# The Authors Respond

FINAL RESPONSE

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Whenever you write something for others' eyes, you wonder how it will be received. There are three possibilities: it could be ignored, it could be praised or it could be decimated. We knew our words about complementary and alternative medicine (CAM) would not be ignored this time, but we did have trepidations about how our colleagues would respond. We are delighted and surprised that the responses have been so constructive. Everyone agrees that CAM is now a significant part of the healthcare landscape and requires serious consideration. This issue of Healthcare*Papers* is a testimony to the growing interest in CAM in healthcare circles in North America and beyond. It is gratifying to receive comments from Australia and the United Kingdom as well as Canada.

We thank our commentators for their well-informed and thoughtful responses and enjoy the range of their perspectives. They have each used their own experiences to invigorate the discussion around the key issues and appropriate policies

that stem from the recent explosion in the use of CAM. In the next few pages, we will highlight their responses and discuss the ramifications in an attempt to advance the discussion. From our perspective as sociologists, three issues stand out across the commentaries: evidence, nomenclature and integration.

## Evidence

All of our commentators paid considerable attention to the nature of evidence and the ways it should be collected. Richardson points out that many advances have been made in adapting RCTs to the assessment of CAM. These new developments capitalize on the individualized approaches of CAM and also on the placebo effect. Verhoef and Findlay also refer to some of the pragmatic trials that are addressing the difficulties in applying RCTs to CAM. Nevertheless, they admit that RCTs may fail to detect the complexity of factors involved in delivering CAM therapies and suggest a combination of different research designs, including both quantitative and qualitative approaches. Richardson argues, as does Ruedy, that it is essential to examine patient experience when we are looking for evidence of efficacy. Ruedy emphasizes the significance of the meaning of the illness and the intervention for researching outcomes of CAM treatment methods. He rejects our call for scientific rigour in research on CAM therapies and argues that it is inappropriate to demand scientific validation of health interventions that are not based on science. He does agree, however, that validation of products requires the same scientific standards as prescription and over-the-counter drugs.

Willis claims that CAM must "climb on the bandwagon" of evidence-based medicine (EBM) even though there may be mixed consequences. The advantage is that if it can be demonstrated using EBM that CAM works, then it doesn't matter if the underlying theories are not accepted as explanations of why it works. The disadvantage is that EBM can be used as a political tool. Funders can decline to support any interventions that cannot show the sort of evidence acceptable under EBM. This is a major problem for CAM modalities since their financial resources are sparse and typically required for political survival rather than for funding research. In concluding his remarks, Willis argues strongly that while evidence has a role to play in establishing the legitimacy of CAM, political, legal and clinical factors are also critical. Scientific evidence will never be the whole story of where CAM fits into the health-care services of a society.

Saunders agrees that using evidence as the sole criterion for patient treatment runs the risk of ignoring the individual patient and his or her special needs and could have the result of denying treatment to people who may benefit. He recommends that the kind of grid developed by the Natural Health Products Directorate (NHPD) be used for evaluating levels and types of evidence. This grid encompasses a range of evidence from a hierarchical perspective, and respects evidence that does not fit the single model of RCTs. The combination of levels makes possible the study of the full gamut of CAM practice.

Kalaria is more interested in evidence for safety and cost-effectiveness than he is in evidence for efficacy. He argues that since CAM practices and products are already in use, the urgent need is to ensure that they are safe. Research on cost-

effectiveness is needed to determine whether it will be "cheaper or dearer"' for the healthcare system. This kind of evidence would make it possible to decide whether governments should participate in the future funding of CAM healthcare. As of now, this is not a research priority, and it may be a long time before data on cost-effectiveness are available for advising government policy.

Rieder and Matsui urge that the safety and efficacy of CAM be demonstrated in all patient populations that are likely to use CAM. They believe it is important to know which therapies benefit which kinds of populations. In particular, their interest is in children and women of child-bearing age. They argue that the unique circumstances of childhood provide compelling reason for investigators to work with conventional and CAM practitioners on evaluating the safety, efficacy and appropriate role of different kinds of CAM when treating children and pregnant women.

These comments reinforce our belief that research methods for gathering evidence on CAM need to be diverse and inclusive, and go beyond the use of RCTs, regardless of the demands from the medical establishment that only "scientific" evidence of CAM's effectiveness is acceptable.

## Nomenclature

The issue of how best to define non-allopathic healthcare services is one that concerns a number of the commentators. Richardson cautions that definitions have political implications that can result in unintended consequences. In the case of "integrative medicine," the danger is that CAM will be assimilated into the conventional system and, as she says, "the dialogue of the 'alternative' is replaced by the discourse of the establishment." Willis reinforces this perspective and points out that there are problems with each of the terms being used: complementary, alternative and, more recently, integrative medicine. He attributes these difficulties to the fact that CAM is defined in terms of "otherness".

Verhoef and Findlay strongly urge that CAM should be termed complementary and alternative healthcare (CAHC). They argue that the term "healthcare" is a more appropriate fit for the range of complementary and alternative systems, modalities and practices than the term "medicine." It is a broader term and not limited solely to medical care. Similarly, they urge that "integrative medicine" be replaced by "integrative healthcare." They point out that in the existing literature a wide range of definitions are used for integrative healthcare, each one representing the particular perspective of the author and typically focusing on one aspect such as the philosophy, structure, process or outcomes of such care.

Saunders also highlights the problems with defining CAM, commenting that the definition has been as broad as the range and practices offered. He sees this lack of clarity as posing a problem for physicians, government authorities and the public. Physicians are unsure about making recommendations, governments have difficulty developing appropriate healthcare policies and the public is uncertain about which therapies can be considered legitimate. He outlines three positions in the literature with regard to nomenclature and argues that the broadest definition is the most appropriate for the delivery of multidisciplinary healthcare.

These difficulties in arriving at a definitive definition for CAM are not just academic disputes but have real consequences for conducting research in the field. We cannot measure what we cannot define. As Ruedy argues, unless scholars of CAM can agree on appropriate, comprehensive and convincing ways to describe the totality of CAM practices, credible research, statutory self-regulation and funding cannot proceed at a speed that corresponds to the current pervasiveness of these practices.

## Integration

More and more people are considering the potential for integrating CAM with conventional medicine. Integration is already occurring in small and diverse ways, from community clinics to private practices to hospital settings. Several of our commentators make a contribution to the ongoing discussion of this issue. Richardson warns that integration can simply mean assimilation into the biomedical model. She points out that the pharmaceutical companies are eager to gain control of herbal medicines and put them into the hands of conventional doctors. She also refers to the tendency for conventional physicians to retain control by taking components of CAM and incorporating them into their own practices. She speculates that this will lead to replacing the concepts of CAM with Western explanations. To create something new, she claims, by combining the different discourses is extremely difficult since there are so many different approaches within CAM and even within conventional medicine.

Verhoef and Findlay speak of a continuum of integrative healthcare. They claim that consumer utilization and demand is the most powerful facilitator of integration. They describe the influence of practitioners and consumers on efforts to integrate as "upward pressure" and see examples of this pressure in the increasing demand by students of university health science programs and professional colleges for courses in integrative healthcare. Just as they argue that CAM consists of a range of whole systems and disciplines such as naturopathy and homeopathy, they also urge that integrative healthcare must be considered as a whole system as well. What they are calling for is the creation of a totally new system to deliver integrative healthcare services.

According to Ruedy, CAM therapies are both unofficial and outside the boundaries of conventional medicine. He argues that they are based on distinctively different beliefs about health and healing than those underlying the biomedical model. This kind of formulation highlights some of the difficulties involved in the process of integration. Nevertheless, with sufficient conceptual development, it may be possible to show that the underlying principles on which the different CAM modalities work are fundamentally similar to the principles of biomedicine. For example, the medicine notion of homeostasis, in which the body works toward achieving some kind of balance, corresponds well to the principle of achieving individual harmony, to which many CAM therapies subscribe.

Kalaria claims that pharmacists have for some time provided a natural bridge between CAM and conventional medicine. They have a responsibility to advise patients who are on medications prescribed by their physicians whether it is safe for

them to also use herbal products that are part of a CAM course of therapy. He sees a clear role for pharmacists in integrating all the various types of products that people use in pursuit of their health.

Rieder and Matsui believe that both conventional therapies and CAM therapies should both receive attention from researchers and also should not be considered separately from each other. Investigators should assess many different kinds of therapies when determining which will result in a better quantity and quality of life.

Integration can take many forms. What is important is that CAM not be co-opted, assimilated or subjugated.

## Building a Research Infrastructure

Verhoef and Findlay agree with our recommendation for developing a research infrastructure on CAM, and they have taken an active role in creating one in Canada. Currently there are several research networks across the country devoted to increasing the capacity for high-quality research that evaluates CAM healthcare and its use. Their activities include building research capacity among CAM practitioners, setting research priorities, facilitating network building, developing CAM curricula for undergraduate medical education and engaging in dialogue with the Canadian Institutes of Health Research on the importance of funding for CAM. The most recent initiative aims to develop an overarching umbrella structure to integrate the various groups and networks across the country. The top priorities that have been identified for this umbrella structure are the safety and efficacy of CAM and the development of new methodologies to study it.

Kalaria also supports the notion of a separate institute for complementary and alternative healthcare to carry out research on CAM products and practices. He recognizes, however, that this goal may not be achievable in the near future. In the interim, he recommends the establishment of an effective method for collecting data on the safety of CAM products that are already being used by millions of Canadians. While he admits that the complexity of CAM may preclude clear answers, he believes that this in no way precludes the need for research, especially in the area of safety. In addition to collecting data, he proposes that a schedule be developed similar to Schedule A of the Food and Drugs Act, which lists conditions for which cure cannot be advertised. This would eliminate unsubstantiated claims about natural health products, which may be misleading to patients.

The idea of a separate institute is also supported Rieder and Matsui. They, however, recommend that it be an Institute of Therapeutics. This would take a broader view and appraise both current and potentially new therapies for safety and efficacy. Such an institute, they claim, would provide an ideal environment to address issues related to the evaluation of conventional therapy as well as CAM.

By comparison, Ruedy is opposed to the expenditure of public monies on research for CAM. He argues that integrating research in CAM "into existing research programs is a more appropriate step than creating another administrative structure." In his view, in a for-profit

system, such as exists for conventional drugs and products from alternative sources, the responsibility for funding should rest with the seller or the manufacturer of the product. He takes issue with the establishment of the Natural Health Products Directorate and describes it as unfortunate that it is proposing a system similar to the one proposed for drugs. Instead, he believes that public monies would be better spent in support of patient registries, which can provide an early alert about potential adverse effects.

Rieder and Matsui also see the need for monitoring the safety of conventional therapies, CAM and the combinations of both. They recommend the establishment of active surveillance systems, which would provide data that are helpful in evaluating outcomes of therapies in vulnerable populations such as children and pregnant women.

We continue to see the necessity for public funding so that research goals and findings will not be biased in favour of those who provide the money.

## A Final Word

It is heartening to see that we are in agreement about the key issues in the field. It is clear from the commentaries that the research methods needed to study CAM are closely intertwined with the way we define it. It is important that we think beyond the differences between conventional medicine and CAM and concentrate on the healing process. It is our hope that this issue of Healthcare*Papers* will serve to emphasize the strength of the CAM movement. More important, we hope that the discussion generated here will help CAM to find its place alongside conventional medicine, with its own respect and legitimacy.