

# COMPLEMENTARY AND ALTERNATIVE MEDICINE: HOW DO WE KNOW IF IT WORKS?



INVITED ESSAY

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## ABSTRACT

*Using a sociological viewpoint, this paper examines the range of definitions for complementary and alternative medicine (CAM) and discusses the evidence base for its efficacy and safety. The question of what constitutes evidence is considered from various perspectives: biomedical, CAM, consumers and practitioners. The authors conclude that all these perspectives are required in order to fully understand the appeal of CAM in Canadian society's search for appropriate healthcare. Most important, the complexity of methods for assessing the evidence about CAM is addressed. An inclusive approach is urged that goes well beyond randomized clinical trials. Policy recommendations are made in three areas: research, regulation and funding.*

## Introduction

Popular interest in complementary and alternative medicine (CAM) is part of a fundamental change in society's orientation to health and healing (Goldstein 1999; Sharma 1992). Demand for CAM services and products have grown in Canada, as in other Western societies (Ramsay et al. 1999; Unschuld 1980; Eisenberg et al. 1998; MacLennan et al. 1996; Ernst et al. 2001; Beaudet 2001). Recent Canadian surveys found that approximately half of the respondents reported using CAM in the past 12 months (Ramsay et al. 1999; Angus Reid Group 2000). There has been a grassroots revolution in the expectations and choices of consumers of healthcare. In this paper, we turn a sociological eye on CAM and view it as a social movement that is assuming a significant place in the healthcare system. We ask questions such as: How do people decide to use CAM products and to consult CAM practitioners? On what kinds of evidence do they base their decisions? Is the evidence convincing? If so, does it convince everyone? What kinds of evidence are required before governments can develop policies supporting the use of CAM?

The use of CAM therapies is not new. They have been widely used in societies such as Asia, Africa and India for hundreds of years. However, on this continent, there is uncertainty concerning what such therapies should be called; alternative, complementary, unorthodox, unconventional, non-scientific and marginal are some of the many descriptors in the literature. Yet, in North America, we consider these options as something that people have only recently discovered.

## Defining CAM

The term *complementary and alternative medicine* is often used residually, as anything that is not included in conventional medical practice. For example, Vincent and Furnham (1997) define the term as an approach that "embraces a wide range of therapeutic practices and diagnostic systems that stands separate from, or in some cases opposed to, conventional scientifically based medicine." Eisenberg et al. (1993, 1998) argue that CAM describes practices and therapies that are not typically taught in conventional medical schools nor practised by most licensed physicians. This assertion, however, is less factual today as the number of medical schools offering courses and programs on CAM in the United States and Canada is on the rise (Bhattacharya 2000; Ruedy et al. 1999).

A comprehensive definition arose out of the National Institutes of Health Panel on Definition and Description (1997): "Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period." Such a definition treats conventional medicine and CAM as equals and avoids negative connotations. It also takes into account the existence of multiple healing systems that have various degrees of dominance and influence. Practices that are considered "alternative" by the majority of people in Western society are thought of as mainstream by people in many other countries (Kelner and Wellman 2000).

It is important to recognize that complementary and alternative therapies include a diverse set of healing practices, each with its own philosophy of healing and traditions of use. There are, however, certain core characteristics that are common to most of them. Most significantly, they focus not just on biomedical processes, but emphasize the natural ability of the body to heal itself. They stress health rather than disease, and their goal is to strengthen the health-promoting forces of the body. The flow of energy is regarded as a crucial source of healing, and pronounced emphasis is placed on the uniqueness of each individual, the subjective experience of patients and the important effects of the environment. CAM therapies are based on the integration of body, mind and spirit and take a holistic approach to healing. The patient is regarded as an active participant in his or her own healthcare and is expected to take personal responsibility for maintaining and promoting good health (Berliner and Salmon 1979; Goldstein 1999; Kelner and Wellman 2000).

When we turn to the question of which kinds of healthcare are included under the umbrella term *CAM*, we quickly become aware that the boundaries within it, and between *CAM* and the conventional medical system, are far from clear or fixed. For example, some physicians practise *CAM* therapies such as acupuncture and relaxation techniques along with their conventional medical treatments. Another example of confusing boundaries is provided by chiropractic; since it is the most widely used *CAM* modality and is covered to a limited degree by public insurance in some provinces, some argue that it is now part of mainstream care. Others refute this view strenuously. A

further complication is that some *CAM* practitioners provide more than one kind of *CAM* healthcare, combining, for example, traditional Chinese medicine with acupuncture, or naturopathy with chiropractic. Clearly, fluid boundaries are a characteristic of the field.

A useful way of classifying the array of *CAM* therapies has been developed by Tataryn (2001) based on their underlying assumptions and approaches. He posits four distinct approaches to healing: (1) Body – examples are diet, herbs, manipulation, etc.; (2) Body-Mind – examples are meditation, visualization, etc.; (3) Body-Energy – examples are acupuncture, therapeutic touch, etc.; and (4) Body-Spirit – examples are prayer, faith healing, etc.

There is also confusion concerning which therapies should be considered complementary and which should be termed alternative. Some therapies such as acupuncture are used as complementary to conventional medical practice, but others such as homeopathy and reiki are based on alternative belief systems and cannot be easily reconciled with conventional medical care. Cassileth (1998) defines complementary therapies in clinical terms as those that can be used in conjunction with conventional medicine or are employed as adjuncts. Therapies that are used instead of medical care, on the other hand, are described as alternative. She contends that it is the intention behind its use that defines an intervention. Saks (1992) sees this distinction in political terms. He argues that until *CAM* therapies are recognized and supported by government, they are in a marginal position in the healthcare system and should be regarded as alternative.

The most recent term to be applied to CAM is *integrative medicine*. This terminology focuses attention on appropriate and evidence-based care across the therapeutic modalities (Chapman-Smith 2000; Jonas 1998; Best and Glik 2000). While the term is not yet widely used, it could prove to be useful because it emphasizes the possibility of combining CAM and conventional medicine. As the field continues to develop, trying to achieve a precise definition of CAM is like struggling to hit a moving target. In spite of the lack of consensus about how to define CAM, however, researchers in Canada have been exploring questions concerning who uses CAM and why they choose to do so.

### **The Canadian Context**

A number of studies of CAM use in specific Canadian populations have been carried out. One of the earliest was conducted in 1994–95 in Toronto (Kelner and Wellman 1997a, 1997b). The research compared the social and health characteristics of patients of five kinds of practitioners: family physicians (used as a baseline group); chiropractors; acupuncture/traditional Chinese medicine doctors; naturopaths; and reiki healers. The patients who had consulted CAM practitioners were more likely to be female, younger (mean age: 44), to have higher household incomes and educational levels, to report their ethnic origin as Canadian and to consider spirituality an important factor in their lives. They were less likely to be in blue-collar occupations and to be religiously affiliated. The range of their health problems was greater, and they tended to rate their physical and emotional health status higher than did the patients of family physicians. Most of these CAM

patients had also visited a family physician about their care. While they had some reservations about conventional medicine with respect to how much help they had received for their chronic conditions, they had not lost confidence in its effectiveness, particularly for acute conditions.

Other Canadian studies have focused on populations with chronic diseases. Research on people with breast cancer and HIV-infected patients found that those who used CAM therapies and products were younger and had higher education and incomes than those who did not (Boon et al. 1999; Ostrow et al. 1997). Among brain tumour patients, younger age and higher income were also significantly related to CAM use, although level of education was not (Verhoef et al. 1999). For people suffering from inflammatory bowel disease, only a higher level of education proved to be significant (Hilsden et al. 1998). In all four of these studies, most of the patients who were using CAM services had not rejected conventional medical treatments but were employing both kinds of care at the same time. Just over half of them reported that they had told their physicians about their use of CAM.

Both values and pragmatic considerations played an important role in why the patients in these Canadian studies chose to use CAM. The most frequently cited reasons included: preventing illness and improving the quality of life, gaining a sense of control over a chronic illness, boosting the immune system, dissatisfaction with conventional medical care, dealing with the side effects of some conventional treatments, wanting to try all options, preferring a more collaborative relationship with their practitioner and having a more holistic understanding of

health and illness. These explanations of why people choose to use CAM correspond to the findings of other empirical research in North America, Australia and the United Kingdom (Astin 1998; Goldstein 1999; McGregor and Peay 1996; Sharma 1992; Vincent and Furnham 1997).

In Canada, CAM products are regulated by the federal government under the Natural Health Products Directorate (formerly the Office of Natural Health Products), established in 1999. The responsibility for regulating CAM practitioners is provincial, although the situation differs from province to province. Most CAM practitioners are not regulated by the government, which means that anyone, with any level of experience and training, may practise (Boon and Verhoef 2001). While some modalities such as massage therapy, naturopathy and acupuncture are regulated in some provinces, chiropractic is the only one to have achieved self-regulatory status in all Canadian provinces. In addition, chiropractors are the only CAM practitioners to be included in and partially funded by provincial health schemes in Ontario, Manitoba, Saskatchewan, Alberta and British Columbia (Boon and Verhoef 2001).

Given that many CAM practitioners and products are not yet regulated, how are we to explain their growing use among the Canadian public? Given that the scientific evidence that CAM works is limited and equivocal, on what kinds of evidence are consumers of CAM services relying?

### **What Constitutes Evidence?**

While most consumers of CAM have been content with anecdotal evidence of

successful healing, recent media attention to problems such as the negative effects of interactions of CAM products with regular drugs is beginning to make the public somewhat more wary. But the call for solid evidence of efficacy and safety is coming primarily from other health professionals and from policy-makers. For example, the White House Commission on CAM policy (Gordon 2002) urges that CAM therapies be held to rigorous scientific standards. Policy-makers recognize that the scientific evidence for CAM therapies is sparse, and they are concerned with what this means for the accountability of CAM practitioners and the regulation of both products and practitioners. Established healthcare providers want evidence so that they can decide if and when to refer patients to CAM practitioners. Governments have a responsibility to protect their citizens from fraud by questionable healers, and to establish assurances that products and practices delivered by the healthcare system are therapeutically effective.

In a recent book on clinical research on CAM (Lewith et al. 2002), the authors assert that there are two crucial issues in developing appropriate evidence. These are rigour and relevance. Rigour refers to management of biases that threaten the valid analysis and interpretation of data. Relevance refers to the use to which specific audiences will put information. It involves values placed on different types of information. The authors think research strategies should start with questions such as: For whom is the information meant and for what purposes? How do the values of patients, practitioners, scientists and providers inspire research? The authors argue that a balanced approach is necessary

to build an evidence base that includes both rigour and relevance. They caution that without balanced strategies that take into account both precision and the values of each audience, the interpretation of individual research studies is incomplete and thus open to error or misapplication.

Accumulating credible evidence about the efficacy and safety of the various CAM modalities is proving to be a difficult and challenging enterprise. How best to test their efficacy and safety is currently the subject of lively debate (see, for example, Ernst 2000; Glik 2000; Walach et al. 2002; Richardson et al. 2001). The crucial issue is deciding upon the most appropriate methods for evaluation. Proponents of the randomized clinical trial (RCT) argue that it is the method of choice for assessing an intervention (Ernst 1996). This method involves ensuring that both the patient and the clinician are unaware of the nature of the treatment. A further refinement is that the assessment of safety or efficacy is carried out by an independent observer who is ignorant of the treatment allocation. The control condition varies according to the nature of the question being addressed; sometimes it is simply a comparison with an untreated group, sometimes it is with a group receiving a placebo, and other times it is a comparison between a novel treatment and a standard one (Vincent and Furnham 1997). But several scholars have suggested that the classic experimental method of the RCT does not do justice to the more holistic and individualized approach of CAM. Hence, they suggest that new methodologies such as qualitative research are needed to reflect the unique characteristics of CAM (Cant and Sharma 1996; Glik 2000; Goldstein 1999;

Kelner and Wellman 2000; Mills et al. 2002; Richardson 2002; Verhoef et al. 2002; Vuckovic 2002).

Underlying this controversy are two different perspectives. The biomedical view holds that science must be objective and based upon universalistic quantifiable criteria, rationality and skepticism. Medical research is based on the premise that biomedicine is impartial and empirically verifiable and that there is only one objective picture of reality and one valid method of verifying it. The CAM perspective, however, is based on the belief that there are different ways of knowing about reality, a variety of valid methods for verifying research and that humanistic and spiritual values influence health (Goldstein 1999; Astin 1998; O'Connor 2000). We will sketch out these and other differing perspectives as they pertain to the issue of what constitutes appropriate evidence.

### **The Biomedical Perspective**

The advocates of the biomedical view call for rigorous scientific testing to establish whether CAM is effective and safe. They argue that the ground rules for evidence-based medicine have already been established and that CAM providers will have to accept these rules. They believe that the only way to convincingly demonstrate the specific effectiveness of CAM (i.e., effectiveness over and above treatment by placebo) is to rely on evidence from controlled randomized clinical trials (Vickers et al. 1997; Ernst 2000). Using this research strategy, they claim, is the way to establish with the highest degree of probability whether an observed effect can be linked causally to a specific intervention. Indeed, some proponents of this point of view have argued that “there is no

alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data, or unproven medicine, for which scientific evidence is lacking” (Fontanarosa and Lundberg 1998). They add that most alternative therapies have not been rigorously tested using scientific tests of efficacy based on accepted rules of evidence, and they regard the lack of convincing evidence as unacceptable and deeply troubling (Angell and Kassirer 1998; Ernst et al. 2001).

Edzard Ernst (2000) contends that evidence exists within a hierarchy of four levels of validity, as follows:

- 1) Systematic review of randomized controlled trials, or meta-analysis.
- 2) Randomized clinical trials (RCTs).
- 3) Controlled clinical trials.
- 4) Uncontrolled data (e.g., case reports, case series, observational studies).

Ernst argues that uncontrolled data in and of itself is only a starting point for generating hypotheses for research. Good evidence, he insists, requires comparative studies through controlled clinical trials and RCTs. He and his colleagues at the University of Exeter have carried out numerous systematic reviews of RCTs on particular CAM practices (Ernst et al. 2001). It is only when data across a number of trials are combined, he believes, that the least biased evaluations of CAM therapies can be produced (Ernst 2000).

Increasing calls for evidence-based medicine are now being heard throughout the entire healthcare system, not just in the case of CAM practices. Among the medical profession, evidence-based medicine (EBM) is accepted as the goal for which all medicine should strive (Sackett

1998). EBM has been described as the “conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients” (Ernst 1996: 71). The crucial point of EBM is that there is a hierarchy of levels of evidence, similar to the ones delineated above by Ernst. Each level of evidence permits different kinds of generalizations to be made. The evidence derived from randomized clinical trials is regarded by medicine as the highest quality for application to clinical practice. Other levels of evidence such as that provided by case studies, ethnographic studies or experiential evidence are regarded with considerable skepticism by conventional medicine (Jonas 2001).

Because the logic of biomedicine has been the dominant influence in Western society on healthcare research, the ideas upon which it was founded are accepted as more accurate, true and correct than are other ideas that have originated from different traditions of healing. Practitioners and researchers who follow the biomedical tradition have gained social authority as the arbiters of truth on issues of health and health policy (Saks 2000; Sharma 2000). Indeed, exponents of this view argue that any explanatory systems that fall short of what biomedicine defines as *evidence* cannot be valid and are only pseudo sciences (Beyerstein 1997). For the medical and scientific community, controlled trials remain the final arbiter of a therapy’s efficacy and safety (Ernst and Fugh-Berman 1998). The dominance of RCTs has meant that many CAM therapies have been ignored or dismissed by the medical establishment because their efficacy or safety has not been demonstrated by this particular research strategy.

### The CAM Perspective

For some CAM therapies, however, gathering evidence by using RCTs is difficult and even inappropriate. What, for example, would constitute a credible placebo for acupuncture? How does a researcher go about *blinding* a physical intervention like massage therapy? Another difficulty lies in the individualized and holistic nature of CAM treatments, which are customarily tailored to a specific patient rather than standardized for a particular condition (Pietroni 1991; Kelner and Wellman 2000; Nahin and Straus 2001). CAM therapies often include several different kinds of interventions and frequently vary in actual practice. They also often apply to non-specific conditions such as stress or lack of energy (Walach et al. 2002; Verhoef et al. 2002). Moreover, the focus of many CAM treatments is on restoring balance to the body rather than treating specific conditions (Verhoef et al. 2002). In other words, the findings of RCTs may not be relevant to what actually happens in clinical practice (Richardson 2002).

It is important to recognize, however, that real progress is being made in scientific research on CAM. For example, glucosamine sulphate has recently been shown to reduce pain during functioning as well as lessening the effect of pain in daily activities (Thie et al. 2001). Mental imagery has been shown to be a clinically feasible and effective adjunctive therapy for stroke patients (Page et al. 2001). Another recent study of the possible adverse effects of acupuncture has demonstrated that adverse events were minimal in a prospective survey of 34,000 treatments by traditional acupuncturists (MacPherson et al. 2001). Similar kinds

of studies are going on in various countries such as Germany, England, the United States and Canada. This upsurge in scientific studies on CAM is reflected in the number of new peer-reviewed journals reporting the results of recent research. Some examples are the *Journal of Alternative and Complementary Medicine* and *Alternative Therapies in Health and Medicine* in the United States, and *Complementary Therapies in Medicine and Focus on Alternative and Complementary Therapies* in the United Kingdom.

A considerable gap still exists between the demands for proof that are coming from established health professionals and governments, and the kinds of results that researchers of CAM are able to demonstrate (House of Lords Select Committee on Science and Technology 2000). Why has the process of providing solid evidence been so slow and difficult?

As has already been suggested, in the case of various therapies as well as some herbs and other natural products, traditional forms of trials are often not appropriate. Randomization can be problematic when it entails offering or not offering a product or service that may benefit a patient in need. Blinding the patient and the practitioner to the therapeutic option is often difficult, given the way CAM practitioners tend to negotiate with patients about treatment options and the degree of active involvement that each party typically adopts in the delivery of CAM. Removing placebo effects makes no sense in the case of most CAM practices, evolving as they have from ancient traditions of healing that emphasize factors such as trust, relationship and the transmission of healing energy. These are inherent components of the therapies, not



something that can be isolated to remove their contaminating effect (Glik 2000; Kelner 2000). The CAM healing encounter often includes factors that may never be quantifiable. Thus, it is the philosophical origins or world view of CAM practices that make many of them inappropriate for RCT testing and, if such trials are conducted, may make the results meaningless (Linde and Jonas 1999).

The individualized nature of CAM treatments also mitigates against the use of RCTs that use population-based techniques. Failure to take individual differences into account may distort or skew the effects of actual practices upon health outcomes (O'Connor 2000; Nahin and Straus 2001; Stone 1996). Furthermore, a number of CAM therapies such as TCM and naturopathy use several approaches simultaneously to treat a given condition. This can create difficulties when interpreting the efficacy of a therapy if all the interventions involved in a therapy are not taken into consideration in the research design (Nahin and Straus 2001; Mills et al. 2002). An additional complication lies in the variable ways in which many CAM therapies are practised. There are a number of different approaches to delivering chiropractic, naturopathy and acupuncture, for example, and one single trial cannot capture these variations (Nahin and Straus 2001).

In addition to the nature of CAM treatments, there are also other problems in designing research that can yield credible evidence of efficacy and safety. While the healthcare system has traditionally focused on curing or coping with disease, consumers are also interested in different kinds of outcomes such as health maintenance and quality of life (Lewith et al. 2002; Truant and McKenzie 1999).

Assessing the effectiveness of a particular therapy has conventionally been done by looking at markers such as symptom progression, organ function or other variables related to disease. But consumers are now demanding that effectiveness be considered in terms of their overall health and well-being and are seeking outcome measures such as quality of life and ability to perform well at work (Long et al. 2000; Truant and McKenzie 1999). CAM ideologies are more amenable to these goals, and this is often a reason why patients seek them out (Ernst 2000).

Inappropriate and inadequate research designs involving small sample sizes, non-homogeneous study populations, lack of follow-up and no analysis of patients who have dropped out of care have also been blamed for the paucity of valid, reliable evidence. Another aspect of the problem is the lack of research capacity among the population of CAM practitioners. Only a few have had systematic training in research strategies and methods, and most of them are thus at a serious disadvantage when submitting research proposals to funding agencies. It is difficult, however, for these practitioners to acquire the necessary tools to do good research because there is so little credible evidence to warrant investing in their training and research. Funding for scientific research has traditionally come from large pharmaceutical companies, foundations and academic institutions. These funders have been reluctant to invest resources to investigate the utility of unproven CAM therapies.

Many of these problems can be resolved over time, especially if adequate and sustained financial support can be provided by governments and industry for research on CAM. In future, we can expect

that dependable research findings will become available as new, more appropriate methodologies are added to RCTs and CAM practitioners become more sophisticated about research (Nahin and Straus 2001; Mills et al. 2002; Verhoef et al. 2002). It is clear that CAM therapies must undergo the same degree of systematic and rigorous scrutiny as conventional medical therapies if they are to win full acceptance and legitimacy in the healthcare field.

According to David Eisenberg, chair of Harvard University's new Division for Research and Education in Complementary and Integrative Medical Therapies, "The tools we have [today] are adequate to investigate the overwhelming majority of alternative and complementary therapies" (Lambert 2002: 100). He mentions new techniques such as scanning technologies to look at brain states so that we can expand our knowledge of the mind-body interface, and robotic tools that can screen thousands of herbal extracts for their effect on biological targets. He argues that since the National Institutes of Health in the United States has seen the potential of research on CAM and has begun to fund it, young scientists are more willing to undertake it. He says: "When the challenge of creating a methodology becomes intellectually stimulating and fun, that's when a field has staying power" (Lambert 2002: 100).

### **The Consumer's Perspective**

Despite problems surrounding credible evidence, consumers have been demonstrating an enthusiastic interest in CAM healthcare. Over the past few decades, people's faith in traditional community, social and religious authorities has faded,

and society has become more questioning and skeptical (Crellin et al. 1997; Putnam 2000). The health sector, like others in society, has been affected by the growing empowerment of the consumer who has developed an interest in health models from other cultures and in complementary and alternative forms of care. These consumers have not waited for medical science to produce solid evidence for the efficacy and safety of CAM. They have gone ahead without such proof and have paid for these therapies out of their own pockets.

The question is: What types of evidence have they been relying on when they decide to do so? One of the most powerful influences on decision-making for CAM has been shown to be the counsel of a *health confidant* (Wellman 2000). Using social network analysis to examine how people come to use alternative types of healthcare, Wellman found that advice from close friends and family had the most impact. People turned to those whose advice they trusted – their health confidants – when they were having problems with their health. When they were ready to consider alternatives to conventional medical care, they listened to those friends and family members who had been helped by CAM and decided that there might be help for them as well. These recommendations from health confidants provide a kind of legitimacy for treatments that are not formally sanctioned by science.

Wellman's research also showed that only a few patients were recommended to CAM by their physicians, although this may be in the process of changing with the introduction of courses on CAM into Canadian medical schools (Ruedy et al. 1999). Testimonies about the positive

effects of CAM practices or products from acquaintances and colleagues at work also influenced the decision to choose CAM, as did recommendations from CAM practitioners themselves. These practitioners often suggested to their patients that they try another type of therapy or a CAM product as an adjunct to the treatments they were giving. Wellman's analysis of patients' health networks also revealed that the larger and more diverse a person's networks are, the more likely it is that he or she will be exposed to someone who has had a positive experience with CAM and will recommend it (Wellman 2000).

Another kind of evidence is provided by media reports of successful outcomes. The press, radio and television have all stepped up the attention paid to CAM in the last few years. Stories of people who have been helped as well as warnings of possible dangers have become commonplace news. Gurus such as Andrew Weil, Deepak Chopra and Dean Ornish have raised the profile of CAM to a pervasive level. Their influence and the multitude of books and journals on the uses of CAM can be powerful forms of evidence for people who have been considering trying CAM products or services.

The power of advertising also has an impact on consumers. More and more advertisements for CAM are appearing in the mainstream media. Formerly restricted to specialized publications and locales such as health food stores, advertisements extolling the merits of particular CAM treatments and products are powerful forms of evidence for people who are seeking new options for their healthcare.

Finally, the power of the Internet has been growing steadily. People are increasingly turning to the Internet today for

health knowledge and advice. In a study conducted in 2001, 500 Internet users who go on-line for healthcare information were surveyed. Just under half (48%) were found to have used it for information about alternative or experimental treatments or medicines (Fox and Rainie 2002). While the quality of the evidence they find there is highly variable, its accessibility and immediacy can have a potent effect on healthcare decisions. All these informal sources of information and influence are acting together; the impact of each is reinforced by the others.

Deciding to choose CAM on the advice of such informal sources suggests that many patients are relying heavily on anecdotal information as evidence. While this is a significant departure from scientific rigour, it is nevertheless very influential (Kelly-Powell 1997). Enkin and Jadad (1998) explain the importance of anecdotal evidence in terms of its fit with patients' belief systems, values and expectations. It seems that scientific evidence of efficacy plays only a limited role in decision-making and that CAM patients are influenced by other, more social and emotional considerations such as frustration with conventional care and a sense of desperation about their health problems (Kelner and Wellman 1997a).

What constitutes evidence for one person will not necessarily work for another. Different groups in society ask different types of questions and require different kinds of data. For example, people in severe pain may be satisfied with anecdotal evidence of relief provided by a CAM therapy, while their physicians may insist on scientific proof of efficacy. Governments are accountable to the public and need to base their healthcare

policies on reliable data about safety and cost-effectiveness. Consumers, on the other hand, are more focused on health maintenance and prevention of illness and will be looking for evidence of good health from the histories of close friends and family.

### **The Practitioner's Perspective**

Another perspective on the need for scientific evidence that CAM works and is safe is that of the CAM practitioners themselves. The views of CAM practitioners were sampled in a recent study conducted in Toronto (Kelner et al. forthcoming). The leaders of three groups (chiropractors, homeopaths and reiki practitioners) were asked about the importance of demonstrating the efficacy and safety of their therapies and practices. There were striking differences in the attitudes of the three sets of leaders. The chiropractors were strongly in favour of ongoing scientific research that might demonstrate the efficacy and safety of their therapies. The homeopaths were less certain that rigorous proof was needed, while the reiki practitioners were not sympathetic to the whole notion of research and believed that "reiki speaks for itself."

These variations in attitudes toward the importance of research and evidence can be partially accounted for by the fact that the three groups are at different stages in the process of professionalizing. The chiropractic leaders encouraged continuing peer-reviewed research because they seek full professional acceptance for their group. They realized that in order to accomplish this goal, they must provide convincing evidence that their practices have a positive impact on health outcomes, are safe and can save the government money in the long run.

Because they have been able to organize effectively and increase their numbers across the country, they are in a position to undertake and fund the required research (Kelner et al. 1980).

The homeopathic group is far smaller and much more divided. While some of the leaders recognized that producing a solid base of evidence could help to win acceptance for their therapies, others expressed no interest in pursuing this course of action. Even if the various factions were to agree that scientific research is a desirable strategy to pursue, the size of the group would be a serious handicap. Producing credible research is a costly undertaking and requires a sizable group of practitioners who are sufficiently committed to the project.

The reiki group is the smallest of the three and consists of several informal communities that have little or no contact with one another. With one exception, the reiki respondents were completely uninterested in encouraging research on their healing practices. The idea of scientific research that could demonstrate the value of their approach to healthcare seemed alien to them. They regarded conventional methods of measuring health outcomes as inappropriate for their philosophy of care. Furthermore, their small size and lack of an organizational structure would make it impossible to carry on this kind of research, even if their negative attitudes toward scientific research were to change.

The findings indicate that healthcare occupations that seek to become professionalized are the most receptive to research on their therapies and practices. CAM groups are increasingly seeking to meet demands from other healthcare professionals and governments for

evidence-based healthcare (Best and Glik 2000; Kelner et al. 2001). Groups that wish to join the mainstream healthcare system recognize that they must respond to these demands. But not all healthcare occupations are at the point in the professionalization process where they are willing or able to undertake rigorous research. Some may never choose to do so, preferring to practise outside the professional sphere. The data presented here provide a picture of three groups with widely differing attitudes toward research and also toward the prospect of fitting the model of a fully legitimate health profession.

### **A Sociological Perspective**

The concept of evidence is clearly complex and multidimensional. From the viewpoint of sociologists, we present an analysis of how the notion of providing reliable evidence can be refined and expanded. Many sociologists subscribe to the view that “reality” is socially constructed and that what people accept as reality varies from person to person, and time to time, even within one society (Berger and Luckman 1966; Cassidy 1994). For example, as circumstances change, people’s notions of what constitutes good health also alter; longevity alone is no longer enough – it is the way one lives that matters. People who are impoverished and from minority cultures perceive their options for living a healthy life as restricted. By comparison, those who are well educated, affluent and well connected see numerous opportunities. So it is with views about what constitutes evidence. For those in different positions in society, the nature of credible evidence will vary. Moreover, people will change their views about evidence at different times, depending

on their place in the life course.

The prevailing wisdom of the moment also significantly influences the way people evaluate what they read and hear. For example, until recently scientific research suggested that hormone replacement therapy had a role in preventing heart attacks and strokes in post-menopausal women. New research, however, shows that estrogen makes women more susceptible to blood clots and that the overall cardiovascular effect is negative (Patterson 2002). Women are now confused and asking themselves what to believe. What people regard as reliable and compelling evidence is intricately connected not only to the circumstances of their everyday lives but also to the socio-cultural climate in which they live (Garfinkel 1967; Koos 1954; Schutz 1967).

Nevertheless, useful scientific research is done, and reality approximated. Two major paradigms or models of reality underlie much of contemporary human thought, including the practice of science: the reductionist paradigm and the holistic paradigm. At present, the first model is the dominant one used in scientific research. But many things in our world do not have logical explanations; this makes it hard to insist on a scientific rationale for everything. For example, modern medicine is predicated on a biomedical perspective, but physicians frequently argue that medicine is also an art. What they imply by this is that science alone does not constitute the whole of reality. In the healing process, the therapeutic relationship, the practitioner’s intuition and experience and the patient’s confidence and participation are all significant influences on the eventual outcome. Sociologists contend that both

models are necessary; each emphasizes different aspects of reality, recognizing the complex interplay of biological, psychological, social, cultural, environmental and spiritual factors underlying health and disease. Therefore, when it comes to evidence about the efficacy and safety of CAM, sociologists tend to take a broad view that includes a variety of types of evidence as well as an open approach to the evaluation of evidence.

We endorse the view that the evidence base for CAM should be on a par with the evidence base for conventional medicine; no more, no less. However, the concept of evidence needs to be broadened. We need an imaginative spectrum of research methods that balances relevance, scientific rigour and feasibility.

### **Recommendations for Policy**

There is a recognition today that we need to develop innovative strategies for providing quality healthcare to all Canadians. As part of this process, we need to promote an understanding of the role of CAM in healthcare. Integral to its role is systematic evaluation of efficacy and safety. At present, the overall infrastructure to accomplish these goals does not exist, despite the presence of small research centres across the country. We suggest some developments that can help create a scientific foundation for complementary and alternative therapies and for the evaluation of their effects. This infrastructure has to provide opportunities for CAM therapies to undergo the same close scrutiny and rigorous testing that have been applied to many conventional medical treatments. To accomplish this, federal, provincial and private support are all necessary.

### **Research**

To build a comprehensive research infrastructure for CAM in this country, we need to develop a cadre of multidisciplinary, accomplished investigators with a special interest in this area of healthcare. Scholars have to develop appropriate conceptual frameworks and methodologies for evaluation. At the same time, researchers need to work on knowledge development and management through systematic literature reviews, bibliographic databases and researcher/practitioner networks. Vitally important in this endeavour is the establishment of linkages with international agencies such as the National Center for Complementary and Alternative Medicine at the National Institutes of Health (NIH) in the United States and the Prince of Wales Foundation in the United Kingdom. Finally, clinicians should be involved in developing standards of practice and peer review processes.

The most effective way to accomplish these goals would be to establish an Institute for Complementary and Alternative Healthcare under the auspices of the Canadian Institutes of Health Research (CIHR). This institute would oversee the development of a coherent national CAM research policy, link researchers across Canada to develop interdisciplinary expertise and act as a resource to other institutes within CIHR as well as to health policy-makers and politicians.

Governments can also play a role by including information about CAM in general health surveys. For example, the Longitudinal National Population Health Survey (NPHS), conducted by the federal government, already includes some questions about CAM, but it does

not go far enough. In addition to the descriptive data it produces, questions on patterns of use of both CAM and conventional medicine should take into account cultural and geographic differences. Besides data on mortality and morbidity, questions that reveal the effect of CAM therapies on prevention and quality of life should be included. Surveys on the use of CAM could also be mounted by the Canadian Institute for Health Information (CIHI).

It is not always necessary to reinvent the wheel. Research findings from other countries can yield valuable information and insights. For example, pharmaceutical companies have taken advantage of accumulated knowledge from elsewhere concerning herbs and other natural elements to develop their own modern scientific products. Existing data can also be found in the numerous studies of natural herbs conducted in Germany and other European countries (see reviews in FACT). Research on CAM in Canada should actively seek out the results of work already undertaken in other parts of the world.

### **Regulation**

Governments have a responsibility to assure that healthcare services are not only responsive to needs but are also safe. In order to provide accountability to the public, the federal government has undertaken to regulate health products (Natural Health Products Directorate). This work is proceeding at a rapid pace, and Canadians will soon have guidelines and standardized codes to assist them in selecting CAM products.

Provincial governments are responsible for regulating healthcare practitioners

so that the public is not harmed or duped. Regulation provides protection from unqualified, incompetent or unscrupulous practitioners who are not well trained and/or treat patients without practice and ethical standards. The regulation of CAM practitioners varies widely between provinces. Most CAM practitioners are not regulated in any way. The only CAM group that is regulated in all provinces is chiropractic, while some other groups, such as massage therapists, naturopathic and traditional Chinese medicine practitioners and acupuncturists, are regulated in a few provinces.

The criteria for achieving statutory self-regulation currently exclude many CAM groups that are providing health services to a broad range of the public. Decisions about which groups merit state-sanctioned self-regulation need to be based on a range of considerations that go beyond the ones that are typically used. Evidence of efficacy, for example, should include not only the results of clinical trials but also take into account positive experiences in other cultures over long periods of time. The fact that many of these CAM therapies such as homeopathy and traditional Chinese medicine are well established in other countries should bear weight on decisions about state-sanctioned regulation. Some CAM occupations impose standards on their members independently of the state, but in these instances the government does not stand behind any sanctions such a group may impose. This presents a problem for the public and suggests that the criteria for attaining statutory self-regulation should be relaxed so that a broader network of protection can be available to Canadians.

## Funding

Government also has a responsibility to manage healthcare services in a cost-effective way. The more the public uses CAM, the more its use becomes a public issue, and that means that the government has to take a role. In an era in which provincial governments are in the process of restructuring the healthcare system to contain costs, the question of who should pay for CAM services is crucial. At the present time, some provinces pay a small amount for selected CAM therapies such as chiropractic. Increasingly, private insurance companies are offering to cover the costs for some of the more widely used CAM therapies. But this means that many people are paying out of their own pockets and that those who cannot pay must do without services that they might want to use and that may help them.

If it can be established that CAM healthcare is cheaper than or equal in cost to conventional medical care for certain conditions, it stands to reason that these services should be publicly funded. Unfortunately, little research has been undertaken that could produce evidence of cost-effectiveness. Admittedly, this is a complex issue. Both short- and long-term effects must be considered, as well as direct and indirect costs. However, if governments are seeking to assure accessibility of care and to minimize costs, they must strongly support this kind of research without prejudice. CAM may provide a cheaper alternative to the highly technological services offered by conventional medicine.

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