

Researching the Appropriateness of Care in the Complementary and Integrative Health Professions: Part I



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ABSTRACT

Objectives: The purpose of this article is to report on the Center of Excellence for Research on Complementary and Alternative Medicine at RAND Corporation. The overall project examined the appropriateness of chiropractic spinal manipulation and mobilization for chronic low back pain and chronic cervical pain using the RAND and University of California Los Angeles Appropriateness Method, including patient preferences and costs, to acknowledge the importance of patient-centered care in clinical decision-making.

Methods: This article is a narrative summary of the overall project and its inter-related components (ie, 4 Research Project Grants and 2 centers), including the Data Collection Core, whose activities and learning will be the subject of a following series of methods articles.

Results: The project team faced many challenges in accomplishing data collection goals. The processes we developed to overcome barriers may be of use to other researchers and for practitioners who may want to participate in such studies in complementary and integrative health, which previously was known as complementary and alternative medicine.

Conclusion: For this large, complex, successful project, we gathered online survey data, collected charts, and abstracted chart data from thousands of chiropractic patients. The present article delineates the challenges and lessons that were learned during this project so that others may gain from the authors' experience. This information may be of use to future research that collects data from independent practitioners and their patients because it provides what is needed to be successful in such studies and may encourage participation. (*J Manipulative Physiol Ther* 2018;41:800-806)

Key Indexing Terms: *Manipulation, Spinal; Chronic Pain; Low Back Pain; Neck Pain; Chiropractic; Complementary Therapies*

INTRODUCTION

Although there is general agreement that all patients should receive health care that is appropriate to their health problem and that inappropriate care is costly,¹ the challenge comes in determining what is appropriate care.² In general, appropriateness comprises the right therapy, for the right problem, and for the right patient.

In the current health care system, one answer to the question of appropriateness is that evidence-based care is appropriate care. However, this answer only shifts the problem from deciding what is appropriate to deciding what is evidence-based. Further, there is considerable debate about what percentage of treatments can claim to be evidence based. Some estimate that as little as 15% to 20% of all medical practice can truly claim to be evidence based.³⁻⁶ Hicks notes, "It is generally accepted that between 20% and 60% of patients either receive inappropriate care or are not offered appropriate care."⁶ For large areas of health care, including complementary and integrative health (CIH; previously known as complementary and alternative medicine [CAM]),^{7,8} we have very little data on how much care is appropriate or evidence based.

In the 1980s, the RAND Corporation^{2,8-13} and the University of California, Los Angeles (UCLA), pioneered a method to study the appropriateness of care that not only takes advantage of the available evidence base, but also draws upon the clinical acumen and experience of

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practitioners.¹⁴ This approach uses a mixed expert and clinician-based panel to consider the available evidence and then judge for a particular treatment whether

“for an average group of patients presenting with this set of clinical indications to an average US physician, the expected health benefit exceeds the expected negative consequences by a sufficiently wide margin that the procedure is worth doing ... excluding considerations of monetary cost.”¹²

This has been the most widely used and studied method for defining and identifying appropriate care in the United States, and it also has been used internationally.¹⁵⁻¹⁷ The RAND/UCLA Appropriateness Method (RUAM) makes it feasible to take the best of what is known from research and apply it—using the expertise of experienced clinicians—over the wide range of patients and presentations seen in real-world clinical practice. Clinicians are, after all, the final translators of evidence into practice, and this approach formalizes the process.¹⁸⁻²⁵

However, according to the World Health Organization, appropriate care is about ensuring that individuals receive care that is clinically effective; cost-effective; consistent with ethical principles; and meets preferences relevant to individuals, communities, and society.^{2,9} This represents a paradigm shift from previous, narrower definitions of appropriateness that only considered effectiveness, efficacy, and safety. This broader World Health Organization perspective makes explicit that the appropriateness of a procedure can be examined at multiple levels (eg, society, community, individual) and is, in part, dependent on the needs, desires, attitudes, expectations, and preferences of the patients who receive the procedure.

We argue that this broader definition is especially critical for determining the appropriateness of CIH treatments, primarily because CIH users are atypical health care users in several important ways. For example, much of CIH is paid for by the patient out of pocket. It is estimated that CIH utilization amounts to out-of-pocket costs for patients of about \$27 billion annually.¹⁰ In addition, most CIH use is consumer-driven, with patients acting as the primary locus of health care integration.¹¹ But while patients are known to play an important role in driving the expanded use of CIH, little is known about how patients make CIH-related decisions, what their preferences are for types of treatments, or what kinds of results they are seeking and would be satisfied with. If appropriateness of care is ultimately about matching clinically effective and cost-effective treatments with the physical, mental, and emotional needs of affected individuals, then a more thorough understanding of patient-centered desires, expectations, attitudes, and preferences, as well as the cost of these therapies, is required to make health care more effective and more efficient. This study was intended as a step in this direction.

The problem, therefore, for providers, patients, and policymakers is how to decide what is or is not appropriate care. For researchers, it is how to measure appropriateness, how much of health care is appropriate, what effect patient preferences and costs have on appropriateness, and what effect appropriate care has on outcomes.

In 2013, RAND was funded by the National Center for Complementary and Integrative Health to advance the methodology of determining the appropriateness of care in CIH. The target treatments and exemplars for CIH were spinal manipulation and mobilization (M/M), and the target conditions were chronic low back pain (CLBP) and chronic cervical pain (CCP). One important component of this project was the collection of a large amount of data from doctors of chiropractic and their patients.

In this series of articles in the *Journal of Manipulative and Physiological Therapeutics*, we describe how we gathered the varied and detailed data required to achieve the following study objectives: (1) to measure the appropriateness of M/M for CLBP and CCP and (2) to determine whether patient preferences and costs affect appropriateness, and further, whether appropriateness affects outcomes. In each article, we outline the problems we faced with each step of the data collection effort and the methods developed to overcome those problems. By doing so, we provide a blueprint that can be used by others who wish to study the care provided by various types of practitioners in private practice, including those offering CIH. The purpose of this article is to provide an overview of the overall project and its several parts.

THE RAND CENTER OF EXCELLENCE FOR RESEARCH INTO CIH

In 2013, RAND was funded by the National Center for Complementary and Integrative Health through a cooperative agreement to establish the RAND Center of Excellence for Research Into CIH (CERC) to advance the methodology of researching appropriateness in CIH. In this era of rising health care costs, it is increasingly urgent to evaluate the appropriateness of therapies provided to Americans. Although investigating the appropriateness of CIH therapies is important enough, the point has been reached where such evaluations must also include considerations of outcomes, patient preferences, and cost-effectiveness so that the overall value of these treatments, to patients, providers, and society, can be determined.

In addition to the expanded view of appropriateness, this project was innovative in other ways. First, there has only been 1 previous study published on the appropriateness of CIH care. RAND previously applied the RUAM to M/M for acute low back pain^{23,26,27} and had conducted a literature review and expert panel previously for M/M^{28,29} for cervical manipulation. Those studies demonstrated the

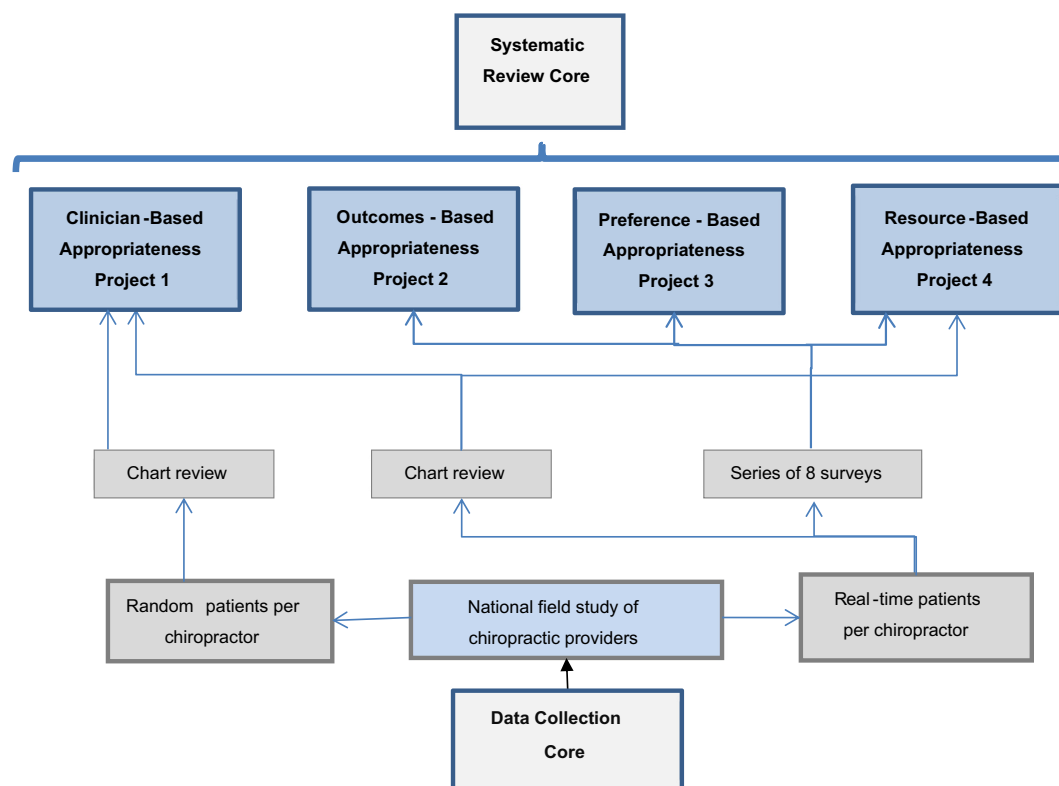


Fig 1. Relationships between the Projects and Cores in the Center of Excellence for Research Into Complementary and Integrative Health.

feasibility of applying appropriateness methods to CIH, and CERC was intended to develop the methods further and make these types of studies possible in a broader selection of CIH for a variety of conditions.

In addition, this study examined whether the Patient-Reported Outcomes Measurement and Information System health-related quality of life measure(s) are adequately sensitive in CIH populations and adapted Consumer Assessment of Healthcare Providers and Systems measures to chiropractic.

Organization of CERC

The CERC study contained 4 R01-sized projects:

- Project 1: Clinician-based appropriateness
- Project 2: Outcomes-based appropriateness
- Project 3: Patient preference-based appropriateness
- Project 4: Resource utilization-based appropriateness

In addition to the 4 projects, CERC had 2 core centers, 1 for conducting systematic reviews (the Systematic Review Core) and 1 integrated data collection center (the Data Collection Core) to collect the data required by all 4 projects (Fig 1). The center involved a collaboration among

RAND, UCLA, and the Samueli Institute but was located and administrated at RAND.

The work of the Data Collection Core (DCC) is the focus of this series of methods articles. Later, we briefly introduce the Systematic Review Core (SRC) and what it provided to the 4 projects. Then we will introduce the 4 projects and note where each requires the data collected by the DCC. Finally, we will provide more detail on the DCC, including its components, which will be explained more fully in the paper series.

SRC

An extensive review of the literature on M/M for CLBP and CCP was done and 2 systematic reviews prepared (including meta-analyses) with the support of the SRC. The systematic review for CLBP has been published,³⁰ and the review for CCP has been submitted for publication.

From these reviews and from sets of indications previously used in RAND's study of acute low back and cervical pain, a set of clinical scenarios for performing M/M for CLBP and CCP was developed for project 1, Clinician-Based Appropriateness. These clinical scenarios categorize patients for their symptoms, past medical history, and results of previous diagnostic tests. In the RUAM, the expert and clinician-based panels rate M/M for CLBP and

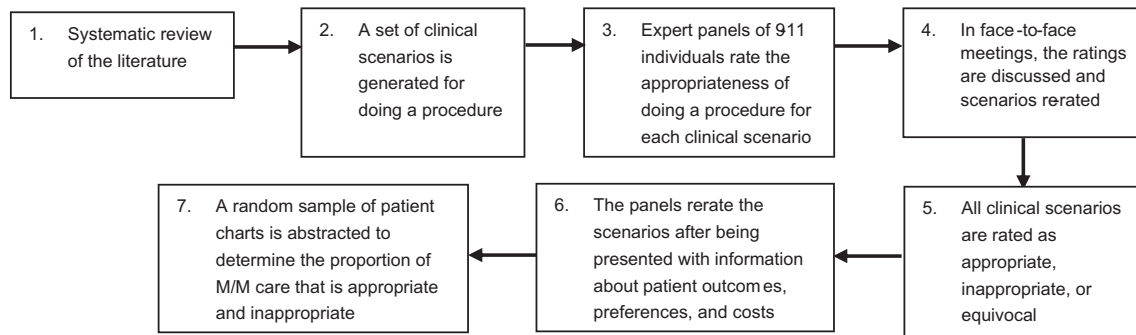


Fig 2. *The RAND/University of California Los Angeles Appropriateness Method.*

CCP for each of these indications. In their ratings, these panelists use the results of the systematic reviews the SRC generated. The SRC also produced literature reviews of the evidence for patient-reported outcomes (for project 2: Outcomes-Based Appropriateness), patient preferences (for project 3: Patient Preferences Appropriateness), and the costs of M/M (for project 4: Resource Utilization–Based Appropriateness).

Project 1: Clinician-based Appropriateness

Once the clinical scenarios were created, 2 multidisciplinary panels of 9 to 11 clinical and research experts each initially received the literature synthesis (systematic reviews and meta-analyses from the SRC) and the set of clinical scenarios. Based on the literature and their own clinical experience where applicable, panelists were asked to rate at home and on their own the appropriateness of M/M for each patient type (clinical scenario) for CLBP panel or for CCP panel. The panels then were brought together in a face-to-face meeting and the results of the ratings shared with the panel members. After group discussions, the panels rerated the indications. Once the ratings of appropriateness were determined for each indication, the charts of a random sample of patients being treated with M/M (by chiropractors) for CLBP and CCP were reviewed to determine the proportion of M/M, given that it was appropriate. Later in the project, in 2 further rounds of ratings, the panels were asked to rerate the clinical scenarios at home and then face-to-face to ascertain if they had changed their ratings based on presented data from projects 2, 3, and 4 on patient outcomes, preferences, and cost. [Figure 2](#) outlines the process used to derive ratings of appropriateness or inappropriateness.

Project 2: Outcomes-based Appropriateness

Project 2 will examine the applicability of standardized patient-reported outcomes that assess patient experiences of care (Consumer Assessment of Healthcare Providers and

Systems) and health-related quality of life (Patient-Reported Outcomes Measurement and Information System) to chiropractic patients who have experienced M/M for CCP or CLBP, and to make modifications to these measures where needed. Testing involved focus groups, cognitive interviews, pilot tests, and then fielding of the measures to our national sample. This project also will use data from the chart reviews to determine whether the appropriateness of M/M received affects patients' experiences of care and health-related quality-of-life outcomes.

Project 3: Patient Preference–based Appropriateness

Given the prevalence of patient self-referral and the health system–wide focus on patient-centered care, this project examined how patient preferences affect what is considered appropriate care. Objectives for this study included understanding how patients with CLBP and CCP decide to use M/M and determining what they believe is appropriate care, drawing on data from our national sample to determine patient preferences for M/M care.

Project 4: Resource Utilization–based Appropriateness

Project 4 had 2 components. The first was to provide information to the panels regarding the relative costs of M/M compared with the other therapies available for CLBP and CCP. These data were used by the panel to determine whether the relative cost or cost-effectiveness of M/M compared with alternatives had an effect on panelists' ratings of appropriateness. The data on relative costs and cost-effectiveness came from 2 simulation models built on the results of studies of different nonsurgical interventions for CLBP and CCP.

The second component of project 4 was to examine whether economics could provide any information about the appropriate duration of M/M care once it was chosen. This analysis was built on biweekly symptom and health care resource use data gathered by the DCC.

DCC

The DCC gathered all the data required by the 4 CERC projects. As discussed above, these data involved abstractions from patient charts as well as nationwide surveys of patients who were being treated by M/M for their CLBP or CCP for their characteristics and outcomes collected from patients.

Doctors of chiropractic associated with 125 practices/clinics were recruited from 6 sites geographically distributed across the United States: Portland, Oregon; San Diego, California; Dallas, Texas; Minneapolis, Minnesota; Tampa, Florida; and Seneca Falls, New York. Although the recruitment and data collection in the practices will be described fully in one of the series papers, a short account will be given here. A detailed description of the patient sample has been published.³¹

Online Survey Data Collection. From each practice, we recruited patients over a 4-week window and asked those who had CLBP or CCP to participate. Once patients consented and we confirmed the chronicity of their pain, we interacted with them via weblinks to online surveys over 3 months, during which they completed a total of up to 8 surveys. At baseline, we enrolled 2024 patients of which 1835 completed the final 3-month follow-up survey. We asked each patient who was enrolled for permission also to scan their patient file/chart, which yielded 1708 files.

The longer surveys were fielded during screening, at baseline, and at 3 months. Shorter biweekly surveys between baseline and 3 months only included health care utilization, pain, and function to minimize patient burden and maximize response rates.

Each practitioner also completed a survey that captured demographic data (age, sex, race, marital status, chiropractic school attended, etc) and asked about their practice and their patients—for example, number of years in practice, number of years at present location, arrangements of practice (solo, group, multispecialty), practice management techniques, practice gross and net income in the last year, insurance coverage, services offered, referral patterns for diagnostic studies, and treatment procedures used.

Collection and Abstraction of Data From Charts. We also selected a random set of files of chronic patients from the practices. This was done to generate a sample of patients that was as representative as possible of all chiropractic patients. This representative retrospective sample allowed us to calculate the amount of appropriate and inappropriate care being offered to chiropractic patients and the proportion of patients being treated who have chronic pain. However, this retrospective sample also was a method to determine the representativeness of the sample of patients who participated in the surveys to determine if the recruited sample was biased in any way. These scanned files (both the patients in the study and the random sample) then were protected in encrypted files and transferred to RAND,

where we abstracted the data and deidentified the files. The chart abstraction was done by 4 doctors of chiropractic.

The project was approved by the Human Subjects Protection Committee at RAND.

DISCUSSION

This overview of the CERC study attests to the complexity of measuring the appropriateness of CIH care and its potential modifications even with an established CIH profession such as chiropractic. To steal a political term, it takes a village to do this work. Sixteen research staff were employed on this project, and the total budget for the project was over \$8 million.

We learned a lot in this project, and in future papers in the *Journal of Manipulative and Physiological Therapeutics* we will elaborate on how we were able to bring the data collection portion of this project to fruition. There were many moving parts that needed to be coordinated and integrated, the parts were highly symbiotic, and each element was required to be able to capture the data needed to answer the question of whether and under what circumstances is M/M appropriate for the treatment of chronic low back and neck pain.

The lessons learned here may provide a basis for others who follow, particularly when combined with the detailed information of what we did to achieve our results in following papers in this series. But the lessons are not just for researchers; we hope that they will highlight the extraordinary contribution made by the practice doctors of chiropractic and their staff in this process and encourage future participation. It is only through participation in studies like this that the chiropractic research agenda can be advanced, and only with that can chiropractic fully participate in the world of evidenced-based practice.

Limitations

This study was done in 6 states of 1 country (United States), thus there is some regional limitation. It also was done in clinics whose practitioners agreed to participate and with patients who agreed to participate. This is acceptable in a center that was funded as a methods center where we are not trying to generalize but are trying to see if this type of research method can be conducted in practices. It also is limited by its focus on chiropractic. Most chiropractic clinics have an organizational structure that includes such things as organized filing systems, including electronic files, computers, and scanning equipment. Although we provided some of this when necessary, for the most part it was possible to work in the clinics with limited disruption. It may be the case that less-established CIH/CAM professions may not have the infrastructures to allow for this. That will need to be discovered in future research.

CONCLUSION

This article delineates the challenges and lessons that were learned during this project. This information may be of use in future research where data are collected from independent practitioners and their patients because it provides what is needed to be successful in such studies and may encourage participation. There are 3 major conclusions from this report:

1. Appropriateness studies based on practices can be done in chiropractic and probably other CIH/CAM practices.
2. Doctors of chiropractic and their staff are not only willing to participate, but also will happily assist in collecting the data and recruiting the patients. They can be trained to participate in quite sophisticated data collection and data protection methods.
3. Where patients feel the clinic is supportive, they are highly receptive to participating and once enrolled tend to stick with the project.

In following articles of this series, we will provide detailed information on Health Insurance Portability and Accountability Act requirements, survey design, building a practice-based network, provider- and patient-centered research, and chart selection and abstraction.

FUNDING SOURCES AND CONFLICTS OF INTEREST

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Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): I.D.C., P.M.H., G.W.R., R.D.H.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): I.D.C., P.M.H., G.W.R., R.D.H., L.G.H., M.D.W.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): I.D.C., P.M.H., G.W.R., R.D.H., L.G.H., M.D.W.
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Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): I.D.C., P.M.H., G.W.R., R.D.H., L.G.H., M.D.W.

Practical Applications

- This paper provides information for CIH researchers who might wish to conduct practice-based research, particularly appropriateness studies.
- This information also assists those in the chiropractic profession who might want, or be asked, to participate in research.

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