

Response to Comments on the “Non-musculoskeletal Conditions” Chapter

We appreciate the thoughtful comments provided by the ACA, ICPA, Alabama and Georgia state associations, and 12 individual chiropractors. Our statements below are made in response not only to these comments, but to the current healthcare environment.

First, we would like to respond to comments questioning the credentials of our team members: All team members have been in private practice for substantial amounts of time (minimum of 12 years for each); this was one of the criteria for their appointment. They also have published, done research, and/or taught and practiced in at least one of the topic areas addressed in the chapter, and focused their literature evaluation on that area. Dr. Hawk has a PhD in preventive medicine and a research focus on nonmusculoskeletal conditions and health promotion. Dr. Ferrance practices pediatrics. Dr. Evans has a PhD and research focus in health promotion. Drs. Killinger and Bougie teach and publish in geriatrics. Dr. Lisi has worked with and published on low back pain in pregnant women.

We will discuss each topic section of the draft chapter separately:

- 1) Chiropractic care for nonmusculoskeletal conditions: in July 2007, some of our team members published a systematic review on this topic in the *Journal of Alternative and Complementary Medicine*, separately from the CCGPP project, in which we included more attention to case reports and did not apply letter “grades” to the evidence. We feel that this article, which was accompanied by an editorial in the journal, provides substantial evidence in building the evidence base for chiropractic care in this area. Since this article is published in a peer-reviewed journal, there is therefore no need to provide an additional document on the topic on the CCGPP website; the JACM has generously allowed us to provide a link on the CCGPP website for interested readers to access the article.
- 2) Health promotion and prevention: We agree that this section should not be termed “wellness.” Because of the very scarce evidence for a health promotion/disease prevention effect of spinal manipulation, we also agree that a published document, such as the CCGPP literature synthesis, is premature. Such evidence is extremely important for the profession to accumulate, but until more progress is made, a literature synthesis only serves to highlight, rather than contribute to resolving, this situation. However, a literature synthesis on every other type of health promotion procedure or practice is beyond the scope and resources of this team. We therefore respectfully recommend that the new FCER project, DC Consult, be considered the best source of this information, since this topic is definitely within its scope, and two of our team members (Drs. Hawk and Evans) have already written articles for DC Consult on prevention topics.
- 3) Pediatrics: We received a number of comments about missing references for this section. This was due to a detail of the CCGPP methodology, which specified that studies considered lower-level evidence were not to be placed in the evidence tables. This was done in order to avoid unwieldy bibliographies. However, we feel that it is important to provide interested stakeholders with the full results of our extensive literature search, and so we will post the complete bibliography for this

section. We have already distributed it individually to anyone who requested it. Additionally, we recommend that:

- a. Due to the scarce literature on musculoskeletal conditions in children, the next iteration of the chapters dealing with musculoskeletal conditions each include a section of how the literature applies to children.
 - b. In order to fill in additional gaps in the literature on chiropractic care for children, we recommend that a formal consensus process be conducted among a group of experts to fill in these gaps. FCER has already appointed such a group, and our team will be represented by Dr. Ferrance. We also have recommended to FCER that Dr. Elise Hewitt of the ACA be invited to join this panel as well.
 - c. The pediatric section of our draft chapter has served its purpose in identifying gaps in the literature, and will be used in the future only as one of the seed documents for the FCER project.
- 4) Geriatrics and pregnant women: We recommend that, as with pediatrics, the chapters addressing musculoskeletal conditions each devote a section to these special populations. We recommend that Drs. Killinger, Bougie and Lisi might serve as consultants on those topics.

We feel that the recommendations above will serve to address the stakeholders' comments and will result in a positive outcome.

Cheryl Hawk, DC, PhD
Team Lead

FINAL DRAFT

“CCGPP Draft Chapter on Chiropractic Management of Prevention and Health Promotion; Non-Musculoskeletal Conditions; and Conditions of the Elderly, Children, and Pregnant Women”

ACA CCGPP Review sub-committee for this chapter:

- Dr. Rick Bruns, Chairman of the ACA Wellness Core Committee
- Dr. Donald Feeney, President, ACA Council on Nutrition
- Dr. Elise Hewitt, President, ACA Council on Chiropractic
- Dr. Ritch Miller, Chairman, ACA Medicare Committee
- Dr. Jon Sunderlage, Member, President, ACA College of Chiropractic Acupuncture
- Dr. Mike Taylor, Chairman, ACA Complimentary and Alternative Health Care Committee, Member, Council on Diagnosis and Internal Disorders
- Dr. David Madison, ACA Board of Governors, District 7

I. CCGPP Chapter Review Question Template - Question 1 through 10

The following is an average of the responses from the committee members: (in caps)

1. The literature synthesis addresses the clinical issues most commonly seen in my practice. –
IS NEUTRAL
2. The literature synthesis provides me with information to form a rational basis for my clinical case management decisions providing testing/treatment options that guide the direction of patient care, to the extent available within the literature. - DISAGREES SOMEWHAT
3. The literature synthesis addresses specific clinical issues that target various patient populations (age, sex, acute, chronic, co-morbidities, etc.) of my practice, to the extent available within the literature. - AGREES SOMEWHAT
4. The literature synthesis appears to have had adequate broad-based chiropractic representation. - AGREES SOMEWHAT
5. The process used to gather and rate the evidence appeared to be thorough and appropriate for the stated objectives. - DISAGREES SOMEWHAT
6. The process used to develop the actual conclusions from the evidence appeared to be appropriate for the stated objectives. - AGREES
7. I find the language and format of the literature synthesis to be clear, easily comprehended, and easy to use. -IS NEUTRAL
8. Given my understanding of the process used, I believe the recommendations are consistent with scientific principles and made independent of any outside influence. - AGREES SOMEWHAT
9. I have confidence that the literature-based recommendations reflect conclusions based on the available evidence, rather than beliefs or opinions of individuals within or outside of the process. - AGREES SOMEWHAT
10. I have confidence that in the absence of adequate evidence, the expert opinion consensus process identified in the literature synthesis was fair and independent. - IS NEUTRAL

II. Comments

On 10-08-07, Dr. Wayne Whalen, Chairman, Council on Chiropractic Guidelines and Practice Parameters (CCGPP), sent a letter to United Health Care addressing their policy regarding treatment of children, and adolescents and for the diagnosis of headaches.

In that letter, the following are several comments that are germane to the discussion of this chapter.

“The Council on Chiropractic Guidelines and Practice Parameters, the principal agency in the United States that evaluates literature of interest to chiropractic practice, reviewed this bulletin and has serious concerns, especially over the potential harm to children as a result of this policy. We are also concerned over the health and welfare of those patients suffering headaches, who as a result of this policy will be denied medically necessary and evidence based chiropractic care.”

“In this bulletin UHC refers to “chiropractic services” presumably and mistakenly equating the licensure of the chiropractic profession with the singular modality/treatment of spinal manipulation. As is known, chiropractic physicians are primary care/portal of entry physicians recognized by statute at both federal and state levels, e.g. Medicare, Medicaid, Department of Defense and Veterans Administration programs, just to name a few. The treatment of special patient populations, e.g. children and adolescents, and specific conditions, e.g. headaches has been established for many years to be well within the scope of a chiropractic practice. Treatment includes not only spinal manipulation, but also active and passive therapeutic modalities, evaluation and management services, instruction on lifestyle modifications, diet and exercise, posture and nutritional advice and other facets of chiropractic practice. Chiropractic is not limited to just spinal manipulation and the UHC bulletin is unclear whether other aspects of a chiropractic clinical encounter are reimbursable.”

“The literature clearly shows that children suffer significant back pain. In fact, in a study of 1,126 children, the prevalence of nonspecific back pain increases dramatically during adolescence from less than 10 percent in the pre-teenage years up to 50 percent in 15- to 16-year-olds. Of 1,122 backpack users, 74.4 percent were classified as having back pain, validated by significantly poorer general health, more limited physical functioning, and more bodily pain. There is widespread concern that heavy backpacks carried by adolescents contribute to the development of back pain.

Other contributing factors to the near epidemic of back pain in adolescents are: sedentary lifestyle, obesity, de-conditioning, excessive sitting, poor diet, etc. These issues not only can all be addressed, but are being routinely addressed with successful therapeutic outcomes, in the normal visit to a chiropractic physician.”

“Given the reality of back pain in children and adolescents, why would UHC restrict access and benefits to the profession best suited to evaluate and treat these conditions? Chiropractic physicians clearly possess more education and clinical skills in the area of musculoskeletal diagnosis and treatment compared to general allopaths and physical therapists. If this policy is permitted, young patients and those suffering headaches will

have nowhere to turn except to general medicine. Will that shift result in dollars saved? The answer is no. A limited or complete loss of chiropractic benefits will result in a shift and increased payment for traditional care with its inherent higher costs for treatment, diagnostics, and risks associated with prescriptions and invasive procedures. Given the fact that our society, especially the young, is already overmedicated, does that policy make good fiscal or epidemiological sense? In CCGPP's opinion, it does not. We are justifiably concerned that UHC's policy will force unnecessary drugs on headache sufferers and on children who suffer back pain and other conditions commonly treated by chiropractic physicians. The side effects of those drugs can easily be avoided by the use of more conservative chiropractic care."

Dr. Whalen stated very clearly that the practice of chiropractic is "not limited to just spinal manipulation" and includes "active and passive therapeutic modalities, evaluation and management services, instruction on lifestyle modifications, diet and exercise, posture and nutritional advice and other facets of chiropractic practice".

In your discussions of your literature search, you repeatedly indicate that to use the Boolean logic of "chiropractic" and "health promotion" OR "prevention" OR "wellness", AND "pediatric" or "paediatric" or "child" or "infant.", AND "pregnancy;" "manipulation" AND "pregnancy." This would automatically exclude all of the other literature available from other professions and groups regarding management of these conditions by chiropractors within the scope of their chiropractic practice.

The ACA Council on Pediatrics has developed a capsule description regarding their specialty which, in part states: The Pediatric Chiropractor is a chiropractor with specialized, advanced training and certification in the evaluation, care, and management of health and wellness conditions of infancy, childhood, and adolescence. This specialist provides primary, comprehensive, therapeutic, and preventative chiropractic health care for newborns through adolescents. Patients of pediatric chiropractors range in age from moments after birth through age 18. Treatment modalities typically used by the pediatric chiropractor include but are not limited to spinal, cranial and extremity manipulations (also called adjustments), soft tissue manipulation, physiotherapeutic modalities, nutritional supplementation, postural and exercise recommendations, and dietary and lifestyle advice. The purpose of the manipulative treatment modalities is to maintain proper biomechanics in the articulations of the body with the aim of normalizing neurological and physiological function to local and systemic structures related to these articulations. The objectives of the non-manipulative treatment modalities are to enhance the function of the child's biomechanical structures and maximize the child's overall health status and wellbeing. Chiropractic care for children has been shown in the literature to be a safe and effective way to address many common conditions of childhood, including but not limited to infantile colic, nursing dysfunction, torticollis, plagiocephaly, chronic constipation, infantile reflux and gastroesophageal reflux disease (GERD), brachial plexus irritations, sleep disturbances, asymmetrical crawling, otitis media, chronic upper respiratory infections, enuresis, asthma, gait abnormalities, epilepsy, growing pains, pediatric back pain, pediatric neck pain, pediatric headaches, scoliosis, chronic abdominal pain, autism, ADD/ADHD and other conditions on the PDD spectrum, sensory integration disorder, pediatric sports and extremity injuries.

The ACA Council on Diagnosis and Internal Disorders has also developed a capsule description regarding their specialty which, in part, states: The DABCI, or chiropractic internist, may serve as a primary care physician or may see patients referred from other providers for evaluation and co-management. Evaluation is focused on the early detection of functional, nutritional, and pathological disorders. A chiropractic internist utilizes the diagnostic instruments necessary for proper examination. In cases where laboratory examination is necessary, a chiropractic internist utilizes a recognized reference laboratory facility. A chiropractic internist may manage his or her own cases or may refer to another specialist when prudent to do so. The chiropractic internist utilizes documented natural therapies, therapeutic lifestyle changes, patient education, and other resources to promote patient health and avoidance of disease. Patients seen by a chiropractic internist are commonly those suffering from chronic symptoms and/or conditions. The etiology of their symptoms is often multi-faceted, requiring thorough evaluation and management. Management of their cases may be complicated by overall poor health, environmental sensitivities, poor nutrition, unhealthy lifestyle, and/or other factors. Conditions seen by a chiropractic internist include, but are not limited to: migraine headaches, tension headaches, insulin resistance, diabetes, sinusitis, rheumatoid arthritis, fibromyalgia, chronic fatigue syndrome, colitis, IBS, PCOS, PMS, menopausal conditions, eczema and insomnia as well as routine annual exams.

Doctors of Chiropractic function as portal of entry physicians and we treat the same conditions that allopaths do in the primary care setting. We make referrals when appropriate and necessary and otherwise offer alternatives to prescription pharmaceuticals and surgery. Of course we would appropriately refer for these services if they are the best course of action. Therefore, I think there are many more disorders/conditions or diagnostic procedures commonly used by doctors of chiropractic. The WHO has a lengthy list of conditions treated by acupuncture that is also utilized by doctors of chiropractic. Diet, nutrition, weight control, herbals, meditation, exercises, yoga, tai chi, chi gong, exercise therapy, soft tissue techniques, stretching, range of motion techniques, weight training and conditioning, massage, orthotics, tapping techniques, homeopathy, herbals, lifestyle counseling, acupuncture, physiotherapy, and other physical medicine modalities constitutes an incomplete list

It is imperative that some discussion be devoted to the modalities beyond manipulation that are commonly used by doctors of chiropractic, clearly and definitively stating that these modalities were not evaluated in this chapter.

It is unacceptable that this chapter focuses almost exclusively on spinal manipulation as the "Chiropractic management" of these conditions and does not broaden its concepts to include these and other practices that are utilized by the chiropractic profession in the management of our pediatric, pregnant, and elderly patients as well as the non-musculoskeletal conditions that are managed by chiropractors on a routine basis.

III. Recommendations

It is our recommendation that the CCGPP indefinitely postpone the release of this Chapter. We recommend a review utilizing all research of all professions that involve all techniques that could be used by chiropractors across this country. There are many studies on the effectiveness of these

interventions which are chiropractic and always have been. It must accurately reflect ALL evidence-based interventions that chiropractic physicians can provide for the full spectrum of primary care disorders that we routinely treat.

There needs to be a clear statement of what was the specific Chiropractic "scope of practice" that was used by the CCGPP as a basis for the conclusions and recommendations. There are multiple references to it in the document but no clear statement of exactly how it was defined.

Our recommendation is that there be included that the discussion of conditions is not intended as a complete listing of all that is managed with chiropractic care and that there be a disclaimer along the lines of "Exclusion of a condition does not indicate ineffectiveness; rather, exclusion simply indicates that research on an excluded condition had not been performed as of April 2005". It is essential that the chapter clearly and emphatically state that there are many conditions for which there is anecdotal evidence of the effectiveness of chiropractic care that to date lack RCT's and hence were excluded from review in this chapter and that their exclusion does not indicate ineffectiveness.

Additional recommendations for modification are to itemize pediatric musculoskeletal conditions in their own table and to itemize non-MS pediatric conditions in their own table in the pediatric section.

The second paragraph of the cover page states:

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

In Dr. Hawk's teleconference on November 15th, she put forth a slide stating:

"What it ISN'T: a practice guideline or best practice recommendation

- It could serve as a seed document for "best practice" development
- No PRACTICE recommendations were made; only ratings of the EVIDENCE
- Broader base of practitioner experts would be required to make practice recommendations"

Our recommendation would be to combine these but make a very clear and bold printed, bulleted statement that would be simple, easy for all to understand, including the practitioner's and third party payers, and not easy misinterpreted or misused. Such as:

- **This document is solely a survey of existing studies as of 2005 and its only purpose is to provide ratings of the evidence in that literature review.**
- **It is not a practice guideline or best practice recommendation**
- **No part of this document is intended to support any litigation or proceeding involving medical necessity or reimbursement eligibility.**
- **It does not establish a standard of care in specific communities, specific cases, or as to the care of any particular individual or condition. Each case must be determined on the basis of a careful clinical examination and diagnosis of the**

- patient, giving due consideration to the specific condition presented and the individual's informed choice as to care and treatment.
- **No part of this document is intended to support any litigation or proceeding involving the standard of care**

IV. Committee Member Comments

**From: Dr. Jon Sunderlage, DC, Dipl.Ac., L.Ac.,
Member, ACA College of Chiropractic Acupuncture**

"I don't see how this information would give me a rational basis in my practice"

"I don't find the format to be very clear, etc."

**From: Dr. Ritch Miller, DC
Chairman, ACA Medicare Committee**

“From a Medicare/Geriatric standpoint this document is very deficient. I find that the literature search, as I understand it, way too narrow and not inclusive enough. It covers very little of the overall care we provide to patients. My personal opinion is that this is a futile effort due to the fact that so little research has been done on what we experience clinically and practically in our practices every day. Are we to make broad statements and draw broad conclusions from so little literature? As I see it this chapter is at this time useless at best and potentially damaging to the point of devastating. Not because that chiropractic care is deficient and/or ineffective, but because the research just has not been done.

I have a real problem with this and see this as a real obstacle to full inclusion into the Medicare and any national health care system. What am I missing? “

**From: Dr. Donald Feeney, DC, DACBN, CCN
President, ACA Council on Nutrition**

“I reviewed this entire document and even called in opinions of my daughter Dr. Karen Feeney DC. Board Certified Neurologist and a Dr Richard Jaffee MD, PhD Board Certified Internist and Nutritionist. The comments range from Dr Jaffee saying the Internist Organization attempted the same thing 12 years ago and it was the worst fiasco and was used against them by insurance companies to cut payments on services. My daughter (10 years in practice) mentioned several professional sources that were not even included and the search terms were too narrow and the language e.g. “all the available literature” too over the top since many areas she knew were not referenced. I after thirty six years in practice find the work too limited and is and reminiscent of the old “Mercy Document” I think all those doctors should be given the opportunity to view the actual articles that are quoted and stopping the search in 2005 does limit many articles that have been published over the last year and one half. The bottom line with all research is who is funding it and what general good will come of it. “

From: Dr. Mike Taylor, DC, DABCI

**Chairman, ACA Complimentary and Alternative Health Care Committee
Member, Council on Diagnosis and Internal Disorders**

“The Executive Board of the CDID noted DIRE concerns for the entire chapter, just as I did. Both my personal opinion, as well as that of the Council, find the CCGPP's decision to include citations/references from predominately those areas dealing with adjustments/manipulation and wellness counseling most perplexing....

Clearly, chiropractic physicians provide far more services than adjusting the patient's spine and counseling on wellness strategies consistent with content within Healthy People 2010. This narrow focus of reference could have devastating effects on the overall practice of chiropractic primary care.

One needs to look no further than the referenced research found within Pizzorno's naturopathic medicine book or Wright and Gaby's references to see the very broad spectrum of efficacious interventions that DC's can, and are providing within our practices, for a variety of primary care conditions.

The delay of this Chapter, in my opinion, as well as the opinion of the ACA's CDID is absolutely necessary.

Further, we would strongly urge the indefinite postponement of the release of this Chapter until such time as we can "get it right". We only have one shot at this and it must accurately reflect ALL evidence-based interventions that chiropractic physicians can provide for the full spectrum of primary care disorders that we routinely treat.”

**From Dr. Rick Bruns, DC,
Chairman of the ACA Wellness Core Committee**

“The paucity of random controlled trials and overall lack of evidence is an indictment ,not of the chiropractic profession or the techniques that we use to get results, but is instead an indictment of the research community and those who fund research for not doing more to understand the practice of chiropractic in its entirety .Dr. Sackett in his initial discussions of evidence-based medicine pointed out that in the absence of adequate scientific evidence, the outcomes in the clinical setting and clinicians judgment ultimately have sway. A positive outcome in response to intervention is the litmus by which all care patterns should be judged. Unfortunately, third-party payers, and even some government agencies would like to misuse evidence-based medicine and science. Therefore we must rigorously defend what attains positive outcomes in the clinical setting, while passing on scientific evidence for consideration by all clinicians. “

“Responding to question 11 on the instructions for review page it is my education, experience, and belief that we function as portal of entry physicians and we treat the same conditions that allopaths do in the primary care setting. We make referrals when appropriate and necessary and otherwise offer alternatives to prescription pharmaceuticals and surgery. Of course we would appropriately refer for these services if they are the best course of action. Therefore, I think there are many more disorders/conditions or diagnostic procedures commonly used by doctors of chiropractic. The WHO has a lengthy list of conditions treated by acupuncture that is also utilized by doctors of chiropractic. Diet, nutrition, weight control, herbals, meditation, exercises,

yoga, tai chi, chi gong, exercise therapy, soft tissue techniques, stretching, range of motion techniques, weight training and conditioning, massage, orthotics, tapping techniques, homeopathy, herbals, lifestyle counseling, acupuncture, physiotherapy, and other physical medicine modalities constitutes an incomplete list. “

“not enough research has been done to adequately address anything”

“too few studies to be of clinical significance increased research is necessary”

“In the brief time that I have been able to search the Internet on these topics there appears to be quite a wealth of information from other professions. i.e., Psychiatry, physical therapy, osteopathic, massage therapy, nursing etc. all of whom are now using manual techniques pioneered in the chiropractic profession and have been given vast sums of money to research themselves. May be a different query of the Internet or examining treatment protocol in total, not in parts would be more effective”

“Unfortunately the format and language are easily misused and misunderstood in the real world. Use other than for guidance to the clinician is inappropriate but will ultimately happen in our current less than scientific reimbursement atmosphere”

“I believe there is too little evidence to draw any conclusions, and that this only points out the need for further research done by chiropractic researchers, who have clinical experience with these conditions. I also believe that the recommendations that they state are not specific to chiropractic, although have in fact been part of the chiropractic model since its inception, long before it became fashionable in other professions the chiropractic profession lead the way in the use of diet exercise counseling, etc. “

“Within the scope of this literature synthesis chapter, are there any related disorders/conditions or diagnostic procedures commonly used by doctors of chiropractic that were not included in this review? If so, what? Diet counseling, weight control nutrition herbals, homeopathy exercise therapy soft tissue techniques stretching range of motion techniques yoga meditation weight training and conditioning lifestyle counseling acupuncture physiotherapy modalities”

“Often times, science lags behind clinical experience, one need only to look at recent events such as the removal of Vioxx from the medical regimen. Even though the pharmaceutical company had put it through the rigors of the FDA approval and many studies. It was proven to be dangerous at the clinical level .recently there has been a mass removal of over-the-counter cough medicines for children that for decades have been perceived to be safe and effective and studied at length. The science lagged. If I am to take one thing away from this exercise, I believe the science here is lagging that there is high patient satisfaction and positive outcomes from chiropractic intervention. In these conditions are being seen regularly in chiropractic offices, often after all other interventions from other providers have failed or patients have become disillusioned with the pharmaceutical approach or surgical approach .chiropractic has high marks in patient satisfaction. And this is a direct result of positive outcomes of care in an atmosphere where her competition and third-party payers are heavily vested in our demise. We must be careful with the scientific community is not used as pawn. Unfortunately, we do not have a perfect process for discovering the truth. Therefore the scientific community should stick to its

scientific principles guarding rigorously against its misuse at the same time that it provides guidance to the practitioner in the field for the benefit of the patient”

“Regarding question 12. My concern overall is with the paucity of information. I was able to do a quick literature search and believe with a different query and more utilization of the research in other professions we may have found more evidence. Unfortunately, in this short length of time it is an exercise in futility. The biggest thing that jumps out at me is how little information is in this document, especially RCT's. It is not an indictment of the CCGPP process or those involved but points out how little research has been done and how few dollars dedicated to the chiropractic profession. “

“I have had less than a week to begin literature search. I was able to pull down articles from massage therapy, PT sites, and osteopathic sites showing the use of manual therapies for these conditions. Many of them are random controlled trials not confined by the definitions of this study, but it was difficult to find time to research the journals they were published in to see if they were peer-reviewed. Certainly, I am not a research person, but as a clinician I can tell you that much of what we do in our practices has not been researched enough. There are biases from the clinical side and from the scientific side. Research dollars need to be made available to chiropractic researchers able to ask the appropriate questions off the research and to realize its limits. Clinicians must likewise discard what does not work and publish the outcomes of what does. From that kind of co- operation we will find a direction for the research and guidance for clinical practice that will first do no harm, and second maximize best outcomes.”

“It is my opinion that very few conclusions can be drawn from the paucity of evidence that currently exists. I would encourage the involvement of all of our councils and teaching institutions to get involved in designing research that would garner meaningful evidence to support what clinicians are doing in practice. We must also realize that often the research lags behind the clinical setting. We need not look far to see that well vetted pharmaceuticals are removed from the market when clinical results do not match the research. Vioxx and cough medicine for children are just a couple recent examples. “

Because of the limitations and deficiencies of this chapter, would you recommend that they postpone releasing it and redo their literature search? What parameters would you suggest for that search?

“Yes. I would recommend a review utilizing all research of all professions that involve all techniques that could be used by chiropractors across this country we are not limited except that we do not to pharmaceuticals or surgery but certainly probable scopes of practice in most states allow us to do everything else and there are many studies on the effectiveness of these interventions which are chiropractic and always have been.”

**From Elise G. Hewitt, DC, CST, DICCP
President, ACA Council on Chiropractic Pediatrics**

- 1) MISSING REFERENCES: A significant number of references were excluded from the chapter. I was able to uncover over 25 missing references related to pediatrics and pregnancy in just a week's time, including at least 7 case series articles that discuss 3 or more cases. In my search, I discovered that one entire issue of the *Journal of Clinical Chiropractic Pediatrics* (the profession's only peer-reviewed journal devoted to pediatric topics) had been omitted (issue 2004;6(2)). This concerns me greatly. With such a paucity of evidence to begin with, I feel that it is imperative that we include all the studies that have been published. Please see **Appendix A** at the end of this document for the list of missing references I uncovered.
- 2) Small error cited reference: #172 Vallone S. Chiropractic evaluation and treatment of musculoskeletal... is listed as volume 5 of Jour Clin Chiro Pediatrics; actually vol. 6(1):349-368.
- 3) EXCLUDED CONDITIONS: A significant number of pediatric conditions commonly seen in chiropractors' offices were excluded from this review. I understand that this is no the fault of the CCGPP process; rather, published studies as yet don't exist for most of these conditions. Still, I think it is important that the chapter clearly state that there are many conditions for which there is anecdotal evidence of the effectiveness of chiropractic care that to date lack RCT's and hence were excluded from review in this chapter; that their exclusion does not indicate ineffectiveness.

Below is a list of conditions commonly seen in the offices of chiropractors who treat children. Starred items (*) were included in the review, double star (**) indicates condition was represented only by narrative review, case reports, etc., so was excluded from formal evaluation; no star indicates condition was not included in review:

- Infantile colic*
- Nursing dysfunction**
- Torticollis
- Plagiocephaly
- Birth trauma/intrauterine constraint
- Chronic constipation**
- Infantile reflux and gastroesophageal reflux disease (GERD)
- Brachial plexus irritations
- Sleep disturbances**
- Asymmetrical crawling
- Otitis media*
- Chronic upper respiratory infections
- Enuresis*
- Asthma*
- Gait abnormalities
- Seizures**

- Growing pains
- Pediatric back pain
- Pediatric neck pain
- Pediatric headaches
- Scoliosis
- Chronic abdominal pain
- Chronic nasal congestion
- Autism**
- ADD/ADHD/learning disabilities** and other conditions on the PDD spectrum
- Sensory integration disorder
- Pediatric sports and extremity injuries
- Wellness checkup
- Checkup following trauma

4) Comments specific to the pediatric section of the chapter:

a) PEDIATRIC SECTION SHOULD INCLUDE MS AND NON-MS CONDITIONS:

Even though the first section of the chapter covers non-musculoskeletal (MS) conditions, the “Special Populations: Children” section should cover both MS and non-MS conditions, to be thorough and complete on the topic of pediatrics. Table 7 on page 16 makes it appear that MS conditions are to be included, but there is no further elaboration or discussion of the ms conditions covered in these studies. Do these discuss back pain, headache, torticollis? More detail is needed to educate the reader about the evidence related to pediatric ms conditions and chiropractic care.

b) PEDIATRIC SECTION SHOULD HAVE TABLES DETAILING PEDIATRIC

CONDITIONS: Specifically regarding the topic of pediatrics, it would be very helpful to have a separate table similar to Table 1 that was located in the “Special Populations: Children” section of the chapter that listed articles related to non-MS conditions in pediatric patients. Right now, the way the chapter is laid out, I do not know which conditions in Table 1 describe pediatric patients. For example, in Table 1, are the 5 case reports about constipation describing pediatric patients, adult patients or both? For those interested specifically in the evidence to support chiropractic care for children, it would be much more helpful to have the pediatric section of the chapter be complete in and of itself.

c) Still on this topic, Table 7 on page 16 tells us that there are 8 RCT’s on non-MS conditions regarding children, but doesn’t elaborate as to which conditions these cover. When I try to cross-reference with Table 1 on pages 6-7, I count 7 RCT’s that likely involved children. Where is the 8th? And it is possible that I am incorrect in my assumptions about the first 7 – the only way to know would be for me to read each abstract. So, again, it would be much clearer and more helpful to have separate tables in the pediatric section that itemize just those studies involving pediatric conditions/patients (similar to table 3 on pages 6-7).

5) CHIROPRACTIC IS MORE THAN MANIPULATION: Chiropractic care includes more than manipulation. While I understand that the chapter is limited to manipulative treatment of

non-MS conditions, this could be used as a stepping-stone to limit our scope to manipulation only. I feel that it is imperative that some discussion be devoted to the modalities beyond manipulation that are commonly used by doctors of chiropractic, clearly stating that these modalities were not evaluated in this chapter. I feel the chapter should provide a list of common modalities used in chiropractic offices (and note that the list is not all-inclusive, in case a specific modality is inadvertently omitted.)

a) As an example, in the following article, chiropractors entering the pediatric diplomate program were questioned as to modalities typically used in their offices to treat patients with otitis media and asthma. Here are the results:

Modalities used to address otitis media:

- Spinal adjustments
- Cranial adjustments
- Soft tissue manipulation (lymphatic drainage, etc.)
- Nutritional supplementation (probiotics, vitamins, EFAs)
- Dietary advice (food elimination, eating habits)
- Ear drops
- Homeopathy
- Lifestyle advice

Modalities used to address asthma:

- Spinal adjustments
- Cranial adjustments
- Soft tissue manipulation (incl. neurolymphatic massage)
- Nutritional supplementation (vitamin C, garlic, other)
- Dietary advice (food elimination)
- Lifestyle advice/stress management (stressor reduction - lifestyle, environmental, OTC medication side effects, etc.)
- Homeopathy
- Exercise prescription (general and respiratory)

From: Vallone S, Fallon JM. Treatment protocols for the chiropractic care of common pediatric conditions: otitis media and asthma. *J Clin Chiro Ped* 1997;2(1):113-115.

Appendix A: Missing References from Chapter's Reference List

*indicates study discusses 3 or more cases (making it eligible for formal evaluation)

PEDIATRIC TOPICS:

1) Autism

a) *Aguilar AL, Grostic JD, Pflieger B. Chiropractic care and behavior of autistic children. *J Clin Chiro Ped*. 2000;5(1):293-304. (26 children)

2) Colic/Irritable Infant

a) Hewitt EG. Chiropractic care and the irritable infant. *J Clin Chiro Ped*. 2004;6(2):394-397.

b) Hipperson AJ. Chiropractic management of infantile colic. *Clinical Chiropractic* 2004;7(4):180-186.

3) Dejerine-Sottas Disease

a) Gindl PS. Specific chiropractic adjusting of a child with Dejerine-Sottas disease. *J Clin Chiro Ped.* 2004;6(2):398-402.

4) Erb's Palsy

a) Hyman CA. Chiropractic adjustments and Erb's palsy: a case study. *J Clin Chiro Ped.* 1997;2(2):157-160.

5) Expert Opinion Articles (General)

a) Biedermann H. Manual Therapy in Children: Proposals for an Etiologic Model. *J Manipulative Physiol Ther* 2005;28(3):e1-e15.

b) Vallone S, Fallon JM. Treatment protocols for the chiropractic care of common pediatric conditions: otitis media and asthma. *J Clin Chiro Ped.* 1997;2(1):113-115.

6) Headache (Pediatric)

a) *Anderson-Peacock ES. Chiropractic care of children with headaches: five case reports. *J Clin Chiro Ped.* 1996;1(1):18-27.

b) Hassel TN. Pediatric cephalgia. *J Clin Chiro Ped.* 2004;6(2):383-386.

c) Hewitt EG. Chiropractic care of a 13-year-old with headache and neck pain: a case report. *Journal of the Canadian Chiropractic Association* 1994;38(3):160-162.

d) Luellen J. Chiropractic care of adolescent migraine headache. *J Clin Chiro Ped.* 2004;6(2):403-405.

7) Irregular Bowel Function (Constipation)

a) Mayer Hunt J. Upper cervical chiropractic care of an infant with irregular bowel function: a case report. *J Clin Chiro Ped.* 2000;5(1):312-314.

8) Low Back Pain

a) *Hayden JA, Silvano MA, Verhoef MJ. Evaluation of chiropractic management of pediatric patients with low back pain: a prospective cohort study. *J Manipulative Physiol Ther.* 2003;26:1-8. (54 consecutive patients)

9) Otitis Media

a) *Fallon JM. The role of the chiropractic adjustment in the care and treatment of 332 children with otitis media. *J Clin Chiro Ped.* 1997;2(2):167-184.

10) Plagiocephaly

- a) *Davies NJ. Chiropractic management of deformational plagiocephaly in infants: an alternative to device dependant therapy. *Chiropractic Journal of Australia* 2002;32(2):52-55. (25 cases)
- b) Quezada D Chiropractic care of an infant with plagiocephaly. *J Clin Chiro Ped.* 2004;6(1):342-348.

11) Scoliosis

- a) Lantz CA, Chen J. Effect of chiropractic intervention on small scoliotic curves in younger subjects: a time-series cohort design. *J Manipulative Physiol Ther.* 2001;24:385-393.
- b) Niesluchowski W, Dabrowska A, Kedzior K, Zagrajek T. The potential role of brain asymmetry in the development of adolescent idiopathic scoliosis: a hypothesis. . *J Manipulative Physiol Ther.* 1999;22:540-544.

12) Torticollis

- a) *Bolton PS, Bolton SP. Acute cervical torticollis and Palmer upper cervical specific technique: a report of three cases. *Chiropractic Journal of Australia* 1996;26(3):89-93.
- b) Colin N. Congenital muscular torticollis: a review, case study, and proposed protocol for chiropractic management. *Topics in Clinical Chiropractic* 1998;5(3):27-33.
- c) Fallon JM, Fysh PN. Chiropractic care of the newborn with congenital torticollis. *J Clin Chiro Ped.* 2000;5(1):312-314. *J Clin Chiro Ped.* 1997;2(1):116-121.
- d) McCoy Moore T, Pfiffner TJ. Pediatric traumatic torticollis: a case report. *J Clin Chiro Ped.* 1997;2(2):145-149.
- e) Smith-Nguyen EJ. Two approaches to muscular torticollis. *J Clin Chiro Ped.* 2004;6(2):387-393.
- f) Toto BJ. Chiropractic correction of congenital muscular torticollis. *J Manip Physio Ther* 1993;16(8):556-59.

13) Error in cited reference:

- a) #172 Vallone S. Chiropractic evaluation and treatment of musculoskeletal...
 - i) listed as volume 5; actually vol. 6(1):349-368.

PREGNANCY TOPICS:

14) Pregnancy in General

- a) Kunau PL. Chiropractic prenatal care: a case series illustrating the need for special equipment, examination procedures and supportive therapies for the pregnant patient. *J Clin Chiro Ped.* 1999;4(1):264-277. (6 cases)

15) Webster Technique

- a) *Kunau PL. Application of the Webster in-utero constraint technique: a case series. *J Clin Chiro Ped.* 1998;3(1):211-216.

16) Infertility

- a) Behrendt M. Insult, interference and infertility: an overview of chiropractic research. *JSVR.* 2003 May 2:1-?.
- b) Lyons DD. Response to Gonstead chiropractic care in a 27 year old athletic female with a 5 year history of infertility. *JSVR.* 2003 November 9:1-3.

V. Description of two of the Chiropractic Specialties involved in this review

Board Certified Pediatric Chiropractor – ACA Council on Pediatrics

1. Description

The Pediatric Chiropractor is a chiropractor with specialized, advanced training and certification in the evaluation, care, and management of health and wellness conditions of infancy, childhood, and adolescence. This specialist provides primary, comprehensive, therapeutic, and preventative chiropractic health care for newborns through adolescents. Patients of pediatric chiropractors range in age from moments after birth through age 18.

Treatment modalities typically used by the pediatric chiropractor include but are not limited to spinal, cranial and extremity manipulations (also called adjustments), soft tissue manipulation, physiotherapeutic modalities, nutritional supplementation, postural and exercise recommendations, and dietary and lifestyle advice. The purpose of the manipulative treatment modalities is to maintain proper biomechanics in the articulations of the body with the aim of normalizing neurological and physiological function to local and systemic structures related to these articulations. The objectives of the non-manipulative treatment modalities are to enhance the function of the child's biomechanical structures and maximize the child's overall health status and wellbeing.

Since prevention plays a large role in the maintenance of wellbeing, and since children are generally unable to detect the presence of a subluxation in their bodies, pediatric chiropractors see children for periodic wellness check-ups, similar to the preventative visits made to a pediatric dentist. The infant is often first seen within the first few weeks of life to examine for the presence of subluxations secondary to intrauterine constraint and/or birth trauma. The frequency visits for pediatric chiropractic wellness checkups varies by practitioner, but may occur monthly in the first year of life, bimonthly in the second year of life, then two-to-four times per year in subsequent years.

2. Common Conditions seen by pediatric chiropractor

Chiropractic care for children has been shown in the literature to be a safe and effective way to address many common conditions of childhood, including but not limited to infantile colic, nursing dysfunction, torticollis, plagiocephaly, chronic constipation, infantile reflux and gastroesophageal reflux disease (GERD), brachial plexus irritations, sleep disturbances, asymmetrical crawling, otitis media, chronic upper respiratory infections, enuresis, asthma, gait abnormalities, epilepsy, growing pains, pediatric back pain, pediatric neck pain, pediatric headaches, scoliosis, chronic abdominal pain, autism, ADD/ADHD and other conditions on the PDD spectrum, sensory integration disorder, pediatric sports and extremity injuries.

3. Common treatment modalities used by pediatric chiropractor

Billing codes used by pediatric chiropractors are very similar to those used by chiropractors who treat adults. Pediatric chiropractors typically use CPT codes for E/M, diagnostic testing (blood, stool, etc.), manipulation (98940-98943), massage (97124), manual therapy (97140), physiotherapeutic modalities (muscle stim, cryotherapy, etc.), therapeutic exercise (97110), neuromuscular reeducation (97112), etc. as may be appropriate for a given child and treatment regime. See section 1 above for a list of typical treatment modalities used by pediatric chiropractors.

Board Certified Chiropractic Internist – ACA Council on Diagnosis and Internal Disorders

A Chiropractic Internist (DABCI) must practice in accordance with the laws of the state or residency and licensure.

A DABCI (Diplomat of the American Board of Chiropractic Internists) is a chiropractic physician who, having completed the prescribed course and demonstrated proficiency by passing all required examinations, is board certified in the diagnosis and management of internal disorders. The DABCI, or chiropractic internist, may serve as a primary care physician or may see patients referred from other providers for evaluation and co-management. Evaluation is focused on the early detection of functional, nutritional, and pathological disorders. A chiropractic internist utilizes the diagnostic instruments necessary for proper examination. In cases where laboratory examination is necessary, a chiropractic internist utilizes a recognized reference laboratory facility.

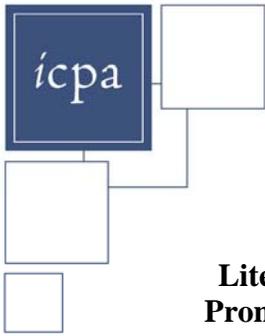
A chiropractic internist may manage his or her own cases or may refer to another specialist when prudent to do so. The chiropractic internist utilizes documented natural therapies, therapeutic lifestyle changes, patient education, and other resources to promote patient health and avoidance of disease.

Patients seen by a chiropractic internist are commonly those suffering from chronic symptoms and/or conditions. The etiology of their symptoms is often multi-faceted, requiring thorough evaluation and management. Management of their cases may be complicated by overall poor

health, environmental sensitivities, poor nutrition, unhealthy lifestyle, and/or other factors. Conditions seen by a chiropractic internist include, but are not limited to: migraine headaches, tension headaches, insulin resistance, diabetes, sinusitis, rheumatoid arthritis, fibromyalgia, chronic fatigue syndrome, colitis, IBS, PCOS, PMS, menopausal conditions, eczema and insomnia as well as routine annual exams.

The following is a list of CPT codes used by chiropractic internists. It is not meant to be an exhaustive listing of codes. Rather, it is provided as a broad sampling of codes that may be used.

99201	New Pt Px, limited	99202	New Pt Px, detailed	99203	New Pt Px, extensive
99204	New Pt Px, compr.	99211	Est. Pt Px, minimum	99212	Est. Pt Px, limited
99213	Est. Pt Px, expanded	98940	CMT	98941	CMT, 3-4
81001	Urinalysis	86001	Allergen; IgG	86003	Allergen; IgE
80053	CMP	80076	Hepatic panel	83090	Homocystiene, serum
36415	Venipuncture	85025	CBC	88175	Pap smear
82652	Vit D	84153	PSA	80061	Lipid panel
84260	Serotonin	82627	DHEA	82530	Cortisol
87075	Bacteriology	86060	ASO titer	86034	CA 125
82038	Calcitonin	93000	ECG	86256	ELISA
87102	Fungus culture	J3420	B12 injection	90782	Injection, therapeutic
90784	IV administration	86664	Mono test	99070	Nutritional support
57410	Pelvic exam	94010	Spirometry	84402	Testosterone
84144	Progesterone	82670	Estradiol	83002	LH
87177	Parasite culture	87045	Bacteria culture	86318	Tapeworm



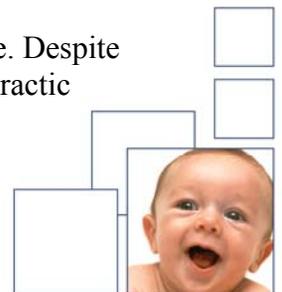
**ICPA Critique Committee of CCGPP Best Practices
Literature Synthesis: Chiropractic Management of Prevention and Health
Promotion; Non-Musculoskeletal Conditions; and Conditions of the Elderly,
Children and Pregnant Women (DRAFT)**

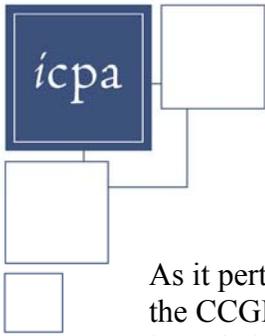
As the Research Director for the International Chiropractic Pediatric Association (ICPA) and a practicing chiropractor and on behalf of the ICPA CCGPP Critique Committee and its over 2500 member constituents worldwide, I am writing in response to the document, **“Literature Synthesis: Chiropractic Management of Prevention and Health Promotion; Non-Musculoskeletal Conditions; and Conditions of the Elderly, Children and Pregnant Women (DRAFT).”** As the largest international chiropractic organization devoted to post-graduate education, research and service in the realm of pediatric chiropractic and family wellness care, the ICPA have several concerns and issues with the veracity and validity of the document stated above. These issues are particular to the practice of pediatric chiropractic but the issues raised are also germane to the care of the elderly and pregnant patients. These are addressed within the Response Framework provided by the CCGPP.

Response Framework

1) Do the documents address the clinical issues most commonly seen in chiropractic practice, providing adequate information to form a rational basis for evaluation and treatment options?

The answer is a resounding **NO** to the above question with respect to the clinical issues most commonly seen in chiropractic practice, providing adequate information to form a rational basis for evaluation and treatment options. Upon first examination, the fact that the practice domains of prevention, health promotion, non-musculoskeletal conditions and conditions of the elderly, children and pregnant women were addressed together in one literature synthesis may be reflective of the state of research (or lack thereof) on these individual topics but also possibly point to the **lack of appreciation** by the CCGPP group into the complexity of each of these practice domains as they relate to patient care. Before addressing the issue of clinical expertise in the care of such patients, we want to point out that the CCGPP has failed to keep its words according to Dr Lewis’ comments in, “Common Questions and Answers Regarding the Best Practices Initiative” by failing to directly address the clinical issue of subluxation (1). According to the National Board of Chiropractic Examiners Job Analysis of Chiropractic 2005 (2), chiropractors address both spinal and extraspinal subluxations with common frequency. The study by McDonald et.al. (3) indicates that subluxation figures prominently in patient care. Despite comments and assurances by the CCGPP group on this important facet of chiropractic care, it was not addressed.





As it pertains to the chiropractic care of patients with non-subluxation based diagnosis, the CCGPP document only reflects the published literature. To the best of our knowledge, we are not aware of any published studies comprehensively examining the types and kinds of pediatric, geriatric and pregnant patient complaints presenting to chiropractors. Until such a study is performed, how then can one adequately form a rational basis for evaluation and treatment options without such information? The ICPA has created the **largest chiropractic practice-based research network in the world** to address, among other topics, such questions. Our preliminary data thus far would seem to indicate that the condition-based topic addressed by the CCGPP is one small aspect of the practice of pediatric chiropractic (4). Furthermore, our study respondents worldwide indicated that subluxation figured prominently in their patient care. The results of our practice-based studies on pregnancy and the care of the elderly are presently on-going. On the issue of wellness incorporating health promotion and disease prevention, the preliminary data from our practice-based research survey thus far provide an insight into how chiropractors (to the extent provided by the respondents) practice within the framework of wellness (5). The findings from our studies thus far point to the prematurity of our over-reliance on the existing literature in making a document for “best practices.”

2) Do you have any other comments or concerns?

The chiropractic care of children is simply not a small, scale-down version of the adult. For example, one aspect of the care of children must take into account the unique biomechanical features of the pediatric spine (6). The clinical encounter with a pediatric patient is complex and this complexity would also hold true for the care of the pregnant patient or in the care of the elderly. As such, the question below begs for an answer and they point to serious concerns.

Team Selection: What is their Expertise?

According to the Methods section of the CCGPP process on **Team Selection and Orientation Training of Team Members**, “Team members were selected from a multidisciplinary list of practitioners and content experts that had been solicited from the Council stakeholders and colleges.” The resultant team members under the leadership of Cheryl Hawk, DC,PHD, CHES are the following:

Randy J. Ferrance, DC, MD

Private practice, chiropractic

Hospitalist, Riverside Tappahannock Hospital, Tappahannock, VA

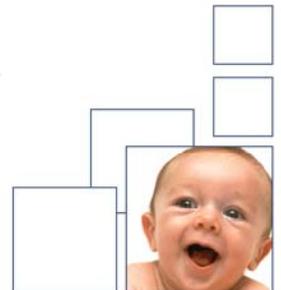
Anthony Lisi, DC

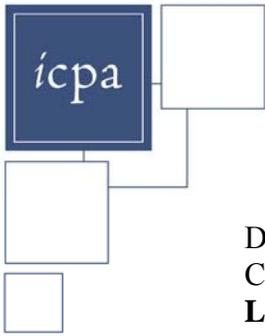
Associate Professor of Clinical Sciences

University of Bridgeport College of Chiropractic

Staff Chiropractor, VA Connecticut Healthcare System, West Haven, CT

Marion Willard Evans, Jr, DC, PhD, CHES





Director, Health Promotion Degree Programs
Cleveland Chiropractic College, Kansas City and Los Angeles

Lisa Killinger, DC

Professor and Chair, Department of Diagnosis and Radiology
Palmer College of Chiropractic, Davenport, IA

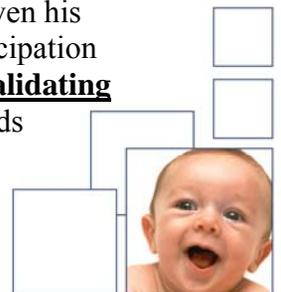
Jacqueline Bougie, DC

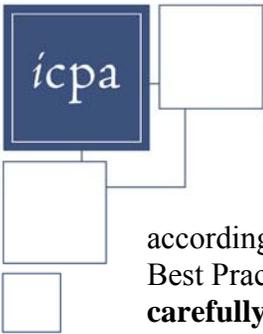
Professor, Department of Diagnosis, Los Angeles College of Chiropractic
Southern California University of Health Sciences, Whittier, CA

With all due respect to the above individuals on their efforts in this process, I question the validity of the team selection process. It may be understandable that Drs. Hawk and Evans are part of this process due to their CHES credentials and their work in the area of health promotion and disease prevention and possibly Dr Lisi's work with the VA Hospital as it pertains to a limited aspect of elderly care. What are the expertise of Drs. Ferrance, Killinger and Bougie as they pertain to the practice domains of interest? Who is an expert in the care of the elderly? Who is an expert in the care of pregnant patients? Who is an expert in the care of children? Is this expertise gained through clinical experience, through chiropractic post-graduate training or both? Insofar as one can discern, none of the above individuals are certified or have attained Diplomate status in a post-graduate program in Pediatric Chiropractic. Only two of the team members (Drs Lisi and Ferrance) have job descriptions that pertain to direct patient care. The question remains as to what aspect of patient care do these two clinicians address – the care of the elderly, children, or pregnant women? Furthermore, what percentage of their clinical contact time are devoted to the care of such patients or is it none at all?

Team Selection: Potential Conflict of Interest

According to CCGPP, "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...." If indeed this is true, then we take issue with Dr Ferrance's participation in this process. There is no doubt that Dr Ferrance is trained as a chiropractor and a medical doctor. In his short biography as an instructor for NCMIC (7), he is listed as "dually boarded in pediatrics and internal medicine." What of his training in pediatric chiropractic? It has been commented upon that, "Pediatric chiropractic is often inconsistent with medical guidelines" (8). There are many reasons for this from a chiropractic perspective and beyond the scope of this writing. However, based on his writings, Dr Ferrance leaves no doubt as to the direction of his philosophical and clinical bent/bias (9-11). Dr Ferrance is listed prominently among the CCGPP team members and one is led to believe that he carries some leadership role among its members. Given his biased sentiments on the role of the chiropractor in the care of children, his participation in this process taints the veracity and legitimacy of the CCGPP process thus **invalidating the process and the CCGPP document**. The CCGPP has failed to keep its words





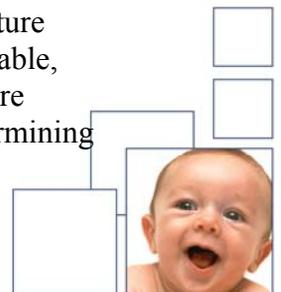
according to Dr Lewis' comments in, "Common Questions and Answers Regarding the Best Practices Initiative." By including Dr Ferrance in the process, the CCGPP failed to **carefully stay away from philosophical conflict**. We further request that in keeping with the purported objectivity, openness and full disclosure of the CCGPP process among its team members and to dissuade further perceptions of conflicts of interest, we respectfully request that they fill out Table 1 below and publish the results in the CCGPP website.

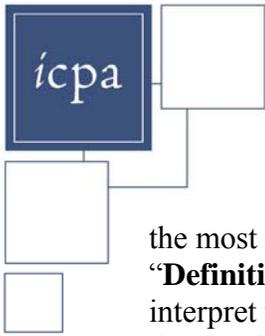
Team Member	Have you ever worked for an Insurance Co as an IME?	Do you work for a state or federal agency?	Do you work for a hospital administration?	Are you a consultant to any 3 rd party payors?	If yes to questions in Column 2-5, list the organizations/companies
Hawk					
Ferrance			Yes		
Lisi		Yes	Yes		
Evans					
Killinger					
Bougie					

Levels of Evidence: Where is it?

The authors of this CCGPP document, as with all previous CCGPP documents, have provided a **"Definitions for Evidence Rating."** This group would seem to have maintained the overall guidelines for the CCGPP evaluation process. As such, we echo the sentiments of the ICA Committee's Critique of CCGPP on the issue of their use of evidence ratings (12). Of great concern is the lack of validity of the process in creating such a "definitions for evidence rating." As the ICA Critique Committee has so adequately pointed out (12), the authors of the CCGPP documents have failed to include "levels of evidence" and "grades of recommendation" and have failed to provide a legitimate basis for the creation of such a rating scheme. As noted above, the tools used to rate each article is of questionable validity. **We therefore again take issue with the CCGPP process and again question the validity of the CCGPP document.**

Furthermore, this CCGPP document is a literature synthesis. As stated, "A literature synthesis is a starting point. It indicates only what we can conclude with supportable, scientific evidence. Appropriate therapeutic approaches will consider the literature synthesis as well as clinical experience, coupled with patient preferences in determining





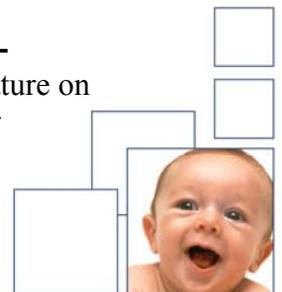
the most appropriate course of care for a specific patient.” Upon examination of the “**Definitions for Evidence Rating**” and “**Summary of Recommendations**” – one may interpret the recommendations made as commenting on the appropriate course of care despite the lack of supporting literature such as expert opinion and patient preferences. Why disseminate such a document prior to completion?

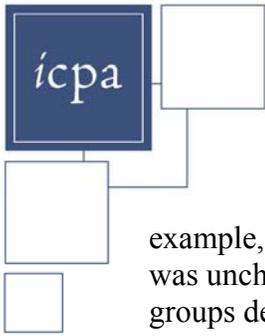
The authors of this CCGPP document have stressed, “To be consistent with overall guidelines for the CCGPP evaluation process, commentaries or expert opinion articles, descriptive surveys and case reports of 1-2 cases were included in the bibliography but excluded from formal evaluation.” The above described methodology further places into question the validity of the process and the tools employed by the CCGPP group. They excluded commentaries and expert opinion articles and descriptive surveys and yet, in their “**Definitions for Evidence Rating**” – there exists **Grade D [Expert opinion, and usual and customary clinical practice. Evidence consists of expert opinion; research cannot be or has not been performed]**. Again, they **place into question** the CCGPP process and the validity of their evidence rating since the team members themselves have not followed their own process.

We also take issue with the CCGPP process in the exclusion of the use “descriptive surveys and case reports of 1-2 cases.” Dr Ferrance, as a member of the CCGPP group has been quoted as stating, “There are many case reports, but they are anecdotal evidence” (13). If Dr Ferrance’s attitude about case reports is reflective of the the rest of his team, then perhaps a lesson in research design is in order. Case reports are not anecdotal evidence. Sackett et.al. (14) incorporate descriptive surveys and case reports as part of the *Levels of Evidence* hierarchy. Case reports and case series provide a description of the clinical encounter between doctor and patient and provide a starting point. Unlike that espoused by the CCGPP group, case reports do not merely “provide evidence that patients with the conditions described have sought care from chiropractors.” They describe the clinical encounter from examination and evaluation, to diagnosis and prognosis, the intervention and outcome in the care of one patient or more. Case reports also focus on the ethical dilemmas encountered in patient care, the use of technology and educational as well as administrative concerns. More importantly, case reports stimulate further research and “help develop practice guidelines and critical pathways.” (15). The CCGPP group seems to have missed this most important aspect of case reports. Case reports actually illustrate “how clinicians integrate the best available research evidence, clinical experience, and patient choice” (15).

Lack of Critical Appraisal of the Literature

Based on “**Table 3. Evidence table for chiropractic care of patients with non-musculoskeletal conditions**” there seems to lack a critical appraisal of the literature on the part of the CCGPP group despite or in spite of a Methodology Checklist. For



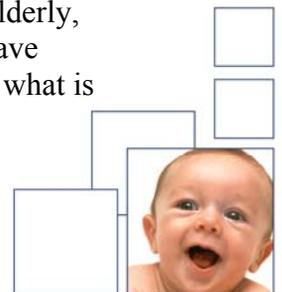


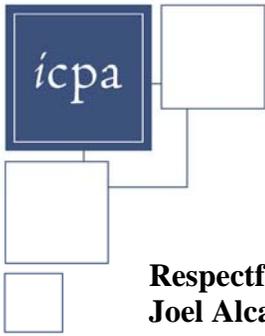
example, the study by Balon et.al. (16) found that the Peak Expiratory Volume (FEV) was unchanged in the treatment and sham groups. Additionally, members of both study groups demonstrated improvements in symptoms, decreased use of β -agonists, and improved quality of life. Balon et.al (16) thus concluded that, “In children with mild or moderate asthma, the addition of chiropractic spinal manipulation to usual medical care provided no benefit.” Upon closer examination of the sham treatment employed, the study authors failed to determine the validity of their sham treatment insofar as being inert. Furthermore, given the description of the sham treatment employed by chiropractors involved in the clinical trial, one may more adequately conclude that a comparison trial took place between chiropractic SMT and another form of manual technique. Other chiropractic studies (17,18) on asthmatic patients would seem to indicate improvement in subjective outcome measures (i.e., symptoms, dependence on medication, quality of life) but not so-called objective measures such as FEV. Given that no studies exist on the sensitivity and specificity of this outcome measure in asthmatic patients under CAM therapies such as chiropractic, its validity is put into question. A study by Ali et.al. (19) is underway consisting of four groups: a chiropractic treatment at centers (3 times per week) group, no treatment at centers group, no treatment at home group, and a control group of non-asthmatic patients with no treatment at home. Preliminary findings thus far indicate improvements in quality of life measures as well as indicators of physiologic response (i.e., cortisol and IgA) to chiropractic treatments (20).

As another example, the study by Olafsdotir et.al.(21) found parent-reported (blinded) improvements in crying improved in both groups (i.e., chiropractic treatment group versus placebo). Upon closer examination of the study, the reported treatment was mobilization rather than a chiropractic adjustment commonly described as site specific, high velocity, low amplitude thrust. Furthermore, the site of spinal treatment was localized to the lumbosacral spinal region. Based on my clinical experience and in conversations with hundreds of chiropractors experienced in the care of children with colic, we would disagree with this approach to patient care, opting instead for fullspine care.

Despite the criticisms in these dissenting studies on asthma and colic, the CCGPP group in their Summary of Recommendations rated **asthma** and **colic** with a **Rating C [Limited evidence to support chiropractic care, including manual procedures, spinal manipulation/mobilization; benefit may be due to nonspecific factors]**.

In closing, we again echo our earlier comments on the inappropriateness and prematurity on the use of the published literature as they pertain to the care of children, the elderly, and pregnant women and in the creation of “best practices” documents. As we have pointed out, the **CCGPP process was flawed, biased and selective** in its use of what is already a literature base that is lacking.

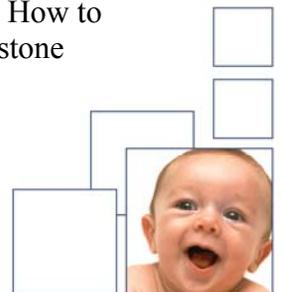


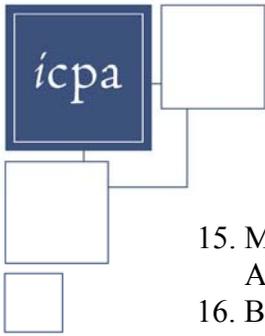


Respectfully,
Joel Alcantara, BSc, DC, MPHc
Director of Research
International Chiropractic Pediatric Association
Private Practice of Chiropractic
San Jose, CA, USA

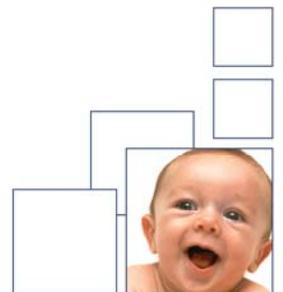
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To my colleagues at CCGPP,

Following are my answers to the four questions posed by CCGPP, as pertaining to the Chapter titled: LITERATURE SYNTHESIS: CHIROPRACTIC MANAGEMENT OF PREVENTION AND HEALTH PROMOTION; NONMUSCULOSKELETAL CONDITIONS; AND CONDITIONS OF THE ELDERLY, CHILDREN AND PREGNANT WOMEN. This chapter is commonly referred to as the Wellness Chapter.

While I did serve on the CCGPP Wellness Chapter Review Committee, of the Alabama State Chiropractic Association, my comments and answers are mine, and not those of the committee.

I thank M. Will Evans, DC, PhD, a CCGPP Wellness Chapter research team member, for helping clarify the issues relating to “Management and Prevention And Health Promotions” and how they relate to Wellness. The following interpretations and comments should not be seen as being endorsed by Dr. Evans. His endorsement of my remarks were not requested or granted.

I must admit that as a forty-eight year chiropractic professional, with a twenty-year involvement in wellness care, I at first saw this CCGPP Chapter as an attempt to limit the practice of chiropractic to MS and limited NMS conditions. I now trust that it is not. Only time will tell.

After communicating extensively with some of my colleagues, both in our scientific and practice communities, I believe that there is simply a profession-wide lack of understanding of, and failure to communicate the nature of, wellness care, which tends to cause sometimes passionate dissensions within our profession of strong individualists. It is with these, hopefully correct, assumptions that I submit the following answers to the questions posed by CCGPP.

Question 1: Do the documents address the clinical issues most commonly seen in chiropractic practice, providing adequate information to form a rational basis for evaluation and treatment options?

My response is NO: Please see my reasons given under question 4 below.

Question 2: Bearing in mind that more chapters are forthcoming on other topics, are there any related disorders / conditions or diagnostic procedures commonly used by doctors of chiropractic that were not included in the current review of literature? If so, what? Include specific literature citations and include the page number and specific conclusion/recommendation you wish to comment upon. Information can be emailed to ccgpp@sc.rr.com or mailed to CCGPP, PO Box 2542, Lexington, SC, 29071.

My response is YES: Please see my reasons given under question 4 below.

Question 3: With regard to the organization, readability and utility of the documents, do you have any suggestions or comments? Recall that this is a literature synthesis and not the final educational instrument (the Chiropractic Clinical Compass[®]), which will have a very user-friendly format.

My response is NO: These items seem to be well organized, readable and usable.

Question 4: Do you have any other comments or concerns?

My response is YES:

1. As pertaining to the *first part* of the official title of this chapter, CHIROPRACTIC MANAGEMENT OF PREVENTION AND HEALTH PROMOTION; I cannot see that this chapter has relevance.

- The chapter describes the “treatment” of conditions, not Prevention and Health Promotion, or Wellness.
- The term “**chiropractic management**” refers to the complete patient experience under chiropractic care; yet the chapter includes only the use of **chiropractic manipulation**, which is just one part of the care provided by most chiropractors. Even the most narrow practice style provided by chiropractors includes the advice of “drink more water”, “eat more fruits and vegetables”, and/or “stop smoking.” In practices that are more broadly *Wellness* oriented the patient experience includes more detailed information and assistance pertaining to spinal health, nutrition, and the management of mental, physical and chemical stress. The basis of many wellness services are well defined in the literature of other health related disciplines, are taught in chiropractic schools, and are well within the scope of chiropractic practice.

2. As pertaining to the *second part of the chapter title*, (CHIROPRACTIC MANAGEMENT OF) NONMUSCULOSKELETAL CONDITIONS; AND CONDITIONS OF THE ELDERLY, CHILDREN AND PREGNANT WOMEN this document does not address the subject matter indicated by its title. It refers to **chiropractic management** but deals only with manipulation.

3. **Also, the use of the term “wellness” in this chapter is inappropriate.**

- ***Wellness is proactive, and has to do with helping people reduce their chances of having health problems that require treatment.***
- ***The management or treatment of health problem is reactive, and has to do with helping people, after health problems develop, when their lack of understanding and/or lack of use of “wellness” measures has allowed them to develop health problems.***

In my opinion, this chapter does a good job of reporting the evidence supporting chiropractic effectiveness in managing a small number of conditions. But, it has no relevance to chiropractic practice in the field of Prevention, Health Promotion / Wellness Care.

RECOMMENDATIONS:

1. Replace the term *chiropractic management* with *chiropractic manipulation*.
2. Completely remove all references pertaining to “wellness” and “Chiropractic Management of Prevention and Health Promotion” from this chapter.
3. Develop a more comprehensive chapter on the “Chiropractic Management of Prevention and Health Promotion / Wellness.” If we are producing scientifically based documents and Chiropractic Clinical Compasses pertaining to wellness practice, we should take a more comprehensive approach to the development of this chapter; . . . Even more comprehensive than was done with the low back pain chapter, because it is a potentially more important area

for our practitioners, our patients, our communities, and our employers, who really need health care providers that will champion wellness. Many chiropractors are already deeply involved in wellness care.

In the development of a Wellness Chapter major efforts should be made to support the use of a broad range of wellness tools, based on years of chiropractic clinical experience and the findings of other scientific groups, that have published on wellness evaluation and management tools, that are available to chiropractic professionals. ***This should include the use of wellness evaluation tools such as whole body subjective outcomes forms and Heart Rate Variability, which is widely used in research and clinical applications.***

These things should be done to prevent outside “stakeholders” from using our own documents to improperly identify us, or limit our involvement in wellness practice.

Wellness care is a relatively young and rapidly growing area of health care. As the benefits of Wellness are better understood by the general public, and by the leaders of American industry and government, this will be recognized as a major area that can reduce human suffering and American health care costs, which are major factors contributing to our ability to compete in the world market place.

It is my understanding that while the terms Disease Prevention and Health Promotion are well defined in the scientific community; Wellness is a term that is not well defined scientifically, but is commonly used in the clinical setting and is more readily understood by the general public. In the medical field the term wellness is commonly connected in disease screening programs, to detect disease. But, many in the wellness field argue that wellness care is the changes one makes in caring for their body, that makes disease screening and treatment less necessary.

It is a fact of the day, that most people, including many practicing chiropractors and chiropractic scientists are, to varying degrees, brainwashed by the dominance of the medical model of sick care. Our chiropractic roots are, however, deeply rooted in the more natural disciplines of true health care, also called “wellness care.”



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October 26, 2007

RE: Review of the CCGPP Wellness Chapter

The Georgia Chiropractic Association has appointed a committee to review the CCGPP Second Draft Chapter, Chiropractic Management of Prevention and Health Promotion; Non-musculoskeletal Conditions; And Conditions Of The Elderly, Children And Pregnant Women.

To answer the question posed by CCGPP, Do the documents address the clinical issues most commonly seen in chiropractic practice by providing adequate information to form a rational basis for evaluation and treatment options?

We feel the chapter does represent conditions that the majority of chiropractors see and treat on a daily basis.

However, counseling for such conditions as tobacco usage, breastfeeding, and limiting use of antibiotics is not typically the office visit/consultation itself, but handled during the visit for CMT as overall good health measures.

We were disappointed at the limiting evidence to support the chiropractic treatment of low back pain in older adults, chronic musculoskeletal pain, and low back pain in pregnant women. We were dismayed that osteopathic research provided most of the research and no chiropractic research. These are conditions that chiropractors treat every day in their offices with great results. We must insist that our chiropractic colleges engage in research for these and other conditions that we treat on a daily basis.

The committee feels it important to make the distinction of actually treating a condition vs. treating a patient with concurrent conditions and the patient's overall well being improve, not necessarily the 'organic' or 'systemic' condition itself. An example would be COPD in a geriatric patient. Because of the difficulty in breathing the patient will recruit shoulder and neck muscles to aid in lung expansion and eventually develop an over use syndrome involving the cervical-thoracic junction. Chiropractic care can greatly improve the function of the over use area and hence the patient feels better, can breathe better and may even require less oxygen, (if on Oxygen) and blood O2 levels may improve. The chiropractor treated the secondary musculoskeletal condition which had a bearing on the primary COPD.

Furthermore, with the recent publication of the Annals of Internal Medicine recommending SMT as a first line of treatment for Acute Back Pain, and a viable option for Chronic Back Pain we question if the literature search was diligent enough and challenge the statement that: RATING: C Limited evidence for spinal manipulation for chronic musculoskeletal pain in older adults.

Respectfully submitted,

Richard Buchanan, D.C.
Mark Cotney, D.C.
Richard Gadd, D.C.
Kathy Webb, D.C.
Tim Willis, D.C.

GCA Insurance Hotline
Medicare CAC Representative
Workers' Compensation Subcommittee Chair
GCA President (former Insurance Committee Chair)
Peer Review Committee Chair

I will be brief. As a wellness based doctor of chiropractic, I find your current guidelines to be inadequate. As a cash practice, I doubt that this will affect me significantly, however I must still share my opinion as I feel your document is detrimental to the profession of chiropractic.

My primary concern at this point is this: I feel that case studies are, in fact, a valid criteria for determine validity of a particular procedure. Your statement, "these reports can only provide evidence that patients with the conditions described have sought care from chiropractors; case reports cannot provide convincing evidence to support best practices," is understandable, but unfair. Chiropractic has never had the financial backing that the medical or pharmaceutical industries enjoy. Case studies, while not perfect, should not be dismissed out of hand, especially when so much is at stake.

I trust you will consider my opinion. Thanks for your time.

I am requesting you to support alternative guidelines for treatment that are subluxation/wellness based such as the Council on Chiropractic Guidelines. Isn't it enough that we have an epidemic of obesity, diabetes, and cardiovascular conditions in our country that are definitely not being adressed well by allopathic medicine??? I am sure, in your hearts, that you know chiropractic treatment combined with nutritional support and guidance is preventative in nature and can save the insurance industry tons of dollars by actually avoiding allopathic treatments for the above conditions and their related secondary conditions. I ask you to be open enough to use case studies as supporting evidence that chiropractic care(including accupuncture, nutrition, exercise guidance, and rehab) is definitely cost effective to insurance companies as well as life changing for people as well.

MY COMMENTS AS A 27 YR.PRACTICING D.C.

CASE STUDIES SHOULD NOT BE IGNORED IN YOUR ASSESSMENTS

TO OMIT THEM IS TO DO A DISSERVICE TO THE PROFESSION

I would like to express my displeasure in seeing your committee feel they can speak for the whole chiropractic profession. I don't feel these guidelines come close to giving a true picture of what I and my friends have encountered in more than 20 years in practice. You saw the negative response your Mercy Guidelines caused and is still causing. I believe the best course of action is to do us all a favor and keep your opinions to yourself, because I know this is one guideline I can do without.

This is in follow up to the release of the Prevention, Health Promotion and Nonmusculoskeletal Conditions Chapter. Please note that on Page 15, second paragraph, the Table numbers referred to do not appear to correlate. I believe there was a lack of updating from a previous draft and the table numbers need to be corrected.

Your efforts to develop "Best Practices" guidelines for CHIROPRACTORS is biased in favor of the practice of medicine... your emphasis is on diagnosis and treatment of symptom complexes...not on the detection & correction of vertebral subluxation.

Your idea of wellness care is not the removal of nerve interference as it should be practiced in our profession, but in counseling smoking cessation and other lifestyle changes...exactly what the medical profession provides. Instead of promoting and defending the uniqueness of chiropractic(vertebral subluxation correction) you are homogenizing ,pasteurizing and folding our profession into the medical mix.

Medicine has so many problems today with healthcare delivery: cost, poor outcomes using their scientific methods(surgery, radiation, chemotherapies)
why on earth would we want to blend ourselves into THAT MESS?

I have been practicing the fine art and science of chiropractic for over 25 years and my father before me practiced 40 years...we have provided this unique and highly effective healthcare service to thousands of Hudson Valley area residents for more than half a century...safe, effective and cost saving chiropractic care. We are not part of the problem within healthcare today...WE ARE PART OF THE SOLUTION. And your organization has become part of the problem when you insist of medicalizing our beloved profession.

I reject your lowback chapter and further request you terminate your best practices project immediately...we will not let you destroy our profession!!

I read the draft on non musculoskeletal conditions and am very impressed with the depth of research on articles written with chiropractic manipulation as the sole source of treatment for those ailments. I am concerned with the draft and its' meaning beyond chiropractic.

Chiropractic manipulation and non musculoskeletal conditions accurately describes what you are listing. Chiropractic treatment, I fear, connotates that this is all we do. YOU are listing chiropractic manipulation as sole treatment. I do not know any practicing chiropractor who would solely use manipulation for a majority of those conditions listed. We would use a lot of different approaches to ge the desired patient relief. Someone outside of our profession is going to read this and connotate that we show no knowledge of modern medical diagnostics and intervention.

Please reconsider the title of the draft - Chiropractic Manipulation.

The chiropractic subluxation is a finding of a reflex at the spinal level or it is a gross mechanical "jamming". Gross mechanical jamming requires a good adjustment. A somatovisceral reflex deserves a doctor with an education in differential diagnosis, a knowledge of diagnostic tests to know where the reflex is coming from, and a whole lot more than an adjustment to fix it naturally. Irregardless of what school we went to we were all taught to protect the innate from needless toxic intervention. Diet, nutrition, adjustments, exercise, balancing techniques etc., is the answer. Please don't peg us into some tiny historical obscurity with manipulation verses what we could do as natural health care providers.

Having reviewed this document I find it extremely well documented as usual. My concern is that the scope of care of this document is extremely limited and although the intentions of this document are not to have it used against us... it will be just that and we will be severely limited by third party payers and, I fear, eventually eliminated for lack of literature support. Especially considering the lack of evidence that a chiropractic physician has in their treatment protocol as outlined in this document.

Perhaps more time should be allotted prior to publication so that physicians within the profession who regularly treat these conditions can submit nutritional and physiological therapies along with their documentation of treatments that are routinely used in the treatment of these conditions. I only know of two D.C.s who limit their treatment of non-NMS conditions to manipulation/mobilization and they are philisophical albatroses.

If used against us this document could eliminate the entire profession.

I agree, although clearly stated that the literature doesn't support manipulation for those conditions - since we treat most of those conditions using alternative methods this document is very dangerous...

I recently read the chapter on ***CHIROPRACTIC MANAGEMENT OF PREVENTION AND HEALTH PROMOTION; NONMUSCULOSKELETAL CONDITIONS; AND CONDITIONS OF THE ELDERLY, CHILDREN AND PREGNANT WOMEN.***

I really like how the first page clarified that it is a literature review and not meant to affect individual decision making, medical necessity, or reimbursement. I think that was not clarified in the original lower back chapter.

I would like to see the elderly section clarified more. "Lower back pain" in that population is very non-specific. I'd like to see the evidence broken down into more specific conditions, including degenerative disc disease, spinal stenosis, disc displacement, etc.

Also, in the pediatric section, I'd like to see the evidence on scoliosis (unless this is coming in another chapter.)

I'm curious about who it is you are working for? Clearly it isn't for the benefit of the chiropractic profession. From what I've been reading regarding your most recent best

practices effort you are towing the AMA line. In your latest effort you have ignored research that clearly promotes chiropractic as a health and wellness profession and continued on a course that will have nothing but dire consequences for the profession of chiropractic. Our enemies have shown themselves capable of being unscrupulous and will stop at nothing and you have given them ammunition with which to continue their assault on our profession. Again I ask who are you working for? What do hope to accomplish? Do you wish to destroy this profession?

I have personally witnessed migraines disappear, asthma clear up, digestive disorders ease, ear infections disappear and the list of maladies goes on and on and I am only one chiropractor. Clearly the persons writing that paper are working for the likes of Stephen Barrett and the many enemies who have never ceased to work against chiropractic. **HOW DARE YOU CLAIM TO REPRESENT MY PROFESSION!!!!**
It is my hope that you are sued out of existence. Foulness of this magnitude has historically backfired on those administering it.

I wanted to have some clarification as to the model of subluxation you are using. Is it the pinched nerve or dysafferentation model. Check the books by Dr. James Chestnut he does a masterful job of scientifically validating the chiropractic paradigm. He has all the research and articles that support what we do.
Thanks in advance for your response.

1) Do the documents address the clinical issues most commonly seen in chiropractic practice, providing adequate information to form a rational basis for evaluation and treatment options?

It is a good beginning - the gathering of documentation that has been rigorously examined. Yet although you have prefaced your document with the last paragraph of the first page, I feel that we are in danger of having people outside the profession utilize this document to "irrationally" exclude treatment options that are based on clinical presentation and provider's experience (which would be "labeled" anecdotal) because of the lack of RCT's related to a specific diagnosis.

2) Bearing in mind that more chapters are forthcoming on other topics, are there any related disorders / conditions or diagnostic procedures commonly used by doctors of chiropractic that were not included in the current review of literature? If so, what? Include specific literature citations and include the page number and specific conclusion/recommendation you wish to comment upon.

1. could you elaborate on the literature or lack of literature concerning chiropractic adjustments used preventatively as a part of a wellness program? If I am reading this correctly, you have graphically demonstrated papers available but the bulk of that section is on wellness education vs. chiropractic adjustments for wellness or prevention.

2. inclusion of information on Breech Turning Technique under section on Pregnancy:

July/August 2002 issue of the Journal of Manipulative and Physiological Therapeutics (JMPT)1: [J Manipulative Physiol There.](#) 2002 Jul-Aug;25(6):E1-9. **The Webster Technique: a chiropractic technique with obstetric implications.**[Pistolese RA.](#)

3. inclusion of information on the KISS Syndrome in section on children: Manual Therapy in Children: Proposals for an Etiologic Model. Journal of Manipulative and Physiological Therapeutics, Volume 28, Issue 3, Pages e1-e15 H. Biedermann
<http://www.ewmm.net/downloads/MT%20in%20children.pdf>

3) With regard to the organization, readability and utility of the documents, do you have any suggestions or comments? Recall that this is a literature synthesis and not the final educational instrument (the Chiropractic Clinical Compass[®]), which will have a very user-friendly format.

I would like to see the final document for user-friendly format. The "ratings" are unclear to me.

4) Do you have any other comments or concerns?

Out of respect for the hard work done on this document, thank you.

I feel that the case report has been under valued in this document as a viable source of information to help a practitioner develop a sense of best practices when faced with situations that are foreign to him or her. The document points out the derth of documented evidence in RCT's, etc. but given the populations and treatments we are talking about, the design of such studies is challenging, to say the least, and may be flawed, as we have seen, based on the difficulty in setting up controls. This is not the venue to make an eloquent argument for case studies, but until we have the financing, facilities and intelligent design for further RCT's it feel important to continue to document the collective experience.