

CHAPTER 11

Complementary Alternative and Integrative Medicine: Current Challenges for Outcomes Measurement

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Increasingly, individuals have been using complementary alternative medicine (CAM) and integrative medicine (IM) approaches to improve their wellness and treat their illnesses (Coulter & Willis, 2007). In the United States, CAM and/or IM have been increasingly seen as part of health care and have been reimbursed by managed care entities, insurance carriers, and hospital providers (Pelletier, Marie, Krasner, & Haskell, 1997). A national survey of adults established that 34 percent used at least one unconventional therapy to treat back problems, insomnia, headaches, anxiety, depression, and cancer. Costs for such care were estimated at \$425 million compared with \$338 million in costs for visits to primary care physicians. Expenditures for CAM/IM were estimated at \$11.7 billion; of this, \$10.3 billion in out-of-pocket expenditures exceeded those for hospital care (\$12.8 billion) and represented half of all physician out-of-pocket expenses (Eisenberg et al., 1993). Today, it is estimated that the prevalence of CAM use is 38 percent for adults and 11.8 percent for children in the United States (Nahin, Barnes, Stussman, & Bloom, 2009). More than

30 billion dollars (\$33.9) are spent on out-of-pocket CAM visits and CAM products, with chiropractic services noted as the most frequently used therapy among manual modalities. In 2003, a national survey of 1,007 U.S. hospitals documented that 16 percent provided IM and more than 27 percent offer some form of CAM (Larson, 2005).

Although the percentage of CAM/IM use is dependent on how CAM and IM are defined (Bhattacharya, 1998), continued, and likely increased, use of CAM/IM is considered more fact than speculation. Studies estimate that 30 percent to 40 percent of medical patients in North America will use some form of alternative health care in the future (Nahin et al., 2009). In the United States, integration of CAM and biomedicine (traditional medicine as practiced in Western culture being led by patients as they combine both approaches to treatment (that is, they typically seek out a biomedical provider before or concurrent to seeking CAM care; Barnes, Powell-Griner, McFann, & Nahin, 2004; Eisenberg et al., 2001; Simile, & Hardy, 2002) on a daily basis to address their physical and mental health needs (Astin, 1998; Eisenberg et al., 1998). In 2003, a national survey of 1,007 United States hospitals documented that patient demand was the most significant factor (83 percent) for incorporating CAM/IM (Larson, 2005).

In addition to a propensity to seek out multiple treatment modalities, the most predictive demographic factors associated with CAM use appear to be gender (women use CAM more than men), age (18 to 65 years old), race/ethnicity (whites use CAM more than other groups), education level (higher level of education), and geographic region (rural more than urban (Barnes et al., 2004; Eisenberg et al., 1998; Graham et al., 2005).

In this chapter, we continue to discuss how additional empirical, philosophical, and theoretical underpinnings surround the measurement and assessment of CAM/IM. It is not our purpose to suggest specific outcome assessment measures but to review some of the main research and measurement approaches being used and their associated challenges, and to make recommendations that offer promising approaches for the future.

Definitions and Integrated Paradigms: The Journey toward Consensus

General Definitional Issues

CAM modalities are thousands of years old (Whorton, 1999). Despite the well known fact, modern day definitions of what constitutes CAM/IM in the United States vary considerably with no agreed-upon uniform definition of what constitutes CAM.

The diversity and range of practices included under the rubric of CAM lessen the usefulness of establishing a definition. They range from focused therapy approaches (modalities) such as reflexology to systems of comprehensive treatment that focus on all aspects of the health of the patient and all the systems/organs of the body, such as traditional Chinese medicine. In the United States, this range includes such therapies as chiropractic medicine, naturopathy, homeopathy, and aromatherapy. Although these modalities share commonalities and are different, none are part of biomedicine.

The issue of what to call the CAM/IM group of approaches also has important social and political ramifications. To term the group of modalities *alternative* may be to claim too much for their role in health care, but to term them *complementary* may make their role seem secondary to primary medical care (Coulter, 2004). But, overall, to define them in terms of “otherness,” that is, by what they are not (as in “not taught in medical schools” or “not practiced by conventional medicine”) is also somewhat useless (Eisenberg et al., 1998). That being said, The National Center for Complementary and Alternative Medicine (2000) defines CAM as those

healthcare practices that are not an integral part of conventional medicine. As diverse and abundant as the peoples of the world, these practices may be grouped within five major domains: alternative medical systems; mind–body interventions; biologically-based treatments; manipulative and body-based methods; and energy therapies. (p. 7)

As CAM is increasingly included in the teaching programs in medical schools and in medical practice, these distinctions are becoming increasingly problematic (Bhattacharya, 1998).

Like those of CAM, definitions of IM can range from simply incorporating CAM into conventional medicine to the notion that integrative health care constitutes a new form of medical practice. A single definition or set of definitions for IM has been difficult to establish even by leading entities that shape health care policy and practice. For example, in one of their recent reports on IM, the Institute of Medicine referred to “integrative medicine” in one section and “integrated medicine” in another, even though integrative medicine and integrated medicine are generally not considered the same thing (Ullman, 2009). Maizes, Schneider, Bell, and Weil (2002) defined the term *integrative medicine* as “medicine that reemphasizes the relationship between patient and physician, and integrates the best of complementary and alternative medicine with the best of conventional medicine” (p. 852). Boon, Verhoef, O’Hara, and Findlay (2004) defined “integrative health care” as the combination of an interdisciplinary, nonhierarchical blending of both CAM and

conventional medicine that uses a collaborative team approach, is guided by consensus building and mutual respect, and shares a vision of health through a partnership of patient and practitioners to treat the whole person.

Currently, organizations that define themselves as IM health care centers or include IM or CAM as part of their care differ in the type of staff that primarily deliver and manage the care (for example, physicians, nurses, specially trained CAM providers); sources of revenues (for example, fee-for-service, health insurance, philanthropy, research grants); type of delivery setting (for example, teaching hospital, nonprofit or for-profit hospital, community clinic); type of care they provide (for example, primary care, adjunctive, maintenance care after conventional medical care is not effective); and in strategic approaches to integrating CAM into biomedicine (for example, incorporating only those CAM therapies and providers that are already credentialed or licensed). The result is that IM care can be delivered in vastly different ways and in vastly different settings and with vastly different therapies. In this chapter, we define IM as a process in which integration or convergence between biomedicine and CAM occurs without implying a degree of integration, the nature of the integration, or the process by which it is achieved.

Paradigms of Health

Before we discuss empirical work and approaches to outcomes measurement for CAM/IM, it is necessary to understand the paradigms that underlie both: Developing, selecting, using, and monitoring outcome measures that represent any dimension of health involves the philosophical and theoretical paradigms on which such measures are based. Actual measures will differ depending on what these assumptions are (Khorsan, Coulter, Hawk, & Choate, 2008). Biomedicine and CAM paradigms have distinct philosophical foundations, a priori assumptions, and metaphysical beliefs that are considered by many to be incommensurable, incomparable in a Kuhnian sense, and contradictory (Kuhn, 1962). Given such differences, many challenges remain to unify these paradigms into one without doing great harm to one or transforming the other (Coulter, 1990). While we would like to share full arguments to support these premises here, space permits only a brief discussion. We encourage the reader to consult references provided in this section for more detail.

The Biomedical Paradigm. Biomedicine in the West can trace its roots to the germ theory of disease, which helped to transform medicine from an art to a science by bringing together the practice of medicine and the scientific method of investigation. This move to a more scientific approach resulted in a reductionist approach to illness. In this paradigm, the search for external,

microscopic causes of disease reduced the consideration of illness to a primary focus on pathology. This shift also elevated the concept of biological determinism. That is, causes of diseases were looked for internally, in the biological structure of the patient (Coulter, 2001). Health came to be seen as an absence of disease, with disease explained in materialistic terms, and a focus on acute illness and trauma taking precedence over chronic illness.

The CAM/IM Paradigm. Although CAM/IM is extremely heterogeneous in practice, many CAM practices arose, or at least developed, in reaction to the biomedical paradigm, in particular the germ theory of disease. Although this reaction took many forms, it was seldom an outright rejection of the theory but more a recognition of its limitations. The most serious opposition concerned the germ theory's "inability" to account for the distribution of disease (Coulter, 1990).

Most supporters of the CAM paradigm postulate that the origin of disease, or health, comes not simply from external causes but from within the body. When disease occurs, it does so because of predisposing factors in the individual. According to this view, germs may be the initiating factor, but lowered resistance is the predisposing factor. The body, when functioning properly, is able to successfully combat disease, and illness is a failure in the body's natural restorative power. Germs by themselves do not cause illness. Biomedicine, in this view, attacks the effects or symptoms of disease but not the cause.

This fundamental a priori difference between CAM and biomedicine leads to a different logic for approaches to treatment. In CAM, the focus is on treating the patient, whose body then will initiate the healing. Whereas in biomedicine the intent of the provider is to cure patients, in CAM the intent is to assist patients in healing themselves. In this approach, diseases are symptoms of a more fundamental underlying cause. Disease here means "dis-ease," or lack of ease in the body, not pathology.

Integration of the Two Paradigms. As we briefly mentioned at the beginning of this chapter, the move to CAM by the public is changing the framework in which medicine is viewed. As Bausell and Berman (2002) state,

What we are observing is really nothing less than a genuine Kuhnian paradigmatic shift in world views [that] may represent a consumer-driven variant of George Engel's call for an actual reformulation of what is meant by the practice of medicine itself (p. 31)... As it truly evolves, truly integrative medicine [will] depend on its philosophical foundations and patient-centered approach on systems of CAM that emphasize healing the person as a whole. (p. 134)

Bell et al. (2002) assert that IM that simply combines biomedicine with CAM

is not integrative. Integrative medicine represents a higher order system of care that emphasizes wellness and healing of the entire person (bio-psycho-socio-spiritual dimension) as primary goals, drawing on both conventional and CAM approaches in the context of a supportive and effective physician–patient relationship. (p. 133)

These assertions, and current events in the health care field, imply that there are three possible scenarios that might describe paradigm integration between CAM and biomedicine: (1) CAM will be adopted (co-opted) into biomedicine itself as largely adjunctive therapy without its philosophical elements; (2) CAM will bring about a surreptitious transformation of medicine that will result from integrating CAM into biomedicine; and (3) a meta-paradigm will be formulated that will allow for both paradigms, and approaches to care, to coexist. A recent article examining the IM curricula in academic health science centers suggests that the first option more accurately describes what is happening in the university-based centers (Benjamin et al., 2007). Likewise, three approaches of integration of IM into biomedicine can be considered: Incorporate into biomedicine those CAM therapies that have (1) passed rigorous scientific scrutiny, (2) passed the test of time, and/or (3) are credentialed or licensed.

Although the chances of the first scenario for integrating CAM and biomedicine paradigms are probably greater than those of the second or third, the most prominent question is whether therapies, from either approach, will have the same success if they are stripped of the paradigm from which they originated. It may be the case that CAM approaches are effective because they are incorporated in a broad-based wellness paradigm. That is, dismantling each individual paradigm and rebuilding aspects of each paradigm into a new scenario may not produce results that are as effective. Regardless of the pathways that the integration of CAM/IM will continue to take, some sort of “whole systems framework” (for example, a broad focus that goes beyond the disease and interventions of clinical studies to include the total organization of the care delivery) is necessary to build upon (Jonas et al., 2006). As such, several issues associated with this process will need to continue to be addressed, including historical professional animosity, changes in work environment infrastructure, culture and relationships, economic competition, the lack of clearly agreed upon principles on which to base integration at organizational and health care system levels, and the variation in organizational models that exist.

CAM, IM, and Outcomes Measurement: Measurement and Research Challenges

Overall, measurement of outcomes for biomedicine and CAM tend to be based on different underlying philosophies, such as objective versus subjective measurement. Objective measures (for example, physiological states) are derived from the philosophy of logical positivism (which sees the world as largely material in nature and which can be subjected and measured empirically) and are based on the view that the human body in health and illness can likewise be studied by material factors and measured in much the same way as the purely physical world of nature. Subjective measures (for example, behavior and quality of life) are derived from such philosophies as existentialism and phenomenology (which evolved and challenged logical positivism and empiricism) and are based on the notion that human beings are agents of their own behavior (Hunt & McEwen, 1980). Regardless of these distinctions, biomedicine and CAM can share some elements in common (Khorsan et al., 2008). With regard to CAM, existential and phenomenological approaches (that is, approaches that are grounded in the meanings held by the patient for their illness or well being) are key aspects of instruments that are likely to collect information about the sick role; the concept of illness as opposed to disease; social/psychological, and in some cases spiritual, aspects of illness; and patient-centered measures (for example, patients perception of daily activities, functioning and disability, quality of life); they also may collect more qualitative than quantitative data. The SF 36 (Garratt, Ruta, Abdalla, & Russell, 1994) and the Health-Related Quality-of-Life (Zahran et al., 2005) are examples. Research approaches to measuring outcomes in biomedicine and CAM/IM also are based on different philosophies and methodological traditions, with some overlap depending on topic. We will touch briefly on some of these methodological approaches and the challenges they pose for CAM/IM, within the context of health services research (HSR), and encourage the reader to consult sources for additional approaches.

HSR is defined as the investigation of the relationship between social structure (for example, personnel, facilities, services available, organizational features, and financing), process (for example, the transaction that occurs between the provider and the patient), and outcomes for personal health services. The strength of *HSR* is the breadth of its focus, which goes beyond the disease and interventions of clinical studies to include the total organization of care delivery. This is also its major contribution to evidence-based practice (Coulter & Khorsan, 2008). As part of the goal to be as evidence based as possible, *HSR* also strives to build and classify its hierarchy of evidence (Linde

& Coulter, in press), which includes the following (from highest to lowest strength): evidence provided by at least one appropriately designed randomized clinical trial (RCT); evidence provided by a controlled trial that is not randomized; evidence provided by a well-designed cohort or case-control study; evidence provided by a multiple time series; descriptive studies, case reports, and opinions of experts or respected authorities (Evidence-Based Medicine Working Group, 1992). Three research approaches that are broadly used within HSR have significance for CAM: studies of efficacy and effectiveness, systematic reviews, and descriptive/observational studies.

The real importance of HSR is its focus on such things as utilization, costs, appropriateness, and outcomes in real settings (Coulter & Khorsan, 2008). In this regard, descriptive studies are extremely significant. Herman, D'Huyvetter, and Mohler (2006) note that of the 84 abstracts they investigated related to HSR and CAM, the majority (30) were from surveys of CAM users and their reasons for using CAM. To design studies that can investigate a fuller range of outcomes in real settings, more CAM studies need to be conducted that build the evidence base on scope of practice, patient characteristics, utilization rates, and patient profiles.

Thus, more studies that measure the efficacy (that is, the causal connections between an intervention and specific outcomes, with the RCT as the most rigorous approach) and effectiveness (that is, studies that measure how well an intervention is working or has worked and the associated outcomes with this) of CAM modalities can follow. Although biomedicine uses RCT as its preferred research model (Luce, Kramer, & Goodman, 2009), several problems arise in applying this approach to CAM/IM. First, the use of controls in RCTs results in a situation that is not like normal practice, in which therapies ultimately will be delivered (Coulter, 2007). That is, many areas of CAM (for example, spirituality, chi, and multi-complex therapies that combine unique combinations of herbs so that no two patients get the same combination) are not amenable to inclusion in RCTs without significantly compromising the very therapy being studied, thereby removing aspects of the holistic therapeutic approach that CAM promulgates (Coulter, in press). Second, exclusion criteria for the subjects in RCTs may ensure that the very subpopulations the provider wants to treat in a CAM situation may not be included in the trial. And third, RCTs require a sham treatment such as placebo. In many areas of CAM/IM, it has proved to be impossible to develop a true sham treatment (for example, for acupuncture). So RCTs, for all their strengths and acceptability as the gold standard in traditional medicine, are not an appropriate methodology for assessing the relevance of CAM/IM to the real world of practice.

Like RCTS, there are several challenges associated with conducting *systematic reviews* (that is, formal assessments of the quality of studies that results in a research synthesis or meta-analysis) about CAM/IM. Compared with other fields of practice in health, the number of studies that exist to include in systematic reviews for CAM, and particularly IM, is far lower. Most systematic reviews are based only on the literature in English. This is a problem, as much of CAM research is not published in English, and publications in English and other languages do not often turn up in the refereed literature found in MEDLINE and PubMed. Most of CAM/IM practice is also not located in the universities or the standard research institutes and is not typically part of scholarly interchanges in mainstream health conferences, faculty exchanges, or joint research projects. Consequently, it has been difficult to establish and use a hierarchy of evidence to assess the scope of knowledge that has been generated. Although systematic reviews privilege certain forms of data and knowledge over others (with the expert or specialist getting the lowest rating), the very studies that are privileged are those that are lacking in CAM/IM. This is complicated further by the fact that whole areas of evidence, such as HSR and program evaluation, tend to be left out of systematic reviews (Linde & Coulter, in press).

As one would expect, then, systematic reviews have established the lack of high-quality, rigorous trials in CAM. Such studies have also shown that some of the so-called quality differences that arise when comparing CAM/IM and whole systems research (which are not RCTs) with approaches to drug research (where the gold standard is rigorous RCTs) are not actually differences in quality but differences in research methodology, which make it inappropriate to use such terms as *superior* or *inferior*. The methodologies are simply different (Coulter, 2006).

For CAM/IM, then, the assessment of quality is laden with methodological and other challenges (Feinstein & Horwitz, 1997). To help address these issues, observational study approaches are often used to develop and assess the data needed for clinical practice decisions and programming (Coulter, 2003). Although there is increasing evidence that observation studies compare favorably to RCTs (Benson & Hartz, 2000), there have been several major strikes against the use of observation studies in systematic reviews. The first is that, because all observational studies lack randomization, true assessment of efficacy is not possible. Furthermore, it is not possible to determine whether provider and patient biases may have influenced the results. Results from observation studies cannot be pooled without caution in a meta-analytic sense; however, qualitative data analysis approaches such as content and thematic analyses can be employed to synthesize data in a similar fashion.

The Way Forward: Systems Model and Comparative Effectiveness Research

It is clear that the use of CAM/IM will continue to grow (Coulter & Willis, 2007). The number of CAM providers is growing, recognition of CAM through licensure is increasing, and coverage of CAM by insurance plans is expanding. However, as we have discussed, the challenge to developing research approaches and measures that are most relevant to CAM/IM involves the acknowledgement, compromise, and integration of philosophical, scientific, political, and social issues.

Two pertinent questions arise. First, what type of theoretical or conceptual model is most appropriate to capture the holistic nature of CAM/IM? We suggest the use of a systems paradigm, general systems theory (Beckman, Fernandez, & Coulter 1996). This theory has several features that make it the appropriate theory for CAM/IM, as it posits multilevel structures (mutually dependent organizational levels in which any changes in any one of the subsystems has impacts throughout the system: a holistic model) within an entire system; an ecological view of the relationship between the system and the environment in which both synchronously affect each other; nonlinear causality, in which self-reinforcing feedback plays a significant role in self-maintenance and self-transformation; self-organization, which recognizes the body's ability to return to a balanced state (homeostasis) and to heal itself (vitalism); self-transcendence, or emergent properties (the whole is greater than the sum of its parts); the belief that the mind is characteristic not only of the individual but of social, cultural, and ecological systems; and a rejection of the concept of dualism between the mind and the body.

The second question is what does this mean for CAM/IM outcome measures? The application of systems theory to CAM/IM is still in its infancy, but it implies that measurement must be done at multiple levels: biological, psychological, social, cultural, and ecological. Consequently, a systems approach to outcomes measurement for CAM/IM will help achieve the following:

- Elevate the notion of person-centered care and patient-centered outcome measures, thereby recognizing the value of patient-focused evidence and aligning with efficacy, effectiveness, and efficiency studies of health care services (Khorsan et al., 2008, 2009)
- Elevate the importance of health measures (for example, health-related quality of life), as opposed to disease measures, and the acceptance that health is not just the absence of disease

- Keep CAM/IM outcomes measurement approaches in HSR centered on practice (Coulter & Khorsan, 2008), with a focus on both patient and provider measures, as seen in recent work on IM (Hsiao et al., 2005)
- Turn attentions to evaluations of programs so that assessments and outcomes are also performed at an aggregate level.

Given the importance of CAM/IM in the health care of the American public, it is somewhat surprising that the amount of funding available for research in this area is miniscule in relation to what is spent on biomedicine. In 2009, the National Institutes of Health spent a total of \$29,835,000,000 on biomedical research while it spent a total of \$584,000 on CAM research (Center for Complementary Alternative Medicine, personal communication, May 22, 2010). That represents 0.02 percent of the Institute's budget. It is therefore not surprising that the development of outcome measures for CAM/IM has lagged considerably behind that in other areas of health. However, given the recent allocation of \$1.1 billion to fund comparative effectiveness research (CER: the "generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policymakers to make informed decisions that will improve health care at both the individual and population levels" [Sox & Greenfield, 2009, p. 203]) from the American Recovery and Reinvestment Act of 2009; other allocations, such as \$300 million for the Agency for Healthcare Research and Quality, \$400 million for the National Institutes of Health, and \$400 million at the discretion of the Secretary of Health and Human Services; and a request for research proposals by the National Centre for Complementary Alternative Medicine for CER Studies of Complementary and Alternative Medicine, it is safe to say that both CER (Conway & Clancy, 2009) and CAM/IM outcomes research have entered a new era.

In many ways, the emphasis on CER should be beneficial for CAM research. CER solves two historical concerns for CAM/IM researchers: It focuses on effectiveness, not efficacy, and tests holistic approaches to care. CER allows providers to care for patients in any way they choose (Coulter, in press), thereby setting the stage for trials that are more in alignment with a whole systems research approach rather than with RCT (Jonas et al., 2006). This approach also allows for variability in the way individuals are treated in the trial, thereby coming closer to personalized medicine (Garber & Tunis, 2009).

Because CER will allow studies to focus on those who are receiving care normally, it includes populations and subpopulations that are normally

seen in practice, which makes results more clinically relevant. The focus will also largely be on what concerns providers and patients (that is, effectiveness) and not as much on what has traditionally concerned scientists (for example, efficacy). CER's focus on observational studies also harmonizes well with the CAM field (Coulter, 2007), broadening the definition of acceptable evidence.

So, then, what is the future for outcome measures in CAM/IM? Like all the health professionals, both CAM/IM providers will be increasingly asked to substantiate what significant outcomes their approach achieves, at what cost, and how these outcomes compare to other available therapies. To achieve this, we would suggest the following agenda:

- Establish clarity about what CAM/IM is. This is a descriptive task and will involve qualitative and observational methods. This type of study must identify what is actually done in the practice of various CAM providers and in IM. For the latter, there is such variability at the moment about which CAM therapies are part of IM that at best there exist only exemplars of IM clinics. There is no one dominant form yet.
- Base outcome measures on what has meaning to the patients and what the providers set out to achieve.
- Develop comprehensive measures that capture the multi-disciplinary nature of IM and the large variability in CAM, by which patients receive highly personalized care.
- Develop outcome measures that capture context process and outcomes (program evaluation) and are sensitive to complexity (that is, whole-system measures).
- Adapt biomedical outcome measures and HSR measures that are appropriate to CAM/IM.

The challenge of this agenda is to make sure these measures are validated for CAM/IM populations. This is largely a psychometric task but does involve qualitative work to establish that these instruments have meaning for these patients. We are certain that this agenda can be achieved if a cadre of stakeholders (researchers, clinicians, patients, managers, policymakers, and advocates) commits to taking on these tasks together, with passion and vigor, and that research funding allocations continue to include CAM/IM as integral parts of health care reform.

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