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Complementary/Alternative Medicine and the Evidence Requirement¹

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1. Introduction

Homeopathy is in certain respects a paradigmatic example of a complementary/alternative therapy (CAM). Homeopathy relies on the premise that “like cures like”, so a homeopath uses the same substances, though extremely diluted, in the treatment of ailments, which in a healthy person is thought to produce the symptoms of the ailment in question. The basic idea in homeopathy is that a putatively active substance is diluted in water and administered to a patient. The distinctive feature of homeopathic medicine, however, is that that dilution is so extreme that at the end of the

¹ This chapter is based on our paper 'The proper role of evidence in Complementary/Alternative medicine' in *Journal of Medicine and Philosophy*, 35: 7-18, 2010. While the text and presentation has been thoroughly revised and rewritten, the main arguments are the same. We would like to thank Miriam Solomon, Harold Kinckaid, Asbjørn Hrobjartsson and Martin Marchman for comments to an earlier draft.

community has been that there are no clinical effects of homeopathy apart from placebo effects if any such are found (Shang 2005).

Though nowhere admitted as a part of established healthcare, homeopathy is nonetheless widely used in most of the western world. Homeopathy is particularly popular in France, where it is the leading alternative therapy; it is advocated strongly by the royal family in England, and according to the 2012 National Health Interview Survey, which included a comprehensive survey on the use of complementary health approaches by Americans, an estimated 5 million adults and 1 million children used homeopathy in the previous year (National Institutes of Health 2015).

Something similar is true of other modes of CAM. Though *prima facie* unlikely to have any effects, and with no systematic evidence of efficacy, they are widely, and perhaps increasingly, used outside the established health care systems. Here we consider some philosophical questions that this raises.

2. What is CAM?

The terms 'complementary/alternative medicine' or 'CAM' cover many different types of therapy. The expression 'alternative' indicates that a therapy is used as an alternative to conventional therapy, whereas 'complementary' indicates that CAM therapies are provided merely to supplement conventional medicine. Apart from homeopathy, typical forms of CAM include e.g. acupuncture, reflexology, herbal medicine, osteopathy,

and meditation.

There are three general characteristics of CAM that are of interest here, and they are illustrated by the case of homeopathy. First, CAM therapies are not based on evidence derived from scientific methods or findings. Second, CAM theories are even in some cases inconsistent with our best and most corroborated theories of the natural world. Third, CAM is not provided in the established health care system, whether this is publicly funded or not. Of course, there are exceptions to these general rules. Yet they hold in many instances, and they are important for what we want to discuss below.

Conventional medicine is conventional in the three senses that CAM is not. Conventional medicine is based on evidence generally provided by the use of methods that are congruent with the methods of inquiry used in science, whereas the efficacy of CAM has proved difficult to establish with the same methods. The efficacy of conventional medicine is explained by, or at consistent with, broadly accepted scientific theories, and conventional medicine is broadly implemented in the established health care.

In the literature, one finds various attempts to offer relatively broad definitions of CAM (e.g., World Health Organization, 2015; National Institutes of Health, 2015). For example, the definition offered by WHO refers to ‘a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system’. [...]. No consensus on a satisfactory definition has emerged in the

literature, but we need not go into this dispute here. It is enough that we have the paradigm cases of CAM in mind and the characteristic features that distinguish CAM from conventional medicine.

3. CAM and the Evidence Requirement

The use of CAM in the Western world appears to be increasing (Eisenberg et al., 1998, World Health Organization, 2013), though the exact extent is difficult to estimate due to the heterogeneity of data, as well as the use of a variety of different definitions of CAM (Eardly et al., 2012).

Below we will focus on some of the wider philosophical questions that this raise. Maybe CAM should be admitted as part of established health care? If not, then what are the exact reasons that justify the exclusion of CAM?

It is easiest to present the various positions in this debate if we start with the main concern that members of the medical profession and the research community often have felt about admitting CAM into the established health care system (e.g. Goldacre 2008; Singh & Ernst 2008):

(1) The Evidence Requirement. Treatments offered in established health care/public health care should undergo testing by randomized controlled trials (RCTs) to ensure evidence of efficacy or effectiveness.

(2) Most CAM interventions have not been evaluated rigorously by RCTs (randomized clinical trials), and those that have show

little or no effect. So, either there is no evidence suggesting that various modes of CAM are effective, or there is evidence to the effect that they are not effective.

(3) So, CAM should not be provided as part of an established health care/public health care system.

Many proponents of CAM have not been persuaded by this argument, and a number of replies to the argument can be discerned in the literature. (a) Some argue that CAM should be exempted from the Evidence Requirement, as evaluation by RCT is impossible even in principle. In section 4, we consider and reject an argument to this effect. (b) Some proponents of CAM have insisted that there are other ways (apart from RCTs) by which one can gather the evidence necessary for evaluating CAM, or that the notion of evidence as presupposed in RCTs is irrelevant for CAM. We discuss this objection in section 5. (c) Finally, it has regularly been suggested that the Evidence Requirement should be rejected. After all, it might be said, conventional medicine is far from always is tested by RCTs, and this shows that we should lower the standards of evidence in general, admitting more and less rigorously tested treatments. We argue in section 6 that this is not the case, though we suggest that the Evidence Requirement needs to be modified.

Finally, in section 7 we discuss the claim that choices of CAM need not be made on the basis of evidence of the sort assumed in the evidence

requirement above. Rather, CAM should be seen as akin to a lifestyle or value choice. Such choices may be entirely reasonable, we argue, even when made in the absence of evidence of efficacy, or when evidence of lack of efficacy is available. We consider whether this would constitute a reason to reject the Evidence Requirement (and argue that it is not), and consider certain other normative implications.

4. Randomized Clinical Trials and CAM

Today's medical practice generally seeks to adhere to the Evidence Requirement, i.e. that medical practices should be backed by evidence. While there are many admissible types of evidence and procedures by which evidence is collected, the gold standard for evidence in medicine is often considered to be the randomized controlled trial (RCT). This is the main idea in what is known as evidence-based medicine.

Let us briefly outline the main idea of a RCT. The aim of a RCT is to assess the effect or efficacy of some sort of clinical treatment or other form of medical intervention, typically a specific medication aimed at a particular health condition, but in principle it could be any form of intervention offered with the aim of improving health. The strategy in RCT is to assess the outcome the intervention by using it on human subjects, typically subjects drawn from a larger group of patients with a particular disorder. The subjects are divided into two groups. One group receives the intervention, and the other group, the control group, does not. The control

group instead receives either placebo, or some well-known treatment. This permits a comparison of the outcome of the intervention. It is considered crucial for the RCT that subjects are divided into an intervention group and a control group by a randomization procedure. Moreover, at least the most rigorous trials are blinded, which means that subjects, administrators and/or researchers are kept ignorant about whether a particular subject belongs to the intervention group or the control group.

The first question is whether the use of RCT is possible or appropriate with respect to CAM. Some CAM practitioners reject this and hence reject the Evidence Requirement. One argument focuses on the claim that CAM essentially is holistic and relies on a unique and individual relationship between the patient and the practitioner (Frank, 2002; Walach, 2003). Thus, the argument goes, the RCT procedure itself will destroy the beneficial property of the treatment. For instance, Walach (2003) writes:

Suppose that the “active” principle of homeopathy resides in a complex mix of the homeopathic situation between patient, practitioner, remedy, history of medicinal substances and their use as codified in the homeopathic material medica, with some mental interaction between the doctor and patient—such as a flash of security, a spark of trust and hope. In other words, suppose homeopathy is a kind of field effect with no single element that can be isolated and attributed to the remedy alone.

If that were the true picture, then testing the remedy alone would be like taking one transistor out of a radio set and testing it for its capacity to play music. (9–10)

The suggestion is that the effect of CAM cannot be assigned to any single causal factor of a specific component in the intervention. CAM is not like a pill whose chemical properties account for the entire effect. Rather, the beneficial effects of CAM reside holistically in the whole of the interaction between patient and practitioner.

This worry about the use of RTC to evaluate CAM fails to acknowledge the distinction between what is known as *explanatory (or causal) trials* and *pragmatic trials* (White, 2002). Explanatory (or causal) trials generally measure *efficacy*, that is, they seek to measure the specific effects of a causally active component in an intervention. Typically, explanatory trials do so by assessing the treatment effects of a treatment produced under ideal, controlled conditions in a research clinic by carefully isolating the treatment effects from other effects. So, typically explanatory trials require substantial deviations from the usual clinical practice.

Pragmatic trials, by contrast, measure what is known as *effectiveness*. They measure the benefit of a treatment produced in routine, ‘real world’ clinical practice, no matter what specific causal factors may contribute to that benefit. So, pragmatic trials typically do not provide conclusive information about causally active components in a particular treatment (Roland and

Torgerson, 1998; Cardini et al., 2006).

Explanatory trials as applied to CAM, then, would seek to investigate the causal efficacy of a specific CAM component, such as the homeopathic medicine as such, or the prick of an acupuncture needle. Pragmatic trials, on the other hand, would aim to evaluate the clinical effectiveness of a CAM practice as a whole. For example, a pragmatic trial of a homeopathic medical intervention would aim to assess the homeopathic consultation as such, rather than of to seek to determine the causal effects of the specific homeopathic component involved in that practice. Pragmatic trials of homeopathic practices can be conducted by providing the treatment group with the whole consultation, including the homeopathic medicine, the meeting with the practitioner, conversation, time spent on the individual, and so on. The control group will receive no treatment, a sham treatment, or the prevailing treatment. The clinical effectiveness of these two regimens can then be compared. So, there is no reason in principle why CAM cannot be assessed in this way. Clearly, however, blinding is bound to present practical difficulties in pragmatic trials, and this may affect the quality of the trials. If a pragmatic trial is not blinded, there is a risk that it shows an effect, while it remains unclear whether this effect is due to the intervention as such, or results from bias due to lack of blinding, or placebo effects.

A somewhat similar objection to the Evidence Requirement highlights what

is felt by some to be a principal obstacle to using conventional research methods to evaluate treatments with a perspective on illness and disease other than that of conventional medicine (Hammerschlag, 1998; MacPherson et al., 2002). The objection is that since CAM and conventional medicine rely on fundamentally different assumptions about the nature of disease and human biology, RCTs cannot be used to measure effect of CAM. The following quote exemplify this view:

The whole process [of evaluating CAM with RCTs] can be equated to asking a sculptor to sculpt with a paintbrush to prove he is an “artist”. The need to conform to an existing tool can undermine the very process we are trying to evaluate. In the case of the sculptor, the need to use the paintbrush undermines his or her ability to demonstrate his or her artistic skills, and in the case of the acupuncturist, the need to use standardized interventions (as in most RCTs) may undermine his or her ability to effectively treat the patient. (Ahn and Kaptchuk, 2005, 41)

Again, it seems that this objection (even if otherwise sound) applies only to RCT in the form of explanatory trials, not to pragmatic trials. So, even if true that the very process of conducting a RCT will 'undermine the very process we are trying to evaluate' this would seem to apply only to explanatory trials, not to pragmatic trials. Nothing in the objection shows

that is not possible to consider a CAM intervention as a whole, and compare it to a conventional intervention.

In saying this, we have not, of course, considered the various logistical and practical problems that are bound to arise in setting up pragmatic trials. Surely, blinding, and in particular double blinding, may pose practical difficulties. It is, for example, not easy to blind an acupuncture trial so that the patient and/or the practitioner does not know whether they actually receive acupuncture. Several attempts have been made to solve this practical problem, however. There have, for example, been RCTs in which the control group received sham acupuncture, conducted by gluing needles to the patients' skin in order to blind the patients (Filshie and Cummings, 1999). Other types of sham acupuncture include shallow needling and needling at non-acupoint sites. The blinding requirement might also be met by blinding either the assessor of the results or the statisticians involved.

There seems to be no reason in principle why CAM could not be evaluated by RCT. Note however, that even if it were correct that CAM could not be evaluated using RCTs (including pragmatic trials), this by itself would *not* imply that CAM should be *exempted* from the Evidence Requirement. All this would show would be that CAM could not even in principle *meet* the Evidence Requirement.

5. Are there other kinds of evidence for CAM?

So far no reason has emerged why CAM cannot be evaluated by using

pragmatic trial. Indeed, a considerable number of RCTs assessing the effectiveness of CAM have been conducted, though the general quality is debatable (a search in the Cochrane Library in June 2015 returned more than 12,000 trials, over 300 Cochrane Reviews and over 1,400 other reviews of complementary therapies). Generally, there are many poor studies allowing for much bias and risk of misleading evidence. The systematic reviews performed on these studies, however, generally suggest that CAM has no discernible effects or that there is insufficient evidence to judge whether a therapy is effective, due to the poor quality of the studies included (e.g. McCarney, Linde & Lasserson 2008; Paley, Johnson, Tashani & Bagnall 2011).

At this point some proponents of CAM insist that there are other sources of evidence that we might draw upon, and they indicate the effectiveness of CAM. Sometimes it is suggested that the fact that most CAM treatments have existed for many years provides evidence of their effectiveness. For example, Walach (2003) argues:

Homeopathy has some clinical effectiveness. If it did not, it would have died out. Indeed it is more sought after now by patients at a time when modern medicine prides itself in being more powerful than ever. (7)

We might refer to these lines of reasoning the *evolutionary argument*. Though the evolutionary argument may at first seem intuitively compelling, it is far

from clear that evolutionary arguments are sound when applied to treatments offered in CAM or medicine in general. For the evolutionary argument to carry conviction, people need to be able to adapt their purchasing choices to what is clinically effective. But it is hardly reasonable to believe that this condition is met. It may seem plausible that people can adapt their purchasing choices to treatments that immediately and significantly decrease pain or improve well-being. However, in general it seems hard to believe that consumers can adapt their purchasing choices to treatments that are clinically effective or more effective than alternatives short of systematic independent information about this. The reason, again, is that it seems impossible for the individual consumer (patient) to predict whether one purchase would be better than another in terms of effect, or whether a purchase was unnecessary because the patient would have recovered spontaneously.

Thus, it is doubtful if the continued existence of a variety of CAMs on the market is best explained by their clinical effect. Consumers and patients simply lack the information necessary to develop preferences ensuring that only clinically effective treatments survive, and no other mechanism to select effective modes is in place. It is worth reminding that many treatments now known to be ineffective were used in conventional medicine up to the 1800s and had at that time existed for hundreds of years. It should also be noted that providers of CAM have a direct financial incentive in maintaining the presumption that the therapies they offer are

effective. Survival on the market is no guarantee for effectiveness.

But there might be other forms of evidence suggesting the effects of CAM, a view suggested in the following quote:

In therapeutics as well, there are numerous examples where the causal relationship of treatment and effect is convincing without appeal to anything other than simple observation of a single case. (Tonelli and Callahan, 2001, 1215)

Both providers and users of CAM could appeal to this idea: at least in some instances, we simply know from our experience of individual patients that CAM is effective. There is surely a certain intuitive appeal to cases where a patient's long-standing symptoms disappear shortly after an intervention. Yet one needs to stress the fundamental problem in this line of reasoning: The practitioner, relying on her sense that individual clients benefit from the treatment provided, simply lacks information about whether the clients would *also* have improved by another treatment, for example, a treatment provided by another practitioner or by no treatment at all (i.e., whether the patient would have recovered spontaneously).

In short, the main problem with appeals to individual experience of clinical effect is the lack of a control group. Control groups are essential to demonstrations of the effectiveness of treatment. No reason why comparison with a control group when considering the effectiveness of CAM is *not* needed has yet been put forward. It seems very unlikely,

therefore, that evidence for the effectiveness of CAM can reasonably come from any other source than RCTs.

6. Lowering the standards of evidence?

As is well known, conventional medicine is far from being fully evidence based in the sense of being thoroughly based on evidence of effectiveness determined by RCTs. Most newly introduced conventional interventions are tested rigorously, but this is not the case for many established interventions that are used routinely. Proponents of CAM may object that the Evidence Requirement cannot be consistently applied to CAM, while parts of conventional medicine is exempted. The question is whether there is a case to be made that the standards of evidence should be lowered for CAM, given that many conventional treatments have not been evaluated by RCTs.

There are two related responses to this objection. First, there are compelling ethical reasons why not all conventional therapies have been tested by RCTs as it would in many cases be ethically objectionable to do so. This typically concerns treatments that are used routinely and where there are good reasons - deriving from observational studies or our background knowledge - to believe that if the treatment is not provided, the patient will die, or suffer great harm. An example could be surgery of children. Few parents are willing to let their child participate in an RCT if the standard treatment is used routinely and there are convincing reasons to believe in the effect of the treatment.

This suggests that one should accept a modified version of the Evidence Requirement:

The Modified Evidence Requirement. Treatments offered in established health care/public health care should undergo testing by RCT to ensure evidence of efficacy/effectiveness, except when ethical constraints prevent this.

Clearly, the Modified Evidence Requirement does not justify exempting CAM from RCT. It is not the case that we have general reasons to fear that the consequences of foregoing a particular mode of CAM will have serious adverse effects. So, there is no ethical obstacle to evaluating CAM by pragmatic trials. Note that the same applies to many the conventional therapies that have not been tested rigorously.

The second reason for not exempting CAM from a requirement of providing evidence for efficacy is more general. CAM and conventional medicine differ significantly with respect to plausibility when viewed against our widely accepted background theories. Consider again homeopathy. The simple fact is that when viewed against the backdrop of the vast accumulated body of relevant scientific theory (in particular physics and chemistry), it is just extremely implausible that homeopathic interventions can have any effects whatsoever. If we accept standard theories in physics and chemistry, we are bound to very skeptical that homeopathy works (and if we accept homeopathic theory, we are committed to rejecting a large

number of physical and chemical theories).

Conventional treatments, by contrast, are fully compatible with established scientific theories. It is generally not the case that acceptance of standard theory commits us to thinking that any particular mode of conventional medicine is very unlikely to have any effects, although the fact that one conventional therapy is compatible with scientific theories is typically not a reason to favor this therapy over *other* equally compatible conventional therapies. In part, this is why RCTs are needed. However, any CAM therapy whose effects appears highly unlikely given accepted scientific theory, thereby incurs an *extra* burden of proof, or more genuine evidence of effectiveness. Hence, it seems reasonable to insist that there is a heavier burden of proof resting on CAMs than on conventional therapies. Extraordinary claims require extraordinary evidence (Vickers, 2000).

7. Should decisions about CAM be made on the basis of evidence of efficacy?

At this point one might take a step back and query the basis of the Evidence Requirement. The most straightforward justification of this demand is a conjunction of two claims. First, a rational individual would want to choose between optional treatments on the basis of reliable information about which treatment is likely to be more effective (or plain effective). Second, this information can be provided only by RCTs, and this holds for both CAM and conventional medicine.

Some commentators, however, suggests that a choice of CAM need not be

based on evidence about clinical effects. For example Borgerson (2005) writes that

... while certain acupuncture points and procedures might be proven effective in RCTs and adopted into mainstream medicine, the underlying philosophy of traditional Chinese medicine, including the existence of the chi or vital force and the commitment to health as the balance of chi will be lost [. . .] the naturopathic approach to health (including a commitment to holism, highly individualized care, and a principle of self-healing) will likely be left behind. For the millions of people choosing to spend out-of-pocket for alternative health care to- day, these elements of healing philosophy are of critical importance, and their loss would be substantial. (506)

Borgerson says that if subjected to RCT, a crucial aspect of CAM is likely to be lost. This must imply that Borgerson thinks that one can chose CAM knowing that no evidence from RCT is available, and she suggests that is because of the crucial importance of one's commitment to a wider healing philosophy. Typically, of course, those accepting a healing philosophy will assume that there are beneficial effects to doing so, and that the particular modes of treatment recommended by the healing philosophy are effective. However, it is natural to interpret Borgerson as implying that the commitment to a wider healing philosophy can be made without possessing

robust evidence to the effects of that commitment, or the particular modes of treatment that it involves.

Whatever the details of Borgerson's view, we think that it is attractive to view choice of CAM in this light. The choice of CAM could be considered a lifestyle choice or a value choice, a decision to join or sustain a community of shared values and beliefs, or perhaps something that is similar to undertaking a religious commitment. This has several implications.

First, this sort of value choice need not be irrational despite not being based on reliable information about clinical effectiveness. Hence, a rational individual might choose CAM without reliable information about clinical effectiveness.

Second, CAM communities and those purchasing CAM treatments might be compared to religious and quasi-religious communities. By implication we might say that CAM communities and those using the services should be accorded the same freedoms and protections as religious communities. There are many ways of spelling out the implications of this. One appeals to what is known as Mill's harm principle (after British philosopher J.S. Mill (1806-1873)) according to which the state is justified in limiting a person's actions or to interfere in a person's way of living only in order to prevent harm to third parties (Gray and Smith, 1991). Accordingly, the state should not interfere if people wish to join a CAM community, as long as their

doing so harms no one and limits nobody's freedom of action. This is so even if there is no evidence showing an effect of the treatment in question or even evidence showing that the treatment does not have any effect. Hence, when CAM use is viewed as a lifestyle choice, the natural implication is that neither the state nor the individual rational agents need require rigorous evidence of the clinical effectiveness of CAM. However, the state might impose restrictions in special or extreme cases: for example, in connection with harmful or dangerous varieties of CAM—say, in the sense that some users are misled into foregoing more beneficial conventional treatments—or when CAM is marketed under what are clearly false pretenses, it being claimed, for example, that there is a well-documented clinical effect.

Arguably a third implication (again, if we accept the basic values of liberal democracy) is that the state or government authorities and public officials should not support CAM, or offer CAM in publicly funded health care, unless reliable evidence testifies to its clinical effectiveness. CAM can be offered privately without making any claim to be backed by evidence on equal terms with, for example, various services offered by religious communities. However, if a CAM treatment is offered by the publicly funded health services, we ought to demand that it is evidence based. State health services should not offer treatments that can be accepted only by those with religious or quasi-religious convictions. The state should only offer treatments that survive rational scrutiny; and evidence is crucial to

fulfill this purpose. A further implication might be that in so far as the state has a role in guaranteeing the quality of the established health care (even if not funding it), the state should adopt a similar stance and back the Evidence Requirement (in its modified form). Consequently, the state should be reluctant to admit CAM in established health care without sufficient evidence of efficacy.

8. Concluding remarks

We have argued that a main controversy regarding CAM concerns the Evidence Requirement. We have argued not only that RCTs can in principle be conducted on CAMs, but also that there is no other way to gather evidence about effectiveness in medicine. The fact that many conventional treatments have not been subjected to RCTs does not justify exempting CAM from rigorous testing. We propose that CAMs could be treated in the same way that the practices of religious and quasi-religious communities are. This implies that the state should not interfere if people wish to join a CAM community, i.e. use CAM or practice CAM, as long as this does not harm other people and does not limit other people's freedom of action, regardless of lack of evidence of the medical effectiveness of the CAM in question. It also implies that the state should not offer CAM in public health care or admit CAM in established health care. The state may legitimately impose restrictions in cases (if there are such) where a CAM is harmful in some way.

Recommendations for further readings:

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