Evaluating the Effectiveness of Complementary and Alternative Medicine

BY SEAN PARK

The dramatic increase in the use of complementary and alternative medicine (CAM) in the Western health care setting has caused much debate. Critics of CAM therapies view research in this field to be scientifically unverified, and as such, not effective or safe to administer to patient populations. Proponents of CAM, however, argue that the evidence-based medicine model that conventional medicine uses focuses to heavily on the randomized controlled trial (RCT) as a source of evidence.

In recent years, much debate and frustration has arisen over the basis, development and delivery of health care, particularly in the Western hemisphere. Key to this debate is the relationship between conventional and unconventional medicine. Unconventional medicine, commonly referred to in many journals as Complementary and Alternative Medicine (CAM), is a very general term given to wide array of therapies. Some have defined these therapies as "medical practices that are not in conformity with the standards of the medical community" or as interventions that are not generally available in hospitals or not usually taught at medical schools (Eisenberg et al., 1993).

The authors that formulated this definition for a study on unconventional medicine in the US analyzed the prevalence of some of the following therapies in the US population (Eisenberg et al., 1993):

UNCONVENTIONAL THERAPIES

Relaxation techniques	Prayer
Massage	Imagery
Spiritual healing	Herbal Medicine
Megavitamin therapy	Self-help groups
Energy healing	Biofeedback
Hypnosis	Homeopathy
Acupuncture	

While a number of these therapies have been in existence for much longer than conventional medicine, their increased use in developed nations has sparked great debate. The issue of CAM use is particularly prominent in the US as conservative estimates of 1997 out-of-pocket spending on CAM therapies reached $27 billion with annual visits to CAM therapists exceeding visits to US primary care physicians (Beyerstein, 2001). Assailants of CAM are now arguing that many, and in some cases all, CAM therapies are scientifically unfounded and carry false promises about safety and efficacy (Beyerstein, 2001). What is the basis for this argument and how will it affect the future of CAM?

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Dr. Ken Rosenthal and the immunological science behind his innovative new AIDS vaccine.

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The Key Component of Rosenthal's Vaccine

Where AIDS vaccines in the past using whole killed virus approaches have been unsuccessful, Dr. Rosenthal's approach champions to success. The key element lies the clever use of an additional substance added to the vaccine, an adjuvant called CpG DNA. In the immunological community, vaccine adjuvants are agents used to boost immune response against foreign invaders. As CpG DNA has a structure resembling that of bacterial DNA, it is believed that the human immune system has evolved to respond potently to it. In specific, the adjuvant boosts the immune system by directly activating B-cells and antigen presenting cells. Activation of B-cells increases antibody production whereas activation of antigen presenting cells such as macrophages, monocytes and dendritic cells increases the number of antigens processed for adaptive immunity. In addition, by causing antigen presenting cells to secrete interferon and cytokines, the adjuvant is capable of activating natural killer (Nk) cells, cells capable of spontaneously recognizing and killing virus infected cells. The combination of these immunostimulatory effects induced by CpG DNA allows the body to respond to the whole killed virus introduced with the vaccine to produce long lasting immunity (Rosenthal, 2002).

Beyond the HIV Vaccine

Beyond the mouse model, the concept of using CpG DNA as an adjuvant holds a candle of hope to victory over the AIDS epidemic. Furthermore, the uses of CpG DNA are not limited to HIV vaccines, the adjuvant may help strengthen other vaccines as well. Currently, Dr. Rosenthal is using a similar concept to develop a vaccine for the herpes simplex virus. At this continued rate, the future of disease control looks very optimistic - it is clear that McMaster is at the forefront of a healthy tomorrow.

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Conflicting Types of Evidence

In the effort to deliver the best and most effective treatments to patients, evidence is necessary to prove how successful a particular treatment is in treating a particular condition. Evidence, however, is a very general term, and it comes in all shapes and sizes (Bloom, 2001). In CAM, subjective accounts of treatment effectiveness and the results of patient-doctor/therapist interactions are put forth as evidence to support the use of a particular therapy. In medicine, the improved health of a population is used as evidence with the randomized controlled trial (RCT), which emerges as the best method of study for predicting outcomes (Bloom, 2001). Use of the RCT has factored immensely into the development of evidence-based medicine (EBM), the current construct that conventional medicine is using to rationalize clinical treatments (Tonelli and Callahan, 2001). Under the philosophy of evidence-based medicine, the use of the best available clinical evidence from systematic research will determine the most effective treatments (Feinstein and Horwitz, 1997). As such, EBM inherently prefers evidence derived from RCTs to all other types of evidence as is indicated by Tonelli and Feinstein.

The basis for the argument that CAM is "unscientific" or cannot produce convincing evidence is largely due to its current lack of ability to meet the "gold standards" that RCTs provide for EBM clinical decisions, and its failure to fit current conventional concepts of disease. These inabilities can be explained in four parts:

1 Many CAM therapies revolve around non-measurable but perceivable factors, such as Qi-body energy and mind-body connections implicated in imagery and biofeedback (Tonelli and Callahan, 2001). Because these factors can only be assessed subjectively; they are often difficult to study in the context of RCTs. However, just because we are unable to measure or accurately define concepts such as spirituality and Qi, we should not be deterred from trying to quantify or define them (Bloom, 2001).

2 A problem arising with the use of RCTs is that they refer to "average" patients, patients that met the conditions for the trial. The results of these trials do not account for the individual differences that exist amongst patients. As such, CAM therapies tailored to unique patient characteristics will not benefit from studies that determine what should be done for the "average" patient (Feinstein and Horwitz, 1997). Similarly, RCTs are appropriate in CAM therapies that promote their effectiveness in a population; however, CAM therapies using different methods based on the unique features of an individual cannot be appropriately examined with RCTs (Tonelli and Callahan, 2001).

3 There have been some CAM research studies that have been applicable under a RCT format. Over 7,500 peer-reviewed English journals have been published since 1970, using RCTs as the basis for determining the efficacy of the CAM treatment (Bloom, 2001). One of the most prominent CAM treatments, acupuncture, is one of the interventions shown to be effective with the use of RCTs. Its acceptance into conventional medicine, however, was not justified until a bio-physiological hypothesis was developed. As such, CAM treatments must not only be proven effective with "the best evidence"; to be accepted, they must also fit into the model of disease as is defined by conventional medicine (Tonelli and Callahan, 2001).

4 Arguments against CAM therapies involve the concept of the placebo. Up until the 20th century, Grollman argues, most medical treatments were ineffective and the placebo effect accounted for the therapeutic responses observed. In his article, Grollman cites evidence that upward of 30% of patients visiting health care professionals experienced symptomatic improvement that was derived from the placebo effect (Grollman, 2001). Can the improvements in health be solely attributed to CAM therapies, and if not, how much of a role does the placebo affect play? This has yet to be resolved.

Denouncers of CAM claim "it cannot be known that any vaunted treatment is effective without blinded comparisons involving placebo-treated controls" (Beyerstein, 2001). This mindset put forth by members of the medical community sets up many barriers for CAM therapists, as the "evidence" they offer is difficult to quantify and is based on very different axioms. This concern is valid, as disproved or unproved treatments are questionable in terms of safety.

The Future of CAM

Given the public demand for CAM and conventional medicine's push for sounder evidence, CAM therapies are increasing subjected to greater investigation. One of the major questions surrounding the future of CAM in the Western healthcare setting is, *"What will it take for research on CAM to be conclusive, applicable and scientifically acceptable?"* At one extreme, skeptics of CAM such as Beyerstein and the National Center for Complementary and Alternative Medicine (NCCAM) demand that only blinded and controlled experiments will suffice as evidence for establishing treatment effectiveness (Marcus, 2001). Proponents of CAM maintain that testimonials and clinical experiences with their treatments are convincing enough to continue usage (Beyerstein, 2001). In light of the present viewpoints, if CAM is to remain a considerable factor in health care, what is to be done to satisfy the scientific requirements of conventional medicine while maintaining the freedom of choice that the public has in making health care decisions? A number of ideas have evolved recently that may deal with this issue.

One consideration in the administration of care, whether it is conventional or unconventional, is the resources required to treat patients. Feinstein cites evidence from a study showing that only 53% of primary treatments on a group of patients in hospital were supported by RCTs, while another similar study showed that 50% of the treatments were supported by convincing, but non-experimental evidence (Feinstein and Horwitz, 1997). Bloom argues that, by stopping support and payment for care that has unknown benefit, resources could be better used to administer treatment that is supported by evidence (Bloom, 2001). It is also possible that some of these resources could be used to research those treatments that are still labeled as ineffective or unproven.

In terms of generating acceptable evidence, some authors have proposed that members of both conventional medicine and CAM work towards developing a framework under which results from CAM research can be fairly assessed. Because of the inherent inability of CAM therapies to fit into the EBM model, Tonelli argues that conventional medicine should redefine "evidence" and insist on more complete and well-defended descriptions on how CAM knowledge and tools are used and developed (Tonelli and Callahan, 2001). Others offer that a thorough review of CAM therapies must include personal accounts from patients and therapists, consideration of differences between patients and the individualized nature of the therapies (Sampson, 2001). In an educational setting, it has been suggested that medical schools take a closer look at CAM therapies. Medical professionals be able to better inform their patients about what is and what is not effective not only through learning about the therapies, but by putting them through critical assessment (Sampson, 2001).

Essentially, the future development and evaluation of CAM will hinge largely on public and medical opinions. Its scientific credibility and capacity to demonstrate its effectiveness, however, will not be completely determined until appropriate methods are developed to account for the different types of evidence, different concepts of disease, and the different ways of treating diseases that characterize CAM.