Readers' Rights
Peer Review in Chinese Medical Publication

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Abstract
Among Western students and clinicians of Chinese medicine the concept of peer review has become associated with specific aspects of academic and scientific writing that have immediate and obvious political and commercial consequences. For example, peer review is often discussed as if it were equivalent to a demand for randomized controlled clinical trials (R.C.T.) or a specific approach to transparency in translation. While these are important issues, peer review is not a single specific practice but a philosophy indispensable to the traditional Western commitment to free expression. It is the critical means by which validity is assessed over time. It is necessary for the formation of consensus within any field. Peer access to information is also essential to recognizing the right of readers to know the sources and methods by which claims of value are made. Since a fundamental set of information needed for effective peer review can be described, the absence of uniform labels and formats is a significant lack that C.O.M.P. should address.

Keywords: Chinese medicine, acupuncture, peer review, technical writing, clinical trials.

Introduction

> The *Web* [*That Has No Weaver*] was originally written as an effort to communicate what I had recently learned in Asia. I was a novice exited to transmit what I had seen in another world. Ted Kaptchuk [1]

Chinese medicine, at first represented by acupuncture alone, came to Western attention beginning in the mid to late 1960's. Although clinical information had been sparsely available in European languages since the seventeenth century and in greater detail since the early 1950's[2], and still-standard academic monographs were available in the early 1980's[3], the seminal English language books were primarily received by small, disconnected groups studying acupuncture in the United States, the United Kingdom and Europe.[4] Everyone was a novice and there was little if any societal support for the process of acculturation. Little attention was paid to developing formal bibliographies or to the understanding of the genres in Chinese medical literature, the scope of that literature, or even the native culture role of the texts that had already been selected for excerption, interpretation or translation.

By the early 1990s as the English language literature developed, it became clear that everything labeled `acupuncture' or `Chinese medicine' was not produced using the same, or even a similar philosophy or approach. Although a few writers began to focus attention on matters of transmission, public discussion of transmission issues was generally limited to opinion regarding preferences in term selection. In response, Blue Poppy Press sponsored a meeting of writers and publishers in Bolder Colorado in the summer of 1995.[5] This, which became the first Council of Oriental Medical Publishers (C.O.M.P.) meeting, concentrated on two issues: 1. The advisability of cross-reference among texts by different writers and publishers and, 2. The advisability of non-proprietary, generic labels for the methods used to produce texts offered to the field. C.O.M.P. guidelines were reported from this initial meeting, then revised in 1997 based on the questions and comments received concerning the original guidelines.[6] C.O.M.P. undertook a passive role hoping to encourage writers and publishers to participate by allaying perceived fears that a more activist organization would exclusively forward the interests of the most active participants, Blue Poppy Press and Paradigm Publications.

Although the C.O.M.P. labels are by no means universally employed, a significant proportion of the books released in recent years have carried C.O.M.P. designations and the absence of cross referencing is now increasingly noted as an impediment to learning by both educators and their students. Understanding of the role of standards has increased and it is broadly apparent that C.O.M.P. is not pursuing an aggressive agenda but is following an established model for standards organizations that has proven successful in a variety of fields. As well, the introduction of *Clinical Acupuncture and Moxibustion Journal* by Harcourt International, a large commercial publisher, and its editorial adoption of the Uniform Requirements (see: **Method**), suggest that a discussion of clinical reporting is timely because standards are already being established.

It is thus appropriate to consider this as another area where cooperative labeling and reporting can continue and support the C.O.M.P. goals. Primary among these issues are claims regarding clinical experience. These range from informal suggestions that the clinical experience of a writer is a sufficient criteria for selecting Chinese text for inclusion and presentation in English, to public claims of efficacy for commercial medicinal preparations. While commercial advertising claims are not the direct subject of this paper, it should not go unnoticed that because there are no shared standards for describing clinical experience, there is no restraint on the ``branding" of T.C.M. by anyone. There are now well-capitalized efforts to market products that have little or no relationship to the principles of traditional Chinese medicine but which nonetheless use the label ``T.C.M." to attach a clinical authority to their product. There is no way to predict the effect of such unrestrained branding but the risk to public perception of Chinese medicine is clear.

It is the thesis of this paper that any reference to clinical experience, regardless of how or where made, constitutes a claim that is essentially no different than any other public claim of validity. While it is the right of any writer to state matters as they see them, it is the right of readers to know the basis for the claims writers make. While clinical assertions in Chinese medicine require different features than have thus far evolved in the peer review literature of biomedicine, the foundation information critical to the evaluation of clinical claims are practically identical. I thus suggest that C.O.M.P.-style labels are also appropriate in these regards and that an examination of peer review standards in the receiving culture is an appropriate foundation for their discussion and development.

Method

Several authorities have studied and reported on criteria for reporting clinical experience. These were examined for common themes:

Guidelines for Authors of Books and Papers on Complementary Medicine by the Research Council for Complementary Medicine[7]

The American Veterinary Medical Association (AVMA) Revised (1996) *Guidelines for Alternative and Complementary Veterinary Medicine*[8]

Uniform Requirements for Manuscripts Submitted to Biomedical Journals (1998) by the International Committee of Medical Journal Editors[8]

Clinical trials comparing acupuncture with biomedical standard care: a critera based evaluation of research design and reporting by R. Hammerschlag and M.M. Morris provided specific critera.[9]

In addition, the publication guidelines of several peer review journals were reviewed to gather a sense of the commonalities and the *Journal of Urology* was selected as a primary example because the table used to present the information required by various claims of clinical efficacy was particularly easy to use.[10] As an exercise to demonstrate the overlap between the essentials of Chinese medical and biomedical claims, this table is experimentally modified to reflect common means of making clinical claims in Chinese medicine.

Results

Whether the elements of a peer review document were developed by individual journals, or through a standards group similar to C.O.M.P., there are four common elements:

1. Standards for submission of manuscripts,
2. Standard formats for reporting,
3. Standards reports for experience claims,
4. Standards for what authors should disclose.

Standards for submission of manuscripts

These standards are production related. While it may be of service to writers to have relatively uniform standards for the means of submission, file and image types, and for the use of article features such as tables and illustrations, discussion of these matters is probably best left until there is a survey of current practices among publishers who volunteer participation. Although these standards receive much consideration in current peer journal submission instructions, their importance is likely to decline as word processing and data transfer software become increasingly interoperable.

Standard formats for reporting clinical experience

The goal of these standards is uniform presentation of the information required for someone possessed of the same skills and knowledge as the writer(s) to judge the claim for themselves. These formats intend to simplify readers' search for information by presenting similar information in uniform sections under uniform headings. Essentially, this makes indexing and searching in large scale databases more accurate and convenient. The International Committee of Medical Journal Editors summarize these in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (Uniform Requirements) :

Title Page: This section established the authorship, contact addresses, and distribution information. Any disclaimer should also appear on this page.

Abstract and Key Words: This section is critical to indexing any paper.

Introduction: This section summarizes the rationale for the study reported.

Methods: This section identifies the methods, equipment, and procedures in sufficient detail for readers to assess the study approach.

Results: This section summarizes the study results, emphasizing the critical observations and conclusions

Discussion: This section provides for reporting the important aspects of the work and the conclusions drawn.

Acknowledgements: This section provides for acknowledging intellectual sources and can include both references and statements concerning individual contributions.

Standards for what is reported

As Uniform Requirements state:

> Describe clearly your selection of the observational or experimental subjects (patients or laboratory animals, including controls). Identify the age, sex and other important characteristics of the subjects. The definition and relevance of race and ethnicity are ambiguous. Authors should be particularly careful about using these categories.
>
> Identify the methods, apparatus (give the manufacturer's name and address in parentheses) and procedures in **sufficient detail to allow other workers to reproduce the results.** [Emphasis added] Give reference to established methods, including statistical methods (see: Statistics); provide references and brief descriptions for methods that have been published but which are not well known; describe new or substantially modified methods, give reasons for using them and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dosage(s) and route(s) of administration. . [11]

The reference to statistics reads as follows:

> Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. [12]

The implicit principle is clear, a clinical claim should be stated so that your peers – others possessing similar skills and access to the information on which your assertion rests – can fully evaluate your claim for themselves. This, the primary principle of peer review, is the goal of the Uniform Requirements. The format elements such as the Abstract and Keywords exist to make the information necessary for peer evaluation routinely and completely accessible.

As an example, the following table (Table One) adapted from the *Journal of Urology* submission standards,[13] lists the qualities that authors are expected to report for three standard study types. These requirements are typical of biomedical journals but the presentation is particularly succinct:

Table One

Analytical Reporting Checklist for Authors	**Animal Experiment**	**Cohort Study**	**Randomized Controlled Clinical Trial**
Primary Objective / major hypothesis	Yes	Yes	Yes
Justification of Sample Size	Yes	No	Yes

Participation rate if patients declined study	No	No	Yes
Inclusion/exclusion criteria	No	Yes	Yes
Source and initial number of patients	No	Yes	Yes
Randomization method	No	Yes	Yes
Blinding techniques	Yes	No	Yes
Accrual dates	No	Yes	Yes
Identification of variable transformations or categorization	Yes	Yes	Yes
Justification if outliers were omitted from analysis	Yes	Yes	Yes
Analysis of patients withdrawn or protocol deviations	No	No	Yes
Time between randomization and start of treatment	No	No	Yes
Number of patients who completed treatment	No	Yes	Yes
Treatment of missing values	Yes	Yes	Yes
Frequency of side effects	No	Yes	Yes
Identification of statistical software	Yes	Yes	Yes
Justification of 1-tailed statistical tests	Yes	Yes	Yes
Verification of statistical test assumptions	Yes	Yes	Yes
Median follow-up time for censored patients	No	Yes	Yes
Lost to follow-up as a proportion of censored patients not evaluated during a specific period	No	Yes	Yes
Reporting the number of patients at risk over time	No	Yes	Yes
Confidence intervals for effect sizes			

Standards for Disclosure

These are signed statements to be provided by writers with their submission. The statements are required either as a formal notice that no disclosure is necessary or a specific statement of the author(s) paid and unpaid, profit or non-profit relationships and affiliations concerning: relationship (e.g.: consultant, corporate officer, etc.), type of involvement (e.g.: self-employed, employed, related, receiving support), and involvement as an institution. As signed statements required for publication these statements impress upon writers publishers' awareness of commercial influences.

Discussion

Standards for submission of manuscripts

As previously noted, current text processing technologies and the ubiquitous use of the Windows and Macintosh operating systems, mass market word processing programs and file formats, tend to vitiate the need for much attention to these issues.

Standards for Disclosure

On the other hand, the issues of bias implicit in current biomedical drug, instrument and procedure economics that have focused attention on investigators' personal and financial interests are fully present in the Chinese medicine field. Commercial publishers comment on educational standards, textbook authors brand proprietary herbal medicines, and the owners of acupuncture schools sit on committees that decide matters that effect the cost of education. There is in effect no difference between biomedicine and Chinese medicine as regards the presence of personal and financial bias. Both are the product of humans; humans are subject to bias. Furthermore, students and practitioners of acupuncture and Chinese medicine are no less suspicious of commercial influence than are biomedical physicians or the general population, perhaps more so. Thus, it seems very likely that bias will become a *cause celebre* in the foreseeable future and that the field would be well served by anticipating the need for a disclosure standard before the first (and inevitable) adverse public attention.

If most people accept the principle of disclosure, the onus is on none and the field as a whole will be respected for social responsibility, while the practitioner population will be assured that interests and biases are being fully reported. Reporting is not evaluation and there is no implication here, or in current publishing practice, that financially involved parties should have no voice. Evaluation of bias is the readers' responsibility. Disclosure is the readers' right.

Standard formats for reporting clinical experience

Standard formats in the biomedical peer literature are reasonably fixed by use. Considering that the major medical databases and libraries have accommodated their users to these formats, adoption of the Uniform Requirements seems practically indicated.

Standards for what is reported

The goal of full, functional disclosure for clinical claims expressed by the Uniform Requirements is no less applicable to acupuncture and Chinese medicine than to biomedicine. There is no reason that an acupuncturist or traditional internist should not be given enough information to evaluate clinical claims for themselves. However, this issue is often confused by the assumption that clinical validity and authenticity are the same.

Determining whether an idea is authentic, when and where it fits in the massive literate and oral traditions of Chinese traditional medicine, is no simple feat. It requires a specialized knowledge of language and the historical literature, a broad understanding of cultural and philosophical developments, as well as a familiarity with history, politics and economics. However, whatever value an individual writer may give to a clinical claim that is authentically made, establishing authenticity does not simultaneously establish clinical validity. Put simply, authentic ideas can be clinically useless and recently invented notions can be clinically valid. Thus, evidence of a continuous presence in the Chinese language literature of claims for the efficacy of a procedure is an obvious source of clinical confidence. It is also a minimal criterion for claims of authenticity. Any study claiming to conclude anything about Chinese medicine cannot be considered valid without demonstrating a basis for the hypothesis tested in the Chinese language literature. However, once authenticity is established such claims of clinical validity nonetheless require evidence that can be practically and publicly scrutinized.

In short, the Chinese literature as regards courses of treatment, acupoint selection, administration formats, doses, and other clinical procedures and observations cannot be ignored in the search for clinical evidence, and departures from the traditional literature or traditional concept definitions require justification, but the authenticated existence of any notion in the appropriate Chinese medical literature does not establish it as clinically valid. It is a first and critical step but, as regards public claims of clinical validity, it is only the beginning.

Formats for clinical claims in Chinese medicine do differ from those in biomedicine and include the following:

Case Studies: In original English language work case studies are often clinical sketches or anecdotes, for example, simple claims of cure for a particular patient who is informally described. However, in East Asian practice case studies can be detailed clinical reports and summaries, for example, a report of the treatment of several patients with a similar condition.

Inter-rater Studies: These establish whether similarly trained practitioners are able to reliably use so-called `subjective' diagnostic criteria. For example, a study showing that the students at an acupuncture school can reliably identify the pulse patterns taught in an appropriately controlled patient population. Although not unique to Chinese medicine these studies have a more significant role in reporting clinical experience in Chinese medicine because there are no objective markers or tests for many of its clinical concepts. These thus become subject to valid testing only after it is established that they can be reliably identified prior to, or as part of, any clinical investigation.

Outcomes Studies: These are clinical research designs called `positive control trials' or `active control equivalence studies (ACES).' This study type establishes how the therapy tested performs in comparison to the outcomes of a matched patient group treated by biomedical standard care. For example, a comparison of stroke patient groups which receive or do not receive acupuncture. Again, although these are not exclusive to Chinese medical research they take on a particular importance because Chinese therapies tend to be individualized and thus difficult to test in R.C.T.

Since Chinese medicine can also be tested in animal studies (e.g. the toxicity of a naturally-occurring drug) and other means used in biomedicine (e.g. a double blind randomized controlled clinical trial of a ``patent" formula), the following adaptation should be considered as in addition to the biomedical standard appropriate to the claim made. The following table (Table Two) adapts the biomedical standards to these basic forms of clinical reporting by assessing the type of evidence required to claim validity:

Table Two

A modified clinical reporting checklist * notes elements to which critics of biomedical methodologies often object	**Case Studies**	**Inter-Rater Reliability Studies**	**Outcomes Trials**
Primary Objective / major hypothesis	Yes	Yes	Yes
Justification of Sample Size	No	Yes	Yes
Participation rate if patients declined study	No	Yes	Yes
Inclusion/exclusion criteria	Yes	Yes	Yes
Source and initial number of patients	Yes	Yes	Yes
Randomization method *	No	Yes	Yes
Blinding techniques *	No	Yes	Yes
Accrual dates *	Yes	Yes	Yes
Identification of variable transformations or categorization *	No	No	Yes
Justification if outliers were omitted from analysis *	No	No	Yes
Analysis of patients withdrawn or protocol deviations	Yes	Yes	Yes
Time between randomization and start of treatment *	No	No	Yes
Number of patients who completed treatment	Yes	Yes	Yes
Treatment of missing values	Yes	Yes	Yes
Frequency of side effects	Yes	No	Yes
Identification of statistical software *	No	Yes	Yes
Justification of 1-tailed statistical tests *	No	Yes	Yes
Verification of statistical test assumptions *	No	Yes	Yes
Median follow-up time for censored patients *	No	No	Yes
Lost to follow-up as a proportion of censored patients not evaluated during a specific period *	No	No	Yes
Reporting the number of patients at risk over time *	No	No	Yes

Confidence intervals for effect sizes *	No	Yes	Yes

Although this is a subjective assessment, it is nonetheless fairly apparent that the basic information needed to evaluate clinical claims in Chinese medicine is very similar to that needed to evaluate claims in biomedicine. This is in no small part because many of the criteria are implicit in the nature of clinical experience. For example, no clinician can know how to value an opinion without some useful gauge of the experience on which that opinion is based in terms that can be fairly related to their own day-to-day reality (e.g. number of patients, follow-up period, etc.). It makes, for example, relatively little difference whether the practice in question is biomedical or Chinese medical in origin. If you do not know the scope of the experience supporting a claim, it is impossible to know its relative value.

In the proceeding table, for example, even the wholesale elimination of criteria that fervent critics of Western evidence-based techniques might argue are inapplicable, (see the * in the Table Two), leaves issues of sample size, selection criteria, and follow-up. In other words, regardless of the cultural and practical differences presented by Chinese medicine, it is impossible to know whether or not a clinical claim is worth your attention unless you can practically access the basic descriptors of the experience on which that claim is based.

This suggests that the basic information any clinician requires to judge any claim includes:

Table Three

1. A description of the hypothesis studied or the conclusion derived,
2. A description and justification of the number of patients and cases included, including the source of those patients,
3. A description and justification of the number of patients and cases excluded,
4. A description and explanation of any patients withdrawing,
5. A description of the number of patients completing the trial or used as the basis for the clinical claim,
6. A description and explanation for any alterations in the protocol for which the claim is being made,
7. A description and explanation for how missing data was handled,
8. A description of the follow-up protocols and an explanation of patients lost to follow-up
9. A description and explanation of any side-effects reported.

In other words, regardless of the class of clinical claim (case history, etc.), the absence of this information essentially denies readers the ability to examine the evidence. With no prejudice as to any eventual C.O.M.P. label that may be considered, the absence of this information renders a claim unavailable for peer review. To put this in perspective, I doubt that a commercial U.S. concern

that was unprepared to provide this information, and yet offered even general health claims for their products, would survive their first product liability case.

The presence of this information, however, is not the same as evidence for validity. This logical exercise noted seeks a minimum set of criteria for a peer reviewable Chinese medical claim by applying a near absolute bias against standard biomedical evaluation methods. It purports to show only that, as regards the basic descriptors of clinical experience, there is a minimum beyond which a claim simply cannot be judged. Put another way, there is an irreducible minimum short of which a medical claim cannot be considered as seriously intended for scrutiny. Further, that minimum is largely independent of the medicine for which a claim is made.

If, beyond the minimums for an individual clinician's assessment, writers hope to make broadly acceptable claims of clinical validity, biomedical evaluation methods cannot be so cavalierly ignored, if only because negative results in Chinese medical studies are often enough the result of research biases that overwhelm the Chinese medical approach, for example, treatment protocols that use an inadequate number of acupoints or a foreshortened treatment schedule.[14] Further, because these research models are broadly believed fair and effective by both East Asian and Western patient populations, failure to address these methods cannot advance public confidence in the efficacy of Chinese medicine. Thus, the difference between biomedical evaluations and Chinese medical evaluations must be squarely faced by writers who hope their work will have a more general influence. Fortunately the study by Hammerschlag and Morris provides an effective model.[15]

The intent of their article is to systematically review ACES studies of acupuncture to provide an assessment of how well these studies succeed in accomplishing their research intent - the ability to make claims about the efficacy of acupuncture. They isolated twenty-five (25) qualities by which to rate studies. These are:

Table Four

1. Was informed consent obtained?
2. Were the inclusion and exclusion criteria described?
3. Was rejection data presented?
4. Was the standard care protocol described?
5. Was the acupuncture protocol described?
6. Was any concomitant therapy addressed?
7. How was the sample size calculated?

8. Was randomization employed?
9. Were the patient demographics presented?
10. Were the end points described?
11. How were the treatment groups selected?
12. Was the withdrawal/dropout data presented?
13. Was medication compliance monitored?
14. Were the treatment assessors blinded?
15. Were duplicate assessments employed?
16. Was the data presented?
17. Were the end point statistics stated?
18. Was the statistician blinded?
19. Were side effects monitored?
20. Was the onset of treatment effects compared?
21. Was the duration of treatment effects compared?
22. Was follow-up data presented?
23. Was/were the acupuncturist/s training stated?
24. Was the funding source acknowledged?
25. Was an R.C.T. of standard care cited?

They report ratings, and their substantiation, for 23 screened articles obtained from MEDLINE, EMBSE, and AMED citations.

The first clear observation is that the list they developed effectively coincides (as the superset) with the lists from the previously cited sources as regards what basic information is required to evaluate clinical claims. The foundation information is extended to include the ethical issues of informed consent and funding disclosure, as well as further fundamental qualities such as training.

The rating system used to produce the systematic review described by Hammerschlag and Morris depends on a consensual measure of adequate/inadequate ratings by two highly trained and experienced researchers. This, while an important guide for researchers, the approach could also be employed to self-assessed claims as part the C.O.M.P. guidelines. The presence or lack of these elements in any formal claim concerning clinical experience would be an appropriate foundation for standard labels. Application of this rating system could also help develop objective editorial judgments where there are shared criteria and experience. For example, a periodical review board could apply this approach as part of its acceptance procedures. However, the question appropriate to the creation of C.O.M.P.

labels is whether or not there is sufficient commonality among writers' perception of the issue to achieve some standard.

Conclusion

In conclusion, claims of clinical validity are vital to the field's development and credibility. Opening the foundations on which claims of clinical validity are based to effective scrutiny is a necessary step in the progress of the field, particularly as regards to its acceptance by Western researchers, patients and opinion leaders. As regards the information required to evaluate the most basic elements of a clinical claim, C.O.M.P. guidelines could focus attention on the critical issues and educate readers to their rights and the effective means for protecting those rights. Thus, C.O.M.P. cooperative labels should be considered. This could be a particularly useful means of educating researchers to the background information required before valid tests of Chinese medicine can be claimed. However, as the various trial types already exist as well-used labels in the scientific literature, and related standards such as those of statistical practice exist within their defining fields, thus providing an well defined set of labels that require no adaptation. Thus, the aim of C.O.M.P. labeling should be to provide readers a reliable guide to the extent of the information provided and the guarantee of validity a writer claims.

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4. See for example: Eckman, P., *In the Footsteps of the Yellow Emperor: Tracing the History of Traditional Acupuncture,* San Francisco (CA): Cypress Book Company, 1996.

5. The initial C.O.M.P. meeting was attended by Dan Bensky (Eastland Press), Steve Birch (Paradigm Publications), Charles Chase (Blue Poppy Press), Andy Ellis (Spring Wind Herbs), Bob Felt (Paradigm Publications), Bob Flaws (Blue Poppy Press), Jake Fratkin (Shaya Publications), James Ramholz (Oriental Medical Journal), Miki Shima (JAF Foundation), and Nissi Wang (Eastland Press).

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