Chapter 1
Introduction

Responsible Organization

This document is the International Chiropractors Association's (ICA) endeavor to improve its Practice Guidelines. Although the ICA did not update it's Practice Guidelines from 2000-2007, recently in 2007, the ICA adopted the new Practicing Chiropractors' Committee on Radiology Protocols (PCCRP) X-ray Guidelines as its official X-ray guidelines (see at www.pccrp.org). The ICA's previous Practice Guidelines (2000)[1] were rated low in 2003 by a group of chiropractors who claimed "conflict of interest: none".[2] It is the position of the ICA that well-known members of a competing trade association, the American Chiropractic Association (ACA) and/or persons, who may work for insurance companies and managed care organizations, which limit compensation available for chiropractic services, reduce payments to the insured, and increase profits for said insurance companies by using "independent medical examiner's" (IME's), would have a direct conflict of interest.

However, the critique of the ICA's 2000 Practice Guidelines used a new guideline instrument (guideline to evaluate guidelines) termed the Cluzeau instrument,[3,4] that was not readily available at the time of the preparation of the ICA's previous Practice Guideline. The Cluzeau instrument[3,4] and the new Agree Instrument[5] have many suggestions, in the form of 37 questions in 3 categories,[3,4] for the evaluation and improvement of clinical guidelines. The Agree Collaboration (Cluzeau et al) have originated the Agree instrument for evaluating Guidelines.[5] While writing and arranging this ICA Best Practices/Practice Guideline (ICA-BPPG), the ICA has followed both the Cluzeau Instrument[3,4] and the Agree Appraisal Instrument[5] suggestions for guidelines, and those suggestions were of some importance in the compilation of this current guideline.

Purposes and Aims

State, Provincial, Federal, and Common Wealth Laws provide broad x-ray and practice privileges for chiropractors in the USA, Canada, United Kingdom, Europe, Asia, Australia, Africa, and worldwide. Notwithstanding the chiropractic privileges mandated by law in different countries, the goals of a trade organization, such as the ICA, are to provide the promotion of the highest professional, technical, and ethical standards for the chiropractic profession.[6]

Additionally, the ICA has three important purposes for providing these current Practice Guidelines: (1) locate, summarize, categorize, evaluate, and rate the evidence for Chiropractic Care of a variety of health conditions, and (2) assist the practicing Chiropractor in making sound, fundamental, clinical decisions when providing Chiropractic Care in clinical practice. (3) Provide Chiropractic colleges and educational institutions with a document to help assist future chiropractic practitioners in the criterion standard of care.

Since it has been estimated that approximately 7-10% of the USA population seeks chiropractic care,[7] this document is for practicing chiropractors and their millions of patients. It has been suggested that the majority of chiropractic patients seek chiropractic services for spinal (axial) pain syndromes. However, without considering patients with axial pain, patients who have been medical failures with a variety of diseases and structural abnormalities have sought chiropractic care in the past and continue to do so. In fact, our evidence appears to demonstrate that the majority of chiropractic patients prior to the introduction of anti-biotics sought care for a variety of non-pain syndromes, diseases and disorders. Additionally, internationally, many undocumented patients continue to be seen for conditions beyond the traditional "head, neck and low back pain."

Given the fact that chiropractic care is a large part of the complimentary and alternative medicine (CAM) utilization, these ICA Practice Guidelines outline the current state of evidence (see Levels 1-4 below) for the Chiropractic care of a vast variety of health conditions, without limitation to the Cochrane Central Register of Controlled Trials, nor limited by publication date, sample size,

methods, nor outcome. Generally, this document attempts to achieve the utmost in honesty and thoroughness of the chiropractic literature as it currently stands.

The aims of these Guidelines continue in attempt to: (1) support, with evidence from the literature, the routine use of Chiropractic care in a variety of health conditions, (2) support, with evidence, the use of Chiropractic care in pediatric cases, (3) indicate where (conditions, spinal, and general health) chiropractic research is needed, and bring to light any that may exist on this condition , (4) provide Chiropractic College Instructors with the actual, updated, evidence for chiropractic clinical practice, in order that the proper information be shared with prospective chiropractors.

These Guidelines are intended to support the clinical, methodological, and documented decisions made by practicing Chiropractors, not only in the USA and Canada, but also in the world at large.

Standard of care

The most common legal definition of standard of care is how similarly qualified practitioners would have managed the patient's care under the same or similar circumstances. This is not simply what the majority of practitioners would have done. The courts recognize the respectable minority rule. This rule allows the practitioner to show that although the course of therapy followed was not the same as the majority of practitioners would have followed, it is one that is accepted by a respectable minority of practitioners.[8]

While the goals of a trade association (ICA) should include the protection and support of it s members, Standards of Practice must be considered. In the past it could be argued that chiropractic Standards of Practice were derived from the common practices of clinicians and, not only what was taught in chiropractic college curricula, but also what was taught in Technique seminars, postgraduate courses, and "named" Technique textbooks. Recently, research has been added to the necessary sources from which Standards of Practice are derived. Standards of Practice are derived from:

1. Content of Chiropractic College curricula
2. Published research
3. Common practices of clinicians.

Uniqueness of Chiropractic Care

There are several unique factors in chiropractic care that distinguish it from medical care and these must be accounted for in any Practice Guideline for chiropractors. The first is the trilogy of chiropractic's unique foundation of Philosophy, Science, and Art. Whereas the chiropractic triad's philosophy is that the human nervous system controls and coordinates the function of every cell, tissue, and organ in the body and that the Science of Chiropractic demonstrates that chiropractic care alters the structure and function of the nervous system through the spinal column and third, that the art of chiropractic is applied after thorough study of the structure and function of the human body.

The second unique factor is the vertebral subluxation and its adverse health implications. The spinal subluxation has been studied for over 100 years using all levels of evidence. This guideline will further illuminate the extensiveness of the research related to the subluxation and its health implications.

The third unique factor is the difference of chiropractic care attempting to restore normal nervous system structure and function, and thus total improvement of health homeostasis through chiropractic adjustments of the spinal subluxations. This is compared to the current state of medical care that appears to attempt specific diagnosis of a single diseased "part" or system and renders treatment in the form of pharmaceuticals or surgical care.

The fourth is the use of any modalities that are ancillary or preparatory to the chiropractic adjustment. The fifth is the minimal examinations to office visits ratios for (a) care visits and (b) costs. While the medical profession has very high ratios in the favor of diagnostic costs and diagnostic visits compared to its treatment visits, chiropractic has very low ratios of diagnostic visits and costs

compared to care visits. Thus, these items must be discussed before discussing "evidence" for practice guidelines.

Vertebral Subluxation

Contrary to what appears to be a small dissident clique in chiropractic, who have continue to falsely claim that there is no scientific or valid definition of vertebral subluxation, the ICA has defined subluxation as, "any alteration of the biomechanical and physiological dynamics of contiguous spinal structures which can cause neuronal disturbances".[9] Additionally, as noted above, in 2007 the ICA has adopted the PCCRP X-ray Guidelines as its official X-ray Guidelines.[10] Section V of PCCRP[10] has a very complete Biomechanical Description of Subluxation, i.e., referenced from the current biomedical literature and supported by mechanical engineering terminology and theorems. This Section V of PCCRP is consistent with USA State Laws and is consistent with the Federal description under Medicare Laws. Contrary to what the small yet vocal proponents of other guidelines believe, according to a recent 2003 survey by Ohio Northern University, almost 90% of practicing Chiropractors adhere to the tenet that spinal subluxation creates interferences with normal nerve function.[11]

Subluxation Based Care vs Condition Based Care

While the medical profession treats health conditions as isolated occurrences in individual body parts, chiropractors historically, traditionally, and currently adjust the spine and extremities to influence the nervous system, which governs growth and repair of all the body parts. This is a fundamental Philosophical principle in Chiropractic: subluxations, which are abnormal spinal positions, create interferences with normal nervous system functions.

Therefore, Chiropractors may use similar evaluations, management, and similar spinal adjustments on patients with a variety of different health conditions. Thus, while the orthodox medical practitioner may attempt entirely different drugs and surgeries to alleviate the different health conditions of different individuals, chiropractors use similar spinal adjustments (albeit at different spinal levels) and a few different preparatory and/or ancillary modalities to reduce the vertebral subluxations of different individuals. Therefore, while the orthodox medical practitioner provides care for health conditions in individuals, chiropractors provide spinal care for individual patients, who have health conditions.

However, by affecting the malfunction or interferences to normal nervous system function at the spinal level, chiropractic care is expected to result in an improvement in the vast majority of health conditions. As evidence to support the previous statement, chiropractors have published hundreds of Case Reports and Case Series over the past 80 years.

Although there are a multitude of different chiropractic technique methods (so called "Named Techniques"), the majority of published clinical trials supporting chiropractic care have utilized general spinal manipulation. However, in the past two decades, some Named Chiropractic Techniques (Gonstead, Activator, Grostic, CBP, Pettibon, Network, etc) have begun to investigate their methods and their patient outcomes.[10]

General spinal manipulations have many similarities to procedures used by European Manual therapists (Maitland), Physical Therapists (Mobilizations), Osteopaths, Bone Setters, and Medical Manual Therapists. However, general spinal manipulations are not the same as the Chiropractic Diversified procedures, nor are these general spinal manipulations similar to the methods of different Named Chiropractic Techniques. These published RCTs on general spinal manipulations are often performed by non-chiropractors and are confined to pain conditions (acute, subacute, and chronic low back pain, neck pain, and headaches).

In summary, the majority of evidence for the efficacy of chiropractic care for a variety of health conditions exists in "Observational Studies" (Cohorts, Case Series, and Case Reports), while evidence for supporting chiropractic care for musculoskeletal pain conditions exists in a few RCTs (128 are in our 2007 ICA data base) and a few Observational Studies. This is an important realization

for the individual, company, association, committee, State agency, Provincial agency, or Federal agency attempting to design guidelines for the chiropractic profession.

If the guideline designing agent restricts the evidence to meta-analysis, systematic reviews, and/or RCTs, the data will support chiropractic spinal manipulation for pain conditions. On the other hand, if the guideline designing agent allows the inclusion of all the levels of evidence, then chiropractic care for the vast majority of health conditions will be supported. This leads us into a discussion of "Levels of Evidence", limitations of RCTs, and Evidence-Based medicine (EBM) or Evidence-Based Practice (EBP).

Levels of Evidence

In this document we will use the more simplified description of evidence provided by the United States Department of Health and Human Services. This description has some simple definitions that are standard and helpful for the reader. There are only 4 "Levels of Evidence" recognized by the United States Department of Health and Human Services:

- **Level 1**. *Randomized controlled trials*—includes quasi-randomized processes such as alternate allocation.
- **Level 2.** *Non-randomized controlled trial*—a prospective (pre-planned) study, with predetermined eligibility criteria and outcome measures.
- **Level 3.** *Observational studies with controls*—includes retrospective, interrupted time series (a change in trend attributable to the intervention), case-control studies, cohort studies with controls, and health services research that includes adjustment for likely confounding variables.
- **Level 4.** *Observational studies without controls* (e.g., cohort studies without controls, case series without controls, and case studies without controls).[13]

Depending on the country or the consensus of what particular agency or group one is reading, there is a different hierarchy of evidence. Table 1 provides examples that will not be used in this document. Notice that some evidence hierarchies include expert opinion as a level of evidence.[14,15]

As stated above, the levels of evidence is a particularly important topic in Chiropractic where approximately 85% of the evidence exists in Observational Studies (Cohort, Case Series, Case Study). Recent competing guidelines by the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) have used systematic reviews and/or RCTs exclusively, while stating otherwise in their introduction.[17-19] The exclusion of evidence Levels 2-4 by CCGPP created the exclusion of all but three non-pain conditions.[19]

In this present ICA Best Practices/Practice Guideline, all four Levels of evidence will be included. For understanding and for support of our decision to include all levels of evidence, it is important to discuss EBM (EBP) and the limitations of RCTs.

Evidence-Based Medicine and Practice

In chiropractic, starting in the later 1990's, the buzz words "Evidence-Based", "Evidence-based Medicine" (EBM), and "Evidence-Based Practice" (EBP) became a common way to condemn patient care methods ("named" Technique Methods) that did not have published research evaluating all possible aspects of care. Chiropractic IMEs began to use EBM ideas to reduce 3rd party benefits for chiropractic patients. This is in contrast to the real purpose of EBM, which was to improve patient outcomes.

In 2007, Fisher and Wood stated that "evidence-based medicine (EBM) has become a commonplace phrase", with 6 citations found in a Medline search in 1993 ballooning into 24, 692

citations found in 2007.[20] While EBM includes the systematic evaluation of research to aid in the best clinical decision-making, it does not ignore the health care provider's clinical experience.[21]

Table 1
Examples of Hierarchies of Levels of Evidence

New South Wales Department of Health (Australia)[14]	**Institute of Medicine Committee to Advise Public Health Service[15]**	**U.S. Preventive Task Force[16]**	**U.S. Medicare Services Advisory Committee[17]**
Level I: Systematic review of all relevant randomized controlled trials or multi-center randomized controlled trials	**Level I:** Meta-analysis of multiple, well-designed, controlled studies	**Level I**: Evidence obtained from at least one properly randomized controlled trial	**Level I**: Evidence obtained from a systematic review of all relevant randomized controlled trials
Level II: One or more randomized controlled trials	**Level II**: At least one randomized controlled trial	**Level II-1**: Evidence obtained from well-designed controlled trials without randomization	**Level II**: Evidence obtained from at least one properly designed randomized controlled trial
Level III: Controlled trials without randomization; cohorts; case-control analytic; multiple time series; before and after studies	**Level III**: Well-designed quasiexperimental studies: non-randomized, single-group pre-post, cohorts, time series, matched case-control studies	**Level II-2**: Evidence obtained from well-designed cohort or case-control analytic	**Level III-1**: Evidence obtained from well-designed pseudo-randomized controlled trials (eg., alternate allocation)
Level IV: Other Observational studies	**Level IV**: Well-designed non-experimental studies, eg., comparative, correlational, descriptive, case-control	**Level II-3**: Evidence obtained from multiple time series with or without intervention. Dramatic results from uncontrolled experiments	**Level III-2**: Evidence obtained from comparative studies with concurrent controls and allocation not randomized (cohort); Case-control, or interrupted time series without a parallel control group
	Level V: Case reports and clinical examples	**Level III**: pinions of respected authorities based on clinical experience; descriptive studies, case reports, or reports of expert committees	**Level III-3**: Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series with controls
			Level IV: Evidence obtained from case-series (posttest or pretest & posttest)

The goals of evidence-based medicine (EBM) were to improve patient outcomes, quality of care, and provide some standardization of treatment.[22-28] Even though the father of EBM, Sackett,[28-30] stated that all levels of evidence, and clinical experience were to be considered, contrary to this, chiropractic publications and guidelines (CCGPP) relied on RCTs and systematic reviews as the only evidence to be considered. The father of EBM, Sackett,[29,30] defined, EBP as, "The conscientious,

explicit, and judicious use of the current best evidence in making decisions about the care of individual patients."[30] He also stated that EBP "is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions."[30]

Thus reviews of available published evidence are required, but bias is rampant in the levels of evidence excluded[31] and the review committee's rating of selected literature. To have "evidence" on all aspects of a certain care method is nearly impossible in any healthcare discipline, including medicine, dentistry, physical therapy, chiropractic, nutrition, naturopathy, homeopathy, or massage therapy. In 2005, for example, Loria and Arroyo found, by using a linear regression analysis, that the number of Medline published articles is increasing at a rate of 8,142 papers per year. This tremendous amount of evidence would be impossible for the average practitioner of any field to thoroughly read, understand, and implement clinically.[32]

EBP is defined as clinical decision-making based on (1), sound external research evidence combined with *individual clinical expertise* and (2), *the needs of the individual patient*.[30,33] (emphasis added) The goal of EBP is to improve patient outcomes, quality of care, and provide some standardization of treatment.

The question being debated is exactly what does and does not provide evidence in EBM.[33-37] In 2001, Bolton[33] discussed the reliance on RCTs in EBM protocols in chiropractic. She stated that RCTs are better suited in pharmacology studies where all variables can be controlled. While the first few published RCTs on spinal manipulation were important for the chiropractic profession, Bolton noted that RCTs are so narrow in methodology as to not often be useful in clinical practice.[33] She stated that the RCT is unarguably the best design, but randomization and controlled conditions play no part in everyday clinical practice and thus, evidence for effectiveness in that arena cannot be accrued through use of RCTs.[33]

Given the limitations of the RCT in evaluating chiropractic care, Bolton stated that it does not make sense to exclusively pursue the RCT in the future.[33] Additionally she pointed out that qualitative research and outcomes research designs are now being recognized as very meaningful ways of providing the evidence in EBM.[33] The qualitative research design observes the complexity and interaction in clinical context as opposed to isolated parts, while outcomes research design permits measures of outcomes in everyday settings that are relevant and meaningful to patients' lives.[33]

EBP protocols have recently been written for several conditions.[21-28] Understanding the relevance and importance of evidence is an important topic when creating evidence based guidelines. Therefore, in order to create a guideline that is truly evidence-based but still relevant to the profession, all levels of evidence need to be considered. In some cases, chiropractic guideline developers appear to have excluded specific types or levels of evidence for unknown reasons, while relying solely on the RCT.[35]

Recently, Rosenfeld discussed the strengths and limitations of the RCT and the outcomes study.[36] A thorough knowledge of the limitations of the RCT, especially applied in Alternative Health Care such as chiropractic, is vitally important when considering what evidence to use in support for a variety of health conditions. Therefore our next topic is a more in depth evaluation of RCTs versus Observational Studies.

RCT: Gold Standard or Just Another Type of Evidence?

The majority of Evidence Based Practice Centers,[37] Agency for Healthcare Research,[37] Medical School faculty,[37] and the founder of Evidence-Based Medicine[28-30] believe in a hierarchy of evidence (see Table 1). While some have argued that EBM is outrageously exclusionary and similar to fascism in the way it sifts knowledge,[39-44] there have been many who have questioned the exclusive use of RCTs in Evidence-Based Guidelines.[33,44-55]

It is known today that well-done case studies most often demonstrate consistent findings to that of the RCT.[45-49] In fact, "since 1984, the results from case reports have been amazingly consistent with the findings from RCT."[47] For examples:

1. Benson and Hartz[46] stated, *"We found little evidence that estimates of treatment effects in observational studies reported after 1984 are either consistently larger than or qualitatively different from those obtained in randomized, controlled trials."*
2. Rosner[47] stated, *"From this discussion, it is apparent that a well crafted cohort study or case series may be of greater informative value than a flawed or corrupted RCT."*
3. Concato et al[48] stated, *"The results of well-designed observational studies (with either a cohort or a case-control design) do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials on the same topic."* And *"The popular belief that only randomized, controlled trials produce trustworthy results and that all observational studies are misleading does a disservice to patient care, clinical investigation, and the education of health care professionals."*
4. Grossman, etal.[49] stated: *"The randomized controlled trial (RCT) is not a gold standard: it is a good experimental design in some circumstances, but that's all. Potential shortcomings in the design and implementation of RCTs are often mentioned in passing, yet most researchers consider that RCTs are always superior to all other types of evidence."* They continue later, *"Because every study design may have problems in particular applications, studies should be evaluated by appropriate criteria, and not primarily according to the simplistic RCT/non-RCT dichotomy promoted by some prominent advocates of the evidence-based medicine movement and by the research evaluation guidelines based on its principles."*[49]

In 2001, Kaptchuk reported on the history of the development of RCTs and the shortcomings of RCTs that others ignore.[44] Kaptchuk stated that the very act of setting up controls might alter the phenomenon sufficiently to yield quite different results.[44] In 1950, Greiner et al presented the first double-blinded RCT and claimed superiority over all other types of clinical studies.[56] They compared their results to a single-blinded trial. In the 1950s and 1960s, researchers often adopted Greiner & Gold's validation approach for demonstrating the new method's objectivity. However, it was noted that the more stringent the methodology, in randomization and blinding, the less efficacious were the results. Thus, for decades, it was thought that observational studies (less rigorous evidence) over-estimated results, while double-blinded RCTs were the only accurate estimations of results. However, in 1998, Kunz and Oxman[57] analyzed 8 studies comparing randomized and nonrandomized controlled trials on the same intervention from 1977 onward. Of the 8 comparisons, while 5 showed that lack of randomization increased the estimation of treatment efficacy, three did not. Thus, when comparing results from RCTs and Non-RCTs, the deviations of results can go either way, from underestimations to over-estimations.

The above review delineating the value of observational studies is relevant and has significance to the chiropractic profession in as much that the 'birth' of the chiropractic profession was based on a case report by Daniel David Palmer.[58] In other words, if not for the case report, the chiropractic profession would not exist as we know it today.

According to Carr, innovation and advancement in spine care (orthopaedic surgery) has in most cases not been by randomized trial (RCT), but by clinicians developing new techniques or implants and reporting their results in case series.[59]

This is also true in chiropractic, where, since 1900, practicing chiropractors have originated innovative technique methods and reported their outcomes as technique texts, original seminars, case reports, and case series. With a few exceptions, chiropractic college faculty researchers ignore "named" techniques, originated by practicing chiropractors, and spend all their research time and funds on studies utilizing generic spinal manipulation (SMT). These same chiropractic faculty often ridicule the "named" technique methods without investigating them, i.e., condemnation before investigation.

In any healthcare discipline, to have RCTs as evidence on all treatment methods is impossible.[60] As previously suggested, there has been much criticism of the abuses of EBM and EBP.[44-55] In 1997, Kahn et al[61] stated that, for evidence-based practice guidelines (EBGs) to be useful,

they need to consider all the best evidence, including that from controlled trials, case series, and case reports, and they must allow for clinical experience and judgment. We reiterate that well-done case studies most often demonstrate findings consistent with that of the RCT. However, there is at times a financial conflict of interest to consider.[62,63]

Table 2
Definitions of Types of Clinical Evidence[64]

Cost-Benefit & Cost-Effective Analysis	A form of economic assessment, usually from society's perspective, in which the costs of medical care are compared with the economic benefits of the care, with both costs and benefits expressed in units of currency or cost per unit of clinical effect. The benefits typically include reduction in future health care costs and increased earnings due to the improved health of those receiving the care.
Case Study (Single Subject Experimental Design)	The intensive study of individuals through experimental designs such as the ABA, multiple baseline, and alternating treatment designs. Study generally used to test possible causes of a disease or disorder, in an individual who has a designated disorder.
Case-Control Study (**Case-Referent** or **Case-Comparison Study**)	Study generally used to test possible causes of a disease or disorder, in which individuals who have a designated disorder are compared with individuals who do not with respect to previous current exposure to a putative causal factor. For example, persons with hepatic cancer (cases) are compared with persons without hepatic cancer (controls) and history of hepatitis B is determined for the 2 groups. A Case-Control Study is often referred to as a Retrospective Study (even if patients are recruited prospectively) because the logic of the design leads from effect to cause.
Case Series:	A series of patients with a defined disorder. The term usually describes a study reporting on a consecutive collection of patients treated in a similar manner, without a concurrent control group. For example, a surgeon may describe the characteristics of and outcomes for 100 consecutive patients with cerebral ischemia who received a revascularization procedure. *See also* Consecutive Sample.
Cohort:	A group of persons with a common characteristic or set of characteristics. Typically, the group is followed for a specified period to determine the incidence of a disorder or complications of an established disorder (ie, prognosis), as in Cohort Study (prospective study). *See also* Inception Cohort.
Inception Cohort	A designated group of persons assembled at a common time early in the development of a specific clinical disorder (eg, at first exposure to the putative cause or at initial diagnosis), who are followed thereafter. *See* also Cohort.
Cohort Analytic Study	Prospective investigation of the factors that may cause a disorder by comparing a cohort of individuals who do not have evidence of an outcome of interest but who are exposed to the putative cause with a concurrent cohort who are also free of the outcome but not exposed to the putative cause. Both cohorts are then followed to compare the incidence of the outcome of interest.
Crossover Trial:	A method of comparing 2 or more treatments or interventions in which subjects or patients, on completion of the course of a treatment, are switched to another. Typically, allocation to the first treatment is by random process. Participants' performance in a period is used to judge their performance in others, usually reducing variability. *See also* Before-After Trial.
Nonrandomized Control Trial	Experiment in which assignment of patients to the intervention groups is at the convenience of the investigator or according to a preset plan that does not conform to the definition of random. *See also* Randomized Trial.
Randomized Trial (Randomized Control Trial, Randomized Clinical Trial)	Experiment in which individuals are randomly allocated to receive or not receive an experimental preventive, therapeutic, or diagnostic procedure and then followed to determine the effect.

In fact, Latov[62] stated that EBM represents a convergence of financial interests, including Managed Care Organizations (MCOs), which want practice guidelines to control costs and maximize profits. He stated that there is a "diminishing role of practicing physicians in shaping medical policies."[62] Since MCOs use EBGs to decide coverages, Latov went on to state that it is foolish to think that EBP guidelines do not restrict options.[62] "Behind the facade of EBGs, MCOs can determine medical policy with impunity."[62]

For these ICA guidelines, all types of clinical studies will be included as evidence. While the rating of evidence seems useful, the exclusion of all other forms of evidence other than RCTs is unreasonable. Some of the clinical studies that should be considered as providing "evidence" are Single Case Study, Case-Control Study, Case Referent Study, Case-Comparison Study, Case Series, Cohort, Inception Cohort, Cohort Analytical, Survey, Cost Benefit Analysis, Cost Effectiveness Analysis, Crossover Trial, Before-After Trial, Nonrandomized Control Trial, and Randomized Control Trial. Some of the basic science studies providing "evidence" would include anatomical studies, spinal modeling, evaluations of loads, evaluation of stresses and strains, comparisons of alignment in patients and controls (spine or posture), posture and spinal coupling (main motion and coupled motion), and spinal buckling. For clinical treatments, these 10 types of clinical studies are provided (defined) in Table 2.[64]

With the background information presented above, it is obviously important to include all types of evidence. However, it is often forgotten that clinical studies are not the only types or categories of evidence. Some of these other categories of evidence are (but not limited to):

1. Clinical studies (Levels I-IV & Definitions 1-10 listed above);
2. Basic Science studies
   a. Spinal modeling
   b. Evaluations of loads, Stresses, & Strains
   c. Normal & abnormal anatomy
   d. Physiology
   e. Chemical composition of human tissues
   f. Pathological processes;
3. Biomechanics, Spinal alignment & Health studies (e.g., Correlation studies with spinal alignment & health)
4. Mechanical evaluations of medical devices;
5. Reliability and validity studies on clinical devices/procedures.

No RCT Support for EBM

It is quite ironic that Practice Guideline developers often use RCTs as the exclusive "Evidence" on which to base their entire recommendations while no such evidence exists for Evidence Based Medicine itself!

In fact, when asking the question: Does providing evidence-based care improve outcomes for patients?, the Center for Evidence Based Medicine,[65-67] featuring the "Father" of Evidence Medicine, Sackett,[28-30] states that **"*No such evidence is available from randomized trials*** because no investigative team or research granting agency has yet overcome the problems of sample-size, contamination, blinding, and long-term follow-up which such a trial requires"(our emphasis).

In fact in 2003, Burrows et al stated,[68] "The examination of the concepts and practice of EBM by clinicians and academics has led to negative as well as positive reactions. The ensuing discussion and debate has reminded us of 3 limitations that are universal to science (whether basic or applied) and medicine ((1) the shortage of coherent, consistent scientific evidence; (2) difficulties in applying any evidence to the care of individual patients; (3) barriers to any practice of high quality medicine). The debate has also identified 3 limitations that are unique to the practice of EBM. First, the need to develop new skills in searching and critical appraisal can be daunting, although (as we pointed out

above) evidence-based care can still be applied if only the former has been mastered and directed toward pre-appraised resources. Second, busy clinicians have limited time to master and apply these new skills, and the resources required for instant access to evidence are often woefully inadequate in clinical settings. Finally, evidence that EBM 'works' has been late and slow to come."

Ratings of Evidence

The Center for Evidenced Based Medicine (CEBM) describes "Levels of Evidence" as having essentially originated when Suzanne Fletcher and Dave Sackett were working for the Canadian Task Force on the Periodic Health Examination in the late 1970's.[69] They introduced "levels of evidence" for ranking the validity of "evidence". They then submitted "grades of recommendations" (A-D) to the advice given in the report, based upon the extent of evidence reviewed. These ICA Guidelines will use the "grades of recommendation" put forth by Phillips et al,[70] but will slightly modify these to fit the non-clinical levels of evidence. See Table 3.

In the Grades of recommendations in Table 3, it is possible to classify all the clinical and scientific publications that the ICA Best Practices Committee wanted as possible evidence for our ICA Guidelines.

However, for this first edition, reliability, validity, population studies, biomechanical, and anatomical studies were not considered (except in the Outcome Assessment Chapter), only clinical studies with patient outcomes were included.

Table 3.
Grades of Recommendation from Phillips et al.[70]

Type of Study	Grades A-D	Grades a-d
Clinical Level I	**A**= Consistent Level I Studies	
Clinical Level II	**B**= Consistent Level II Studies	
Clinical Level III	**B**= Consistent Level III Studies	
Clinical Level IV	**C**= Consistent Level IV Studies or Extrapolations from Level II or III	
Expert Opinion V	**D**= Level V Evidence or Inconsistent Studies of Levels I-IV	
Population Study		**a**= Conistent Class I Studies, **b**= A single Class I Study or Consistent Class II and III Studies, **c**= Consistent Class IV Studies, **d**= Inconclusive Evidence
Basic Science/ Biomechanics/ Validity Study		**a**= Consistent Studies **b**= A Single Positive Study **d**= Inconclusive Studies
Reliability Study		**a**= Conistent Class I Studies, **b**= A single Class I Study or Consistent Class II Studies, **c**= A Single Class II Study **d**= Inconclusive Evidence

There are some additional ideas of how to rate Observational studies.[71-74] While most believe that Observational Studies cannot be rated due to the lack of research design aspects found in RCTs, in 2000, Stroup et al.[74] reported on a method to perform a Meta-analysis of observational studies in epidemiology. Table 4 is the check list for rating Observational Studies proposed by Stroup et al.

The Agency for Healthcare Research and Quality (AHRQ) in the US has recently published a document titled "Systems to Rate the Strength of Scientific Evidence." [http://healthit.ahrq.gov/search/ahrqsearch.jsp]

1. In general, empirical research has shown that quality scores (numeric scores based on arbitrary weights given to each item in a scale) are arbitrary, unreliable, and hard to interpret (Juni JAMA 1999;282(11):1054-60)
2. Our suggestion, therefore, is not to use quality scores
3. We suggest the approach of using individual components of a checklist (and rating such as 'met, partially met, not met').

Costs, Risks versus Benefits

According to Fisher and Wood,[20] there are 5 steps involved in the practice of EBM: 1) defining a question or problem, (2) searching for the evidence, (3) critically appraising the evidence, (4) applying the results, and (5) auditing the outcome. While this outline fits well with condition-based care, as described above, it does not fit well with chiropractic care, especially item #1. Thus, for item #1 in this document, we formulated some general questions discussed above in our purposes and aims.

Table 4.
Proposed Rating Checklist of Observational Study Adapted from Stroup et al.[74]

Reporting of Back ground	Problem definition & Type of Study design
	Hypothesis statement
	Description of study outcomes
	Study population and subject characteristics(age, sex, ht, wt, city)
Reporting of Search strategy	State who did the searches
	Search strategy, time period, search words used
	Effort to include all studies
	Databases searched & Search software used
	Use of any hand searches
	List of citations found, & those excluded
	Were languages other than English used
	Description of contact with any authors of citations
Reporting of Methods	Describe relevance of studies
	Rationale for selection & coding of data
	Assessment of confounding factors, heterogeneity, & Study quality
	Description of statistical methods
	Provision of tables & graphs
Reporting of Results	Summarizing study estimates & overall estimates
	Results of sensitivity testing (subgroup analysis)
	Statistical analysis of uncertainty
Reporting of Discussion	Quantitative assessment of bias
	Justification of exclusion of subjects
Reporting of Conclusions	Consideration of alternative explanations
	Generalization of conclusions
	Guidelines for future research
	Disclosure of funding source.

Additionally, Fisher and Wood[20] stated, “Treatment recommendations evolving from critical appraisal, however, are no longer just based on levels of evidence, but also the risk benefit ratio and cost.” These (risk benefit ratio and cost) are extremely important aspects of Chiropractic care. In the next section, it is shown that chiropractic care has a very low risk benefit ratio and very low costs compared to standard medical care.

The very low risk benefit ratio and the very low costs of chiropractic care indicate that guidelines are not needed to restrict and control chiropractic care. In fact, evidence in Chapter IV indicates that more utilization of chiropractic services would result in more saving in reduced utilization of medical services.

Evidence for Medicine, CAM & Chiropractic

While Chiropractic is being criticized for not having research to support its care methods, one might ask how much of orthodox medicine is evidence based?

Recently from the British Medical Journal’s website (BMJ),[75] one can determine that of about 2500 treatments supported by good evidence, only 15% of treatments were rated as beneficial, 22% as likely to be beneficial, 7% part beneficial and part harmful, 5% unlikely to be beneficial, 4% likely to be ineffective or harmful, and in the remaining 47% the effect of the treatment was "unknown." The text says, "The figures suggest that the research community has a large task ahead and that most decisions about treatments still rest on the individual judgments of clinicians and patients." On 9 October 2007 the situation had changed-but not for the better. Treatments rated "beneficial" had decreased from 15% to 13%.

Thus, in conclusion for this chapter, we note that (1) Chiropractic has a spinal adjustment approach to health care, while medicine has a condition approach, (2) there are generally accepted Levels of Evidence, (3) RCTs are not the “Gold Standard” that has been traditionally accepted since 1950, (4) RCTs and Observational Studies on the same topic can have varying results that may be under-estimated or over-estimated, (5) Evidence Based Medicine has its flaws, one of which is that there is no RCT supporting evidence for EBM, (6) Observational studies often have consistent results to RCTs, (7) Evidence includes, not just RCTs, but non-randomized studies and the experience of the clinician, and (8) an accepted method of rating Observational studies is to give points for items that are present in the paper, while no points are given for important items omitted.

These ICA Guidelines will follow Sloop et al’s suggestion[74] in tem #8 above when rating Observational studies and RCTs.

References

1. International Chiropractors Association. Recommended clinical protocols and guidelines for the practice of chiropractic. Arlington, VA: International Chiropractors Association; 2000.
2. Cates JR, Young DN, Guerriero DJ, Jahn WT, Armine JP, Korbett AB, Bowerman DS, Porter RC, Sandman T, King RA. An independent assessment of chiropractic practice guidelines. J manipulative Physiol Ther 2003; 26(5): 282-286.
3. Cluzeau FA, Littlejohns P, Grimshaw JM, Feder G. Appraisal instrument for clinical guidelines. London: St. George’s Hospital Medical School; 1997: 1-5.
4. Cluzeau FA, Littlejohns P, Grimshaw JM, Feder G, Moran SE. Development and application of a generic methodlogy to assess the quality of clinical guidelines. Int J Qual Health Care 1999; 11(1): 21-28.
5. AGREE Collaboration. Agree Instrument: Appraisal of Guidelines for Research and Evaluation. London: St. George’s Hospital Medical School; 2001: 1-22.:

6. Constitution of the international Chiropractors Association. 2006 Article 1. Arlington, Virginia: International Chiropractic Association, 2006.
7. Hurwitz EL, Coulter D, Adams AH, Genovese BJ, Shekelle PG. Use of chiropractic services from 1985 through 1991 in the United States and Canada**.** Am J Public Health. 1998;88(5): 771–776.
8. 'Lectric Law Library. Standard of Care. http://www.lectlaw.com/files/exp24.htm
9. Constitution of the international Chiropractors Association. 2006 Article 1; section 4, definitions. Arlington, Virginia: International Chiropractic Association, 2006.
10. Harrison DE. Editor of PCCRP. Practicing Chiropractors' Committee on Radiology Protocols. Arlington, VA: International Chiropractors Association; 2007. Accessed January 1, 2008 at www.pccrp.org.
11. McDonald W, Durkin K, Iseman S, Pfefer M, Randall B, Smoke L, Wilson K. How Chiropractors Think and Practice. The survey of North American Chiropractors. Ohio Northern University: The Institute for Social Research, 2003.
12. United States Department of Health and Human Services. Levels of Evidence. at http://www.ahrq.gov/
13. Liddle J, Williamson M, Irwig L. Method of evaluating research and guideline evidence. Sydney: NSW Department of Health, 1996.
14. Preventive Services Task Force. Guide to clinical preventive services: Report o the U.S. Preventive Services Task Force. Baltimore: Williams & Wilkins, 1996.
15. Institute of Medicine Committee to Advise the Public Health Service on Clinical Practice. Clinical Practice Guidelines: Directions for a new program. Washington, DC: National Academy Press, 1990.
16. Medicare Services Advisory Committee. Funding for new medical technologies and procedures: Application and assessment guidelines. Canberra: AusInfo, 2000.
17. Triano JJ. What constitutes evidence for best practice?, Introduction in Chiropractic Best Practices: A Systematic review by the Research Commission of the Council on Chiropractic Guidelines and Practice Parameters, http://www.ccgpp.org/LB%20draft%20with%20highlights.pdf , accessed Oct 2007
18. Meeker W. Team Lead for Best Practices: Chiropractic management of low back pain and low back related leg complaints. Low Back Chapter in Chiropractic Best Practices: A Systematic review by the Research Commission of the Council on Chiropractic Guidelines and Practice Parameters, http://www.ccgpp.org/LB%20draft%20with%20highlights.pdf , accessed Oct 2007.
19. Hawk C. Team Lead for Literature Synthesis: Chiropractic management of prevention and health promotion; nonmusculoskeletal conditions; and conditions of the Elderly, Children, and Pregnant Women. Chapter in Chiropractic Best Practices: A Systematic review by the Research Commission of the Council on Chiropractic Guidelines and Practice Parameters, http://www.ccgpp.org/ accessed Oct 2007.
20. Fisher CG, Wood KB. Introduction to and Techniques of Evidence-Based Medicine. Spine 2007; 32(19S):S66-S72.
21. Lipman G. Evidence-based pain management and palliative care. J Pain Palliat Care Pharmacother 2002; 16(2): 1-3.
22. Fishbain DA, Cutler RB, Rosomoff HL, Rosomoff RS. Can patients taking opioids drive safely? A structured evidence-based review. J Pain Palliat Care Pharmacother 2002; 16(1): 9-28.
23. Rossdale PD, Jeffcott LB, Holmes MA. Clinical evidence: an avenue to evidence-based medicine. Equine Vet J 2003; 35(7): 634-35.
24. Caramanica L, Cousino JA, Petersen S. Four elements of a successful quality program. Alignment, collaboration, evidence-based practice, and excellence. Nurs Adm Q 2003; 27(4): 336-43.

25. Jordan KM, Arden NK, Doherty M, et al. EULAR recommendations 2003: an evidenced based approach to the management of knee osteoarthritis: Report of a Task force of the standing committee for the International Clinical Studies Including Therapeutic Trials. Ann Rheum Dis 2003; 62(12): 1145-55.
26. Wassem RA, Stillion-Allen KA. Evidence-based management of the fibromyalgia patient. In search of optimal functioning. Adv Nurse Pract 2003; 11(11): 34-38, 41-43.
27. Hasenfeld R, Shekelle PG. Is the methodological quality of guidelines declining in the US? Comparison of the quality of US Agency for Health Care Policy and Research (AHCPR) guidelines with those published subsequently. Qual Saf Health Care 2003; 12(6): 428-34.
28. Sackett DL. Evidence-based medicine. Editorial. *Spine* 1998;23(10):1085-6.
29. Sackett DL, Richardson WS, Rosenberg W, Haynes RB. *Evidence-Based Medicine: How to Practice and Teach* EBM. New York: Churchill Livingstone, 1997.
30. Sackett DL, Rosenberg WMC, Gray JAM, et al: "Evidence based medicine: what it is and what it isn't." *BMJ* 1996;312:71-72.
31. Davison KW, Goldstein M, Kaplan RM, et al. Evidence-based behavioral medicine: What is it and how do we achieve it? Ann Behav Med 2003; 26(3): 161-71.
32. Loria A, Arroyo P. Language and country preponderance trends in MEDLINE and its causes. J Med Libr Assoc 2005 93(3):381-385.
33. Bolton JE. The evidence in evidence-based practice: what counts and what doesn't count? J Manipulative Physiol Ther 2001;24:362-366.
34. Bolton JE. Whence the evidence from evidence-based practice? Br J Chiropr 2000;4:2-3.
35. Triano JJ. CCGPP: Best Practice "The process to select relevant research". http//www.ccgpp.org.
36. Rosenfeld RM. Meaningful outcomes research. In: Isenberg SF, ed. Managed care, outcomes and quality. New York: Thieme, 1998:99-115.
37. Atkins D, Fink K, Slutsky G. Better information for better health care: The evidence-based practice center program and the agency for healthcare research and quality. Ann Internal Med 2005;142(12-part 2):1035-45.
38. Brighton B, Bhandari M, Tornetta P, Felson DT. Part I: Issues in the design of orthopaedic studies. Hierarchy of evidence: From case reports to randomized controlled trials. Clin Orthop Related Res 2003;413:19-24.
39. Holmes D, Murray SJ, Perron A, Rail G. Deconstructing the evidence-based discourse in health sciences: truth, power and fascism. Int J Evid Based Healthcare 2006; 4:180-86.
40. Holmes D, Perron A, O'Bryrne P. Evidence, virulence, and the disappearance of nursing knowledge: A critique of the evidence-based dogma. Worldviews Evid Based Nurs 2006; 3(3):95-102
41. Healy B. Who says what's best? US News & World Report 2006; September.
42. Hunink MGM: "Does evidence based medicine do more good than harm?" *BMJ* 2004;329:1051. http://bmj.bmjjournals.com/cgi/content/full/329/7473/1051
43. Horwitz RI. The dark side of evidence-based medicine. Cleveland Clinic Journal of Medicine 1996;63: 320-323.
44. Kaptchuk TJ. The double-blind, randomized, placebo-controlled trial: Gold standard or golden calf? J Clin Epidem 2001;54:541-549.
45. Venning GR. Validity of anecdotal reports of suspected adverse drug reactions: The problem of false alarms. BMJ 1982;284:249-252.
46. Benson K, Hartz AJ. A comparison of observational studies and randomized controlled trials. N Engl J Med 2000;342:1878-1886.
47. Rosner A. Fables or Foibles: Inherent problems with RCT's. J Manipulative Physiol Ther 2003;26(7):460-467.
48. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. New England J Medicine 2000;342(25):1887-1892.

49. Grossman J, Mackenzie FJ. The randomized trial: Gold standard, or merely standard? Perspectives Biol Med 2005;48(4):516-34.
50. McKee M, Britton A, Black N, et al. Interpreting the evidence: choosing between randomized and non-randomized studies. British Med J 1999;319:312-315.
51. Kent C: "Evidence-based chiropractic: fad, folly, or fascism?" *The Chiropractic Journal*. Jan 2007. http://www.worldchiropracticalliance.org/tcj/2007/jan/kent.htm
52. Worrall J. Why there's no cause to randomize. Brit J Phil Sci 2007;58:451-488.
53. Norris SL, Atkins D. Challenges in using nonrandomized studies in systematic reviews of treatment interventions. Ann Internal Med 2005;142(12-part 2):1112-1119.
54. Merritt L. Case reports: an important contribution to chiropractic literature. J Can Chiropr Assoc 2007; 51(2):72-74.
55. Bluhm R. From Hierarchy to network: A richer view of evidence for evidence-based medicine. Perspectives in Biol Med 2005;48(4):535-47.
56. Greiner T, Gold H, Cattell M, Travell J, Bakst H, Rinzler SH, Benjamin ZH, Warshaw LJ, Bobb AL, Kwit NT, Modell W, Rothendler HH, Messeloff LJ, Kramer ML. A method for the evaluation of the effects of drugs on cardiac pain in patients with anina on effort. A study of Khellin (Visammin). Am J Med 1950;9:143-155.
57. Kunz R, Oxman AD. The unpredictability paradox: review of empirical comparsons of randomized and non-randomized clinical trials. Br Med J 1998;317:1185-1190.
58. Lillard H. In: Palmer DD, Editor. The Chiropractor 1897;17:3.
59. Carr AJ. Evidence-based orthopaedic surgery. J Bone Joint Surg Br 2005; 87:1593-94.
60. Caplan LR. Editorial. Evidence based medicine: concerns of a clinical neurologist. J Neurol Neurosurg Phsychiat 2001; 71:569-576.
61. Kahn DA, Docherty JP, Carpenter D, Frances A. Consensus methods in practice guideline development: a review and description of a new method. Psychophamacol Bull 1997; 33:631-38.
62. Latov N. Evidence-Based Guidelines: Not Recommended. J Amer Physicians Surgeons 2005; 10(1):18-19.
63. AMA News in Brief. Michigan Blues introduce bonus program. American Medical News 2004; Dec:18.
64. Archives of Physical Medicine and Rehabilitation. Information to Authors. http://www.archives-pmr.org/authorinfo.
65. Center for Evidence Based Medicine. University of Toronto. http://www.cebm.utoronto.ca/]
66. Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-based Medicine: How to Practice and Teach EBM. Second Edition. Churchill Livingstone: Edinburgh, 2000.
67. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-based Medicine: How to Practice and Teach EBM Third Edition. Churchill Livingstone: Edinburgh, 2005.]
68. Burrows E, Johnston R, Raulli A, Bryan E. Methodology for assessing the effectiveness of interventions for which case series evidence only is available to inform policy decisions in Australia. *Annu Meet Int Soc Technol Assess Health Care Int Soc Technol Assess Health Care Meet.* 2003; 19: abstract no. 232. http://gateway.nlm.nih.gov/MeetingAbstracts/102276150.html
69. Canadian Task Force on the Periodic Health Examination: The periodic health examination. CMAJ 1979;121:1193-1254.
70. Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, Dawes M. Levels of Evidence and Grades of Recommendation. http://www.cebm.net/levels_of_evidence.asp. Accessed July 10th, 2006.
71. School of Public Health. Systematic reviews of non-experimental (observational) studies. UC Berkeley. 2002.
72. Wells GA , et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. http://www.lri.ca/programs/ceu/oxford.htm

73. Agency for Healthcare Research and Quality (AHRQ). http://healthit.ahrq.gov/search/ahrqsearch.jsp
74. Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, Moher D, Becker BJ, Sipe TA, Thacker SB. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA. 2000 Apr 19;283(15):2008-12.
75. British Medical Journal (BMJ) website: http://www.clinicalevidence.bmj.com/ceweb/about/knowledge.jsp