ICA Committee's Critique of CCGPP's Best Practices: Chiropractic Management of Low Back Pain and Low Back Pain Related Leg Complaints

ICA Committee Recommendation

Since these CCGPP "Best Practices" Low Back Pain Guidelines, disguised as a "Database", is fraught with major fatal flaws, we recommend that the ICA, ICA Affiliated Chiropractic Colleges, and ICA associated State/Provincial Associations/Societies reject these CCGPP Low Back "Best Practices". Additionally, this committee requests that the ICA send this critique to CCGPP both "Electronically" and in the mail as "Return Receipt Requested".

Major Flaws

1. <u>Potential Financial Conflict of Interest</u>

On page 24, we note that several of these "team members" either still are or have worked in State or Federal Government positions utilizing Guidelines, Hospital Administrators, and/or IMEs for insurance companies.¹⁻⁴ According to Linton & Peachy⁵, "Guidelines must emanate from a credible and acceptable source. Governments do not qualify on either ground." Additionally, "The second group of non-medical organizations that might attempt to impose standards includes third-party payers, insurance groups, and, perhaps hospital administrative organizations".

In an article published in JAMA investigating potential conflict of interest of authors of Clinical Practice Guidelines (CPG's), Chaudrey stated, "if individual authors have relationships that pose a potential conflict of interest, readers of these CPG's may wish to know about them to evaluate the merit of those guidelines."⁶ The author continues, "Financial conflicts of interest for authors of CPGs are of particular importance since they may not only influence the specific practice of these authors but also those of the physicians following the recommendations contained within the guidelines."⁶ Based upon this information, we desire to ascertain detailed information regarding the funding of both the CCGPP in general, and a review of past, present and future research funding of all members of the CCGPP Research Commission in order to identify potential financial conflicts of interest. Chaudry stated, "Unfortunately, bias may occur both consciously and subconsciously, and therefore, its influence may go unrecognized."⁶

The CCGPP website (http://www.ccgpp.org/concerns.htm) states, "CCGPP has purposely designed this document to appeal to all philosophies and, by the very nature of a best practices document, it should be useful for all types of practitioners. Our intent is that it will serve as a useful information source for all chiropractors as well as those who interact with the chiropractic profession." However there are issues we raise with the selection of some of the "Team" members for the Low Back Draft. The glaring bias of some of the members of this panel, listed in Table 1 below, against Subluxation-Based chiropractic in general is well known.⁷⁻¹² Subluxation-based chiropractors comprise a significant percentage of the profession at large. Let it be known that your group and your rough document do not appeal to the constituents of the International Chiropractic Association.

Eccles is quoted as stating, "There are good theoretical reasons to believe that individuals' biases are better balanced in multidisciplinary groups, and that such balance will produce more valid guidelines."¹³ "Multidisciplinary" composition for a guideline of this nature (for the chiropractic profession) does not imply the inclusion of medical and/or osteopathic physicians. Rather, we believe that a more representative group of chiropractic researchers (to include "Straight" chiropractic researchers—yes, they exist) would be appropriate.

Therefore, in summary, since several members of the CCGPP's Low back Pain committee are IMEs for 3rd party payers (insurance companies or managed care organizations), work for State

Government (Washington), are Hospital Administrators, and have strong biases against a significant percentage of practicing chiropractors (Subluxation-Based), these CCGPP Low Back Guidelines are *completely invalidated*.

If CCGPP claims that their "Team Members" are not IMEs for 3rd party payers (insurance companies or managed care organizations), work for State Government (Washington), and are Hospital Administrators, then CCGPP should have them fill out the following Table 1.

	Table 1								
Last Name	Have you ever worked for an Ins. Co. as an IME?	Do you work for a State or Federal agency?	Do you work for a hospital administration?	Are you a consultant to any 3 rd party payer?	If yes in columns 2-5, then list which organization?	What is your income/ year for your IME/consulting work ?			
Meeker		ugeney.			organization.	work .			
Bronfort									
Cates									
Green		yes							
Handell			yes						
Lawrence									
Micozzi			yes						
Updyke									
Mootz		yes							
Triano	yes								

2. MD is a Member of the "Team Members" of CCGPP's Low Back "Best Practices"

What are an MD and a Hospital Administrator doing on a Chiropractic Guideline/ "Best Practices"? Does anyone in our profession believe that any MD group would have a chiropractor on their Guideline's committee? This is exactly why DCs have always complained that nurses, PT's, and MD's should not be IMEs on chiropractic claims review, they are not our peers and they do not represent our profession.

3. <u>Complete Lack of "Levels of Evidence"</u>

On page 12, the CCGPP authors describe their method of "*Evidence Rating*" as "A, AB, B, BC, and C". However, they fail to define the "*Levels of Evidence*" used in their review process. The Center for Evidenced Based Medicine (CEBM) describes "Levels of Evidence" as having essentially originated when Suzanne Fletcher and Dave Sackett were working for the Canadian Task Force on the Periodic Health Examination in the late 1970's. ¹⁴ They introduced "levels of evidence" for ranking the validity of "evidence" concerning the merit of medical procedures. They then submitted "grades of recommendations" to the advice given in the report, based upon the extent of evidence reviewed. The authors of this CCGPP document fail to define "levels of evidence" and "grades of recommendations". Instead, the authors refer to the American College of Physicians (ACP) publication of the Physician's Information and Education Resource (PIER) program.

We believe it is completely inappropriate that the most basic element of Guideline development, i.e., the chosen levels of evidence (CCGPP only provided what they called "Rating of Evidence") went unreferenced in the document. Despite this, we discovered that this PIER program is available for members of ACP (Medical physicians only) or available for subscription through web-based medical service sites such as Ref!Stat (<u>www.statref.com</u>). Interestingly, upon review of PIER's program, we found their "Evidence Ratings" to be nothing like those of the CCGPP document.

CCGPP authors stated that PIER language was, "modified as appropriate to address relevant *diagnostic* [emphasis ours] studies..." However, no mention was made regarding the modification of PIER language for studies of prevention or treatment. The "Evidence Ratings and Criteria" summarized in the PIER document is detailed, verbatim, in Table 1. For comparison, the CCGPP Evidence Rating is detailed in **Table 1** as well. Upon comparison of the language, one can see there is only minor similarity. So, we ask the question, what is the basis for the authors described "Evidence Rating"?

PIER vs. CCGPP—Evidence Ratings (Treatment)							
PIER Evidence Ratings and Criteria	CCGPP's Evidence Rating, page 12						
 [A] The preponderance of data supporting this statement is derived from level 1 studies, which meet all of the evidence criteria for that study type. [B] The preponderance of data supporting this statement is derived from level 2 studies, which meet at least one of the evidence criteria for that study type. [C] The preponderance of data supporting this statement is derived from level 3 studies, which meet none of the evidence criteria for that study type or are derived from expert opinion, commentary or consensus. [1] Studies that meet all of the evidence criteria for that study type. [2] Studies that meet at least one of the evidence criteria for that study type. [3] Studies that meet none of the evidence criteria for that study type or are derived from expert opinion, commentary or consensus. Criteria: Studies of prevention or treatment must meet these additional criteria: Random allocation of participants to comparison groups Follow-up (end-point assessment) of at least 80% of those entering the investigation Outcome measure of known or probably clinical importance 	 A – The method of treatment is supported by at least one good randomized controlled trial, a meta analysis or the preponderance of evidence considered individually or in a systematic review. AB – The method of treatment is supported by at least one good randomized controlled trial and by cohort, case-control, observational studies or case series. B – The method of treatment is based on research data that are less compelling than a randomized controlled trial (e.g. cohort, case-control, or observational studies, case series). BC – The method of treatment is based on research data that are less compelling than a randomized controlled trial (e.g. cohort, case-control, or observational studies, case series). BC – The method of treatment is based on research data that are less compelling than a randomized controlled trial (e.g. cohort, case-control, or observational studies, case series) and on expert opinion or consensus or on historically, generally accepted standards of clinical practice not based on evidence. C – The method of treatment is based on <i>expert opinion or consensus</i>, or on historically, generally accepted standards of clinical practice not based on evidence. 						

Table 2.
PIER vs. CCGPP—Evidence Ratings (Treatment)

It seems inappropriate to invent a system of "Rating Evidence" and provide a bogus reference. In addition, the authors are grouping together "Levels of Evidence" with "Rating of Evidence". These are not the same. Commonly accepted "Levels of Evidence" have been described and employed elsewhere. For example, we quote from the United States Department of Health and Human services (http://www.ahrq.gov/):¹⁵

Level 1. Randomized controlled trials (RCTs)-includes quasi-randomized processes such as alternate allocation.

Level 2. Non-randomized controlled trial (NCTs)—a prospective (pre-planned) study, with predetermined eligibility criteria and outcome measures.

Level 3. Observational studies with controls—includes retrospective, interrupted time series (a change in trend attributable to the intervention), case-control studies, cohort studies with controls, and health services research that includes adjustment for likely confounding variables.

Level 4. Observational studies without controls (e.g., cohort studies without controls, case series without controls, and case studies without controls)

5.

4. <u>Expert Opinion is Used as "Evidence", But Not Case Studies</u>

We note that the proposed A through C system of the CCGPP neglects to rate the Case Study. In Table 2 above, CCGPP lists "*Expert Opinion*" or "*Consensus*", which most agencies view as Level 5 evidence and is rated <u>*BELOW*</u> Case Study (Level 4)!

As stated above, case studies without controls are Level 4 Evidence, according to the United States Department of Health and Human Services, Agency for Healthcare Research and Quality. We believe that the case study is *extremely* important in establishing Chiropractic "Best Practices", in that a preponderance of the evidence in support of chiropractic for conditions other than LBP exists at this level.

Vandenbrouke described the hierarchy of evidence "...with the randomized trial "on top" serves one purpose admirably: the final evaluation of therapies or tests, especially when their clinical value is not immediately clear-cut. Case reports and case series, however, have other aims that are equally important in the progress of medical science and education."¹⁶ Other studies have also found that well designed case reports are consistent with the results of RCT's¹⁷⁻²² and thus well performed Level 3 and Level 4 investigations are good evidence.

In fact, the American College of Physicians/PIER website²³ states, "Unlike most guidelines, PIER includes recommendations based on all levels of medical evidence including RCTs, cohort and observational studies, *case reports* [emphasis ours], and expert opinion."²³ Again, we ponder, is the CCGPP using the PIER format or are they contriving their own?

Even though the CCGPP authors submit to (claim to) the review of "case series" to be included in rating "BC" of evidence, they fail to review the preponderance of case series reports. The "Quick reference Source" on page 25 astutely points out the direction of this document by defining the Scope as "Low back pain and low back related leg pain". However, a review of the applicable ICD codes reveals diagnoses outside of "Pain" conditions. For example, the code 737.30 is listed. This code on page 117B of the ChiroCode® Deskbook (2006 ed) defines this as "Scoliosis [and kyphoscoliosis], idiopathic". We note that most patients with idiopathic scoliosis have little or no back pain, particularly in adolescence when this condition predominately begins. In addition to being unrelated to "low back pain and low back related leg pain", Scoliosis was not listed among the topics (acute low back pain, subacute low back pain, chronic low back pain, and sciatica/radicular/radiating leg pain).

In a recent survey of the intention of chiropractors to manage adolescent idiopathic scoliosis, 86% of responding chiropractors reported that they would utilize exercises in their treatment plan.²⁴ Many studies exist investigating the effectiveness of exercises alone, and in combination with other procedures, in the management of lumbar scoliosis. Studies on scoliosis efficacy with chiropractic intervention,^{25,26} as well as exercise interventions²⁷⁻⁴⁰ were ignored.

No Frequency and Duration (i.e. no suggested visits allowed per time periods) Because CCGPP eliminated all Level 2, 2/3 of Level 3, and all Level 4 evidence, they are left with only low back pain and leg pain studies to be included in their "Selective Database". This care by "per condition" (pain) offends ICA members.

On page 7, Triano stated, "The potential value of such a work effort can be significant. Not the least of which is a common database of information on a national level, reviewed by *stakeholder representatives* and available generally for members to apply in the context of their local needs." Our emphasis indicates our collective fears. By "stakeholders", on page 10, Triano defined, "the largest group of stakeholders (patients, chiropractors, associations, colleges, policy makers)". We believe that Triano omitted the main "stakeholders" for this CCGPP document: MCOs, Government, and insurance companies, since we note these groups listed on page 25 under "*Intended Audience*".

On page 7, when discussing the CCGPP's data base, Triano stated, "From these, the stakeholders of healthcare may use the database to derive their own guideline recommendations

as may be applicable under varying local circumstances and challenges." Now if there is no reported frequency and duration, as we saw in the Mercy Center Document, then CCGPP will appear innocent when MCOs, insurance companies, and Government entities use their selective database (with only 66 RCTS and 11 Cohorts) to deny chiropractic care.

We have noted that RCTs, with SMT as a treatment, seldom have more than 12 visits (see Table 4, from Oakley et al 2005).⁴¹ There are several different ways to interpret this data:

- 1. using the maximum ranges for 5 studies in our Table 3⁴¹, the average number of SMT visits for the low back RCTs is <u>7.7</u>!! This is how MCOs and insurance companies have and will use the CCGPP's "Selective" Database, i.e., 6-12 visits.
- 2. we note that the patients in these low back RCTs (in our Table 3) are only 44% pain recovered (NRS: 2.0/4.6 = 44%); *NOT symptom free* as often claimed by IMEs, MCO, Governments, and insurance companies. Therefore, if all the studies are included for averaging, an average of 17.5 visits (x = [7.7]100/44) are estimated to be needed to achieve pain free subjects from this "Selective" data.
- 3. if we only use the visits from studies that reported both pain scales and visits, we have 9.9 visits at 44% improved, which provides an average of 22.5 visits (x = [9.9]100/44) estimated to be needed to achieve pain free subjects from this "Selective" data.

Rating and analysis of 25 SMT RCTs for low back pain								
	# Treated	# visits	Pre/post	Treatment	Diversified	General	Rating	
Low Back Pain RCT	patients		VAS/NRS	Done by	used?	SMT ?		
*Glover et al, 1974 ⁴¹	43	1	NR	PT	no	yes	8	
*Godfrey et al, 1984 ⁴²	22,22	1	NR	MD/DC	no	yes	6	
Hadler et al, 1987 ⁴³	26	1	NR	MD	no	yes	6	
*MacDonald et al, 1990 ⁴⁴	49	5	NR	DO	no	yes	8	
Mathews et al, 1987 ⁴⁵	165	<10	NR	PT	no	yes	8	
*Bronfort et al, 1996 ⁴⁶	71,51	10	5.4 / 3.7	DC	yes	no	10	
Burton et al, 2000 ⁴⁷	20	6-18	NR	DO	no	yes	6	
*Coxhead et al, 1981 ⁴⁸	8G of 16	5-10	NR	PT	no	yes	6	
Herzog et al, 1991 ⁴⁹	16	10	3.2 / 1.8**	DC	no	yes	8	
Pope et al, 1994 ⁵⁰	69	9	2.4 change	DC	no	yes	10	
Triano et al, 1995 ⁵¹	47	12	3.8 / 1.3	DC	no	yes	10	
*Anderson et al, 1999 ⁵²	83	12	4.9 / 3.2	DO	no	yes	10	
Cherkin et al, 1998 ⁵³	133	6.9	5.5 / 2.0	DC	no	yes	10	
Doran et al, 1975 ⁵⁴	116	6	NR	MD	no	yes	8	
Evans et al, 1978 ⁵⁵	15,17	9	NR	MD	no	yes	6	
Giles et al, 1999 ⁵⁶	23	6	5.0 / 2.5	DC	NR	NR	8	
Hoehler et al, 1981 ⁵⁷	56	2-8	NR	MD	no	yes	8	
Hsieh et al, 2002 ⁵⁸	49	9	NR	DC	yes	No	8	
*Hurwitz et al, 2002 ⁵⁹	171	NR	4.7 /2.5**	DC	NR	yes	10	
Meade et al, 1990 ⁶⁰	384	9	NR	DC	NR	?	8	
Postacchini et al, 1988 ⁶¹	87	16-22	NR	DC	no	yes	8	
Skargren et al, 1997 ⁶²	138	7	NR	DC	NR	NR	8	
*Wreje et al, 1992 ⁶³	18	1	4.0 / 4.0	MD	no	yes	8	
Williams et al, 2003 ³⁷	72	3	NR	DO	no	yes	8	
Licciardone et al, 2003 ³⁸	91	7	NR	DO	no	yes	8	
Totals (visits, Pain,		193/25	Mean				202	
Rating) Average		= 7.7	4.6 / 2.6					

Table 3

(Table 4 from Oakley et al. J Canadian Chirop Assoc 2005)⁴¹

Thus, eliminating Level 2, 2/3 of Level 3, and all Level 4 evidence (really, we observed that on page 36, CCGPP eliminated all Level 2, Level 3, & Level 4 evidence), while allowing only "66 RCTs and 11 Cohorts", the "Team Members" of CCGPP's Low Back Pain "Best Practices" have eliminated most of the evidence in the Chiropractic literature (Case Studies with visit regimes of 20 or more). This selective literature database will allow MCOs, Governments, and insurance companies to devise their own Guidelines that will restrict chiropractic utilization.

We strongly believe that they (CCGPP Committee) have omitted the "Frequency & Duration" on purpose because they know how mad every DC would be if they saw it! Additionally, if CCGPP had a schedule of visits (frequency & duration), we could critique it, but if they leave it to MCOs, IMEs, Governments, and insurance companies to derive Guidelines from CCGPP's "Selective database", then <u>it will be extremely difficult and almost impossible</u> (with an intensive amount of time, effort, and money) <u>to critique, revise, and alter each</u> restrictive guideline from these various groups, one at a time!

On their web site, CCGPP sated that their "guidelines" will be available through the Official Disability Guidelines web site. This web site also has connections to ACOEM.<u>www.disabilitydurations.com</u>

Thus, we believe that the CCGPP guidelines will result in an average of 6 visits for low back pain unless there is "Severe LBP" = 7,8, or 9 on the NRS scale. This belief comes from, NOT the CCGHPP "Data base", but from the Frequency and Duration already existing on the *Official Disability Guidelines* 11^{th} edition web site:

"Chiropractic Guidelines:

Therapeutic care --Mild: 6 visits over 2 weeks Severe: Trial of 6 visits over 2 weeks Severe: With evidence of objective functional improvement, total of up to 18 visits (12 additional) over 6-8 weeks, avoid chronicity of care Elective care -- As needed"

Thus, we believe that 6-12 visits will be a Mercy Center thing of the past; the new CCGPP "Guidelines" will result in only 6 visits unless there is pain rated at NRS = 7.8, or 9, which seldom occurs.

6. Inadequate Review of Natural History of LBP

While it is refreshing that page 14 presents what CCGPP thinks is the "Real" Natural History of low back pain, this page 14 still references the flawed study by Dixon.⁴² This would lead the reader to the conclusion that there is a dichotomy in the evidence on "Natural History" of low back pain, but there is NOT. Since 1980, the1973 study by Dixon has been inappropriately used to cut legitimate chiropractic low back claims by Chiropractic IMEs, MCOs, Governments (State), and insurance companies. The Dixon study is FLAWED. Dixon³⁵ claimed a "90% recovery" of acute LBP. Problematically, Dixon⁴² used a retrospective review of one doctor's records to label patients, who did not return for care, as being "*symptom free*".⁴² This is obviously an unjustified assumption since only subjects, *who show up for follow-up evaluation*, are to be included in statistics for a study.

While Triano et al (CCGPP pages 14-15) present some literature to suggest 31%-40% of low back pain suffers continue to have pain months later, their review is inadequate, as the percentage is a lot higher. In fact, besides no evidence supporting the claim that 80–90% of LBP patients become pain free within one month,⁴³ a minimum of 75% of patients with acute uncomplicated LBP will continue to have problems. At 3 and 12 months follow up, only 39/188 (21%) and 42/170 (25%) respectively will be recovered.⁴⁴ The same general trend, that neck pain does not improve on its' own, can be found for population based prevalence studies on chronic neck pain.⁴⁵⁻⁴⁷

We are suspicious of the CCGPP review on pages 14-15 because MCOs, State Governments, IMEs, and insurance companies will be receiving this document. It is clear that CCGPP does not report the "actual" Natural History of LBP. They added another separate discussion of this topic on pages 72-73.

7. <u>Use of Medical Studies Applied to Chiropractic Care</u>

It is of fundamental concern that the "Introduction" by Triano (pages 1-23) cites a plethora of "Medical studies" and few chiropractic studies. It should be obvious that medical studies (treatments with chemistry [= pharmacology] & surgery) do not fit chiropractic practice (treatment is mainly physical forces applied to spines). Of 58 references on pages 20-23, Triano cites 3 chiropractic references, of which 2 are his own. If there are no chiropractic references, then there is neither data nor conclusions to apply to chiropractic care. The fundamental differences in treatment between medical and chiropractic care imply a fundament difference in outcomes. It is irritating that Triano thinks we will not notice that he has applied Medical study results and conclusions to Chiropractic situations. The only Medical studies that might apply in certain Chiropractic care situations, with reservations, are physical medicine studies and exercise studies. Since they used medical references to establish their agenda, we will use them to report the glaring Flaws in their whole process.

8. <u>Objectives of CCGPP</u>

On page 25, the Scope, Objectives, and Intended Audience of this CCGPP low back "Database" are presented. Specifically, we note that "Types of evidence ultimately to be rated include: Guidelines, meta-analyses, systematic reviews, randomized controlled trials, cohort studies, case series." This is exactly our fears from Triano's Introduction (pages 1-23). We note that, in the past, contrary to Sackett's suggestion of including all levels of evidence, all of "Guidelines, meta-analyses, systematic reviews" utilize only RCTs as evidence.

Additionally, CCGPP has eliminated Level 2 evidence (Non-randomized Control Trials = NCTs). They claim that they are going to include "cohort studies, case series", which are actually Level 4 when control groups are not specified. However, we believe CCGPP meant Cohort-Control and Case Series-Control, which are Level 3 evidence. If so, then CCGPP has omitted NCTs and Level 4 evidence which is all observational studies without control groups (cohort studies without controls, case series without controls, and case studies without controls), while choosing to include only 2/3 of Level 3 evidence (Cohort-control and Case series-control are included, but Case Study-control is omitted). Actually 1/3 of Level 3 since they omitted Case Series later on.

This was one of our major concerns previously stated, CCGPP has eliminated 90% of chiropractic evidence by eliminating all case studies.

Additionally, we note, after reading through page 140, that CCGPP did <u>NOT</u> include any case series-control studies and only 11 Cohort-control studies (see page 44), but they <u>did not</u> <u>specifically list the actual 11 Cohort studies that they included?</u>?

We demand to know why NCTs, Case Study-Control, and all Level 4 evidence have been omitted by CCGPP? What is their motive if not a "selected" database for 3rd party payers to reduce Chiropractic utilization? <u>The entire Chiropractic Profession should demand that</u> <u>CCGPP add all these studies (all Levels of Evidence) to the evidence base!</u>

9. <u>CCGPP's Intended Audience</u>

On page 25, CCGPP listed 7 members of their intended audience, of which 4 are chiropractic groups and one is patients. However, what are "Third-party payers and Government agencies" doing here? Best Practices and Evidence-Based Practices (Guidelines) are to help the

healthcare provider give the best possible care to the patient, not for 3rd-party payers and Government agencies to restrict care.

However, we now see that CCGPP has an additional motive, to provide their IME committee members with a "selective database" that may be given to their "Third-party payers and Government agencies" for which they have worked and/or consulted or still do.

10. Limited "Practices and Interventions considered"

On page 25, CCGPP lists "Therapeutic" "Practices and Interventions", as

- 1. "Assurance and advice
- 2. Bed rest
- 3. High velocity, low amplitude manipulation, mobilization and massage
- 4. Exercise
- 5. Selected modalities
- 6. Medical / surgical referral"

Firstly, we wonder what items #1, #2,and #6 are doing in this list? Secondly, since the ICA is composed of members, who practice a wide variety of different Chiropractic Techniques with different force applications, this list is totally inadequate. How are the light forces in DNFT, NUCCA, Grostic, Atlas Orthogonal, etc covered by this list? How is the use of a Drop Table (Thompson, Pierce-Stilwagon, Stucky Integrated Methods, Leander, & CBP) considered in this list? Where would the head weighting and body weighting in Pettibon and CBP be included? Where is the Cox flexion-distraction technique included? When not explicitly provided for in this list, will any different forces applied in various Chiropractic Techniques be labeled "experimental" and not covered by MCOs, 3rd-party payers, and Government agencies (see Aetna, ASHN, and ACN denial letters to prospective Chiropractic providers)?

11. <u>Methods used to select/collect evidence</u>

On page 26, we find, "Selection: Topics were selected based on the most common disorders seen, and most common classifications of treatments used by chiropractors based on the literature." This is exactly what makes practicing chiropractors upset. Since chiropractic is in its early stages of literature, because we believe its does not have the millions of \$ from NIH and drug companies to fund research, chiropractic's few RCTs cover pain only. However, practicing chiropractors are faced with medical failure patients, who desperately need help from some where. By eliminating all Case Studies, these patients, with a variety of diseases and structural abnormalities, will not be included in chiropractic coverages by 3rd party payers, but more importantly, their chiropractor may face a State/Provincial Board which will threaten his/her license for attempting to adjust their subluxations.

A better way of approaching this problem would be, instead of restricting CCGPP's "evidence" to low back pain and leg pain, CCGPP should have looked at the anatomical locations of nerve supply from the lumbar and lumbo-sacral plexus (trauma to, pathologies of, and diseases of). When the normal nerve supply from the lumbar plexus and lumbo-sacral plexus is altered, there may be pathological or disease processes in various stages of development, including, but not restricted to, diseases of the following anatomical structures:

- 1. Skin over the abdomen
- 2. Skin over the low back
- 3. Skin over the buttocks
- 4. Skin between the legs
- 5. Skin over the legs
- 6. Muscles of the abdomen
- 7. Muscles of the low back
- 8. Leg & pelvic muscles

- 9 Abdominal organs
- 10. Pelvic organs
- 11. Low back and leg blood supply
- 12. Ligaments of the spine, SI joints, and legs
- 13. Discs of the low back
- 14. Bones of the lumbar spine, pelvis, and legs
- 15. Nerves originating from all lumbar/sacral levels

Why has the CCGPP restricted chiropractic care to low back and leg pain, when the above lists includes syndromes, diseases and pathologies affecting chiropractic patients? We believe that the answer comes from combining the Financial Conflicts of Interest, with the Elimination of many Types of Evidence, with what MCOs, insurance companies, and Governments who would like to restrict (not pay for) chiropractic services.

The sad thing is that, from these CCGPP "Best Practices", there will be disseminated "evidence" to State/Provincial Boards in an effort to restrict chiropractic care to Back Pain and Leg pain only, even if the DCs have cash practices.

12. CCGPP's Primary Conclusions (Treatments) Do Not Utilized their own Rating

On pages 27-30, CCGPP presents their "Primary Conclusions: Summary of Conclusions and Strength of evidence rating" for "treatment". However, we note that they did not even use their own contrived "evidence rating" methods on pages 12 and 13. In fact, their rating scale for "treatment" is "A, AB, B, BC, C", while their "diagnostic tests" rating scale is "A, B, C, D".

We note that no AB or BC rating was given on pages 27-30, but a rating of "D" was given to "modalities" on page 29 for "Sciatica/radicular/radiating pain" and "D" was given to "Computerized ROM" on page 30 for "Diagnostic".

Thus, it might appear to those not familiar with (1) levels of Evidence and (2) Rating of Evidence that CCGPP "Team Members" have used "Diagnostic ratings" for both Clinical "Treatments" and for "Diagnostics". However, while ignoring their own "Rating Methods" on pages 12 & 13, we noticed that they appear (out of the blue!) to be using a "Rating Method" suggested by Sackett <u>WITHOUT REFERENCING SACKETT AND TELLING US</u>. For examples of how they have confused the reader and evidently themselves, we noticed that <u>CCGPP has multiple ratings scales</u>, (one might ask which are they using?):

- 1) page 12, "evidence rating: A, AB, B, BC, C "
- 2) page 13, "diagnostic tests: A,B,C,D"
- 3) page 19: if there is no evidence: "in recommendations for provider considerations when guidance is absent"
- pages 27-30: have "Primary Conclusions: Summary of conclusions and strength of evidence ratings with page numbers for references": using A, B, C, D for Clinical Treatment & Diagnostics
- 5) page 39-41: "Definitions for evidence rating" using a different A, B, C, D (From Sackett ???)

CCGPP's entire methodology for rating low back pain and leg pain is flawed, they have confused their own references and ratings, and they cannot be corrected by just switching "A, AB, B, BC, C" for "A,B,C,D" (4 categories for diagnosis do not transfer to 5 categories of treatment). Since they started out using the wrong categories (Diagnostic ratings) for clinical treatments, they must start entirely over from the beginning.

13. <u>CCPP's X-ray Utilization Rating is Flawed</u>

On page 30, CCGPP Team members rated "Full spine plain film X-ray", "Plain film X-ray", and "Videofluoroscopy" as "Not supported for routine screening or diagnosis of

pathological conditions", "Not supported for initial screening of uncomplicated low back pain", and "Not supported", respectively (Rated "D" = Expert Opinion).

For "evidence" on "Plain Film Radiography" on page 68, CCGPP uses (1) "The Mercy document" from 1993. <u>Has nothing been published on "Plain Film radiography" since</u> **1993??** The second source that CCGPP uses for "evidence" for "Plain Film Radiography" is Beachley 2002 and CCGPP claims this is from the American College of Radiology (ACR) guidelines. We went to the ACR web site and discovered something quite different (see Section **#24** below).

This CCGPP X-ray determination is the perfect example of an agenda being perpetuated against the practicing chiropractors of the USA and Canada. Chiropractors have X-ray privileges mandated by State Laws and Provincial Laws in the USA and Canada. By making these unsupported "Expert Opinion" claims about X-ray usage, these "Team Members" are showing their bias for MCOs, insurance companies, and Government agencies, who do not wish to pay for Chiropractic examinations and X-rays. Chiropractors do NOT want 3rd parties dictating when and where X-ray may be used; it is up to the individual DC to determine on individual patients.

However, the most obvious indication of an agenda by CCGPP to limit Chiropractors' usage of X-ray comes from CCGPP's blatant "selected" literature review.

We performed a quick superficial search of the literature and found the following ratings for Table 4. Not only did we utilize CCGPP's restricted evidences of Guidelines, systematic reviews, RCTS & Cohort studies, but we utilized a few Chiropractic NCTs and level 3 & 4 evidence (Cohort studies, Case Series, and Case Studies with & without controls) in Table 4.

However, we found so many "Diagnostic Plain film X-ray" publications that we had to limit our references to <u>only</u> the low back region for references 48-204. We will have separate Tables for "Diagnostic Plain film X-ray" publications in the thoracic and cervical regions when the CCGPP comes out with their "Database" for those regions. By looking at the data in Table 4 (References 48-204), the reader can observe that the CCGPP "Team" has an agenda, which excludes hundreds of references on routine X-ray usage in clinical practice. We note that they rate Full spine views "supported in scoliosis evaluation" (without a letter "A, B, C, or D"), but how can one tell if a thoraco-lumbar scoliosis of 10° or more exists without a screening x-ray?

How is it possible that "experts" at retrieving references by "hand searches of published literature (Primary Sources, Searches of Electronic Databases)" (CCGPP page 26) could only find a meager few of the 157 references that we just found on X-ray? We believe that it is not possible that CCGPP "Team Members" missed this many references on X-ray without it being on purpose. They excluded most all these X-ray references (48-204) in order that their "opinions" about X-ray usage in clinical practice stand alone as "evidence".

On page 70, CCGPP uses a reference to "Spitzer, LeBlanc et al. **1987**" to claim that "There is insufficient evidence of clinical utility in diagnosing spinal pain syndromes in routine practice settings at this time". <u>We believe you in 1987 that might have been true, but NOT</u> now in 2006!¹⁶⁴⁻²⁰⁴

From our Table 4 above, while CCGPP rated X-ray use as Not supported for routine screening with "D" = "Expert Opinion", the reader will note that we found enough evidence in the CCGPP's own restricted (unreferenced) categories to rate routine screening of plain films as "**B: supported for routine screening**". However, we did not include very many Chiropractic Case Studies, which CCGPP purposefully eliminated from their ratings of evidence. Notice that we have a different decision (routine use vs <u>NO</u> routine use) and a different rating ("B" vs "D").

Торіс	Rating from Relevant studies	References
Full spine plain film X-ray	B : Routine Screening & Diagnosis; Supported by good evidence from relevant studies for routine screening (Guidelines, Reliability, Validity, NRCTs, Cohort Studies, Case Series)	48-80
Plain film X-ray	B: Routine Screening & Diagnosis; Supported by good evidence from relevant studies for routine screening (Guidelines, Reliability, Validity, NRCTs, Cohort Studies, Case Series)	81-163
Videofluoroscopy	B : Routine Screening & Diagnosis in trauma cases; Supported by good evidence from relevant studies (Guidelines, Reliability, Validity, NRCTs, Cohort Studies, Case Series)	164-204

Table 4
Proper "Diagnostic" Rating of X-ray Clinical Utilization from
Searching PubMed, Mantis, CINAHL

How can they possibly convince us that "Expert Opinion" (lowest level allowed as evidence by CCGPP) is acceptable evidence while Case Studies are not acceptable evidence? How can CCGPP have "consensus on topics with out evidence" as acceptable, when Case Studies have been eliminated from evidence?

Thus, any topic (treatment or diagnosis) could be/is severely restricted in any Chiropractic "Guideline", "Best Practices", or "Database" when Case Studies are eliminated as possible evidence.

<u>The evidence demands</u> that (1) <u>CCGPP change its Diagnostic rating of x-ray to "B:</u> <u>Routine screening supported"</u> and again we demand that (2) <u>CCGPP include Case Studies as</u> <u>evidence</u>.

14. <u>Radiography Discussion on Pages 78-79 is Inept</u>

On page 78 continuing onto the top of page 79, CCGPP makes a mockery of chiropractic clinical results. They listed (1) 3 studies that showed spinal changes (their references 60-62) and 2 studies that did not (their references 63,64) and (2) they stated "again the evidence on reliability is scant to absent (51,65,66)".

Firstly for item (1), this is exactly, what we, as practicing chiropractors, are complaining about when Case Studies are eliminated from the evidence. There are hundreds of references of the Case Study Level 4 type that show spinal change.¹⁰³ In fact, the authors of this ICA's Critique were also some of the authors on the new ICA PCCRP Guidelines¹⁰³ and we had no trouble identifying more than 100 chiropractic case studies, most of which reported spinal changes. However, we believe CCGPP purposely left out recent studies by CBP, which did report spinal changes.¹⁰⁴⁻¹⁰⁵

Secondly for item (2), <u>we are outraged at CCGPP's contempt for the literature</u> on reliability and validity of radiographic analysis. In the new ICA's PCCRP Guidelines, <u>151</u> <u>references on x-ray line drawing reliability and validity are referenced</u>. We referenced some of these in this diocument.⁸¹⁻¹⁰²

It is obvious that CCGPP's "Team Members" did <u>NOT</u> perform a review of the literature on x-ray reliability and validity. One might ask why? We have our own opinion: They have an agenda to perpetuate on the chiropractic profession for their 3^{rd} party affiliates.

15. <u>CCGPP's Statement about "Leg Length Inequality" is Absurd</u>

On page 78, CCGPP makes a statement about "leg Length Inequality": "Finally, the procedure [radiographic measurements] has not been studied as to its validity, making the use of this as an outcome questionable (59)." Interestingly, their reference #59 is a 1<u>985</u> review in JMPT by Lawrence. <u>Has any thing been published on Leg Length Inequality (LLI) since 1985??</u>

In fact there sure has been. We performed a quick PubMed search on LLI and reference some of these here.²⁰⁵⁻²³⁶ LLI has been related to LBP and radiographic evaluation has been shown to be the most accurate method to evaluate it²⁰⁵⁻²²⁰. Correction of LLI has shown symptomatic improvement.²²¹⁻²³⁶ Prevention of future lumbar degeneration and stress fractures has also been noted as benefit.²³³⁻²³⁴ A high compliance has been shown with the use of heel lifts²²⁹ In 2005, Knudson²³⁶ reported that an estimated 90% of the population has a LLI of 5mm or more.

From our review on LLI, we can determine two things: (1) CCGPP "Team Members" did not do a med-line on LLI, and (2) routine radiographic screening for LLI is supported by the literature.

16. <u>CCGPP "Team Leads" Have Potential Financial Conflicts of Interest</u>

In Item/Flaw #1 above, we pointed out that several "Team Members" of the CCGPP Low Back document have potential financial conflicts of interest. Now on page 34, we observe a table of "Team Leads". At least 3 of these "Team Leads" have potential financial conflicts of interest. No "Team lead" of a Guideline, Best Practices, or Database for Guidelines should have worked for in the past or still work for a 3rd party payer.

It is bad enough to <u>invalidate</u> any Guideline, Bests Practices or Database for a Guideline when committee members have potential financial conflicts of interest, but "Team lead" is going way past what the chiropractic profession can tolerate. Triano, Murphy, and Perle must resign and this document must start over with persons who qualify as "a credible and acceptable source".⁵

We demand that the other "Team Leads" fill out the Table 5 below and be disqualified if they answer yes to any of Columns 2-5:

Potential Conflicts of Interest by CCGPP "Team Leads"								
	Have you	Do you	Do you work	Are you	If yes in	What is your		
	ever worked	work for a	for a hospital	NOW a	columns 2-5,	income/ year		
Last	for an Ins.	State or	administration?	consultant to	then list	for your		
Name	Co. as an	Federal		any 3 rd party	which	IME/consulting		
	IME?	agency?		payer?	organization?	work?		
Triano	yes							
Meeker								
Murphy	yes							
Cates								
Souza								
Perle	yes							
Lawson								
Hawk								

Table 5

17. CCGPP only Reviewed 13 guidelines, 14 systematic reviews, 66 RCTs, 11 Cohorts.

Is it 70 RCTs or 66 RCTs (see page 44 and page 26)? Make up your mind. On page 26 the CCGPP authors impress us with the identification of 887 source documents. On page 36, they claim to rate "a total of 14 guidelines, 70 RCTs and 13 systematic reviews/meta analyses and 11 cohort studies' (only 108/887 = 12.2% of evidence is accepted & rated?). However, on page 26,

under "Number of source documents", we are dismayed that they then state, "Conclusions were drawn from 70 RCT's 12 guidelines and 14 systematic reviews."

How could cohort studies or case series (listed in their "Evidence Ratings" on page 12) not play a role in producing conclusions?

Now we finally observe that they have eliminated <u>ALL</u> level 2, Level 3, and Level 4 evidence and <u>ONLY</u> RCTs are considered!

On Page 31 they state, "the diversity of professional practice makes the review of all related literature to conclude evidence on Best Practices an *impossible* [emphasis ours] task. If this task is "impossible", then do not pretend it was performed in this glorified systematic review of RCT's on SMT for LBP. And do not interchange "low back pain and low back related leg pain (symptoms)" on page 25 with "low back and related disorders" (page 31).

18. CCGPP Should Not Have Been Released Until All Ratings Are Completed

Finally on page 36, the authors discuss their disregard for "Case Series" in this 1st review draft ("iteration"). They state, "Based upon the CCGPP formation of an iterative process and the volume of work available, the team elected to limit consideration in this first iteration to guidelines, systematic reviews, meta analyses, randomized controlled trials (RCT's) and cohort studies."

Don't make excuses for releasing this document early for your 3^{rd} party interests. If you cannot rate all the evidence (CCGPP admits to not rating Case Series), then your document cannot be released until all evidence is rated. Again, we state that <u>ALL</u> evidence must mean <u>ALL</u> Levels 1-4 evidence, i.e. add in all NRCTs and observational studies into your "database".

19. CCGPP Did Not Provide Included or Excluded Studies, Nor How Each Was Rated

On page 71, we note a Table of the number of studies reported and rated, but we do not know which these are in the CCGPP reference list. We are not provided with the rating of each publication. Now we note that their "evidence" has been reduced to 64 RCTs (add up row #1: 17+7+32+6+2), i.e., 887 identified publications has been reduced to 64 RCTs + 6 Case Series (2 were rated low) + 11 Case-control/cohorts = 81 or <u>9% of the evidence is considered</u>. Whenever, 9% of the evidence is considered, one wonders, what a different 9% might yield?

Additionally, we note at the bottom of the table that "Number of case-control/cohort studies" is 12 and 1 is rated "-", but we are not informed which publications in their references these might be.

No one can dispute CCGPP's rating of "their evidence" because they (1) do not report the rating of individual studies, nor do they (2) tell us which studies were excluded and which were included. CCGPP only provides lists of references in different categories:

- 1. Team Doc Body ref list pages 80-94, references 1-164
- 2. Team Doc Review List 1, pages 94-95, 16 references
- 3. Team Doc-Review List 2, pages 95-99, 39 References
- 4. Back School, pages 99-103, 44 references
- 5. References to other published versions of this review, pages 103-104, 1 reference
- 6. Behavioral Therapy, pages 104-107, 28 references
- 7. Additional References, pages 107-117, 110 references

When rating Systematic Reviews, Meta Analyses, Guidelines, and RCTs (and any other evidence), there must be a reference list of:

- 1. all References located and how these were located,
- 2. all References/studies accepted
- 3. all References/studies rejected

4. rating of each Reference/study accepted.

No one can tell what CCGPP did for Treatments because there are no items #1-#4 above found for each **<u>Treatment</u>** topic of:

- A. Spinal adjustment and manipulation
 - 1. all References located,
 - 2. all References/studies accepted
 - 3. all References/studies rejected
 - 4. rating of each Reference/study accepted
- B. Exercises
 - 1. all References located,
 - 2. all References/studies accepted
 - 3. all References/studies rejected
 - 4. rating of each Reference/study accepted
- C. Traction
 - 1. all References located,
 - 2. all References/studies accepted
 - 3. all References/studies rejected
 - 4. rating of each Reference/study accepted
- D. Massage
 - 1. all References located,
 - 2. all References/studies accepted
 - 3. all References/studies rejected
 - 4. rating of each Reference/study accepted
- E. Bed Rest
 - 1. all References located,
 - 2. all References/studies accepted
 - 3. all References/studies rejected
 - 4. rating of each Reference/study accepted
- F. Lumbar supports
 - 1. all References located,
 - 2. all References/studies accepted
 - 3. all References/studies rejected
 - 4. rating of each Reference/study accepted
- G. Back school
 - 1. all References located,
 - 2. all References/studies accepted
 - 3. all References/studies rejected
 - 4. rating of each Reference/study accepted.

No one can tell what CCGPP did for Diagnostics because there are no items #1-#4 above found for each **Diagnostic** topic of:

- A. Patient History
- B. Manual exams
- C. Physical exams
- D. Laboratory
- E. Computerized ROM
- F. Full spine plain film x-ray
- G. Plain film x-ray
- H. Specialized imaging
- I. Spinal Ultrasound
- J. Surface EMG

K. Videofluoroscopy

We can only surmise that CCGPP "Team Members" believe that we, as a profession, are so ignorant of proper evidence gathering, rating, and reporting that we will not be able to decipher that they have broken most all protocols for developing a proper "Guidelines"/ "Best Practices"/ "Rating of the Evidence"/ "database".

20. <u>CCGPP Rated "Surface EMG" Incorrectly</u>

On page 30 for rating of "Diagnostics", the CCGPP Low Back "Team" rated "Surface EMG" as "<u>B</u>: Not supported by fair evidence from relevant studies". Recall that a "Rating" can be either bad or good, i.e., in this case, CCGPP claims there are (from page 40) supporting evidence consisting of "several RCTs" with "differing results although overall the results support the conclusion".

The most glaring deficiency is that on page 70, CCGPP admits that the "evidence" for SEMG comes from the 1993 Mercy Center document and from a 1994 study by HendersonD, Chapman-Smith D, et al. <u>We ask are there no publications on SEMG since 1994!</u>

It is known that if Surface EMG methods include "Normalization", then the results are reliable and valid.²³⁷⁻²⁴³ If one goes to the references of these 7 studies with Surface EMG, one will get a plethora of additional references. The reader will note that one of these "Surface EMG" studies is a Meta-Analysis.²⁴³ In this Meta-Analysis, Geisser et al.²⁴³ stated, "the largest effect size was observed for SEMG while standing" and "SEMG measures of flexion-extension appear to distinguish LBP subjects from controls with good accuracy".

The main obvious determination from these 7 references is that "Surface EMG" has a Meta-Analysis and Non-randomized Clinical Control Trial as evidence, in addition to several basic science studies as evidence. Therefore, by CCGPP's own (unreferenced) rating scale (page 39-41), "Surface EMG" must be rated "<u>A</u>: Supported for Routine Clinical use by fair evidence from relevant studies".

The *literature evidence demands* that CCGPP change the rating of "Surface EMG" on page 30.

21. <u>CCGPP Has Incorrectly Rated "Traction" (page 29)</u>

On page 29, CCGPP rated (low back) Traction as "B: Not supported by fair evidence from relevant studies." This is totally inaccurate as DCs know that spine "Traction" is a catch all term. CCGPP needs to separate the "Low Back Traction" into its 3 components:

- 1. Flexion-distraction²⁴⁴⁻²⁴⁷
- 2. Axial/Longitudinal Traction^{CCGPP}
- 3. Extension Traction²⁴⁸⁻²⁵¹

The evidence suggests that "Flexion-distraction" and "Extension Traction" should both be rated " \underline{C} : Routine clinical use supported by NRCTs & Cohort studies", while axial traction is as CCGPP has incorrectly rated all of low back traction.

22. What is "Referral/ comanagement" Doing on Page 29??

On page 29, under "treatment" methods, we find a curious item: "*Referral/ comanagement*". What is this doing here? If practicing DCs do not refer out cases for "Discectomy, Chemonucleolysis, epidural steroid injections, and high severity of symptoms", will we lose our licenses? Will we be guilty of malpractice? Will we be guilty of being below the "Standard of Care"?

In fact, this attempt by CCGPP to "force" DCs to refer to medical doctors is against State Case Law. In 1987, in *Kerkman v. Hintz*, the supreme court of the State of Wisconsin adopted a three-part standard, holding: A chiropractor has a duty to (1) determine whether a 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.* (*Id.* at 421-22, 418 N.W.2d at 803).

Notice that the Wisconsin Supreme Court Judges changed the Lower Court Ruling from "(3) refer the patient to a medical doctor when a medical mode of treatment is indicated" to "(3) to if the ailment presented is outside the scope of chiropractic care, inform the patient that the ailment is not treatable through chiropractic means."

We suggest that ICA, ACA, and WCA contact their Association Attorneys and ask for a "*legal implication*" of this "*Referral/ comanagement*." In the meantime, we demand that this, and all references supporting it, be deleted from a "Database" for "Best Practices" for Chiropractic.

It is inconceivable that CCGPP put this kind of item in a "Best Practices" for our profession while eliminating Case Studies from allowable evidence.

23. Left out Multiple RCTs, NRCTs, Cohorts, Case Series (& Case Studies)

We note that CCGPP claimed to have rated studies up to 2004 (page 65, "Material appearing since 2004 that has been collected but not yet rated", however, they listed a 2002 study by Harrison et al. (Archives of Physical Medicine and Rehabilitation 2002) as "not yet rated"?

We believe that CCGPP's "Team Members" left out, refused to rate, or rejected many Chiropractic studies that do not fit their own restrictive rating scale. This can occur if they have a preconceived agenda that does not include making chiropractic appear in the best possible way, i.e., "Best Practices". We performed a brief review of Chiropractic studies and quickly found studies omitted by CCGPP.

In partial support of our previous statement, CCGPP listed a 2006 study by Santilli et al (page 66), but none of the following could be found in their reference lists?:

Clinical Trials

- 1. Harrison DE, Cailliet R, Betz JW, Harrison DD, Colloca CJ, Haas JW, Janik TJ, Holland B. A **non-randomized clinical control trial** of Harrison mirror image methods for correcting trunk list (lateral translations of the thoracic cage) in patients with chronic low back pain. Eur Spine J. 2005 Mar;14(2):155-62. Epub 2004 Oct 27.
- 2. Shearar KA, Colloca CJ, White HL. A **randomized clinical trial** of manual versus mechanical force manipulation in the treatment of sacroiliac joint syndrome. J Manipulative Physiol Ther. 2005;28(7):493-501.
- 3. Giles LG, Muller R. Chronic spinal pain: a **randomized clinical trial** comparing medication, acupuncture, and spinal manipulation. Spine 2003;28(14):1490-502; (in discussion 1502-3. maximum of 9 weeks treatment, at 2 treatments per week > 6-12 visits as in CCGPP's "Database").
- Keller TS, Colloca CJ. Mechanical force spinal manipulation increases trunk muscle strength assessed by electromyography: a comparative clinical trial. J Manipulative Physiol Ther 2000; 23(9):585-95. (Non-randomized Clinical trial: 20 treatments subjects compared to 2 control groups).
- 5. Plaugher G, Long CR, Alcantara J, Silveus AD, Wood H, Lotun K, Menke JM, Meeker WC, Rowe SH. Practice-based **randomized controlled**-comparison clinical trial of chiropractic adjustments and brief massage treatment at sites of subluxation in subjects with essential hypertension: pilot study. J Manipulative Physiol Ther. 2002;25(4):221-39.

Cohort

6. Frymann V. Relation of disturbances of craniosacral mechanisms to symptomatology of the newborn: **study of 1,250 infants**. J Am Osteopath Assoc June 1966; 65: 1059-1075. (online: J

Amer Osteopathic Institute)

- 7. Cox JM, Shreiner S. Chiropractic manipulation in low back pain and sciatica: statistical data on the diagnosis, treatment and response of **576 consecutive cases**. J Manipulative Physiol Ther. 1984;7(1):1-11.
- 8. Cox JM, Fromelt KA, Shreiner S. Chiropractic statistical survey of **100 consecutive** low back pain patients. J Manipulative Physiol Ther. 1983;6(3):117-28.

Case Series

- 9. Colloca CJ, Polkinghorn BS. Chiropractic management of Ehlers-Danlos syndrome: a report of **two cases**. J Manipulative Physiol Ther 2003; 26(7): 448-59.
- Kirkaldy-Willis WH, Cassidy JD. Spinal manipulation in the treatment of low back pain. Can Fam Phys 1985; 31:535-540. (4 patients given 12-15 visits > 6-12 visits proposed by CCGPP's Database)
- 11. Plaugher G, Cremata EE, Phillips RB. A retrospective **consecutive case** analysis of pretreatment and comparative static radiological parameters following chiropractic adjustments. J Manipulative Physiol Ther. 1990;13(9):498-506.
- 12. Morningstar MW, Woggon D, Lawrence G. Scoliosis treatment using a combination of manipulative and rehabilitative therapy: a retrospective **case series**. BMC Musculoskeletal Med 2004; 5: 32.
- 13. Cox JM, Cox JM 2nd. Chiropractic treatment of lumbar spine synovial cysts: a report of **two cases.** J Manipulative Physiol Ther. 2005;28(2):143-7.
- 14. Harrison DE, Bula J, Harrison DD. Non-operative Correction of flat back syndrome with conservative lumbar extension traction: **Case Series of Three**. J Chiro Ed 2003; 17(1):13-14.

24. <u>Referenced to ACR for X-ray Indications is Inadequate (page 68-69)</u>

There are approximately 30,000 MD Radiologists. They (American College of Radiologists = ACR) have a web site at <u>www.acr.org</u>.²⁵²

CCGPP has misrepresented their "Indications" for spine radiography in children and adults by citing Beachley 2002 instead of the ACR Web site in 2003-2006. It is of interest to list the indications for spine radiographs in children and adults advocated by ACR and compare it to CCGPP's table L5 on their page 69.

ACR²⁵² stated that their "Indications include, but are not limited to:

- A. All anatomic regions
 - 1. Trauma to, or potentially involving, the spine.
 - 2. Pain or limitation of motion.
 - 3. Planned or prior surgery on the spine.
 - 4. Evaluation of suspected primary and secondary malignancy.
 - 5. Arthritis.
 - 6. Suspected congenital anomaly of the spine and syndromes associated with spinal abnormality.
 - 7. Evaluation of spinal abnormality seen on other imaging studies.
 - 8. Follow-up of previous spinal abnormality.
 - 9. Suspected spinal instability.
- B. Cervical spine
 - 1. Shoulder or arm pain suspected to result from radiculopathy.
 - 2. Occipital headache
- C. Thoracic Spine
 - 1. Pain radiating around the chest wall
 - 2. Osteoporosis; compression fractures.
 - 3. Evaluation of scoliosis and kyphosis
- D. Lumbar spine

- 1. Pain radiating into the legs.
- 2. Osteoporosis; compression fractures.
- 3. Evaluation of scoliosis and kyphosis
- 4. In children, limping or refusal to bare weight and in children with hip pain."²⁵²

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

We can only surmise that they did not like the updated ACR Web Site with its extremely reasonable "Indications" for spine radiography in children and adults, and thus, they found a more restrictive reference. The readers of this critique must be getting quite suspicious of CCGPP's motives, as to which fact we the authors of this critique have arrived.

25. <u>Why Cochrane and Bronfort?</u>

It appears that the CCGPP "Team Members" did not do as much work as they claim to have done. In fact, we note that they have used ratings of systematic reviews from Bronfort and from Cochrane. In fact from pages 118 to 131, we observed that they just adopted Cochrane Reviews:

- 1. Appendix 1. Cochrane review of massage therapy, pages 118-119, 9 references
- 2. Appendix 2. Cochrane review of <u>exercises</u>, pages 119- 126, 77 references
- 3. Appendix 3. Cochrane review of <u>Back Schools</u>, pages 127-129, 26 references
- 4. Appendix 4 Cochrane review of <u>Lumbar Supports</u>, pages 129-130, 15 references
- 5. Appendix 5 Cochrane review of <u>Bed Rest, pages</u> 130-131, 13 references

26. <u>CCGPP is under no organization's control, therefore their Financial Conflict of</u> <u>Interest can express itself without censure</u>

Finally, we arrive at the most questionable item, the fact that CCGPP is controlled by no Chiropractic organization. They have some board members from different groups, but not enough to out vote the main players. Since there is no controlling body to make them "toe-the-line" in gathering evidence, including/excluding evidence, rating evidence, and reporting "their" final results as a "selective " database, any potential conflicts of interest can drive their motives.

27. CCGPP Requests that the reader fills out an "Agreement/Disagreement" rating

In a June 5, 2006 letter, COCSA stated that they supported CCGPP and that "State associations need to encourage their members to visit the CCGPP web site (<u>www.ccgpp.org</u>) to review the draft document and provide comments to CCGPP through the online survey." Additionally, State association's "duly elected CCGPP representative" can send an official

response to one of five District Representatives. To help interested parties with the CCGPP survey, we provide ours below. There are 10 statements that the survey requests that one assign their opinion of CCGPP: "(a) strongly agrees, (b) agrees, (c) agrees somewhat, (d) is neutral, (e) disagrees somewhat, (f) disagrees, or (g) strongly disagrees."

Question #	(a)	(b)	(c)	(d)	(e)	(f)	(g)
1							X
2							X
3							X
4							X
5							X
6							X
7							X
8							X
9							X
10							X

 Table 6

 ICA's CCGPP "Agreement/Disagreement" Survey

In addition, COSCA requests:

- 11. Within the scope of this best practice chapter, are there any related disorders/conditions [*seen by DCs*] or diagnostic procedures commonly used by doctors of chiropractic that were not included in this review? If so, what?
- <u>Answer</u>: Yes, multiple conditions seen by DCs were excluded by not including Case Studies in this "Best Practices", which is a selective "Database". The exact conditions and number of conditions excluded can only be determined by including case studies.
- 12. Do you have any other comments/concerns?
- **<u>Answer:</u>** Yes, after reviewing our whole critique above, please throw this CCGPP in the garbage.
- 13. If you rated any of the above statements at a level of disagreement and if you have documentation or evidence in support of that disagreement that you would like to submit for review, please explain and submit your documentation electronically, if possible. Evidence/literature supporting your comments can also be sent to CCGPP, PO BOX 2542, Lexington, SC, 29071.
- <u>Answer:</u> We will do both because you might claim you lost our computer file, so we will send the paper edition as "Return Receipt Requested".

Finally, we believe that history will repeat itself in the future as this CCGPP Selective "Database" is made available to 3rd party payers (IMEs on the committees will make sure), i.e., chiropractic reimbursement will be reduced again.²⁵³ In a survey with 454 ICA members responding in 1996, 63% stated that the Mercy Center Guidelines had been used against them to cut claims.²⁵³

Additionally, we note that Dr. Lewis in one of his annual reports to FCLB stated that CCGPP would be used by State and Provincial Boards to establish "overutilization". Overutilization is an insurance industry term; it is not a clinical practice term. Chiropractic clinical practice is the application of chiropractic to the suffering patients who seek us out; this includes however many visits are needed to help the individual patient. Practicing DCs do not

want to be restricted by evidence from a select few RCTs with SMT treatment performed by European Manual Therapists, MD's, PT's, and DO's.

The *best* "Best Practices" would include all Levels of Evidence in their ratings without eliminating any studies (when "Team Members" are allowed to vote to eliminate evidence, their biases come to the forefront). The epitome of "Best Practices" would show the public, the Government, and 3rd party payers that we chiropractors help patients with a variety of conditions. This can only be shown by including Case Studies as ratable evidence.

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Full Spine Plain Film X-ray

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