness of treatment is being questioned on all fronts and for all disciplines. As much as 85% of current health care practices remain scientifically invalid despite the jurisdictional claims of medicine to scientific supremacy [2]. The perception of over-utilization and inappropriate utilization of care have been widely discussed and the importance of under-treatment has been acknowledged but with lesser emphasis. The unsuitable conduct of a minority of professionals; health care providers and attorneys has been used by policy makers and payers to leverage clinical decision making from the confidential realm of the doctor-patient relationship through the interjection of third-party case managers.

Although the imposition of third party payers into the directing of key aspects of clinical decision-making helped slow the health cost increases during the 1990's, savings came primarily from reduction of reimbursements and some administrative efficiencies. In fact, the additional administrative oversight has increased overhead costs for doctors and reduced the face-to-face time the can

spend with patients and read the literature. The cost of additional bureaucracy now is a factor. Health care costs have begun to increase again. This has slowed the advancement of new knowledge through research, and increased distrust between patient and provider. It has fostered suspicion among all members of the health care infrastructure and a loss of faith in the idea of a durable and adequate social safety net for patients. Undertreatment, especially in the management of pain, is a serious problem. Some suggest that there is evidence of increasing chronicity and expense associated with under-treatment. The American Pain Society and World Health Organization have called attention to both under-treatment of pain and acceptable standards of care. In 43% of households in the United States at least one member experiences chronic pain. Of these, 84% have medical insurance (42% indemnity, 20% Medicare and supplemental, 6% Medicare only). Skeletal pain accounts for 48% (back pain 35%, L BP 23%, disc 9%, upper/mid back 4%, knee 5%, neck 4%, shoulder/arm 3%, ankle/foot 2%, joints 2%, bones 2%, hip 2%, chronic bursitis 1%). Those with LBP are less likely to be under care (p=0.0002) than other disorders. A total of 40% of interviewees suffer constant pain while 60% are intermittent in their symptoms. As reported by Lazarus and Neumann (2001) [3], the majority do not consider their current treatment adequate. Seventy-six percent have tried alternative therapies including chiropractic with results rated somewhat successful (50%), very successful (19%), and extremely successful (8%). Pain effects on the quality of life have been documented: Nineteen percent say it affects their employment (6.2 hours per month per patient). Severe pain patients lose 8.2 hrs per month. Pain interferes with normal activities of daily living as well as preventive health efforts - Exercise 46%; Sports 43%; Sleep 37%; Daily tasks 35%; job performance 19%; Coping ability 18%; Socialization 18%; personal hygiene 8%. Clearly, the social and economic impact of under-treated pain is a significant problem to patients and to society that often is ignored in deference to concerns on over-treatment [3].

A series of recommendations have been made in effort to address the adequacy of health care delivery. They include a plethora of guidelines development and pathways of care. For the most part, these efforts have failed to alter the course of frustration. To a large extent, dissemination [4] of and seminars [5] on guidelines have had little impact[5-7]. Individual physicians often have failed to voluntarily implement various guidelines within their practices. Many professional associations have shied from the controversy leaving a void in professional leadership. Noncompliance with guidelines result in part from a conscious decision by the physician, as indicated by concerns for patient age and comorbid illness[8] Instead, third party payers have often used proprietary data from multiple sources that was constructed from in-expert opinion using limited or outdated literature have imposed guidelines. Many of those guidelines, as they relate to chiropractic practice, are inconsistent with each other and promote wide variation and fail to meet standards of validation expected of data within the public domain. Their use by various stakeholders often has been to foster economic or

political agendas and to manage system resources rather than to seek what is known and what is accepted as the best approach to care for each individual patient.

The Council on Chiropractic Guidelines and Practice Parameters (CCGPP) has been charged with the effort to develop a more equitable and fair basis for judgments of health care delivery specifically as it applies to the chiropractic profession. After years of discussion and debate, the Commission of the CCGPP recommended in 2001 that the current emphasis on guidelines and prior efforts to codify practice parameters, while a step consistent with professional accountability and responsibility to the public, were fundamentally flawed in various ways. Rather, the Commission argued, development of an evidence base on practices commonly available for the care of patients broadly seeking chiropractic services for specific disorders / complaints would be more valuable. Such a body of evidence may be more easily updated through addendum periodically. By constructing such a database, it is felt that users of the information may be able to focus on the two substantive elements of practice worth emphasis: the health / response of the patient and the process of care that defines quality practice. From these, the stakeholders of healthcare may use the database to derive their own guideline recommendations as may be applicable under varying local circumstances and challenges.

The product of this effort will be the accumulation, evaluation, reporting and rating of evidence – organized by condition (e.g. subluxation, herniation, stenosis, colic etc.) with conclusions as to what level of support exists. It will begin with both the more common conditions and types of care and is designed to progress by iteration to less common and complementary alternatives. The potential value of such a work effort can be significant. Not the least of which is a common database of information on a national level, reviewed by stakeholder representatives and available generally for members to apply in the context of their local needs.

Evidence-based practice: Best Practices versus Guidelines:

There are two principal dimensions of quality of care for individual patients; access and effectiveness. Stated more simply, Campbell et al (2000) [9] suggest that quality in health care is provided when two questions can be answered affirmatively, “Do users get the care they need, and is the care effective when they get it?”. Evidence-based medicine (EBM) is not new. It has its origins in the mid-19th century. Its current emphasis often is economically driven rather than patient centered [10]. The objective of EBM is the conscientious, explicit and judicious use of current best evidence, from various sources including the literature, in making decisions about the care of individual patients [11]. Clearly a useful concept for a practitioner seeing patients one at a time, currently the applicability of evidence may be limited to populations or to single

patients with multiple diseases [12]. The medical literature, moreover, has recently been characterized as disorganized and biased (BMJ.1998;317[7152]:160) with little accountability for ensuring that publications meet minimum standards for quality or clinical relevance. One response to this circumstance has been the restriction of evidence used in guidelines for care delivery to that derived from randomized clinical trials and results of meta-analyses. While in principal these forms are the strongest type of clinical evidence available, there are practical limitations that act as powerful constraints on their ability to identify effective treatment. The positive value of these sources is that high quality studies that demonstrate efficacy of methods of care represents strong evidence favoring the use under the conditions of the study. The primary limitations of RCTs include: 1) the generalizability of results to circumstances that vary from the study conditions, and 2) the variability of opinion as to the quality of the study itself. For meta-analysis, the primary limitations include: 1) selection criteria for inclusion of studies within the analysis that may be a biasing factor, 2) the absent of standardized analyses and systematic method to validate new analysis methods, and 3) the consistency and/ or accuracy of investigator application of criteria during the analysis [13]. As a result, it is incumbent upon the consumers of medical literature to be capable of evaluating the various forms of evidence according to reasonable and widely accepted standards in the context of their applications.

Sackett has described the practice of evidence-based health care eloquently:

> "[EBM] means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that we individual clinicians acquire through clinical experience and clinical practice. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. Good doctors use both individual clinical expertise and the best available external evidence, and ***neither alone is enough*** [emphasis added]. Without clinical expertise, practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, practice risks becoming rapidly out of date, to the detriment of patients. [14]."

While similar in expression, Higgs and colleagues reiterate these ideas but amplify:

> "What challenges do practitioners face in blending clinical reasoning with evidence-based practice? In this article, the authors argue against basing clinical practice on narrow definitions of evidence, relying solely on experimental findings or, even more exclusively, on randomized controlled trials. Instead of defining best practice narrowly by the strength of the current empirical evidence used to guide clinical decisions, it should be defined broadly by what is the best information to use to make decisions for a given patient in a particular setting. Credible and accountable clinical decisions rely on a number of forms of knowledge and evidence. This evidence includes findings from across the range of research methods, including experimental, interpretive, and action research. …. Professionals, particularly advanced and expert clinicians …use clinical reasoning to guide their practice in the uncertainty of clinical practice contexts. This reasoning helps … make judgments about the relevance of particular research and clinical evidence for a specific patient and setting [15]"

Best practices are those with the strongest evidence that their use in a specific patient circumstance have higher probability of providing better outcomes, the diagnosis or treatment of a single patient or clinical question, one patient at one time. They are the product of agreement on the preponderance of evidence that must then be judged by the individual provider and the patient [16] in the context of clinical expertise and the complexity of the individual case. As stated by Driever,

> "Best practice is not a specific practice *per se* but rather a level of agreement about research-based knowledge and an integrative process of embedding this knowledge into the organization and delivery of health care. Best practice requires a level of agreement about evidence to be integrated into practice. Best practice, built on a foundation of EvBP, can bridge the practice-research gap and provide a basis for researchers and clinicians to work together to translate research into meaningful practice [17]."

Rigid standards and guidelines, which frequently are interpreted rigidly, must be avoided to allow for individual considerations and scientific innovation [18].

How do we determine and use Best Practices?:

The characteristics of quality care are summarized by Brown (as reported by Driever [17]). It is patient centered, scientifically based, population outcomes based, refined through quality improvement and benchmarking and individualized to each patient. The contents of efforts attempting to enhance quality of care by blending best-practices with clinical reasoning should include as many of the following features as are available within the state-of-art: a statement of purpose and scope, the method of development; the authors' and reviewers names and affiliations; an analysis of the specificity, sensitivity, and predictive power of mechanisms of illness or injury, symptoms, signs and tests; findings that point to a complicated, serious or emergent condition and factors of delayed recovery; diagnostic criteria; and analysis of the evidence underlying the common treatment elements or alternatives. Statistics on disability/illness duration and an outline for reassessment of those patients whose health concerns remain after a reasonable recovery period [17;19] along with a discussion of management after reassessment, including behavioral referral, further testing, and procedures, may be useful benchmark tools [4].

Each constituent of the health care infrastructure has its role in ensuring adequate care and quality to offset patient illness, dysfunction and suffering. The CCGPP effort to help identify best practices in chiropractic practice cannot and does not determine the bounds of clinical expertise or the elements of individual cases. It can, however, provide resources to understanding the available evidence to inform individual treatment approaches. It is the responsibility of the academic training institutions modern to use data within curricula and post-graduate training programs, to engage in scientific inquiry and to challenge the existing gaps and uncertainties in the knowledge base. The various third party participants are obligated to use modern body of knowledge in assessing benefits to their subscribers and the individual providers must conscientiously keep abreast of the accumulating evidence and document the elements and characteristics of individual cases as they are being treated, appropriately evaluating and responding to patient status along the course of recovery. The Commission has recommended that the method that may serve to communicate to the largest group of stakeholders (patients, chiropractors, associations, colleges, policy makers) is a condition-based review of the literature that focuses on treatment of common complaints attended within the chiropractic practice.. Evidence from the indexed and peer-reviewed literature (e.g. Index Medicos, CINAHL, Mantis, Cochrane, published guidelines etc) and clinical content experts will be surveyed in a manner outlined below. The literature will be evaluated using standardized instruments widely accepted to determine the quality of the evidence reported. For example, instruments are available to assess individual RCTs (CONSORT), diagnostic studies (STARD), meta analyses (Sackett / QUOROM), epidemiological study (MOOSE), published guidelines (AGREE) and cost analyses (Sackett / Drummond).

Topic Areas

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. Each team will handle the review of literature organized into the areas in the listing that follows. Individual ICD codes (including subluxation) used in clinical practice and relevant to the region of discussion will be identified and cited in a summary to provide clarity as to what clinical problems the discussion of best practices applies.

> Draft topics list: 1) introduction; 2) low back (including subluxation) and low back related extremity conditions; 3) cervical spine (including subluxation), headache and neck related extremity conditions; 4) thoracic conditions (including subluxation); 5) upper extremity disorders; 6) lower extremity disorders; 7) soft tissue conditions; 8) other nonmusculoskeletal disorders.

Teams will rate the available evidence according to a standardized rating system (see below) and will conduct spot checks of the original literature evaluated by reviews or meta analyses for accuracy and consistency of interpretations as necessary. Teams will consist of a content expert acting as team captain, one member of the commission, and a minimum of three other members selected from nominees from members of the CCGPP and stakeholders. A separate team of experts on overlapping issues (e.g. physiological therapeutics and technology assessment) will serve as consultants for each of the other topic teams.

Developing Recommendations

The key stages in developing recommendations on best practices should include the following:

1. Methodological evaluation using the checklist tools (e.g. STARD, MOOSE, QURUM etc.)
2. Synthesis of evidence with development of evidence tables as necessary.
3. Considered judgment looking at the volume and quality of evidence, consistency, applicability and clinical impact.
4. Grading of the evidence.

Rating of Evidence

The process of scientific investigation has been widely accepted as the best means to minimize the likelihood of fooling oneself. The quality of evidence arising from investigations can be rated based on the degree to which each report meets the broadly accepted tests of internal and external validity based on the care and attention to detail demonstrated by investigators in their work. Over the past three decades, the methods of systematic evaluation of evidence have evolved and are in broad use. The following evidence ratings have been adopted by the Commission of CCGPP as a guide and basis for evaluating evidence based on the current American College of Physicians PIER (Physician's Information and Education Resource). The PIER language has been modified as appropriate to address relevant diagnostic studies as noted below.

Evidence rating:

Clinical trials / evidence on treatment

A - The method of treatment is supported by at least one good randomized controlled trial, a meta analysis or the preponderance of evidence considered individually or in a systematic review.

AB – The method of treatment is supported by at least one good randomized controlled trial and by cohort, case-control, observational studies or case series.

B – The method of treatment is based on research data that are less compelling than a randomized controlled trial (e.g. cohort, case-control, or observational studies, case series)

BC – The method of treatment is based on research data that are less compelling than a randomized controlled trial (e.g. cohort, case-control, or observational studies, case series) and on expert opinion or consensus, or on historically, generally accepted standards of clinical practice not based on evidence.

C – The method of treatment is based on expert opinion or consensus, or on historically, generally accepted standards of clinical practice not based on evidence.

Diagnostic tests

A – The method of evaluation / diagnosis is supported by at least one study or of systematic reviews of studies meeting standards for reporting diagnostic accuracy; validating cohort studies with good reference standards; validated clinical decision rules; and studies which measure post-test probabilities.

B – The method of evaluation / diagnosis is supported by exploratory cohort studies with good reference standards; instrumentation studies of reliability and validity.

C - The method of evaluation / diagnosis is supported by non-consecutive studies without appropriate reference standards; case control studies.

D - The method of evaluation / diagnosis is supported by expert opinion or consensus; case reports or clinical science prevailing knowledge.

Individual CCGPP teams may adopt modifications of these definitions to meet needs imposed by the search question and literature under consideration. In each case, the definitions used will be explicitly listed.

Common Issues:

There are a few over-arching issues that apply to all of the areas that are to be reviewed as described in the section titled Topic Areas. They include benchmarking of care (natural history & process-of-care evaluation, case complexity & risk stratification), physiologic therapeutics, documentation and technology assessment.

Benchmarking

Benchmarking care has been attempted in a number of ways. Non-professional observers who are focused on economical constraints frequently

use issues of frequency and duration of care as sole criteria. Contrasting the individual patient's recovery rate to population data on natural or treatment history has also been used. The problem with isolated quantitative benchmarks using number of visits and duration of care is that it ignores the individual case risk factors and complexity. In addition to these pitfalls, the use of natural history is widely misunderstood as more recent understanding of the natural intermittency and more extensive chronicity than was reported in the 1980s and early 1990s has largely been ignored. It is a reasonable assertion that there are only three outcomes to treatment of compliant patients: alternatively, the patient improves in a timely manner, there is no change or the patient condition deteriorates. The direction in which the case progresses is dependent upon the appropriateness of care administered, the complexity of the case and the intervention of factors outside the control of the provider and sometimes the patient. These factors cannot be assessed with simple comparisons. Rather, they require an assessment of the documented process of care. This asks if the attending doctor is responding in his/her evaluation and management of the case (process of care) to the circumstances with reasonable clinical efforts to intervene with appropriate diagnostics, altered treatment plans or referral. Where the process of care is reasonable, it is counterproductive for third party intercession to hinder, stop or alter care. It is the intent of the CCGPP to assist stakeholders in reaching agreement and promoting best practices in the process of care and to facilitate improved outcomes for patients by optimizing the chance of recovery and minimize the administrative interference that can result in disruption of continuity of appropriate care while encouraging provider due-diligence in pursuing appropriate care.

The "Real" Natural History of Low Back Pain

Press (World Spine III, 2003) pointedly surveyed the difference between early and modern evidence on the natural history, at least for low back pain. Each team will address the modern evidence as available for their topic area. Using LBP, the more common complaint observed in a chiropractic setting as being illustrative, this section will discuss the implications of the current understanding of natural history on the process of care.

Early evidence suggests that 40-50% of back pain is improved in one week and 85-90% in 6 – 12 weeks (Berquist-Ullman). As much as 90% of cases have been estimated to resolve without intervention (Dixon). While true to the extent studied in early sample populations, it provides an incomplete picture of prognosis. Von Korff (1996) [21]has shown that a significant amount of even acute LBP patients have persistent pain if followed for 1 to 2 years. As many as 62% of those patients will have one or

more relapses during a one-year follow-up of an index episode and 40% will still have LBP at 6 months (Phillips & Grant, 1991). Initial relapses tend to occur at six to seven week intervals, with a decreasing number of cases suffering renewed pain each time. While 95% of patients may have returned functionally to near pre-episode function within 6 months, 31% continue to suffer pain with those activities[22] . In the most recent studies [23,24] [25] worker's compensation injury patients were tracked for a one-year interval while recording symptom severity and work status. While 50 percent experienced no work time loss within the first month after injury, 30 percent of them had work absence because of their injury at the end of one year. Moreover, of those who had work absence within the first month (12%) and had returned, an additional 19% had absence later in the year. Clearly, reports of return to work experience at one month that are in general use do not capture the chronic, episodic nature of back problems. Many patients who appear to have improved and returned to stable employment continue to experience subsequent injury-related symptoms and work absences. Thus, assuming the typical case mix attended by an individual practitioner, the presence of symptoms and impairment beyond 12 weeks may be as high as between 31% to 40%, not the typical 10% often quoted.

Moreover, recent evidence shows that there is a significant difference in the morbidity of neck and back pain for women, at least in the aging population {Hartvigsen J., Christensen, et al. 2004 2356 /id}. Overall patients, as age progresses, the prevalence of low back pain is 15%, neck pain 11% and combined low back and neck pain 11%.

Complexity and Risk Stratification

Ideally, there should be no dispute over the complexity of a case if the attending physician has compiled adequate and appropriate historical and diagnostic documentation. In a simple example, it is well known that patients with uncomplicated low back pain generally improve more quickly than a patient who also has radicular leg pain [26]. Medicare widely recognizes the complicity of comorbid disease in retarding expected treatment response in the management of subluxation. Prior history, comorbidity, traumatic causation, ergonomic and environmental conditions, age, fitness and psychosocial factors are among the constellation of factors that may influence patient recovery. Documentation of these factors and relevant comorbid diagnoses can help anticipate prolonged recovery and help focus resource use to those more in need. Teams will assess the relevant factors for their topic area and provide an assessment of the level of evidence available to support or refute them.

In general, the complexity of an individual case may be assessed by observation of its factors. Much emphasis has been given to psychosocial factors, tending to overshadow biomechanical or physical factors as risk for low back pain [27]. While the recognition of worker satisfaction and other psychological factors represent a contribution to the understanding of managing spine disorders, the intensity by which it has been invoked is misplaced. Psychosocial factors are able to explain only 15% of the problem associated with incidence and recurrence of back pain complaints. A dispassionate review of the literature shows substantial effect of biomechanical factors including interaction between physical and psychosocial effects [28]. Together they identify factors of causation, recurrence and delayed recovery. The following points, summarized by McGill [29] are relevant:

- Biomechanical risk factors are linked to both the incidence of first-time low back complaints, absenteeism and subsequent episodes.
- Psychosocial factors are more important to subsequent episodes of back pain.
- Tissue damage can initiate a chain of events resulting in pain and activity intolerance that may affect some patients for as long as ten years.
- Mechanical tissue damage is often unable to be determined by modern imaging and testing procedures but are apparent on dissection/surgery [30]

Some confirmed risk factors for injury, absenteeism and subsequent episodes of spine pain.

CATEGORY	FACTOR
Personal	Age (older)[23;24;31]
	Gender (female [23;24;25]
	Severity of symptoms[23;24;25]
	Leg pain > back pain[25;26]
	Increased spine flexibility[32]
	Reduced muscle endurance [32;33]
	Prior recent injury (< 6 months) including surgery[23;24;29;34 25;35;36 37 26;38]
	Prior surgery[37 38]
	Asymmetric atrophy of multifidus up to 5 years later[39 40]
	Abnormal joint motion with or without abnormal emg function of medial spine extensors[41]
	Poor body mechanics[34]
	Falling as mechanism of prior injury[29 42]

Biomechanical	**Prolonged static posture > 20 degrees (odds ratio 5.9)[43]**
	Poor spinal motor control[44]
	Vehicle operation > 2 hours per day[45]
	Sustained (frequent / continuous) trunk load > 20 lbs[45]
	Materials handling (Static work postures, frequent bending and twisting, lifting demands, pushing, pulling and repetitive exertion)[29]
Psychosocial	**Condition chronicity**
	Employment history (<5 years same employer)[23;24 25]
	Employment satisfaction[27]
	Lower wage employment[25]
	Family / relationship stress[27]
	Attorney retention
	Expectations of recovery

Caution is necessary in considering risk factors. Practice experience shows that many patients with significant risk factors respond well to treatment and achieve significant improvement and return to function. Best practices are intended to guide treatment planning and provide the greatest likelihood of benefit for the majority of patients. Patients with a significant number of risk factors warrant close observation and quick reaction if treatment response is below expectations.

Process of Care

Donabedian[46] has suggested that development of quality for therapeutically necessary care requires a triad of elements (structure => process => outcome). Past efforts to evaluate quality of care in individual cases was by performing peer review. While peer review in complex cases may have a role, the consistency and reliability of opinions between reviewers has been shown to be poor (0.40)[47]. Patients deserve good processes of care as well as favorable outcomes. Significant relationships [48] between processes and outcomes exist. Effective process provides the best opportunity for good outcome by ensuring that realistic expectations exist and appropriate treatment pathways have been attempted for patients whose response is lower than expected. Realistic expectations are derived from adequate diagnosis and documentation of risk factors and active comparison of the clinical course under care with benchmarks. . Health care is only one determinant of health and other factors have important effects on health outcomes, such as nutrition, environment, lifestyle and poverty[49]. Process of care effectively translates, in the individual case, to the manner in which the doctor responds to the characteristics and constellation of factors unique to each case. How is the doctor reacting to patient process? How is he or she coordinating and organizing resources to address the problems? How has the patient been assessed? What avenues of treatment have been considered? What rationale has been

used? Process of care illustrates an episode of care to assess appropriate resource use within a practice[50]. It encourages a patient centered practice, using provider experience in conjunction with evidence to create effective treatment strategies for reducing the cost per episode of care and optimizing quality while moving from managing costs to managing the care process[50]. Ahton et al [51] have shown that process management has substantial validity and greater inter-rater reliability in measuring the quality of care.

For therapeutically necessary care, provider behavior is an important component in all performance measures[52]. Management of a care episode has only three alternative outcomes: a) the patient progresses favorably and in reasonable similarity to relevant benchmarks; b) the patient's progress is below expected benchmarks and the provider has interceded with appropriate diagnostic or therapeutic modifications in response; or c) the result of patient's care is outside the bounds expected by appropriate benchmarks and appropriate action has not been taken. Appropriate processes of care result in documentation of risk factors, setting realistic expectations and altering the course of treatment to accommodate. Where appropriate process is or has been followed, then provider decision-making should not be questioned[53].

Physiologic Therapeutics

Physiologic therapeutics and their application span the gamut of musculoskeletal complaints. As such, the review of evidence can become redundant across topic areas. The CCGPP process will provide a team of content experts who will serve as resource persons to the other teams in formulating comments regarding the evidence on the use of various modes for treatment of different regions and the specific disorders that affect them, as may be appropriate.

Technology Assessment

As review of common disorders and treatments progresses, it may be necessary to review new or existing technologies more prevalent in use within the chiropractic profession and for which there may be a lack of knowledge or evidence external to the profession. Each team will evaluate the relevance of technology to their topic areas. Where appropriate, technology assessment will be independently conducted following standard and widely recognized methodologies [54].

Dissemination, Review and Revision

It is widely recognized that evidence changes with time and the commitment of resources to study the effects of care. The CCGPP is working with other professional organizations, both inside and outside the profession, who are experienced in dissemination of guidelines / best practices to make the Commission database available to the broadest group of stakeholders. The potential of a broadly disseminated database on best practices that has strong professional input is to minimize the variation in the interpretation of the evidence and the means by which the evaluation of practice is conducted.

While the Commission of the CCGPP is actively pursuing its work on establishing the database, the Council is establishing the means of broad stakeholder review. By modularizing the process, the Commission believes it will be more efficient to periodically review and update the database as sufficient circumstances may dictate.

...and if there is no evidence?

The CCGPP recognizes both the humanitarian charge to doctors to alleviate patient suffering, the social responsibility for managing resources responsibly and the occasional ethical conflict that may arise between these two priorities in a given case. As a result, the CCGPP adopts the positions of Sackett[55] and of Sox[56] (in recommendations for provider considerations when guidance is absent.

1. **Review and summarize available studies.**
2. **Biological thinking may help. Is it physiologically plausible?**
3. **Be sure that current thinking is based on valid evidence. Trust differences in subgroup results only when the intervention works unambiguously in one and fails utterly in another.**
4. **Costs do matter.**
5. **Primum No Nocere. "Many believe that this principle has particular force when applied to healthy persons. . . when we are in doubt we should take special care to avoid actions that might cause harm."**
6. **Talk to the patient**
7. **Plan for the usual, adapt for the unusual. Algorithms are applied to usual patients and modified for unusual patients. Patient care decisions should be made on an individual basis.**

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BEST PRACTICES: CHIROPRACTIC MANAGEMENT OF LOW BACK PAIN AND LOW BACK RELATED LEG COMPLAINTS

- DRAFT FOR STAKEHOLDER CRITIQUE -

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Scope: Low back pain and low back related leg pain.

Chronicity range: acute, subacute, chronic and recurrent

Applicable ICD codes: 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

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. Relevant sources that inform on issues of outcome measures, diagnosis, technology assessment, natural/treatment history and prognosis and risk stratification will be reviewed.
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. Unique or particularly current diagnostic methods will also be considered.

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:

- Diagnostic –
  - Patient history
  - Physical, manual and laboratory examinations
  - Plain film radiographs
  - Advanced or specialized imaging
  - Computerized range of motion
  - Surface EMG
  - Spinal ultrasound
- Therapeutic
  - Assurance and advice
  - Bed rest
  - High velocity, low amplitude manipulation, mobilization and massage
  - Exercise
  - Selected modalities
  - Medical / surgical referral

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 70 RCTs, 12 guidelines and 14 systematic reviews

Additional TBC* sources were identified as the team's work sent for format editing and summarized under a section entitled "As yet, not rated".

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

Multidisciplinary panel review and rating of
- Published Meta-Analyses & Systematic Reviews
- Cohort studies
- Case series
- Diagnostic studies

Review of evidence on natural history, complexity and risk factors

Methods to formulate conclusions

Two strategies were used in consolidating and rating the literature: a) 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 in motion. Initial conclusions, herein, are being submitted for stakeholder review. Comments will be reviewed and responded to by the team. Final conclusions with comments and responses released.

*** TBC = To be clarified**

Primary conclusions: **Summary of conclusions and strength of evidence ratings with page numbers for reference to the discussion of review of the evidence from the low back and related leg pain team (conclusions and strength of evidence ratings are preliminary, to be reviewed for final determination pending review of stakeholder comments and submitted documentation and clarification.)**

	(Conclusions exclude patients with RED Flag findings)	
TOPIC	Conclusion and Strength of Evidence Rating	Page(s)
Assurance and advice to stay active	– B, Supported by fair evidence from relevant studies	43, 46, 48, 49, 53
Adjustment / Manipulation / Mobilization		44 - 55
Acute low back pain		46 – 48
(< 6 weeks duration)	Backschool – C, Not supported by limited evidence from studies or reviews.	50, 46
	Manipulation – A, Supported by good evidence from relevant studies.	47, 55
	Specific exercise – A, Not supported by fair evidence from relevant studies.	46, 58 – 61
	McKenzie maneuvers – C, Supported by limited evidence from studies or reviews.	47, 61
	Lumbar supports/corsets – Not supported as a primary therapy but better than no therapy. B: Supported by fair evidence from relevant studies.	53, 56 – 58
	Bed rest for 2-4 days – A, Supported by good evidence from relevant studies.	43
	Ice or heat – An option for pain relief and relaxation prior to using other documented treatments. C: Supported by limited evidence from studies or reviews. In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs.	46, 56 – 58
	Transcutaneous electrical nerve stimulators (TENS), short-wave diathermy, massage, ultrasound, interferential therapy– Not supported as a primary therapy. C, Supported by limited evidence from studies or reviews. In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs.	46, 56 – 58
	Referral for injections – A: Supported by good evidence from relevant studies. .	47, 61
Subacute low back pain		48 – 49
(6 to 12 weeks)	Assurance and advice to stay active – B, Supported by fair evidence from relevant studies	48, 43
	Manipulation – A, Supported by good evidence from relevant studies.	49, 55
	Customizable exercise programs – B, Supported by fair evidence from relevant studies. Intensive training for severe pain – C, Supported by limited evidence from relevant studies.	48, 58 – 61
	TENS – C, Not supported by limited evidence from	48, 58

	studies or reviews.	
	Lumbar supports/corsets – C: Not Supported by limited evidence from studies or reviews	48, 56
	Bed rest for 2-4 days – B, Not supported by fair evidence from relevant studies	48, 43
	Backschool – C, Not supported by limited evidence from studies or reviews	56
Chronic low back pain		49 - 52
(>12 weeks)	Assurance and advice to stay active in activities of daily living (ADL) – B, Supported by fair evidence from relevant studies	49, 43
	Manipulation – A, Supported by good evidence from relevant studies. .	52, 55
	Massage – B: Supported by fair evidence from relevant studies but is considered less effective than high-velocity, low amplitude (HVLA) manipulation/mobilization.	50, 55
	Traction – B: Not supported by fair evidence from relevant studies.	50, 57
	Exercise – A, Supported by good evidence from relevant studies. Multi-disciplinary rehabilitation for severe back pain with functional loss and for post-surgical rehabilitation	51, 58 – 61
	Back School - A short program that minimizes the number of sessions may be appropriate for patients who clearly need rehabilitation. C, Supported by limited evidence from studies or reviews	50, 56
	TENS, Short-wave diathermy, massage, ultrasound, interferential therapy– a closely monitored, short-term trial of modalities that raise or lower tissue temperature, temporarily reduce tissue sensitivity and / hypertonicity may be appropriate to help the patient tolerate use of documented manual and / exercise methods of care in patients that have locally high nociceptive pain levels . In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs. C, Supported by limited evidence from studies or reviews.	53, 56 – 58
	Lumbar supports/corsets – C: Supported by limited evidence that rigid supports may provide more improvement than supports without rigid inserts.	53, 56
	Bed rest for 2-4 days – B, Not supported by fair evidence from relevant studies	53, 43
Sciatica/radicular/ radiating leg pain		53 – 54
	Assurance and advice to stay active in ADL – B, Supported by fair evidence from relevant studies	53, 43
	Manipulation – C, Supported by limited evidence from studies or reviews.	54, 55
	Bed rest for 2-4 days – C: Supported by limited evidence from studies or reviews	53, 43
	Ice or heat – Supported as an option for acute pain relief and relaxation prior to using other documented treatments. C: Supported by limited evidence from relevant studies.	53, 56 – 58

	Short-wave diathermy, massage, ultrasound – a closely monitored, short-term trial of modalities that raise or lower tissue temperature, temporarily reduce tissue sensitivity and / hypertonicity may be appropriate to help the patient tolerate use of documented manual and / exercise methods of care in patients that have locally high nociceptive pain levels . In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs. C: Supported by limited evidence from studies or reviews.	53, 56 – 58
	TNS – I: No recommendation can be made because of insufficient or non-relevant evidence.	53, 58
Massage	Supported by emerging evidence for massage as an effective treatment for subacute and chronic low back pain. C: Supported by limited evidence from studies or reviews.	55,
Backschool	Not supported for acute or subacute back pain. Insufficient to recommend their use for chronic low back pain. A short backschool program that minimizes the number of sessions may be appropriate for patients who clearly need rehabilitation. C: Supported by limited evidence from studies or reviews	56,
Lumbar supports/corsets	Only better than no treatment and for rigid supports in chronic back pain. C: Supported by limited evidence from studies or reviews.	56,
Modalities	a closely monitored, short-term trial of modalities that raise or lower tissue temperature, temporarily reduce tissue sensitivity and / hypertonicity may be appropriate to help the patient tolerate use of documented manual and / exercise methods of care in patients that have locally high nociceptive pain levels . In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs. D, Supported by expert opinion, and usual and customary clinical practice.	56 – 58
Traction	B: Not supported by fair evidence from relevant studies.	57
Diathermy	See “Modalities” above.	57
Ultrasound	See “Modalities” above.	57
Electrical stimulation	See “Modalities” above.	58
Exercise	Not supported for acute back pain, B. Supported for subacute (B), chronic back pain (A) and post-surgical rehabilitation, (C).	58 – 61
Referral / comanagement	Discectomy supported for patients with nerve root symptoms due to disc herniation that persist despite conservative management. A, Supported by fair evidence from relevant studies.	61
	Chemonucleolysis supported as an option but less efficacious than discectomy. B, Supported by fair evidence from relevant studies.	61
	Epidural steroid injections are supported for acute low back and radiating leg pain with nerve deficit. B, Supported by fair evidence from relevant studies.	61
	Cases with high severity of symptoms may benefit by referral for comanagment of symptoms with medication. –	61

	B, Supported by fair evidence from relevant studies.	
Diagnostics		63 – 68
Patient history for red flags	A: Supported for suspicion of cancer (Age > 50, history of cancer, unexplained weight loss, unrelieved pain on bed rest, persistent pain > 1 month)	63 – 65
	A: Supported for suspicion of infection (IV drug use, urinary tract infection, skin infection, age > 50)	63 – 65
	A: Supported for suspicion of cauda equine syndrome (difficulty with micturition, loss of anal sphincter tone, fecal incontenance, saddle anesthesia, progressive leg motor weakness, gait abnormality)	63 – 65
	A: Supported for suspicion of fracture (Age > 70, corticosteroid use, recent trauma history)	63 – 65
	A: Supported for suspicion of spinal stenosis (Reduced walking distance, non-radicular leg pain)	63 – 65
Manual examination for red flags	B: Supported by fair evidence from relevant studies for localization of pain.	63 – 65
Physical examination for red flags	A: Supported by good evidence from relevant studies for evaluation of infection (Fever, vertebral tenderness), disc herniation with sciatica (straight leg and crossed straight leg raise)	63 – 65
Laboratory examination for red flags	A: Supported by good evidence from relevant studies for evaluation of suspected cancer (ESR > 20mm)	65
Computerized ROM	D: Supported by expert opinion, and usual and customary clinical practice. for documenting functional capacity during rehabilitation in appropriate patients.	65
Full spine plain film x-ray	Supported in scoliosis evaluation; Optional in evaluating complex biomechanical aberration and multi-level disorders; Not supported for routine screening or diagnosis of pathologic conditions. B: Supported by fair evidence from relevant studies	65
Plain film x-ray	Supported when consistent with history & physical findings suggesting degenerative conditions, inflammatory conditions, fracture, neoplasm and infection; Not supported for initial screening of uncomplicated low back pain. A: Supported by good evidence from relevant studies.	65
Specialized imaging	MRI or CT: Optional for patients with non-responsive, deteriorating or lingering symptoms after 4 weeks. A: Supported by good evidence from relevant studies.	66
Spinal ultrasound	C: Not supported by limited evidence from studies or reviews.	66
Surface EMG	B: Not supported as a diagnostic tool by fair evidence from relevant studies	67
Videofluoroscopy	B: Not Supported by fair evidence from relevant studies	67

Process Description

A schematic of the process followed in developing the conclusions for best practices is given in Figure 1. Process development was guided by experience of Commission members with the RAND consensus process, Cochrane collaboration , AHCPR and published recommendations{National Health and Medical Research Council 1999 4118 /id} 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:

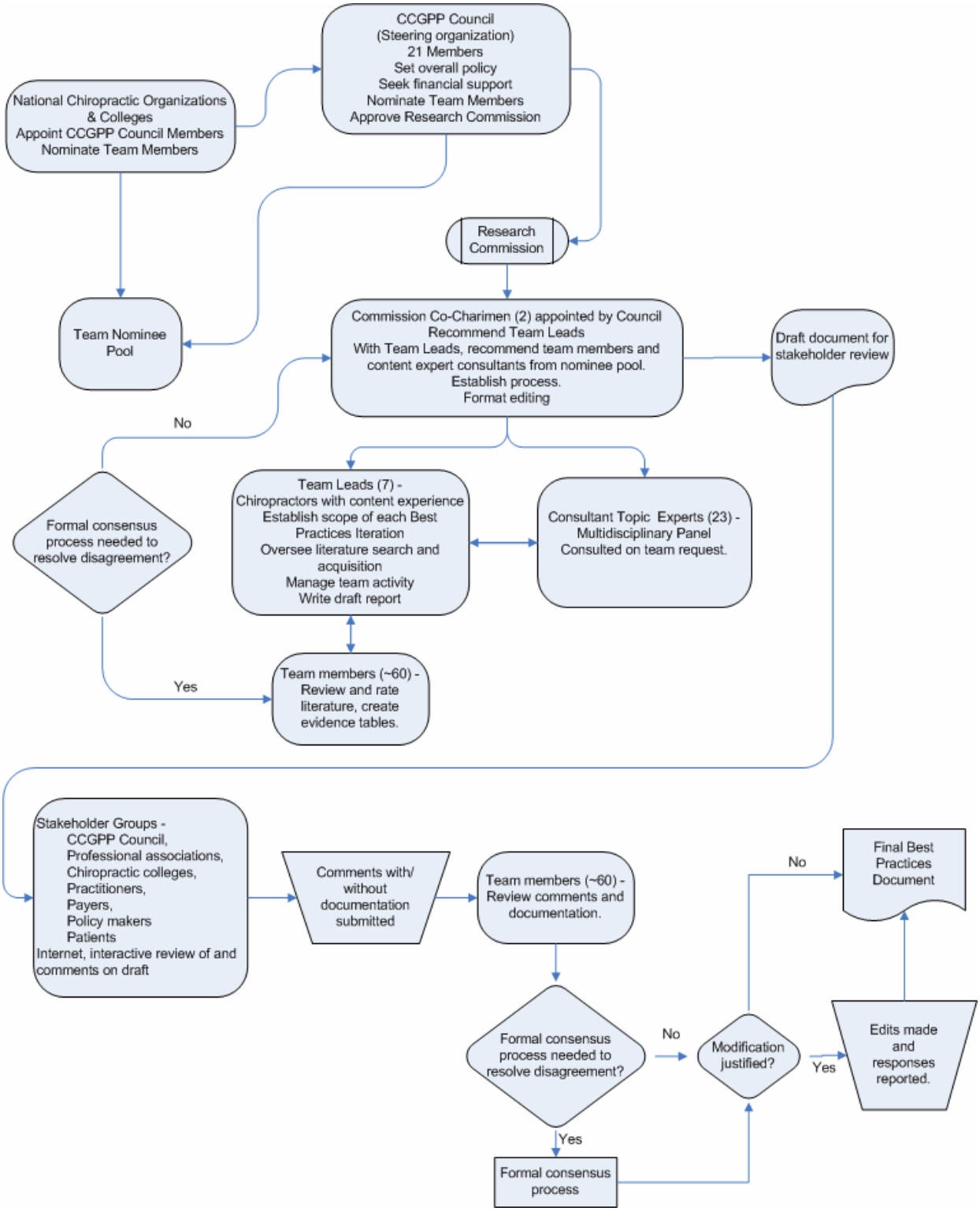
Balancing patient-centered and evidence-based values imparts similar internal tensions with tendency for the best intent of individuals to succumb to training biases and personal preferences (See Appendix Table A4). Four strategies were used to minimize this problem while empowering legitimate and informed 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, based on Delphi and Nominal Group 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. Finally, others address more general health problems, prevention and special populations{McDonald 2003 4078 /id}{Sarnat & Budgell 2005 4116 /id}. 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.

Figure 1: CCGPP flow chart describing the process of best practices development.



The Council on Chiropractic Guidelines and Practice Parameters (CCGPP) and its organizational structure are described in the Introduction (to be added in final draft). Representing its constituent member organizations, the Council approved a listing of disorders by ICD9-CM codes (Table L1) 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 (Table L2) and the list was given to the CCGPP Research Commission who used it to bound the literature searches within each domain. The domain for this report is that of low back pain and low back-related leg symptoms. Using surveys of the profession{McDonald 2003 4078 /id}{Christensen, Kerkoff, et al. 2000 1489 /id},{Christensen, Kollasch, et al. 2005 4117 /id} and publications on practice audits {Hurwitz, Coulter, et al. 1996 723 /id}{Hurwitz E.L., Coulter I.D., et al. 0 369 /id}{Coulter I. & Shekelle P. 2005 3730 /id}, the team selected the topics for review by this first 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 L1: Applicable ICD9-CM codes used as boundaries for disorders to be addressed, as set by the CCGPP Council, to provide clarity as to what clinical problems the discussion of best practices applies.

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

Table L2: Practice domains identified for grouping of similar conditions for searching the literature and reporting of best practices.

Best Practice Domain	***Team Lead***
Introduction	John J. Triano, DC,PhD,FCCS(C)
Low back pain and related disorders of the lower extremities	William C. Meeker, DC, MPH
Neck pain, headache and neck related disorders of the upper extremities	Donald Murphy, DC
Thoracic spine and costovertebral joint disorders	Jeffrey Cates, DC, MS
Upper extremity disorders	Thomas Souza, DC
Lower extremity disorders	Stephen Perle, DC, MS
Soft tissue disorders	Gordon Lawson, DC, MS
Wellness, non-musculoskeletal disorders, prevention and special populations	Cheryl Hawk, DC, PhD

Team selection and orientation training of team leaders

The CCGPP Council appointed two 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 members 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 best practice synthesis, designed to address as well as possible the practical problem of care for individual patients, it was necessary to cast a wider net for literature collection than often 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 (See Table L1).

The central questions for management of low back and related lower extremity symptoms that were posed included;

1. Is there evidence for or against the effectiveness of common chiropractic treatment methods?
2. Is there evidence of clinical utility, sensitivity/specificity, validity and appropriateness for the common diagnostic methods used by chiropractors?
3. Is there evidence to help risk stratify or estimate complaint complexity and to inform appropriate management and process of care?

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{Bombardier, Bouter L.M., et al. 2004 4119 /id}, but was modified to accommodate the needs of CCGPP (See the Appendix). 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. Professional librarians from several members of the Association of Chiropractic Colleges were available both to assist the team in literature search and obtaining copies of articles not available electronically.

Forming Conclusions from the Evidence

Two strategies were used in consolidating and rating the literature: a) Rate and accept /reject existing published reviews of the various types, independently reviewing the underlying literature if the rating was considered substandard and b) 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; 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 14 guidelines, 70 RCTs and 13 systematic reviews/meta analyses and11 chohort studies.

Minimally clinically important change

Debates have raged on how important clinical changes reported in studies may be. Such discussions are a clear example where interpretation bias (See Table A4) becomes apparent. In evaluating the relative importance of results, current literature was used to set judgment of clinically important differences at 20 points for pain (using a 100mm VAS) and 10 points for improvement in function {Bombardier, Hayden, et al. 2001 4073 /id}{Salafi, Silvestri, et al. 2004 4072 /id}. In this report, minimally clinically important change criteria were explicitly applied only in the literature for exercise.

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 (AppendixTable A4). 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.

The CCGPP best practices effort summarizes both past and recent literature, up through 2004, attempting to minimize bias through the use of standardized criteria by multiple assessors. Where disagreement on rating was identified between assessors, formal Delphi process was used to reach consensus. Standardized ratings were accomplished by first matching the type of literature to the appropriate scoring system before random distribution to the team members.

More recent relevant literature, appearing as this report has been compiled, have been summarized in a separate section identified “Literature as yet not rated” in order to be as current as possible. These latter reports will be rated in the next iteration.

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. The individual instruments applied by the team are provided in the Appendix of this report.

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 (see the Appendix) 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{Bronfort, Haas, et al. 2004 3489 /id} and by way of participation as an author with the Cochrane collaboration{Bombardier, Bouter L.M., et al. 2004 4119 /id} 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{Petrie, Grimshaw, et al. 1995 4120 /id} 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. Copies of the instruments used are available in the Appendix. A brief review of the features for each of the methods used to rate RCTs follows.

The Bronfort method consists of eight items, each with three choices: yes (+), partial (P), or no (-). One point is given for a yes, half a point for a partial, and no points for a no. Criteria for scoring accompany each entry. The point total is divided by 8 and them multiplied by 100 to create a 100-point scale. The eight 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;
- The 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 are given for each treatment arm of the study.
- All the subjects are analyzed using an intention to treat analysis);
- Multisite studies have comparable reporting methods at all sites.

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 two 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{Appraisal of Guidelines for Research & Evaluation [AGREE] instrument 2001 4121 /id}

instrument for rating guidelines and MOOSE rating system for systematic reviews/meta analyses. These can be found in the Appendix as Tables 7 and 8. 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{Stroup, Berlin, et al. 2000 4122 /id} evaluates thirty-four 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. Must be included in evidence tables and as a reference(s) for best practices.**

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 diagnostic tests - a systematic review of studies meeting standards of reporting diagnostic accuracy; or at least 1 study meeting standards of diagnostic accuracy, including cohort studies with good reference standards.
- 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. Must be included in evidence tables and as reference(s) for best practices.**

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 major 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.
- For diagnostic tests, exploratory cohort studies with good reference standards, or instrumentation studies of reliability and validity.
- For a question of harm or adverse events, the evidence might consist of 2 or more independent case control studies with similar conclusions and minimal bias and research design flaws.

GRADE C: **Supported by limited evidence from studies or reviews. Do not include in evidence tables but as reference(s) for best practices.**

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.

- For diagnostic studies, the evidence might consist of non-consecutive studies without appropriate reference standards and case control studies unconfirmed by other studies.
- For a question of harm, the evidence might consist of results from a single case control study, or case series.

GRADE D:
Details: **Supported by expert opinion, and usual and customary clinical practice. Include as reference(s) for best practices.**
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, a position statement from a national body without citations of the results of research studies, and single case reports.

GRADE I: **No recommendation can be made because of insufficient or non-relevant evidence. It should not be included in evidence tables or as reference(s) for best practices.**
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 data bases, 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{Shekelle P., Morton, et al. 2003 4123 /id} 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.

Use of Consensus (to be completed with final draft after stakeholder input)

Considered judgment (To be added following stakeholder review input.)

Stakeholder review and implementation

Stakeholder review of best practices is a critical step to facilitate final recommendations and implementation. This process affords the opportunity for individuals and groups that can be impacted by best practices to provide comment and documentation for consideration by the team. Stakeholders for the low back and related lower extremity symptoms are considered to include doctors of chiropractic, students and prospective students, educators and teaching institutions, professional organizations and agencies, third-party payers, governmental agencies and patients.

Three separate strategies have been used to inform interprofessional stakeholders on progress during the development of the best practices document. By providing periodic updates, colleges, associations and providers were made aware of the pending release for review and comment. The three methods included 1) periodic articles published in interprofessional news media, 2) presentations at the Association of Chiropractic Colleges, the Federation of Chiropractic Licensing Boards meetings, and 3) providing a speaker's bureau for use in presentations to state professional association meetings.

Two strategies were used to reach stakeholders for review and comment on the document itself. On completion of the draft document of best practices, a summary of the best practices document was posted on a widely accessed health care web site (Spine-health.com) that experienced a public hit rate of 2.5 to 3.0 million per month during 2005. Separately, on the CCGPP web site, the document was posted and notification made to colleges, state and national associations and third-party payers.

Interactive electronic questionnaires, developed by the Dissemination, Implementation, Evaluation and Review (DIER) Committee of CCGPP are available for stakeholder comments on-line. Those choosing to comment are invited to submit documentation for their opinions directly to CCGPP. The postings will be maintained for 60 days and comments harvested electronically and provided to the co-chairs of the Commission. The co-chairs will group similar comments and develop summary questions that will be posed, with the original comments and any supportive documentation, to the team for review and response. A tally of comments by group along with the questions and responses from the team will be made a part of the Appendix in the final document release.

The final document will reflect any changes in conclusions of the team made in response to stakeholder input.

Audit and Review

As noted earlier, the best practices effort of the CCGPP is designed as an iterative process. The low back and related lower extremity best practices document is intended to be reviewed with inclusion of any new evidence and extension of the domains considered on a 2 to 5 year cycle, depending on the state of the art in the literature. (Details on Audit and Review to be completed in conference with the DIER committee following the stakeholder review and comments.)

Best Practices 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 three parties: providers, patients and third-party payers. After nearly two 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.

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.

Brief Review of methods used for this work: (see the earlier methods section 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. 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, validated and structured instruments for rating the quality of and results from the literature.
3. Formal consensus process, based on Delphi and Nominal Group 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.

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 that they help discern best practices. Best practices are defined as being those decisions and actions that reduce symptoms, improve function, optimize individual involvement in patients' own health while having an awareness of costs.

An Ongoing Work in Progress:

This is a first 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. As a result, rules were agreed upon in advance to guide the scope of each iteration, moving from the most common disorders, diagnostic methods and treatments to the less common.

Rated Literature:

The search strategy used by the team identified a total of 13 guidelines, 14 systematic reviews, 66 RCTS and 11 cohort studies.

Literature on Assurance and Advice

The search strategy employed by the team was that developed by van Tulder et al {van Tulder M.W., Assendelft, et al. 1997 4126 /id} 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{Hagen, Kilde, et al. 2004 4125 /id} 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 {Bronfort, Jacobsen, et al. 2004 4128 /id}. The review was considered to be of high quality and was recommended by the team.

The Danish work found four systematic reviews (including Hagen{Hagen, Kilde, et al. 2004 4125 /id}) and four additional randomized trials and six sets of guidelines. The conditions for which evidence was available included acute low back pain and sciatica. The Cochrane review by Hilde et al {Hilde, Hagen, et al. 2002 4137 /id} 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{Waddell, Feder, et al. 1997 4138 /id}. 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 six guidelines included in the Danish review{Bronfort, Jacobsen, et al. 2004 4128 /id} (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 four 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 the best practices 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. For more detailed review of biomechanical characteristics, see the reviews by Kawchuk et al{Kawchuk G.N. & Herzog W. 1993 663 /id} and Triano{Triano .J. 2000 1421 /id}.

The team found that the recent systematic review by Bronfort et al{Bronfort, Haas, et al. 2004 3489 /id} (Quality score 88), which covered literature up to the year 2002, and its findings should be adopted. The team elected to separately rate fifty-two papers published since 2002 and including a number not captured within Bronfort's criteria.

Bronfort's review covered thirty-one randomized trials (25 addressed manipulation alone, 3 mobilization and 3 addressed them together) from a cull of an original forty-six. 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 (see the Appendix) and was 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 (12)- 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 (13)- 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 (14). Meade (15, 16)- contrasted manipulation and hospital care, finding greater benefit for the manipulation group over both short and long term periods. Finally, Doran and Newell (17) treated a mixed pain group and found that SMT resulted in greater improvement than physical therapy or corsets.

The randomized clinical trials (RCTs) rated independently, their reference numbers and quality scores are listed in the Appendix as Table A9. The results for each are summarized in the paragraphs that follow. Some of these RCTs overlap with those considered by Bronfort et al{Bronfort, Haas, et al. 2004 3489 /id}. For convenience, the team has grouped the literature by chronicity and body region.

Acute low back pain

Sick list comparisons

Seferlis (99) 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 (100) 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 six-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).

Backschool programs

The Danish systematic review{Bronfort, Jacobsen, et al. 2004 4128 /id} examined two international sets of guidelines and three systematic reviews of back school programs for acute low back pain (Quality Score- TBC). Studies were of poor quality and the evidence was insufficient to recommend their use for acute low back pain.

Physiological therapeutic modality and exercise comparisons

Hurley and colleagues (101) tested the effects of manipulation combined with interferential therapy compared to either modality alone. Their results showed all three 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 (103) found no differences between groups at the 2-3 week observation time frame (Quality score- 19).In the study by Rasmussen (107), 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{Bronfort, Jacobsen, et al. 2004 4128 /id} examined twelve international sets of guidelines, twelve systematic reviews and ten 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). Similarly, lumbar corsets or supports had minimal evidence of benefit only over no treatment. Ice and heat, locally applied for pain relief showed temporary benefit.

Sham and alternate manual method comparisons

Hadler's study (102) 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 (102,113) demonstrated that there was a benefit for a single session of manipulation

compared to a session of mobilization (Quality score- 69). Erhard (104) 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 (106) 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 (108) compared 2 different forms of manipulation for low back pan 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 (111) (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 (112). 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 (109), 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(17). 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 (110) 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 (105) 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 (114) 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).

The Danish systematic review{Bronfort, Jacobsen, et al. 2004 4128 /id} examined three systematic reviews and three international guidelines on injections for low back pain (Quality Score- TBC). They concluded that there was insufficient evidence to support use of facet, ligamentous or muscle injections for treatment of acute back.

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 (93) 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 (92) 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"(95,96). 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 (97) 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 two 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{Bronfort, Jacobsen, et al. 2004 4128 /id} examined twelve international sets of guidelines, twelve systematic reviews and ten 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 (94) 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 (98) 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 (94) 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 (82) 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 (84), 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 (85) 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 on 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 (86) (Quality Score- 43). Further work by the same group (87) 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). Mead and associates (15) observed that chiropractic treatment was more effective than hospital outpatient care, as assessed using the Oswestry scale (Quality score- 31). Rupert (90) performed an RCT in Egypt that compared three 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 (78). 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).

Backschool Programs

The Danish systematic review{Bronfort, Jacobsen, et al. 2004 4128 /id} examined five international sets of guidelines and three systematic reviews of back school programs for chronic low back pain (Quality Score- TBC). Studies were of poor quality and the evidence was insufficient to recommend their use for chronic low back pain. A short backschool program that minimizes the number of sessions may be appropriate for patients who clearly need rehabilitation.

Physiological therapeutic modality comparisons

A negative trial for manipulation was reported by Gibson (79) (Quality score- 38). Detuned diathermy was reported to achieve better results over manipulation, although there were baseline differences between groups initially. Koes (85) 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 (86) (Quality Score- 43). Despite the fact that many patients in the non-manipulation groups received additional care (87) 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 (88) 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{Mathews, Morkle, et al. 1988 4139 /id} found that manipulation hastened recovery from low back pain more than the control did (SIGN rating- no).

Two systematic reviews and four international guidelines were evaluated by the Danish review group {Bronfort, Jacobsen, et al. 2004 4128 /id} for effects of modalities(Quality Score- TBC). Study quality was poor. There is insufficient evidence to recommend use of lumbar supports, physical agents/modalities, TENS or traction as {Harvey, Burton, et al. 2003 2403 /id}primary treatment for acute low back pain. Usefulness of modalities that temporarily reduce tissue sensitivity to help the patient permit manual methods in patients that have high nociceptive pain levels remains a common practice that is untested.

Exercise modality comparisons

Hemilla (72) 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 (73) 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 (76) 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 (77) found no differences between manipulation, exercise or back education in reducing either pain or disability (Quality score- 6). Aure (82) 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. This result persisted for both the short term and the long term (Quality score- 81.25). In the paper by Niemisto and colleagues (84), 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{Harvey, Burton, et al. 2003 2403 /id} 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{Lewis, Hewitt, et al. 2005 4140 /id} found improvement occurred when patients were treated by combined manipulation and spinal stabilization exercises versus a that seen through use of a 10-station exercise class (SIGN rating- yes).

The Danish systematic review{Bronfort, Jacobsen, et al. 2004 4128 /id} examined twelve international sets of guidelines, twelve systematic reviews and ten 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 (78) 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 (80) 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 (13)- found that no real significant value for HVLA over back school or myofascial therapy (Quality score- 63). In the study by Licciardone (83), 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 (47) (Quality score- 44). In the work of Kinalski (89), 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 (81). 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 (74) demonstrated that HVLA led to greater short-term improvements in pain and disability than did chemonucleolysis for managing disc herniation (Quality score- 38). Bronfort (75) 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 (91). 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).

The Danish systematic review{Bronfort, Jacobsen, et al. 2004 4128 /id} examined five systematic reviews and three international guidelines on injections for low back pain (Quality Score- TBC). They concluded that there was insufficient evidence to support use of facet, ligamentous or muscle injections for treatment of chronic back.

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 (118). 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 (116). 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 (116). Outcomes from manipulation were better for neurological and motor function as well as disability (Quality score- 18.75). Postacchini (118) 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 (119) 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 (76). 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).

Five systematic reviews and three international guidelines were evaluated by the Danish review group {Bronfort, Jacobsen, et al. 2004 4128 /id} for effects of modalities(Quality Score- TBC). Study quality was poor. There is insufficient evidence to recommend use of lumbar supports, physical agents/modalities, TENS or traction as primary treatment for acute low back pain. Usefulness of modalities that temporarily reduce tissue sensitivity to help the patient permit manual methods in patients that have high nociceptive pain levels remains a common practice that is untested. Heat and cold therapy may be useful for pain management and reduction of localized muscle tension prior to using other treatment methods.

Exercise modality comparisons

In the case of low back pain following laminectomy, Timm (117) 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 (76) 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 (115) 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 (118). Medication management fared better than did manipulation when radiating leg pain was present (Quality score- 6). Conversely, for the work of Mathews and colleagues (119) 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). The Danish systematic review{Bronfort, Jacobsen, et al. 2004 4128 /id} examined eight systematic reviews and three international guidelines on radiation leg pain (Quality Score- TBC). They concluded that epidural steroid injections can provide

relief for patients with radiating leg symptoms. Considering the potential for significant but uncommon risks, they might be considered only after the patient fails other pain management efforts. Insufficient evidence was found to support use of facet, ligamentous or muscle injections for treatment of acute or chronic radiating leg pain.

Disc herniation

Nwuga (120) 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 (46) 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).

The Danish systematic review{Bronfort, Jacobsen, et al. 2004 4128 /id} examined two Cochrane systematic reviews on surgery that covered twenty-seven studies: one for lumbar disc herniation and the second for chemonucleolysis (Quality Score- TBC). They concluded that there is good evidence to support discectomy for carefully selected patients with nerve root symptoms from disc herniation that persist inspire of non-surgical management. Chemonecleolysis is a less invasive option in contrast to discectomy. While better than placebo, it appears less effective than discectomy.

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 grade 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 comanagment 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 paper to support a higher rating (Rating: C).**

Massage and soft tissue treatments

The Danish team headed by Bronfort{Bronfort, Jacobsen, et al. 2004 4128 /id} conducted a systematic review of soft-tissue treatments (Quality Score-TBC). They found two systematic-reviews of massage that covered eight studies. Their conclusion suggested that there is emerging evidence for massage as an effective treatment for subacute and chronic low back pain. Often, information on massage was indirect as it was used as a control or alternate treatment in trials targeting other therapies. For example, von Buerger (106) examined soft-tissue massage as an alternative to manipulation for acute low back pain. He reported that the manipulation group responded better than the soft-tissue group (Quality score- 31). Similarly, Godfrey et al (103) found no differences between groups at the 2-3 week observation time frame (Quality score- 19).

One RCT each was reported by the Danish group, for muscle energy techniques and for proprioceptive neuromuscular facilitation. Muscle energy seemed to perform better than a control group receiving no treatment and proprioceptive neuromuscular facilitation was better than Williams flexion exercise in the short term. Despite the positive results in each, the group considered that there was insufficient evidence to make a determination.

Backschool

The Danish team headed by Bronfort{Bronfort, Jacobsen, et al. 2004 4128 /id} conducted a systematic review of backschool. They found three systematic reviews and five international guidelines regarding treatment of acute back pain. A total of three systematic reviews and two guidelines were available on treatment of chronic pain. Wide variation in the format and information contained in backschool programs was found. Information on anatomy and function as well as modern strategies to stay active and avoid fear-avoidance may be the more effective. In the presence of inconsistent evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs. A short backschool program that minimizes the number of sessions may be appropriate for patients who clearly need rehabilitation.

Lumbar supports / corsets

Doran and Newell involved a combination of individuals with pain of less than 1 week and more than 4 weeks (17). One treatment arm used lumbar

corsets, which performed the same as other treatments over time (Quality score- 25). Coxhead et al (76) showed supports were less effective compared to manipulation in the short term for chronic low back pain (Quality score- 25).

For acute low back pain, one systematic review and three guidelines were identified by Bronfort et al {Bronfort, Jacobsen, et al. 2004 4128 /id} (Quality Score-TBC). None of the studies included on review were primarily interested in corset effectiveness and a mix of both acute and chronic patients was the rule for most of them. Corset use for acute low back pain was considered to provide some pain relief versus no treatment but not better than when provided with other treatment. Conflicting evidence was present for use to improve disability in comparison to other treatment. The recommendations from international guidelines were similar with three of the four reported suggesting that there is no evidence of clinical benefit from corset use.

A single systematic review was identified that examined corset/support use for chronic low back pain. Again, most studies included were a mixed population of acute and chronic. Conclusions were mixed on effectiveness with limited evidence that rigid supports may provide more improvement than supports without rigid inserts.

Physiological & therapeutic modalities

The literature on modality use as a primary treatment is sparse and generally of poor quality. Often, information is indirect from use of these treatments as alternate control groups for study of other therapies. These methods, historically are widely used and controversial. Based on consensus and a single guideline recommendation{Bronfort, Jacobsen, et al. 2004 4128 /id} (Quality Score – TBC), a closely monitored, short-term trial of modalities that raise or lower tissue temperature, temporarily reduce tissue sensitivity and / hypertonicity and help the patient tolerate use of documented manual and / exercise methods of care in patients that have high nociceptive pain levels may be appropriate. In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs.

Traditional traction

Mathews et al (Mathews W, Morkle M, Mathews J. Manipulation and traction for lumbago and sciatica: physiotherapeutic techniques used in two controlled trials. Phys Pract 1988;4:201-206) examined traction as one form of treatment for low back pain and radiating leg pain(SIGN rating- no). Traction was not effective in providing relief.

Based on one systematic review and four international guidelines identified by the Danish group{Bronfort, Jacobsen, et al. 2004 4128 /id} (Quality Score-TBC), conflicting results were reported for traction use in acute back pain. The systematic review, relying on two low quality studies, concluded that there was limited support for use while two of the guidelines reflected that there was insufficient evidence to reach conclusion and the other two recommended against its use.

For chronic back pain, one systematic review was identified{Bronfort, Jacobsen, et al. 2004 4128 /id} which found no basis for traction to be used in these patients. These recommendations were in agreement with the three international guidelines reviewed.

All of the literature discussed here concern traditional traction and not more recently developed axial decompression technologies, which are yet to be reviewed.

Diathermy

Two guidelines have reviewed the evidence with respect to diathermy in acute low back pain patients, as reported by Bronfort{Bronfort, Jacobsen, et al. 2004 4128 /id} (Quality Score-TBC). Diathermy had no effect on outcome, but suggested that heat be considered for pain relief for localized muscle pain, or for initial pain relief and relaxation prior to using other documented treatment methods.

In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs.

Ultrasound

Two guidelines have reviewed the evidence with respect to ultrasound in acute low back pain patients, as reported by Bronfort{Bronfort, Jacobsen, et al. 2004 4128 /id} (Quality Score-TBC). Results were mixed. One guideline found no evidence of benefit. The second found no evidence of use as a primary therapy but suggested that heat be considered for pain relief for localized muscle pain, or for initial pain relief and relaxation prior to using other documented treatment methods. For chronic low back pain, there was no evidence of benefit from ultrasound.

In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs.

Electrical stimulation

Hurley and colleagues (101) tested the effects of manipulation combined with interferential therapy compared to either modality alone. Their results showed all three groups improved function to the same degree, both at 6 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 (103) found no differences between groups at the 2-3 week observation time frame (Quality score- 19). Pope's study (92) demonstrated that manipulation offered better pain improvement than did transcutaneous electrical nerve stimulation (Quality score- 38).

Acute low back pain, with or without radiating leg pain, treated with TENS was covered in one systematic review and three guidelines identified by the Danish work{Bronfort, Jacobsen, et al. 2004 4128 /id} (Quality Score-TBC). Low quality studies with conflicting results were reported. In the case of chronic low back pain, one systematic review of three high quality studies showed no benefit. Conclusions of three guidelines ranged from recommendation against use, one that could not determine a recommendation and one that gave limited support for use of TENS for some chronic low back pain patients.

In the absence of evidence, clinicians should consider treatments that have minimal side effects, are acceptable to patients, and have reasonable costs.

Exercise

Exercise is one of the most well studied forms of treatment for lowback 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{Hayden, van Tulder, et al. 2005 4148 /id} (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 L3 to reach its conclusions.

Table L3: 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), seven 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; two 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, two 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 about exercise:

"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 three-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 seven 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."

A complete list of papers covered by the Cochrane review are included in Appendix 2.

The Danish{Bronfort, Jacobesen, et al. 2004 4128 /id} group review of exercise was able to identify five systematic reviews and 12 guidelines that discussed exercise for acute low back pain, one systematic review and 12 guidelines for subacute, and seven systematic reviews and weven guidelines for chronic. Further, they identified one 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 four to six weeks after disk surgery over light exercise programs.

Referral / Comanagment

Bronfort et al{Bronfort, Jacobesen, et al. 2004 4128 /id}(Quality score- 82) have reviewed the results of surgery for herniated discs. Relying on a Cochrane review of 27 studies on discectomy and 16 on chemonucleolysis. They concluded that discectomy is efficacious for carefully selected patients with nerve root symptoms due to disc herniation that has failed to respond to conservative management. In addition, a chemonucleolysis is a less invasive intervention second only to discectomy in effectiveness.

Additional review of interventional anesthesia (injection) procedures was carried out by Bronfort{Bronfort, Jacobesen, et al. 2004 4128 /id}. They identified one systematic review suggesting limited evidence favoring epidural steroid injections (ESIs) for acute low back pain with nerve root pain and radicular neurologic deficit, not responding to conservative management. Two international

guidelines both reached similar conclusions but failed to find evidence support for ESIs for acute back pain or for trigger point, ligamentous or facet injections as treatment methods. None of these procedures was considered useful for chronic low back pain based on contradictory but mostly negative results.

Treatment literature as yet unrated

Material appearing since 2004 that has been collected but not yet rated by the CCGPP process is summarized below.

As noted under the rated literature section, Bronfort et al{Bronfort, Haas, et al. 2004 3489 /id}Bronfort conducted a review of the literature through 2002 with findings supportive of the use of high velocity, low amplitude manipulation (HVLA) or mobilization at various stages of back pain chronicity. In 2006 the Cochrane collaboration reissued an earlier (2004) review of SMT for back pain performed by Assendelft et al{Assendelft, Morton, et al. 2006 4127 /id}. This reported on 39 studies up through 1999, several overlapping with those reported by Bronfort et al{Bronfort, Haas, et al. 2004 3489 /id}, using different criteria and a novel analysis. They report no difference in outcome from treatment with manipulation versus alternatives. As several additional RCTs have appeared in the interim, the rationale for reissuing the older review without acknowledging new studies was unclear.

Descarreaux et al (23) have extended the work of Haas et al examining the relationship of treatment dosage and duration. They treated two small groups of patients for four weeks (three times per week) after first receiving two baseline evaluations separated by four weeks. One group then received treatment every three weeks whereas the other did not. While both groups had lower self-reported disability (Oswestry) scores at twelve weeks, at ten months the improvement only persisted for the extended SMT group.

Muller and Giles (15) evaluated HVLA procedures in contrast with medication and acupuncture groups. Manipulation led to greater improvement in outcome measures (frequency of back pain, pain scores, Oswestry, and SF-36) compared to one for the other two interventions. Improvements lasted over one year. Weaknesses of the study were use of a compliers-only analysis as intention to treat for the Oswestry and VAS scales were not significant.

Harrison et al{Harrison, Cailiet, et al. 2002 4151 /id} reported a nonrandomized cohort controlled trial of treatment for chronic low back pain consisting of three point bending traction designed to increase curvature of the lumbar spine. The experimental group received HVLA for pain control during the first three weeks (nine treatments) into the protocol. The control group received no treatment. Follow-up at a mean of 11 weeks showed no change in pain or

curvature status for the controls but a significant increase in curvature and reduction of pain in the experimental group. Average number of treatments to achieve this result was 36. Long-term follow-up at 17 months showed retention of benefits. No report of relationship between clinical changes and structural change was given.

Santilli and colleagues{Santilli, Beghi, et al. 2006 4141 /id} have studied the effects of HVLA versus soft-tissue pressing without any sudden thrust in patients with moderate acute back and leg pain. HVLA procedures were significantly more effective in reducing pain, reaching a pain-free status, and the total number of days with pain. Clinically significant differences were noted. The total number of treatment sessions was capped at 20 on a dosage of five times per week with care depending on pain relief. Follow-up showed relief persisting through six months.

Four treatment arms contrasted outcomes for care models in work by the Hurwitz group. Chiropractic care with and without use of modalities and medical care with and without physical therapy formed the treatment groups. The improvements in pain, disability and 18-month risk of remission were a little greater for the chiropractic group over the medical group. Differences were not considered clinically important. A greater likelihood of patient-perceived improvement was associated with chiropractic care.

Recent work has shown that patient confidence and satisfaction with care are related to outcomes (17, 18, 99). Seferlis (99) found that patients were more satisfied and felt that they were provided better explanations about their pain from practitioners who utilized manual therapy. Regardless of treatment, highly satisfied patients at four weeks were more likely than less satisfied patients to perceive greater pain improvement throughout 18-month follow-up in a study by Hurwitz et al (18). Goldstein and Morgenstern (19) found a weak association between treatment confidence in the therapy they received and greater improvement in low back pain. A frequent assertion is that benefits observed from application of manipulation methods are a result of physician attention and touching. Studies directly testing this hypothesis were conducted by Hadler et al (20) in acute patients and by Triano et al (21) in subacute and chronic patients. Both studies compared manipulation to a placebo control. In Hadler, the control balanced for provider time attention and frequency while Triano et al also added an education program with home exercise recommendations. In both cases, results demonstrated that while attention given to patients was associated with improvement over time, patients receiving manipulation procedures improved more quickly.

Literature on Diagnostics

History, Physical and Laboratory Examination

The purpose of the history is to elicit patterns of symptoms and signs that might indicate serious pathology and, coupled with the physical examination, may determine the appropriate course of treatment and calm patients' concerns{Bronfort, Jacobesen, et al. 2004 4128 /id}{Haldeman S., Chapman-Smith D., et al. 1993 1369 /id}{Henderson D., Chapman-Smith D., et al. 1994 526 /id}. The Danish systematic review{Bronfort, Jacobesen, et al. 2004 4128 /id} summarizes important history findings for specific pathologic causes of lower back or leg pain where advanced evaluation should be considered. Such conditions are often heralded by "Red" or "Yellow" flags (See Tables A2 and A3 in the Appendix). Table L4 {Bronfort, Jacobesen, et al. 2004 4128 /id} lists the conditions of greatest concern and their historical and physical exam findings with highest reliability and/or sensitivity and specificity.

Table L4: Summary of important history and examination findings for specific pathologic causes of low back pain. (Adapted from {Bronfort, Jacobesen, et al. 2004 4128 /id}).

Pathology	Historical Factor	Physical Exam Finding
Cancer	Age > 50 History of cancer Unexplained weight loss Pain unrelieved or aggravated by bed rest Pain > 1 month Failure to improve with 1 month of conservative care	ESR > 20 mm
Infection	Intravenous drug use Urinary tract infection Skin infection Age > 50	Fever Vertebral tenderness
Cauda Equina Syndrome / Widespread neurological disorders	Difficult micturition Fecal incontinence Progressive motor weakness	Reduced sphincter tone Saddle anesthesia Gait disturbance
Fracture	Age > 70 Corticosteroid use Recent history of trauma	Focal tenderness / swelling at the suspected fracture site.
Ankylosing spondylitis	Posterior pelvic pain / lower back pain > 3 months Morning stiffness Relief with exercise	Restricted chest expansion Reduced lateral flexion HLAB-27 ESR > 20 mm

		ANA +
Spinal Stenosis	Age > 65 Bilateral, non-radicular leg pain Reduced walking distance Relief by stooping or sitting	Positive stoop test Pain free stationery bicycling Treadmill test < 5 min Wide based gait Modified Romberg test
Disc herniation	Radicular pain	Straight leg raise test Crossed straight leg raise test Motor weakness
Psychosocial factors	Work dissatisfaction Marital stress Exaggerated / unrealistic symptoms	Nonanatomical pain drawings Waddell signs

Literature on Diagnostics – Computerized Range of motion (ROM)

Computerized range of motion: A number of digital versions of inclinometers are available for use in assessing range of motion. These are more precise than the standard mechanical goniometers or inclinometers{Boline, Keating, et al. 1992 4129 /id} that have been shown to be reliable for use in the clinical setting{Stude, Goertz, et al. 1994 4130 /id}{Chiarello & Savidge 1993 4131 /id}. They do not, however, overcome intersubject variability from movement to movement. Such instruments have clinical utility in documenting restrictions of motion associated with disability or for quantifying function at the inception of and follow-up during intense exercise/rehabilitation programs.

Literature on Diagnostics – Plain Film Radiography

The Mercy document{Haldeman S., Chapman-Smith D., et al. 1993 1369 /id} notes that plain films are considered an adequate initial step in the evaluation of certain conditions affecting the low back, including degenerative or inflammatory conditions, fracture, neoplasm and infection. Full-spine films may be used for evaluating scoliosis, as well as complex biomechanical aberrations and multi-level problems, but should not be used for routine screening or diagnostic analysis. In general, the use of plain film radiography for cases on uncomplicated low back pain is not recommended, as the procedure offers little diagnostic utility.

The American College of Radiology guidelines{Beachley 2002 4143 /id} (Quality Score- TBC) provides a concise review of indications for plain film radiology summarized in Table L5.

Table L5: Indications that apply generally and to specific anatomic regions.

Anatomical Region	Indications
All regions	Significant trauma Painful and limited motion Suspected malignancy Suspected arthritis Suspected congenital anomaly or syndromes associated with anomaly of the spine Suspected instability
Cervical	Shoulder or arm pain suspected from radiculopathy Occipital headache
Thoracic	Radiating chest pain Suspected osteoporosis Suspected spinal fracture Deformity evaluation
Lumbopelvic	Pain radiating into the legs Suspected osteoporosis Suspected spinal fractures Deformity evaluation Childhood limp or refusal to bear weight Childhood hip pain

Special studies may be appropriate when history and exam suggest specific disorders. For example, a) bilateral oblique views when cause of extremity symptoms is suspected to be a foraminal stenosis, b) flexion-extension lateral views when regional instability is suspected and c) articular pillar views for suspected pillar fracture.

Literature on Diagnostics – Specialized Imaging

Both MRI and CT remain important imaging modalities for the spine. MRI has the added advantage of avoiding ionizing radiation. Both modalities are excellent for imaging the spine and related structures. The American College of Radiology guidelines{Jarvik, Bowen, et al. 2001 4144 /id} (Quality Score- TBC) provides a concise review of indications for plain film radiology summarized in Table L6. MRI of the spine is a useful tool for the evaluation and assessment of severity for diseases of the spine, spinal column and vasculature.

While spinal MRI is one of the most sensitive diagnostic tests for detecting anatomic abnormalities results may be misleading if not closely correlated with the history and clinical examination, or physiologic tests.

Table L6: Indications that apply for differential diagnosis of the following conditions:

Disc protrusion / extrusion

Extradural soft tissue and bony neoplasms
Intradural extramedullary masses
Intramedullary tumors
Intrinsic spinal cord pathology
a) Demyelinating disease
b) Inflammatory conditions
Spinal vascular malformations and/or vertebral artery disorders (MRA procedures)
Spinal infections
a) Disk space infection
b) Vertebral osteomyelitis
c) Epidural abscess

Literature on Diagnostics – Spinal Ultrasound

Spinal ultrasound: Ultrasound has the advantages of being non-invasive, quick to be completed, low cost and safe. While its use for imaging the abdomen is established{Stine, Avila, et al. 1988 4132 /id}{Coleman 1985 4133 /id}, its use for imaging musculoskeletal system is much less so. It appears to have its best use in evaluating muscles and related structures{Van Holsbeek & Inrocaso 1991 4134 /id}, e.g., one condition in which it has shown promise is with regard to tears of the rotator cuff{Drakeford, Quinn, et al. 2006 4135 /id}. In uncomplicated low back pain its use would be experimental at best{Haldeman S., Chapman-Smith D., et al. 1993 1369 /id}.

Literature on Diagnostics – Surface EMG

The team review of the literature found no new evidence to support clinical utility of surface EMG as a diagnostic technology beyond that observed by Haldeman et al{Haldeman S., Chapman-Smith D., et al. 1993 1369 /id} and Henderson et al{Henderson D., Chapman-Smith D., et al. 1994 526 /id}. Insufficient evidence is available to recommend its use.

Literature on Diagnostics – Videofluroscopy

Few chiropractors have access to the technology which allows for videofluoroscopy. Its value is in the evaluation of spinal motion, but to do so effectively requires a digitization process and internal reference frame and modern image intensifiers. Only with such technology can inter-vertebral angular motion patterns be accurately measured in routine clinical settings. Then, reliability in individual subjects can be judged from the variance of their averaged inter-vertebral angles and by observing automated image registration{Breen, Muggleton, et al. 2006 4136 /id}. There is insufficient evidence of clinical utility in diagnosing spinal pain syndromes in routine practice settings at this time{Spitzer, LeBlanc, et al. 1987 1361 /id}.

Diagnostic literature as yet unrated

Gilbert et al{Gilbert, Grant, et al. 2004 4145 /id} conducted a randomized controlled trial on the influence of MRI results on diagnosis, treatment planning and outcomes of care. Patients with continuing symptoms who received an MRI within the first three months of the onset of their problem had better outcomes from treatment. Counterintuitively, there was not a statistically significant difference in the diagnoses or the treatment plans between the care before and after the imaging was performed. Rather, provider and patient confidence and commitment to the treatment plan were altered, leading to statistically significant improvement in outcomes.

Number of sources rated by the interdisciplinary team of reviewers and used in formulating conclusions of chiropractic best practices.

	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 rates 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 one week, while nearly 90% of it will be gone by 12 weeks (22). Even more, Dixon demonstrated that perhaps as much as 90% of low back pain will resolve on its own, without any intervention whatsoever. (23). Von Korff (24) demonstrated that a significant amount of acute low back pain patients will have persistent pain if they are followed out to two years.

Phillips (25) found that nearly four out of ten people will have low back pain after an episode at six months from onset, even if the original pain has disappeared, because over six in ten will have at least one relapse during the first year following an episode. These initial relapses occur within eight 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 (26). 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 (27), 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 (28), 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 (29). 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 (30) 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 (31). 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 (32) 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. (33). 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 (34). 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

Ijelenberg and Burdof 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{Ijelenberg & Budof 2005 4149 /id}. 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{Jarvik, Hollingsworth, et al.

2005 4150 /id}. They found the use of MRI to be a less important predictor of LBP than depression.

What are the relevant outcome measures?

The Canadian Guidelines (35) 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.

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. Activity 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 (36) Thus, it seems that either will report meaningful and reliable information when used in trials of manipulation for low back pain.

Patient Perception Outcomes: Another important set of outcomes are 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 0-100 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 which describe the quality of pain. From the results, 6 different pain variables can be determined.

Borg Pain Scale: This is a VAS which 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 (37). 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). (38). Dan Cherkin noted that the Visit Specific Satisfaction Questionnaire can be used for chiropractic outcome assessment. (39)

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.).

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 (40) found the use of the rangiometer moderately reliable.
- Nansel (41) found that using five repeated measures of cervical spine motion with an inclinometer to be reliable.
- Liebenson (42) found that the modified Schrober technique, along with inclinometers and flexible spinal rulers, had the best support from the literature.
- Triano and Schultz (43) 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 (41,44-47).

Thermography: Thermography is a method of measuring the heat radiated from the human body, using a system that involves either a thermocouple or more sophisticated computer technology systems. It does not appear to be a reliable method for assessing the function of the lumbar spine and the procedure has not been used as an outcome for an RCT involving spinal manipulation and low back pain.

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 (13,48, 49).

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 (13), and other studies have shown the dynamometer to have good reliability (50).

Posture: In a small number of studies, posture has been used as an outcome for changes following manipulation (51; 52). 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 (53-58).

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 (59).

Radiography: The concept of chiropractic spinography has long been a part of chiropractic practice. By using standard radiography and by marking or measuring specific points and landmarks on the spine, it is possible to look for evidence of change over time or to look for evidence of time specific alterations in bony position. One example of such a measurement is the atlanodental interspace, which ought to measure a certain amount but when widened may indicate the presence of damage to ligaments at the atlas and dens. There are many such measurements, and few have been studied for validity and reliability. However, their use as a means to determine where and when to adjust the spine is a long-accepted part of many chiropractic practices. There are a few studies which show that there are changes in these measurements following adjustment (60-62), and at least two that showed no such change (63,64).

The above papers address vertebral position. It is also possible to examine abnormal motion using radiographic means; however, again the evidence on reliability is scant to absent (51,65,66).

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 (67). Fisher found increases in tissue compliance with subjects involved in physical therapy (68). Waldorf looked at prone segmental tissue compliance and found that the procedure had a good test/retest variation of less than 10% (69).

Pain tolerance can also be assessed using these means. The procedure has been found reliable for doing so (66,70) and Vernon found it was a useful measure in assessing the cervical paraspinal musculature after adjusting (71). The Canadian Chiropractic Guidelines group concluded that “the assessments are safe and inexpensive and appear to be responsive to conditions and treatments commonly seen in chiropractic practice.” (35)

Electromyography: EMG provides a means by which one can measure actual muscular activity. The are two ways to do so, one involving the use of needle placement and one using surface means alone. With regard to the latter, while this is a procedure that has a certain level of popularity in the chiropractic profession, its use is not supported by a significant body of literature or research. One of the problems it faces is that it cannot be very muscle specific, assessing all electric signals at play in the body at any given time. Further, in terms of managed care, many organizations will not pay for the procedure, nor will they credential people who use it. Needle EMG is beyond the scope of chiropractic in all but a handful of states; however, curricula and training programs have been offered by a few chiropractic colleges which lead to certification in its use (National University of Health Sciences, Texas College of Chiropractic). Its use as an outcome is therefore limited to those with the training to use it and in research settings.

STAKEHOLDER COMMENTARY

We thank you for reading this chapter draft. References for the lower back draft follow on subsequent pages. At this point, stakeholders are requested to please complete a short list of questions and also provide additional comments, if appropriate, on the CCGPP survey site

http://www.surveymk.com/s.asp?u=617621934097

Team Doc – Body ref list

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Team Doc – Bronfort Refs used
Evidence tables. [Additional evidence tables can be found in Bronfort (11)].

Definitions/Descriptions of Headings for Evidence Tables.

• **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 (ie, "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 (ie, "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

Team Doc – "Appendices" titles to be revised.
REF **Appendix 1. Papers included in Cochrane review of massage therapy for non-specific low back pain. (N>9, since one paper reports data over 2 periods of time in additional papers).**

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Appendix:

Table A1: Applicable ICD Codes

720.0	Ankylosing Spondylitis
720.2	Sacroiliitis, not elsewhere classified
721.15	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 of sacrum
724.8	Others symptoms referable to back
724.9	Other unspecified back disorders
728.85	Spasm of muscle
737.30	Scoliosis (or kyphoscoliosis), idiopathic
738.4	Acquired spondylolisthesis
739.3	Nonallopathic lesion, not elsewhere classified- Lumbar region
756.12	Spondylolisthesis
782.0	Disturbance of skin sensation
729.1	Myalgia and myositis, unspecified
739.4	Non-allopathic lesion, not elsewhere classified- Sacral region

Table A2. Clinical suspicion of urgent/emergent "Red Flag" conditions accelerate evaluation and management decision making and differential diagnostic efforts.

Spinal fracture:	New onset pain with history of fall, traumatic injury, lifting accidents, osteopenia.
Cancer:	Prior history of cancer, unexplained weight loss, pain increased by rest or nonresolving with usual care.
Infection:	Nonresolving pain or new pain with elevated temperature, unexplained pulse and respiratory increase or aberrant white blood cell count.
Cauda Equina Syndrome:	Neurological sequelae such as bowel or bladder dysfunction, loss of sphincter tone or saddle paresthesia/anesthesia.
Rapidly progressing neurological deficit:	Patient history or direct observation of increasing neurological symptoms that may be consistent with myelopathic or peripheral neuropathy origin.
Constant progressive non-mechanical pain:	Red flags may include limb motor weakness or other signs of poly/mononeuropathy or of internal disorders with somatic pain components.
Unexplained weight loss:	Suggestive of undiagnosed cancer, chronic infectious or disorders associated with cachexia/wasting such as chronic pulmonary disease, digestive disorders, endocrine disease and mental conditions, among others.
Drug use:	Abuse of prescription use, polypharmacy or recreational drug use
Pain that worsens at night or when the patient lies down:	Suggestive of undiagnosed tumor, systemic metabolic bone or infectious condition.

Table A3. Suspicious "Yellow flags" suggesting undiagnosed pathologic or psychological factors.

Treatment response failure or deterioration	Unsatisfactory restoration of activities
	Failure to return to work
	Lingering or frequently recurring symptoms
	Demand for care e.g. diagnostic tests, medication, passive treatment
Signs of psychosocial overlay/somatization	Waddle signs, discordant pain drawings, family/work discord, failure to respond to appropriate care
Multisite/comorbid pain	Multiple somatic pain, multiple prior surgery, multiple injuries

Table A4: Sources of interpretation bias in the literature.

Type of Bias	Source of Bias	Definition of Bias
Experimental{Sackett 1998 1603 /id}	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{Pittler, Abbott, et al. 2000 4147 /id}	Favored outcome	Author / Editor preference or expectation for a given result
Interpretive{Kaptchuk 2003 4147 /id}	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

Table A5: Bronfort RCT Scoring System {Bronfort, Haas, et al. 2004 3489 /id}

SCORING SYSTEM- BEST PRACTICE PROJECT

Scoring: The critical evaluation list contains eight items with three choices: yes (+), partial (P) and no (-). One point is awarded for a yes rating, a half point is assigned for a partial rating, and 0 points is given for a no rating. The quality score is determined by dividing the point total by 8 and multiplying the result for 100 to create a 100-point scale.

1. Similarity of baseline characteristics to adjusted effects reported.
   Yes: Comparability established by tabulating important predictor variables, including baseline values of outcome variables. If not comparable, adjusted between-group effects computed (e.g., analysis of covariance).
   P: Baseline comparability established for some but not all of the important predictor variables.
   No: Baseline comparability not established, and appropriate statistical adjustments not made or possible.

2. Concealment of treatment allocation.
   Yes: The randomization process and allocation concealment established explicitly and appropriate.
   P: incomplete description of randomization/concealment.
   No: Only randomization established.

3. Blinding of patients.
   Yes: Patient blinded to treatment.
   P: Patient partially blinded or blinding not clearly documented.
   No: Partial blinding or not established.

4. Blinding of provider/attention bias.
   Yes: Provider blinded to treatment.
   P: Partial blinding achieved or documentation that provider enthusiasm/attention equivalent among groups. For example, two providers used such that a blinded provider interacts with the patient and an unblended provider renders treatment.
   No: Provider not blinded and provider enthusiasm/attention not controlled.

5. Blinding of assessor/unbiased outcome assessment.
   Yes: Outcomes assessor blinded to treatment. For self-administered outcomes, patients not influenced by study personnel (e.g., mailed questionnaire).
   P: Partial blinding or influence unclear.
   No: Assessor not blinded. For self-administered outcomes, patients likely influenced by providers or investigators during self-assessment.

6. Dropouts reported and accounted for in the analysis.

Yes: Described for each group separately and impact on outcomes analyzed, or dropout rate less than 5%.

P: Incomplete description/analysis.

No: Not analyzed, or omission not justified.

7. Missing data reported and accounted for in the analysis.

Yes: Described for each group separately and impact on outcomes analyzed or missing data rate less than 5%.

P: Incomplete description/analysis.

No: Not analyzed, or omission not justified.

8. Intention-to-treat analysis/balanced co-intervention.

Yes: All patient data analyzed according to group of initial random allocation. In studies with documented full compliance with allocated treatments, no differential co-intervention between groups.

P: Unclear from article whether intention-to-treat analysis was used and how.

No: No intention-to-treat analysis used when applicable.

Table A6: SIGN RCT Scoring System

S·I·G·N¤	**Methodology·Checklist·2:·Randomised·Controlled·Trials¤**		
Study·identification·(*Include·author,·title,·year·of·publication,·journal·title,·pages*)¶ *****¤			
Guideline·topic:·*****¤		Key·Question·No:·*****¤	
Checklist·completed·by:·*****¤		Date·—·*****¤	
SECTION·1:·–·INTERNAL·VALIDITY¤			
In·a·well-conducted·RCT·study…..¤		*In·this·study·this·criterion·is::¤*	
1.1¤	The·study·addresses·an·appropriate·and·clearly·focused·question.¶ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.2¤	The·assignment·of·subjects·to·treatment·groups·is·randomised¶ ¤	☒·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.3¤	An·adequate·concealment·method·is·used¶ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.4¤	Subjects·and·investigators·are·kept·"blind"·about·treatment·allocation¶ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.5¤	The·treatment·and·control·groups·are·similar·at·the·start·of·the·trial¶ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.6¤	The·only·difference·between·groups·is·the·treatment·under·investigation¶ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.7¤	All·relevant·outcomes·are·measured·in·a·standard,·valid·and·reliable·way¶ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.8¤	What·percentage·of·the·individuals·or·clusters·recruited·into·each·treatment·arm·of·the·study·dropped·out·before·the·study·was·completed?¤	*****¤	
1.9¤	*All·the·subjects·are·analysed·in·the·groups·to·which·they·were·randomly·allocated·(often·referred·to·as·intention·to·treat·analysis)*↵ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
1.10¤	Where·the·study·is·carried·out·at·more·than·one·site,·results·are·comparable·for·all·sites¶ ¤	☐·Well-covered¶ ☐·Adequately·addressed¶ ☐·Poorly·addressed¤	☐·Not·addressed¶ ☐·Not·reported¶ ☐·Not·applicable¤
SECTION·2:·–·OVERALL·ASSESSMENT·OF·THE·STUDY¤			
¤	How·well·was·the·study·done·to·minimise·bias?·How·valid·is·the·study?¶ *Code·+,·n,·or·–¤*	☐·+¶ ☐·n¶ ☐·-¤	

Table A7: AGREE score rating of guidelines

Agree Appraisal Instrument (Guidelines)				
Bibliographic reference of study				
EndNote No. *****				
Author: *****				
Title: *****				
Journal: *****				
Appraiser: *****				
Date: *****				
	Strongly agree - 4	3	2	Strongly disagree - 1
Scope And Purpose				
1. The overall objective(s) of the guideline is (are) specifically described.	☐	☐	☐	☐
This deals with the potential health impact of a guideline on society and populations of patients. The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem. For example, specific statements would be: • Preventing (long term) complications of patients with diabetes mellitus; • Lowering the risk of subsequent vascular events in patients with previous myocardial infarction; • Rational prescribing of antidepressants in a cost-effective way.				
Comments: *****				
2. The clinical question(s) covered by the guideline is(are) specifically described.	☐	☐	☐	☐
A detailed description of the clinical questions covered by the guideline should be provided, particularly for the key recommendations (see item 17). Following the examples provided in question 1: • How many times a year should the HbA1c be measured in patients with diabetes mellitus? • What should the daily aspirin dosage for patients with proven acute myocardial infarction be? • Are selective serotonin reuptake inhibitors (SSRIs) more cost-effective than tricyclic antidepressants (TCAs) in treatment of patients with depression?				
Comments: *****				
3. The patients to whom the guideline is meant to apply are specifically described.	☐	☐	☐	☐
There should be a clear description of the target population to be covered by a guideline. The age range, sex, clinical description, comorbidity may be provided. For example: • A guideline on the management of diabetes mellitus only includes patients with non-insulin dependent diabetes mellitus and excludes patients with cardiovascular comorbidity. • A guideline on the management of depression only includes patients with major depression, according to the DSM-IV criteria, and excludes patients with psychotic symptoms and children. • A guideline on screening of breast cancer only includes women, aged between 50 and 70 years, with no history of cancer and with no family history of breast cancer.				
Comments: *****				
Stakeholder Involvement				
4. The guideline development group includes individuals from all the relevant professional groups.	☐	☐	☐	☐
This item refers to the professionals who were involved at some stage of the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations. This item excludes individuals who have externally reviewed the guideline (see item 12). Information about the composition, discipline and relevant expertise of the guideline development group should be provided.				

Comments:				
5. The patients' views and preferences have been sought.	☐	☐	☐	☐
Information about patients' experiences and expectations of health care should inform the development of clinical guidelines. There are various methods for ensuring that patients' perspectives inform guideline development. For example, the development group could involve patients' representatives, information could be obtained from patient interviews, literature reviews of patients' experiences could be considered by the group. There should be evidence that this process has taken place.				
Comments:				
6. The target users of the guideline are clearly defined.	☐	☐	☐	☐
The target users should be clearly defined in the guideline, so they can immediately determine if the guideline is relevant to them. For example, the target users for a guideline on low back pain may include general practitioners, neurologists, orthopedic surgeons, rheumatologists and physiotherapists.				
Comments:				
7. The guideline has been piloted among target users.	☐	☐	☐	☐
A guideline should have been pre-tested for further validation amongst intended end users prior to publication. For example, a guideline may have been piloted in one or several primary care practices or hospitals. This process should be documented.				
Comments:				
Rigor Of Development				
8. Systematic methods were used to search for evidence.	☐	☐	☐	☐
Details of the strategy used to search for evidence should be provided including search terms used, sources consulted and dates of the literature covered. Sources may include: electronic databases (e.g. MEDLINE, EMBASE, CINAHL), databases of systematic reviews (e.g. the Cochrane Library, DARE), handsearching journals, reviewing conference proceedings and other guidelines (e.g. the US National Guideline Clearinghouse, the German Guidelines Clearinghouse).				
Comments:				
9. The criteria for selecting the evidence are clearly described.	☐	☐	☐	☐
Criteria for including/excluding evidence identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. For example, guideline authors may decide to only include evidence from randomized clinical trials and to exclude articles not written in English.				
Comments:				
10. The methods used for formulating the recommendations are clearly described.	☐	☐	☐	☐
There should be a description of the methods used to formulate the recommendations and how final decisions were arrived at. Methods include for example, a voting system, formal consensus techniques (e.g. Delphi, Glaser technique). Areas of disagreement and methods of resolving them should be specified.				
Comments:				
11. The health benefits, side effects and risks have been considered in formulating the recommendations.	☐	☐	☐	☐
The guideline should consider health benefits, side effects, and risks of the recommendations. For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes. These may include: survival, quality of life, adverse effects, and symptom management or a discussion comparing one treatment option to another. There should be evidence that these issues have been addressed.				
Comments:				
12. There is an explicit link between the recommendations and the supporting evidence.	☐	☐	☐	☐
There should be an explicit link between the recommendations and the evidence on which they are based. Each recommendation should be linked with a list of references on which it is based.				
Comments:				
13. The guideline has been externally reviewed by experts prior to its publication.	☐	☐	☐	☐
A guideline should be reviewed externally before it is published. Reviewers should not have been involved in the development group and should include some experts in the clinical area and some methodological experts. Patients' representatives may also be included. A description of the methodology used to conduct the external review should be presented, which may include a list of the reviewers and their affiliation.				
Comments:				
14. A procedure for updating the guideline is provided.	☐	☐	☐	☐
Guidelines need to reflect current research. There should be a clear statement about the procedure for updating the guideline. For example, a timescale has been given, or a standing panel receives regularly updated literature searches and makes changes as required.				

Comments:				
Clarity And Presentation				
15. The recommendations are specific and unambiguous.	☐	☐	☐	☐
A recommendation should provide a concrete and precise description of which management is appropriate in which situation and for what patient group, as permitted by the body of evidence. • An example of a specific recommendation is: Antibiotics have to be prescribed to children of two years or older with acute otitis media if the complaints last longer than three days or if the complaints increase after the consultation despite adequate treatment with painkillers; in these cases amoxicillin should be given for 7 days (supplied with a dosage scheme). • An example of a vague recommendation is: Antibiotics are indicated for cases with an abnormal or complicated course, however, evidence is not always clear cut and there may be uncertainty about the best management. In this case the uncertainty should be stated in the guideline.				
Comments:				
16. The different options for management of the condition are clearly presented.	☐	☐	☐	☐
A guideline should consider the different possible options for screening, prevention, diagnosis or treatment of the condition it covers. These possible options should be clearly presented in the guideline. For example, a recommendation on the management of depression may contain the following alternatives: a. Treatment with TCA b. Treatment with SSRI c. Psychotherapy d. Combination of pharmacological and psychological therapy				
Comments:				
17. Key recommendations are easily identifiable.	☐	☐	☐	☐
Users should be able to find the most relevant recommendations easily. These recommendations answer the main clinical questions that have been covered by the guideline. They can be identified in different ways. For example, they can be summarized in a box, typed in bold, underlined or presented as flow charts or algorithms.				
Comments:				
18. The guideline is supported with tools for application.	☐	☐	☐	☐
For a guideline to be effective it needs to be disseminated and implemented with additional materials. These may include for example, a summary document, or a quick reference guide, educational tools, patients' leaflets, computer support, and should be provided with the guideline.				
Comments:				
Applicability				
19. The potential organizational barriers in applying the recommendations have been discussed.	☐	☐	☐	☐
Applying the recommendations may require changes in the current organization of care within a service or a clinic which may be a barrier to using them in daily practice. Organizational changes that may be needed in order to apply the recommendations should be discussed. For example: i. A guideline on stroke may recommend that care should be coordinated through stroke units and stroke services. ii. A guideline on diabetes in primary care may require that patients are seen and followed up in diabetic clinics.				
Comments:				
20. The potential cost implications of applying the recommendations have been considered.	☐	☐	☐	☐
The recommendations may require additional resources in order to be applied. For example, there may be a need for more specialized staff, new equipment, expensive drug treatment. These may have cost implications for health care budgets. There should be a discussion of the potential impact on resources in the guideline.				
Comments:				
21. The guideline presents key review criteria for monitoring and/or audit purposes.	☐	☐	☐	☐
Measuring the adherence to a guideline can enhance its use. This requires clearly defined review criteria that are derived from the key recommendations in the guideline. These should be presented. Examples of review criteria are: • The HbA1c should be < 8.0% • The level of diastolic blood pressure should be < 85 mmHg • If complaints of acute otitis media last longer than three days amoxicillin should be prescribed.				
Comments:				
Editorial Independence				
22. The guideline is editorially independent from the funding	☐	☐	☐	☐

body.¤				
Some guidelines are developed with external funding (e.g. Government funding, charity organisations, pharmaceutical companies). Support may be in the form of financial contribution for the whole development, or for parts of it, e.g. printing of the guidelines. There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations. Please note: If it is stated that a guideline was developed without external funding then you should answer "Strongly Agree".¤				
Comments:¤				
23. Conflicts of interest of guideline development members have been recorded.¤	☐¤	☐¤	☐¤	☐¤
There are circumstances when members of the development group may have conflicts of interest. For example, this would apply to a member of the development group whose research on the covered by the guideline is also funded by a pharmaceutical company. There should be an explicit statement that all group members have declared whether they have any conflicts of interest.¤				
Comments:¤				
Would you recommend these guidelines for use in practice?¤				
☐ Strongly recommend ¶ ☐ Recommend (with provisos or alterations)¶ ☐ Would not recommend¶ ☐ Unsure¤				
Other Comments:¤				

Table A.8: Moose score rating of systematic reviews/meta-analyses

Reporting of background should include	
	Problem definition
	Hypothesis statement
	Description of study outcome(s)
	Type of exposure or intervention used
	Type of study designs used
	Study population
Reporting of search strategy should include	
	Qualifications of searchers (e.g., librarians and investigators)
	Search strategy, including time period included in the synthesis and keywords
	Effort to include all available studies, including contact with authors
	Databases and registries searched
	Search software used, name and version, including special features used (e.g., explosion)
	Use of hand searching (e.g., reference lists of obtained articles)
	List of citations located and those excluded, including justification
	Method of addressing articles published in languages other than English
	Method of handling abstracts and unpublished studies
	Description of any contact with authors
Reporting of methods should include	
	Description of relevance or appropriateness of studies assembled for assessing the hypothesis to be tested
	Rationale for the selection and coding of data (e.g., sound clinical principles or convenience) Documentation of how data were classified and coded (e.g., multiple raters, blinding, and interrater reliability)
	Assessment of confounding (e.g., comparability of cases and controls in studies where appropriate)
	Assessment of study quality, including blinding of quality assessors; stratification or regression on possible predictors of study results
	Assessment of heterogeneity
	Description of statistical methods (e.g., complete description of fixed or random effects models, justification of whether the chosen models account for predictors of study results, dose-response models, or cumulative meta-analysis) in sufficient detail to be replicated
	Provision of appropriate tables and graphics
Reporting of results should include	
	Graphic summarizing individual study estimates and overall estimate
	Table giving descriptive information for each study included

	Results of sensitivity testing (e.g., subgroup analysis)
	Indication of statistical uncertainty of findings
Reporting of discussion should include	
	Quantitative assessment of bias (e.g., publication bias)
	Justification for exclusion (e.g., exclusion of non–English-language citations)
	Assessment of quality of included studies
Reporting of conclusions should include	
	Consideration of alternative explanations for observed results
	Generalization of the conclusions (i.e., appropriate for the data presented and within the domain of the literature review)
	Guidelines for future research
	Disclosure of funding source

Score by putting page numbers in the left-column. Tally the number of checks and represent as the percentage of items present by dividing by 34 and multiplying the result by 100.

Table A9. Quality Scores for RCTs.

Author	Reference Number	Quality Score
Andersson	98	50
Arkuszewski	116	18.75
Aure	82	81.25
Blomberg	105	56.25
Bronfort	114	31
Bronfort	75	81
Burton	74	38
Cherkin	14	50
Cote	80	50
Coxhead	76	25
Coyer	109	37.5
Doran	17	25
Erhard	104	25
Evans	134	19
Farrell	135	25
Gemmell	108	37.5
Gibson	79	38
Gilbert	136	37.5
Giles	137	31
Glover	138	50
Godfrey	103	19
Grunnesjo	93	50
Haas	81	62.5
Haas	139	93.75
Hadler	102	69
Hemila	72	75
Hemila	73	63
Herzog	77	6
Hoehler	112	25
Hoiriis	94	75
Hsieh	13	63
Hurley	101	81.25
Hurwitz	12	63
Kinalski	89	0
Koes	87	50
Koes	86	68
Koes	85	43
Koes	140	62
Koes	88	50
Licciardone	83	62.5
MacDonald	111	38
Mathews	119	19
Meade	15	31
Niemisto	84	81.25
Nwuga	120	12.5
Ongley	91	87.5
Pope	92	38
Postacchini	118	6
Rasmussen	107	18
Rupert	90	50
Seferlis	99	62.5
Siehl	115	31.25
Sims-William	95	43.75
Sims-William	96	37.5
Skargren	97	50
Timm	117	25
Tobis	141	0
Triano	78	31
von Buerger	106	31
Waagen	47	44
Wand	100	68.75
Waterworth	110	62.5
Wreje	142	13
Zylbergold	121	38

Table A10. AGREE scores rating of guidelines.

Name	Reference	D1	D2	D3	D4	D5	D6	Status
Philadelphia Panel	143	66.67	33.33	61.9	50	0	33.33	Rec
Koes	144	33.33	33.33	57.14	41.66	0	50	Rec
Occupational Medicine	145	66.67	58.33	61.9	83.33	55.55	50	Rec
Waddell	146	100	83.33	95.24	83.33	22.22	16.67	Rec
New Zealand	8	55.56	66.67	66.67	66.67	22.22	0	Rec
Minnesota	147	11.11	8.33	7	25	0	0	Not Rec
Canadian Guidelines	35	77.78	75	66.67	58.33	33.33	16.67	Rec
New Jersey	148	0	83.33	0	83.33	0	0	Not Rec
Waddell and Burton	149	66	16	57	83.33	44	50	Rec
European Commission	150	33.33	41	38	0	0	0	Not Rec
Danish Institute	151	100	50	42	100	44	33	Rec
Royal College	152	100	75	80	75	0	16	Rec
Danish Society	TBC	TBC	TBC	TBC	TBC	TBC	TBC	Rec

*** TBC = to be confirmed for the final draft.**

Table A11. MOOSE scores for rating systematic reviews/meta-analyses.

Principal Author	Reference	Score
Anderson	153	91
Bronfort	11	88
Ernst	154	50
Ferreira	155	62
Furlan	156	50
Guzman	157	79.41
Hayden*		TBC
Koes	158	68
Malone	159	23.52
Oliphant	160	44.11
Ottenbacher	161	59
Pengel	162	53
van Tulder	163	76.47
Vernon	164	26

* TBC – to be clarified.

Table A12. 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. Additional evidence tables can be found in Bronfort (11) and are adopted herein by reference.

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 (72)	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 (102)	Acute < 1 mo	"Some" had signs of radiculopathy	None reported	Not reported	Short arc, high velocity OR long lever arm moves	Mobilization n 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 (104)	< 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 (105)	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 (80)	Chronic	Excluded	Sclerotomal	Trigger points	Side posture	16/30 Total	Neither CMT nor mobilization

	74 months		Pain	at: 1) erector spinae muscles at L5 level; 2) posterior sacroiliac ligament; 3) gluteus muscle group.	manipulation Short lever, high velocity side thrust.	1 treatment	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 (99)	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 (81)	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 (100)	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 (93)	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 (101)	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 (94)	Subacute LBP of 2-6 weeks	Excluded	excluded	Not described	HVLA adjusting, Grostic instrumented adjusting	8 visits over a 2 week period, with a 9th 2	After 1 month and long term follow up all groups improved (man ther, exercise, and MD care); pts more

	duration					weeks later. 50 in chiropractic group.	satisfied with manual care and exercise; more satisfied with explanation of care in manual ther group
Ongley (91)	"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 (82)	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 (83)	>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 (84)	>3 months	with or without	unknown	unknown	muscle-energy technique (voluntary contraction of the patient's muscles against a distinctly controlled counterforce from a	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.

					precise position and in a specific direction; 4 treatments over 4 weeks		
Buerger (106)	Sudden onset, recent onset of 2-3 weeks duration (no more specific)	Not clear	Not included	Palpation of paravertebral tissues	Rotational manipulation (included rotational thrust to stretch muscles), soft-tissue massage	83/1649 randomly selected for rotational manipulation and soft tissue massage, 892/1649 selected for spinal manipulative therapy	All patients received 10mg diazepam prior to treatment: G1 (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 (156)	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 (85)	> 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 (86)	>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 (89)	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	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

					Kubis		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 (107)	< 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.

Table A13: Literature Search Strategy

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. electrostiulation.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

Bed Rest

The general search strategy for MEDLINE and CENTRAL was:

1. the Optimally sensitive search strategy for identifying randomized controlled trials, as noted in the Cochrane Reviewer's Handbook (http://www.cochrane.org/resources/handbook/, accessed October 7, 2005)
2. low back pain (MeSH) or back pain (tw) OR sciatica (MeSH) OR lumbosacral region (MeSH)
3. bed rest (MeSH) OR rest (tw) or active* (tw)
4. 1 AND 2 AND 3

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)

STAKEHOLDER COMMENTARY

We thank you for reading this chapter draft. At this point, stakeholders are requested to please complete a short list of questions and also provide additional comments, if appropriate, on the CCGPP survey site

http://www.surveymk.com/s.asp?u=617621934097