

Draft Standards of Practice Guidelines : Chiropractic Care of Children
Chiropractors Registration Board of Victoria

An *ab intio* approach to evaluating any practice guidelines begins with a validated and internationally accepted tool for assessing the quality of guidelines. Towards this end, the Appraisal of Guidelines Research and Evaluation (AGREE)¹ instrument was used to assess the quality of the practice guideline (the Guidelines) on the chiropractic care of children as released by the Chiropractors Registration Board of Victoria (the Board). AGREE is the result of an international collaboration of researchers and policy makers who sought to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment. The AGREE Instrument is a 23-item questionnaire that address the 6 domains or dimensions of the quality of a practice guideline. These domains are:

1. Scope and Purpose: Concerned with the overall aim of the guideline, the specific clinical questions and the target patient population.
2. Stakeholder Involvement: Focuses on the extent to which the guideline represents the views of its intended users. Guideline development should involve all stakeholders whose activities are likely to be covered in the proposed guideline. This should also include patient groups.
3. Rigour of Development: Relates to the process used to collect and synthesize the evidence, the methods to formulate the recommendations and to update the guideline. This includes information about the literature searches that were carried out, the criteria used to select the evidence and the methods used for formulating the recommendations. The recommendations should be explicitly linked to the supporting evidence.
4. Clarity and Presentation: Deals with the language and format of the guideline. Clinicians need simple, patient-specific, user-friendly guidelines that are easy to understand. A good guideline presents clear information about the management options available and the likely consequences of each option.
5. Applicability: Pertains to the likely organizational and cost implications of applying the guideline.
6. Editorial Independence: Concerned with the independence of the recommendations and acknowledgement of possible conflict of interest from the guideline development group.

Scope and Purpose of the Draft Proposal

1. The overall objective(s) of the guideline is (are) specifically described.

There is no doubt that this Guideline on the chiropractic care of children will impact chiropractors and the population they serve. The overall objective(s) of the guidelines are stated as:

(a) To assist the practitioner in providing acceptable standards of care for the treatment of children and

(b) To protect the public by assisting the practitioner to comply with the Act and avoid allegations of unprofessional conduct.

Standards of Care may be defined as, “Level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.”²

Clinical Practice Guidelines is defined by the Institute of Medicine as, “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”³

The above definitions would seem to be incongruent in that one has legal implications whereas the other involves optimizing patient care. Rosenfeld and Shiffman⁴ defined what guidelines are not and state:

- Guidelines are NOT reimbursement policies.
- Guidelines are NOT performance measures.
- Guidelines are NOT legal precedents.
- Guidelines are NOT measures of certification or licensing.
- Guidelines are NOT for provider selection or public reporting.
- Guidelines are NOT recipes for cookbook medicine.

The Guidelines as written have not considered these aspects. Practice guidelines represent the best judgment of the guidelines developers based on the best scientific evidence for a particular topic. Practice guidelines are NEVER intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance⁵. According to Rosenfeld and Shiffman⁴, clinicians should always act and decide in a way that they believe will best serve

their patients' interests and needs, regardless of guideline recommendations. As written, the Guidelines has not taken the above statements into consideration.

2. The clinical question(s) covered by the guideline is(are) specifically described.

The guideline is lacking in providing detailed description of specific clinical scenarios for the chiropractor on the chiropractic care of children. The **Introduction** section is seriously lacking. The statement on risk/benefit analysis was inadequate given the seriousness and implications of this document for chiropractors and their patients. It is commonly believed that practice guidelines can improve the quality, appropriateness, and cost-effectiveness of health care interventions³ and provide valuable educational tool for clinicians, future clinicians and the general public⁶. The relevance of practice guidelines should have been discussed in the context of the practice of pediatric chiropractic. For example, an examination of pediatric chiropractic in the context of complementary and alternative medicine (CAM) for children would provide an understanding and possible justification for clinical practice guidelines for chiropractors. Consider that approximately 20% to 40% of healthy children seen in outpatient pediatric clinics⁷⁻¹⁰ and more than 50% of children with chronic, recurrent, and incurable conditions use CAM, almost always in conjunction with mainstream care¹¹⁻¹³. Smith and Eckert¹⁴ performed a cross-sectional, population-based survey of 2985 adult and 911 children aged 15 years or less, in South Australia and found the overall 12-month prevalence of CAM use in children was 18.4% or approximately 1 in 5 children. A variety of CAM modalities were used by children including ingestible therapies (33%), chiropractic (34%) and massage (20%). Common reasons for using CAM were to prevent illness or to maintain health (39%) and for musculoskeletal conditions (22%), respiratory problems (20%) and skin complaints (18%). In the interest of public health, the training of chiropractors places them in a unique position to counsel such patients on the use of nutritional supplements, dietary interventions, and to maintain health and prevent illness¹⁵⁻¹⁶. The Guidelines has failed to address this trend in pediatric care and the important role that chiropractors play in health promotion and disease prevention. According to Kemper et.al.¹⁷, factors to consider in a risk/benefit analysis should include the severity and if the illness is acute or chronic; the effectiveness of "conventional care"; the degree of invasiveness; toxicities and adverse effects of conventional treatment; the quality of evidence for safety and effectiveness; the family's understanding of informed consent, voluntary acceptance of those risks, and persistence of the family's intention to use the specific services. These have not been considered by the Guidelines as written. The chiropractic care of children adheres

to the principle of *primum non nocere*¹⁸. Chiropractic is the most popular form of CAM therapy for children^{19,20}. Recent studies indicate that pediatric chiropractic is safe^{21,22} with only anecdotal evidence to indicate adverse events. With respect to effectiveness, principles of evidence-based practice must be adhered to at all times²³. A number of systematic reviews have been published on the chiropractic care of children²⁴⁻²⁶. What information did these systematic reviews provide in the development of these guidelines and what deficits/limitations do they present in the context of a non-allopathic intervention such as the chiropractic care of children? Chiropractic is a holistic and vitalistic approach to patient care, having both specific and non-specific effects, invoking multi-factorial elements to the clinical encounter. A Whole Systems approach to patient care, involving specialized knowledge and expertise through individualized non-reductionist approach to the diagnosis and treatment of patients are now advocated by CAM practitioners²⁷⁻²⁹. How has this Guideline given Whole Systems patient care due consideration?

General comments on the “significant anatomical, physiological, neurodevelopmental and psychological differences between children and adults” are inadequate. What are some specifics to guide the clinician in the implementation of these guidelines? Consider that the primary approach to the chiropractic care of children is the use of the chiropractic adjustment (aka: spinal manipulative therapy) to address sites of spinal and extraspinal subluxations (aka: segmental dysfunctions)³⁰⁻³¹. The application of a manual procedure must take into consideration the unique biomechanical features of the pediatric spine. These unique characteristics have been described in the context of pediatric care³². A growing pediatric spine, and characteristics of malleability, adaptability, hypermobility, a changing spinal contour, changing applied forces and overall, an immature neuromusculoskeletal system must be considered in the totality of the clinical encounter.

3. The patients to whom the guideline is meant to apply are specifically described.

The target population covered by the guideline is inadequately described. The patient population is described as: “*Child: A person between the ages 0-13 years (approximately).*” What is “approximately”? What is the basis of this age range for the patient population? In characterizing the chiropractic care of children, Lee et.al.³⁰ defined “children” as <21 years of age as per the American Academy of Pediatrics. The National Board of Chiropractic Examiners Job analysis of Chiropractic³³ defined the pediatric population as <17 years of age. Specific conditions mentioned in the guideline such as scoliosis involve the care of children beyond the age of 13 years³⁴. Consider the care of children with low back pain.

There are indicators that children with low back pain, if not addressed, have low back pain beyond 13 years of age and well into adulthood³⁵. These have not been given due consideration in the Guidelines.

Stakeholder Involvement in the Draft Proposal

4. The guideline development group includes individuals from all the relevant professional groups.

The Guidelines do not refer to any chiropractors involved in the development process except for the acknowledgement of Daryl Efron, MD and Randy Ferrance, MD for their “valuable input.” Who reviewed/rated the evidence to support the guideline recommendations. Who externally reviewed the guidelines prior to their release? What are their disciplines and relevant expertise to the guideline development. It is unconscionable that two medical doctors were consulted for the development of this chiropractic guideline and yet no chiropractic expertise was included. Since this Guidelines was stated as a “standards of care”; were members of the legal profession invited for their input? Were 3rd party payor (i.e., insurance) input sought? Why or why not?

What is Dr Efron’s specialty and expertise in the context of the Guideline development in pediatric chiropractic that was sought for input? A *google* of Dr Efron finds his expertise listed on a University of Melbourne website “Find An Expert”³⁶ His qualifications are stated as:

- Bachelor Medicine & Surgery
- Principal Investigator of “Building preschooler’s emotional competence: evaluating an early intervention for children with behavior problems” and funded by the Aust Rotary Health Research Fund in 2006
- He has numerous publications in book chapters and various medical journals. As a co-author in the implementation of evidence-based guideline for asthma³⁷ and CAM therapies for children with ADHD³⁸, what was his expertise? What were they paid?

What was Dr Ferrance’s specialty and expertise to the development of these Guidelines? Dr Ferrance is well known in the pediatric chiropractic arena in the United States for his contribution as a member of the Council on Chiropractic Guidelines and Practice

Parameters (i.e., referred to as CCGPP) on the “Chiropractic management of prevention and health promotion; non-musculoskeletal conditions; and conditions of the elderly, children and pregnant women.”³⁹ He is licensed as a chiropractor and medical doctor (Internal Medicine & Pediatrics). In addition to his hospital affiliation(s), he works for or has worked for one of the largest malpractice insurance carriers for chiropractors in the United States – National Chiropractic Malpractice Insurance Carrier (NCMIC)⁴⁰⁻⁴¹. The extent of his work as a consultant for other organizations (i.e., the insurance industry in the United States and elsewhere) remains to be revealed. What were his contributions to the development of this Guideline? Pediatric chiropractic is said to be often inconsistent with medical guidelines³⁰. The question therefore remains as to his expertise as a chiropractor in the care of children. Based on his writings and philosophical bent⁴²⁻⁴⁴, Dr Ferrance’s involvement in this process or any guideline process in chiropractic for that matter is suspect to “conflicts of interest” and divisiveness. Finally, the involvement and influence of Drs. Efron and Ferrance in the creation of this guideline may be reflected in the focus of the Guideline recommendations for immediate medical referral rather than a focus on the chiropractic care of children.

5. The patients’ views and preferences have been sought.

Information about experiences and expectations from parents and their children did not contribute to the development of this Guidelines. There is no evidence that patient/parent representatives or literature from the parent/patient perspective was included. Consider that a recent survey of patients from the United States, Europe and Australia found that more than 40% of chiropractic patient visits were initiated for the purposes of health enhancement and/or disease prevention and not necessarily for a specific condition⁴⁵. Rubin triaged the presenting complaints of new and existing pediatric and pregnant patients⁴⁶. In the pediatric patient population; in addition to the common conditions of childhood such as otitis media, respiratory complaints, etc., “wellness care” was a common reason for seeking care. The Guidelines has not taken this into consideration.

The Board commented:

“Some parents seek chiropractic care for “Type O” conditions for their children. The Board is of the view that there is currently an overwhelming lack of good quality scientific evidence to support the use of spinal manipulation in the treatment of most of these conditions. “

What evidence supports this point of view? According to Cohen⁴⁷, 4 basic principles of

biomedical ethics should include : (1) respect for patients' autonomy; (2) nonmaleficence (avoiding harm); (3) beneficence (putting the patient's interest and well-being first); and (4) justice (fairness in providing access to essential care). This seems to have been dismissed or overlooked on the part of the creators of this Guideline.

6. The target users of the guideline are clearly defined.

The target users are chiropractors. However, given the stated objectives in this Guidelines; are members of the legal profession, governmental agencies, and medical doctors the target users as well?

7. The guideline has been piloted among target users.

There is no documentation that the Guidelines was piloted before released on the website.

Rigour of Development of Draft Document

8. Systematic methods were used to search for evidence.

Disappointingly, no evidence has been put forth in the creation of this Guideline. As defined by Sackett and colleagues⁴⁸, evidenced-based practice is the explicit, conscientious, and judicious use of the current best research evidence, the integration of the clinical expertise of the clinician and the thoughtful identification and compassionate use of an individual patient's predicaments, rights, and preferences in making clinical decisions about their care. The Guideline developers have failed to apply the basic principles of evidence-based practice.

9. The criteria for selecting the evidence are clearly described.

No evidence was provided. Therefore no criteria for selection of evidence are clearly described.

10. The methods used for formulating the recommendations are clearly described.

Was there a consensus process (i.e., Delphi and Glaser Techniques, etc.) to formulate the recommendations contained in the Guidelines? Clearly, no description was provided and therefore does not exist.

11. The health benefits, side effects and risks have been considered in formulating the recommendations.

Health benefits, side effects, and risks have not been evaluated in the context of recommendation of these Guidelines.

12. There is an explicit link between the recommendations and the supporting evidence.

There does not exist an explicit link between the recommendations made in this guideline and the evidence on which they are based upon.

13. The guideline has been externally reviewed by experts prior to its publication.

The Board is to be commended on their requests for “any comments or suggestions about the content of any of these documents.” It is understandable that chiropractors and pediatric chiropractic organizations and experts would have a vested interest in providing feedback but the Board has not indicated a means of including patient representation in these feedbacks. Nor are there any indicators that this Guideline was reviewed by “experts” except Drs. Ferrance and Efron.

14. A procedure for updating the guideline is provided.

No procedure has been described to reflect current research.

Clarity and Presentation of Draft Document

15. The recommendations are specific and unambiguous.

The Guidelines as presented have failed to provide specific and unambiguous recommendations.

An example of a vague recommendation involves the following:

“Many paediatric musculoskeletal conditions are amenable to chiropractic care, either alone, or in conjunction with other health care professionals.”

This statement is reflective of the lack of supporting evidence in this Guideline. What musculoskeletal (MSK) conditions are being referred to in the above statement? A simple review of the literature using Pubmed [1965-2008] with the search terms “musculoskeletal conditions AND chiropractic” limited to All Child: 0-18 years revealed 11 possible relevant articles. None of them addressed the issue of effectiveness of

chiropractic in the pediatric population. The search term “low back pain” in the same context revealed the studies by Ebrall⁴⁹⁻⁵⁰ on his work with the anthropomorphic and epidemiology of adolescent low back pain. Hayden⁵¹ described the chiropractic management of low back pain in patients (N=54) between the ages of 4 and 18 years, as well as outcomes and factors associated with the outcomes. When “neck pain” was the search term, no publications were found. It is appreciated that evidence is not always so clear-cut and that “absence of evidence is not evidence of absence.” However, the Guideline developers failed to address even the most rudimentary aspects of “clinical uncertainty” and the experience of chiropractors in the care of children, given the lack of evidence.

16. The different options for management of the condition are clearly presented.

A guideline should consider the different possible options for screening, prevention, diagnosis or treatment of the condition it covers. Aspects of these were covered superficially in the Guidelines.

On the issue of Screening, the Guidelines recommended:

(A) ‘Screening’ for health problems may be associated with harms such as false positives which may generate anxiety, resulting in unnecessary treatment.

(B) The results of any test or procedure used with screening must be valid, reliable, and reproducible.

(C) It is not appropriate for the health professional who conducts a public screening to offer to provide intervention for identified problems - this represents a conflict of interest. Further, chiropractors must have the pre-requisite training and experience in the conditions being investigated in such screenings.

No evidence was provided to support the above recommendations. What specific conditions are being referred to? What clinical conditions are associated with “falls positives” referred to in the Guidelines? Considers two aspects of pediatric chiropractic - scoliosis screening and idiopathic adolescent spinal pain. Scoliosis screening have been shown to clinically benefit many children through early detection and treatment, as it is clearly stated in the Consensus Paper which has been published by the Society on Scoliosis Orthopaedic and Rehabilitation Treatment⁵². Chiropractors are more than adequately trained to perform scoliosis screening⁵³. With respect to adolescent spinal pain, an excellent review on the topic was provided by Jeffries and colleagues⁵⁴.

According to Jeffries and colleagues, there is strong evidence that pain prevalence increases with age in the adolescent period (i.e., defined as age 10-19 years of age⁵⁵), with a predisposition towards girls, possibly corresponding with the time of puberty. Their review also indicates that based on longitudinal studies, adolescent spinal pain, including the “back,” “neck and shoulder,” and “low back,” is significantly associated with spinal pain in adult life. Idiopathic adolescent spinal pain (IASP) and its potential causes have been a concern to both clinicians and researchers. IASP is thought to have at its underpinning a biopsychosocial model including postural abnormalities⁵⁶⁻⁵⁷. Incorrect posture has been implicated in the pathophysiology of low back pain in children⁵⁸ and is considered a risk factor for low back pain. Note that the system of postural reflex control does not reach maturity until the age of 15-16 years⁵⁹ and possibly as old as 18-21 years⁵⁸. This provides clinical justification for postural screening for primary (i.e., prevent disease), secondary (i.e., early detection followed by appropriate intervention) and tertiary (i.e., reduce the impact of the disease and promote quality of life) prevention measures.

17. Key recommendations are easily identifiable.

The recommendations are easily identifiable.

18. The guideline is supported with tools for application.

For a guideline to be effective it needs to be disseminated and implemented with additional materials.

These may include for example, a summary document, or a quick reference guide, educational tools, patients’ leaflets, computer support, and should be provided with the guideline.

Applicability of Draft Document

19. The potential organisational barriers in applying the recommendations have been discussed.

No discussion has been made as to the potential barriers in applying the Guideline recommendations. Several conditions/clinical scenarios have been recommended as requiring immediate referral. Basic considerations such as the medicolegal and ethical implications of such actions were not addressed by the

Guidelines.

20. The potential cost implications of applying the recommendations have been considered.

To the extent applicable and warranted within each chiropractic practice, the Guidelines does not discuss potential cost implications.

Editorial Independence of Draft Document

**21. The guideline presents key review criteria for monitoring and/or audit purposes.
This is not addressed in the Guideline**

22. The guideline is editorially independent from the funding body.

If one makes the assumption that The Board funded for the development of these guidelines – clearly then, the views and interests of The Board have influenced the recommendations made in this Guideline. According to the AGREE document, this is a conflict of interest.

23. Conflicts of interest of guideline development members have been recorded.

Since the guideline development members have not been identified, one cannot know if conflicts of interest (i.e., financial and others) are recorded and known. Given that two medical doctors were identified as making a significant input into the development of this Guideline, disclosure of possible conflict of interest should have been made by these two individuals. Financial bias is but one aspect that should have been addressed with the participations of Drs. Efron and Ferrance. Other potential sources of bias also exist, such as a person's long-term service to government committees or private insurers, their previously established "stake" in an issue, the way that one makes one's a living and personal experiences⁶⁰. One only needs to read Dr Ferrance's credentials and see that there may be possible conflicts of interest.

Overall Assessment

Overall, **this Guideline should not be recommended for use in practice.** Based on our preliminary results of 20 chiropractor appraisers using the 23-item AGREE questionnaire, the draft Guidelines document as released by the Board are of extremely low quality. The 20 chiropractors consisted of 19 chiropractors from Australia and 1 from the United States. With respect to gender, 10 are males and 8 females with 2 not indicating. Their practice experience average 12.9 years and range from 1 -38 years (median = 10 years in practice; mode = 3 years in practice). The domain scores were calculated as Instructed in the AGREE INSTRUMENT and are provided in Table 1 below.

Domain	Scoring
Scope and Purpose:	36%
Stakeholder Involvement	14%
Rigour of Development	3.5%
Clarity and Presentation	12%
Applicability	5%
Editorial Independence	10%

Ideally, based on the calculations, a 100% score would indicate a guideline of high quality. One can observe that Rigour Development received the lowest scoring (i.e., 3.5%) while Scope and Purpose received the highest scoring, albeit at 36%. All domains were deemed of poor quality according to the appraisers.

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