# COUNCIL ON CHIROPRACTIC PRACTICE Clinical Practice Guideline

Third Edition - 2008

"Vertebral Subluxation in Chiropractic Practice"

## **Clinical Practice Guideline:**

## **Vertebral Subluxation**

## **In Chiropractic Practice**

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#### Disclaimer

The purpose of these guidelines is to provide the doctor of chiropractic with a "user friendly" compendium of recommendations based upon the best available evidence. It is designed to facilitate, not replace, clinical judgment.

As Sackett wrote, "External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thereby whether it should be applied.<sup>1</sup>

The most compelling reason for creating, disseminating, and utilizing clinical practice guidelines is to improve the quality of health care. The recommendations made in this guideline are specific to the clinical entity of vertebral subluxation and are applicable to the stated goals of the guideline. Consistent with Sackett's statement, the recommendations are meant to be flexible based upon each patient encounter and the goals of both the practitioner and the patient being cared for.

These guidelines are for informational purposes. Utilization of these guidelines is voluntary. They are not intended to replace the clinical judgement of the chiropractor. It is acknowledged that alternative practices are possible and may be preferable under certain clinical conditions. The appropriateness of a given procedure must be determined by the judgement of the practitioner and the needs and preferences of the individual patient.

It is not the purpose or intent of these guidelines to provide legal advice, or to supplant any statutes, rules, and regulations of a government body having jurisdiction over the practice of chiropractic.

These guidelines address vertebral subluxation in chiropractic practice, and do not purport to include all procedures which are permitted by law in the practice of chiropractic. Lack of inclusion of a procedure in these guidelines does not necessarily mean that the procedure is inappropriate for use in the practice of chiropractic.

Participation in the guidelines development process does not necessarily imply agreement with the final product. This includes persons who participated in the technique conference, leadership conference, open forum, and peer review process. Listing of names acknowledges participation only, not necessarily approval or endorsement. The guidelines reflect the consensus of the panel, which gave final approval to the recommendations.

1. Sackett DL. Editorial: Evidence-based medicine. Spine 1998; 23(10):1085.

## COUNCIL ON CHIROPRACTIC PRACTICE CLINICAL GUIDELINE NUMBER 1. VERTEBRAL SUBLUXATION IN CHIROPRACTIC PRACTICE.

#### 2008 UPDATE AND REVISION.

This document contains the changes, additions and revisions to the 1998 (1<sup>st</sup> Edition) and 2003 (2<sup>nd</sup> Edition) Council on Chiropractic Practice Clinical Guideline. Vertebral Subluxation in Chiropractic Practice, and is organized in the following manner:

- Introduction to the development of Clinical Guideline Number 1 and the updating and revision process for the 2<sup>nd</sup> and 3<sup>rd</sup> Editions.
- Description of the development methodology for the 1998, 2003 and
- 2008 documents.
- A description of the changes, additions and revisions to the Recommendations, Sub-recommendations and Commentary as a result of the 2008 review.
- If changes to a Recommendation have been made this is listed and discussed.
- If changes in Commentary following any recommendation have been made this is listed and discussed.
- If changes to a Conclusion have been made this is listed and discussed.
- If additional literature on the topic was found and reviewed then these references are listed at the end of the chapter.
- If a Recommendation, Commentary or Conclusion was added that was not included in the 1998 or 2003 Guidelines, these are noted.

IF A RECOMMENDATION, COMMENTARY OR THE LITERATURE REMAINS AS IT DID IN THE 1998 OR 2003 GUIDELINES, A SIMPLE STATEMENT THAT THE RECOMMENDATION, COMMENTARY OR LITERATURE REMAINS UNCHANGED FOLLOWS THAT SECTION OR TOPIC.

#### **TABLE OF CONTENTS**

I.	Introduction and Methodology	<u>Page</u>
	The Council on Chiropractic Practice	8
	Inclusion in the National guideline Clearing House	
	Overview of the development of the 1998 Guidelines	
	Guidelines Development Process and Methodology	
	Rationale and Importance of the Guidelines	
	Vertebral Subluxation & Evidence-Based Practice	
	Participants in the CCP Guideline Development Process	
	Mechanics of the Review	
	Ratings and Categories of Evidence	16
	Scope	18
	Development	
	Dissemination	
	Review.	19
	Review, Updating and Revision of the 1998 and 2003 guidelines	19
	Healthcare Costs: A National Dilemma	20
	Cost-Effectiveness of Chiropractic Services	
	Patient Preferences	28
	Referral Issues.	29
	Diagnosis	29
	Asymptomatic Care	30
	The Role of Value Judgements	31
		31
	History of Chiropractic	
	ACC representation of the objection paradiam	33 33
	ACC Clarification / Definition / Clinical Management of the Sublementary	34
	ACC Clarification/Definition/Clinical Management of the Subluxation	
	2008 Updates and Revisions	35
	References	36
II.	CCP Clinical Guidelines 3 <sup>rd</sup> edition: Update and Revision	
	Section 1: History and Chiropractic Examination	55
	Section 2: Instrumentation	
	Section 3: Radiographic and Other Imaging	115
	Section 4: Clinical Impression and Assessment	146
	Section 5: Reassessment and Outcomes Assessment	154
	Section 6: Modes of Adjustive Care	
	Section 7: Duration of Care for Correction of Vertebral Subluxation	205
	Section 8: Chiropractic Care for Children	211
	Section 9: Maternal Chiropractic Care	236
	Section 10: Subluxation and Well-Being	247
	Section 11: Behavioral and Mental Health Issues	266
	Section 12: Patient Safety, Privacy and Advocacy	279
	Section 13: Professional Development	
	Section 13. Professional Development	292
	III. Appendix Material	
	Appendix 1: The CCP Workgroup	295
	Appendix 2: Methodological Standards for Practice Guidelines	317
	Appendix 3: Criteria for Choice of Peer-Reviewers	318

#### I. INTRODUCTION AND METHODOLOGY

#### THE COUNCIL ON CHIROPRACTIC PRACTICE

In the summer of 1995, chiropractic history was made in Phoenix, Arizona with the formation of the Council on Chiropractic Practice (CCP). This initial meeting was attended by an interdisciplinary assembly of distinguished chiropractors, medical physicians, basic scientists, attorneys, and consumer representatives. 1-2

The CCP was founded as an apolitical, non-profit organization. It is not affiliated with any other chiropractic association. The development of the CCP represents a grass-roots movement to produce practice guidelines which serve the needs of the consumer, and are consistent with "real world" chiropractic practice.

The mission of the CCP is "To develop evidence-based guidelines, conduct research and perform other functions that will enhance the practice of chiropractic for the benefit of the consumer."

The Council on Chiropractic Practice developed and published its first set of clinical guidelines in 1998 titled Clinical Guideline Number 1 *Vertebral Subluxation in Chiropractic Practice*.<sup>3</sup> An abbreviated version of the document was also published in the *Journal of Vertebral Subluxation Research* in November 1998.<sup>4</sup>

The CCP Guides were intended to be used by practicing chiropractors, health care educators, chiropractic organizations, patients, insurance companies, attorneys, governmental officials and any other individual or group needing information about the practice of subluxation-centered chiropractic.

This guideline went on to become widely distributed and accepted within and outside the chiropractic profession. Following publication the Council on Chiropractic Practice mailed 50,000 copies of the document to licensed chiropractors in the United States and a similar effort occurred in Canada with the document being distributed throughout several provinces.<sup>5,6</sup>

Some state licensing boards and state associations either adopted the guidelines as an acceptable standard of care and/or officially endorsed the document including Washington and Indiana.<sup>7-9</sup>

On Mar. 17, 1999 Congressman Frank Pallone, Jr., of New Jersey who serves on the Health and Environment Subcommittee of the House Commerce Committee, addressed the Speaker of the House of the U.S. House of Representatives and publicly commended the Council on Chiropractic Practice for their efforts in developing and distributing the guidelines.<sup>10</sup>

In May 1999 the CCP Guidelines were ratified by the Manitoba Chiropractors Association and in 2000 the CCP Guidelines were officially recognized by the College of Chiropractors of Alberta and the Chiropractic Awareness Council of Ontario also adopted the Guidelines.<sup>6, 11, 12</sup>

Other licensing boards and professional associations in other countries have adopted or endorsed the guidelines including the Israeli Doctors of Chiropractic (IDOC) and the Chiropractors Association of Ireland.<sup>13, 14</sup>

In addition to the broad acceptance of the document, the guidelines themselves were also reviewed and subsequently incorporated into a separate guidelines document published by the International Chiropractors Association titled: Recommended Clinical Protocols and Guidelines for the Practice of Chiropractic. 15

The Council on Chiropractic Practice has been working with the World Health Organization as that entity develops international guidelines for the practice of chiropractic. As part of that effort the CCP worked with the World Chiropractic Alliance and the World Health Organization to develop a document titled: *Guidelines on Training and Safety in Chiropractic*. <sup>16</sup>

#### INCLUSION IN THE NATIONAL GUIDELINE CLEARING HOUSE

Following publication of the CCP Guidelines the document was submitted to the National Guideline Clearinghouse (NGC) for consideration for inclusion. The NGC is sponsored by the U.S. Agency for Health Care Research & Quality and is in partnership with the American Medical Association and the American Association of Health Plans. Their mission is as follows:

The <u>NGC mission</u> is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use.<sup>17</sup>

The AHRQ contracts with ECRI, a non-profit health services research agency, to perform the technical work for the NGC. ECRI is an international non-profit health services research agency and a Collaborating Center of the World Health Organization. In November of 1998, following review by ECRI, the CCP Guidelines were accepted for inclusion within the National Guideline Clearinghouse and are presently the only chiropractic guidelines listed by the NGC.

#### **OVERVIEW OF THE DEVELOPMENT OF THE 1998 GUIDELINES**

In harmony with the general principles of guideline development at the time, the CCP originally created a multidisciplinary panel, supported by staff, and led by a project director. The guidelines were produced with input from methodologists familiar with guidelines development.

The first meeting of the Council on Chiropractic Practice took place on June 8, 1995 in Chandler, Arizona and the Council was subsequently incorporated as a non-profit organization. The first endeavour of the panel was to analyze available scientific evidence revolving around a model, which depicts the safest and most efficacious delivery of chiropractic care to the consumer. A contingent of panellists, chosen for their respective skills, directed the critical review of numerous studies and other evidence.

The process began with a detailed literature search which was broad in nature utilizing both electronic search vehicles including Medline and MANTIS, the

Cumulative Index to Nursing and Allied Health Literature (CINAHL) as well as stack searches to ensure that all applicable literature relevant to vertebral subluxation in chiropractic clinical practice was gathered. To further ensure that all relevant literature and evidence was gathered and reviewed the panel held a second meeting to interview technique developers to ascertain the degree to which their procedures can be expressed in an evidence-based format. Individuals representing over thirty-five named techniques participated. Others made written submissions to the panel. The technique developers presented the best available evidence they had to substantiate their protocols and assessment methods.

A primary goal of the panel was to stimulate and encourage field practitioners to adapt their practices to improve patient outcomes. To achieve this objective, it was necessary to involve as many practitioners as possible in the development of workable guidelines. It was also important to the panel to secure input from field practitioners who would be one class of the end users of any guidelines produced.

Consistent with the recommendations of AHCPR (now AHRQ), an "Open Forum" was held where any interested individual could participate. Practitioners offered their opinions and insights in regard to the progress of the panel. Field practitioners who were unable to attend the Open Forum session were encouraged to make written submissions. Consumer and attorney participants offered their input. A meeting was also held with chiropractic consultants and organizational leadership to secure their participation and gather feedback.

The literature and other information gathered during this process were reviewed by a panel of experts who submitted critical review using an "Abstraction Form." The reviews included questions on:

- Interventions
- Outcomes
- Harms
- Instrumentation & Analysis
- Spinal Analysis
- Study Findings
- Study Design Flaws

After sorting and evaluating the evidence gathered in the literature search, technique forum, leadership forum, written comments, open forum and the review process, the panel rated and categorized the evidence. After sorting, evaluating, rating and categorizing the evidence (rating and categorizing criteria is discussed later in this document) an initial draft of the guidelines was prepared and distributed to the panel for review and criticism. A revised draft was prepared based upon this input.

International input from the field was obtained when the working draft guidelines document was submitted to 195 peer reviewers in 12 countries. After incorporation of the suggestions from these reviewers, a final draft was presented to the panel for approval. This document was then submitted for proofreading and typesetting and was subsequently published.

#### **GUIDELINES DEVELOPMENT PROCESS AND METHODOLOGY**

Since the original 1998 and 2<sup>nd</sup> 2003 version of the CCP Guidelines much has been written on the subject of guidelines methodology and more information for

guideline development has been made available. A detailed search of the guideline development methodology and implementation literature published since 1995 was undertaken by members of the guidelines committee and pertinent concepts and procedures incorporated into the process. <sup>18-75</sup> particularly, the panel sought to more explicitly describe its methodology. While the methodology followed for the 1998 process was clearly described in various trade journals as well as amongst the participants, the CCP Guides were criticized for not describing its methods of development more clearly. Unfortunately, these criticisms were at times based on guidelines development literature published only after the CCP guides were created and distributed. This new literature was reviewed carefully and the recommendations incorporated into the current process of revision and updating.

In particular the panel found the article by Shaneyfelt et al particularly helpful. <sup>18</sup> Many of the key elements outlined in the article were utilized in the development of the guidelines and are used as topic headings throughout this document. Table 1 summarizes these key elements. *Purpose of the CCP Guidelines* 

The CCP has developed practice guidelines for vertebral subluxation and one of the purposes of these guidelines is to provide the doctor of chiropractic with a "user friendly" compendium of recommendations based upon the best available evidence. The purpose is to facilitate, not replace, clinical judgment and ultimately to improve the quality of health care.

These guidelines are for informational purposes, utilization of these guidelines is voluntary and they are not intended to replace the clinical judgment of the chiropractor. It is acknowledged that alternative practices are possible and may be preferable under certain clinical conditions. The appropriateness of a given procedure must be determined by the judgment of the practitioner and the needs and preferences of the individual patient.

It is not the purpose or intent of these guidelines to provide legal advice, or to supplant any statutes, rules, and regulations of a government body having jurisdiction over the practice of chiropractic.

These guidelines address vertebral subluxation in chiropractic practice, and do not purport to include all procedures which are permitted by law in the practice of chiropractic. They do not purport to include the management of conditions or clinical findings other than vertebral subluxation and its components. Lack of inclusion of a procedure in these guidelines does not necessarily mean that the procedure is inappropriate for use in the practice of chiropractic. The reader is encouraged to consult other guidelines that address the application of chiropractic in other clinical situations.

Participation in the guidelines development process does not necessarily imply agreement with the final product. This includes persons who participated in the technique conferences, leadership conference, open forum, and peer review process. Listing of names acknowledges participation only, not necessarily approval or endorsement. The guidelines reflect the consensus of the panel, which gave final approval to the recommendations.

#### RATIONALE AND IMPORTANCE OF THE GUIDELINES

These guidelines for vertebral subluxation were developed because the Council and its constituents recognized the need for guidelines that dealt specifically with the vertebral subluxation and its management. Other guidelines have been developed that address a myriad of conditions and symptoms reported to be amenable to chiropractic intervention and/or spinal manipulation. These other guidelines blur the boundaries regarding care for the amelioration of various pain syndromes and at the same time blur the boundaries regarding the interventions used to affect a response. In addition, none of these guidelines have been updated since their original dissemination and one of them, the *Mercy Guidelines*, is approaching a decade since publication.

One of the rationales for the development of a guideline specifically addressing the clinical entity of vertebral subluxation is to bring clarity to the issue of what entities, conditions, disorders, or symptoms chiropractors deal with and the procedures they use to do it with. Clarity is considered an attribute of good practice guidelines by the Institute of Medicine. An example of the clarity portrayed in the CCP Guides would be the distinction between the terms adjustment and manipulation. While a manipulation may be used by a host of health care providers to affect joint function, only the chiropractor uses the adjustment to reduce or correct vertebral subluxation. The CCP guides do not address the use of a chiropractic adjustment for any other clinical situation.

The importance of this distinction cannot be overemphasized since the profession of chiropractic entails many types of providers and the profession enjoys a broad scope in most if not all jurisdictions. Because of this latitude in scope of practice there are differing styles of practice based on the extent of the implementation of procedures and management by individual chiropractors. Some practitioners choose to practice at the extreme limits of their practice scope. This means that chiropractors in Oregon, for example, may choose to diagnose and treat gynecological problems because their scope allows for it and they desire to do so, or they may elect to strictly limit their practice to the detection and correction of vertebral subluxation.

It is the opinion of the Council that it would be prudent for those interested in the applications of gynecological diagnosis and management for example, to consult guidelines that address these issues as opposed to expecting that chiropractic guidelines address all conditions and disorders that a particular scope allows.

There have historically been groups of chiropractors in the profession that choose to practice in various ill defined categories where scope is the limiting or expanding factor. These various groups are becoming more clearly defined and as a result of this, more specific guidelines such as these that seek to address vertebral subluxation only, are extremely important. The importance is manifested when chiropractors address or get involved with payer groups, the government, legal issues/groups and especially the consumers of the health care provided by chiropractors. Recent accreditation and legal issues confronting the chiropractic profession only serve to heighten the importance of these distinctions and the importance of guidelines that address them. The importance of the second in the importance of guidelines that address them.

The importance of a guideline that addresses vertebral subluxation is also illustrated by the widespread adoption of the Association of Chiropractic Colleges *Paradigm Statement*.<sup>79</sup> This Statement was discussed briefly in the 1998 CCP Guidelines publication, however since that time this Statement, developed and signed by the Presidents of all of the North American Chiropractic Colleges, has enjoyed unprecedented endorsement throughout the chiropractic profession.<sup>80</sup> It has

received such widespread support that some have remarked that never in the history of the profession has there been this extent of agreement on anything. This statement has been endorsed and/or adopted by every major national and international chiropractic organization in the profession including:

The World Chiropractic Alliance

The Council on Chiropractic Practice

The Council on Chiropractic Education

The International Chiropractor's Association

The American Chiropractor's Association

The World Federation of Chiropractic

The Congress of Chiropractic State Associations

The Association of Chiropractic Colleges

The Foundation for Chiropractic Education & Research

The Federation of Chiropractic Licensing Boards

National Board of Chiropractic Examiners

The National Association of Chiropractic Attorneys

The Paradigm Statement defines the responsibility of chiropractors to include the detection and correction of vertebral subluxation and its resultant neurological interference. The existence of subluxation is in accordance with this paradigm statement and the ACC defines the purpose, principles and practice of chiropractic as the finding and reduction of vertebral subluxations, which will prevent and restore health by removing interference to the body's inherent recuperative powers. This document, among other things, states that chiropractic as a profession "focuses particular attention on the subluxation."

Further to this, the majority of state laws and the United States Federal Government all define the responsibility of chiropractors to include the detection and correction of vertebral subluxation and its resultant neurological interference.

The assessment and management of vertebral subluxation is either taught as part of the regular curriculum of all chiropractic colleges in North America or as part of their post graduate programs. All of these programs, including the general curriculum of the chiropractic colleges and the post graduate programs are approved and accredited by the Council on Chiropractic Education which is subject to the rules and authority of the United States Federal Government's Department of Education. These schools also hold accreditation through various local and regional accrediting bodies.

The Council on Chiropractic Education, mentioned above, accredits all of the chiropractic programs in the United States and has reciprocal arrangements with accrediting bodies in Europe and other regions. According to the Policies document of the CCE: 81

The Council on Chiropractic Education (CCE) accepts the physiological principles of organization in living things and the manifestation of the self-regulatory mechanisms inherent in the body.

CCE accepts that the nervous system is vulnerable to disturbances resulting from derangements of the neurobiomechanical system, including the vertebral column and vertebral subluxations.

The educational process should be a reinforcement of the validity of the basic principles of chiropractic and an encouragement to the student to apply those

principles in his or her clinical programs, with emphasis given to detection and correction of derangements of the neurobiomechanical system, including vertebral subluxation."

The American Medical Association, in its Guides to the Evaluation of Permanent Impairment, lists the following as acceptable means to rate impairment: 82

- Impairment due to loss of muscle power and motor function,
- impairment due to abnormal motion of the spine,
- impairment due to loss of motion segment integrity,
- impairment due to disc problems,
- impairment due to pain or sensory deficit, and segmental instability.

The above are, in fact, components of the Vertebral Subluxation Complex. 83, 84

The Guidelines for Evaluation and Management Services published by the Health Care Financing Administration of the United States Federal Government and the American Medical Association (May 1997) <sup>85</sup> outline what an objective examination should consist of and these include commonly used neuromusculoskeletal exam procedures within chiropractic such as: postural analysis, palpation, assessment for subluxation, range of motion and assessment of muscle tone. All of these are used to assess and manage subluxation and are specifically addressed by the CCP Guidelines.

The Federal Government of the United States specifically defines what chiropractors do as the detection and correction of subluxation under Medicare and Federal worker's compensation laws. Common to all state statutes is the adjustive process being utilized to reduce subluxations and the resultant interference to nerve transmission. A majority of states employ the term adjustment in licensing laws in reference to the procedures applied by chiropractors and others additionally include the concept of manipulation. A majority of states contain specific references to responsibility for neurological complications of biomechanical origin (subluxation) and over half the chiropractic profession practice in these states. In addition, many states specifically discuss the concept of subluxation in their statutes by using the term and for those that do not specifically use the term there is an implied understanding of the concept in their statutes.

The existence of subluxation and its acceptance is spelled out in explicit detail by published policy statements of chiropractic organizations<sup>86, 87</sup> as well as federal and state laws regulating the practice of chiropractic. The epidemiology of subluxation has been researched since the inception of chiropractic over 100 years ago with basic science and clinical research to further elucidate the nature of it continuing to this day.

Considering the centrality of vertebral subluxation to the practice of chiropractic and the profession, the importance of guidelines that specifically address it are clearly needed. This is especially true considering that other guidelines addressing chiropractic practice and procedures either do not address it at all or give only a cursory consideration. 88-90

A few individuals within the profession contend that the existence of subluxation is questionable and have chided the CCP Panel for not addressing their contention in its earlier publication. 91-93 While the CCP Panel acknowledges that certain individuals

and groups within the profession do make such an assertion, the Council does not take such contentions seriously. The above review of the subluxation within the chiropractic profession, government, state law, chiropractic educational bodies and scientific literature serves as evidence of its entrenched status. Further, according to Rome there are 296 variations and synonyms of subluxation used by medical, chiropractic and other professions leading him to remark "It is suggested that with so many attempts to establish a term for such a clinical and biological finding, an entity of some significance must exist." <sup>94</sup> Additional discussions to shed light on the concept of subluxation continue below.

#### **VERTEBRAL SUBLUXATION & EVIDENCE-BASED PRACTICE**

Evidence-based clinical practice is defined as "The conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients... (it) is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions." <sup>95</sup>

This concept was embraced by the Association of Chiropractic Colleges in its first position paper. This paper stated:

Chiropractic is concerned with the preservation and restoration of health, and focuses particular attention on the subluxation.

A subluxation is a complex of functional and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health.

A subluxation is evaluated, diagnosed, and managed through the use of chiropractic procedures based on the best available rational and empirical evidence. <sup>96</sup>

#### PARTICIPANTS IN THE CCP GUIDELINE DEVELOPMENT PROCESS

The CCP has developed practice guidelines for vertebral subluxation with the active participation of field doctors, consultants, seminar leaders, and technique experts. In addition, the Council has utilized the services of interdisciplinary experts in the Agency for Health Care Policy and Research (AHCPR), guidelines development, research design, literature review, law, clinical assessment, chiropractic education, and clinical chiropractic.

The Council additionally included consumer representatives at every stage of the process and had individuals participating from several major chiropractic political and research organizations, chiropractic colleges and several other major peer groups. The participants in the guidelines development process undertaken by the CCP are listed in Appendix 1.

Following the development of the guidelines and the construction of a draft of the final recommendations the guidelines were reviewed by over 100 peer reviewers. These reviewers were chosen based on several characteristics. See Table 3

The Guideline Panel, as well as the various reviewers, was solicited via several announcements for participants in trade journals and/or individuals were

directly approached by representatives of the panel and asked to participate. Those who participated in the development and review of the 1998 process were encouraged to participate once again.

#### **MECHANICS OF THE REVIEW**

The significant difference for the 2003 update and revision was the use of an on line review process. Considering the sheer number of reviewers, the cost and time involved in copying, mailing and waiting for feedback from this number of reviewers would have prohibitive. This model of on line review worked well and it is hoped that it will serve to assist other guidelines developers who face similar hurdles.

Essentially, the final draft of the guidelines revision was placed in a secure on line Forum where reviewers were required to provide a LOGON and PASSWORD to enter and access the draft. Once the individual reviewed the draft they then filled out an on line form with any recommendations or changes. Their response was immediately routed to the Project Manager for review and any needed action. Recommendations for additions or changes to the draft based on this review were then circulated electronically to the Panel for feedback. Other than an Assistant to the Project Manager no individual received remuneration for work performed on behalf of the Council to develop these guidelines.

#### RATINGS AND CATEGORIES OF EVIDENCE

During the process of updating and revising the CCP Guidelines the issue of how to rate and categorize the evidence and scientific literature used resurfaced.

The original panel that developed the guidelines created a Ratings and Categories of Evidence system that they felt would best allow for a clear and easily understandable method of evaluating the evidence. This clarity served the panel well and it was felt this would also best serve the end user as well as any future evaluator of the guideline's quality since, as discussed previously, one of the attributes of a good clinical guideline has been defined as *Clarity*.

Other guidelines developers within the chiropractic profession have similarly developed their own ratings and category of evidence schemes. <sup>15,60,61</sup> The CCP reviewed these schemes and felt that while they might have served those other guidelines panels, they were too unwieldy and unnecessary in light of the fact CCP was limiting its guideline recommendations to a single clinical entity – vertebral subluxation. A review of the guideline development literature found no directive that one or another rating or category of evidence scheme held more promise than another or that there was a method that was more valid or reliable. The consensus of the literature was that some method should be used and that method should be explicitly stated. <sup>63</sup>

The following ratings and categories were utilized in the original 1998 version of the CCP Guidelines and were also utilized in the updating and revision of the 2003 and 2008 CCP Guidelines:

#### **RATINGS**

**<u>Established.</u>** Accepted as appropriate for use in chiropractic practice for the indications and applications stated.

<u>Investigational.</u> Further study is warranted. Evidence is equivocal, or insufficient to justify a rating of "established."

<u>Inappropriate.</u> Insufficient favourable evidence exists to support the use of this procedure in chiropractic practice.

#### **CATEGORIES OF EVIDENCE**

- **E:** Expert opinion based on clinical experience, basic science rationale, and/or individual case studies. Where appropriate, this category includes legal opinions.
- **L:** Literature support in the form of reliability and validity studies, observational studies, "pre-post" studies, and/or multiple case studies. Where appropriate, this category includes case law.
- **C:** Controlled studies, including randomized and non-randomized clinical trials of acceptable quality.

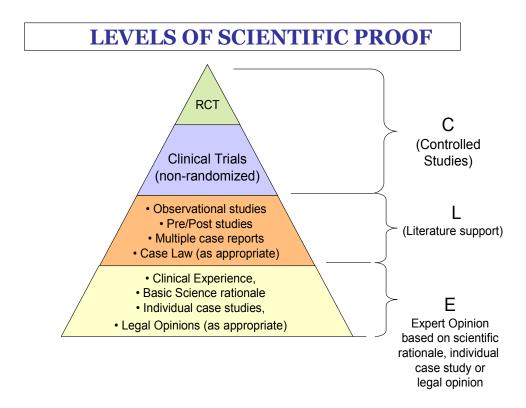


Figure 1: Levels of Scientific Proof

These categories of evidence can best be thought of in a hierarchical fashion as depicted in Figure 1. Note that the base of any culture of evidence, **designated as E** on the rating scale, is expert opinion, basic science rationale, and/or individual case studies; this base is also rich in legal opinions. Building upon this base of evidence are the scientific literature supported studies (**designated as L**) composed

of a variety of experimental designs (e.g., reliability/validity studies, observational and pre/post studies, multiple case series, and where appropriate case law. Finally, at the pinnacle, and building upon the weight of previous literature, are the controlled studies (**designated as C**) using randomized or non-randomized design known as clinical trials. These must be of appropriate design and acceptable quality to advance the knowledge in this area.

#### SCOPE

Chiropractic is a dynamic profession. During a large part of the past century educators and leaders in the field have engaged in an ideological debate over professional identity on 1) scope of practice, 2) adjusting techniques, and 3) philosophy. 97-114 Unfortunately, this debate has been fractious and divided the profession into seemingly rival camps now best termed Broad Scope and Focused Scope, groups previously termed "mixers" and "straights", respectively. 115 In a large, representative survey of chiropractors, the Broad scope group represented 34.3% of the profession and the focused scope 19.3%. However, they also found that the plurality (46.4%) of chiropractors representing a "Middle Scope" group; this group embraces both ends of the ideological spectrum.

However, a representative survey conducted with 687 randomly selected chiropractors in the United States, Canada and Mexico reveals that when it comes to the broad scope vs. focused scope label, the old stereotypes are misleading (see below) and it was concluded that on most issues, broad scope and focused scope chiropractors differ more in degree than in kind. <sup>116</sup>

The report revealed that in spite of differences in scope of practice (broad scope, middle scope and focused scope), adjusting technique and philosophy, chiropractors as a group are surprisingly homogeneous. In particular, 88.1% agree to term Vertebral Subluxation Complex (VSC) should be retained, 89.8% state that adjustments should not be limited to musculoskeletal conditions and rate the subluxation as a significant contributing factor in 62.1% of visceral ailments. Similarly, the typical North American chiropractor performs a broad spectrum of clinical services and practices aimed toward improving patient health lifestyle. Of interest, 97.8% recommend exercise and 51% recommend weight loss counselling; the other parameters of health lifestyle listed above were recommended by 86-94%.

These guidelines are written for the profession, but largely those chiropractors who self-identify as focused- and middle-scope practitioners. In fact, these individuals represent the majority (65.7%) of the profession who identify themselves as subluxation-centered.

#### DEVELOPMENT

This 3<sup>rd</sup> Edition of Clinical Practice Guidelines "Vertebral Subluxation in Chiropractic Practice" Guidelines were developed by the CCP Workgroup between January 2007 and June 2008 (see appendix I for full membership of the group).

Literature searches were carried out in 2007-08 by searching Mantis, Medline and the Cochrane Library. These were supplemented by hand searching the current chiropractic journals, the references listed in key articles and personal collections. The literature was updated until Spring 2008.

The evidence was reviewed by members of the working panels and classified according to the criteria of the US Agency for Health Care Policy and Research. 117

Each individual was sent a structured appraisal form, requesting evidence-based comments. Replies were sent to the respondents, and, where appropriate, changes made. Minor changes were also made in the light of new literature received during the final review process up to the cut-off date of September 1, 2008.

During 2007-08, members of the CCP working group took responsibility for drafting the first version of guidance on specific topics. This synthesis addressed the content and precise wording of the text and recommendations and accuracy of the grading of the evidence. Drafts were circulated within the Group for comment and amendment and editing.

#### DISSEMINATION

This document will be disseminated to all stakeholders. It will also be available on CD ROM and hosted on the Website of the Council on Chiropractic Practice (<a href="www.ccp-quidelines.org">www.ccp-quidelines.org</a>) for downloading.

The draft document was placed on line and representative stakeholders were invited to provide comments/suggestions for revision. These comments were incorporated into the final document.

#### **REVIEW**

This document will be reviewed in May 2013 with the plan of submitting the final version to the National Clearing House by September, 2013.

#### REVIEW, UPDATING AND REVISION OF THE 1998 & 2003 GUIDELINES

Since the guidelines process is one of continuing evolution, the Council on Chiropractic Practice did not endeavour to develop a set of guidelines and then cease to function. It was decided early in the process that the Council would continue to exist and that new evidence would be considered at periodic intervals to update the model of care defined by the guidelines. It was the decision of the Council on Chiropractic Practice to keep to the five-year recommendation of the National Guideline Clearinghouse for updating and revision.

In the spring of 2001 during the Council on Chiropractic Practice's annual meeting, the Council began the process of updating the 1998 guidelines. One of the first steps was a meeting of technique developers and experts that occurred as part of the same CCP meeting. Additional technique systems that were not involved in the development of the original document participated and those previously involved were invited to submit additional and/or supplemental material. Over 40 named technique systems were represented at this meeting.

In the spring of 2002 during the annual meeting of the Council, the Guidelines Committee was reconstituted, a Project Manager was appointed and the further structure of the review, updating and revision was discussed and planned. A nearly identical process was used for the updating and revision. The Project Manager, who serves as Chair of the Guidelines Committee, assembled a panel of area experts

who assisted in the search for literature, the subsequent gathering of that literature and its critical assessment.

As in the original process an "Abstraction Form" was utilized and suggestions for changes in the Ratings, Recommendations and Commentary were sought from this panel and the Guidelines Committee as a whole. The literature and other evidence utilized in the update spanned the time period1996-2003. The literature search was evidenced based and broad in nature adhering to Sackett's admonition to track down "...the best external evidence with which to answer our clinical questions." The panel relied heavily on the peer reviewed chiropractic literature as well as the general biomedical literature where applicable.

A detailed search of the guideline development methodology literature published since 1995 was undertaken by members of the guidelines committee and pertinent concepts and procedures incorporated into the process. Particularly, the panel sought to more explicitly describe its methodology. While the methodology followed for the 1998 process was clearly described in various trade journals as well as amongst the participants, the CCP Guides were criticized for not describing more clearly its methods of development. 91-93 Unfortunately, these criticisms were at times based on guidelines development literature published only after the CCP guides were created and distributed. This literature was reviewed carefully and the recommendations incorporated into this revision and updating.

A significant difference in the process for the updating and revision consisted of easier access to literature due to improvements in electronic searching and the developments of additional electronic databases that index chiropractic peer reviewed literature. The literature was searched utilizing MANTIS, CINAHL, The Index to Chiropractic Literature, Medline, individual electronic journal searches such as the *Journal of Manipulative and Physiological Therapeutics* and the *Journal of Vertebral Subluxation Research*. Hand and stack searches were also employed to assure the most extensive gathering of relevant literature.

#### **HEALTHCARE COSTS: A NATIONAL DILEMMA**

Health care spending in the United States first exceeded \$2 trillion in 2006, and is projected to exceed \$4.2 trillion by 2017. Federal forecasters have projected that within a decade, health care expenditures will represent 20% of the USA's gross domestic product (GDP). According to a 2005 report by the California Health Care Foundation, health care spending in 2003 was about 4.3 times the amount spent on national defense. Medicare hospital insurance is projected to become insolvent by 2019, the date of the predicted exhaustion of the Trust Fund.

**Where is the money going?** It is clear that the overwhelming majority (ca. 70%) is spent on chronic illnesses, <sup>122</sup> such as:

- Cardiovascular disease and Stroke--\$210 billion/yr
- Diabetes--\$92 billion/yr
- Obesity-Related--\$75 billion/yr
- Arthritis--\$22 billion/yr

What are we getting for it? Not as much as one would like. Despite the tremendous cost of health care, both economic and human, the United States ranks 37<sup>th</sup> in overall health system performance of 191 countries evaluated by the World Health Organization. <sup>123</sup> In 1994, an article in Journal of the American Medical Association (JAMA) <sup>124</sup> noted that "180,000 die each year partly as a result of iatrogenic injury, the equivalent of three jumbo-jet crashes every 2 days." The

situation remains grim. Medical errors and iatrogenic episodes are still a leading cause of death in the United States. 125

What happened to plans to implement preventative (i.e., wellness) strategies? Relatively little of the current health care dollar goes to "health care." It supports "sick care". Consider Medicare. The Medicare Act requires that covered services be "reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member." Specifically excluded as "not medically necessary" is any form of preventative strategies, i.e., "maintenance care", defined as follows: "A treatment plan that seeks to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition." This strategy and the philosophy behind it are responsible for the current health care crisis in the USA.

According to Julie Louise Gerberding MD, MPH, Director for the United States Center for Disease Control (CDC), the problems with health care goes well beyond the direct costs of medical services. Gerberding states ".....only a nickel out of every medical-care dollar spent in the USA goes toward keeping Americans healthy, many countries have put more emphasis on health promotion than the United States." <sup>127</sup>

Accordingly, the CDC has launched the "Healthiest Nation Campaign" to keep Americans healthy by promoting prevention and integrating health into social policies across all sectors of the economy (e.g., consider the broad-reaching implications of promoting health by providing better public transportation to assistance with health-related transportation, healthier environmental strategies, more bike and hiking trails, and facilities for child-care enabling parents to attend regular health visits, etc.).

Economist Paul Zane Pilzer summarized the situation well: "The sickness business is *reactive*. Despite its enormous size, people become customers only when they are stricken by and react to a specific condition or complaint...the wellness business is *proactive*. People *voluntarily* become customers -- to feel healthier, to reduce the effects of aging, and to avoid becoming customers of the sickness business. Everyone wants to be a customer of this earlier-stage approach to health."

#### **COST-EFFECTIVENESS OF CHIROPRACTIC SERVICES:**

Studies suggest that chiropractic, when implemented broadly, would result in significant savings of health care dollars. Substantial health benefits and cost savings to the employer are documented when chiropractic benefits are added to the employee benefits package. <sup>141</sup>

One of the earliest and best estimates of the potential savings with chiropractic comes from a 1996 study by Stano and Smith. Their study compares health insurance payments and patient utilization patterns for episodes of care for common lumbar and low back conditions treated by chiropractic vs. medical providers. Using 2 years of insurance claims data, this study examines 6,183 patients who had episodes with medical or chiropractic first-contact providers. Multiple regression analysis, to control for differences in patient, clinical, and insurance characteristics, indicates that total insurance payments were substantially greater for episodes with a medical first-contact provider. The mean total payment when DCs were the first providers was \$518, whereas the mean payment for cases in which an MD was the first provider was \$1,020, 133 i.e., almost a 50% cost savings when chiropractors are part of the health team.

Several years later, a ground breaking randomized clinical trial (RCT) evaluated the financial impact of provider assignment in the management of neck pain. 142 Patients who saw general practitioners for neck pain were randomly allocated to manual therapy (spinal mobilization), physiotherapy (mainly exercise) or general practitioner care (counselling, education and drugs). Throughout this 52-week study, patients rated their perceived recovery, intensity of pain and functional disability. Manual therapy proved to be the most effective treatment for neck pain. The clinical outcome measures showed that manual therapy resulted in faster recovery than physiotherapy and general practitioner care. While achieving this superior outcome, the total costs of the manual therapy-treated patients were about one-third the cost of physiotherapy or general practitioner (MD) care.

The remaining parts of this section review the growing literature supporting the cost-effectiveness of chiropractic across the various third-party payers in the United States (Medicare, State Workman's Compensation, Private insurance) and Internationally.

#### **MEDICARE:**

Analyses in this age demographic have been conducted with insurance databases comparing persons receiving chiropractic care with non-chiropractic patients. One study consisted of senior citizens over 75 years of age. It was reported that the persons receiving chiropractic care reported better overall health, spent fewer days in hospitals and nursing homes, used fewer prescription drugs, and were more active than the non-chiropractic patients. The chiropractic patients reported 21% less time in hospitals over the previous 3 years. 143

Another study surveyed 311 chiropractic patients, aged 65 years and older, who had received chiropractic care for 5 years or longer. Chiropractic patients, when compared with US citizens of the same age, spent only 31% of the national average for health care services. There was a 50% reduction in medical provider visits. The health habits of patients receiving maintenance care were better overall than the general population, including decreased use of cigarettes and decreased use of non-prescription drugs. 144

A 2001 study, commissioned by the American Chiropractic Association, examined cost, utilization and effects of chiropractic services on Medicare costs. The study compared program payments and service utilization for Medicare beneficiaries who visited DCs and those who visited other types of physicians. The results indicated that chiropractic care could reduce Medicare costs. Medicare beneficiaries who had chiropractic care had an average Medicare payment of \$4,426 for all Medicare services. Those who had other types of primary care had an average of \$8,103 Medicare payment for all Medicare services. The average per claim average payment was also lower with chiropractic patients, being \$133 per claim compared to \$210 per claim for individuals who did not have chiropractic care.

#### STATE WORKMAN'S COMPENSATION PROGRAMS:

Large retrospective studies have been conducted with data from workers' compensation claims evaluating those receiving care from chiropractors vs. physician providers for low back injuries. One study in Texas, analyzed claims from 1996-2001, and found that chiropractor costs were lowest of all providers. Their data

clearly demonstrated that increased utilization of chiropractic care would lead to declining costs relative to lower back injuries. 146

An earlier analysis of worker's compensation claims was conducted in Florida on claims from June through December of 1987. All of the claims analyzed were related to back injuries. The main purpose of this study was to compare the cost of osteopathic, medical and chiropractic doctors. The cost of drugs was not included in the analysis. They conclude that individuals treated by chiropractors had significantly fewer hospitalizations and lower claims than physicians. The study also concludes that chiropractic care is a "relatively cost-effective approach to the management of work-related injuries."

Another retrospective study of Florida workers' compensation claims over a five-year period from 1994-1999. In this study the average total cost for low-back cases treated medically was \$16,998 while chiropractic care was less than half (\$7,309). Patients managed by chiropractors were found to reach maximum medical improvement almost 28 days earlier than those treated exclusively by physicians. These authors conclude that considerable cost savings and more efficient claims resolution may be possible with greater involvement of chiropractic treatment in specific low back cases and other specific musculoskeletal cases. 148

An analysis of 5000 claims from 1986 and 5000 from 1989 were examined for injured individuals in the Utah Worker Compensation Fund. The study compared cost for those who received chiropractic care and those who received medical care exclusively. From 1986 to 1989 the cost of care for chiropractic increased 12% while medical care increased 71%. The replacement of wages increased 21% for those receiving chiropractic care and 114% for those receiving medical care. <sup>149</sup>

Another study of workman's compensation claims in Utah indicated that health care costs for conditions with identical diagnostic codes were significantly higher for medical claims than for chiropractic claims. The sample consisted of 3062 claims or 40.6% of the 7551 estimated back injury claims from the 1986 Workers' Compensation Fund of Utah. Findings indicate that cost for care was significantly greater for medical vs. chiropractic claims.

An analysis has also been conducted of the Iowa State Workman's' compensation records. Investigators evaluated the claims from individuals in with back or neck injuries in 1984. Of those who missed work and received compensation, there was a substantial benefit. Those receiving chiropractic missed on average 2.3 days from work than individuals where care was managed by MDs, 3.8 days less than individuals who saw DOs. Smaller disability claims were associated with patients receiving chiropractic care for their injuries. On average, the disability compensation paid to workers whose care was managed by chiropractors was \$263.66; it was \$617.85 for care managed by MDs, and \$1565.05 for those managed by DOs.

The Workman's' Compensation program in Oregon has been evaluated in several major studies. Nyiendo and colleagues examined 201 randomly selected workers' compensation cases that involved low back injuries that were disabling. The study found individuals who utilized DCs less frequently had a higher incidence of injury-related hospital visits than those under care of physicians. A follow-up study focused on time lost at work. For similar severities of injury, the median missed work days was 9.0 days for those under care of DCs and 11.5 days for exclusively under care of physicians. Individuals managed by chiropractors returned

to work, on average, within one week or less. An important finding was that there were no differences in lost work time for individuals managed by DCs and MDs as long as there was no previous history of back injury. However, for claimants with a history of low back problems, the median loss of work was almost four-times higher when higher when managed by MDs (34.5 days) compared to management by chiropractors (9 days). It was concluded that chiropractors are better able to manage injured workers with a history of chronic low back problems and to return them more quickly to productive employment.

#### PRIVATE (MANAGED-CARE) INSURERS:

Significant decreases in the utilization of medical services, and their attendant costs, were noted when doctors of chiropractic or other "CAM oriented" practitioners were used as primary care providers. In an Independent Care Association (IPA) which permitted patients to select a doctor of chiropractic as their primary care physician, an initial report concluded that when DCs served as the primary care providers, there was a: 1) 43% decreases in hospital admissions, 2) 52% reduction in pharmaceutical costs, and 3) 43% fewer outpatient surgeries and procedures. A follow-up study at the same facility, based on 70,274 member-months over a seven-year period, demonstrated that when managed by chiropractors there is a reduction of: 1) 60.2% in hospital admissions, 2) 59.0% in total hospital days, 3) 62.0% in outpatient surgeries and procedures, and 4) 85% pharmaceutical costs when compared with medical doctors.

In other studies, chiropractic care in general, and chiropractic care directed at reduction of vertebral subluxation, in particular, have demonstrated positive effects on physiological outcome measures. In a review of literature related to objective physiological changes following chiropractic care, Hannon discusses more than twenty studies documenting objective health benefits in subjects who were specifically described as "asymptomatic," "healthy," "normal," or "free from physical injury." Nearly an equal number of studies were found documenting objectively measured health benefits in subjects in which no symptomatic presentation was described. <sup>156</sup>

Two major studies evaluated a private health plan database to determine whether chiropractic was being utilized as "substitution" care (for medical visits) or whether it was an "add-on" to the corporate medical plan when they were offered a chiropractic benefit. The study was conducted over a 4-year period, and involved claims from 8 million members. The important finding was that patients use chiropractic as a direct substitution for medical care, choosing chiropractic 34% of the time. Of considerable importance to the employer and insurance company, the chiropractic benefit rider did not increase the number of patients seeking care for neuromusculoskeletal complaints. <sup>157</sup>

A parallel analysis was conducted in a subset of 1.7 million of these health plan members. At issue were the employer costs of having a chiropractic benefit in their HMO insurance plan. The data revealed that members with the chiropractic benefit had lower overall total annual health care costs. Back pain patients with chiropractic coverage also realized lower utilization of plain radiographs, low back surgery, hospitalizations and MRI's. Back pain episode-related costs were also 25% lower for those with chiropractic vs. MD coverage (\$289 vs. \$399).

Another paper from this cohort concluded, on a per-episode basis, that the use of advanced imaging, surgery, impatient care and plain-film radiographs was reduced by the following amounts in the chiropractic benefit group: surgery, 32%; advanced imaging, 37%; inpatient visits, 40%; and plain-film radiographs, 23%. This

study supports the likelihood that substitution of chiropractic care for medical care for the treatment of back and neck pain leads to less use of these other costly procedures. 159

In a final article from this cohort, the analysis of data from 1.7 million subscribers over four years indicated that the employer groups with chiropractic coverage had a younger population and significantly lower rates of common chronic diseases than subscribers who had access only to medical care for neuromusculoskeletal complaints. The employers who chose the chiropractic rider had a patient population with a more favourable risk profile, thereby decreasing the health care costs of the health plan. 160

## COST- EFFECTIVENESS STUDIES CONDUCTED INTERNATIONALLY (Canada, UK, and Australia):

Chiropractic is International. Thus, it is important to evaluate the cost-effectiveness of the profession in other countries with different models of health-care reimbursement. The studies reviewed below demonstrate the cost effectiveness of chiropractic in Canada and UK where there is largely a single-party payer model, vs. Australia where there is a hybrid (public-private) model comparable to the USA.

<u>Canada</u>: Several major feasibility studies were conducted by one of Canada's foremost health economist Pran Manga PhD, a professor at the University of Ottawa and one of the architects of the Canada Health Act. 161-163 At the time, chiropractic was not covered by the Ontario Health Insurance Plan (OHIP). Their first report in 1993, funded by the Ministry of Health of Ontario, concluded that chiropractic coverage would result in greater utilization, but ultimately produce a net savings in both direct and indirect costs of managing neuromusculoskeletal disorders.

A revision of the study in 1998 further concluded that the potential savings to the Ontario's healthcare system of as much as \$380-\$770 million by implementing chiropractic. This extrapolated to a potential savings of two billion dollars if implemented across all of Canada.

In making their recommendations, the Manga reports, as they have come to be known, concluded that spinal manipulation is not only more cost effective than MD care for musculoskeletal disorders, it is also safer and more effective than the regiment of drugs, bed rest, and analgesics that standard of care being offered by general practice medical doctors for low back pain patients. 161

Again in year 2000, Ontario Health Economist Pran Manga PhD makes the case that if chiropractic is further integrated into the health care system; he predicts reduced costs and improved outcomes. He pointed to the extensive body of literature which demonstrates that chiropractic is effective for neuromusculoskeletal disorders and the repeated evidence that patients often prefer chiropractic care over a medical approach. Evidence of effectiveness for medical care is not nearly as convincing for management of neuromusculoskeletal conditions. <sup>163</sup>

However, In spite of the favourable recommendations, the Ontario government in an attempt to reduce costs in the OHIP premiums, elected a complete cancellation of patients' chiropractic coverage in 2004. The Ontario Government reported that eliminating chiropractic would save \$47 million during the remainder of that fiscal year and almost \$100 million annually thereafter. By delisting chiropractic,

there was some savings, but the substitute expenses incurred by the system when patients turned to other providers far exceeded the amount saved as predicted by the earlier Manga reports. Since this time, there have been multiple and often contentious attempts to revise the OHIP system, stressing greater accountability and evidence-based decision-making, but the costs continue to escalate and chiropractic remains delisted.<sup>164</sup>

In Canada, there was one unusual example where cost savings with open access to chiropractic could be evaluated. Until 1992, the residents of Saskatchewan had full access to chiropractic under Medicare. Their use of chiropractic services was comparable (av. 8 visits/yr) to the national average, 6-9 visits/yr, for access to all other providers.

Then, access to chiropractic was restricted in Saskatchewan. These restrictions did not stop the long-term growth of the profession in that province. Moreover, as a result of restriction of chiropractic services, the utilization of medical doctors increased, as did overall health costs in Saskatchwan.

Private insurance and Medicare records in other provinces demonstrate that patient access to chiropractors tends to be on an as-need basis, rather than a provider generated demand that concerns health economists about the cost of care provided by medical doctors. <sup>165</sup>

<u>United Kingdom (UK)</u>: One recent study has evaluated the cost-effectiveness of chiropractic in the UK. 166 It compared the benefits of spinal manipulation and exercise to "best care" in general practice for patients consulting for back pain. A total of 1,287 patients were recruited, divided into treatment groups and followed for more than one year. Patients receiving manipulation and exercise had lower relative treatment costs and received more treatment benefits than those treated with general medical care. The authors believe that their study was able to show convincingly that manipulation alone and manipulation followed by exercise provided cost-effective additions to general practice.

Australia: The utilization of chiropractic for workman's' compensation injuries in Australia has been documented. Tuchin and Bonello<sup>167</sup> reported preliminary findings in an analysis of Work Cover Authority data from New South Wales. Of 1289 cases reviewed, 30% had back problems and 12% employed chiropractic care for treatment of spinal injury and workers' compensation claims. The total payments for all cases using chiropractic and physiotherapy care were \$25.2 million, which was 2.4% of the total payments. When 20 claims were chosen at random the average chiropractic cost of care was \$299.65, while the average medical cost was \$647.20. A trend in data collected indicated that when greater than 60% of total cost of treatment came from chiropractors, the average missed work was 9.5 days. When less than 60% of total cost of treatment came from chiropractic care the number of days missed from work, on average, was five-times greater (i.e., 50.3 days).

An almost identical cost/benefit ratio was obtained in an Australian study by Ebrall. His study reviewed claims to the Victorian Workcare Scheme over in a twelve-month period involving work-related mechanical low-back pain. Management by chiropractors vs. MDs was compared. Only 39% of claims reviewed and managed by chiropractors required compensation, whereas 78% of those managed by MDs required compensation. The average number of compensation days needed for those managed by chiropractors was only 6.26 days, compared to 25.56 days for those managed by medical practitioners.

#### SUMMARY:

Representative surveys reveal that the number of individuals in North America who utilize chiropractic is low (ca. 5-10%), <sup>168</sup> and this low number has remained unchanged for over 20 years. On the other hand, an analysis of all available health databases in Canada, indicate that about 30-40% of total health care costs are related directly or indirectly to issues involving the spine. <sup>169</sup> The 4-8 fold disparity between chiropractic utilization and health needs is disturbing from a financial perspective, but it is also a concern for the safety and well-being of the public.

Chiropractors are specifically trained in spinal care and have general training in primary care mandated during their four-year chiropractic education.

In particular, the basic science and clinical training of chiropractors compares favourably to that of four-year medical education programs. The public is often unaware that education of Doctors of Chiropractic is at the same level as Medical doctors (see Table 1 below). In fact, a recent comparison was conducted by Sandefur and colleagues, <sup>170</sup> to evaluate the primary care knowledge of a group of final-term chiropractic students versus a sample of medical students just entering their residency program. A team composed of MDs and DCs created a 100-item exam to test the students' training in 52 primary care tasks. The chiropractic students performed almost as well as the medical students, except in the musculoskeletal portion of the examination, in which the chiropractic students scored higher.

Given these favourable comparisons with regards to training and clinical skills, it is important to review the literature on cost-effectiveness that strongly favors chiropractors serving as primary health providers. The literature reviewed above is based upon an analysis of claims data from public (Medicare, Workman's Compensation) and private sources (HMO). It will be shown that there are major cost savings among patients utilizing chiropractic care in addition to their regular medical visits. This brief summary draws attention to the fact that Chiropractic is grossly underutilized, and should be considered to ease the run-away costs of health care in the United States and Worldwide.

Finally, a serious and meaningful restructuring of health care systems, as proposed by the CDC with their new "Healthiest Nation Campaign" and the restructuring proposed by the Manga Report in Canada, but not implemented, should apply the lessons learned from the past. Dr. Don Nixdorf is one of Canada's most prominent chiropractors. For more than a decade, he has served as a member on national and provincial agencies, Executive-Director of the British Columbia Chiropractic Association since 1985, and a veteran of countless encounters with the stakeholders of health care reform in Canada- the health ministers, other professionals, media, insurance companies and community organizations. In his recent book for the popular media, "Squandering Billions: Health Care in Canada", Nixdorf draws attention to the details the "Manga Report" and health reform concepts of other prominent health economist. Accordingly, the 10 most common obstacles to overcome in implementing successful health care reform include:

1. Patient awareness and accountability, to maintain a healthy lifestyle and balance their personal interests with those of society.

- Reassessment of the basic reimbursement requirement only for "medically necessary services". Health is not the sole domain of the medical establishment, and health claims and access need to be integrated across all sectors of the economy.
- 3. When different services are being considered, governments need to understand the difference between "substitution" (shifting care from one sector of the economy, e.g., from primary care MDs to chiropractors or nurse practitioners) vs. the typical bureaucratic interpretation of adding "additional" costs (i.e., services not now covered, that would be covered over and above current costs). Significant health care reform will require a "substation" of providers and services, and not the "addition" of new services.
- 4. The bureaucracy and non-service delivery-related infrastructure must be scrutinized and reduced at all levels.
- 5. Improve the non-competitive environment. There is insufficient competition because of medical, dental and pharmaceutical monopolies.
- 6. The modes of primary care delivery, needs to be vastly improved from the physician gate-keeper model to direct access to a variety of well-trained providers (e.g., chiropractors, nurse practitioners).
- 7. Home care, convalescent hospitals and small surgi-centers should be dramatically expanded, each with the aim of providing adequate "substitution" for more expensive acute care hospitals and trauma centers.
- 8. Pharmaceutical utilization and costs are out of control and need to be examined.
- 9. Manga states that "good policies work if the leaders are prepared to be tough". Frequently this is not the case, and will be an absolute requirement at all levels for health care reform to be successful.
- 10. "Progress gets lost in minutiae" says Manga. Unanimous and even perfect solutions prevent any improvements from taking place. Get started now with a good (albeit not perfect) plan.

Potential benefits of increased chiropractic utilization may include reduced medical costs, improved productivity, and effective techniques for coping with stress. The benefits to society are potentially enormous and include economic and health-related issues. We encourage the further exploration of conservative, subluxation-centered chiropractic care on health outcomes and health care expenditures and urge health policy officials to carefully consider ten-obstacles above in implementing health policy reform.

#### **PATIENT PREFERENCES**

While the CCP Guidelines were developed for a wide variety of interested parties the major group impacted by these guidelines is the consumers of health care

services. An overriding theme as regards the establishment of health promotion activities is the concept of patient empowerment.<sup>172, 173</sup> Patients must have the right to choose the type of health care they desire and not be restricted or forced to acquire their care from practitioners they do not wish to see, to have procedures they do not wish to have nor engage with systems of healing with which they disagree.

Every consumer of health care is ultimately responsible for his/her own health choices and the patient's expectations should be consistent with the provider's goals. If the patient perceives those goals as anything different, proper and safe choices cannot be assured. Thus, it is important to recognize that chiropractic is a limited, primary profession which contributes to health in one way by addressing the safe, detection, location, and correction or stabilization of vertebral subluxation(s). It is important that the chiropractor take the steps necessary to foster proper patient perception and expectation of the practitioner's professional goals and responsibilities. Several topics related to this concept of patient preferences are discussed below.

#### **PATIENT REFERRAL ISSUES**

Professional Referral: Professional referral requires authority and competence to acquire accurate information concerning matters within the scope and practice of the professional to whom a referral is made. There are two types of professional referrals made by chiropractors:

- (A) Intraprofessional referral: Chiropractors, by virtue of their professional objective, education, and experience, have authority and competence to make direct referrals within the scope and practice of chiropractic. Such a referral may be made when the attending chiropractor is not able to address the specific chiropractic needs of a particular patient. Under these circumstances, the chiropractor may refer the patient directly to or consult with another chiropractor better suited by skill, experience or training to address the patient's chiropractic needs.
- (B) Interprofessional referral: In the course of patient assessment and the delivery of chiropractic care, a practitioner may encounter findings which are outside his/her professional and/or legal scope, responsibility, or authority to address. e.g., 174 The chiropractor has a responsibility to report such findings to the patient, and record their existence. Additionally, the patient should be advised that it is outside the responsibility and scope of chiropractic to offer advice, assessment or significance, diagnosis, prognosis, or treatment for said findings and that, if the patient chooses, he/she may consult with another provider, while continuing to have his/her chiropractic needs addressed.

#### **DIAGNOSIS**

While training and statute may allow the chiropractor broad diagnostic scope, chiropractors may also elect to limit their practice and diagnostic scope to the detection, characterization and care of vertebral subluxations, and determining the safety and appropriateness of chiropractic care.

There exists a wide variety of health care practitioners, systems of health care and cultural overlays that effect how the public utilizes health care services. While every practitioner should be sensitive to this wide variety of cultural and individual practices, it is not possible to dictate a particular class of provider that a

patient must see for evaluation of unusual findings. This must be done on a case by case basis and must be a decision the patient is empowered to make.

Nothing here absolves the chiropractor from knowing the limits of his or her authority and skill, and from determining the safety and appropriateness of chiropractic care. The chiropractor has a duty to disclose to the patient any unusual findings discovered in the course of examination, and may collaborate with other health professionals when it is in the best interests of the patient to do so.

#### **ASYMPTOMATIC CARE**

Chiropractic care to detect and correct vertebral subluxations may offer benefits for all people, including those who do not demonstrate symptoms of a disease or health condition. <sup>156</sup>

Therefore, the presence or absence of symptoms and/or a medical diagnosis should not be a factor in determining the need for, or appropriateness of, chiropractic analysis and/or adjustments, nor should the presence of symptoms be required by any chiropractic board, insurance company or court of law to justify the rendering of chiropractic care to any patient.

Further support for this can be found in the Association of Chiropractic Colleges' Position Paper No. 1, endorsed by all chiropractic colleges in the U.S. and Canada and virtually every chiropractic organization in the world. It states in part: "The practice of chiropractic includes: establishing a diagnosis; facilitating neurological and biomechanical integrity through appropriate chiropractic case management, and; promoting health" (section 3.0, The Chiropractic Paradigm).

The paper goes on to state: "Chiropractic is concerned with the preservation and restoration of health, and focuses particular attention on the subluxation; A subluxation is a complex of functional and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health; A subluxation is evaluated, diagnosed, and managed through the use of chiropractic procedures based on the best available rational and empirical evidence." (Section 4.0, The Subluxation). Nowhere does this defining document state or imply that chiropractic is to be used only for patients exhibiting symptoms.

The use of health care procedures on asymptomatic patients is commonplace in all medical and alternative care fields, both as "primary" and "secondary" preventive measures and in recognition of the fact many health conditions do not exhibit outward signs, particularly in their early stages. This stands in contrast to "tertiary" prevention- i.e., sickness care- where disease is already present and intervention is designed to reduce its negative impact by restoring function and reducing disease-related complications.

The need for chiropractic care by asymptomatic patients is one that has been widely supported by the chiropractic profession. It is estimated, based on the findings of an expert panel of seven chiropractic researchers, that 97% of the chiropractic profession provides chiropractic services to asymptomatic patients if subluxations are present.<sup>4</sup> A textbook published in 2008 and written through a collaborative work of an entire clinical department at a chiropractic college echoes this key objective as a vision statement in the preface of the text: ".... Conceived on the premise that people

are better off when no vertebral subluxations are present, endeavor to address the goal of empowering practitioners to assist individuals striving to live a vertebral subluxation-free life. This core value, centered on vertebral subluxation, serves to guide professional decision-making in various ways... To appreciate the value of such a vision is necessary to consider the role of professional objectives in defining a profession". <sup>247</sup>

A "Terms of Acceptance" is the recorded, written informed consent agreement between a chiropractor and the patient. This document provides the patient with disclosure of the responsibilities of the chiropractor and limits of chiropractic, and the reasonable benefit to be expected.

This enables the patient to make an informed choice, based on their preferences, either to engage the services of the chiropractor, aware of the intended purpose of the care involved, or not to engage those services if the proposed goals are not acceptable or not desired. This embodies the responsibility of assuring patient preference and safety by not providing false or misleading promises, claims or pretences to the patient. <sup>175-180</sup>

#### THE ROLE OF VALUE JUDGEMENTS

Clearly the individuals involved in the development of these guidelines share common values regarding the existence of the vertebral subluxation and the importance of identifying its manifestation in patients, followed by its reduction and/or correction. This becomes obvious as one looks at the various backgrounds which the individuals bring to the process. It can also be said that the Panel's views on the subluxation and the literature reviewed mirrors that of the average practicing chiropractor. This general view of the subluxation is based on a recent representative survey of chiropractors that found significant agreement amongst chiropractors regarding the concept of subluxation and how it is diagnosed and managed.<sup>98</sup>

Another issue that is somewhat apparent is the panel's adherence to an evidence-based model for evaluation and characterization of vertebral subluxation. This additionally reflects the value placed on the objective identification of subluxation and assessment of outcome following the introduction of care intended to correct it. This is further reflected in a newly published textbook on the analysis, location and correction of vertebral subluxation. Dr. Myron Brown writes in the preface: the subluxation-centered approach "... is unique in its purpose and precision (location, analysis and correction of vertebral subluxation) and can be clearly distinguished from 'manipulative therapies' as applied to the condition-centered model....". <sup>247</sup>

#### HISTORY OF CHIROPRACTIC

<u>Chiropractic</u> is the third largest health discipline in the United States, after medicine and dentistry. The current number of approximately 60,000 licensed chiropractors in the US is estimated to reach 100,000 by the year 2010.<sup>181</sup> Chiropractic services are used more often than any other CAM providers, and the satisfaction with chiropractic is high. 182, 183

DD Palmer founded chiropractic in the 1890's and his son BJ Palmer helped to expand it in the early 1920s. As such chiropractic is a distinct health profession with a separate scope of practice. Today the discipline is worldwide with the majority of its members in the United States; 20% of all US chiropractors are located in

California. Most members of the profession are unaffiliated, meaning that they do not belong to, or are not active in, any professional organization. Affiliated chiropractors belong to one of three professional organizations: the largest is the American Chiropractic Association (ACA) and there are two smaller international organizations the International Chiropractic Association (ICA) and the World Chiropractic Alliance (WCA).

As with the other major health professions (medicine, nursing, dentistry), chiropractic has established Evidence-Based Clinical Practice Guidelines developed by a peer-review process. The first consensus based document was the Mercy Guidelines. These were replaced by the first evidence based guidelines developed by the Council of Chiropractic Practice (CCP). The first edition of the CCP Clinical Practice Guidelines #1 Vertebral Subluxation in Chiropractic Practice was published in 1998. The revised edition was published in 2003 the only clinical practice guidelines for vertebral subluxation recognized by the National Guideline Clearing House (<a href="https://www.guideline.gov">www.guideline.gov</a>) and is has been distributed to the Health Ministers of 191 Nations.

The 19 colleges in the United States and Canada are accredited by the Council for Chiropractic Education (CCE). CCE seeks to insure the quality of chiropractic education by means of accreditation criteria to assess how effectively programs and institutions plan, implement and evaluate their mission and goals, program objectives, inputs, resources and outcomes of their chiropractic programs. Chiropractic Colleges in other countries are accredited and evaluated by similar agencies, e.g., Council on Chiropractic Education International (CCEI), The Council on Chiropractic Education- Canada (CCEC and the Canadian Federation of Chiropractic Regulatory and Educational Accrediting Board (CFCREAB), the European Council on Chiropractic Education (ECCE), and for Australia and New Zealand, the Council of Chiropractic Education- Australasia (CCEA)

A typical four-year chiropractic and medical curriculum are compared in Table 1 below: \*

Subject	Chiropractic	<u>Medicine</u>
Anatomy	570	368
Biochemistry	150	120
Microbiology	120	120
Public Health	70	289
Physiology	305	142
Pathology	205	162
Total Basic Science	1,420	1,200
Total Clinical Science **	3,406	3,467
Total contact Hours (Basic + Clinical yrs)	4,826	4,667
** Total Clinical Science hrs Include	es:	
Chiropractic Science	1,975	-0-
Clerkships	1,405	3,467

<u>Table 1</u>: A comparison of typical curriculum content and hours from accredited fouryear programs in chiropractic and medicine. (\* source: Center for Studies in Health

Policy, Inc, Washington, DC. And unpublished data from Meredith Gonyea, PhD. <a href="http://www.chiropracticresearch.org/NEWSSchiroeducation.htm">http://www.chiropracticresearch.org/NEWSSchiroeducation.htm</a>.)

A close evaluation of Table 1, reveals that chiropractic education is highly comparable to that of medicine, and includes considerable scholarship from chiropractic college administrators, faculty and graduates.

Of particular interest during this past five-year Guidelines update, there has been considerable growth of educational scholarship that focuses on at least ten different topic areas:

- 1. Scope of Practice <sup>187</sup>
- 2. Professionalism 188-197
- 3. Student Recruitment and Diversity 198
- 4. Clinical Skills and Competency 199-212
- 5. Curriculum and Educational Delivery <sup>213-223</sup>
- 6. Student Assessment and Satisfaction 224-232
- 7. Teaching and Institutional Effectiveness 233-237
- 8. Patient Education <sup>238-240</sup>
- 9. Research and Evidence-Based Chiropractic <sup>241-245</sup>
- 10. Philosophy 246

As an overarching measure of quality control, the Presidents of the Chiropractic Colleges have united together to form the Association of Chiropractic Colleges (ACC) that represents all colleges and programs, accredited by the CCE. The member Colleges of the ACC have recently drafted a consensus statement that includes three important characterizations of the profession: 1) the ACC position on chiropractic, 2) the ACC representation of the chiropractic paradigm-, and 3) the ACC clarification regarding the definition and clinical management of the subluxation". These principles define the field of chiropractic, and are the foundation of the profession (http://www.chirocolleges.org/)

ACC Position on Chiropractic: "Chiropractic is a health care discipline which emphasizes the inherent recuperative power of the body to heal itself without the use of drugs or surgery. The practice of chiropractic focuses on the relationship between structure (primarily the spine) and function (as coordinated by the nervous system) and how that relationship affects the preservation and restoration of health. In addition, Doctors of Chiropractic recognize the value and responsibility of working in cooperation with other health care practitioners when in the best interest of the patient".

ACC representation of the chiropractic paradigm:

PURPOSE: "The purpose of chiropractic is to optimize health".

<u>PRINCIPLE</u>: "The body's innate recuperative power is affected by and integrated through the nervous system".

<u>PRACTICE</u>: "The practice of chiropractic includes: 1) establishing a diagnosis, 2) facilitating neurological and biomechanical integrity through appropriate chiropractic case management; and 3) promoting health".

<u>FOUNDATION</u>: "The foundation of chiropractic includes philosophy, science, art, knowledge, and clinical experience".

<u>IMPACTS</u>: "The chiropractic paradigm directly influences the education, research, health care policy and leadership, relationships with other health care providers, professional stature, public awareness and perceptions; and patient health through quality care".

#### ACC Clarification on the Definition of Clinical Management of the Subluxation:

"Chiropractic is concerned with the preservation and restoration of health, and focuses particular attention on the subluxation. A subluxation is a complex of functional and/or pathologicalarticular changes that compromise neural integrity and may influence organ system function and general health. A subluxation is evaluated, diagnosed, and managed through the use of chiropractic procedures based on the best available rational and empirical evidence."

## II. COUNCIL ON CHIROPRACTIC PRACTICE CLINICAL GUIDELINE NUMBER 3. VERTEBRAL SUBLUXATION IN CHIROPRACTIC PRACTICE.

#### 2008 UPDATE AND REVISION.

The remainder of this document contains the changes, additions and revisions to the 2003 Council on Chiropractic Practice Clinical Guideline Number 2. Vertebral Subluxation in Chiropractic Practice and is organized in the following manner:

- A description of the changes, additions and revisions to the Recommendations, Sub-recommendations and Commentary as a result of the 2008 review.
- If changes to a Recommendation have been made this is listed and discussed.
- If changes in Commentary following any recommendation have been made this is listed and discussed.
- If changes to a Conclusion have been made this is listed and discussed.
- If additional literature on the topic was found and reviewed then these references are listed at the end of the chapter.
- If a Recommendation, Commentary or Conclusion was added that was not included in the 2003 Guidelines, this is noted.

If a Recommendation, Commentary or the literature remains as it did in the 2003 guidelines a simple statement that the Recommendation, Commentary or literature remains "unchanged" follows that section/topic.

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# **SECTION 1: History and Chiropractic Examination**

#### 1.1 CASE HISTORY

**RECOMMENDATION (Unchanged)** 

Rating: Established

Evidence: E, L

A thorough case history should precede the initiation of chiropractic care. The elements of this history should include general information, reason for seeking chiropractic care, onset and duration of any symptomatic problems, family history, past health history, occupational history, and social history.

### **COMMENTARY**

The purpose of the case history is to elicit information which might reveal salient points concerning the patient's spinal and general health that may lead the chiropractor to elect appropriate examination procedures. The case history may provide information which will assist the chiropractor in determining the safety and appropriateness of chiropractic care as well as the nature of additional analytical procedures to be performed. History taking is considered a key element of quality patient care necessary for effective doctor-patient communication and improving patient health outcomes. <sup>1-6</sup> Verbal, nonverbal and cognitive assessment are also included in the patient history. The chiropractic case history should emphasize eliciting information relevant to the etiology and clinical manifestations of vertebral subluxation.

### 1.2 CHIROPRACTIC EXAMINATION

**RECOMMENDATION (Unchanged)** 

Rating: Established

Evidence: E, L

The initial chiropractic examination shall include a case history and an assessment for the presence of vertebral subluxation, which, if present, is to be noted with regard to location and character. A review of systems may be conducted at the discretion of the practitioner, consistent with individual training and applicable state laws.

Reassessments may be conducted periodically throughout a course of chiropractic care to assess patient progress. Such reassessments typically emphasize re-examination of findings which were positive on the previous examination, although need not be limited to same. Reassessment is also indicated in the case of trauma or change in the clinical status of a patient.

### COMMENTARY

The term "Vertebral Subluxation" defines the chiropractic profession, and is distinct from the term "subluxation" that is common domain medical term. The earliest non-chiropractic English definition is attributed to Randall Holme in 1668. Holme defined subluxation as "a dislocation or putting out of joint." <sup>10</sup> In medical literature, subluxation often refers to an osseous disrelationship which is less than a dislocation. <sup>11</sup> However, B.J. Palmer, the developer of chiropractic, hypothesized that the "vertebral subluxation" was unique from the medical use of the term "subluxation" in that it also interfered with the transmission of neurological information independent of what has come to be recognized as the action potential. Since this component has yet to be identified in a quantitative sense, practitioners currently assess the presence and correction of vertebral subluxation through parameters which measure its other components. <sup>12</sup> These may include some type of vertebral biomechanical abnormality, <sup>13-19</sup> soft tissue insult of the spinal cord and/or associated structures <sup>20-54</sup> and some form of neurological dysfunction involving the synapse separate from the transmission of neurological information referred to by Palmer. <sup>55-62</sup>

As noted, chiropractic definitions of subluxation include a neurological component. In this regard, Lantz<sup>63</sup> stated "common to all concepts of subluxation are some form of kinesiology [al...Sic] dysfunction and some form of neurologic [al...sic] involvement." In the position paper of The Association of Chiropractic Colleges they defined subluxation as follows: "A subluxation is a complex of functional and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health." The case history and examination are means of acquiring information pertinent to the location and analysis of subluxation. This information is primarily used to characterize subluxation regarding its presence, location, duration, and type. Additionally, the information gained through analysis guides the practitioner to ascertain which chiropractic techniques best suit the patient to effect correction of the condition.

Data collected during the patient's initial consultation and examination, pertaining to the health history and presenting concerns, thus supports the decision-making process of the practitioner. This information, relayed by the practitioner to the patient, further serves to incorporate the patient into the decision-making process regarding chiropractic care.

# 1.2.1 ELEMENTS OF THE EXAMINATION

## **1.2.1.1 HISTORY**

Important elements of the case history include previous and present social and occupational events revealed by the patient; unusual sensations, moods or actions relative to the patient, with dates of occurrence and duration; previous chiropractic and non-chiropractic intervention; and other factors. The case history usually includes the following:

- 1. Patient clinical profile.
  - A. Age.
  - B. Gender.

- C. Occupation.
- D. Other information germane to the presenting complaint, if any.
- 2. Primary reasons for seeking chiropractic care.
  - A. Primary reason.
  - B. Secondary reason.
  - C. Other factors contributing to the primary and second reasons.
- Chief complaint, if one exists. This may include onset and duration of symptoms as well as their subjective and objective characteristics, and location, as well as aggravating or relieving factors.
  - A. Trauma, by etiology, when possible.
  - B. Chief complaint.
  - C. Characteristics of chief complaint.
  - D. Intensity/frequency/location, radiation/onset/location.
  - E. Aggravating/arresting factors.
  - F. Previous interventions (including chiropractic care), treatments, medications, surgery.
  - G. Quality of pain, if present
  - H. Sleeping position and sleep patterns.
- 4. Family history.
  - A. Associated health problems of relatives.
  - B. Cause of parents' or siblings' death and age of death
- 5. Past health history.
  - A. Overall health status.
  - B. Previous illnesses.
  - C. Surgery.
  - D. Previous injury or trauma.
  - E. Medication and reactions.
  - F. Allergies.
  - G. Pregnancies and outcomes.
  - H. Substance abuse and outcomes.
- 6. Social and occupational history.
  - A. Level of education
  - B. Job description.
  - C. Work schedule.
  - D. Recreational activities.
  - E. Lifestyle (hobbies, level of exercise, drug use, nature of diet).
  - F. Psychosocial and mental health.

#### 1.2.1.1 CHIROPRACTIC ANALYSIS

Complementing the case history is the necessity of conducting a thorough chiropractic analysis. This involves procedures which indicate the presence, location, and character of vertebral subluxation. Inherent in this process is the noting of unusual findings, both related and unrelated to vertebral subluxation. This information is useful in determining the safety and appropriateness of chiropractic care.

The analysis is based partly upon the recognition that vertebral subluxation may be asymptomatic, yet still exert various physiological effects. Thus, by assimilating information relative to certain body systems, the presence of vertebral subluxation may be inferred. Examination protocols have been developed by field practitioners and researchers. Many of these protocols have been deemed acceptable by the various chiropractic educational institutions. This acceptance is expressed either through adding the protocols to the curriculum, or awarding continuing education credit to post-graduate seminars instructing these protocols, thus judging them to be sufficient in safety, efficacy, and validity to be included in clinical practice.

Manual palpation is a basic element of the chiropractic examination. This aspect of analysis includes palpation of the bony elements of the spine and includes assessment of the motion of the spine as a whole as well as the individual vertebral motion segments. Palpation of the numerous muscles which attach to and control the stability, posture, and motion of the spine is included. Static vertebral position is analyzed for abnormality. The chiropractor is additionally interested in locating areas of abnormal segmental motion to identify hypermobile segments and segments with decreased joint play (hypomobility). Palpation may also include evaluation of soft tissue compliance, tenderness, and asymmetric or hypertonic muscle contraction. The presence of vertebral subluxation may bring with it varying degrees of attendant edema, capsulitis, muscle splinting, and tenderness to digital palpation. There may be tenderness of the spinous processes upon percussion of these structures when vertebral subluxation is present.

Neurological components of the subluxation, postural distortions and other factors may bring deep and superficial myospasm to muscles of the spine, pelvis and extremities. <sup>65-75</sup> Palpation may reveal myofascial trigger points which are associated with the articular dysfunctions accompanying vertebral subluxations. Muscular involvement may manifest as "taut and tender" fibers.

Visual inspection of the spine and paraspinal region may reveal areas of hypo- or hyperemia associated with vertebral subluxation. Observation of patient posture is an important element of chiropractic analysis. Posture has far-reaching effects on physiology, biomechanics, psychology, and aesthetics. Proper body alignment relates to functional efficiency while poor structural alignment limits function. Changes in posture are considered in some chiropractic approaches as a measure of outcome. Plain film radiographs, as well as other forms of imaging may provide information concerning the

integrity of osseous and soft tissues as well as juxtapositional relationships. <sup>86-87</sup> Other assessments such as leg length analysis, <sup>88-112</sup> palpatory and strength challenges <sup>113-149</sup> are also employed to assess states of muscular responses to neurological facilitation. Spinal distortions and resultant neurological interference may create postural or neurological reflex syndromes which result in a functional change in apparent leg length. This information is also combined with skin temperature assessments <sup>150-157</sup> and/or electromyography <sup>158-186, 194-199</sup> as well as technique-specific examination procedures to evaluate the integrity of the nervous system. <sup>200-206</sup> Although clinical tradition supports the use of orthopedic and neurological tests in chiropractic practice, research to support the applicability of many of these tests to the assessment of vertebral subluxation is lacking or negative. <sup>187-193</sup> Orthopedic and neurological tests are indicated only when relevant to the assessment of vertebral subluxation, or when determining the safety and appropriateness of chiropractic care.

It is recognized that research will continue to evolve the most efficacious applications of assessment techniques described in this document. However, the literature is sufficiently supportive of their usefulness in regard to the chiropractic examination to warrant inclusion as components of the present recommendation.

The chiropractic examination may include, but not be limited to:

- 1. Clinical examination procedures.
  - A. Palpation (static osseous and muscular, motion).
  - B. Range of motion.
  - C. Postural examination.
  - D. Muscle strength testing.
  - E. Orthopedic/neurological tests.
  - F. Mental status examination procedures.
  - G. Quality of life assessment instruments.
  - H. Substance abuse and outcomes.
- 2. Imaging and instrumentation
  - A. Plain film radiography.
  - B. Videofluoroscopy.
  - C. Computerized tomography.
  - D. Magnetic resonance imaging.
  - E. Range of motion.
  - F. Thermography.
  - G. Temperature reading instruments.
  - H. Electromyography.
  - I. Pressure algometry.
  - J. Nerve/function tests.
  - K. Electroencephalography.
- 3. Review of systems.
  - A. Musculoskeletal.
  - B. Cardiovascular and respiratory.
  - C. Gastrointestinal.

- D. Genitourinary.
- E. Nervous system.
- F. Eye, ear, nose and throat.
- G. Endocrine.

## 1.2.1.3 CLINICAL IMPRESSION

An appropriate interpretation of case history and examination findings is essential in determining the appropriate application of chiropractic care within the overall needs of the patient. The clinical impression derived from patient information acquired through the examination process is ultimately translated into a plan of corrective care, including those elements which are contraindicated. The clinical impression serves to focus the practitioner on the patient's immediate and long-term needs. It is through this process that a clear picture is created regarding the patient's status relative to chiropractic care.

# 1.2.1.4 INITIAL CONSULTATION

The initial consultation serves the purpose of determining how chiropractic care can benefit the patient. It is during this interchange that the practitioner presents and discusses examination findings with the patient. Additionally, during the initial consultation, the practitioner should take the opportunity to present his/her practice objectives and terms of acceptance. The terms of acceptance provides the patient with information regarding the objectives, responsibilities and limitations of the care to be provided by the practitioner. This reciprocal acknowledgment allows both practitioner and patient to proceed into the plan of care with well-defined expectations.

While not limited to the following, it is suggested that the initial consultation include the following parameters:

- 1. <u>Description of chiropractic</u>: Chiropractic is a primary contact health care profession receiving patients without necessity of referral from other health care providers. Traditionally, chiropractic focuses on the anatomy of the spine and its immediate articulations, the existence and nature of vertebral subluxation, and a scope of practice which encompasses the correction of vertebral subluxation, as well as educating and advising patients concerning this condition, and its impact on general health.
- 2. <u>Professional responsibility</u>: To assess the propriety of applying methods of analysis and vertebral subluxation correction to patients; to recognize and deal appropriately with emergency situations; and to report to the patient any nonchiropractic findings discovered during the course of the examination, making referral to other health professionals for care or for evaluation of conditions outside the scope of chiropractic practice. <sup>207-212</sup> Such referral does not obviate the responsibility of the chiropractor for providing appropriate

chiropractic care.

3. <u>Practice objective</u>: The professional practice objective of the chiropractor is to correct or stabilize the vertebral subluxation in a safe and effective manner. The correction of vertebral subluxation is not considered a specific cure or treatment for any specific medical disease or symptom. Rather, it is applicable to any patient exhibiting vertebral subluxation, regardless of the presence or absence of symptoms and diseases.

#### 1.2.1.5 DUTY TO DIAGNOSE

It is imperative that the chiropractor be familiar with applicable statutes, rules, and regulations for the jurisdictions in which each practice is located. Case law indicates a division of opinion concerning a chiropractor's duty to diagnose. The diagnostic responsibility of a chiropractor is not uniform throughout the world.

A case in the Michigan Court of Appeals ruled that a chiropractor does not have a duty to recognize and diagnose cardiac symptoms, or refer a patient to a medical practitioner. The court held that doing so would require a chiropractor to undertake a "medical analysis" beyond the scope of chiropractic practice." <sup>213</sup>

In a previous case, *Attorney General v. Beno*, the Supreme Court of Michigan held, "We do not believe the Legislature intended to authorize chiropractors to engage in general diagnostic techniques. Had such a result been intended, it could have been clearly stated...Rather than authorizing general diagnostic techniques, the statute limited chiropractors to those methods, which might reveal the existence of misaligned or displaced vertebrae. We fail to see how taking urine samples or throat cultures will reveal the existence of subluxations. <sup>214</sup>

These cases, however, do not mean that a chiropractor does not have a duty to diagnose. At issue is the extent of that duty. The scope of chiropractic is delineated by statute. The Michigan statute defines chiropractic practice as including, *inter alia*, "Diagnosis, including spinal analysis, to determine the existence of spinal subluxations or misalignments that produce nerve interference, indicating the necessity for chiropractic care." Diagnosis" by a chiropractor in Michigan includes determining subluxation and nerve interference. It does not include full-body medical diagnosis.

Two Wisconsin cases are instructive. In *Kerkman v. Hintz*,<sup>216</sup> the Supreme Court of Wisconsin noted, "For purposes of malpractice action against a chiropractor, chiropractor's decision to treat cannot be tested in accordance with medical knowledge; rather, it must be tested in accordance with chiropractic knowledge."

Furthermore, the Court stated, "The legislature has recognized the practice of chiropractic as a separate and distinct health care discipline...By limiting chiropractors to the use of chiropractic adjustments and the principles or techniques of chiropractic science in the diagnosis, treatment or prevention of disease while prohibiting the use of traditional

medical tools, e.g. drugs and surgery, the legislature has recognized that the practice of chiropractic is distinct from the practice of medicine."

In *Kerkman*, the Court very clearly defined the extent of a chiropractor's duty to diagnose: "In summary, we hold that a chiropractor has a duty to (1) determine whether the patient presents a problem which is treatable through chiropractic means; (2) refrain from further chiropractic treatment when a reasonable chiropractor should be aware that the patient's condition will not be responsive to further treatment; and (3) if the ailment presented is outside the scope of chiropractic care, inform the patient that the ailment is not treatable through chiropractic means."

In *Goldstein v. Janusz*,<sup>217</sup> the Court of Appeals of Wisconsin relied on *Kerkman* when it ruled, "Chiropractors have no duty to recognize medical problems." The rationale was that "to do so would require chiropractors to make medical determinations which, under Wisconsin law, they are not licensed to make." The Court further noted "Although chiropractors may take and analyze x-rays, they only do so for diagnostic or analytical purposes in the practice of chiropractic."

Should a chiropractor unlawfully perform procedures, which constitute the practice of medicine, the DC may be subject to tort liability in addition to being charged with the unauthorized practice of medicine.

In *Treptau v. Beherens Spa, Inc.*, a chiropractor undertook to examine and treat a patient's foot using bandages and diathermy. The Wisconsin Supreme Court stated, "Plaintiffs do not claim there was malpractice on the part of the defendant while Beherens was engaged in the practice of chiropracty (sic) by chiropractic manipulation or adjustments of the spine. Instead, plaintiffs contend there was malpractice when he and his associates went beyond the practice of chiropracty (sic) and entered into the general field of the practice of medicine...in so far as there was thus an invasion of the general field of that practice, the methods thus used by defendant's employees in diagnosis and treatment were subject to the rules applicable to the practice of medicine and surgery." <sup>218</sup>

The court in *Treptau* relied on *Kuechler v. Volgmann*. The *Kuechler* court held, "When a chiropractor assumes to diagnose and treat disease he must exercise the care and skill in so doing that is usually exercised by a recognized school of the medical profession." <sup>219</sup>

In *Rosenberg v. Cahill* <sup>220</sup>, the New Jersey Supreme Court held that "chiropractic is a subset of medicine" while acknowledging that a medical doctor is "not always qualified to testify in cases involving the asserted malpractice of a chiropractor. The act of negligence must involve the breach of a duty that the medical doctor can evaluate. When the standard of care is within the doctor's field of expertise, and thus is common to both professions, the doctor would be qualified to testify as an expert on that issue."

Every chiropractor should be familiar with applicable state statutes, rules, and regulations. A DC should also understand the implications of relevant case law. This article is not a substitute for legal advice. It should, however, apprise the chiropractor of the peril of unlawfully encroaching upon the practice of medicine.

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#### **SECTION 2: INSTRUMENTATION**

RECOMMENDATION (Unchanged)

Rating: Established

Evidence: E, L

Information is indicated for the qualitative and/or quantitative assessment of the biomechanical and physiological components of vertebral subluxation. When using instrumentation, baseline values should be determined prior to the initiation of care.

# Commentary

The chiropractor uses a variety of procedures to assess the vertebral subluxation. These methods may include history taking, physical examination, imaging procedures and instrumentation. Though information gained from research and personal experience, the chiropractor generally assigns a personal value to each procedure in a particular clinical circumstance. The intent of this chapter is to describe clinical applications for the various instruments that may be used by chiropractors in examining their patients for evidence of vertebral subluxation.

<u>Definition of instrumentation</u>: The use of any tool or device used to obtain objective data, which can be recorded in a reproducible manner, about the condition of the patient relative to vertebral subluxation. Such instrumentation as that described below may provide information concerning the biomedical and/or neurological aspects of vertebral subluxation.

## 2.1 POSTURAL ANALYSIS

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Postural analysis using plumb line devices, computerized and noncomputerized instruments may be used to evaluate changes in posture associated with vertebral subluxation.

### Commentary

Posture analysis is recommended for determining postural aberrations associated with vertebral subluxation. The findings of such examinations should be recorded in the patient record. In order to encourage standardization of reporting, it is suggested that findings be recorded in a form consistent with manufacturers' recommendations.

Posture analysis may include the use of such devices as the plumb line, scoliometer and posturometer. Posture is often analysed by x-ray methods 9-13 where the determination for care is based on the radiographic profile. The procedure is often enhanced by a plumb line and other vertical and horizontal lines.

It is recommended that posture also be assessed dynamically since vertebral subluxation has been implicated in altering postural dynamics. High speed photography, electrogoniometry, accelerometry, electromagnetic, and video-based systems have all been used to measure the segmental positions and orientation of the moving body. <sup>2</sup>

### 2.2 BILATERAL AND FOUR-QUADRANT WEIGHT SCALES

**Sub-Recommendation** (Unchanged) Rating: Established

Evidence: E, L

Bilateral and four-quadrant weight scales may be used to determine the weight distribution asymmetries indicative of spinal abnormalities.

### Commentary

Unequal weight distribution has been shown to be indicative of spinal abnormalities.<sup>53-58</sup> Weight scales are a simple and effective means to determine weight distribution asymmetries.

#### 2.3 MOIRE CONTOUROGRAPHY

**Sub-Recommendation** (Unchanged) Rating: Established

Evidence: E, L

Moire contourography may be used to provide a photographic record of changes in body contour associated with vertebral subluxation.

# Commentary

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Moire contourography is a photographic technique which yields information regarding body contours and their variations for the purpose of evaluating structural abnormality. It is useful to the chiropractor because body surface asymmetries may be indicative of the presence of vertebral subluxation. <sup>59-73</sup>

#### 2.4 INCLINOMETRY

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Inclinometry may be used as a means of measuring motion against a constant vertical component of gravity as a reference. Changes in ranges of spinal motion may be associated with vertebral subluxation.

# Commentary

Mechanical, electronic and fluid-filled inclinometers are available. Inclinometer measurements have been thoroughly studied regarding their ability to measure complex motions of the spine. Inclinometers are considered superior to goniometers for assessing spinal motion. Inclinometers have been shown to be accurate within 10% of those obtained by radiographic evaluation. Achieving acceptable reliability is dependent upon use of standardized procedures.

#### 2.5 GONIOMETRY

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Goniometry, computer associated or not, may be used to measure joint motion. Inclinometry is superior to goniometry when standardized procedures are employed.

# Commentary

A goniometer is a protractor that may be held in the proximity of the area being measured to provide a means by which to determine degrees of motion.<sup>75</sup> Although goniometry is common, a wide range of variance has been reported.<sup>137-140</sup> expressing up to 10°-15° error.<sup>141, 142</sup>

### 2.6 ALGOMETRY

<u>Sub-Recommendation</u> (Unchanged) Rating: Established

Evidence: E, L

Algometry may be used to measure pressure-pain threshold. Changes in sensory function associated with vertebral subluxation may produce changes in pressure-pain thresholds.

### Commentary

A pressure-pain threshold meter yields a measurement of when a patient feels a change from pressure to tenderness as the device produces mechanical irritation of deep somatic structures. Pressure-pain-threshold measurements produce acceptable levels of reliability. Algometry has been shown to be very useful in measuring changes in paraspinal tissue tenderness as the thresholds are symmetrical. This renders the procedure applicable to chiropractic analysis.

# 2.7 CURRENT PERCEPTION THRESHOLD (CPT) TESTING

<u>Sub-Recommendation</u> (Unchanged) Rating: Established

Evidence: E, L

Current perception threshold devices may be used for the quantitative assessment of sensory nerve function. Alterations in sensory nerve function may be associated with vertebral subluxation.

### Commentary

The current perception threshold device is a variable voltage constant current sine wave stimulator proposed as a simple non-invasive and quantitative measure of peripheral nerve

function. One type of current perception threshold instrument, the neurometer, has been shown to be appropriate for rapid screening for neural dysfunction. 168

# 2.8 ELECTROENCEPHALOGRAPHY (EEG)

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Electroencephalographic (EEG) techniques including brain mapping and spectral analysis, may be used to assess the effects of vertebral subluxation and chiropractic adjustment associated with brain function.

### Commentary

Standard EEG and computerized EEG techniques, including spectral analysis and brain mapping, have been shown to change following chiropractic adjustments or manipulation. Such procedures may be useful in evaluating possible effects of chiropractic care on brain function.

# 2.9 SOMATOSENSORY EVOKED POTENTIALS (SSEP)

**Sub-Recommendation** (Unchanged) Rating: Established

Evidence: E, L

Somatosensory evoked potentials may be used for localizing neurological dysfunction associated with vertebral subluxations.

### Commentary

Somatosensory and dermatomal evoked potentials are used for localizing neurological abnormalities in the peripheral and central conducting pathways. These findings are useful as objective indicators of the level or levels of involvement. One study reported that improved nerve root function was observed in subjects who received a high-velocity chiropractic thrust: similar changes were not observed in controls.

#### 2.10 SKIN TEMPERATURE INSTRUMENTATION

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Temperature reading devices employing thermocouples, infrared thermometry, or thermography (liquid crystal, telethermography, multiple IR detectors etc.) may be used to detect temperature changes in spinal and paraspinal tissues related to vertebral subluxation.

### Commentary

The measurement of paraspinal cutaneous thermal asymmetries and other measurements of anomalies have been shown to be a mode of sympathetic nervous system assessment, <sup>214-247</sup> which may be used as one indicator of vertebral subluxation. Demonstrable changes in thermal patterns have been observed following chiropractic adjustment. <sup>59, 219</sup> Thermocouple instruments have been shown to demonstrate an acceptable level of reliability and clinical utility applicable to the assessment of vertebral subluxation-related changes. <sup>214, 216, 223, 231, 238, 244, 246</sup> Normative data have been collected concerning the degree of thermal asymmetry in the human body in healthy subjects. <sup>232</sup> These values may serve as one standard in the assessment of sympathetic nerve function and the degree of asymmetry as a quantifiable indicator of possible dysfunction. <sup>233</sup>

### 2.11 SURFACE ELECTROMYOGRAPHY

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L, C

Surface electrode electromyography, using hand-held electrodes, or affixed electrodes, may be used for recording changes in the electrical activity of muscles associated with vertebral subluxation.

## Commentary

Surface electromyographic (SEMG) techniques using both hand-held electrodes and affixed electrodes are widely used <sup>248-330</sup> and have demonstrated an acceptable level of reliability for general clinical usage. <sup>248-353, 255-262, 270-277, 278</sup> Other studies have demonstrated that significant changes in muscle electrical activity occur following adjustment or spinal manipulation. <sup>252, 254, 267, 277</sup> Protocols and normative data for paraspinal EMG scanning in chiropractic practice have been published. <sup>263-266, 268-269</sup> Surface EMG techniques may be used to assess changes in paraspinal muscle activity associated with vertebral subluxation and chiropractic adjustment.

### 2.12 MUSCLE STRENGTH TESTING

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Muscle strength testing may be used to determine bilateral differences or other differences in patient resistance. These differences may be characterized by the experienced examiner based on various technologies. Manual, mechanized and computerized muscle testing may be used to determine changes in the strength and other characteristics of muscles. These changes may be a result of alterations of function at various levels of the neuromuscular system and/or any other system related to the patient. Such changes may be associated with vertebral subluxation.

### Commentary

Muscle testing as a means of evaluation and diagnosis of patients within chiropractic as well as other disciplines, is well documented. Muscle testing techniques may be used to assess the effect of vertebral subluxation on various aspects of muscle strength. Research has shown manual muscle testing to be sufficiently reliable for clinical practice. Studies concerning manual muscle testing have also demonstrated electromyographic differences associated with various muscle weaknesses, and differences in somatosensory evoked potentials associated with weak versus strong muscles. Other studies have demonstrated clinical utility and reliability of hand-held muscle strength testing devices.

Muscle strength and endurance testing may be used to ascertain and track muscle force generation and neuromuscular status. Clinically, it may be useful to quantify differences in strength between limbs or bodily segments. The evaluation of strength may be characterized by the experienced examiner based on various technologies. Manual, mechanized and

computerized muscle testing may be used to determine changes in the strength and other characteristics of muscles. These changes may be a result or a cause of alterations of function at various levels of the neuromuscular system and/or any other system related to the patient. Vertebral subluxation may be associated with alterations in muscular strength and has the potential to affect multiple organ systems and overall health.<sup>358-361</sup>

# 2.13 QUESTIONNAIRES

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Questionnaires may be used in the assessment of the performance of activities of daily living, pain perception, patient satisfaction, general health outcomes, patient perception outcomes, mental health outcomes, and overall quality of life, throughout a course of chiropractic care. Questionnaires provide important information, but should not be used as a substitute for physical indicators of the presence and character of vertebral subluxation.

### Commentary

There are a variety of questionnaires of demonstrated reliability and validity which may be used to document outcomes, 374-410 including pain and symptoms, although these are not necessary correlates of vertebral subluxation. However, correction of vertebral subluxation and reduction of the abnormal spinal and general functions associated with it may be accompanied by reduction or elimination of pain and symptoms. It must be emphasized that the clinical objective of chiropractic care is the correction of vertebral subluxations. No questionnaires exist which assess the presence or correction of vertebral subluxation. Therefore, it is inappropriate to employ questionnaires to determine the need for chiropractic care, but questionnaires are appropriate as one aspect of monitoring patient progress and the effectiveness of subluxation-centered care.

#### 2.14 HEART RATE VARIABILITY

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Heart rate variability may be used to assess autonomic dysfunction associated with vertebral subluxation.

# Commentary

Variability in heart rate reflects the vagal and sympathetic function of the autonomic nervous system, and has been used as a monitoring tool in clinical conditions characterized by altered autonomic nervous system function.<sup>411</sup> Spectral analysis of beat-to-beat variability is a simple, non-invasive technique to evaluate autonomic dysfunction.<sup>412</sup>

Heart rate variability analysis has been used in the assessment of diabetic neuropathy and to predict the risk of arrhythmic events following myocardial infarction. The technique has also been used to investigate autonomic changes associated with neurotoxicity, hphysical exercise. In anorexia nervosa, he brain infarction, and an another rate variability have been collected. Another than the technology appears to hold promise for assessing overall fitness. Gallagher et al. Compared age matched groups with different lifestyles. These were smokers, sedentary persons, and aerobically fit individuals. They found that smoking and a sedentary lifestyle reduces vagal tone, whereas enhanced aerobic fitness increases vagal tone. Dixon et al. Pixon et al. Dixon et al. Pixon et al. Pixo

In occupational health, the effects of various stresses of the work environment of heart patients and asymptomatic workers may be evaluated using heart rate variability analysis.<sup>425</sup> Heart rate variability has been shown to be responsive to chiropractic care.<sup>426-427</sup>

### 2.15 COMPUTER ASSISTED DIFFERENTIAL SPINAL COMPLIANCE

# Sub-Recommendation (New) Rating: Established

Evidence: E, L

Computer assisted differential spinal compliance instruments may be used to assess changes in spinal and paraspinal tissue compliance associated with vertebral subluxation.

# Commentary

Computer assisted differential spinal compliance instruments employ a piezoelectric sensor to record the signal that is reflected after a light force is introduced into the spine and paraspinal tissues. These devices are often employed in conjunction with multiple impulse adjusting instruments. 428-432

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#### SECTION 3: RADIOGRAPHIC AND OTHER IMAGING

RECOMMENDATION (Unchanged) Rating: Established

Evidence: E, L

Diagnostic imaging procedures may be utilized to characterize the biomedical manifestations of vertebral subluxation, and to determine the presence of conditions which affect the safety and appropriateness of chiropractic care.

### 3.1 PLAIN FILM RADIOGRAPHY

<u>Sub-Recommendation</u> (Unchanged) Rating: Established

Evidence: E. L.

Plain film radiography is indicated: to provide information concerning the structural integrity of the spine, skull and pelvis; the misalignment component of the vertebral subluxation; the foraminal alteration component of the vertebral subluxation; and the postural status of the spinal column. Imaging procedures, including post-adjustment radiography, should be performed only when clinically necessary. It is common for lines of mensuration to be drawn on the radiographs to assess subluxation and alignment. These procedures may be done by hand, or the chiropractor may utilize computerized radiographic digitization procedures.

### Commentary

In considering the use of imaging methods employing ionizing radiation as a component of patient assessment, the clinician should determine if the methods of subluxation correction, patient safety, and management require the use of such procedures. The patient should be asked about any conditions which may contraindicate certain imaging procedures.

Reliability studies of several systems of biomechanical analysis, including radiographic marking systems, have been published. Imaging is a necessary component of a number of

different chiropractic analyses. The preponderance of evidence supports the reliability of these procedures when properly performed. 1-8, 12, 15-27, 29-32, 36-39, 42-61, 64-68, 70-79, 163-185 Moreover, radiographic imaging has revealed statistically significant changes in the direction of atlas positioning following chiropractic adjustment(s) 14, 28, 33-35, 156-158 The effect of chiropractic care on lateral curvature of the cervical spine has been investigated, with significant changes in the cervical curve noted in patients receiving chiropractic care. 9, 62, 63, 69, 159-162, 188-190

### 3.2 DOSAGE AND SHEILDING

<u>Sub-Recommendation</u> (Unchanged) Rating: Established

Evidence: E, L

Imaging procedures employing ionizing radiation should be performed consistent with the principles of obtaining films of high quality with minimal radiation. This may include the use of gonad shielding, compensating filters, and appropriate film-screen combinations.

### Commentary

A number of dosimetry studies using supplemental filtration and single-speed screens have revealed that in the case of 14 x 36 inch AP full-spine radiographs, the radiation levels were less than sectional films of like-sized subjects. Shielding of radiosensitive structures may be used when it does not obliterate structures of clinical interest. Such shielding results in a reduction of radiation exposure.  $^{10, 11, 13, 192-198}$ 

#### Conclusion

The judicious use of spinographic techniques can be valuable in characterizing aspects of the biomechanical manifestations of vertebral subluxation. The use of post-adjustment radiographs may also assist the chiropractor in determining effects of chiropractic adjustments on the spine when other less hazardous examination techniques cannot reveal the desired information.

#### 3.3 VIDEOFLUOROSCOPY

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Videofluoroscopy may be employed to provide motion views of the spine when abnormal motion patterns are clinically suspected. Videofluoroscopy may be valuable in detecting and characterizing spinal kinesiopathology associated with vertebral subluxation.

## Commentary

A videofluorscopic system consists of an x-ray generator capable of operating at low (1/4 to 5) milliamperage settings, an x-ray tube assembly, an image intensifier tube, a television camera, digital tape, DVD recorders and a monitor. The heart of the system is the image intensifier tube. This tube permits imaging at very low radiation levels. It is used instead of intensifying screens and film as an image receptor.

The role of videofluoroscopy in the evaluation of abnormalities of spinal motion has been discussed in textbooks, medical journals, and chiropractic publications. <sup>19, 20, 23, 80-83, 140, 155, 201, 202, 206-215, 217-224, 231, 265</sup> Studies have appeared in the literature comparing the diagnostic yield of fluoroscopic studies versus plain films, as well as reporting abnormalities detected by fluoroscopy which could not be assessed using plain films. <sup>191, 203-205, 216, 225, 228-230</sup>

Reliability has been addressed in a number of studies.  $^{200, 226, 227, 259}$  Additionally, in a study evaluating the interexaminer reliability of fluoroscopic detection of fixation in the midcervical spine, two examiners reviewed 50 videotapes of fluoroscopic examinations of the cervical spine. The examiners achieved 84 percent agreement for the presence of fixation, 96 percent agreement for the absence of fixation, and 93 percent total agreement. The Kappa value was 0.80 (p $\leq$  0.001). The authors concluded, "The current data indicate that VF determination of fixation in the cervical spine is a reliable procedure."

#### Conclusion

Observational and case studies support the use of videofluoroscopy to evaluate vertebral motion when this information cannot be obtained by other means.

# 3.4 MAGNETIC RESONANCE (MR) IMAGING

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

MR imaging may be employed to assess suspected neoplastic, infectious and degenerative conditions of the spine and related tissues as well as the stages of subluxation degeneration. Its use is generally restricted to instances where the desired information cannot be obtained by less costly procedures.

### Commentary

Magnetic resonance imaging enables clinicians to obtain clear images of the human body without ionizing radiation.

Literature supports the use of MR imaging for the detection and characterization of numerous manifestations associated with subluxation degeneration.<sup>84-107, 141-154, 239-243, 257</sup> These studies cover a spectrum of phenomena, including:

- 1. Osseous misalignment
- 2. Intervertebral disc desiccation and degeneration
- 3. Osteophytosis
- 4. Corrugation/hypertrophy of the ligamentum flava
- 5. Spinal canal stenosis
- 6. Foraminal stenosis
- 7. Disc herniation and disc bulging
- 8. Facet asymmetry
- 9. Facet degeneration
- 10. Altered cerebrospinal fluid dynamics
- 11. Cord compression
- 12. Gliosis and myelomalacia
- 13. Spinal cord atrophy

#### Conclusion

MRI may be employed to disclose manifestations of vertebral subluxation when this information cannot be obtained by more cost-effective means. MRI is also appropriate for evaluating patients with clinical evidence of conditions which may affect the safety and appropriateness of chiropractic procedures.

# 3.5 COMPUTED TOMOGRAPHY (CT)

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

CT imaging may be employed to assess osseous and soft tissue pathology in the spine and contiguous tissues. Its use is generally restricted to instances where the desired information cannot be obtained by less costly procedures.

### Commentary

Computed tomography (also referred to as CT of CAT scanning) is an imaging technique which produces axial (cross sectional) images of body structures using x-radiation. Computer reconstruction methods may be used to depict other planes.

Manifestations of subluxation degeneration which may be demonstrated by CT scanning include disc lesions, spinal canal stenosis due to infolding of the ligamentum flava, osteophytosis, and bony aclerosis. 108-139, 154, 244-246, 255, 256, 258, 265 In addition, CT may be used to evaluate developmental variance and pathologies which could affect the chiropractic management of a case.

#### Conclusion

CT may be employed to disclose manifestations of vertebral subluxation when this information cannot be obtained by more cost-effective means. CT is also appropriate for evaluating patients with clinical evidence of conditions which may affect the safety and appropriateness of chiropractic procedures, particularly fractures, degenerative changes, and osseous pathology.

### 3.6 SPINAL ULTRASONOGRAPHY

<u>Sub-Recommendation</u> (Unchanged) Rating: Established- SC Size

**Investigational- inflammation** 

Evidence: E, L (SC size)

I, L (inflammation)

Spinal ultrasonography may be used to evaluate the size of the spinal canal (SC), and to detect pathologies in the soft tissue surrounding the spine. It applications in the assessment of the facet inflammation and nerve root inflammation remain investigational at this time.

### Commentary

Sonographic imaging is a technique which utilizes echoes for ultrasonic waves to produce an image on a cathode ray tube. Sonographic techniques have been employed to measure the lumbar canal, as well as determining focal stenosis and disc disease.<sup>247-254, 266, 267-272</sup>

A small study compared sonographic results in patients with back pain previously examined by MRI, x-ray and standard orthopedic examination. The study concluded that the correlation with MRI, x-ray, orthopedic and neurologic examination was approximately 90 percent. <sup>252</sup>

#### Conclusion

The low cost, availability, ease of application, and noninvasive nature of sonographic imaging make it an attractive addition to the chiropractor's armamentarium. Furthermore, it has the potential to image various components of the vertebral subluxation. However, caution must be exercised in evaluating the claims of promoters of sonographic equipment, particularly those relating to the assessment of nerve root inflammation and facet joint disease. Further research toward the establishment of chiropractic protocols should be undertaken to explore the clinical utility of spinal sonography in chiropractic practice.

# 3.7 RADIOISOTOPE SCANNING (Nuclear Medicine Studies)

Sub-Recommendation (Unchanged) Rating: Established

Evidence: E, L

Radioisotope scans performed by qualified medical personnel may be used by a chiropractor to determine the extent and distribution of pathological processes which may affect the safety and appropriateness of chiropractic care when this information cannot be obtained by less invasive means.

## Commentary

In this procedure, bone-seeking radioisotopes are injected, and an image is produced demonstrating the degree of uptake of the radioisotopes. The examination is sensitive to regional changes in osseous metabolism, but is not specific. Abnormal bone scans may be due to metastasis, infection, fracture, osteoblastic activity or other pathology. Robert No studies or case reports were found linking abnormal bone scans with vertebral subluxation. Bone scans may have limited value in determining the safety and appropriateness of chiropractic procedures.

#### Conclusion

Radioisotope scans have a limited role in chiropractic practice. Bone scans are a sensitive, but nonspecific indicator of abnormal metabolic activity in bone.

# 3.8 Radiographic Digitizing Analysis

### **Sub-Recommendation**

Rating: Established

Evidence: E, L

Computerized X-ray analysis may be used by chiropractors to objectively analyze the biomechanical and misalignment improprieties related to vertebral subluxation. Clinical necessity is justified for assessing the degree of insult and the effect upon the patient's health and future well-being by way of impairment rating.

## Commentary

Diagnostic imaging methods may be utilized for obtaining information concerning the vertebral subluxation and other malpositioned articulations and structures, primarily the osseous misalignment component. Although advanced imaging can provide important information regarding foraminal alteration and possible nerve impingement, it is also possible to demonstrate aberrant motion and position which may impact upon the safety, appropriateness and outcome of chiropractic care.

Computer aided digitizing mensuration analysis software has demonstrated accuracy to 0.0023 mm. While hand mensuration should not be overlooked, it cannot approach the accuracy attainable with advanced computer technology. Computer aided digitizing mensuration analysis provides biomechanical analyses with a high degree of accuracy in order to make a chiropractic differential diagnosis and/or to determine care protocols. Mensuration also provides a definitive baseline for follow-up radiological examinations as an assessment of outcome.<sup>273-351</sup>

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#### SECTION 4: CLINICAL IMPRESSION AND ASSESSMENT

RECOMMENDATION (Unchanged) Rating: Established

Evidence: E, L

Practitioners should develop a method of patient assessment which includes a sufficient diversity of findings to support the clinical impression as related to vertebral subluxation. <sup>1-24</sup> In this regard, it is considered inappropriate to render an opinion regarding the appropriateness of chiropractic care without a chiropractic assessment, including a physical examination of the patient by a licensed chiropractor. When management of patient care is carried out in the collaborative setting, the chiropractor as a primary contact health care provider is the only professional qualified to determine the appropriateness of chiropractic care. The unique role of the chiropractor is separate from other health disciplines, <sup>25-35</sup> and should be clarified for both the patient and other practitioners. The patient assessment, specific to the technique practiced by the chiropractor, <sup>36-50</sup> should minimally include a biomechanical and neurophysiological component. It is inappropriate to make a retrospective determination of the clinical need for care rendered prior to the assessment.

## **Commentary (Unchanged)**

The procedures employed in the chiropractic assessment may include some or all of the, but are not limited to the following:

## Physical examination:

Palpation (static osseous, static muscle, motion)

Range of motion

Postural examination

Comparative leg length (static, flexed, cervical syndrome)

Manual muscle tests

Nerve function tests

Mental status examination and psychosocial assessment

## Instrumentation examination:

Range of motion

Thermography

Temperature reading instruments

Muscle testing

Electromyography

Pressure algometry

Nerve-function tests

Electroencephalography and brain mapping Bilateral and four quadrant weight scales Heart Rate Variability

# Imaging examination:

Spinography
Videofluoroscopy
Computerized tomography
Magnetic resonance imaging
Radiographic Digitizing Analysis

Following the determination of a clinical impression, the patient should be made aware of the findings and consent to the proposed plan of care.

Literature support for the use of these technologies may be found in the chapter on chiropractic examination, instrumentation and diagnostic imaging (Chapters 1-2).

\*See Chapters on Instrumentation and Imaging for related Commentary and references

#### 4.1 RECORD KEEPING

## Sub-Recommendation (unchanged) Rating: Established

Evidence: E, L

Since record-keeping practices may be technique/method specific and may depend on the practice objective of the practitioner, chiropractors should develop a method of reporting the care they provide to their patients that is consistent with their practice objectives. Record keeping systems for practitioners who limit their care to the analysis and correction of vertebral subluxation should minimally reflect the segments/regions adjusted and the techniques or methods employed if they are not self-evident. Other pertinent information may be included on an as needed basis.

\*This Sub-recommendation is in no way meant to contradict other recommendations made in these Guidelines that address issues related to Outcome Assessment, History and Examination, Duration of Care and Instrumentation.

## Commentary

Since the determination of the necessity for past, present and future care can only be made when all relevant information is contained in the patient records, the issue of record keeping is an important one.

Many chiropractors provide care solely directed at addressing vertebral subluxation and its related components. The record-keeping practices of these chiropractors will normally contain descriptions of the care that is unique to his/her particular method or technique system. These methods for recording subluxation and their correction can be highly idiosyncratic. These recordings should be considered acceptable as long as they adequately describe the care being provided to reduce, correct or stabilize the subluxation.

Attending chiropractors should not need to provide anything more than a simple legend that describes any non-standard abbreviations or descriptions regarding their note taking. Notes indicating the level(s), type, positions, listing, coordinates of subluxation(s) should be considered adequate. Notes may also contain information regarding the methods used to correct the subluxation(s). If a particular method is to be used on each visit it should not be considered necessary that the attending chiropractor describe this each and every visit as this would be redundant. Brief notations as to any deviation from the plan should be considered adequate.

In many cases chiropractors are expected or required to structure their notes in an S.O.A.P type format. However, if a patient is undergoing "wellness" type care, does not present with symptoms, and is purely undergoing subluxation analysis and resultant reduction it may not be always be necessary to provide subjective reports (S) from the patient and/or a detailed

assessment (A). The notes in such a case may only indicate the information pertaining to the objective, subluxation oriented chiropractic findings and the resultant plan to correct them during that visit. The assessment (A) might be considered redundant in such a case since this information (listings, coordinates, segments adjusted etc) may exist in the objective (O) section. Further, if the practice objective of the chiropractor is narrowly focused on subluxation then the practitioner may not have a listing of diagnoses other than subluxation and these might be listed in the objective section already. More detailed assessments as to long term response to care may be handled during re-examinations. Chiropractic spinal evaluation, evaluation for subluxation and other similar terms should be considered an appropriate subjective (O) notation when applicable.

Beyond the plans (P) for that particular visit additional notations regarding future plans may or may not be necessary depending on the type of care or method being rendered. Simply noting that the patient should return as needed (PRN) should be considered acceptable depending on the nature of the case.

Other note taking formats should be considered acceptable such as DAP notes.

D = DATA A= ASSESSMENT P= PLAN

In this system the subjective and objective portions of the note are combined and might be more amenable to chiropractic note-taking where the practitioner's goals revolve more around wellness care. Other similar methods of note taking should be considered acceptable as long as pertinent information is provided. The use of abbreviated notations, examination checklists, and computerized notation systems should be encouraged and considered acceptable as long as patient care is not compromised.

The construction of detailed narrative reports or progress reports may be advantageous in a situation involving litigation or reporting to a third party for various reasons. If this is necessary for the third party to make a decision regarding payment or some other need, then the requesting party should expect to compensate the attending chiropractor for their time, effort and energy expended to compile such a detailed report. Administrative costs and time associated with the recording, storage, copying and retrieval of patient records, if overly burdensome, can interfere with what is best for the patient, may distract the doctor from the task at hand, and use up valuable resources.

The performance and/or recording of extraneous examination procedures that are not germane to the evaluation of a particular patient should be discouraged as this wastes time, money and energy and adds nothing to the patient's health benefit. This would include any mandate that an attending chiropractor perform some predetermined procedure(s) such as provocative orthopedic manoeuvres or extensive neurological examination procedures, especially if these procedures have been shown to be unreliable or invalid.

The determination of the need for such procedures should be made on a case by case basis and considered necessary only if indicated by the patient's presenting complaints or if a

need becomes apparent through the patient history or initial examination findings and so long as they are consistent with the chiropractor's practice objective.

If the performance of a particular examination procedure will add nothing to the determination of what the attending chiropractor is going to do with the patient then it should be apparent that this procedure is not necessary in the care of that particular patient.

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### SECTION 5 REASSESSMENT AND OUTCOMES ASSESSMENT

RECOMMENDATION (Unchanged) Rating: Established

Evidence: E, L

Determination of the patient's progress must be made on a per-visit and periodic basis. This process provides quantitative and qualitative information regarding the patient's progress which is utilized to determine the frequency and duration of chiropractic care. Per-visit reassessment should include at least one analytical procedure previously used. This chosen testing procedure should be performed each time the patient receives chiropractic care.

Concomitant with this process, the effectiveness of patient care may also be monitored through the development of an outcomes assessment plan. Such a plan may utilize data from the patient examination, assessment and reassessment procedures. Patient-reported quality of life instruments, mental health surveys, and general health surveys are encouraged as part of the outcomes assessment plan. The analysis of data from these sources may be used to change or support continuation of a particular regimen of patient care and/or change or continue the operational procedures of the practice.

# Commentary

The reassessment provides information to determine the necessity of an adjustment on a per-visit basis. Partial reassessment involves duplication of two or more preceding positive analytical procedures. Full reassessment involves duplication of three or more preceding positive analytical procedures. Any additional or complementary analytical procedures should be performed as indicated by the patient's clinical status. The frequency of partial and full reassessments should be at the discretion of the practitioner, consistent with the objectives of the plan of care.

A substantial body of literature attests to the methods and significance of measuring outcomes. For the practicing chiropractor the implication is that regular evaluations of practice and procedures provides a form of quality control. Outcomes assessments can alert the practitioner to problems with, as well as reinforce aspects of practice which might otherwise be overlooked. In addition, on-going evaluation provides information about the clinical value of care to both patients and third-party providers. It is important to point out that there is no one "ideal" way to assess outcomes. While the responsibility to conduct this type of assessment rests with the chiropractor, so does the choice of how it is to be implemented.

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## **SECTION 6: MODES OF ADJUSTIVE CARE**

RECOMMENDATION (Unchanged) Rating: Established

Evidence: E, L

Adjusting procedures should be selected which are determined by the practitioner to be safe and effective for the individual patient. No mode of care should be used which has been demonstrated by critical scientific study and field experience to be unsafe or ineffective in the correction of vertebral subluxation.

## Commentary

This chapter is concerned with the modes of adjustive care (techniques) associated with the correction of vertebral subluxation. The literature reveals many articles on adjusting modes. These articles include technique descriptions, various applications of techniques, and reliability studies usually assessing inter- and intra-examiner reliability. A number of review articles provide discussion of the modes of care. Available research data has been complemented with professional opinion, derived from two separate forums of chiropractic experts' The International Straight Chiropractic Consensus Conference, Chandler, Arizona (1992) and the Council on Chiropractic Practice Symposium on Chiropractic Techniques, Phoenix, Arizona, (1996), both of which served to validate procedures by common knowledge and usage.

The intent of this chapter is not to include nor exclude any particular technique, but rather to provide a guideline, drawing upon the commonality of various techniques, which contributes to the chiropractic objective of correcting vertebral subluxation. Any technique which does not espouse the correction of subluxation would be considered outside the scope of the Guidelines.

A list of descriptive terms and definitions related to chiropractic adjustive care as commonly practiced follows:

**Adjustment**: The correction of a vertebral subluxation.

**Adjustic Thrust**: The specific application of force to facilitate the correction of vertebral subluxation.

**Adjusting Instruments**: Fixed or hand-held mechanical instruments used to deliver a specific, controlled thrust to correct a vertebral subluxation.

**Amplitude**: Magnitude; greatness of size or depth.

**Blocking Technique**: The use of mechanical leverage, achieved through positioning of the spine or related structures, to facilitate the correction of vertebral subluxation.

**Cleavage**: The movement of one vertebra between two other vertebrae.

**Concussion**: An adjustic thrust produced by arrested momentum. Momentum is the result of weight (mass) in motion and also of speed. An adjustic concussion depends more on speed than mass.

**High Velocity Thrust with Recoil:** A controlled thrust delivered such that the time of impact with the vertebra coincides with the chiropractor's contact recoil, thus setting the vertebra in a specific directional motion.

**Impulse**: A sudden force directionally applied to correct a malpositioned joint.

Low Velocity Thrust with Recoil: A controlled thrust administered at low speed with a sudden pull-off by the practitioner, setting the segment in motion.

**Low Velocity Thrust without Recoil**: A controlled thrust administered at low speed coupled with a sustained contact on the segment adjusted.

**Low Velocity Vectored Force without Recoil**: A short or long duration (usually ranging from 1 to 20 seconds) contact with the segment being adjusted, with or without a graduation of force.

**Manually Assisted Mechanical Thrust**: A manually delivered specific thrust enhanced by a moving mechanism built into the adjusting table.

**Manipulation**: The taking of a joint past its passive range of motion into the paraphysiological space but not past the anatomic limit, accompanied by articular cavitation (Kirkaldy-Willis). It is not synonymous with chiropractic adjustment, which is applied to correct vertebral subluxation.

**Multiple Impulse**: Impulses delivered in rapid succession.

Recoil: The bouncing or springing back of an object when it strikes another object.

**Tone**: The normal degree of nerve tension.

**Thrust**: The act of putting a bony segment in motion using a directional force.

**Toggle**: A mechanical principle wherein two levers are hinged at an elbow giving mechanical advantage. Combinations of toggles may be used to multiply or strengthen mechanical advantage.

**Toggle Recoil with Torque**: A method of using the toggle with rotation (twist) as the toggle straightens, causing the adjusting contact to travel in a spiral path.

**Torque**: A rotational or twisting vector applied when adjusting certain vertebral subluxations.

**Velocity**: The speed with which a thrust is delivered.

Attempts have been made by certain regulatory and licensing agencies, state boards, insurance companies and managed care organizations to categorize certain chiropractic technique systems as more efficacious than others. These categorizations are then used to disallow the use of the technique, deny entrance into a managed care program or sanction the chiropractor for utilizing such a technique. Many times these categorizations are based upon such items as whether they are part of the regular educational program at chiropractic institutions and/or are substantiated by the existence of peer reviewed literature.

Since the Missions of chiropractic educational institutions and programs are not uniform, it is unrealistic to expect that all institutions would expose their students to specific techniques. Further, additional techniques are offered through the post graduate programs of many chiropractic institutions, state association conventions and various other educational programs affiliated with the profession.

Since there are purported to be over 300 named techniques in use within the profession it is unrealistic to expect that every chiropractor would be proficient in each of these techniques. Lastly, these 300 plus techniques have not been compared to one another in such a fashion that any individual or group could ascertain that one technique is more efficacious than another.

Given the state of research regarding the efficacy of techniques and technique systems the best empirical evidence suggests that direct and indirect measures of outcome related to vertebral subluxation and its components are the manner to best determine efficacy of technique application. Examples of these include various health outcomes, physical, biomechanical and physiological measurements – many of which are discussed in these guidelines.

#### Conclusion

Considerable evidence substantiates the adjustment being administered for the purpose of correction of vertebral subluxation. Studies regarding the different modes 4, 12-521 compare low force methods to those employing a high velocity thrust without recoil, and low velocity vectored force without recoil, high velocity thrust with recoil, low velocity thrust with and without recoil, manually and mechanically assisted thrusts, blocking techniques, and sustained force. These studies are often presented in the context of effects on various physical and physiological parameters. Although providing useful information, the majority of these studies are limited by uncontrolled variables and lack of statistical power. They do, however, demonstrate that the application of various modes of adjustive care is accompanied by measurable changes in physical and physiological phenomena. The importance of this information, in terms of its linkage to processes used by the body in the correction of subluxation, will be assessed through continued research.

The CCP guidelines consider the modes of adjustive care that are 1) in common usage, and 2) which adhere to one or more of the descriptive terms presented in this chapter, as appropriate for correction of subluxation. However, studies regarding their theoretical basis and efficacy are often conducted by advocates of (those practicing or instructing) the respective techniques. While the information attained in the numerous investigations is not in question, since many of the studies have not passed the scrutiny of peer and editorial review, it is

suggested that the advocates of particular modes of adjustive care encourage research by chiropractic colleges, independent universities and other facilities to extend the level of credibility already achieved.

Continuing research and reliability studies are necessary to better understand and refine the underlying mechanisms of action common to the various modes of adjustive care. In addition, it is suggested that more observational and patient self-reporting studies be conducted which deal with quality of life assessments and overall "wellness," to demonstrate the pattern of health benefits which heretofore have been the purview of the patient and the practitioner. A conference sponsored by U.S. Department of Health and Human Services, Public Health Service Agency for Health Care Policy and Research, proposed many different approaches for studying the effects of treatments for which there is no direct evidence of health outcomes. 522

The CCP recognizes that many subluxation-based chiropractors do not adhere, in totality, to the current hypothetical model thus far described. These practitioners consider two additional components. One is interference with the transmission of nonsynaptic neurological information which is homologous to the Palmer concept of mental impulse. The other limits the misalignment component of the subluxation to the vertebrae and their immediate articulations. While these practitioners may adhere to some concepts of other subluxation models, their practice objectives are based on correction of the vertebral subluxation as proposed by Palmer, which has recently been elaborated by Boone and Dobson. 523-525

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# SECTION 7: Duration of Care for Correction of Vertebral Subluxation

**RECOMMENDATION (Unchanged)** 

Rating: Established

Evidence: E, L

Since the duration of care for correction of vertebral subluxation is patient specific, frequency of visits should be based upon the reduction and eventual resolution of indicators of vertebral subluxation. Since neither the scientific nor clinical literature provides any compelling evidence that substantiates or correlates any specific time period for the correction of vertebral subluxation, this recommendation has several components which are expressed as follows:

- a) Based on the variety of assessments utilized in the chiropractic profession, the quantity of indicators may vary, thus affecting the periodicity of their appearance and disappearance, which is tantamount to correction of vertebral subluxation.
- b) Vertebral subluxation, not being a singular episodic event such as a strain or sprain, may be corrected but reappear, which necessitates careful monitoring and results in a wide variation in the number of adjustments required to affect a longer-term correction.
- c) Based on the integrity of the spine in terms of degree and extent of degeneration, the frequency of assessments, and the necessity for corrective adjustments, may vary considerably.
- d) Because the duration of care is being considered relative to the correction of vertebral subluxation, it is independent of clinical manifestations of specific dysfunctions, diseases, or syndromes. Treatment protocols and duration of care for these conditions are addressed in other guidelines, which may be appropriate for any practitioner whose clinical interests include alleviation of such conditions.

# Commentary

Attempts have been made to identify an appropriate number and frequency of chiropractic visits based on type of condition and degree of severity. 1-24 Unfortunately, these recommendations are based merely on consensus, and research to support these recommendations is lacking. Moreover, little to no delineation has been made in the duration of care literature base between care for specific symptomatic profiles such as low-back pain, and long-term subluxation-specific care.

Two studies were found which addressed quality of life issues in patients under chiropractic care. One large, well-designed retrospective study assessing patient reported quality of life found no clinical end point where improvement reached a plateau. A second study involved a detailed examination of a database collected during a randomized clinical trial testing the effectiveness of a comprehensive geriatric assessment program. It was reported that compared to non-chiropractic patients,

chiropractic patients in this population were less likely to have been hospitalized, less likely to have used a nursing home, more likely to report a better health status, more likely to exercise vigorously, and more likely to be mobile in the community. Furthermore, they were less likely to use prescription drugs.<sup>26</sup>

It is the position of the Guideline Panel that individual differences in each patient and the unique circumstances of each clinical encounter preclude the formulation of "cookbook" recommendations for frequency and duration of care.

The appropriateness of chiropractic care should be determined by objective indicators of vertebral subluxation.

Chiropractors are encouraged to employ a clinically driven variable length of care format in which the duration of care is determined by each individual patient's progress toward meeting measurable objectives, set in individualized care plans and identified during individual assessment. This application ensures that patients are not over- or underutilizing a health-care resource and are currently receiving the best possible care.

When developing a care plan based on reduction, correction and stabilization of the subluxation the attending chiropractor should take into consideration many associated and aggravating factors. These will include details about the extent and character of the patient's subluxation. For example: How long have they been subluxated? How is this subluxation affecting biomechanics, their nervous system, muscles, ligaments and involved joints? The relationship between X-ray findings, chiropractic and physical exam findings and instrumentation readings may need to be correlated.

It is important to consider the patient's age in respect to their subluxation and how the age will impact the outcome. Since physical trauma is one of the potential causes of subluxation it is important to consider whether or not the patient had previous injuries, traumas or accidents. This should not be limited to single instances of trauma but also consider repetitive injuries, microtrauma on a daily basis etc. These should all be considered in terms of how they will interfere with subluxation correction and affect long term outcome.

Other co-existing health conditions may also affect the patient's response to care since if a patient is dealing with chronic health problems of any sort this may impede progress. The patient's work and home life demands may also have a bearing on how much of a correction they attain and should be considered in determining in a care plan and prognosis. The patient's sleeping habits may interfere with long-term correction and stabilization of the subluxation and should be considered.

A patient's ability to exercise or their lack of compliance to a prescribed exercise regimen may impede their progress and diminish their response. And in some cases the patient's weight may have a bearing on their recovery. Other factors include smoking, alcohol, nutritional problems and socio-emotional aspects of their life.

Justification for high frequency initial and extended wellness care plans should be based on a combination of basic science, technique, objective assessment of physiological function, structural changes and quality of life issues. The practitioner should ideally choose from several of these to develop their care plan and to justify its implementation.

No matter which of the various models of vertebral subluxation one chooses to address in clinical practice there are two components that are common to all models. These components are Kinesiopathology and Neuropathology. Kinesiopathology deals with issues related to misalignment and/or abnormal motion and neuropathology deals with the neurological changes related to the abnormal motion and/or misalignment.<sup>27</sup>

In discussing kinesiopathology the most significant basic science information relative to this is Wolf's Law, which states:

As bones are subjected to stress demands in weight bearing posture, they will model or alter their shape accordingly. <sup>28</sup>

Wolf's Law has a less well-known corollary for soft tissue called: Davis' Law that states:

Soft tissue will model according to imposed demands.<sup>29</sup>

These two Laws form the foundation of the rheology associated with subluxation and these rheological properties are essential elements in the epidemiology of vertebral subluxation, which must be considered with regards to care plans that have as their goal to make structural changes. Rheology is the study of the change in form and the flow of matter including elasticity, viscosity and plasticity. The longer a subluxation is allowed to set in the further along the path of immobilization degeneration the subluxation is allowed to progress. The extent of immobilization degeneration and the patient's individual ability to reverse it may be a determining factor in the frequency of the initial care plan and its duration. This will also affect long term care whether from a palliative or wellness perspective once a substantial correction has been made.

The other significant basic science issue related to frequency and duration of care has to do with neuroplasticity. This has to do with the nervous system's propensity to undergo "plastic" changes and learn to habituate a response and is a fundamental aspect of the nature of self-regulating repair processes that use the plasticity of the nervous system as it's conduit. In order to overcome plastic neurological changes that have set in secondary to subluxation the nervous system will need to "rewire" in order to create new plastic changes for the better. This may necessitate frequent adjustments and other inputs into the CNS over a long duration in order to make these changes. This neuroplasticity and the accompanying rheological changes discussed above secondary to subluxation are what need to be overcome in order for the patient to have a reduction in vertebral subluxation.

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# **SECTION 8: CHIROPRACTIC CARE FOR CHILDREN**

RECOMMENDATION (Unchanged) Rating: Established

Evidence: E, L

Since vertebral subluxation may affect individuals at any age, chiropractic care may be indicated at any time after birth. As with any age group, however, care must be taken to select adjustment methods most appropriate to the patient's stage of development and overall spinal integrity. Parental education by the subluxation-centered chiropractor concerning the importance of evaluating children for the presence of vertebral subluxation is encouraged.

# Commentary

Schneier and Burns <sup>1</sup> published the results of a blinded study describing the relationship of atlanto-occipital hypermobility to sudden infant death syndrome (SIDS). These authors described the phenomenon of "atlas inversion" where the posterior arch of C-1 enters the foramen magnum. They further stated, "Relative measurements suggested that a correlation existed between instability in the atlanto-occipital articulation and sudden infant death syndrome." Instability is a manifestation of vertebral subluxation. These findings corroborate those of Gilles, Bina and Sotrel in their paper, "Infantile atlanto-occipital instability." These investigators studied 17 infant cadavers. Eleven were SIDS cases and six were non-SIDS cases. Ten of the 17 cases demonstrated atlas inversion, and all ten cases were in the SIDS group. These authors also suggested that atlanto-occipital instability may be a factor in other conditions. They stated, "At this early stage in the development of our notions about the potential contribution of atlanto-occipital instability to deaths in infants, it is very difficult to assess the role of this proposed mechanism in the death of an infant with a conventional disease. Thus, one might anticipate that the 'controls' will be contaminated by children who had a conventional disease, but whose death was, in fact, caused by this mechanism."

Towbin <sup>3</sup> addressed the clinical significance of spinal cord and brain stem injury at birth, noting that such damage is often latent and undiagnosed. According to Towbin, "Death of the fetus may occur during delivery or, with respiratory function depressed, a short period after birth. Infants who survive the initial effects may be left with severe nervous system defects. In some, the neurologic sequellae are attributable directly to the primary lesion in the cord or brain stem; in others, secondary cerebral damage results, and a consequence of the imposed period of hypoxia at birth." Chesire <sup>4</sup> described three cases of traumatic myelopathy in children without demonstrable vertebral trauma. In this paper, the classical mechanism of trauma is said to be hyperextension of the cervical spine in a difficult breech delivery. Although tetraplegia may result, the x-rays are described as "usually normal."

Complicated deliveries represent a higher risk to the child of suffering spinal cord damage during the birth process. High cervical spinal cord injury in neonates is a specific complication of forceps rotation. The vacuum extractor exerts considerable traction force. Fetal skull fracture can result, and its true incidence may be higher than expected, considering that few neonates with normal neurologic behavior undergo skull x-ray.<sup>5-7</sup> Byers <sup>8</sup> published an excellent review paper addressing spinal cord damage

during the birth process. Traction and rotational stresses applied to the spinal axis were listed as causes of spinal cord injury during birth.

The vagus nerve is involved in mechanisms associated with control of tidal volume, breathing rate, and respiratory reflexes. Sachis et al. performed histological examinations of the vagus nerve in infants who died of SIDS and those who died of other conditions. Significant differences were noted between the two groups. Several hypotheses were proposed by authors to explain the data, including damage to the vagus nerve resulting in delayed development.

Gutman <sup>10</sup> described how "relational disturbance" between occiput and atlas can lead to "blocked atlantal nerve syndrome" in children and adults. The author listed a variety of conditions which appear clinically related to this syndrome. Although SIDS was not discussed as an entity, the author stated that a brain stem component is a part of this syndrome. It was concluded that for those affected, "manual treatment" by a qualified practitioner is appropriate.

In her paper "Physical stresses of childhood that could lead to need for chiropractic care," presented at the first National Conference on Chiropractic and Pediatrics, McMullen <sup>11</sup> stated, "Any condition that arises to change the normal birth process... frequently results in subluxation at the level of greatest stress. This conclusion is supported by a number of recent papers. <sup>12-22</sup> Severe subluxation resulting in nerve damage may be clinically obvious at birth (e.g., Bell's, Erb's and Klumpke's palsies); however, more frequently the trauma remains subclinical with symptoms arising at a later time. These symptoms include, but are not limited to, irritability, failure to thrive syndrome and other neurological signs and behavioral problems, <sup>60-87</sup> gastrointestinal issues (e.g., colic and irritable bowel syndrome), <sup>23-41</sup> asthma and respiratory problems, <sup>42-59</sup> ophthalmic symptoms, <sup>88, 89</sup> postural and musculoskeletal disorders, <sup>90-93</sup> and those syndromes associated with lowered immune responses <sup>94, 95</sup> and chronic middle ear infections. <sup>96-105</sup> These subluxations should be analyzed and corrected as soon as possible after birth to prevent these associated conditions."

Bonci and Wynne <sup>106</sup> and Stiga <sup>107</sup> published papers discussing the relationship between chiropractic theory and SIDS etiology. Banks et al. <sup>108</sup> stated "Functional disturbances in the brainstem and cervical spinal cord areas related to the neurophysiology of respiration may contribute the clinical factors associated with sudden infant death syndrome...Any process, whether genetic, biochemical, biomechanical or traumatic, that alters normal development of the respiratory control centers related to spinal constriction and compression following birth trauma may be contributory to sudden infant death syndrome." <sup>109-114</sup>

Other traumatic events of childhood may produce vertebral subluxations. Orenstein et al. 115 Did a retrospective chart review involving 73 children who presented at a children's hospital with cervical spine injuries. Sixty-seven percent of these injuries were traffic related resulting from motor-vehicle crashes. The injured children were passengers in an automobile, pedestrians, or bicyclists. The mean age of the patients surveyed was 8.6 years, with bimodal peaks at 2 to 4 and 12 to 15 years. The authors noted that younger children sustained more severe injuries than older children. Distraction and subluxation injuries were the most common injuries in children aged 8 years and younger. Fractures were more common in older children.

Glass et al. 116 evaluated 35 children with lumbar spine injuries following blunt trauma. Thirty-one of these children were injured in motor-vehicle crashes.

Abnormalities noted on plain radiographs and CT scans included subluxation, diestraction, and fracture alone or in combination. The authors stated, "Children involved in motor-vehicle crashes are at a high risk for lumbar spine injuries... Lumbar spine radiographs are necessary in all cases with suspected lumbar spine injury..." This paper underscores the need to evaluate the entire spine in cases of motor-vehicle accidents, not just the cervical region. It may be cited when claims for lumbar radiographs are questioned in cases of children involved in car accidents.

Rachesky et al. <sup>117</sup> reported that on the cervical spine radiographs of children under 18 they examined, vehicular accidents accounted for 36% of radiographic abnormalities. It was further stated that clinical assessment of a complaint of neck pain or involvement in a vehicular accident with head trauma would have identified all cases of cervical spine injury.

Other authors have described aspects of cervical spine injuries in children involved in motor-vehicle accidents. Hill et al. 118 noted that 31% of the pediatric neck injuries reviewed were the result of motor-vehicle accidents. In younger children (under 8 years of age) subluxation was seen more frequently than fracture. Agran 119 stated that non-crash vehicular events may cause injuries to children. Noncrash events discussed in this paper included sudden stops, swerves, turns, and movement of unrestrained children in the vehicle.

Roberts et al. <sup>120</sup> described a case where a child involved in a motor-vehicle accident sustained a "whiplash" injury resulting in immediate neck and back pain. Neurobehavioral abnormalities increased in the two-year period following the accident. Four years after the accident, symptoms persisted. Position emission tomography (PET scan) demonstrated evidence of brain dysfunction.

The clinical manifestations of pediatric cervical spine injury may be diverse. Biedermann <sup>121</sup> stated that a wide range of pediatric symptomatology may result from suboccipital strain. The disorders reported include fever of unknown origin, loss of appetite, sleeping disorders, asymmetric motor patterns, and alterations of posture. Maigne <sup>109</sup> stated that trauma to the cervical spine and head can cause such problems as headaches, vestibular troubles, auditory problems and psychic disturbances. Gutmann <sup>122</sup> discussed the diverse array of signs and symptoms which can occur as a result of biomechanical dysfunction in the cervical spine. Others have also reported various pathoneurophysiological changes in children, <sup>123-128</sup> as well as reduction of pathology following chiropractic care. <sup>23-27</sup>, <sup>42-45</sup>, <sup>62</sup>, <sup>127-128</sup> In the chiropractic literature, Clow <sup>42</sup> published a paper addressing pediatric cervical acceleration/deceleration injuries.

Two peer reviewed journals, Chiropractic Pediatrics and the Journal of Clinical Chiropractic Pediatrics are being published to disseminate critically reviewed papers in this field. Additionally, courses in pediatrics are offered at the professional and postgraduate levels at accredited chiropractic colleges and by the International Chiropractic Pediatric Association. Finally, it must be remembered that chiropractic shows some benefit even from the moment of conception, and in the fertility issue itself. A number of case reports have documented improved fertility in woman undergoing chiropractic care. <sup>130-141</sup> This issue is examined in greater detail in Section 9 (below).

The pediatric case history and physical examination necessarily differ in content and scope from those of adult patients. Even taking into consideration the difference between the two populations, however, a recent quasi meta-analysis reveals an extremely low risk for chiropractic pediatric patients receiving adjustments.<sup>61</sup>

# The Chiropractic Care of Children

Although the history of manual therapy is lost to antiquity, the first documentation of manual therapy can be traced to Hippocrates (460 BC to 375 BC) when he taught his students to apply a high velocity low amplitude (HVLA) thrust on a gibbus or a prominent vertebra followed with advice to exercise. There is no reason to believe that children, like adults, suffered from similar maladies and therefore would be candidates to similar care, manual therapy or otherwise. Within chiropractic, there are indications that the chiropractic care of children has been around since the profession's inception. A chiropractor by the name of M. Kueck wrote Old Dad Chiro that, I think I have all Chiros beat on the youngest patient. Our daughter was adjusted when she was one day and two hours of age.... Palmer's response was, "BJ's child was adjusted when he was 4 hours old..."

In the modern era, we look to the 1990s when, contemporaneous with the seminal publication by Eisenberg and colleagues<sup>144</sup> that found one in three Americans used some form of alternative therapy at a cost of \$13.7 billion with \$10.3 billion paid out of pocket, Spigelblatt and colleagues<sup>145</sup> published their findings on the frequency and sociodemographic factors associated with complementary and alternative medicine (CAM) use by children. Based on 1911 completed questionnaires, approximately 11% (N=208) indicated having consulted one or more CAM practitioners for their complaint. Of the various types of CAM therapies used (i.e., homeopathy, naturopathy, oligotherapy, acupuncture, etc.), chiropractic was the most popular to address complaints involving the respiratory, ear-nose and throat and musculoskeletal systems. In 1994, Lee and colleagues 146 characterized the chiropractic care of children. The authors extrapolated that 30 million pediatric visits were made to chiropractors in the US in 1998 at a cost of \$1 billion with approximately \$510 million paid out-of-pocket by parents. The 2005 Job Analysis of Chiropractic, published by the National Board of Chiropractic Examiners<sup>147</sup>, confirms the continuing popularity of chiropractic for children with the findings that the percentage of patients under 17 years of age has increased by 8.5% compared to a 1991 survey of practitioners. The chiropractic care of children therefore represents a significant aspect of chiropractic and pediatric care in general.

#### Unique Biomechanical Features of the Pediatric Spine

The chiropractic care of children is simply not a scaled-down version of the care of the adult. In addition to the findings that pediatric patients present to the chiropractor for a variety of conditions with an emphasis on non-musculoskeletal and wellness care, <sup>148</sup> the approach to patient care must be tempered with due consideration to the unique biomechanical features of the pediatric spine within the context of the pathogenesis of the vertebral subluxation complex (VSC). <sup>149</sup> Furthermore, within the pediatric population, such considerations are unique for those of the newborn versus a 3 year old versus a 6 year old versus a 12-13 year old. These features include growth, malleability, adaptability, hypermobility, changing spinal contours, changing applied forces and an immature neuromusculoskeletal system. Let us examine these features in the context of chiropractic care and the pathogenesis of the VSC.

A dynamic process, growth of the pediatric spine and the individual occurs at all levels of complexity at the molecular level to organs and tissue systems. Anatomically, consider that the height of the  $C_0$  is approximately 50% that of the adult. Furthermore, the horizontal orientation of the  $C_0$ - $C_1$  functional spinal unit (FSU) is much flatter. <sup>150</sup> Add to this the higher head to body mass ratio, there are higher torque and shear forces at the  $C_0$ - $C_1$  and  $C_1$ - $C_2$  FSU. The results are that the upper cervical spine in the child is prone to subluxation (i.e., lateral displacement of

the atlas). Additionally, consider the varying forces applied to the newborn in the process of birth. Recent publications indicate that major birth trauma occurs in 3% of all live-born infants, accounts for 2% of all neonatal mortality, and accounts for 10% of all neonatal deaths in full-term infants. <sup>151-153</sup> In the sagittal plane, the joint surfaces are more steeply aligned with the facet joints more shallow and angled. With underdeveloped spinous processes and physiologic anterior wedging of the vertebral bodies, these factors in addition to those mentioned above contribute to hypermobility – an increase in physiologic range of motion.

In a study involving 160 pediatric patients with no history of cervical spine trauma, 46% of children less than 8 years old had pseudosubluxation of C<sub>2</sub> on C<sub>3</sub> on lateral flexion and extension radiographs of the cervical spine. Is In situations involving trauma such as that in hyperflexion/hyperextension injuries, these pseudosubluxated segments may be more prone to injury in the way of subluxation. With respect to malleability, the pediatric spine is easily deformed with external applied forces. For our purpose, consider deformational plagiocephaly, a condition where the child's head and possibly his or her face are deformed as a result of prenatal and/or postnatal external molding forces. Deformational plagiocephaly has been attributed to intrauterine constraint, premature birth, the use of forceps and vacuum extraction during delivery, dystocia, malposition and malpresentation pregnancies, multiple birth, and primiparity. Risk factors include the male gender, non-varying head position when asleep, sleeping supine, developmental delay, and lower activity level. Placing the child in the prone position when awake for 5 minutes a day seems to be a protective factor. Cranial techniques have been found to be effective in correcting deformational plagiocephaly.

What of adaptability – the ability to withstand and adapt to stresses? This is often true of the pediatric patient with presenting complaints that are sub-clinical in nature. With the infant's inability to fully communicate, the chiropractor must be astute with his/her history and physical examination. The patient's demeanor (i.e., is the child described as more "fussy"?), the frequency and character of his/her crying, napping time and duration, and feeding habits must be taken into consideration and must augment the hands-on physical examination/findings of the patient. Chiropractors have always advocated for a physiologically aligned spine not only for cosmetic appearance (i.e., proper posture) but also for proper functioning of the spine and the whole person. We instill in our patients that a properly aligned spine leads to the maintenance and restoration of health. Towards this end, consider the body of literature on this topic as published by Harrison and colleagues. In the area of prevention, one needs only consider the findings by Kumar and colleagues that demonstrated that effective maintenance of a saggital plane in the lumbar spine leads to alleviation of negative outcomes such as segmental degeneration.

Degenerative processes do take place in the young spine and continue well into adulthood if not addressed. With respect to saggital curvatures, the neonate begins with a slight lordosis in the cervical and lumbar spine and a slight kyphosis in the thoracic spine. As the child grows, the saggital spinal alignment has been found to change. This changing spinal contour requires constant adaptations in the morphology and orientation of the pelvis (i.e., skeletal loads, muscle fatique and energy expenditure) to maintain an adequate sagittal balance and appropriate configuration in the lumbopelvis. Mac-Thiong and colleagues demonstrated that there exists a significant statistical correlation between adjacent anatomical regions of the spine. From the point of view of a kinematic chain, the pelvic incidence and sacral slope affect the development of the lumbar lordosis, the thoracic kyphosis and presumably the cervical lordosis. In view of the physiologic and morphologic changes that occur during spinal development and efforts to maintain an adequate spinal balance, chiropractic care is indicated and would be prudent even in the absence of pain symptoms. Restoration and maintenance of

spinal alignment is the cornerstone of chiropractic care. Failure to address misalignment in childhood may lead to pathology in adulthood.

Consider the finding by Hestbaek and colleagues<sup>164</sup> that found low back pain in adolescence was a significant risk factor for low back pain in adulthood with odds ratios as high as four. Lastly, the pediatric spine is associated with an immature neuromusculoskeletal system. As such, supporting soft tissue structures (i.e., muscles, ligaments, tendons) have mechanical properties inferior compared to that of the adults to withstand changing and applied forces. Additionally, reflex effects that are well developed in the adult are just beginning to be established as the child matures. As such, intentional forces applied to the spine in the way of an adjustment must be tempered to prevent sprain and strain injuries to the FSUs. Although no studies thus far have measured the forces applied to the pediatric spine utilizing an HVLA type thrust; using a straight posterior-to-anterior HVLA thrust to the transverse process of T3-T10 reinforced with hypothenar contact, Herzog and colleagues<sup>165</sup> measured an average peak total force was 238.2 N over a target area of 25 mm² in asymptomatic adults. For children, a fraction of this may be applied with HVLA-type maneuvers ranging from 30-70 N of force.<sup>166</sup>

#### **Evidence-Based Pediatric Chiropractic**

In a recent publication, Gotlib and Rupert<sup>167</sup> performed a systematic review of the literature on the use of chiropractic for a variety of pediatric conditions. The authors found that low levels of scientific evidence supported chiropractic care for various pediatric health conditions. The evidence rested primarily with clinical experience, descriptive case studies and very few observational and experimental studies. This systematic review was an update to a systematic review performed by the authors in 2005<sup>168</sup> that found similar findings. We do not disagree with the findings of Gotlib et. al.<sup>167-168</sup> per se. In fact the authors are to be commended for their contribution to chiropractic research.

As defined by Sackett and colleagues, 169 evidenced-based practice is defined as the conscientious, explicit, and judicious use of current best research evidence, the integration of the clinical expertise of the clinician and the thoughtful identification and compassionate use of an individual patient's predicaments, rights, and preferences in making clinical decisions about their care. Towards this end, the review by Gotlib and colleagues 167-168 provide an incomplete assessment of the state of chiropractic research on the chiropractic care of children. There is a growing movement among CAM providers and researchers that recognize that existing research methodologies and dependence on randomized controlled clinical trials as the "gold standard" may not be sufficient or appropriate for CAM therapies. 170 As pointed out by Verhoef and colleagues. 171 non-allopathic therapies such as chiropractic are complex with individualized rather than standardized treatments. With a holistic and vitalistic approach to patient care, chiropractic addresses non-specific, multifactorial elements of the patient beyond the specific condition at hand (i.e., restoring homeostasis in the person). Recruitment for RCTs may be incongruent with a person's beliefs, practices and general worldview and as already exemplified in chiropractic research, an appropriate sham/placebo treatment may be impossible to identify. Lastly. RCTs minimized or exclude the impact of non-specific effects (i.e., patient-provider relationship) whereas in chiropractic, these effects are embraced.

As such, chiropractic and other CAM therapies may be more amenable to whole systems research (WSR). Whole systems can be defined as "approaches to health care in which practitioners apply bodies of knowledge and associated practices in order to maximize the patients' capacity to achieve mental and physical balance and restore their own health, using individualized, non-reductionist approaches to diagnosis and treatment." Furthermore,

assessing the evidence in pediatric chiropractic research using traditional methods such as systematic reviews becomes painfully obvious in its limitations. Only a handful of pediatric conditions (i.e., asthma and colic) under chiropractic care have research utilizing RCTs. Therefore, a meta-analysis cannot be performed with systematic reviews. However, the use of qualitative research in both allopathic and non-allopathic care has gained some ground in recent years. Qualitative research investigates phenomena in their natural context and generates specific information regarding the why and how of individual experiences. One specific approach of qualitative research is meta-synthesis. Defined as "the bringing together of findings on a chosen theme, the results of which should, in conceptual terms, be greater than the sum of the parts", <sup>173</sup> meta-synthesis may also provide a tangible approach to the evaluation of research thus far published. Hawk and colleagues 174 recently developed a checklist to evaluate the merits of chiropractic research in the context of WSR. Although preliminary in nature, the checklist is the only one of its kind created by chiropractors and specific for chiropractic. For metasynthesis, the cross-case analysis approach is performed where categories are identified in individual studies and then refined and cross-referenced with other studies. The WSR and meta-synthesis approach to the chiropractic care of children with otitis media is applied here as an example.

# Systematic Review of the Literature on the Chiropractic Care of Children with Otitis Media: Incorporating Whole Systems Research and Qualitative Meta-Synthesis.

To perform the systematic review, a comprehensive search was performed to identify all relevant reports pertaining to the chiropractic care of children (age ≤ 18 years) with otitis media. The following electronic databases were searched: MANTIS [1965-2008]; ICL [1984-2008]; Pubmed [1966-2008]; EMBASE [1974-2008], AMED [1975-2008], CINAHL [1965-2008], Alt-Health Watch [1965-2008] and PsychINFO [1965-2008]. Key words used were otitis media (OM), ear infections, acute otitis media(AOM), chronic otitis media (COM), otitis media with effusion (OME) in combination and chiropractic incorporating the Boolean operators and the application of related words when appropriate. The search was limited to publications in the English language and in peer-reviewed journals. Additionally, chiropractic journals (i.e., Journal of Manipulative and Physiological Therapeutics, Journal of the Canadian Chiropractic Association, Clinical Chiropractic, The Chiropractic Journal of Australia and the Journal of Clinical Chiropractic Pediatrics) were hand-searched for the last five years for possible relevant materials. Key informants and experts in the field were also contacted to provide assistance in providing relevant literature. The gray literature was also searched as well as the bibliography lists of all retrieved articles and relevant studies.

The title and abstracts of all articles generated from the electronic database search as well as from the reference lists of relevant articles and other data sources were examined for their appropriateness for this review. The full manuscripts of reports relevant to the chiropractic care of children were retrieved by applying the following set of eligibility criteria: (1) the study was a primary investigation/report (i.e., case reports, case series, case control, randomized controlled trials and survey or surveillance studies) in a peer-reviewed journal; (2) part or all of the study population was 18 years or younger and; (3) the topic involved the care of a patient with otitis media.

A systematic review of the literature on the chiropractic care of children revealed 20 articles. These consisted of the following: four commentaries, a survey study, six case reports, five case series, three prospective cohort studies and one prospective, parallel-group, observer-blinded, randomized feasibility study on the chiropractic care of children with chronic OM. The WSR checklist and results of the WSR scoring are provided in Table 1. A total of 15

studies were amenable for WSR evaluation. The average score was 7.06 (median=7; mode=8). Based on the rating score by Hawk and colleagues (5) (maximum score = 11; 0-3 = low; 4-7 = medium; 8-11 = high quality); the peer-reviewed literature on the chiropractic care of children are of "medium" quality.

The case analysis approach to the literature examined various aspects of the management. To date, the article by Lamm and Ginter<sup>190</sup> provides for the most comprehensive description on the management approach for chiropractors on the care of patients with otitis media. This is augmented by the diagnostic approach to the care of the patient with otitis media by Bowers<sup>191</sup> Based on the published literature, the approach to the patient with otitis media begins with a history and physical examination. The prevailing findings from the history examination were unsuccessful medical care with antibiotics despite recurrence and chronicity of otitis media. The physical examination procedure incorporated both aspects of allopathic and chiropractic approaches. In 8 of the 14 publications, an otoscopic examination was performed to further augment the diagnosis of otitis media. The study by Fallon<sup>188</sup> demonstrated the clinical utility of the tympanogram as an examination and outcomes instrument in the care of patients with otitis media. Essential to patient care was in determining the sites of spinal subluxations upon which the adjustment is predicated upon and dependent on the specific technique utilized by the attending clinician.

With respect to the chiropractic care rendered, Activator Methods, Gonstead Technique, Toftness Technique, Chiropractic Biophysics and Diversified Technique were utilized. Although spinal examination and care involved both regional and fullspine approaches, there was an emphasis or focus on adjustments to the upper cervical spine. Only one case described utilizing a cranial technique. Two authors, Evans<sup>180</sup> and Erickson<sup>194</sup> utilized a dietary intervention while Fysh<sup>184</sup> and Erickson<sup>194</sup> utilized soft-tissue manipulation to enhance lymphatic flow in cervical region. Surprisingly, no studies described the use of homeopathic remedies, which from a clinical point of view is commonly utilized by chiropractors.

This systematic review of the literature on the chiropractic care of children with otitis media utilizing WSR and meta-synthesis highlights the detection and correction of spinal subluxations augmented with adjunctive modalities. This approach to patient care would seem universal in patients with other pediatric conditions such as enuresis, asthma, colic, etc. Based on our findings utilizing WSR evaluation and qualitative meta-synthesis, the chiropractic care of pediatric patients is evidence-based. The systematic review reflected the notion that chiropractors utilize best practices, depend on their collective clinical expertise and are mindful of the needs and wants of the patient/parent.

### The Safety of Pediatric Chiropractic

In addressing the role of the evidence-based clinician on the safety and effectiveness of manual therapy for children, including chiropractic. Huijbregts<sup>195</sup> points out that there is no clear evidence of harm. Furthermore, research on outcome and harm for one treatment approach cannot be applied to all. Given the continued popularity and utilization of chiropractic for children, there are ongoing concerns regarding their safety and effectiveness<sup>196</sup> both from within and outside the profession.

Ernst, <sup>197</sup> in a systematic review of the literature addressed the issue of adverse events associated with unconventional therapies in children. Most of the adverse events were associated with herbal medications due to contamination with toxic plant material, heavy metals, or adulterated with synthetic drugs. The adverse events described included bradycardia, brain

damage, cardiogenic shock, diabetic coma, encephalopathy, heart rupture, intravascular haemolysis, liver failure, respiratory failure, toxic hepatitis and death. With respect to the use of SMT in children, Ernst<sup>197</sup> referenced the paper by Di Fabio<sup>198</sup> that examined 177 cases involving SMT of the cervical spine as reported in 116 articles published between 1925 and 1997. Although the subjects' age ranged from 4 months to 87 years, the majority of the cases involved adult patients. Ernst<sup>197</sup> further described one case of an infant with congenital torticollis treated with chiropractic spinal manipulation.<sup>199</sup> Within a few hours of this therapy the child suffered from respiratory distress, quadriplegia and seizures. A holocord astrocytoma with excessive acute necrosis was found and resected.

To address the issue of safety of pediatric osteopathic spinal manipulative therapy (OMT), Hayes and Bezilla<sup>200</sup> performed a retrospective review of medical records of pediatric patients receiving osteopathic manipulative therapy (OMT) looking for documentation of treatment-associated aggravations and complication as previously defined. Of 502 records reviewed, 346 files met inclusion criteria (i.e., patient received  $\geq$  2 office visits) for analysis. No OMT-related complications were documented. Nine percent (N=31) of 346 patients reported an OMT-associated aggravations. Hayes and Bezilla<sup>200</sup> concluded that OMT appears to be a safe treatment modality for the pediatric population.

Vohra and her colleagues<sup>201</sup> recently performed a systematic review of the literature on the adverse events associated with pediatric SMT. Using 8 databases and spanning a period 0f 104 years, Vohra et. al.<sup>201</sup> found 14 instances of adverse events associated with pediatric SMT. The adverse events documented included irritability (N=1) and loss of consciousness (N=1), midback soreness (N=1), acute lumbar pain (N=1), headache and stiff neck (N=1), severe neurological deficits (N=5), Anterior dislocation of atlas and fracture of odontoid axis at C2 (N=1), atlas dislocation (N=1) and eventual death (N=2). Considering that the chiropractic adjustment is the primary treatment approach of chiropractors, not surprisingly, the majority of cases (10 of 14 cases) were attributed to chiropractic. A critical appraisal by Alcantara<sup>202</sup> on the adverse events attributed to chiropractic by Vohra et.al.<sup>201</sup> provided convincing arguments against cause and effect inferences to chiropractic care and the resultant adverse events. Five of the 10 cases were minor, self-limiting, and did not require hospitalization or medical attention. In the cases involving severe neurological loss, fracture or death, a pre-existing condition or history of trauma preceded the chiropractic care. As Alcantara<sup>202</sup> pointed out, cetaris parabis, the findings by Vohra et.al.<sup>201</sup> would seem to indicate that pediatric chiropractic is safe.

Recently, Miller and Benfield<sup>203</sup> reported possible adverse outcomes with pediatric chiropractic care at the Anglo European College of Chiropractic. From 697 children receiving a total of 5242 chiropractic treatments (with 85% of parents reporting an improvement), 7 parents reported an adverse effect. The authors reported a reaction rate of approximately 1 child in 100, or one reaction reported for every 749 treatments. No serious complications resulting from chiropractic treatment were reported by the authors. Despite the reported and perceived safety reported by Miller and Benfield, <sup>203</sup> the expectation of 1 report of an adverse event for every 100 children receiving chiropractic care is disagreeable. First, three of the 7 cases were in fact not adverse events per se but more likely "perceived" or misinterpreted by the authors as an adverse event on initial interpretation. Secondly, the reported adverse events were based solely on reports on the part of the parent(s) of excessive crying of their child within a teaching institution. No further documentation in support of an adverse event beyond crying was assessed. In most of the cases, the children were receiving care for infantile colic with one for KISS Syndrome. As pointed out by the principle author (Miller) in a separate publication.<sup>204</sup> infantile colic and KISS Syndrome are conditions of childhood characterized with excessive crying. The extent to which care rendered by chiropractic students is similar or dissimilar to care rendered by experienced and/or licensed practitioners was not addressed by the authors. The issue of confounding was also not addressed by Miller and Benfield. The rates of adverse events reported by Miller and Benfield<sup>203</sup> are therefore suspect and arguably much less than they report.

The International Chiropractic Pediatric Association recently launched their Practice-Based Research Network to address research on the chiropractic care of children. On the issue of safety, a study modeled on the work of Hayes and Bezilla<sup>200</sup> was launched to examine treatment associated aggravations and complications associated with chiropractic care of children. Aggravations and complications were operationally defined so that aggravations were "worsening of symptoms" while complications involve such situations as fractures, dislocations, stroke, death, etc. Based on preliminary findings thus far, a survey of chiropractors provided care to 577 children for a total of 5438 clinical encounters - no treatment-associated complications have been documented and less than 4 cases of treatment-associated aggravation have been reported (unpublished data).

The results were similar with the parent survey from 239 children attending a total of 1735 visits. No documentation of treatment-associated complications was made with 2 instances of treatment-associated aggravation (unpublished data). All reported aggravations (from chiropractor and parent survey) were minor, self-limiting, and did not require hospitalization or medical attention. More importantly, the complaints were addressed by the treating chiropractor in subsequent visits and did not dissuade the parents from continuing chiropractic care for their child.

Table 1. Whole Systems Research checklist and WSR scoring of studies on the chiropractic care of children.

WSR Checklist	References	WSR
1 Intervention included entire clinical encounter (rather than single procedure		Scoring
only) 1a • Intervention tested "package" of care	DL:11: (25)	7
	Phillips (35)	7
2 Patient preferences/expectations assessed	Burnier (36)	5
2a • Treatment preference or expectations assessed	11 (27)	
3a • Practitioner could use clinical judgment to modify procedures	Heagy (37)	8
3b • Practitioner could use clinical judgment to modify number of visits, duration of care	Peet (38)	7
4 Intervention representative of usual practice	Evans (39)	8
4a • Delivered by experienced practitioners	2,4110 (07)	
4b • Procedures/protocols based on usual practice, as documented by case reports, case series or large observational studies	Marko (40)	6
4c • Principal investigator delivered treatments (-1)	Webster (41)	8
4d • Fees for services were representative of usual practice	Fysh (43)	8
5a • "Real-life" comparisons such as no treatment, waiting list, or standard medical care used	Froehle (44)	8
5b • Sham/placebo procedure same as procedures used in usual practice (such as soft-tissue therapy) (-1)	Thomas (45)	8
6a • Primary outcomes were patient-based measures (pain, function, health status)	Fallon (47)	7
6b • Satisfaction assessed	Sawyer and Colleagues (51)	7
7a • Health status or QOL instrument administered pre- and post-intervention	Saunders (51)	6
	Zhang et. al. (52)	7
	Erickson and colleagues (53)	6
	Mean Score= 7.06 (Median=7; Mode= 8)	

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#### **SECTION 9: MATERNAL CHIROPRACTIC CARE**

RECOMMENDATION (Unchanged) Rating: Established

Evidence: E, L

In pregnancy a woman's body experiences numerous biomechanical adaptations and physiological changes. These changes often have an adverse affect on her neuro-musculo-skeletal system affecting quality of life in pregnancy, birth outcome and the future well-being of her baby. Because of these physiological compensations, practitioner care must be taken to select the specific analysis and adjustment most appropriate for the complex changes throughout the various stages of pregnancy. The increased potentials for spinal instability in the mother and the resulting subluxations in the woman's spine throughout pregnancy affect the health and well-being of both her and her baby. This warrants regular chiropractic check-ups in all women throughout pregnancy. Patient education pertinent to chiropractic care in pregnancy is encouraged.

# Commentary

The doctor of chiropractic plays an essential role in both the mother and baby's musculoskeletal and nerve system throughout pregnancy and in preparation for birth. Weight gain, compensating postural changes and hormonally induced ligament laxity add to the woman's propencity towards spinal subluxations in pregnancy. An increase of spinal subluxations lead to an elevation in low back pain affecting quality of life and labor outcome. Spinal subluxations also affect neurological function of the uterus affecting pregnancy and birth outcome. Additionally, the loss of biomechanical integrity of the mother's pelvic muscles and ligaments and their resulting uterine support may adversely cause a condition known as intrauterine constraint affecting infant positioning in pregnancy and birth.

Varney's Midwifery text states, "The potential for damage in pregnancy and the postpartum period to a woman's neuro-musculo-skeletal structure is great. Shifts in the center of gravity forward and slightly up destabilize her posture and realign the carriage of weights and forces through her joints, predisposing nerves, muscles, bones, and connective tissues to damage. Increased levels of relaxin and elastin further aggravate this situation." Gait compensations and increased biomechanical loads lead to further strain on spinal segments and their supporting structures.

Female sacroiliac joints tend to be flatter, with a wider retroarticular space and longer interosseous ligaments, all promoting greater mobility. As hormonal changes affect supporting musculature and ligament laxity, there is an increase in spinal and sacroilloiac articulations compensation and mobility. If a motion segment is compensating for a lack of mobility at an adjacent level, then these segments may become more hypermobile. 3,4

Chiropractors Forester and Anrig write, "Maternal weight gain is most significant during this gestational period. This contributes largely to the profound biomechanical compromise of the lumbosacral spine. With a drastic shift in the gravitational weight bearing of the mother, pelvic musculoskeletal function, principally of the sacroiliac and hip joints is imperiled. This leads to often significant soft tissue structure changes such as hypertonicities or ligament laxity, which in turn creates biomechanical instability. Not just the lumbosacral spine but compensatorily, the thoracic and even cervical spines acquire a diversity of combinations of aberrant segmental and global motion. The unfortunate typical short radius sacral curve of later pregnancy provides the foundational imbalance for thoracic hyperkyphosis and cervical kypholordosis. Cellular edema and inflammation, along with anatomical yielding of the intervetebral foraminae, generate neurophysiology of the important spinal nerve tissues with resultant cellular and aggregate tissue malfunction. Summarily, the potential for extensive vertebral subluxation complex in the maternal patient is physiologically inherent for the last 3 gestational months.<sup>5</sup>

Varney's midwifery states, "In the antepartal period, changes in posture occur gradually and can be responsible for a great many discomforts over the course of the pregnancy." The prevalence of low back pain during pregnancy can be as low as 42.5% and as high as 90% One study revealed that 28% of women experience back pain by the twelfth week of gestation. Because of the biomechanical compensations discussed above, it is not unusual for pregnant women to experience pain in multiple areas of her spine including sacral, lumbar, thoracic, cervical and cranial.

## Low Back Pain in Pregnancy

Back pain in pregnancy is a frequent clinical problem. Out of 200 women, seventy-six percent reported back pain at some time during pregnancy. Sixty-one percent reported onset during the present pregnancy. 30% with the highest pain score reported great difficulties with normal activities.<sup>10</sup>

Another study showed One survey reports the prevalence of LBP in pregnant women to be about 50%. It further states that the most common reason for severe low back pain in pregnancy was dysfunction of the sacroiliac joints.<sup>11</sup>

It is important to note that the prevelance of back pain in pregnancy, the need to address these concerns without the harmful effects of drugs and the significance of this pain on the woman's quality of life and function are all significant reasons to establish safe and reliable models of care as provided by chiropractic adjustments for this population. 12-15

Currently, most published research on chiropractic care in pregnancy addresses the efficacy of the adjustment for the resolution of low back pain. One study revealed that 75% of women who received chiropractic adjustments during their pregnancy stated that they experienced relief of their pain and discomfort. 16 Two other studies address the incidence of increased LBP in pregnancy and the positive results of spinal and pelvic adjustments. <sup>17,18</sup> Another study concludes that intensive spinal adjustments are not only effective for the initial intensive care of low back pain, the authors also suggest that maintenance spinal adjustments after initial intensive care may be beneficial to patients to maintain subjective post intensive disability levels. <sup>19</sup>

Another study looked at back pain in both pregnancy and delivery and found a statistically significant association of back pain between the two events. The group of women who received chiropractic adjustments also experienced less pain during labor.<sup>20</sup>

This study not only recommended adjustments for low back pain in pregnancy, it recommended on-going maintenance care beyond the initial symptomatic, initial intensive care. Based on the results, the researchers concluded: "This study appears to confirm previous reports showing that LBP and disability scores are reduced after spinal manipulation. It also shows the positive effects of preventive chiropractic treatment in maintaining functional capacities and reducing the number and intensity of pain episodes after an acute phase of treatment.<sup>21</sup>

## **Maternal and Infant Physiological Function in Pregnancy**

In studies done on laboratory animals a relationship between vertebral lesions in the lumbar area and interference to physiological function of that region were noted. It was also suggested that upper cervical lesions contributed to physiological disturbances in the mother such as: cardiac and thyroid malfunction, and sexual disturbances. Of further interest was that lesions in these laboratory animals produced miscarriages, behavioral changes, premature births, stillbirth, "runty" offspring, and early death of the young. In human pregnancy, Burns noted that women with vertebral lesions had pregnancies and labors that were abnormal compared with non-lesioned pregnant women. Further various obstetrical complications occurred with mothers suffering from lumbar lesions. <sup>22,23</sup>

In regards to the health of the developing young rabbits, the offspring of lesioned mothers demonstrated stunted growth, erratic behavior, slow development and implications of anatomic deformities.<sup>22</sup> Chiropractic textbook author, Plaugher, recommends, additional studies are clearly warranted based on these results with animals.<sup>24</sup>

# Biomechanical Pelvic Balance for Optimal Fetal Positioning and Safer, Easier Birth Outcomes

Additionally, subluxation of the sacrum in the pregnant pelvis may be a major contributing factor to intrauterine constraint. Intrauterine constraint is defined as any forces external to the developing fetus that obstructs the normal movement of the fetus.

The link between a biomechanical dysfunction and an in utero constraint situation is the ligamentous attachments of the uterus the bony maternal pelvis. The sacral torsion thought to be transmitted by ligaments to the uterus, creating an uneven muscular tension in the uterine walls. This muscular dysbalance constricts fetal motion so it does not have the freedom any more to turn into the vertex position. Anatomically the uterus is suspended by 3 major ligaments a) the broad ligaments b) the uterosacral ligaments and c) the round ligaments

The broad ligaments are double layers of peritoneum extending from either sides of the uterus to the lateral walls and floor of the pelvis. The base of the broad ligament, which is quite thick, is continuous with the connective tissue of the pelvic floor. These ligaments are the most important ones for the proper position of the uterus and preventing uterine prolaps.

Each *uterosacral ligament* extends from an attachment posterolaterally to the supravaginal portion of the cervix to encircle the rectum, and thence insert into the fascia over the second and third sacral vertebrae. The uterosacral ligaments are composed of connective tissue and some smooth muscle and are covered by peritoneum. They prevent the uterus from displacing anterior and inferior. It is proposed by this author, that a sacral joint dysfuntion and subsequent sacral rotation may transmit a unilateral force by the uterosacral ligament on to the uterus torquing the uterus and resulting in a restricting tension within the uterine wall.

The round ligaments extend from lateral, superior portion of the uterus towards the labia major, inserting with the inguinal ligament within a fold of the peritoneum continuous with the broad ligament. They are comprised of smooth muscle cells continuous directly with those of the uterine wall and a certain amount of connective tissue. They prevent the uterus from moving posterior, keeping it in a normal anterior position. It is proposed by this author, that unilateral tension in the round ligament as caused by a torqued uterus from sacral dysfunction increases uterine tension and imbalance.<sup>25</sup>

Forrester and Anrig say, "Specifically, sacral rotation causes an anterior torquing mechanism on the uterine ligaments and musculature, decreasing space and altering the environment for the fetus... When correction of the sacral subluxation occurs, the structure and therefore the function of the uterine structures are improved allowing the fetus to position itself properly." <sup>26</sup>

Intrauterine constraint contributes to abnormal fetal positioning in pregnancy and labor. Fetal presentations other than cephalic or positions other than anterior may result in frequent birth complications for the mother and baby.

Intrauterine constraint in pregnancy may cause irregular spinal development of the fetus as well. Compromised spinal development of the baby may have permanent adverse effects on the baby's nerve system. Forrester and Anrig write: "The critical effects of in-utero constraint involve the biomechanical considerations on fetal development., the potential for a reduced efficiency in labor resulting in a longer harder labor process with an increased incidence of anoxia, brain damage, asphyxia, prolapse of the umbilical cord and intrauterine death and a greatly elevated propensity toward operative delivery which exacerbates the danger of trauma to the neonate."<sup>27</sup>

Therefore chiropractic care in pregnancy increases quality of life for the mother and also has significant implications on the future health and well-being of the infant.

### **Techniques**

Many specific chiropractic analysis and techniques have adapted protocols to suit the pregnant patient. Some post graduate college courses specific to perinatal chiropractic include: Gonstead, Thompson, Logan, SOT, Activator, Diversified.

One specific chiropractic analysis and diversified adjustment, the Webster technique was developed particularly for the pregnant patient. The Webster technique has been utilized to correct the muscular skeletal causes of intrauterine constraint. Personant resulting in better fetal presentation and positioning at birth. The Webster technique is defined as "a specific chiropractic analysis and adjustment that reduces interference to the nerve system, facilitates balance in the pelvic muscles and ligaments, which in turn reduces torsion in the woman's uterus, alleviating intrauterine constraint, and optimizing fetal positioning." 38

There are several text books and reference manuals in chiropractic which each address the importance of chiropractic care in pregnancy.<sup>39-43</sup> Each text includes some or all of reasons for chiropractic care throughout pregnancy discussed above.

# **Safety**

There are no known contraindications to chiropractic spinal and pelvic adjustments throughout pregnancy.

Chiropractic adjustments characterized as high-velocity, low amplitude thrusts are frequently applied to sites of vertebral subluxations in the pregnant patient. To date, no reported adverse events have been associated with this type of care.

The International Chiropractic Pediatric Association has conducted two Practiced Based Research Surveys relevant to pregnancy. Both studies received IRB approval from Life University.

Preliminary results of the ICPA's first PBRN: Chiropractic Care and the Webster Technique collected data from 274 cases. No adverse effects were reported. 13 aggravations (slight soreness post first adjustment with 100% resolution) were noted by the doctors. The results of these preliminary findings PBRN have been presented at several conferences and have been submitted for publication.<sup>44</sup>

The ICPA's second PBRN: Chiropractic Care in Pregnancy is still in progress. At the time of this writing, there were over 100 cases submitted. To date, no adverse affects were reported by either the doctor or patient. Only two aggravations (slight soreness post first adjustment with 100% resolution) were reported by the doctors. In 48 of the cases submitted, the doctor used the Webster technique. The remaining adjusting techniques used were those described above in the Technique section of this paper.

A recent survey study conducted by the ICPA of 214 midwives in the US reported: 100% of the midwives perceived chiropractic to be safe for pregnant patients. This paper has been submitted for publication.<sup>44</sup>

### Perinatal Chiropractic and Its Supportive Role in Natural Birthing

In addition to continuously staying abreast of academic knowledge and clinical adjustive skills pertinent to care in pregnancy, it is important that the doctor of chiropractic understand the biomechanics of the pregnant female pelvis and its relationship to the neuro muscular causes of dystocia. Dystocia is abnormal function in labor and is the number one cause for invasive intervention in birth that leads to trauma and subluxation in the mother and infant.

In Williams Obstetrics Textbook, the authors define dystocia as "Abnormal Labor." They further emphasize, "Dystocia is very complex, and although its definition- abnormal progress in labor seems simple, there is no consensus as to what 'abnormal progress' means. Thus, it seems prudent to attempt a better understanding of normal labor in order to determine departures from normal."

Williams Obstetrics list the causes of dystocia to be:

- 1. Abnormalities of the expulsive forces— either uterine forces insufficiently strong or inappropriately coordinated to efface and dilate the cervix (uterine dysfunction), or inadequate voluntary muscle effort during the second stage of labor. (*Power*)
- 2. Abnormalities of the maternal bony pelvis—that is pelvic contraction (*Passage*)

- 3. Abnormalities of presentation, position, or development of the fetus (presented in chapter 19) (Passenger)
- 4. Abnormalities of the soft tissue of the reproductive tract that form an obstacle to fetal descent.<sup>46</sup>

When examined from a neuro-muscular perspective, each of these causes of dystocia may potentially be prevented with specific chiropractic adjustments of the pregnant woman's spine and pelvis throughout pregnancy in preparation for birth. In other words, each cause of dystocia is addressed with specific, regular chiropractic care throughout pregnancy.

Correlating the causes of dystocia with the corrective accomplishments of the chiropractic adjustment is as follows:

- 1. Uterine dysfunction may very well be caused by a decrease in adequate nerve innervation to the uterus which normally initiates strong contractions and maintains adequate muscle function throughout labor. Additionally, dilation of the cervix is dependant on normal nerve innervation. Spinal and cranial adjustments throughout pregnancy and during birth restore adequate nerve supply to the uterus and therefore normal function to the uterus. Normal uterine function is imperative for the prevention of dystocia. 47-53
- 2. Pelvic contraction is defined by William's Obstetrics as misalignment of the pelvic bones (particularly sacral displacement) caused by physical trauma to the woman. Specific chiropractic adjustments offer the means for sacral and pelvic realignment reducing the prevalence of sacral displacement leading to dystocia.
- 3. Abnormalities of presentation, position or development are known to be caused by intrauterine constraint. Preliminary studies with the Webster technique are demonstrating the musculoskeletal relationship between sacral adjustments, the alleviation of intrauterine constraint and therefore optimal fetal positioning. Optimal foetal positioning is a key ingredient in the prevention of dystocia. <sup>28-38</sup>
- 4. Preliminary, clinical findings are showing reduction in fibroids and migration of placenta attachment to more desirable positions while the patient is under chiropractic care. Both fibroids and placental position are examples of the soft tissue of the reproductive tract that form an obstacle to fetal descent. Data is currently being collected from doctors of the International Chiropractic Pediatric Association (ICPA, Inc) in regards to the association of chiropractic adjustments and the reduction of these obstacles.

Understanding these neuro muscular contributors of dystocia provide the doctor of chiropractic with even greater technical expertise, higher patient compliance and an increase of interprofessional referrals with birth care providers.

#### **Birth Outcome**

There have been several studies emphasizing the significance of spinal and cranial adjustments as performed by trained doctors for the prevention or elimination of dystocia 47, 48, 49, 50, 51

Additional benefits relevant to birth outcome have included: Decreases in the following: labor time, meconium staining of amnionic fluid, preterm delivery, umbilical cord prolapsed, use of forceps, and c-sections. 47-53

C-section are determined mainly by the failure of labor to progress (dystocia). In the US, over one fourth of all children born annually are delivered by c-section.<sup>54</sup> The Wrold Health

Organization recommends that the c-section rate should be about 10-15%.<sup>55</sup>.With this increased c-section rate comes its questionable validity and the accompanying adverse effects to both the mother and infant.<sup>56</sup>

Therefore, the prevention of dystocia by nautral non-invasive methods and its service in public health is reason enough for further research into the association of chiropractic care for better birth outcome.

#### Conclusion

There is much to be done in the clinically based research arena to continue to substantiate the efficacy of chiropractic care in pregnancy. Beyond the presence of back pain or other overt symptoms, regular chiropractic adjustments during pregnancy offer promise in the reduction of the neuromuscular causes of dystocia. This increases the opportunity for the mother and baby to have a safer, easier more natural birth experience. All pregnant women should be routinely examined throughout pregnancy by a Doctor of Chiropractic for the presence of VSC. Facilitating a healthy pregnancy and restoring a normal physiological environment with the chiropractic adjustment for natural birth is well within the chiropractic scope of practice.

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#### **SECTION 10: SUBLUXATION AND WELL-BEING**

RECOMMENDATION (new) Rating: Established

Evidence: E, L

"Doctors of Chiropractic advise and educate patients and communities in structural and spinal hygiene and healthful living practices." <sup>1</sup>

"Doctors of Chiropractic establish a doctor/patient relationship and utilize adjustive and other clinical procedures unique to the chiropractic discipline. Doctors of Chiropractic may also use other conservative patient care procedures, and, when appropriate, collaborate with and/or refer to other health care providers." <sup>1</sup>

## Commentary:

These recommendations are from the 1996 Paradigm Statement by the Association of Chiropractic College (ACC), and come from the section titled "Health Promotion". The entire document was generated by the membership of the ACC, composed of the senior leadership from all the CCE-Accredited Chiropractic Colleges, provide the basis by which chiropractors conduct themselves professionally and clinically.

The CCP Guidelines address a distinct manner in which chiropractic clinicians utilize this information along with feedback and empirical results from each patient. For this reason, the Guidelines are not linked to various diseases or conditions the patient may or may not have, before or after care has initiated as can be the intent of some chiropractic intervention. cf. 2-49

The World Health Organization defines health as being "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity." <sup>50</sup> Given this broad definition of health, epistemological constructs borrowed from the social sciences may demonstrate health benefits not disclosed by randomized clinical trials. Health benefits such as improvement in self-reported quality-of-life, decreased health care costs, behaviors associated with decreased morbidity, and patient satisfaction may be evaluated using such methods.

This performance-based domain focuses the doctor-patient relationship on the standards set by personal baselines and establishes guidelines for the utility of various chiropractic techniques. This type of chiropractic care is in a context with other non-invasive disciplines and is stratified into discrete application-based domains across a spectrum of parameters related to well-being.

Techniques and methods for correcting subluxation must be judged on their intended outcome and most if not all chiropractic techniques have some physiological and/or structural

outcome that measures their results. Further, some techniques have as their goals - improvement in quality of life, an improved sense of well-being and a better sense of relationship with the patient's environment and society.

Several studies discussed previously warrant further discussion in this context. Blanks, Schuster and Dobson <sup>51</sup> published the results of a retrospective assessment of subluxation-based chiropractic care on self-related health, wellness and quality of life. This is the largest study of its kind ever undertaken regarding a chiropractic population. After surveying 2,818 respondents in 156 clinics, a strong connection was found between persons receiving chiropractic care and self-reported improvement in health, wellness and quality-of-life. 95% of respondents reported that their expectations had been met, and 99% wished to continue care.

Coulter et al.<sup>52</sup> performed an analysis of an insurance database, comparing persons receiving chiropractic care with non-chiropractic patients. The study consisted of senior citizens over 75 years of age. It was reported that the persons receiving chiropractic care reported better overall health, spent fewer days in hospitals and nursing homes, used fewer prescription drugs, and were more active than the non-chiropractic patients.

Rupert, Manello, and Sandefur <sup>53</sup> surveyed 311 chiropractic patients, aged 65 years and older, who had received "maintenance care" for five years or longer. Chiropractic patients receiving maintenance care, when compared with US citizens of the same age, spent only 31% of the national average for health care services. There was a 50% reduction in medical provider visits. The health habits of patients receiving maintenance care were better overall than the general population, including decreased use of cigarettes and decreased use of nonprescription drugs. Furthermore, 95.8% believed the care to be either "considerably" or "extremely" valuable.

Rupert <sup>54</sup> reports that 79% of chiropractic patients have maintenance care recommended to them, and nearly half of those comply. In an online survey with 3018 respondents by Miller, <sup>55</sup> 62% responded affirmatively when asked, "Although you feel healthy, would you follow your family member's lead and visit a doctor who focuses on wellness and prevention just so you can stay feeling that way?"

Several additional studies have addressed this issue since the publication of the 1998 Guidelines. One of the studies consisted of a three arm randomized clinical trial with two control groups (one of which was placebo controlled). This was a single blind study utilizing subluxation-centered chiropractic care implemented in a residential addiction treatment setting. <sup>56, 57</sup> A total of 98 subjects (14 female and 84 male) were enrolled in the year and a half study. 100% of the Active (chiropractic) group completed the 30-day program, while only 24 (75%) of the Placebo group and 19 (56%) of the Usual Care group completed 30 days.

The Active group showed a significant decrease in anxiety while the Placebo group showed no decrease in anxiety. The frequency of visits to the Nurse's station was monitored during the course of the study and among the Active treatment group only 9% made one or more visits, while 56% of the Placebo group and 48% in the Usual Care group made such visits. This poor performance by the placebo group suggests that the chiropractic care had no positive placebo effect.

Treatment was five days per week over a period of 30 days, for a total of 20 treatment encounters. Therefore, a 100% retention rate was achieved in a residential treatment setting using subluxation-centered chiropractic. The possible mechanism for such a response is elaborated on in an earlier paper by Holder et al, in which they describe the Brain Reward

Cascade in relationship to vertebral subluxation and its role in resolving (RDS) Reward Deficiency Syndrome.<sup>57</sup>

In a review of the research literature, Hannon<sup>58</sup> describes over forty studies where people with no symptoms of disease experienced objective health benefits under chiropractic care. Dr. Hannon's conclusion is a positive statement on the effects of chiropractic on human potential and healing: "Improved function can be objectively measured in asymptomatic individuals following chiropractic care in a number of body systems often by relatively non-invasive means. It is plausible that chiropractic care may be of benefit to every function of the body and have the potential for long-term, overall health benefit to those receiving chiropractic care."

Cohort studies require large numbers of well-characterized patients to properly control for all patient variables. A large cohort study by Blanks and colleagues, 51 include the analysis of 2818 patients from 160 offices through the United States. Canada, Puerto Rico, and Australia. 51,71,72 Because of the need to control for the many different types of adjustment techniques currently being used in chiropractic, and the potential impact of the adjustment technique on outcome, their studies have been limited to only one chiropractic technique called Network Spinal Analysis. Results indicated that patients reported significant positive perceived change (p< 0.000) in all four domains of health, as well as, overall quality of life. Effect sizes for these difference scores were all large (>0.9). Wellness was assessed by summing the scores for the four health domains into a combined wellness scale, and comparing this combined scale "presently" and "before Network." These benefits are evident from as early as 1-3 months under care, and appear to show continuing clinical improvements in the duration of care intervals studied, with no indication of a maximum clinical benefit. These findings are somewhat limited because they apply only to NSA and are difficult to apply to chiropractic in general because of the many different techniques employed. The research design was cross-sectional, meaning that one can only conclude a statistical association between NSA and self-reported changes in QOL and not a cause-effect relationship. Finally, although an important first step, these patientcantered outcomes must be correlated with clinical and objective outcome measures, and be documented over time to show causality, i.e., a cause-effect link between the intervention and the health outcome benefits.

A second series of papers by Schuster et al.<sup>71,72</sup> performed an analysis on patient data from one of the chiropractic techniques (Network Spinal Network Analysis, NSA) and examined outcomes in relation to health lifestyle practices and self–reported health and wellness. The study was a cross-sectional, self-administered survey that included two thousand five hundred and ninety-six (2,596) patients from 156 offices of doctors who were members of the Association for Network Chiropractic (currently titled Association for Network Care); estimated response rate was 69%. Exogenous variables entered into the structural equation model include gender, age, education, income marital status, ailments, life change, and trauma. A wellness construct consisted of calculated difference scores between two referents, "presently" and "before Network" care, for self-reported items representing wellness domains of physical state, mental-emotional state, stress evaluation, and life enjoyment. Positive reported change in nine items assembled into dietary, health practices, and health risk dimensions serve as indicators of the construct of changes in health lifestyle practices. The NSA care construct consisted of duration of care in nine months, awareness of energy, and awareness of breathing since beginning network care.

Of the exogenous variables only gender, age, and education remain in the final structural equation model, indicating that chiropractic self-reported wellness benefits are greater

among women, younger, and better-educated patients. This study provides further evidence that the health and wellness survey instruments are particularly appropriate for investigating wellness-oriented disciplines such as practiced by the overwhelming majority (93.6%) of chiropractors as indicated by a recent national poll.<sup>50</sup>

<u>Biomarkers of Wellness</u>: Wellness has become a popular concept that has been applied by the mass media to fitness and self-help products and services, work-site wellness/health promotion programs, and biomedical research incorporating health-related quality-of-life assessments.<sup>59</sup> Self-rated health (SRH), a formalized measure of subjective health, has been found to be an independent predictor of clinical outcome and mortality. Even when numerous health status indicators are available, poor SRH is independently associated with increased mortality in different socioeconomic groups, in different age groups, in men and women, over time and among persons with or without chronic illness. 62-67

It has been previously shown that low ratings of health are strongly associated with low fitness and energy, daily discomforts, and presence of pain.<sup>67</sup> However, until recently the mechanisms for these associations were unknown. In the last decade, it has become increasingly clear that signals from the immune system also affect the brain circuits to produce changes in behavior, cognition, and emotion. This coordinated set of changes is collectively called sickness behavior, and is caused by pro-inflammatory cytokines such as interleukin (IL)-1, IL-6 and tumor necrosis factor (TNF)- $\alpha$ . In sickness, the individual experiences nonspecific symptoms of weakness, listlessness, changed sleep patterns, hyperalgesia and decreases in motivation and appetite. 68, 69 Lekander et al. 70 examined the immune status of 265 consecutive primary health care patients (174 women and 91 men), in relation to self-rated and physicianrated health. Self-rated health correlated with levels of IL-1β (r = 0.27; p < .001), IL-1ra (r = 0.19; p < .05) and TNF-  $\alpha$  (r = 0.46; p < .001) in women but not in men. Thus, poorer subjective health was associated with of higher levels of inflammatory cytokines. Even when controlling for age, education, physical health, and diagnoses in multiple regression analyses, self-rated health was an independent and more robust predictor of cytokine levels than physician-rated health. The exciting finding from Lekander et al. 70 suggests that an individual's health perception may be coupled to circulating cytokines.

The basic science research related to chiropractic is growing.<sup>73-77</sup> Several recent studies have begun to identify the chemical mediators of pain reduction and other physiological benefits of the adjustment. A recent study by Ineyan et al. determined that the adjustment was associated with reduction in circulating proinflammatory cytokines but substance P often associated with pain mediation. <sup>74</sup> Another study on acute low back pain patients found that pain scores and endogenous opioids (beta-endorphine) levels were closely linked. <sup>75</sup> Other candidate peptides mediating these effects have been proposed. <sup>76</sup>

However, one of the most exciting recent findings linking the chiropractic adjustment with general health and well-being comes from the study of Kent and colleagues in 2005. These authors assessed the short- and long-term effects of chiropractic on serum thiol levels in asymptomatic subjects. Serum thiol was choses as a measure of human health status, because it is a surrogate marker of DNA repair enzyme activity, most notably poly ASP-ribose polymerase or PARP. In this case-controlled retrospective analysis, serum thiol levels were examined in patients with active disease (n=46) and compared with levels in age-matched asymptomatic subjects (n=21) with 8-52 weeks of care. Mean serum thiol levels were lowest in patients with active disease and neuromuscular complaints, and highest in asymptomatic individuals undergoing chiropractic care. They concluded "Asymptomatic or primary wellness subjects under chiropractic care demonstrated higher mean serum thiol levels than patients with

active disease and produced some values that were higher than normal wellness values." Additional studies are required, but it appears that the chiropractic adjustment can affect the even the fundamental properties of cellular function, repair, and post-translational (epigenetic) activities.

Modern biology recognizes three "supersystems" in the body (nervous, endocrine, and immune systems) that interact functionally at many levels to control all life functions. There is now strong evidence that chiropractic can impact all three of these systems. The nervous system is discussed separately (see SECTION 10).

In this section, the evidence for chiropractic's influence on the other two supersystems is discussed, namely the immune system and endocrine system.

In terms of immune function, small clinical trial and case reports document changes in immune status of patients under care. <sup>78-80</sup> Immune system related diseases such as allergic asthma<sup>81-87</sup> are documentd in case reports to show improvement with chiropractic. Factors that medically alter immune status, such as immunization, remain a concern for some chiropractors and policies are developed to discuss these issues with patients. <sup>88, 89</sup> There are also reports of secondary benefits of chiropractic in patients suffering from disorders of the endocrine system, eg., hypothyroidism and diabetes . <sup>90, 91</sup>

One of the very exciting recent breakthoughts, is the impact of chiropractic care in areas of womans health, likely to result from beneficial effects on the adjustment on the reproductive and endocrine systems. A large number of case reports and case-controlled series have evaluated the effects of the chiropractic adjustment of fertility, 92-112 regulation of the menstral cycle and pelvic dysfunction, 113-116 ease of delivery and control of peripartituational pain, 117-123 hormone replacement therapy. 124 There is also a growing discussion about devising guidelines for counceling patients with metastatic cancer, 125-128 health-education, perceptions and recruitme of woman into chiropractic research studies. 129-135 Finally, a great deal of scholarship has been directed towards the role of chiropractors in educating patients about the psychosocial aspects of health. Woman are frequently the health surregots, and champions of social reform such as homelessness, but they are also targeted by domestic violence. These woman's health topics are receiving more and more attention by chiropractors.

However, in what might be termed chiropractic greatest gift, the field has led the wellness revolution in health promotion and disease prevention. By educating patients about health promoting activities the chiropractic profession has taken the lead in primary and secondary prevention. Some have termed the concept the "Chiropractic Lifestyle", nicely defined almost 15 years ago by Dr. Cheryl Hawk "....In addition to specific care of the spine, chiropractors usually suggest therapeutic exercises, general fitness recommendations and advice on nutrition, vitamins, weight loss, smoking cessation, and relaxation techniques." These shared health beliefs, values and behaviors have been assessed in chiropractors, 60 and patients in large representative surveys. In a major survey of chiropractors, their overwhelming support and commitment to the "chiropractic lifestyle" demonstrated that 97.8% recommend exercise, 93.6% maintenance/wellness care, 93.2% made ergonomic recommendations, 87.7% provide general nutritional advice, and 86.4% recommended stress reduction activities.

As described previously, sophistocated structural equation modeling of self-reported data from individuals under chiropractic care indicate that life style behavioral change, acquired while under care, impacts health along a path in the derived health model which is almost as

important as the adjustment itself.<sup>71,72</sup> The combination of regular chiropractic care and lifestyle modification was considered optimal in the model for promoting general self-reported health.

Many research articles have been written during the five-year review period about the health promotion and disease prevention aspects of chiropractic. These have covered a broad range of topics including chiropractic, nutrition and exercise, the role of patient preference and perceptions, client-centered wellness education for smoking cessassion, etc., fall and accident prevention, and preventive and healthy aging strategies. Many of these were educational documents or case or case-series reports. Of note, a study by Rupert conducted a representative survey of chiropractors that concluded their general acceptance of the health promotion and prevention strategies for chiropractors. Rupert and colleagues evaluated the health promotion services administered to US chiropractic patient age 65 and older. Several comprehensive reviews of the overall topic of health promotion attitudes of chiropractors have been published by Hannon, Hawk et al. Hawk et al. Hawk et al. Households and McDonald et al.

<u>Summary</u>: Chiropractors have historically recommended initial care plans that involve a high frequency of visits as well as extended care plans of long duration to encompass corrective care and wellness based care. Care plans that do not base care solely on the presence or absence of symptoms have as their basis some very fundamental scientific laws that govern the connective tissue and neurological responses to abnormal biomechanical loads and neurological interference while also addressing the quality of life issues discussed above. The goal of care becomes the reversal of these insidious processes and an enhanced sense of well-being so that any judgment of that care must take into consideration those outcomes as well as outcomes related to the technique being applied.

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## SECTION 11: BEHAVIORAL AND MENTAL HEALTH ISSUES

RECOMMENDATION (new) Rating: Established

Evidence: E, L

Chiropractic is not a treatment for specific behavioral or mental health conditions. However, chiropractic care is established as a clinical strategy that may improve the clinical status of persons with general health issues and certain behavioral or mental health conditions.

# Commentary

The chiropractic profession has been actively involved in the field of what is now broadly termed "neuroscience" since it's founding in 1895 by D.D. Palmer. Neuroscience is a compendium of health disciplines including psychology, behavioural science, psychiatry, and neurology. This section reviews the historical involvement of chiropractic in mental health aspects of neuroscience from its inception over 100 years ago. The strong neurological perspective prospered during a four decade period from 1920-1960, at which time there was a division into two ideological groups (focused- vs. broad-scope) that persist today. The dominant, broad-scope group focusing largely on the spine and musculoskeletal system, and focused-scope, albeit smaller faction, retaining the earlier neuromuscular skeletal roots and focus upon detection, analysis and correction of the subluxation.

This historical review is followed by the evidence-based documentation supporting the neuroscience rationale of chiropractic.

# **Historical perspective:**

The inventor of chiropractic, D.D. Palmer, described a postulated mechanism for "insanity." According to his son, B.J. Palmer, "D.D. Palmer was the first man to discover that insanity was caused by displaced cervical vertebrae, that by replacing them the patient could be restored to normal condition." <sup>4</sup> B.J. Palmer himself wrote, "If an atlas is subluxated it makes abnormal the functions of the brain ...What is to be done in insanity? Go back to cause? Adjust that and return that brain to its normal capacity and capability. Interpretation then will be normal and expression follows likewise, then what have you? Coordination—health, in all that the word implies." <sup>5</sup>

Willard Carver, an attorney and chiropractor, authored several books exploring the relationship of psychology to physiology and chiropractic. Carver wrote, "Between the Psychology and the Physiology I have built the Biologic bridge that scientifically connects these two very important departments of human experience." <sup>6</sup> Carver was a controversial figure, as he advocated utilizing adjunctive therapies to supplement the adjustment of vertebral subluxations.

In the era from the 1920s to the 1960s, several chiropractic inpatient facilities were operated that catered to patients suffering from "Nervous and mental disorders." Two of these were located in Davenport Iowa. In 1922, the Chiropractic Psychopathic Sanitarium was established. The facility was later known as Forest Park Sanitarium. North Dakota Judge A. W.

Ponath noted that at the North Dakota state mental hospital, the "cure and discharge rate" ranged from 18-27%, compared to 65% at the chiropractic facility in Forest Park. Clear View Sanitarium was an inpatient chiropractic psychiatric facility that operated in Davenport, IA, from 1926 to 1961. In 1951, Clear View was acquired by the Palmer School of Chiropractic. Dr. W. Heath Quigley, who directed the sanitarium, described the clinical protocol: "Each day, each patient was examined with the neurocalometer (NCM). If the clinician interpreted the NCM to indicate nerve impingement, the patient was adjusted." The NCM, crude by modern day standards, is often thought of as the forerunner of the galvanic skin response used as an indirect of sympathetic outflow to sweat glands in the skin. Quigley reported that the rooms were "sunny and bright," and that meals included "large servings of fresh vegetables...from a garden."

Unfortunately, both institutions closed, (Forest Park in 1959 and Clear View in 1961) in large measure because of third-party pay issues. Insurance companies often refused to pay the costs of care. Iowa statutes at the time did not provide for licensing specialized hospitals; only full service medical hospitals could be licensed. Clear View functioned legally as a nursing home, and was never licensed as a hospital.

The 1970s saw a renewed interest in chiropractic care and mental health issues. In 1973, Dr. Herman S. Schwartz, a chiropractor, published a book titled "Mental Health and Chiropractic: A Multidisciplinary Approach." <sup>10</sup> In 1949, Dr. Schwartz had published a preliminary report of 350 patients afflicted with a "nervous or mental disorder" and reported that the majority of them showed improvement under chiropractic care. <sup>11</sup> Dr. Schwartz was active in the ACA Council on Mental Health (formerly Council on Psychotherapy), which survived through the '70s, but no longer exists.

### **Evidence-based rationale supporting neurologic chiropractic:**

In 1983, Dr. Quigley published an article describing a four decades period, from 1920-1960, where "treatment of the mentally ill was a highly motivated discipline within the chiropractic profession." <sup>1</sup> Several years later Dr. Goff, an Ed.D., published a review of the theory and practice of "chiropractic treatment for mental illness." <sup>12</sup>

Interest in this field continues. Blanks, Schuster and Dobson <sup>13</sup> published the results of a retrospective assessment of subluxation-based chiropractic care on self reported health, wellness and quality of life. These authors specifically assessed questions about patient "Mental and Emotional Well-Being" and "Stress Indicators". This is, to our knowledge, the largest study of its kind ever undertaken regarding a chiropractic population. After surveying 2,818 respondents in 156 practices, a strong connection was found between persons receiving Network care and self reported improvement in health, wellness and quality of life.

Genthner et al.<sup>19</sup> reported on a series of 15 patients with a history of depression. The Beck Depression Inventory II was used to measure the baseline level of depression and any post care changes following orthospinology care. A paired t-test demonstrated significant improvement in depression test scores with chiropractic. Depression relief is noted with chiropractic care in other studies. e.g. 15, 16

At the moment, the mechanism(s) underlying chiropractic effects on depression are unclear. Depression is complex to diagnose and treat and can have multiple etiologies. Genetics is one predictive factor. It can also be "situational" such as with bouts of depression

accompanying the loss of a loved one, job or ones health.<sup>cf 17</sup> Situational depression often accompanies serious illness or pain, and will resolve when the illness or pain syndrome is treated.<sup>18</sup> Additional research is required, but it could be argued that chiropractic effects on depression acts on the "situational" components of depression, i.e., the patients depression improves as their presenting complaint is treated by care. An important clue about depressive symptoms comes from several new epidemiological studies with identical twins. A comparison of the genetically identical siblings, resulted in the conclusion that depressive symptomatology is close correlated with metabolic syndrome, <sup>19</sup> and independent measures of abnormal autonomic outflow, i.e., lower heart rate variability.<sup>20</sup> These studies are consistent with the hypothesis that genes and other factors (environmental, diet, exercise, trauma, stress, etc.) promoting inflammation (leading to metabolic syndrome and cardiovascular stress response) are involved in the pathogenesis of depressive disorders. Future studies will need to control for general medical status and proinflammatory events to better understand the mechanism(s) underlying the effects of the adjustment on depressive disorders.

A systematic review of psychological outcomes in randomized controlled trials (RCTs) described the results of 12 RCTs of spinal manipulation which had adequately reported psychological outcomes. The authors concluded that there was some evidence that spinal manipulation improved psychological outcomes compared with verbal interventions employed with the control group.<sup>21</sup>

Other small studies and case reports have reported favorable outcomes in persons with behavioral and mental health issues following chiropractic care<sup>22-32</sup> These include disease-related<sup>33</sup> or post traumatic stress disorder,<sup>34</sup> attention deficit hyperactivity disorder (ADHD),<sup>35-38</sup> general health status measured using the RAND-36 and Global Well-Being Scale,<sup>39-40</sup> quality of life in public safety personnel,<sup>41</sup> learning disabilities and dyslexia,<sup>42-43</sup> and autism.<sup>44</sup> Studies regarding addiction and compulsive disorders have been discussed in Section 9.

Similarly, there are small studies and case reports demonstrating benefits with certain neurological disorders such as multiple sclerosis and Parkinson's disease<sup>45</sup> (however, see<sup>46</sup>), Bell's palsy,<sup>46</sup> Cerebral palsy,<sup>48</sup> the autonomic outflow and its effect on stress, blood pressure, heart rate variability and somatovisceral effects,<sup>49-82</sup> myasthenia gravis,<sup>83</sup> headaches,<sup>84-87</sup> tempromandibular joint disorder,<sup>88-90</sup> and vertigo, dizziness and motion sickness.<sup>90-93</sup> In particular, the latter seems relevant as a model of secondary maladaptation to neck trauma given the functional interaction of the vestibular, visual and neck joint afferents in the etiology of cervicogenic vertigo/dizziness.<sup>94,95</sup>

Lastly, there are a variety of general neurological health issues that are supported by small studies and case reports and one clinical trial. These are mentioned here given their connection with the neurological (neuro-musculoskeletal) model of chiropractic. 66-125 The clinical trial is important because it examined the effects of combining manual therapy and exercise on respiratory function in normal individuals. Normal subjects (n = 20; aged 18-28 years) were randomized into three groups: exercise only, manual therapy only and combined exercise and manual therapy consisting of 6 intervention sessions over a 4-week period. The control (exercise only) group showed a decrease in forced vital respiratory capacity(FVC) and forced expiratory volume in the first second (FEV<sub>1</sub>); the manual therapy showed a significant increase in both FVC and FEV<sub>1</sub>, and subjects receiving combined manual therapy showed a double benefit, i.e., increased FVC and FEV<sub>1</sub> immediately after the adjustment followed by an additional increases after exercise. Such studies are important because they demonstrate the potential for manual therapy (and exercise) to improve respiratory function even in healthy individuals, and thereby improve sports performance via extended exercise potential.

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### **SECTION 12: PATIENT SAFETY, PRIVACY, AND ADVOCACY**

## 12.1 Patient Safety

## **RECOMMENDATION (Unchanged)**

Rating: Established

Evidence: E, L

Patient safety encompasses the entire spectrum of care offered by the chiropractor. Consequently, it is important to define at the onset, the nature of the practice as well as the limits of care to be offered. Minimally this should include a "Terms of Acceptance" document between the practitioner and the patient. Additionally, all aspects of clinical practice should be carefully chosen to offer the patient the greatest advantage with the minimum of risk.

# Commentary (new)

Patient safety is assured by more than the practitioner's causing no harm. Since every consumer of health care is ultimately responsible for his/her own health choices, patient safety is also a matter of the availability of accurate and adequate information with which the patient must make these choices. The patient's expectations should be consistent with the provider's goals. If the patient perceives those goals as anything different, proper and safe choices cannot be assured. Thus, it is important to recognize that chiropractic is a limited, primary profession which contributes to health by addressing the safe detection, location, and correction or stabilization of vertebral subluxation(s). It is important that the chiropractor take the steps necessary to foster proper patient perception and expectation of the practitioner's professional goals and responsibilities. It is within this context that patient safety is addressed in this chapter.

A "Terms of Acceptance" is the recorded written informed consent agreement between a chiropractor and the patient. This document provides the patient with disclosure of the responsibilities of the chiropractor and limits of chiropractic, and the reasonable benefit to be expected. This enables the patient to make an informed choice either to engage the services of the chiropractor, aware of the intended purpose of the care involved, or not to engage those services if the proposed goals are not acceptable or not desired. This embodies the responsibility of assuring patient safety by not providing false or misleading promises, claims or pretences to the patient.<sup>1-9</sup>

Professional Referral: Professional referral requires authority and competence to acquire accurate information concerning matters within the scope and practice of the professional to whom a referral is made. There are two types of professional referrals made by chiropractors:

Intraprofessional referral: Chiropractors, by virtue of their professional objective, education, and experience, have authority and competence to make direct referrals within the scope and practice of chiropractic. Such a referral may be made when the attending chiropractor is not able to address the specific chiropractic needs of a particular patient. Under these circumstances, the chiropractor may refer the patient directly to or consult with another chiropractor better suited by skill, experience or training to address the patient's chiropractic needs.

<u>Interprofessional referral</u>: In the course of patient assessment and the delivery of chiropractic care, a practitioner may encounter findings which are outside his/her professional and/or legal scope, responsibility, or authority to address. The chiropractor has a responsibility to report such findings to the patient, and record their existence. Additionally, the patient should be advised that it is outside the responsibility and scope of chiropractic to offer advice, assessment or significance, diagnosis, prognosis, or treatment for said findings and that, if the patient chooses, he/she may consult with another provider, while continuing to have his/her chiropractic needs addressed.

# **Patient Safety**

Considerable visibility and public scrutiny surrounds possible risks associated with Spinal Adjustment and Manipulation. Non-serious side effects are relatively common and may consist of localized discomfort, headache, or fatigue that resolves within 24-48 hours. The concern raised by scientific and popular media reports in the United States and Canada are that chiropractic "manipulation" of the cervical spine is associated with stroke. 10-21

However, not only is the incidence stroke difficult to determine with chiropractic adjustment, some argue that there is no rationale for linking chiropractic adjustment with vascular dissection at all.<sup>22</sup> Case reports of adverse events following spinal "manipulation" are common as are published commentaries on the relative risks of chiropractic.<sup>23-58</sup> However, solid scientific evidence of a causal relationship between such adverse events and the "manipulation" is lacking.<sup>59-75</sup> Furthermore, spinal adjustment and spinal manipulation are not synonymous terms. In the case of strokes purportedly associated with "manipulation," the panel noted significant shortcomings in the literature. The relevant literature follows:

Lee <sup>76</sup> attempted to obtain an estimate of how often practicing neurologists in California encountered unexpected strokes, myelopathies, or radiculopathies following "chiropractic manipulation." Neurologists were asked the number of patients evaluated over the preceding two years who suffered a neurological complication within 24 hours of receiving "chiropractic manipulation." Fifty-five strokes were reported. The author stated, "Patients, physicians, and chiropractors should be aware of the risk of neurologic complications associated with chiropractic manipulation." No support was offered to substantiate the premise that a causal relationship existed between the stroke and the event(s) of the preceding 24 hours.

In a letter to the editor, Myler <sup>77</sup> writes, "I was curious how the risk of fatal stroke after cervical manipulation, placed at 0.00025% <sup>78</sup> compared with the risk of (fatal) stroke in the general population of the United States." According to data obtained from the National Center for Health Statistics, the mortality rate from stroke in the general population was calculated to be 0.00057%. If these data are correct, the risk of a fatal stroke following "cervical manipulation" is less than half the risk of fatal stroke in the general population.

Jaskoviak<sup>79</sup> reported that not a single case of vertebral artery stroke occurred in approximately five million cervical "manipulations" at the National College of Chiropractic Clinic from 1965 to 1980.

Osteopathic authors Vick, et al. <sup>80</sup> reported that from 1923 to 1993, there were only 185 reports of injury associated with "several million treatments."

Pistolese <sup>81</sup> has constructed a risk assessment for pediatric chiropractic patients. His findings covering approximately the last 30 years indicate a risk of a neurological and/or vertebrobasilar accident during a chiropractic visit about one in every 250,000,000 visits.

An article in the "Back Letter" <sup>82</sup> noted that "In scientific terms, all these figures are rough guesses at best... There is currently no accurate data on the total number of cervical manipulations performed every year or the total number of complications. Both figures would be necessary to arrive at an accurate estimate. In addition, none of the studies in the medical literature adequately control for other risk factors and co-morbidities."

Leboeuf-Yde et al. <sup>83</sup> suggested that there may be an over-reporting of "spinal manipulative therapy" related injuries. The authors reported cases involving two fatal strokes, a heart attack, a bleeding basilar aneurysm, paresis of an arm and a leg, and cauda equina syndrome which occurred in individuals who were considering chiropractic care, yet because of chance, did not receive it. Had these events been temporally related to a chiropractic office visit, they may have been inappropriately attributed to chiropractic care.

In many cases of strokes attributed to chiropractic care, the "operator" was not a chiropractor at all. Terrett <sup>84</sup> observed that "manipulations" administered by Kung Fu practitioner, GPs, osteopaths, physiotherapists, a wife, a blind masseur, and an Indian barber were incorrectly attributed to chiropractors. As Terrett wrote, "The words chiropractic and chiropractor have been incorrectly used in numerous publications dealing with SMT injury by medical authors, respected medical journals and medical organizations. In many cases, this is not accidental; the authors had access to original reports that identified the practitioner involved as a non-chiropractor. The true incidence of such reporting cannot be determined. Such reporting adversely affects the reader's opinion of chiropractic and chiropractors."

Another error made in these reports was failure to differentiate "cervical manipulation" from specific chiropractic adjustment. Klougart et al.<sup>85</sup> published risk estimates which revealed differences which were dependent upon the type of technique used by the chiropractor.

The panel found no competent evidence that specific chiropractic adjustments cause strokes. Although vertebrobasilar screening procedures are taught in chiropractic colleges, and some ongoing research to detect pre-existing contra-indications <sup>86-99</sup> no reliable screening tests were identified which enable a chiropractor to identify patients who are at risk for stroke.

After examining twelve patients with dizziness reproduced by extension rotation and twenty healthy controls with Doppler ultrasound of the vertebral arteries, Cote, et al. 100 concluded, "We were unable to demonstrate that the extension-rotation test is a valid clinical screening procedure to detect decreased blood flow in the vertebral artery. The value of this test for screening patients at risk of stroke after cervical manipulation is questionable." Terrett 101 noted, "There is no evidence which suggests that positive tests have any correlation to future VBS (vertebrobasilar stroke) and SMT (spinal manipulative therapy)." Despite this lack of evidence, some have suggested that failure to employ such tests could place a chiropractor in a less defensible position should litigation ensue following a CVA. 102

A systematic review of the available literature in chiropractic published in the 1<sup>st</sup> Edition of the CCP Guidelines (1998)<sup>76-85, 100-102</sup> concluded, "The panel found no competent evidence that specific chiropractic adjustments cause stroke". Indeed, no serious complications have been found in more than 73 controlled clinical trials or in any of the prospectively evaluated case series published to date. <sup>c.f. 104</sup> Jaskoviak <sup>39</sup> reported that not a single case of vertebral artery

stroke occurred in approximately five million cervical "manipulations" at the National College of Chiropractic fro 1965-1980. Shekelle et al. 105 report the incidence of serious complications from lumbar spinal manipulation as extremely rare, representing an estimated 1 case per million patients. The risk of cerebrovascular accident from upper cervical manipulation was estimated to range from 1 in 400,000 from 10,000,000. Reliability of these estimates is an issue because they are based upon retrospective study design or practitioner report and represent estimates at best.

In contrast, hard evidence was produced by a large cohort study, representing 99% of chiropractors in Demark evaluated over a ten year period 1978-1988. From this population there were five serious complications and one death representing approximately one serious complication for every 1 million cervical adjustments.

From the medical literature it is know that patients with vertebralbasilar disease are largely asymptomatic for years. It is, therefore, uncertain whether these serious complications resulted from the adjustment or whether the mechanical forces applied to the spine aggravated underlying pathology. Adding further to the difficulties of interpretation and, in particular, the correlation of chiropractic adjustment and stroke, Kent<sup>22</sup> points out that the incidence of stroke in the general population is 0.00057% (National Center for Health Statistics). Estimates of stroke from chiropractic of 0.00025% by Dabbs and Lauretti<sup>63</sup> are less than twice that in the general population.

# 12.2 Patient Privacy

## **RECOMMENDATION (Unchanged)**

Rating: Established

Evidence: E, L

Respecting patients' right of privacy has always been both an ethical and a legal duty. New federal regulations place specific, enforceable obligations on most chiropractors and their employees. Knowledge of and compliance with these regulations is essential in order to remain in practice.

## Commentary (added)

Chiropractors have always had an ethical obligation to safeguard confidential information that they obtain from and about their patients. Some states have adopted laws codifying this duty, and most states recognize a private cause of action in tort for invasion of privacy.

It is not always clear, however, where the outer boundaries of this obligation are located. May a chiropractor discuss a person's condition with his or her parent or spouse? Such a question might have been answered in the past on the basis of the doctor's view of the patient's best interest. In the twenty-first century, however, the answer must be informed by a myriad of federal and state statutes, regulations and court decisions. Violations of these laws may result in lawsuits, revocation or suspension of licenses, and/or debarment from Medicare.

One manner in which chiropractors can limit their exposure to liability, while meeting their patients expectations at the same time, is by posting a Notice of Privacy Practices is his or

her office and by handing a copy to every new patient (and by repeating this process every time a change is made in the text of the Notice). This is required of those doctors who are covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and is a sound legal practice for every healthcare professional to state his policy in advance and then adhere to it.

It is also mandated by HIPAA, and important for all chiropractors, to have patients (or the parents or guardians of minor patients) sign an "Authorization for Use or Disclosure of Information for Purposes Requested by Chiropractor" and a "Consent for Purposes of Treatment, Payment & Healthcare Operations" before collecting, utilizing, transmitting or disclosing any "protected health information" as that phrase it defined by law.

Finally, it is mandated by HIPPA to have a "Business Associate Agreement" signed by all those vendors and others who might have access to protected health information. 107-113

The foregoing are to be regarded as minimum clinical practice guidelines and not as a comprehensive legal analysis of the law of privacy nor as a substitute for the opinion of an attorney licensed in the state in which the chiropractor conducts his or her practice.

### **12.3 PATIENT ADVOCACY**

**RECOMMENDATION (new)** 

Rating: Established

Evidence: E, L

Patient advocacy is an important part of advancing safety, efficacy and utilization of chiropractic services. Effective patient advocacy programs promote quality, safety, appropriateness of service, support patient choice of adjustive care and appropriateness of referrals inside and outside the profession.

#### Commentary:

A strong patient advocacy program ensures informed and effective programs for patient privacy, quality control, patient's rights and responsibilities, conditions of acceptance, and favourable policy. To organize and carry out the operations of the advocacy program chiropractors need to develop required infrastructure (websites, patient newsletters, education materials, etc.). There is extensive literature in the field to assist with informing patients about the profession, the type of care they will receive in the office, wellness perspectives of learning about the "chiropractic lifestyle", and special, health promotion and disease prevention literature (e.g., nutrition, exercise, smoking cessation, etc.). The reader is directed to the literature summarized in Sections 9 and 10. Other specific references of patient advocacy are listed below.

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## **SECTION 13: PROFESSIONAL DEVELOPMENT**

# **RECOMMENDATION (Unchanged)**

**Established** 

Evidence: E, L

Rating:

The science, art and philosophy of chiropractic, and hence its practice, continues to expand in understanding and development. Continuing professional development, as in all responsible health professions, is a necessary component of maintaining a high standard for both the practitioner and the profession. Continuing development should be directed to areas germane to each individual practice, including but not limited to credentialing, continuing education programs, participation in professional organizations, technique protocols and application, radiographic and other imaging, instrumentation, philosophy, research, practice liability issues, legal issues, and ethics.

Since all state licensing jurisdictions are ultimately responsible for patient health and safety, these guidelines recommend that all subjects congruent with state law be considered appropriate for continuing education credits in respective states.

# Commentary

Continuing professional development is currently widely mandated by most licensing jurisdictions, or encouraged through most professional organizations. Perhaps the most compelling reason for advocating this type of on-going education is to afford practitioners the opportunity to keep abreast of the most current developments in chiropractic which serve to enhance patient care and safety. To maintain the continuing level of education (both voluntary and mandatory) an affordable fee for even the beginning practitioner is desirable.

The fact that most programs are conducted by individuals skilled in the topics presented also provides a high level of knowledge and information delivered in a relatively short period. Thus, professional development serves not only the practitioner, but also the patient through a broad base of acquired skills that benefit both.<sup>1-14</sup>

In addition to formal postgraduate education courses, other opportunities for professional development may include:

- Reading scholarly journals
- Attending scientific symposia
- Participation in research
- Publication of clinical and scientific papers
- Audio and videocassette courses
- Teleclasses
- Distance education programs

There has been an emphasis on moving from an input-based system to an outcomesbased system regarding continuing education. That is, proposals to modify existing continuing education offerings in the chiropractic profession to reflect adult learning models. Up to the present, continuing education has emphasized passive learning approaches that have as their chief outcome measure some sort of documentation that the doctor sat through a particular number of hours in the subject. This tells the licensing body nothing about what was learned or what competency was achieved. Likewise, it drives the practitioner's focus not toward mastery or applicability to day-to-day practice, but rather toward satisfying a numerical requirement. None of the recent literature reviewed discussed using periodic examinations of licensed practitioners as a way to ensure continued professional development and competence, although some of the chiropractic news press has reported that this is a looming possibility.

To be more specific, the literature on this subject reports that the driving factors in ongoing professional development include increasing levels of public scrutiny, an increased marketplace emphasis on quality assurance and the growing popularity of evidence-based practice models. We have moved into an information age, and it is clear that keeping up with the discipline requires regular engagement with a variety of materials. Professional development based upon these motivations should ultimately benefit the patients under the care of chiropractic practitioners.

Because the dominant model of chiropractic continuing education has been centered upon verification of attendance rather than demonstrable change in knowledge, skills or attitudes that will improve patient care or enhance professional competencies, chiropractors may find transition to a new model challenging.

Suggested approaches to this type of professional development include portfolio-based and experiential models. Whereas traditional lecture-based formats have the teacher as the deliverer of content, in these formats the teacher functions as a facilitator. A major challenge for regulatory bodies that wish to implement these models relates to adequate assessment and documentation – regulatory boards must certify to the public that practitioners are maintaining an appropriate level of training and are keeping up with new developments in their field to ensure quality care. So, while a shift from documenting attendance to tracking learning goals in a portfolio makes sense for adult learners, it creates difficulties for those who must evaluate the work done by practitioners to stay current or acquire new knowledge or skills. It is difficult to come up with valid and reliable criteria upon which someone's learning plan or portfolio will be judged. Further, such a protocol would require training evaluators.

There is also a shift in the location of continuing educational programs. With the proposed moves to adult learning models, the practitioner not only develops a set of learning goals and a plan for achieving them, but also takes responsibility for creating learning opportunities and experiences – often in the setting of his/her own practice. Again, verification that work is actually being done becomes a question for regulatory bodies. This question also arises when more traditional continuing education programs are delivered via distance education.

Such programs must have internal checks to verify that the person completing the work on-line is the licensee seeking credit. Some states have been quicker than others to move toward acceptance of distance education programs for relicensure. Continuing education delivered in this format presents a couple of very obvious advantages to the practitioner – it can be completed at the doctor's convenience without requiring travel.

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# Technique Panel – 1998 & 2003

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Sherman College of Straight Chiropractic

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Applied Spinal Biomechanical Engineering

Dr. David Bellin Thompson Technique

Dr. Fred H. Barge Barge Method

Dr. Charles Blum SOTO, USA

Dr. Sue Brown

Bio-Geometric Integration

Dr. Christopher Colloca

Dr. Christina Cunliffe McTimoney Technique

Dr. Ralph Davis
Upper Cervical Technique

Dr. Leander Eckard Leander Technique

Dr. Donald Epstein Network Spinal Analysis

Dr. Kirk Eriksen Orthospinology

Dr. Patrick Foran NUCCA/Grostic

Dr. Jay Hafner

Dr. Jay M. Holder Torque Release Technique

Dr. Rob Jackson Thompson Technique

Dr. Barbara James Micro-Chiropractic

Dr. Spence Jahner Pierce Technique

Dr. Paul A. Jaskoviak Contact Reflex Analysis

Dr. Joanne Jezequel Advanced Technique Review

Dr. Christopher John Directional Non-Force Technique

Dr. Jesse Jutkowitz Advanced Biostructural Correction

Dr. Renee Kale Kale Technique

Dr. Wallace King King Concept Technique

Dr. Robert Klingensmith SOTO-USA

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Dr. Howard Lewis Sacro-Occipital Research Society International

Dr. Jack Masche Concept Therapy

Dr. Yannick Pauli NSA/Torque Release

Dr. Burl Pettibon Pettibon Biomechanics

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Dr. John Pryzbylak XYZ Analysis

Dr. Keith Rau Extraspinal Technique

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Dr. Simon Senzon

Dr. Glenn Stillwagon

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Dr. James Thompson Thompson Technique

Dr. Steve Troyanovich

Dr. Adrian Wenban

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Dr. Linda Mullin Gonstead Technique

Dr. David Toftness Toftness Technique

Dr. Michael Hawkinson Toftness Technique

Dr. Victor Frank

**Total Body Modification** 

Dr. Ted Morter

Bio-Energetic Synchronization Technique

Dr. Liz Anderson Peacock

Pediatrics

Dr. Jerry Hochman Dynamic Spinal Analysis

Dr. Donald W. Olson

Applied Spinal Biomechanical Engineering

Dr. Roy Sweat Atlas Orthogonality

Dr. Scott Walker

Neuro-emotional Technique

Dr. Matthew McCoy Mears Technique Dr. Jeannie Ohm

Webster In-Utero Constraint Technique

Dr. Richard Grostic Grostic Technique

Dr. R.B. Mawhinney Mawhinney Technique

Dr. Lowell Ward Stressology

Dr. Catherine Franklin Concept Therapy

Dr. Robert Kessinger Upper Cervical Specific

Dr. Michael Burcon Burcon Cervical Specific

Dr. Mark Postles

Sacro-Occipital Technique

Dr. Robert Wiegand Access Technique

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Dr. Roger Morrison Blair Technique

Dr. John Pinto Atlas Orthogonality

Dr. Stuart Warner Pediatric Technique

Dr. Mark Filippi

Dr. Harold George

Pierce/Stillwagon Technique

Dr. Margaret Banitch Blair Technique

Dr. Mark Dietch Motion Palpation

Dr. Steve Ward Stressology

Dr. George Fleet Concept Therapy

Dr. Zahra Yousefi Directional Non-Force Technique

# Appendix 2: Methodological Standards for Practice Guidelines

Adapted From: Shaneyfelt, T.M., Mayo-Smith, M.F., Rothwangl, J. Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature. JAMA, May 26, 1999 – Vol 281, No. 20. With the Permission of the *Journal of the American Medical Association* 

Frequency of Adherence to Methodological Standards on Guideline Development and Format

- 1. Purpose of the guideline is specified
- 2. Rationale and importance of the guideline are explained
- 3. The participants in the guideline development process and their areas of expertise are specified.
- 4. Targeted health problem or technology is clearly defined
- 5. Targeted patient population is specified
- 6. Intended audience or users of the guideline are specified
- 7. The principal preventive, diagnostic, or therapeutic options available to clinicians and patients are specified
- 8. The health outcomes are specified
- 9. The method by which the guideline underwent external review id specified
- 10. An expiration date or date of scheduled review is specified.

Frequency of Adherence to Methodological Standards on Evidence Identification and Summary

- 11. Method of identifying scientific evidence is specified
- 12. Time period from which evidence is reviewed is specified.
- 13. The evidence used is identified by citation and referenced
- 14. Method of data extraction is specified
- 15. Method for grading or classifying the scientific evidence is specified
- 16. Formal methods of combining evidence or expert opinion are used and described.
- 17. Benefits and harms of specific health practices are specified
- 18. Benefits and harms are quantified
- 19. The effect on health care costs from specific health practices is specified
- 20. Costs are quantified

Frequency of Adherence to Methodological Standards on the Formulation of Recommendations

- 21. The role of value judgments used by the guideline developers in making recommendations is discussed
- 22. The role of patient preferences is discussed
- 23. Recommendations are specific and apply to the stated goals of the guideline
- 24. Recommendations are graded according to the strength of the evidence
- 25. Flexibility in the recommendations is specified

# Appendix 3: Criteria for Choice of Peer-Reviewers

# Peer Reviewers were chosen based on several characteristics including but not limited to:

- Technique expertise
- Involvement in Regulatory Board Activity
- Experience in research or publication
- Experience in chiropractic education
- Knowledge of chiropractic education accreditation standards
- Hold advanced post graduate degrees in chiropractic sciences and/or other specialties within chiropractic
- Practice experience
- International practice
- Specialty practice i.e. pediatrics
- Political Experience
- Legal expertise
- Experience in Guideline Development Methodology
- Vendors with an interest in chiropractic guidelines
- Patients
- Government experts