# IS HEALTH SERVICES RESEARCH THE HOLY GRAIL OF COMPLEMENTARY AND ALTERNATIVE MEDICINE RESEARCH?

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In a 2006 article in *Alternative Therapies in Health and Medicine*, Herman et al argued cogently that adopting a health services research (HSR) paradigm would help resolve some of the issues that the complementary and alternative medicine (CAM) community and those researching CAM face with randomized controlled trials.<sup>1</sup> Although the article makes a strong case for HSR and CAM, it fails to discuss some of the work in HSR that is uniquely relevant to CAM or to provide a critique of the view one

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ne way of viewing the contribution of health services research (HSR) is from the perspective of evidence-based practice (EBP).<sup>2,3</sup> EBP has been contrasted with traditional care that is characterized as "practical, prudent, and personal."<sup>4(p1288)</sup> It places a premium on using current evidence to answer clinical questions.<sup>5</sup>

There are 4 areas relating to EBP within HSR that have significance for CAM: (1) descriptive studies; (2) studies of effectiveness; (3) studies of health-related quality of life (HRQL); and (4) studies of the appropriateness of care (systematic reviews).

## DESCRIPTIVE STUDIES

Today many individuals involved in healthcare are familiar with the percentage of the population using CAM, mostly due to the article by Eisenberg et al,<sup>6</sup> which has stimulated a huge interest in CAM among mainstream and non-mainstream healthcare providers and researchers. Though this work has established the magnitude of the use of CAM, it has not provided an empirical gets from HSR about CAM. There is within the studies of chiropractic a sufficient body of HSR, which can help to assess what the contribution of HSR has been in the past and also what its limitations are today. It provides a cautionary tale for CAM. This article looks at HSR in relationship to evidence-based practice and will discuss the limitations and dangers of the view of CAM from the perspective of HSR using chiropractic studies as an exemplar. (*Altern Ther Health Med.* 2008;14(4):40-45.)

base that describes what is actually done in CAM practices. Herman et al note that of the 84 abstracts related to HSR and CAM, "the bulk of these studies (30) were surveys of CAM users that often included their reasons for using CAM. The next largest group of studies (13) was made up of surveys of various CAM providers to obtain their characteristics, the characteristics of their patients, and the specific therapies they provide."<sup>1(p80)</sup>

It would be difficult to exaggerate the importance of the descriptive studies for CAM. Until we know more about the practice, scope of practice, patient characteristics, utilization rates, and patient numbers, it is difficult to design appropriate studies or to even know which issues are worth studying. The studies on epidemiology, insurance, and cost effectiveness can all contribute to our understanding of CAM. For the overwhelming majority of CAM practices, there is a lack of evidence about what is being done in the practices, to whom it is being done, for which conditions it is being done, at what cost is it being done, by whom is it being done, and what education and training practitioners have to be doing it. Combining this with the fact that CAM practices are seldom ever portrayed in films or on television, describing them as a black box is apt.

To the extent that science is supposed to be about discovery and then explanation, it often seems that the research community and funding agencies have it reversed. The National Institutes of Health (NIH) usually favors hypothesis-generated research and identifying biological mechanisms over descriptive studies. These agencies often provide large sums of money to fund biological mechanistic research and randomized controlled trials (RCTs) but nothing for descriptive studies. This is simply not good science, and the slightest knowledge of the history of science establishes the incredible importance of descriptive work (eg, the taxonomies of plants, the classifications of phyla/genera/species, the classification of diseases). In the case of CAM, the paucity of descriptive work is such that the very classification of something as CAM is problematic, as we do not know what the common elements of CAM practices are.

### **Studies of Effectiveness**

The dominant focus of EBP has been the RCT. Although other forms of study designs may be included in a systematic literature review (clinical controlled trials, cohort studies, and simple pre/post case series), the RCT is given greater weight because it is the design that most clearly establishes efficacy. The majority of RCTs generally test a therapy under ideal conditions and often with homogeneous populations to ensure comparability of the groups when comparing outcomes.7 This can be a strength as well as a weakness of the design, but ultimately EBP requires therapies that can be applied in normal practice-that is, effectiveness studies.8 Efficacy involves testing a therapy under ideal conditions in which most of the variables can be controlled and where the outcome can therefore be attributed to the therapy being tested. Effectiveness involves testing the therapy under normal practice conditions in the real world. Furthermore, therapies with equal or comparable efficacy may differ considerably in terms of effectiveness.9 In general, "assessing efficacy is not equivalent to assessing effectiveness."10(p116)

The definition of HSR given by Herman et al<sup>1</sup> implies that HSR is conducted at the clinical level, the institutional level, the systemic level, and the contextual level.<sup>11</sup> The structure and process across organization types (eg, managed care) can affect efficacy and clinical outcomes. At the systemic level, the way healthcare is organized (ie, a nationally funded and organized healthcare system) clearly impacts the patient-provider transaction. At the contextual level, other policies (eg, welfare policy) also have an impact. But the real importance of HSR here is its focus on such things as utilization, costs, appropriateness, and outcomes in real settings. Ultimately, EBP is about adopting the most efficacious, effective therapies with the best outcomes within real practices and using the resources available and with real and average providers in real and average healthcare settings. As Coulter noted in a 2001 article, "in this way HSR introduces a badly needed dose of realism into the evidence-based practice movement."7(p714)

In a very real sense, EBP may not be possible without the contribution of HSR because it focuses largely on practice-centric research. Such research, with its focus on patients, access, utilization, services, cost, quality of care, appropriateness of care, the health encounter, and outcomes, would place the focus squarely on the actual practice of CAM.

Part of this shift in emphasis would also mean a shift from a focus on efficacy (trials) to a focus on effectiveness (what works in practice under everyday conditions with average patients and with average providers). When something has been shown to be effective in practice, we should move to trials to determine efficacy. When we know something is both effective and efficacious, we should move to understanding the biological mechanisms involved. Today, this would be an almost complete reversal from the way research proceeds and the way government agencies, including the NIH, fund research.

## PRACTICE-BASED RESEARCH AND EVIDENCE-BASED PRACTICE

In the case of CAM, if we are going to advance EBP, we need to advance practice-based research (PBR). Here we need to see what makes a healthcare provider a CAM provider by observing his or her everyday practice (what is actually being practiced) by using ethnographic research and observation studies. This cannot be accomplished simply by looking at patient files or by interviewing patients and practitioners. It requires observation of practices using methods such as a rapid ethnographic assessment to compile a comprehensive account of what CAM providers are actually doing in the health encounter.

A second requirement is for practices to become the sites for collecting data. CAM groups have recognized the necessity of forming practice networks in assembling data. They have recognized that there is no alternative as they also face the challenge of substantiating that their practices are evidenced-based.<sup>12</sup> Can HSR put the practice back into the equation for CAM? To answer this question we need to look to 2 areas where HSR measurement of outcomes harmonizes well with CAM: health-related quality of life and appropriate care.

### Health-related Quality of Life

The essential feature of this type of research is that it moves the perspective from the provider to the patient.<sup>13</sup> The earliest health measures were objective indices of disease that were based on the judgment of the provider. Over time these have been supplemented with measures that are often subjective, patient-centered, and psychosocial in nature.<sup>14</sup> The quality-oflife measures continue this trend with a focus on those things that are important to the patient (eg, comfort, ability to function, impact on socializing, and spiritual wellness).

Within HSR there has been considerable work from the 1980s onward in developing health-related quality measures. It is a perspective that meets one of the major objectives of CAM practice: good patient outcomes. It is difficult to think of an area more crucial to determine EBP than evidence that the outcomes are favorable to and valued by the patient. A technically great outcome that confers no benefit to the patient, in the patient's point of view, would be a dubious achievement. For many outcomes, only the patient is competent to evaluate the desirability and value of care. Patients' utilities, such as those outcomes they value most for a given cost, should play an important part in selecting the appropriate care.<sup>15</sup>

## **Studies of Appropriate Care**

Clinical practice always involves a balance between care that is appropriate and inappropriate, necessary and unnecessary.

The challenge of EBP is to distinguish appropriate from inappropriate care and necessary from unnecessary and ultimately to reduce both inappropriate and unnecessary care. It is important to note that care can be appropriate but unnecessary, but never necessary but inappropriate.

Questions of appropriateness, however, involve judgment calls, particularly in those areas where research evidence does not allow for a definitive resolution. Where a strong body of evidence exists about efficacy, as in a meta-analysis of RCTs, or effectiveness, as in the case of a substantial body of HSR documenting positive outcomes, there should be little doubt about what is appropriate. Those procedures for which there is strong evidence are the most appropriate. Those for which there is a massive "gray" zone where the evidence is indeterminate or equivocal. This gray zone is where much of health practice falls.

During the last decade, increasing attention to HSR has been turned toward examining the appropriateness of care, and an increasing body of research has delineated the amount of inappropriate medical care. The impetus for this work was the demonstration of both small- and large-scale variations in the amount of medical care delivered to different populations that could not be attributed to variations in the populations themselves.<sup>16-19</sup> Surgical rates were shown to have a 6-fold difference in different geographic areas. This led to investigations into the causes of those variations, and although the incidence and prevalence of disease, socioeconomic factors, and underlying differences in the healthcare delivery system have all been shown to contribute, they do not adequately explain these observed variations.<sup>20</sup> One major factor that has been studied is the appropriateness of care delivered, and the research has established that a substantial proportion of the medical care delivered is considered inappropriate.<sup>21-23</sup> The rate of inappropriate use of such procedures as carotid endarterectomy was 32%; for coronary artery bypass graft surgery it was 14%.<sup>24,25</sup> Such inappropriate treatment clearly poses a challenge to the aim of providing quality care.<sup>26-28</sup>

The applicability of appropriateness to CAM is obvious, but the methodology is also applicable. The RAND Corporation has applied this method to investigate the appropriateness of chiropractic manipulation.<sup>29,30</sup>

In the field study done to determine the rate in practice, RAND found that 29% of the manipulation was judged to be inappropriate, 46% was appropriate, and 25% was judged uncertain.<sup>31</sup> However, for those patients who did not receive manipulation for low back pain, 38% of the cases were judged to be appropriate for manipulation. This result implies that there was a problem of both over- and under-use of manipulation for low back pain for those patients. This research was conducted through field studies in which a random sample of practices was used to generate a random selection of files. A research abstractor was sent to each of the selected practices. Patient records, for abstraction, were randomly selected by the abstractor from the chiropractic offices, so the research was both practice- and patient-centered.

#### CHIROPRACTIC AND HEALTH SERVICES RESEARCH

Chiropractic is probably unique among the CAM group in that it not only has been extensively studied by HSR but has been studied in virtually all the major categories listed above. A review of this HSR work in 1997 listed more than 100 articles.<sup>32</sup> Furthermore, 2 distinct bodies of literature have developed, which for the most part do not reference each other. In addition to HSR there is an extensive list of publications spanning over 40 years in sociology and anthropology.

Major areas of interest in HSR have included workman's compensation care, <sup>33,34</sup> the comparison of medical and chiropractic care, <sup>35-38</sup> evaluation by patients, <sup>39,40</sup> the testing of various hypotheses about chiropractic utilization using empirical data, <sup>41-43</sup> studies on the efficacy of chiropractic in clinical trials, <sup>44-46</sup> meta-analyses of studies on chiropractic care, <sup>47</sup> the appropriateness of spinal manipulation, <sup>4750</sup> and the economic costs of chiropractic. <sup>34,51-54</sup>

There is also a large body of descriptive studies. There are studies based on data from a single state, <sup>55</sup> data from areas within a state, <sup>56</sup> and data from outside the United States. <sup>57,59</sup> Within the United States, community-based data has been used, although much of the analysis is based on data that are now dated. <sup>60</sup> More recently studies have been done through an established chiropractic practice network. <sup>61,62</sup> There exists, therefore, an extensive body of data that describes the practice, the patients, and the providers of chiropractic. <sup>63,65</sup>

## THE CONTRASTING VIEWS OF HEALTH SERVICES RESEARCH AND THE SOCIAL SCIENCES

The 2 distinct views of chiropractic have previously been contrasted by Coulter.<sup>66,67</sup> The first view is from the HSR perspective, using data on the epidemiology of chiropractic and of health services utilization, efficacy, effectiveness, costs, appropriateness, quality of care, and outcomes.<sup>60</sup>

When chiropractic is examined epidemiologically, it is clear that the overwhelming majority of patients present for a narrow scope of conditions. Three conditions account for around 58% of the conditions presented: general back/spine, neck/shoulder, and lower back. All other categories have less than 5% of the patients reporting.<sup>63</sup> National surveys by the National Board of Chiropractic Examiners (1993) also indicate that spinal subluxation/joint dysfunction and headaches are the conditions routinely seen.<sup>68</sup> In addition, conditions listed as "often seen" are overwhelmingly neuromuscoloskeletal in origin. Furthermore, manipulation is the most frequently billed service by chiropractors.<sup>60</sup>

Overall, the picture presented of chiropractic is that of a limited specialty focusing on neuromusculoskeletal conditions<sup>31,69</sup> and using predominantly spinal manipulative therapy.<sup>68</sup> Studies show patients presenting with a very limited number of health problems.<sup>70</sup> Chiropractic is seen as limited in scope both in terms of the therapies used and the type of health condition brought to chiropractors by patients. This has led some to argue that chiropractic is akin to a sub-specialty within medicine and not a broad-based alternative to traditional medicine.<sup>6971</sup>

Studies also suggest, nonetheless, that chiropractic healthcare

is not used exclusive of medical care but in addition to it.<sup>41,43,55,58</sup> Comparatively speaking, there now exists an extensive body of controlled trials on manipulation,<sup>72</sup> the findings of which indicate that manipulation is an efficacious therapy for non-chronic low back pain<sup>47,73</sup> and for some cervical problems.<sup>50</sup> However, the majority of the work to date deals with efficacy, not effective-ness—that is, outcomes from its use on patients in average and real clinical settings. The problem with such an approach is that it gives no indication about the nature of the health encounter or the type of care that is delivered.

## THE SOCIAL SCIENCES

The second view is from the anthropology and sociology perspectives and is entirely different from the above. In the anthropology and sociology literature chiropractic is viewed as a broad-based, distinct alternative health paradigm with its own metaphysic, philosophy, language, therapies, and health practices and as one providing a unique health encounter. Numerous terms have been used to describe this paradigm (eg, a patient-centered, holistic wellness paradigm), but regardless of the terms, chiropractic cannot be reduced to simply the manipulation of the spine and other joints. Several authors have suggested that the traditional positivist/empiricist/quantitative research paradigm is incapable of capturing a grounded understanding of chiropractic practice and must be supplemented with qualitative studies.<sup>7476</sup> This can be done only via observation-based studies of chiropractic practice focusing on the chiropractic health encounter.

A 1980 Canadian study by Kelner et al that used rapid ethnographic observation study of the clinics showed that despite what appears to be a very limited epidemiological scope in the practice around these conditions of apparent limitations, the chiropractor has constructed a broad-based health paradigm.<sup>57</sup>

In 1985 Coulehan interviewed and observed chiropractors in the United States and described a health encounter very similar to the one documented by Kelner et al.<sup>57,77</sup> According to Coulehan, chiropractors bring to the encounter a belief system with not only a positive regard for the patient and "genuineness" (ie, the ability to be oneself in the relationship without hiding behind a role or facade) but also with a positive view that what they do helps the patient. As Coulehan states, "the net effect is a logical set of beliefs which appeal to common sense, use scientific terminology, yet promote a natural, non-invasive, holistic approach rather than a medical approach."<sup>77(p388)</sup> Coulehan concludes, "Chiropractic care, as opposed to spinal adjustment as an isolated treatment, must be viewed as a process or interaction."<sup>77(p388)</sup>

In 1993 Jamison observed Australian clinics, interviewed practitioners, and viewed patient files and concluded that the chiropractors were providing holistic care.<sup>78</sup> The objective for the chiropractor is the total well-being of the patient even if the initial focus is manipulation of a specific lesion. At the level of the presenting symptoms and during the application of therapy, the encounter may resemble that of a reductionist, non-holistic practitioner. This, however, overlooks how the therapy is actually being delivered within a much broader paradigm.<sup>78</sup>

Oths, in analyzing communication in a chiropractic clinic in the United States in a 1994 article, also stressed that chiropractic explanations are simple and understandable and harmonize very well with the way individuals conceptualize things in an industrialized society.<sup>79</sup> She further notes that there is a high degree of congruence between the explanations the patients give for their illness with those of the chiropractor. Her conclusion is that patients internalize the chiropractic model of disease to a high degree.

These observation studies collectively show that chiropractic care is characterized by a holistic regard for the patient. While manipulation may be the major therapy, it is delivered within a broad-based wellness/holistic paradigm. To reduce chiropractic to manipulation of neuromuscoskeletal problems is to misconstrue the nature of chiropractic.<sup>57,779</sup>

### WHY THE DIFFERENCES?

Epidemiology and HSR have focused on such matters as the presenting condition, the diagnosis, the distribution of conditions among the patients, utilization patterns, cost of the care, objectively measured outcomes and satisfaction with the care, and efficacy of the care, which usually means the efficacy of manipulation.<sup>32</sup> On the other hand, sociologists and anthropologists have been more likely to focus on the total health encounter and the effectiveness of the care. They tend to consider all elements making up the social/cultural/psychological aspects of the care. In this sense they are more concerned with care than are health services researchers, who are more concerned with treatment.

HSR researchers also have tended to collect quantitative data derived from patient files, <sup>31</sup> surveys, <sup>12</sup> billing records, <sup>51</sup> clinical assessment instruments, <sup>80</sup> validated health status instruments, <sup>81</sup> and validated satisfaction instruments. <sup>82,83</sup> Anthropologists and sociologists, however, have been much more likely to use observation techniques and collect qualitative data. <sup>84</sup> They are more interested in discovering the meaning of the care to the patient, which is more likely to be predicated on the use of a qualitative research methodology. There are exceptions where both methods are used by social scientists.<sup>57,79</sup>

The 2 groups also have different research objectives. In anthropology and sociology, much more emphasis is placed on discovery, at least in areas where the body of knowledge is sparse, than on justification of therapy. The dominant concern of much of HSR, however, as evidenced in the elevation to supremacy of the RCT and the use of systematic literature reviews and metaanalyses, is for determining "legitimacy" of a therapy by efficacy studies. Herein can be seen the difference between a focus on efficacy and one on effectiveness. In studies on effectiveness by social scientists, the outcome of the therapy is measured within the context of the whole health encounter as it occurs in real practice and not just for manipulation in a controlled trial. Here legitimacy includes both patient assessment of outcomes and socio-cultural legitimacy. By contrast, in efficacy studies, the patient assessment of outcomes is thought to be suspect because of the placebo effect, and therefore emphasis is not placed on the whole encounter.

But a more fundamental difference might lie in the fact that

much of social science is not concerned with outcome at all but simply capturing and describing the nature of the paradigm as a social and cultural system. Here both the objective and obligation of the researcher are different. The social scientist is more concerned with grounded research, ie, grounded in the perspective of the social actors. Capturing that perspective accurately is more important than evaluating it. A social scientist would not usually be researching the effectiveness of Catholicism vs Judaism. They would be interested in describing both and looking at their impact.

### CONCLUSION

The chiropractic experience would suggest that while HSR is important and clearly has made significant contributions, it is also incomplete. More importantly, it is incomplete in ways that can hurt CAM. To the extent that health insurers, institutional healthcare providers, and legislative bodies use HSR for informing themselves about chiropractic and what services should be provided, HSR runs the risk of painting chiropractic into a very narrow scope of practice. Where institutions such as hospitals are creating integrative medical centers, many are arguing that only evidenced-based CAM will be included. By "evidenced-based," they usually mean only those CAM therapies with strong HSR evidence about efficacy. From that point of view, chiropractic would seem to be one of the strongest of the CAM group. But such research focuses on a very small part of chiropractic practice and may miss entirely its major contribution, which might not be manipulation but manipulation delivered within a holistic health encounter. To that extent, both chiropractic and the public lose.

So it would seem that HSR is neither a panacea nor the Holy Grail. It clearly has an important contribution to make, but as with all research paradigms, it addresses only one way of knowing. It may be a truth, but is not the only truth and certainly not the whole truth. To the CAM community, "proceed with caution" might be the appropriate guideline.

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