

Questionable Gate-keeping: Scientific Evidence for Complementary and Alternative Medicines (CAM): Response to Malcolm Parker

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Abstract The more popular complementary and alternative medicine (CAM) has become, the more often it is demanded that the integration of CAM should be limited to those approaches that are scientifically proven to be effective. This paper argues that this demand is ethically and philosophically questionable. The clinical legitimacy being gained by CAM and its increasing informal integration should instead caution against upholding the biomedical framework and evidence-based medicine as conditions of acceptance. Patients' positive experiences with CAM deserve a truly scientific exploration of non-biomedical conceptualizations of health and illness. It is also problematic to request scientific evidence when there is proven resistance against CAM in research institutions, under-funding and a lack of suitable research methodologies. This is even more so, when much conventional medicine is not practiced with the same level of evidence as demanded from CAM.

Keywords Complementary therapies · Evidence-based medicine · Philosophy · Medical

Questionable Gate-keeping: Scientific Evidence for Complementary and Alternative Medicines (CAM)

Few issues have been debated as fervently in medicine as the status of complementary and alternative medicines (CAM), particularly since it has become evident that the use of these therapies is steadily increasing and that, despite their marginal place, they have become an integral part of the public's regular health care [1]. A survey conducted in the US in 1997 showed that 42.1% of the American population was visiting alternative medicine practitioners, which was a 47.3% increase in visits compared to 1990 [2]. Similar high use was found in other Western countries: for example 48% in Australia, 70% in Canada, 38% in Belgium and 75% in France [3].

Positions range from urging that CAM should be fully integrated [4], to an outright dismissiveness of these healing modalities by "a large and prestigious group of clinicians and biomedical researchers" [5:vii]. Regardless of the controversy, governments have begun regulating CAM. Some governments even offer avenues to statutory registration. (New Zealand, for example, now makes statutory regulation for CAM modalities possible through the Health Practitioners

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Competence Assurance Act 2003). With so many people consulting CAM practitioners, the need for a formal response becomes pressing. Regulation is desirable, so it is stated, in order to enhance public safety. By setting practising standards and making practitioners accountable, it is believed consumers will be better protected than they would be in an unregulated environment. There has also been a political need to acknowledge the appeal of CAM.

Regulation has mostly been welcomed within the field of CAM. Prospects for future state funding of CAM health care services and CAM research, and the increased legitimacy that particularly statutory registration will bring, make up for the increased bureaucratic and financial burden on individual practitioners.

Some authors strongly oppose this greater legitimacy. They argue that formal integration should not be driven by popularity but should be undertaken only after the CAM modality in question is shown to be effective. Patient or practitioner testimonies have no place in determining what is and what is not effective. Only statistical significance and the scientific methods of evidence based medicine (EBM) should be given that credibility.

Most commentaries along this line are found in mainstream medical journals. The following statements are typical:

There cannot be two kinds of medicine – conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work” [6:841].

There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which evidence is lacking [7:1618].

Within the debate on CAM within medical ethics, several commentators also promulgate this position by arguing that it is not ethical practice to offer CAM therapies that have no scientific evidence base, and that consequently any kind of formal integration should be based on prior proof of effectiveness [8–14].

My own research on this topic has led me to a very different conclusion [15]. Even though the value of a scientific research base for therapeutic practice is not in question, there are considerations that I believe are far more vital at this point in time than making a case

for giving credibility and legitimacy only to an evidence-based CAM. First, the popularity of CAM itself has to be understood. Why do people increasingly turn to CAM, and what do they gain from this? These questions should be approached with a much broader scientific curiosity than is shown at present. There should also be a greater willingness to explore non-biomedical perspectives seriously and respectfully, and to find research methodologies that are suitable for those other illness philosophies.

To support my stance I will approach this subject from several angles. I will begin by explaining the conceptual inconsistencies I perceive in the mainstream discourse. As Parker provides a thorough outline of the theoretical reasoning behind the demand for an evidence-based CAM, I will respond predominantly to the arguments given in his paper [14]. I will also draw on some empirical research into the reasons people give for choosing CAM. Then I will take a critical look at the evidence-base of orthodox medical practice, which is much more limited than one is led to believe. Finally, I will briefly point to the external conditions that make it impossible for CAM to reach anywhere near a level playing field with orthodox medicine when it comes to building an equivalent scientific evidence base.

Parker argues that only an evidence-based CAM should be integrated, and that integration of CAM can occur by means of two different approaches: a “totally integrated evidence based model” (TI), and a “multi-cultural–pluralistic model” (MP). He rejects MP, but is in favour of adopting TI because TI is supposedly consistent with evidence-based, scientific orthodox medical practice. This last assumption, which is commonly upheld and frequently repeated in the discussions about CAM, contains two fundamental mistakes of reasoning, and consequently cannot provide a sound foundation for the conjectures that build on it. Firstly, it incorrectly portrays orthodox medical practice as being evidence-based, and secondly, it wrongly conflates EBM and science.

Even the term ‘science’ is used in a confusing way in the context of this debate. Parker claims that “Science is not a member of the group of perspectives or world-views which postmodernism treats as equally valid” [14: abstract]. Although this statement is intended as a clarification, the statement is in fact ambiguous. One meaning would be that ‘science’ and ‘perspective’ belong to different categories, the other

that science is indeed also a ‘perspective’, but with a special (superior?) status compared to others.

Using the term ‘science’ to signify ‘the systematic inquiry into natural phenomena’ (which it does stand for at times) would rightfully put ‘science’ into another category than that of ‘world views’ or ‘perspectives’. However, most authors in this discussion, including Parker, use the word ‘science’ to allude to the premises of the biomedical sciences. Yet these premises can be quite accurately delineated for their specific disease-and-molecular-based framework [16]. The assertion that “science is not a member of a group of perspectives” therefore does not logically follow.

Accepting that biomedical science represents a particular perspective, the next point relates to its validity and how and by whom this is to be judged. Whether the value of a perspective is considered superior, equally valid, or inferior clearly has mostly to do with the beholder. Within the health care context, judgements about value come from two positions: from an objective, academic position (for example that of medical researchers), and from that of patients. As medicine is foremost a practice and meant to be useful to the individual patient, the final appraisal will consequently come from the patient’s position. Nordin goes as far as arguing that medicine does not operate on a scientific so much as a technical paradigm, because it has the goal of solving practical problems:

The nature of practical problem solving is such that there is often more than one feasible method. The competition between various technological paradigms therefore differs from the competition between scientific paradigms. A scientific theory is either true or false. If several theories compete with regard to giving an explanation of a natural phenomenon, at most one (perhaps none of them) is true. However, two technological paradigms competing with regard to solving one and the same practical problem may both work [17:299].

The sheer popularity of CAM approaches, with their various takes on health and illness, proves that they must be seen as useful for solving health problems despite their lack of scientific validation. Willis and White [18] have called this ‘clinical legitimacy’ in contrast to ‘scientific legitimacy’. Astin’s 1998 survey was a confirmation of this

clinical legitimacy. He questioned 1,035 randomly selected participants, and asked what their main grounds for the use of alternative medicine were:

The two most frequently endorsed benefits were, “I get relief for my symptoms, the pain or discomfort is less or goes away, I feel better,” and “The treatment works better for my particular health problem than standard medicine’s [19:1552].

One can pass this off as ‘consumer demand’ and criticise doctors who adopt CAM practices as straying away from medical science. Equally, however, not responding to this trend could be seen as another form of medical paternalism that ignores patient experiences and a refusal to acknowledge that there are helpful ways to conceive of health and illness other than biomedicine. Parker dismissively calls this a “cacophony of perspectives” and argues that it is right and ethical to defend the premises of biomedical sciences as the only valid ones and exclude what does not fit into this framework [14]. Increasingly, however, patients and also doctors are becoming aware that they cannot rely solely on the tools of orthodox medicine, and that the so-called “effectiveness gaps” in the biomedical treatment options are often successfully filled by non-orthodox approaches [20].

This includes the benefit that a non-biomedical diagnostic framework can have for patients, particularly in situations where symptom patterns are not explainable by the disease categories of orthodox medicine. When patients present with a variety of symptoms that do not fit into a medical diagnosis, their suffering is regrettably and all too often dismissed by doctors as not being “real”. Well-known examples of this come from patients with chronic fatigue or fibromyalgia. For a long time these conditions were not considered to be real diseases because they lacked the usual prerequisites for physical symptoms to be categorized into a distinctive disease entity—that is, no measurable biological disturbance or morbid anatomy could be identified. As a consequence, those patients often had to put up with being called hysterical, hypochondriacal, or malingering [21–23].

O’Connor provides some poignant research findings on the usefulness of a non-orthodox diagnostic framework from her qualitative study into CAM use [24]. One example comes from Dr Davis, one of O’Connor’s research participants. Dr Davis had been

suffering from a number of seemingly unrelated symptoms but the greatest bother was a longstanding recurrent posterior tibial tendonitis and chronic foot and ankle pain. After going through many unsuccessful conventional treatment attempts she finally consulted a practitioner of traditional Chinese medicine (TCM). The TCM practitioner told her that all her health problems were lying on the kidney meridian and that they were due to the deficiency of kidney-qi:

Dr. Davis is stunned to hear the practitioner identify a common diagnostic category in TCM which has no counterpart in conventional biomedicine, and which describes and provides an explanatory framework (though entirely novel to Dr. Davis) that encompasses not only her immediate problem but also other bothersome symptoms that she heretofore considered to be concurrent but unrelated [24:61].

The ensuing TCM treatment was successful, and not only for the tendonitis pain but for her other health problems as well. For Dr Davies both the notion of a kidney-qi deficiency and the therapeutic interventions had value in this situation. There are many stories of success that are similar to this one, if one makes the effort to inquire. This makes it hard not to question the ethics of excluding other diagnostic and therapeutic perspectives just because they do not fit into the biomedical framework.

This case is also a good lead-in to examining the use and limits of EBM for CAM research. As previously noted, the terms ‘EBM’ and ‘science’ are often used as if they were synonyms. Although EBM was developed in the context of orthodox scientific medicine, it is obviously not confined to it, otherwise it would make no sense to ask for evidence-based CAM. EBM is an empirical system and can be defined as a practice of medicine in which clinicians use medical knowledge that has come out of systematic research studies. Several types of methodologies make up the accepted research arsenal, all of which are well suited to the biomedical disease framework, because they usually seek population-based answers and those that have singular causal links and measurable outcomes.

However, if researchers want to learn about the effects certain treatments have on complex illness phenomena, particularly when these do not fit into disease categories, the present tools of EBM are less

than ideal [25]. This becomes even more obvious when one considers how the holistic perspective of CAM therapies affects both the therapeutic aims and the working methods of CAM practitioners. The goal of many CAM modalities is to stimulate the patient’s self-healing properties, often by responding to an individual’s particular symptom pattern and his/her bio–psycho–social–spiritual context, rather than to a particular disease entity. Successful treatment might require a multi-angle approach and also hinges strongly on an effective therapeutic relationship between patient and practitioner. The treatment effects are often more subtle than those of biomedical interventions and there is a lesser focus on objectively measurable changes. Greater attention is given to the patient’s subjective experience (although not exclusively so).

To conduct a research study which is able to capture these complex treatment objectives as well as reflect the actual conditions of practice, appropriate research methods are essential. Researchers who have taken on the challenge of developing such methods have realised that a huge amount of thought and effort is required to take all the necessary factors into account [25–28]. If research methodology is unsuitable, however, it is highly likely that they will yield false negative results. This could lead to the discrediting of potentially valuable therapeutic interventions.

Nevertheless, the existing EBM methods *are* capable of capturing *some* of the effects of CAM treatments. The present EBM methodology is relatively suitable for evaluating herbal medicine, for example. When there is a defined outcome that can be directly linked with a particular intervention and randomization and blinding is possible, the degree of effectiveness of the treatment for this outcome can easily be determined. On this basis, quite a number of CAM therapies have now been scientifically validated as effective.

Returning to Parker’s assertions that a “cacophony of perspectives” should not be accepted, but that evidence-based CAM should be accepted, the contradiction becomes only too obvious. Even though the radar of EBM is not suited to catching all effects of treatment, EBM as an empirical system does not differentiate between effects that are produced by a biomedical treatment or by a treatment that is based on a different philosophy, such as homeopathy. The framework of homeopathy is seen as completely incompatible with western scientific thinking, and it often derided as implausible because of the extremely

diluted remedies that are used. Even though there is still controversy about whether homeopathy is more effective than placebo [29, 30] there are a growing number of well-conducted randomised controlled trials that have shown statistically significant results [31, 32]. The potential implications of such unexpected positive empirical findings for the basic assumptions of biomedical science are momentous. To defend against this threat, some authors resort to the so-called 'theoretical plausibility criterion' argument which demands that every therapeutic intervention has to be explainable in terms of biological mechanisms [33, 34]. If that cannot be done, it is perfectly justified to dismiss positive results regardless whether they come from rigorous and well-conducted studies. If this criterion were applied, however, research into certain CAM approaches like homeopathy would be pointless from the outset, as it would be a foregone conclusion that any positive findings would be dismissed.

It is also widely assumed that orthodox medical practice is predominantly evidence-based and therefore should, for reasons of coherence and ethics, demand an equally evidence-based CAM before an integration is approved. This assumption demands close scrutiny on the grounds that have been argued convincingly elsewhere: as much as orthodox medicine promotes its evidence base, its practice does not live up to its representation. In fact, it is far from achieving its own ideal [35]. This seems particularly surprising in view of the extensive research efforts that have been made since the first truly randomised controlled trial in 1948 on the effectiveness of Streptomycin in the treatment of tuberculosis. It is even more extraordinary when considering that over \$55 billion are now spent every year by the biomedical and applied research enterprise worldwide [36].

There is not enough space here to examine all of the obstacles for an evidence-based orthodox practice [35, 37–40]. I will nevertheless outline some of the problems for primary health care, which has the greatest difficulties in being evidence-based. Primary health care is of course also the same sector where CAM modalities are practised. The major criticism that clinicians have voiced pertains to the relevance of the available research data for clinical practice. Some of the arguments include the following:

- Patients seen by general practitioners are quite different to the 'ideal' research subjects, who have been selected for the research because they exhibit

only the one condition for which the effectiveness of a treatment is being tested. In contrast, the patient population that is encountered in general practice usually suffers from several medical conditions simultaneously. It can be expected that having additional physical problems will influence the responses of the body to treatment and therefore make the research data an unreliable foundation for treatment.

- Co-morbidity requires the implementation of multiple treatments, which leads to further uncertainty, as the combination of therapies possibly have very different effects than each treatment might have on its own.
- There is a general lack of research that takes place in the general practice setting. Most research is conducted in hospitals and in the context of the different specialities.
- Most research focusses on disease- or organ-specific outcome measures rather than overall well-being.
- Many patients who consult general practitioners come with disorders that do not meet the criteria of a medical diagnosis in the first instance or are presenting in the early stages of disease, where little is known about this phase. There has been scant research conducted to address this shortcoming [37, 41–44].

Despite there being obviously a significant level of uncertainty in orthodox medicine, this is not openly and sufficiently acknowledged, especially not when debating CAM convergence. Instead, the impression of a great contrast is upheld between on the one hand un-evidenced, dubious, irrational CAM therapies and on the other the scientifically proven and trustworthy approaches of conventional medicine.

This view of evidence-based conventional medical practice leads some authors to condemn doctors who recommend non-evidenced CAM treatments as acting unethically on the basis that they cannot fulfil their obligation to provide patients the research findings that are needed to make an informed choice [10, 14]. It is implicit in this criticism that orthodox practitioners can do this, and do in fact do this. Although informed choice is an ideal we should aspire to, appropriate information has to be available in the first place. If it is not, it would be ethical to state this to patients openly (as many doctors, using CAM therapies now do as part

of the decision-making process) and not leave patients believing that all treatments are scientifically validated. In orthodox general practice, which as previously shown has only a limited evidence-base, patients are usually not explicitly made aware of this fact. It is also generally known and supported by research that there are many obstacles to a thorough informed decision-making process in that setting, one of which is the lack of time [45].

Finally, I wish to set the demand for an evidence-based CAM into its real-world context by looking at the actual feasibility of this request. As Kant argued, “ought implies can”, by which he meant that one can rightfully request something only if conditions exist that make compliance achievable. It is of no use demanding something when it is clear from the outset that the party in question is in no position to respond adequately. In that situation, insisting on such a demand becomes itself morally dubious, and even more problematic when the requirement is considered essential, but the prohibitive conditions are ignored.

When viewing the conditions for CAM research, the demand for an evidence-based CAM is hardly realistic, as there are too many factors that have hindered the development of a sufficient research base. Ezkinazi [46] reviewed those factors in 1998 and although there have been initiatives meanwhile the situation has only improved marginally. One reason Ezkinazi cites is the debarment of CAM research from medical research institutions:

For decades Western academia has excluded alternative medicine research and practice; this has contributed much to the paucity of data in this area. Established academic researchers have been discredited and have had difficulties when attempting to conduct alternative medicine research. At times, explicit threats were made by mainstream medicine to individuals and institutions that would associate with alternative medicine practitioners. Consequently, most alternative medicine research has been conducted outside of academia by individuals with limited research training and resources, and their investigations are often methodologically inadequate [46:1622].

Or from another author:

Unconventional interests – let alone actual research – have such a strong anti-tenure effect that

most of us know at least several research scientists who have strong interests in CAM but never mention those interests within their medical school [47:205].

Callahan’s questions are equally telling:

How is sense to be made of the fact that a large and prestigious group of clinicians and biomedical researchers seem so utterly hostile to CAM while a large portion of the public (and the educated public at that) seems so attracted to it? Is it simply a case of the informed squaring off against the ignorant? More particularly, how is it to be explained that, when the proposal was first made in the mid-1990s that the national Institutes of Health (NIH) initiate formal research on CAM, there was such resistance from important parts of the research community? [5:vii]

It comes as no surprise therefore that biomedical institutions have the reputation of being prejudiced against CAM. In the US, the fact that CAM was clearly very popular [2] did not hold enough sway to bring about research from within medical academia. It required public intervention through a Congressional mandate to create an Office of Unconventional Medical Practices (now the National Center of Complementary and Alternative Medicine) as part of the NIH to begin the process of rectifying this situation. “Many voters thought that the unconventional treatments they believed to be warranted by their experience were not getting a fair hearing in the scientific arena” [47:206]. Nonetheless, although only 0.02% of the NIH’s annual budget was earmarked for research into CAM, the response from within the NIH was less than enthusiastic despite high public expectations [46].

In the United Kingdom, the House of Lords Select Committee on Science and Technology recommended the implementation of similar government-funded research centres of excellence in their report in 2000 [48]. The greater openness towards complementary and alternative medicines that had developed by that time was acknowledged as were the practical difficulties that researchers were facing.

From the evidence we have received it is clear that there has been a change of attitude of a few higher education institutions towards CAM as a legitimate subject for both quantitative and qualitative research. However, the small base

and fragmentation from which this research will have to be conducted would seem to be a major barrier to progress [48: 7.57]

In a number of countries, governments or charitable trusts are now making efforts to fund research into CAM. However, compared with the amount of research that is conducted by pharmaceutical corporations, these enterprises are miniscule and are also only able to support small research trials. This situation is not likely to change, as there is little incentive for profit driven pharmaceutical companies to take on such research:

For example, research into homeopathy or medicinal plants usually does not lead to economic advantages for sponsors, because these products are not proprietary. [46:1622]

This social and economic backdrop cannot be ignored in the debate about the scientific evidence base of CAM, because these conditions dictate what is practically possible. Most CAM practitioners stand outside academia and do not have the skills and resources or the clout to be on an equal footing with well-supported and well-trained biomedical researchers. Small, public or charity-funded research studies can never compete with the weight of large multi-centred industry-funded trials.

Although it might appear plausible and logical at first glance that one should demand an evidence-based CAM, at this point in time one needs to ask the question whether this stance will truly serve people. We also have to remember that, however much we value our scientific knowledgebase in medicine, the practice of medicine has existed for millennia without it and had included many of the approaches that are now under the umbrella term CAM. Biomedical science has undoubtedly brought enormous benefits to humanity but this does not mean that treatments that are built on different philosophical perspectives can now be discarded. There are too many attestations about their usefulness. Listening to those accounts might open our eyes towards a fuller understanding of health and illness than presently offered by a predominantly biomedical view. It might also help our imagination towards the development of appropriate methodological tools so that we will find ways to capture the often complex and subtle effects of CAM interventions. A focus on this area of research could be

exactly what is needed at a time when we are grappling with burgeoning ethical problems that are mostly a by-product of the narrow pursuit of biomedicine.

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