

Systems for classifying the acceptability of clinical treatment methods

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The increasingly frequent demands for standards of quality of care have prompted a variety of systems for classifying the acceptability of various clinical methods for particular health problems. However, these systems have employed terms which characterize clinical methods along multiple, frequently orthogonal dimensions; unfortunately, the distinctiveness of these dimensions is often obscured. To aid in evaluating these terms and evaluations, three types of judgements are identified: basic science rationales, judgements of the breadth of clinical use, and the experimental status of particular clinical intervention strategies. Each type or classification of evaluation is sub-divided into two or more descriptors. Several examples of the application and limitations of these classification schemes are provided.

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KEY WORDS: chiropractic, quality of care, standards, manipulation.

La demande accrue de normes de qualité concernant les soins de santé a donné naissance à une variété de systèmes, visant à classer l'acceptabilité de diverses méthodes cliniques ayant trait à certains problèmes de santé. Mais ces systèmes se servent de termes caractérisant des méthodes cliniques suivant des dimensions multiples, souvent orthogonales : malheureusement, le caractère distinctif de ces dimensions y est souvent obscurci. Pour aider à évaluer ces termes et ces évaluations, l'article identifie trois types de jugements, à savoir : les considérations scientifiques fondamentales, les jugements fondés sur l'éventail de l'usage clinique, et le statut expérimental de certaines stratégies d'intervention clinique. Chaque classe ou chaque type d'évaluation est subdivisé en plusieurs termes descriptifs. L'article fournit plusieurs exemples de l'application et des limitations de ces systèmes de classification.

(JCCA 1991; 35(1):13-16)

MOTS CLÉS : chiropratique, qualité des soins, normes, manipulation.

Introduction

Increasing calls for professional accountability in health care have begun to impact on the chiropractic profession. During the past decade the absence of standards of care have resulted in the imposition of fairly arbitrary reimbursement criteria (e.g., 12 or 20 visit annual caps) for chiropractors under third-party pay systems such as Medicare and Blue Cross. The concern of the profession and its leadership over these events is reflected in the recent decision of the American Chiropractic Association to underwrite standards development by the Rand Corporation. The recent Consensus Conference on the Validation of Chiropractic Methods (see Chiropractic Technique, August, 1990, Volume 2, Number 3) further suggests the growing recognition among chiropractic physicians that technique anarchy cannot

continue. Chiropractors have begun to heed the warnings that standards will be set, with or without chiropractic input.

The lack of clinical outcome data by which standards of quality of care might be formulated have prompted several groups to formulate evaluation strategies for chiropractic clinical procedures (e.g., ^{1,2}). These authors have attempted to specify the logic and types of information needed to render judgements about the acceptability of particular clinical methods. The "Kaminski model",²⁻⁴ for example, results in classification of methods as "unsubstantiated", "provisional acceptance", or "full acceptance"; these designations result from a detailed sequence of rational analysis and evaluation of experimental data. Kaminski³ notes additional classification systems developed by the Quebec Task Force and the American Medical Association. Similarly, Vear⁵ has proposed a three-category classification system for chiropractic procedures: "orthodox", "experimental", or "anecdotal"; Vear does not indicate how such designations will be determined for any particular clinical method. Other terms sometimes suggested to characterize the acceptability and/or level of knowledge con-

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cerning clinical methods include "empirical", "accepted by consensus", "usual and customary", and "proven".

Some of the terms mentioned above refer to the reasonableness of a clinical procedure in light of basic science knowledge (e.g., provisional acceptance), while others refer to the extent and/or results of clinical outcome investigations (e.g., full acceptance, experimental, anecdotal), and still others to the extensiveness (perceived or polled) of use of a procedure within the profession (e.g., usual and customary, accepted by consensus). Some of these terms are extremely vague, or communicate little information about the manner by which they are applied. For instance, the dictionary definition of the term *orthodox* provides little help to those who would judge a clinical procedure based on this designation: "sound or correct in opinion or doctrine".² How was the soundness or correctness of the procedure determined? Use of some of these terms is obfuscated by widespread misunderstanding within the profession. For example, does the designation "experimental" refer to the basic science foundations of a method, or to on-going clinical trials of the procedures's effectiveness? The confusion among chiropractors concerning the term "empirical" has elsewhere been suggested.⁶

With such a variety of adjectives and classification schemes for clinical procedures, communication within the profession and between chiropractors and other interested parties is often difficult, and decision-making can therefore become capricious. To aid in clarifying classifications and improving communications concerning the acceptability of clinical treatment methods, a multicomponent classification system is proposed.

Classification systems

Any clinical treatment procedure can be evaluated in three ways: in terms of its consistency with the known facts of the basic sciences, in terms of the extensiveness of the methods³ approval and/or use in the profession, and in terms of the degree of clinical-experimental testing which has been conducted (and the results thereof). Within each of these domains several levels of acceptability vs prematurity vs unacceptability can be identified (see Table 1).

For instance, the rationale for employing spinal adjusting as a means of improving the function of the immune system may be considered logical in light of current basic science knowledge, or may be considered implausible given our current fund of knowledge in this area of biology (see Table 2). These judgements do not assure the effectiveness of the procedures, but rather suggest the plausible utility and testability of the clinical method. Of course, clinical methods which seem rational may or may not be effective, and conversely, apparently irrational procedures may be demonstrated effective when put to an experimental test. "Rational" in this scheme is analogous to Kaminski et al.'s² designation of "provisional acceptance". Methods judged to be without logical foundation in the basic sciences would be considered "unsubstantiated" in the Kaminski model.

TABLE 1
Three types of judgements/classifications
of the acceptability of a clinical treatment method

1 BASIC SCIENCE RATIONALE
a. rational
b. without scientific/logical foundation
2 CLINICAL USE/ACCEPTANCE
a. usual and customary
b. limited use
c. novel
3 CLINICAL-EXPERIMENTAL STATUS
a. proven/substantiated
b. experimental
c. pre-experimental
i. quantitative
ii. private empiricism

TABLE 2
Judgements of the rationality or basic science
consistency of a clinical treatment method

a. Rational
Use of the procedure for a particular health problem is consistent with the known facts of the basic sciences.
b. Without scientific/logical foundation
Use of the procedure for a particular health problem is not consistent with the known facts of the basic sciences, or is based on knowledge outside the basic sciences.

Secondly, the extensiveness of use of a procedure may be rated as usual and customary or something less: limited use or novel (see Table 3). Methods considered "usual and customary" are those accepted by a consensus of some significant proportion of practitioners. The acceptability of such procedures may change, for example, when clinical research suggests a lack of effectiveness (or hazard) of the method in question.

Lastly, the degree of scientific confirmation (or lack thereof) of the effectiveness of a particular procedure when applied to a specific health problem can be indicated by a method of classification which distinguishes between repeatedly successful outcome experiments vs less extensive (or unfavourable) investigations (see Table 4). A method considered proven or substantiated ("full acceptance" in the Kaminski model) has survived repeated experimental attempts to falsify hypotheses concerning its beneficial effects. Treatment methods designated "ex-

TABLE 3
Judgements of the extensiveness of clinical use
or acceptance of a clinical treatment method

- | | |
|-------------------------------|---|
| a. Usual and customary | Widespread use for a particular health problem has been documented, or the legitimacy of widespread use has been affirmed by a sizable portion of the profession; pervasiveness of the procedure may be regional rather than national or international. |
| b. Limited use | Use of the procedure for a particular health problem has found some small acceptance in the profession. |
| c. Novel | Use of the procedure for a particular health problem is new, and/or has been tried by only a few in the profession. |

TABLE 4
Judgements of the clinical-experimental status
of a clinical treatment method

- | | |
|--------------------------------|--|
| a. Proven/substantiated | Effectiveness for a particular health problem has been established by multiple replications in controlled outcome trials. |
| b. Experimental | Effectiveness for a particular health problem is under investigation by means of controlled outcome trials. |
| c. Pre-experimental | <ul style="list-style-type: none"> i. Quantitative: effectiveness for a particular health problem has not yet been tested by controlled outcome trials, but quantitative, quasi-experimental and/or non-experimental outcome reports (e.g., case studies, uncontrolled clinical series) are available. ii. Private empiricism: effectiveness for a particular health problem has not been reported in critically reviewed science journals; effectiveness is supported by clinical legends, anecdotes and/or testimonials. |

perimental" in the current classification scheme are those which have begun to undergo controlled tests, but for which strong evidence (i.e., successful replications) of effectiveness is still lacking. Veal's⁵ use of the term "tentative" is roughly

analogous to "b. Experimental" as suggested here (Table 4); Kaminski's classification scheme would employ the terms "unsubstantiated" or "provisional acceptance" depending on the perceived rationality of the method.

Pre-experimental treatment methods are those for which no controlled experimental outcome tests can be identified. In some situations it may be useful to distinguish between two categories of pre-experimental methods: those for which no published data are available (private empiricism), and those for which quantitative, but uncontrolled data support the method.

Application

A few examples will illustrate application of these classifications. The acceptability of instrument adjusting for the purpose of decreasing elevated blood pressure can be judged in three ways. Firstly, those knowledgeable in the basic sciences can assess the rationale for this type of intervention: is it credible, in terms of anatomy and physiology, that manipulation of the bony encasement of the spine could alter the neural regulation of cardiac function? Assuming this (or other rationale) does seem plausible, knowledge of the basic sciences might then be applied to judging whether the treatment procedure, as typically described or performed, seems likely to accomplish the intended effect. Positive answers to all of these questions would lead to a judgement of "rational", that is, acceptable in its rationale.

Secondly, the extent of approval and/or use of mechanical manipulation to reduce blood pressure could be judged by questionnaires administered to the field. If a pre-determined level of acceptance among doctors were found for this procedure (e.g., a survey of practitioners reported regular use of the procedure), a judgement of "usual and customary" might be made.

Finally, a literature search could be conducted to determine the extent of empirical (i.e., data-based) support for instrument adjusting for this purpose. In the case of instrument adjusting to reduce blood pressure, at least one reasonably well-controlled report is presently available,⁷ but replications with robust effects are not available. Accordingly, a judgement of "experimental" seems appropriate, since this method of regulating circulatory tension has some controlled, quantitative, published support, but has a long way to go before it can be considered substantiated by repeated experimentation.

It should be noted that the classification of a treatment method for one purpose does not indicate its usefulness for another. For example, even if Gonstead or diversified adjusting had been experimentally proven to be effective for relief of chronic low back pain, the data upon which such effectiveness were based would not of itself substantiate the effectiveness of these manual procedures for patients with headache disorders.

Limitations

The limitations of this classification are important to note. For instance, judgements about the "rationality" of a procedure can be debated, as not all may interpret basic science knowledge

similarly. Further, how inclusive should we be in our literature searches and in our judgement of similarity among procedures? For example, should data favourable to Activator instrument adjusting for high blood pressure be considered supportive of adjustments delivered with the Life Upper Cervical adjusting instrument or supportive of manual manipulation of the spine (e.g., Gonstead or diversified techniques) for the same purpose? Should trials involving long-lever manipulation be grouped with studies reporting the effects of the short-lever, high-velocity thrusts which chiropractors prize? Relatedly, no hard and fast rule is available for the number of successfully replicated clinical experiments needed to qualify a procedure as "proven" or "substantiated".

Nor does this scheme attempt to incorporate information of judgements concerning the possible risks of a treatment method. Moreover, the model does not offer a classification scheme for the scientific status of diagnostic/assessment strategies, although such could probably be extrapolated from the current classification system for therapeutic interventions. Additionally, this author hesitates to suggest how extensively a procedure must be used to qualify as "usual and customary": should it be 25% or 50% or more?

Despite these limitations, the current system has value in that it serves to clarify and distinguish among the types of judgements which may be made (rationality, experimental evidence of effectiveness, extent of clinical implementation) in the process of clinical standard setting. Ultimately, all standards are opinions; however, the manner by which facts are judged and

integrated into opinion-formation will no doubt have a potent effect on standards of practice. Surely, we must reach some agreement on what kinds of facts will be considered before we can decide on the best means of aiding patients. Hopefully, the classification system offered here will aid in this process.

Lastly, this system is offered for discussion, and no sense of finality is intended.

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