

AN INDEPENDENT ASSESSMENT OF CHIROPRACTIC PRACTICE GUIDELINES

Jeffrey R. Cates, DC,^a David N. Young, DC, PhD,^b David J. Guerriero, DC,^c Warren T. Jahn, DC,^d Jesse P. Armine, DC,^e Alan B. Korbett, DC, DO,^f Daniel S. Bowerman, DC,^g Robert C. Porter, MD,^h Terry Sandman, DC, MPH,ⁱ and Robert A. King, DC^j

ABSTRACT

Objective: To evaluate the quality of *Recommended Clinical Protocols and Guidelines for the Practice of Chiropractic* (ICA guidelines) published by the International Chiropractors Association (ICA), August, 2000.

Methods: The Appraisal Instrument for Clinical Guidelines (Cluzeau instrument) was applied to the ICA guidelines by 10 independent experienced evaluators. An independent, global assessment was also made by each evaluator.

Results: Mean scores (with 95% confidence limit) for each of the instrument's 3 dimensions were Rigor of Development, 27% (5.1); Context and Content, 18.3% (9.4); and Application, 2% (3.9). The unanimous global assessment was "not recommended as suitable for utilization in practice." Comparison of the ICA guideline scores with the Council on Chiropractic Practice's *Clinical Practice Guideline No. 1, Vertebral Subluxation in Chiropractic Practice* (CCP guidelines) scores and *Guidelines for Chiropractic Quality Assurance and Practice Parameters* (Mercy guidelines) Cluzeau instrument-based scores revealed that the ICA guidelines received slightly higher scores than the CCP guidelines but substantially lower scores than the Mercy guidelines for all dimensions.

Conclusion: The ICA guidelines were assessed as not suitable for utilization in chiropractic practice. (J Manipulative Physiol Ther 2003;26:282-86)

Key Indexing Terms: *Guidelines; Chiropractic; Clinical Practice; Validity*

INTRODUCTION

It is widely acknowledged that peer review and testing of health care guidelines should be performed prior to their acceptance as valid and their subsequent utilization in clinical practice.¹ Cates et al assessed the Council on Chiropractic Practice's *Clinical Practice Guideline No. 1, Vertebral Subluxation in Chiropractic Practice*² (also known as the CCP guidelines) and *Guidelines for Chiropractic Quality Assurance and Practice Parameters*³ (also known as

Mercy guidelines)⁴ using The Appraisal Instrument For Clinical Guidelines (Cluzeau instrument),⁵ an instrument with established reliability and validity.^{4,6,7} The Cluzeau instrument was utilized in this study to assess the *Recommended Clinical Protocols and Guidelines for the Practice of Chiropractic*⁸ (ICA guidelines) recently published by the International Chiropractors Association (ICA).

METHODS

The ICA guidelines were reviewed by 10 experienced, volunteer appraisers using the Cluzeau instrument and its user guide, version 1. All the volunteer appraisers had prior experience in guideline evaluation and had participated in prior evaluations of the Mercy and CCP guidelines.⁴ Each of the volunteers possessed advanced training in research methods and/or scientific literature evaluation. The volunteers were instructed to objectively adhere to the instrument's user guide to avoid bias.

The same instrument that was used to evaluate the Mercy and CCP guidelines was utilized to evaluate the ICA guidelines. Detailed descriptions of the instrument and its utility, reliability, and validity are available elsewhere.^{4,6,7} Assessment with the same instrument and by the same appraisers allowed for the pooling of data, additional assessment of the

^aPrivate practice of chiropractic orthopedics, Oregon, Ill.

^bPrivate practice of chiropractic orthopedics, Chula Vista, Calif.

^cPrivate practice of chiropractic medicine, Orlando, Fla.

^dPrivate practice of chiropractic orthopedics and sports, Roswell, Ga.

^ePrivate practice of chiropractic, Havertown, Pa.

^fPrivate practice of adult, child and adolescent psychiatry, Snellville, Ga.

^gPrivate practice of chiropractic orthopedics, Philadelphia, Pa.

^hPrivate practice of occupational medicine, Rockford, Ill.

ⁱPrivate practice of radiology, Roselle, Ill.

^jPrivate practice of chiropractic and quality assurance and utilization review, Purcellville, Va.

Submit requests for reprints to: Dr. Jeffrey Cates, 200 N 6th Street, Oregon, IL 61061

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Table 1. Mean dimensional scores for ICA, CCP, and Mercy guidelines

	ICA	CCP	Mercy*
Rigor of development	27.0 (5.10)	20.0 (4.13)	77.0 (4.89)
Context and content	18.3 (9.37)	10.8 (6.46)	69.2 (9.13)
Application	2.0 (3.92)	0.0 –	52.0 (13.32)
Total	20.8 (4.47)	14.3 (3.95)	71.1 (5.70)

CI α = .05. ICA, International Chiropractors Association; CCP, Council on Chiropractic Practice.

*Guideline for Chiropractic Quality Assurance and Practice Parameters.

Table 2. Definitions

Terminology	Agreement
Unanimous agreement	100%
Substantial agreement	>75%
Moderate agreement	>65%
Disagreement	<65%

Cluzeau instrument, and direct comparisons between the 3 guidelines.

The ICA guidelines were assessed across the instrument's 3 dimensions: rigor of development, context and content, and application of guidelines. As a check of the instrument's validity, each evaluator formulated an independent global assessment of "strongly recommended for use in practice," "recommended for use with some modification or proviso," or "not recommended as suitable for use in practice." The relationship between the global assessment and pooled ICA, CCP, and Mercy guidelines dimension scores was assessed with Pearson correlation.

RESULTS

Application of the assessment instrument produced the following mean dimension scores for the ICA guidelines (Table 1): Dimension 1, Rigor of Development, 27% of possible score; Dimension 2, Context and Content, 18.3% of possible score; Dimension 3, Application, 2% of possible score. The mean total score was 20.8% of total possible score. There was substantial agreement regarding overall attribute assessment (see Table 2 for definitions). There was moderate to unanimous agreement for the individual attributes.

Rigor of Development

Responsibility, Development Group. There was substantial agreement that the agency responsible for the development of the guidelines was identified and that the guidelines lacked a declaration sufficient to judge the presence of external funding and associated bias. There was substantial agreement that the guidelines lacked a description of interest group

participation and unanimous agreement that they lacked representation of key disciplines and groups within the chiropractic profession.

Evidence. There was moderate agreement that the guidelines failed to provide a description of the sources of information. The appraisers unanimously assessed the sources of information to be inadequate. Although the guidelines were assessed as having provided a description of the methods used to interpret and assess the evidence, there was substantial agreement between appraisers that the methods used to interpret and assess the evidence were unsatisfactory.

Formulation of Recommendations. There was moderate agreement among the evaluators that there was not a description of the methods used to formulate the recommendations and unanimous agreement that any methods used were not satisfactory. There was substantial agreement between appraisers that the guidelines lacked an indication of how the views of interested parties not on the panel were considered and that clear links between the major recommendations and supporting evidence were lacking.

Review, Piloting. There was moderate agreement that the guidelines were not independently reviewed prior to their publication and that the guidelines lacked explicit information about how comments were addressed. There was unanimous agreement that the guidelines were not piloted.

Updating. There was substantial agreement between the appraisers that the guidelines contained information regarding the date and body responsible for updating the guidelines.

Overall Assessment of Process. There was unanimous agreement among the appraisers that potential biases of guideline development were not dealt with adequately in these guidelines.

Context and Content

Objectives, Context, Clarity, Costs and Benefits There was some disagreement as to whether or not the reasons for developing the guidelines were clearly stated. There was substantial agreement between the appraisers that the guideline objectives were not clearly defined. There was moderate agreement that the guidelines described the patients to whom they should apply. There was substantial agreement that the guidelines failed to consider exceptions to the recommendations. There was disagreement as to whether or not the guidelines took patient preferences into consideration. There was substantial agreement that the guidelines did not clearly describe the condition to be detected, treated, and prevented. There was unanimous agreement that the recommendations were not clearly presented and did not contain alternative treatment options. There was unanimous agreement that the guidelines did not provide an adequate description of the health benefits likely to be gained or cost expenditures to be incurred by following the recommendations. There was substantial agreement that the guidelines failed to provide an adequate description of potential risk and harm and unanimous agreement that the guideline recommendations were not supported by the risks and costs of intervention.

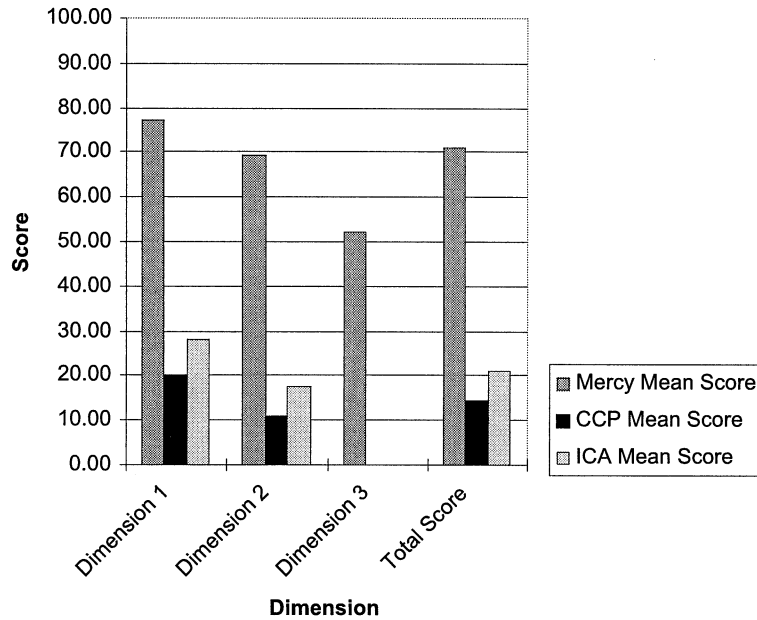


Fig 1. Graphical comparison of the Mercy, CCP, and ICA guidelines' quality assessment scores.

Application

There was unanimous agreement that the guidelines did not contain suggestions for implementation and that they failed to define measurable outcomes that could be monitored. There was substantial agreement that the guidelines did not provide for consideration and development of local guidelines.

The global assessment of the ICA guidelines by our evaluators was unanimously "not suitable for use in clinical practice." Pearson correlation coefficients were calculated for pooled raw data from all 3 guideline evaluations. Global assessment was correlated with scores for rigor of development ($r = 0.8714, P < 0.01$), context and content ($r = 0.7825, P < 0.01$), and application ($r = 0.7967, P < 0.01$).

Comparison of the ICA guideline scores with CCP guideline scores and Mercy guideline Cluzeau instrument-based scores⁴ revealed that the ICA guidelines received substantially lower scores than the Mercy guidelines in all dimensions (Fig 1). The ICA guidelines scored slightly higher in all dimensions than the CCP guidelines, despite the fact that our evaluators found the former to be much harder to follow and poorly organized and edited compared to the CCP guidelines. The slightly higher dimension scores were attributable to a better description of the methods used to interpret and assess the strength of the evidence, inclusion of a responsible body and date for reviewing and updating the guidelines, and clearer information regarding patient application.

DISCUSSION

In this study, assessment by the Cluzeau instrument produced measures of evaluator agreement consistent with

prior assessments of the instrument.^{4,6} The only notable exception was the statistical assessment of dimension 3. In this study, the pooled data resulted in a statistically significant correlation between the global assessments and dimension 3. In our prior assessment of the instrument, the correlation approached statistical significance.⁴ Our results from analyses of the 3 chiropractic guidelines are within the range of results Cluzeau et al⁶ report for their analysis of 60 other guidelines. This fact supports the notion that this instrument was applied and has functioned as intended by its authors. Our independent appraisers reached a significant consensus supporting the reliability of this study's outcomes and further supporting the reliability of the Cluzeau instrument.

The *Recommended Clinical Protocols and Guidelines for the Practice of Chiropractic* is the first edition of guidelines produced by the International Chiropractors Association.⁸ Although the ICA Committee on Chiropractic Practice Guidelines and Protocols has endeavored to follow the recommended methodology for evidence-based guidelines, they failed to incorporate input from many of the major organizations representing the profession, to use standard methods of gathering and evaluating or presenting scientific evidence, and to clearly tie recommendations to supporting evidence. These flaws in the ICA guidelines resulted in low assessment scores.

The ICA guidelines are a statement of the International Chiropractor Association's core values and opinions regarding the practice of chiropractic and, as such, lack balanced input from the general chiropractic profession at large. There was no notable participation in the ICA guidelines formulation from groups outside of the ICA panel and Council on Chiropractic Practice (CCP) authors. College,

educational, and political institutions, such as the American Chiropractic Association (ACA), Council on Chiropractic Guidelines and Practice Parameters, World Federation of Chiropractic, Association of Chiropractic Colleges (ACC), Foundation for Chiropractic Education and Research, National Association for Chiropractic Medicine, or American College of Chiropractic Consultants, and others are not listed as having had input into the ICA guidelines. The guideline development process should have input from groups whose activities would be impacted by acceptance of the guidelines in order to limit bias.⁹ Development panels dominated by a single group without diversity can result in intellectually and financially biased guidelines.¹⁰

The ICA criterion for literature inclusion/exclusion is flawed. For example, chapter 3 of the ICA guidelines incorporates the CCP guidelines, which have been criticized^{4,11,12} and in one study assessed as unsuitable for use in clinical practice.⁴ Both the ICA and CCP guidelines present a biased assessment of the chiropractic subluxation. Biased selection of evidence appears to account for the numerous conflicts with currently employed guidelines and literature.

Due to the flawed process of literature selection and evaluation, many of the resulting recommendations and opinions differ with currently accepted guidelines and literature. One example of this conflict is the chiropractic subluxation. In the scientific community, there is a spectrum of opinions ranging from those that question the existence of the chiropractic subluxation to those that feel it has profound significance. This study does not evaluate or advocate any single perspective in this debate, as we do not intend to become embroiled in the controversy revolving around the existence or significance of the chiropractic subluxation. However, an objective assessment of the literature indicates that a controversy exists,¹³⁻²⁰ and we strongly recommend that all chiropractic guidelines acknowledge it and address the issue in a straightforward manner. The ICA guidelines provide a narrow perspective of the controversy. Other perspectives include the ACA policy, which notes that "The chiropractic use of the term 'subluxation,' in reporting, is usually valid as an objective descriptor, but is not acceptable as a diagnostic term, unless demonstrable as a scientifically acceptable and classified entity."²¹ Several authorities note that there is "little hard data regarding the reliability and validity of its clinical identification and pathophysiologic impact," and others caution chiropractors not to treat the chiropractic subluxation as a "sacred cow" but rather to submit the theories to appropriate scientific testing.²²⁻³¹

Nelson²⁷ sums up the controversy well and notes "whether chiropractors are actually treating lesions, or not, is a question of immense clinical and professional consequence. Resolution of the controversy will not be found through consensus panels nor through semantic tinkering, but through proposing and testing relevant hypotheses."

We recommend that a valid guideline must objectively address the absence of rigorous scientific validation of the subluxation and its clinical significance so that the chiropractor, patient, and third parties might have information with which to evaluate the necessity and risk/benefit of chiropractic treatment of the condition. It is also appropriate for guidelines to address issues such as the natural history and prevalence of disorders such as the subluxation, selectivity and specificity of associated tests, and efficacy of various treatment procedures.

There are additional conflicts with existing guidelines and organizational positions. For example, the ICA guidelines fail to address the concerns of those groups that question the necessity of adjusting asymptomatic children. Additionally, the ICA guidelines conflict with scientific evidence and guidelines in areas including thermography, surface electromyography, chiropractic treatment of organic conditions, full spine radiography, measurement of bony vertebral position, and various types of instrumentation.^{3,32,33} Limited or no explanations are given for differences with currently accepted medical and chiropractic guidelines and evidence-based literature.

The ICA guidelines may be open to bias due to the limited participation of the profession in their construction, a bias toward a single perspective in the subluxation controversy, and limited consideration of credible scientific literature. Hayward et al¹⁰ warn us that reviewing the validity of guidelines is important, because a physician can be misled by guidelines based on biased selection of evidence or idiosyncratic values. We recommend that future revisions include input from all interested organizations, provide clear documentation of literature sources and the criteria for inclusion and exclusion of material, and provide clear links between recommendations and the supporting literature.³⁴ Some authors also recommended that guideline developers include disclosure of competing interests. We recommend similar reporting be incorporated into future chiropractic guidelines.^{35,36}

CONCLUSION

The Cluzeau instrument was found to be a reliable instrument for the purpose of guideline assessment.

Currently, 3 sets of chiropractic guidelines have been assessed with the Cluzeau guideline evaluation instrument. In this study, the ICA guidelines scored poorly and were assessed "not recommended as suitable for use in clinical practice." In a prior study, the CCP guidelines also scored poorly and were assessed as "unacceptable for use in clinical practice," while the Mercy guidelines scored reasonably well and were assessed as "acceptable for use in clinical practice with proviso."⁴

The ICA guidelines do not appear to be either a profession-wide consensus or objective, evidence-based practice guideline

but rather a synopsis of ICA policies, ethics, and resolutions with particular focus on the Association's values and bias.

We hope that this work will assist chiropractors in the evaluation and selection of valid guidelines which optimize patient care and result in health gain at the expected costs and guideline developers in their ongoing quest to perfect chiropractic practice guidelines.

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