FOREWORD

The International Chiropractors Association (ICA) recognizes, as do all realistic and responsible professional organizations, that in the current climate of accountability and concern for quality and appropriateness of care, clinical practice protocols and guidelines for all health professions are in the public interest. It is vitally important to recognize, however, that such protocols and guidelines are not a substitute for legal obligations and authorities, nor a replacement for the best clinical, ethical and professional judgement of the attending doctor.

All doctors of chiropractic must practice within the rules and procedures established in their respective states and jurisdictions, and within their best judgement. The protocols and guidelines presented here recognize and respect these immutable obligations on the doctor's part, also recognizing that no general guidelines can offer specific recommendations for care for any individual patient as each patient is not only different, but unique in their condition and need for care.

These practice protocols are a reflection of the growing consensus within the chiropractic profession on the general parameters of chiropractic science and practice. They are also offered to the profession and the public in the context of the Statement on the Chiropractic Paradigm first developed and adopted by the Association of Chiropractic Colleges and subsequently endorsed, approved or adopted by most of the major chiropractic organizations in the United States. This Paradigm Statement has been unanimously approved and adopted by the Board of Directors of the International Chiropractors Association, and the ICA heartily embraces and shares the core values reflected in this widely adopted position statement. These practice protocols seek to embody the spirit of this broadly supported position statement which reads, in part, as follows:

> *Chiropractic is a health care discipline which emphasizes the inherent recuperative power of the body to heal itself without the use of drugs or surgery.*
>
> *The practice of chiropractic focuses on the relationship between the structure (primarily the spine) and function (as coordinated by the nervous system) and how that relationship affects the preservation and restoration of health. In addition, Doctors of Chiropractic recognize the value and responsibility of working in cooperation with other health care practitioners when in the best interest of the patient.*

ICA has submitted this document for profession-wide and public examination and comment for a period of six months via the Internet and through widespread circulation of printed copies of this protocol in draft form prior to publishing this completed version. Over 200 comments and submissions were received from the chiropractic profession during that time. All of those comments were carefully reviewed and evaluated by the Clinical Practice Protocols and Guidelines Committee of the International Chiropractors Association and major revisions and corrections of the draft were made as a result of this extensive positive input. Over 100 comments were also received from members of the public. The nature of those public comments and inquiries assisted the committee in shaping this document to provide for better patient/consumer understanding of chiropractic procedures and practice protocols.

For a period of nearly two years, the draft of this document was subject to the critical review and input from the Board of Directors, Representative Assembly and postgraduate councils of the International Chiropractors Association. These organizational bodies are comprised of over l00 individuals from all parts of the United States and Canada, as well as many nations around the world. In many respects, this group fulfilled

an organizational peer review function both before and after the document was submitted for profession-wide and public comment. The input from these people has had a significant impact on the nature and quality of the final version of these protocols.

ICA fully appreciates the likelihood of important improvements coming from the on-going research and review process and pledges full and objective consideration of all new clinical, scientific, and other relevant developments. ICA is committed to the maintenance of this document and pledges ongoing review and the issuance of a revised edition of these guidelines no less than every four years, or as dictated by research, legislative, legal or other developments.

The procedure and methodologies employed in the development of these guidelines were initially drawn from procedures developed by Herve Guillain, M.D., Senior Policy Analyst, with the Agency for Health Care Policy and Research, Washington, DC. However, these AHCPR procedures were developed to evaluate specific conditions and the effectiveness of the various treatments offered for those conditions. The reach of this document extends far beyond any one specific condition and attempts to deal with the practice of an entire profession. Therefore, other authorities, including state and federal statutes, educational standards and requirements, the judicial record, and professional consensus, have been consulted.

Furthermore, these protocols are intended to reflect the core values and policies of the International Chiropractors Association, as articulated in the above referenced Statement on the Chiropractic Paradigm.

The International Chiropractors Association understands that there are wide areas in chiropractic clinical practice where no concrete parameters will ever be possible and that there remains a wide area of discretion available to the individual practitioner. The judgement of the practitioner is vital in these areas, and it is hoped that these protocols offer any doctor of chiropractic support and guidance in these areas of discretion to help meet the needs of the patient in a clinically sound and ethical manner.

In a paper entitled, "*The Agenda for Health Care Policy and Research and the Development of Clinical Guidelines,"* Dr. Herve Guillain wrote:

> "The mission of the Agency is to enhance the quality, appropriateness, and effectiveness of health care services as well as to improve access to these services."

This is also the central mission of these chiropractic clinical practice protocols.

Chiropractic care has been evaluated to a greater degree than most medical interventions. A large and growing body of clinical research comprised of trials, observations, outcome assessments, etc. exist as a basis for evaluating chiropractic procedures. Overwhelmingly, regardless of methodology, chiropractic has been demonstrated to be safe and effective for patients of all ages. ICA also recognizes that the operational basis for many health care procedures rests on decades of clinical experience, and that "gold standard" research findings simply do not exist as a means to definitively evaluate most aspects of all health care practices.

ICA values and respects the great body of clinical experience collectively gained in over a century of clinical chiropractic practice. That body of knowledge and experience is a worthy basis on which to base procedural and clinical protocols until such time as replicated research findings offer a basis for changing prevailing thinking. The International Chiropractors Association is dedicated to fully exploring and understanding the potential of chiropractic science, and its limitations. The ICA urges the widest possible research on all aspects chiropractic science and practice and understands that such findings might certainly have a significant impact on the nature of these practice protocols.

After careful review of all literature and documents produced to date and an evaluation of the other

sources of authority and experience, we are confident that the enclosed practice protocols offer a responsible and clinically sound guide to the practice of chiropractic worldwide.

Understanding These Practice Protocols:

A. Introduction

The majority of standard procedures utilized by all health providers, have not been validated by formal scientific methodology. Various sources have cited findings that indicate only about 15% of medical interventions are supported by valid evidence and many may have never been assessed objectively at all (Smith R, Eddy D). Thus, where possible valid evidence will be used and appropriately weighted. In those frequent situations where such studies do not exist, the cumulative weight of clinical experience will be the frame of reference and the validating mechanism for protocol components.

B. Format

These protocols and guidelines appear in topic chapters under the following headings:

> Chiropractic Science and Practice; Authorities and Definitions; Basic Essential Care; Subluxation Guidelines; Chiropractic Child Care Protocols; Routine Check-ups, Prevention and Public Health; Collaborative Care; Consultation, History and Examination; Record Keeping and Patient Consents; Clinical Impression; Modes of Care; Frequency and Duration of Care; Reassessment; Outcome Assessment; Professional Development. Diagnostic Imaging; Instrumentation; and Contraindications and Complications.

Each chapter is organized according to a similar outline, namely: I. Overview; II. List of Subtopics; III. Literature Review; IV. Recommendations; V. Comments, Summary or Conclusion; and VI. References. There are instances, however, in which a slightly varied format is followed, depending on the nature of the information presented.

The "Recommendations" in each chapter are the guidelines. Subjects covered by guidelines in each chapter are indicated in the "list of subtopics."

Ratings Systems - Procedure Ratings (System I)

This system is suited to scientific/technical areas of practice:

1. Procedures are judged, in descending order of approval, established, promising, equivocal, investigational, doubtful and inappropriate.

2. The first three ratings (established, promising, and equivocal) are all positive.

The remaining three ratings (investigational, doubtful, and inappropriate) are negative. A procedure currently rated "investigational" has the potential to be raised to an acceptable level and a positive rating on the basis of future clinical and scientific evidence.

A specific procedure may have more than one current rating depending upon the circumstances in which it is used.

As noted previously, the rating chosen for a procedure is linked to the quality of evidence in support of utilization of that procedure.

Procedure Ratings (System II)

This system is suited to procedural/administrative aspects of practice. Accordingly it is used in chapters such as Collaborative Care, Consultation, History and Examination, and Record Keeping and Patient Consents .

1. Rating levels are: necessary, recommended, discretionary and unnecessary.
2. Rating is once again linked to quality of evidence - see Figure 2 for details.

Special Rating System for Complications

A special third rating system has been developed for the unique area of potential complications of high-velocity thrust procedures. - Contraindications and Complications) The basic rating is the level of contraindication, which may be:

- No identifiable contraindication
- Special circumstances: Situations in which clinical findings indicate the need for additional evaluation or in which high-velocity thrust procedures may be used with additional appropriate care and/or modification"
- Special circumstances situations to identifiable contraindication: "careful clinical judgment dictates whether special care is needed or an identifiable contraindication is present with each specific patient"
- Identifiable contraindication.

Chapter 17 lists the various potential complications and/or the need to adapt or modify high-thrust procedures under categories of:

- Articular Derangements
- Bone Weakening and Destructive Disorders
- Circulatory and Cardiovascular Disorders
- Neurological Disorders

Rating System (III)

A. Types

1. Strong positive recommendation: The doctor of chiropractic, under most circumstances, would employ the procedure.

2. Positive recommendation: The doctor of chiropractic, under many circumstances would employ the procedure.

3. Discretionary: The chiropractor under some circumstances would employ the procedure.

4. No recommendation: The circumstances within which this procedure would be appropriate have not been determined.

B. Support Categories:

1. E: Based on available expert opinion, clinical experience or effectiveness studies.

2. L: Based on available refereed literature or published monographs, legal decisions and/or authority,

statutory authority, statement of professional consensus.

3. C: Based on available controlled studies.

Procedure Ratings (System I)

Established: Accepted as appropriate by the practicing chiropractic community for a given indication in the specified patient population.

Promising: Given current knowledge, this appears to be appropriate for the given indication in the specified patient population. As more experience and long-term follow-up are accumulated, this interim rating will change. This connotes provisional acceptance, but permits a greater role for the current level of clinical use.

Equivocal: Current knowledge exists to support a given indication in a specified patient population, though value can neither be confirmed nor denied. As more evidence and experience accumulates this rating will change. Expert opinion recognizes a need for caution in general application.

Investigational: Evidence is insufficient to determine appropriateness. Further study is warranted. Use for a given indication in a specified patient population should be confined to research protocols. As more experience and evidence accumulate, this rating will change.

Doubtful: Given current knowledge, this appears to be inappropriate for the given indication in the specified patient population. As more experience and long-term follow-up are accumulated, this interim rating will change.

Inappropriate: Regarded by the practicing chiropractic community as unacceptable for the given indication in the specified patient population.

Quality of Evidence

Class I: Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity.

Class II: Evidence provided by one or more well-designed controlled observational clinical studies, such as case-control, cohort studies, etc.; or positive predictive value, discriminability, sensitivity, and specificity; and published in refereed journals.

Class III: Evidence provided by expert opinion, descriptive studies or case reports.

Strength of Recommendation Ratings

Type A: Strong positive recommendations. Based on Class I evidence or overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B: Positive recommendation based on Class II evidence.

Type C: Positive recommendation based on strong consensus of Class III evidence.

Type D: Negative recommendation based on inconclusive or conflicting Class II evidence.

Class E: Negative recommendation based on evidence of ineffectiveness or lack of efficacy based on Class I or Class II evidence.

Figure 2 Procedure Ratings (System II)

Necessary: Strong positive recommendation based on Class I evidence, or overwhelming Class II evidence when circumstances reflect compromise of patient safety.

Recommended: Positive recommendation based on consensus of Class II and/or strong Class III evidence.

Discretionary: Positive recommendation based on strong consensus of Class III evidence.

Unnecessary: Negative recommendation based on inconclusive or conflicting Class II, III evidence.

Quality of Evidence

The following categories of evidence are used to support the ratings:

Class I: A. Evidence of clinical utility from controlled studies published in refereed journals.

B. Binding or strongly persuasive legal authority such as legislation or case law.

Class II: A. Evidence of clinical utility from the significant results of uncontrolled studies in refereed journals.

B. Evidence provided by recommendations from published expert legal opinion or persuasive case law.

Class III: A. Evidence of clinical utility provided by opinions of experts, anecdote and/or by convention.

B. Expert legal opinion.

REFERENCES

Rachlis N, Kuschner C. *Second Opinion: What's Wrong with Canada's Health Care System and How to Fix It*, Toronto: Collins, 1989.

Smith R. (1001) Where is the Wisdom: The Poverty of Medical Evidence *BMJ* 303:793-799. Quoting David Eddy MD, Professor of Health Policy and Management, Duke University, NC.