TOWARDS A MODEL FOR PLANNING CLINICAL RESEARCH IN ORIENTAL MEDICINE

Kell N. Julliard, MA,[1#] Claudia Citkovitz, MS, LAc,[2] and Douglas McDaniel, MTOM, LAc[3]

Background: Oriental medicine (OM) is widely practiced internationally and embraces many schools of thought. Western medical research is currently struggling to understand OM in purely biomedical terms, with limited success.

Objective: We propose a research model for applying Western research methodologies to OM in a way that respects its theory and modes of clinical application. This would facilitate systematic investigations of OM's specific assumptions and make explicit the way OM studies could build on each other.

Methods: To develop this model, the authors extracted key assumptions of Western research methodology germane to clinical research, put them in a developmentally logical sequence, and related them to the diagnostic and clinical processes of OM.

Results: The model categorizes studies into seven levels. Foundation studies (level one) establish the conceptual basis for OM research by establishing the internal validity of its basic "truth statements." Measurement studies (level two) determine how OM identifies and measures diagnostic indicators, treatment outcomes, and other basic aspects of health. Group studies (level three) describe populations in ways meaningful to their health. Pattern/diagnosis studies (level four) identify and define OM patterns of disharmony. Treatment technique studies (level five) describe particular techniques or principles of treatment, their indications, and rationale. Treatment effectiveness studies (level six) evaluate techniques of treatment, often by comparing the results of one technique with those of another in similar patients. Systematic reviews (level seven) draw together studies on the same topic to see if conclusions are thereby strengthened.

Conclusion: The levels can be used to establish relationships between already published studies, determine if sufficient background research has been done to enable a study idea to be carried out, and generate ideas for future studies.

Key words: Research methods, research design, investigative techniques, complementary therapies, acupuncture therapy, Oriental Traditional Medicine, Chinese Traditional Medicine

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INTRODUCTION

In contemporary biomedicine, research often informs clinical practice; new drugs, diagnostic methods, and medical devices are often tested experimentally before they are applied in the clinic. In the case of Oriental medicine (OM), however, American practitioners legally perform techniques–such as acupuncture, moxibustion, Chinese herbology, *tuina*, *gua sha*, Chinese dietary therapy, Qigong, and cupping–that have been stable elements of Chinese clinical study and practice for over 2,000 years but have not been thoroughly validated by biomedical research methods. This remains so in spite of the exponential increase over the last decade in the amount of OM research being conducted.

This lack of research validation of OM is troubling in light of research's influence on acceptance of new techniques by the biomedical community. Oriental Medicine appears to be successfully surviving its transplantation to the West without research validation, as evidenced by increasing use by the public and a burgeoning number of practitioner training programs. However, continued growth of OM practice without a corresponding increase in biomedical understanding and acceptance would be undesirable and potentially dangerous, as patients underreport alternative medicine usage to biomedical practitioners who are not perceived as understanding or supporting it.[1]

As emphasized by Walach et al,[2] when the treatments under consideration have been in use for some time, as is the case with OM, evaluation of treatment effectiveness starts with observational and other types of nonexperimental research designs. Most current research simply attempts to evaluate OM in biomedical terms, whether its concepts are able to be studied within the biomedical framework or not.

The assumption that standard biomedical research methods are adequate to address complementary and alternative medicine (CAM) and OM questions lacks justification. Conducting CAM research presents challenges not easily met by conventional study designs.[3,4] Research designed to establish causal links, such as randomized controlled trials, might not lead us to the best CAM research evidence.[4-6] This is a particular danger for OM, which comprises a vast international body of clinical and theoretical work, only a fraction of which is represented in the acupuncture techniques typically studied by randomized

1 Lutheran Medical Center, Brooklyn, New York; Department of Family Practice, State University of New York Downstate Medical Center, Brooklyn, New York

2 Department of Acupuncture and Oriental Medicine, Touro College, New York, New York; and Lutheran Medical Center, Brooklyn, New York

3 New York Chiropractic College, Department of Acupuncture and Oriental Medicine, Seneca Falls, NY; Pacific College of Oriental Medicine, New York, New York

Corresponding Author. Address:
Lutheran Medical Center, 150 55th Street, Station 2-30, Brooklyn, NY 11220
e-mail: kjulliard@lmcmc.com

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controlled trials (RCTs). Indeed, by imposing the culturally specific intellectual constructs of biomedicine onto OM research, we may be obscuring exactly those areas where it could benefit us most. New research strategies and a variety of research methodologies (especially those that take whole systems into consideration) are needed to explore the relationship between orthodox and unorthodox medicines.[7-9]

In mentoring acupuncture masters students in their thesis research, the first author (K.N.J.) observed that many of these students wished to carry out randomized controlled trials to prove the effectiveness of OM in treating many conditions. Not only did they have little awareness of the existence and value of the many other research methodologies, they did not understand how to assess whether sufficient foundational research had been done to make appropriate design of a clinical trial possible for a given condition. They also had great difficulty adapting the theory of OM to fit biomedical research models. This situation prompted the first author to develop a conceptual tool that would assist these masters students and potentially other researchers in successfully negotiating these issues.

Of course, the research literature has many helpful and well-considered resources that offer methodological advice for CAM research in general and OM research in particular. For instance, Jonas' concept of an evidence house arranged the main research domains of scientific investigation in a way useful to both complementary and biomedical systems.[5] Its semihierarchical but flexible approach offered research domains ("rooms" in the "house") for investigating the relevance and utility of healthcare practices, as well as domains that seek out causal attributions and mechanisms of action. Building on this evidence house model, Lewith et al[8] added concepts related to model validity of research in CAM (ie, how accurately a study takes into account the assumptions of the CAM system under investigation). These authors also explored how key conceptual issues can differ radically between biomedical and CAM systems, such as their dramatically different approaches to diagnostic classifications.

Also addressing CAM in general, Thomas and Fitter[3] presented a framework that outlined the important types of research questions and linked them to research designs of use in answering them. The framework of Thomas and Fitter had three main divisions: (1) proving studies that address the efficacy, effectiveness, and safety of interventions; (2) exploratory studies that lay the groundwork for conducting proving studies; and (3) improving studies that aim to improve practice through enhancing understanding of the clinical process. Similarly, the five-data box model of Wittmann and Walach[10] provided a way of categorizing research designs for CAM that spanned observational, experimental treatment, nonexperimental treatment, and outcome and evaluation research.

These approaches have much to offer research in OM through their flexibility, practicality, and wide perspective on the way healthcare practices are implemented. Even so, their intention was not to provide a systematic way of taking the unique theories of OM into account while utilizing the strengths of Western research methodologies. The work of MacPherson et al[11,12] helped remedy this by highlighting how biomedical methodologies such as case-control and cohort studies and randomized controlled trials can be used to investigate issues important to traditional East Asian systems of medicine. Also aware of this need, Sherman[13] in 2004 took a fresh and invigorating approach by identifying top research priorities for the acupuncture community. Because research methods follow from the questions that are asked,[3] the pithy questions posed by Sherman should give rise to new or modified research methods in the attempt to answer them.

Focusing on acupuncture specifically, Lao et al[14] in 2001 offered a systematic, stepwise approach to investigating efficacy. These authors recommended adopting the phased approach of the U.S. Food and Drug Administration to develop clinical trials of Chinese medicine. Along with providing valuable suggestions for addressing some of the thorny issues of Chinese medicine research, they identified a need for an integrated research model of Chinese and biomedicine and recommended research within the medical paradigm of Chinese medicine itself. In posing such questions as How valid are the diagnostic methods of traditional acupuncture? and What does each part of the acupuncture consultation contribute to the overall benefit?–White,[6] like Lao et al,[14]–strongly suggested that acupuncture be researched on its own terms. The focus of White's article, however, was not on this issue but rather on how to best conduct explanatory (tightly controlled, causal) clinical trials from a more biomedical point of view.

Similarly, an article on developing a research strategy for acupuncture by Lewith et al[15] astutely addressed the need to look at acupuncture as a whole system, taking into account nonspecific, placebo effects, the difficulty of measuring the effect size of acupuncture, and the importance of looking at effectiveness as well as efficacy. Like Bell et al,[4] Campbell et al,[16] and Verhoef et al,[7] these authors also recommended using qualitative research within randomized controlled trials to better understand patient-perceived benefits of treatment.

Thus, although many research models related to CAM and OM have been developed and much good advice for linking OM research questions with research methods has been offered, a model is still needed that can harness the powerful biomedical tools of research design without importing assumptions that may be invalid for OM.[4] Through such a method, OM could be researched on its own terms, "within its own medical paradigm" and using its own rich intellectual resources, but in a way still recognizable to biomedically trained readers as evidence based.[14] This paper explores the conceptual foundations for such a model as applied to clinical research.

The seven categories, or levels, proposed here build from fundamental, often tacit assumptions about health and disease (level one), through techniques of measurement (level two), description of groups (level three), diagnosis and pattern identification (level four), description of treatment techniques (level five), evaluation of treatment effects (level six), up to the systematic reviews that are often considered the highest level of evidence (level seven). If applied by OM researchers, this framework could serve several purposes. First, this framework could be used to investigate specific assumptions and observations from various types of OM systematically. Second, this framework makes explicit a way that OM studies could build on each other. Third, it could improve our ability to design and critique research studies by giving us a concrete way to determine whether