THE CHIROPRACTIC REPORT

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RAND Report on Cervical Manipulation and Mobilization

A. Introduction

1. Medical students have traditionally had no exposure to spinal manipulation, and 15 years ago it was standard medical practice to advise patients that spinal manipulation for back pain was inappropriate.

Research and recent authoritative multidisciplinary clinical guidelines in Europe[1] and North America[2] have now established that manipulation is a first line approach to management of most back pain patients, those with mechanical or non-specific back pain, and today many family physicians refer such patients to chiropractors. The 1991 RAND reports titled *The Appropriateness of Manipulation for Back Pain*[3,4] were an influential step in the process of medical acceptance.

2. However, often because of anecdotal evidence of harm, many physicians maintain a cautious attitude towards any manipulation of the neck or cervical spine. Two major evidence-based multidisciplinary reports in the past year will now begin to change that attitude, as before with back pain:

a) In May 1995 the Quebec Task Force on Whiplash Associated Disorders presented its report *Redefining Whiplash and its Management*.[5] An elite international inter-disciplinary panel, comprised principally of medical specialists from Canada, Europe and the US, recommended manipulation, mobilization and early exercise for patients with soft tissue cervical spine injuries - in other words similar management to that currently recommended for back pain. (For a full review of the Quebec Report see the July 1995 issue of The Chiropractic Report (Vol 9 No. 4)).

b) Now in July 1996 a second independent multidisciplinary report, this from the RAND Corporation in California and titled *The Appropriateness of Manipulation and Mobilization of the Cervical Spine*[6], supports the appropriateness of cervical manipulation for many patients.

3. This RAND Report, which comprises literature reviews on effectiveness and complications of manipulation and mobilization, and ratings on appropriateness for specific conditions by an expert panel, delivers three basic messages:

i) Having regard to the scientific evidence on risks and benefits, manipulation and mobilization are appropriate for many patients with many common categories of neck pain and headache.

ii) Cervical manipulation, which has significant but extremely rare complications, is far safer than a number of medical treatments given for the same symptoms.

- Serious complications from manipulation occur with a frequency of 1 per 1 million treatments.
- Serious gastrointestinal events from NSAIDS are 1000 per 1 million, serious neurological complications from cervical spine surgery are 15,600 per 1 million.
- Mortality rates are .3 per million (i.e. 3 per 10 million) for cervical manipulation, 6,900 per million for cervical spine surgery.

iii) Much more good research is required. There may be more randomized controlled trials showing efficacy of manual therapy than other treatments for the cervical spine, but the literature is still sparse.

Fortunately researchers are heeding this call. Since the RAND literature review closed in 1995 there have been trials - with positive results for chiropractic manipulation - from Italy[7] and Denmark.[8] Further trials of chiropractic cervical manipulation are about to be reported by Niels Nilsson DC MD MSc (University of Odense, Denmark: cervicogenic headache - chiropractic manipulation v standard medications), Larry Morries DC et al (University of Colorado, US: neck pain - manipulation v standard medica-

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Professional Notes

North American Cervicogenic Headache Society

A North American Cervicogenic Headache Society (NACHS) was established at a conference in Toronto in September 1995. It has a multidisciplinary board, membership is already over 400 and includes many chiropractors, and this may be of interest to you for the following reasons:

- NACHS President is Peter Rothbart MD, a Toronto anaesthesiologist and pain management specialist who frequently refers patients with headache for chiropractic care. Vice-President is Horst Blume MD PhD from the University of South Dakota. Chiropractic board members include Howard Vernon DC FCCS(C) , Associate Dean of Research, CMCC, Toronto and Scott Haldeman DC MD PhD, Santa Ana, California.

Although based in North America there are international board members including Nikolai Bogduk MD PhD and Michael Anthony MD from Australia, C. Saunte MD from Trondheim, Norway and A. Kuritzky MD from the Headache Unit, Department of Neurology, Tel Aviv University, Israel.

- These extracts from the Society's first mailing illustrate its background and purpose: "The cause of headaches is not elucidated, and treatment is largely empirical. An anatomical,

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tions), and Craig Nelson DC et al (Northwestern College of Chiropractic, Minneapolis, US: migraine headache - manipulation v standard medications). A number of other trials are underway and all this evidence is to be reviewed at the World Federation of Chiropractic's 1997 Symposium *The Cervical Spine* to be held in Tokyo June 6-8, 1997.

4. The RAND Report is available from RAND (for details see Figure 1). Like the Quebec Report, much of it has been summarized in an article in *Spine* (August 1996).[9] This Report now comments on the RAND study and its significance.

B. The RAND Report

5. The RAND ('Research and Development') Corporation, is a non-profit private corporation in Santa Monica, California, which conducts research and development for the US government and the private sector and commands international respect. It first gained prominence with research for the U.S. military in World War II. Its current research programs include classified defence research for the military, applied economics, education, sociology, civil justice and health sciences. With respect to health sciences:

- RAND's health sciences department is the largest non-university based research center in the US.
- For the past 15 years a central concern has been the development and application of methods to assess the appropriateness of health care procedures.
- RAND has assisted many health provider groups with research aimed at establishing practice standards or guidelines, including the American Medical Association.

6. RAND's research on spinal manipulation, firstly with respect to the lumbar spine and now the cervical spine, has been funded by the Consortium for Chiropractic Research, which represents chiropractic colleges and professional associations in North America.

The continuing study on back pain started with three projects and reports - a literature overview, the ratings of an interdisciplinary panel, and the ratings of an all-chiropractic panel - and is now looking at compliance with these ratings in actual chiropractic practice throughout North America. In other words, in practice is spinal manipulation generally given for appropriate patients (compliance) or inappropriate patients (non-compliance with the RAND ratings of appropriateness).

This first report on the cervical spine combines two projects - a literature review and the ratings of an interdisciplinary panel.

7. **Process**. The RAND Report was prepared after this process:

a) A full literature review, which found 507 articles on efficacy, complications and indications for manipulation and mobilization of the cervical spine.

b) Development of a set of 1436 possible clinical indications for use of manipulation and mobilization.

c) Findings or ratings of the appropriateness of manipulation and mobilization for each of these 1436 indications by a multidisciplinary panel of 9 experts drawn from the fields of chiropractic, family medicine, orthopedics and neurology.

8. **Expert panel**. Following standard RAND methodology this had 9 members, some of whom used the treatments being assessed and some of whom did not. For this panel there were 4 chiropractors, 4 medical physicians and 1 joint chiropractor/medical physician chosen with regard to clinical expertise, professional repute, geographic diversity in North America and a balance of academic and community practice experience. They are listed in the report as follows:

Arthur Croft, DC, Coronado, California - a chiropractor in general practice who has published widely on whiplash and cervical injuries.

Peter Curtis MD, University of North Carolina, Department of Family Medicine, Chapel Hill, North Carolina - an academic primary care physician trained in physical manipulation.

Thomas Ducker, MD, Annapolis, Maryland - an academic neurosurgeon and editor of a major professional journal on the spine.

Ronald Evans, DC, Des Moines, Iowa - a chiropractor in general practice

Steve Garfin, MD, University of California, San Diego Medical Center, San Diego, California - an academic orthopedic surgeon and associate editor of a major professional journal dealing with the spine.

George McClelland, DC, Christianburg, Virginia - a chiropractor in general practice.

David Sherman, MD, Department of Medicine, University of Texas Health Sciences Center, San Antonio, Texas - an academic neurologist who has published in the area of complications of cervical spine manipulation.

Rand Swenson, MD PhD DC, Monadnock Hospital, Peterborough, New Hampshire - an academic neurologist with a doctorate in anatomy, who also trained as a chiropractor.

Howard Vernon, DC, Canadian Memorial Chiropractic College, Toronto, Ontario, Canada - an academic chiropractor who has conducted research and

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Figure 1
RAND Report - How to Order?

Order from: RAND Distribution Services, P.O. Box 2138, Santa Monica, CA 90407-2138, Credit Card orders - Tel: 310-451-7002/310393-0411, Fax: 310-451-6915.

The Appropriateness of Manipulation and Mobilization of the Cervical Spine, Coulter ID, Hurwitz EL, Adams AH et al, Document No. MR-781-CCR: Cost - US $15.00 plus $3.00 handling (US), $4.00 handling (International).

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published in the area of headache.

9. **Definitions of Manipulation and Mobilization**. RAND continues the established trend of now regarding manipulation and mobilization as separate treatments. They are given different definitions, the essence of which is that spinal manipulation involves high velocity thrust but mobilization does not (slightly different definitions appear in each of the full Report and the *Spine* article), and for each of the 1436 clinical indications there are different ratings for manipulation and mobilization.

10. **Literature Review - Efficacy**.

a) From 362 primary articles on cervical spine manual therapy, 108 were deemed of value on the question of effectiveness - 16 randomized controlled trials (RCTs), 13 cohort studies, 27 case series and 52 case reports. First priority was given to the RCTs, which were ranked for quality using the Koes et al criteria.[10]

b) ***Neck Pain:*** Six trials of manipulation (5) and mobilization (1) for subacute (3-13 weeks) and chronic (over 13 weeks) neck pain, and 7 other studies, support the conclusion that "cervical spine manipulation and/or mobilization may provide at least short-term pain relief and range of motion enhancement for (patients) with sub-acute or chronic neck pain."

Only one trial gives long-term results - follow up at 12 months after treatment. This, by Koes et al in the Netherlands, was the best designed neck pain trial and reported better long-term results for the patients receiving manipulation than those receiving standard medical care or a placebo (detuned diathermy). However it is rightly concluded that more studies are needed to justify a clear finding of long-term benefits.

Interestingly, there are no trials for patients with acute neck pain (less than 3 weeks). Looking at the back pain evidence one would be very safe in concluding there are benefits for patients with acute neck pain, given that there is benefit with sub-acute and chronic pain, but at the purely scientific level there remains a lack of evidence.

c) ***Headache:*** With respect to muscle tension headaches, 5 RCTs of manipulation (4) and mobilization (1), and 9 other studies, support the conclusion that "cervical spine manipulation and/or mobilization may provide short-term relief for some patients with muscle tension and other non-migraine headaches." Once more, trial evidence of long-term benefit is lacking.

With respect to migraine, there is only one RCT, the Parker trial in Australia, [11] and five other studies of manipulation. This evidence suggests manipulation may be effective, and there was long-term benefit in the Parker trial. However the RAND Report concludes "the literature is too limited to support or to refute the use of cervical spine manipulation and/or mobilization."

Headache is, of course, an area afflicted with huge diagnostic confusion. Are tension-type headaches and migraine really distinct, or are they part of a continuum? How many of these patients have cervicogenic headache (CGH), as defined by the International Headache Society? Recent studies show CGH is as common as migraine.[12]

Using the North American Cervicogenic Headache Society (NACHS) definition of CGH, "referred pain perceived in any region of the head caused by a primary nociceptive source in the musculoskeletal tissues innervated by the cervical nerves", many patients with a medical diagnosis of migraine or tension headache will in fact have CGH amenable to manual therapy.

No one doubts that the next 10 years will see major changes in the classification and management of patients with headache. Toronto pain specialist Peter Rothbart MD, who operates a specialist headache clinic and is NACHS President, reports that 80% of the patients he sees on referral from family practice may be classified as having tension headache. However the majority of these also fall within the definition of CGH and many receive best clinical results when they are referred for chiropractic manipulation.[13]

d) ***Other Conditions:*** Cervical manipulation and mobilization are used for a variety of other conditions, including referred pain to the shoulder/arm/hand, thoracic outlet syndrome, carpel tunnel syndrome, and TMJ disorders. Again the literature is slight, and "insufficient to support or to refute the use of cervical spine manipulation and/or mobilization." The RCTs and case series research reviewed by RAND does, however, report short and long-term benefit.

11. **Literature Review - Complications**
A particularly valuable aspect of the RAND Report is the thorough and objective analysis of the literature on complications. 110 cases of serious complications following cervical manipulation and/or mobilization are found in the English literature and reviewed. It is noted:

a) Complication rates are produced by assuming that the published reports represent one tenth of the actual complication caseload.

b) Overall estimate of the rate of serious complications as a result of cervical spine manipulation is 1 per 1 million manipulations. The great majority of complications involve vertebrobasilar accidents (VBA) with consequences such as brainstem and/or cerebellar infarction, Wallenburg's Syndrome and Locked-in Syndrome. RAND notes that more systematic evidence is necessary for a precise estimate of risk and that "the true incidence of serious complications from cervical manipulation may be smaller".

This literature review (pgs 33-40 in the Report) is now the best material to send family physicians and others for a balanced analysis of risk. Another recent informed and balanced review, by Dutch medical researchers Assendelft WJJ et al published in the US *Journal of Family Practice,* confirms that the incidence of serious complications is low, that most cases involve excessive rotation, and that family physicians should refer to practitioners who "do not apply rotary cervical manipulation".[14] Anyone with formal education and competence, of course, now appreciates the need to avoid significant rotation and extension.

12**. Expert Panel - The Concept of Appropriateness**. *Appropriate* care is defined by RAND as meaning that "expected health benefits to the patient (e.g. increased life expectancy, relief of symptoms, reduction of anxiety and improved functional capacity) exceeded expected health risks (e.g. mortality, morbidity, pain produced by the procedure) by a sufficiently wide margin that the procedure is worth doing." Related concepts used by RAND are:

a) Panellists had to rate appropriateness for each indication on a 9 point scale where extremely inappropriate is 1, uncertainty with the risks and benefits about equal or unknown is 5, and extremely appropriate is 9.

b) Three categories for appropriate-

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ness were created - inappropriate, uncertain, and appropriate.

c) An indication was appropriate if the panellists gave a median rating in the 7-9 range without disagreement, was inappropriate if they assigned a 1-3 rating without disagreement, and was uncertain if there was a rating of 4-6 or disagreement.

13. **Definitions of Agreement and Disagreement**.

a) *Agreement:* After discarding one extreme high and one extreme low rating the remaining 7 fall within any 3 point range.

b) *Disagreement:* After discarding one extreme high and one extreme low rating at least 2 of the remaining 7 fall in the lowest 3 point region (1-3) and at least 2 fall in the highest (7-9).

Accordingly there were three possibilities - agreement, disagreement, and uncertainty with neither active agreement nor disagreement as defined. At the end of the process there was agreement on 40% of ratings, disagreement on 2% and uncertainty on 58%. Very importantly, wherever there was uncertainty, there could not be a positive rating for the appropriateness of either cervical manipulation or mobilization.
Why was there this uncertainty? Two points are made in the Report:

- The rate of uncertainty is not unusual. One reason, quite normal on RAND health care panels which bring together those who use the treatment and those who do not, is that those using the treatment tend to give higher ratings.
- Most of the uncertainty reflected a lack of literature, again a normal problem. It did not represent concerns about safety and the degree of uncertainty indicates "the need for additional scientific data about the efficacy of cervical spine manipulation" (pg.44).

14. **The 1436 Clinical Indications**

Armed with the literature review, clinical experience and expert advice, the RAND panel developed a list of all indications for use of cervical manipulation and mobilization that might arise in practice. The initial list was prepared by RAND project staff using the literature review and the advice of chiropractors, medical physicians and physical therapists. This was then reviewed by chiropractic and medical consultants, and then reviewed a second time by the multidisciplinary expert panel. This process resulted in 1436 indications which were grouped into 13 categories or chapters as follows:

1. Acute neck pain and signs of painful and/or limited active range of motion and pain anatomically consistent with a musculotendinous distribution and no radiculopathy.
2. Subacute or chronic neck pain and signs of painful and/or limited active range of motion and pain anatomical ly consistent with a musculotendinous distribution and no radiculopathy.
3. Peripheral pain of probable sclerotogenous distribution.
4. Pain consistent with musculotendinous involvement of the temporomandibular joint (TMJ).
5. Acute neck pain and clinical suspicion of cervical nerve root involvement.
6. Subacute or chronic neck pain and clinical suspicion of cervical nerve root involvement.
7. Generalized neck pain.
8. Acute constant headache.
9. Acute or subacute intermittent headache.
10. Chronic intermittent headache.
11. Persistent neuralgic pain consistent with cranial nerve distribution; insidious facial palsy; idiopathic insidious ver tigo and/or dizziness; insidious spasmodic torticollis in the absence of congenital, postsurgical, or postfracture etiologies; or idiopathic insidious pharyngeal dysfunction.
12. Miscellaneous (with radiographic evidence).
13. Miscellaneous (cardiovascular related conditions).

To illustrate one clinical indication - and how such a large total of 1436 clinical indications can be developed - let us take an example from Chapter 1 above relating to acute neck pain with certain signs and symptoms. One sub-category or indication within that chapter was a patient with minimal or no trauma, no clinical risk factors for radiographic contraindications to cervical manipulation and no cervical radiographs, no other conservative care received, and no prior experience of manual therapy. (For this indication both manipulation and mobilization were rated appropriate by the panel).

Alteration of any of the variables (e.g. substantial trauma, or prior experience of manual therapy, or clinical risk factors for radiographic contraindications and no cervical radiographs, etc.) all give rise to separate indications. The panel made ratings for each of the 1436 indications for each of manipulation and mobilization. These appear in Appendix B to the Report - comprising 48 fine print pages.

15. **Ratings Procedure**. Standard RAND methodology was used. In the first round panel members made individual ratings of appropriateness based on the literature, their clinical judgement and treatment by an average clinician or provider trained in the procedure - i.e. not the best or worst treatment, but treatment assumed to be competent .

In the second round the panel met and final ratings were made using formal RAND consensus procedures. After the first round there was agreement on 20% of ratings, disagreement on 10%. (See para 13 above for definitions of agreement and disagreement). After the second round there was agreement on 40% of the ratings, disagreement on 2%.

16. **Overall Results of Ratings**. For the 1436 clinical indications there were these ratings for cervical manipulation and mobilization:

a) Appropriate - 122 indications (16%).

b) Uncertain - 586 indications (41%).

c) Inappropriate - 623 indications (43%).

For details one must consult all the condition-by-condition panel rating charts in Appendix B. Here are examples, one each for neck pain and headache:

a) *Sub-acute or chronic pain with painful or limited active range of motion and no radiculopathy (Chapter 2):* Where there is minor trauma and radiographs show no contraindications, the panel found manipulation and mobilization *appropriate*, both in the presence or absence of psychosocial distress. However the presence of clinical risk factors for radiographic contraindications and the absence of cervical radiographs make manipulation and mobilization *uncertain* - there was no panel agreement. Substantial trauma, make both manipulation and mobilization *inappropriate*.[15]

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b) *Chronic intermittent headache (Chapter 10)*: If there is throbbing with prodrome, cervical signs and symptoms, cervical radiographs which show no contraindications, and favourable prior experience of manipulation, both manipulation and mobilization are *appropriate*. However if there has been no response to prior manipulation or mobilization, or there are no cervical signs and symptoms, then the panel rates both interventions as *uncertain* - neither appropriate nor inappropriate.

Summary comments concerning the overall ratings are:

a) There are many clinical circumstances in which the medical and chiropractic professions, as represented by experts on this RAND panel, now agree that cervical spinal manipulation - by definition involving high-velocity techniques - is appropriate.

b) In many more circumstances there is uncertainty, arising from insufficient literature on efficacy rather than concerns on harm.

c) For almost half of the clinical indications listed, 623 or 43%, manipulation and mobilization are found to be inappropriate. As RAND explains this does not mean that inappropriate care is common. In practice manipulation and mobilization may generally be used for appropriate indications. To understand the frequency of appropriate and inappropriate use now requires the structured collection of patient data on persons presenting with cervical spine symptoms.

This work, a huge and expensive research project, is presently being done by RAND for the lumbar spine through a sample survey of chiropractic practices throughout North America. It will now be done for the cervical spine also. Chiropractors will be pleased to know that the source of the CCR funding for the RAND cervical spine research is interest on monies paid to the profession in settlement of costs in the *Wilk v AMA et al* anti-trust case.

C. Conclusion

17. The new RAND Report, prepared by panellists and researchers relying principally on randomized controlled trial evidence, is by its nature very conservative. It may be compared for example with the much more enthusiastic assessment of appropriateness given by chiropractic and medical experts familiar with the practice of cervical manipulation.

A recent Canadian case involved minor residual injury following medical manipulation for a patient with severe chronic headaches that had not responded to medication. As an expert witness Charles Godfrey MD, Professor Emeritus of Physical Medicine and Rehabilitation, University of Toronto, who has practised manipulation for over 20 years, strongly supported the use of manipulation and assessed an 80% prospect of success. Risk was so minimal, he explained, that he never raised it with patients. As to the literature on this "popular and effective" treatment:

"Treatment of torticollis with associated muscle spasm and pain and radiation to the occiput, hand or shoulder regions by manipulation is a common practice. Numerous papers have been published demonstrating the effectiveness of this type of therapy."[16]

18. However, even on the conservative assessment of appropriateness by the RAND panel, there is clear support for the use of cervical manipulation for many patients with neck pain and headache and other symptoms. One significant aspect of this is that the family physician who was previously reluctant to refer patients for cervical manipulation, because of anecdotal and exaggerated evidence of harm, now has a secure scientific and professional basis for doing so.

If you are a chiropractor, the RAND Report and a bottle of dry white wine - that other famous treatment for tension headache - may be an excellent present for your medical colleagues this Christmas.

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15. Supra ref 6, pp. 55, 57 and 59.

16. *Leung* v *Campbell*, Ontario Court of Justice No. 23108/87, judgement dated January 6, 1995 and Dr. Godfrey's expert report.

physiological and physical explanation for cervically generated headaches has been clearly established. This has important ramifications for the appropriate approach to treatment of cervically generated headaches.

Most headachologists, however, are trained as neurologists and do not have the skills or desire to examine and investigate the neck. They continue to limit their investigations to intracranial causes for headache.

We feel it is thus very important to continue the study of how neck pathology can cause headaches, so that ultimately this information becomes integrated into the mainstream of headache etiology and treatment. We are therefore starting the NACHS."

- The Society has adopted the following definition of cervicogenic headache - "referred pain perceived in any region of the head caused by a primary nociceptive source in the musculoskeletal tissues innervated by cervical nerves."

The NACHS is submitting this definition, together with a description of clinical features, diagnostic criteria and pathology, to the International Association for the Study of Pain for inclusion in the IASP's next Taxonomy of Pain.

- The Society is holding its next Cervicogenic Headache Conference at the Monte Carlo Resort and Casino, Las Vegas, March 21-24, 1997, where speakers will include Professor Bogduk and Dr. Vernon.

This new emphasis on cervicogenic headache, fostered by a committed and expert society with multidisciplinary involvement, obviously has major importance for the chiropractic profession and the future management of headache. Enquiries concerning the NACHS and its Las Vegas meeting should be directed to NACHS Secretary Bess Lokach at York Mills Centre, 16 York Mills Road, Unit #125, Box 129, North York, Ontario M2P 2E5, Tel: 416-512-6407 Fax: 416-512-6375.

ACC Defines Chiropractic and the Subluxation

Association of Chiropractic Colleges Position Paper No. 1 July 1996.

The presidents of all 16 accredited chiropractic colleges in North America have been meeting this year to establish a common position on the essentials of chiropractic education and practice, and on the contemporary role of chiropractic in the health care system. Their first position paper, released in August as the formal position of the Association of Chiropractic Colleges (ACC), is important because:

- It is unanimous, and carries the signatures of all Presidents.
- It defines the model or paradigm for chiropractic - see Figure A.
- It defines the practice of chiropractic and the subluxation.

On the practice of chiropractic the ACC position is:

"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."

Noteworthy elements are the exclusion of use of drugs (this, remember, being a unanimous decision - in recent years a few colleges have questioned the fundamental principle of drugless practice but that is now laid to rest) and the emphasis on cooperation with other health care providers (also found at the foundation of the paradigm - see Figure A).

On subluxation the ACC states:

"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."

The emphasis on best available evidence is found elsewhere in the ACC position paper, which contains a satisfying blend of respect for traditional principle and for necessary evolution in education and practice.

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Figure A