

IMPLICATIONS OF EVIDENCE BASED MEDICINE FOR COMPLEMENTARY & ALTERNATIVE MEDICINE

by Wainwright Churchill

At the present time, there are many calls, mainly from the orthodox medical profession and regulatory authorities, for medical interventions of all types to be practised and regulated on the basis of whether they work as determined by clinical trials. Medicine of this sort is called 'Evidence Based Medicine' (EBM). On the surface, EBM seems eminently reasonable. However, for Complementary and Alternative Medicine (CAM), many problematic issues arise. EBM is not neutral. Many assumptions enter into designing, interpreting and disseminating the results of clinical studies, and taking action based on their results. Because the biomedical paradigm will in practice be the basis for EBM, CAM modalities risk losing their autonomy in a system based on EBM. EBM is likely to be a means of subordinating CAM modalities to the biomedical paradigm in ways that this article will explore.

Fundamental questions that can be asked about a medical intervention by EBM are:

- 1 Does it work?
- 2 How does it work?
- 3 Is it safe?

Additional questions that should be asked are:

- 4 How does one determine 'Does it work?' and 'How does it work?'
- 5 Should a form of medicine be permitted until 1. 2. and 3. have been determined?

Looking at these considerations closely, a large number of problematic issues arise for CAM modalities.

1. Does it work?

i. What is the 'it'? In the case of acupuncture, is the 'it' reducible to placing needles in the body? Should the treatment being researched be individualised for each patient? Does it involve the personal relationship between the acupuncturist and patient? Does it comprise the theoretical basis with which treatment is being carried out? If so, is it only important that the acupuncturist be aware of this, or is

the patient's awareness of the theoretical model something that alters the patient's response to treatment? Does it involve the patient's expectations, conscious or unconscious, of the treatment? ii. What does 'work' mean? Is this confined to disappearance or abatement of symptoms? Is the illness to be defined in biomedical terms, or other terms? Must there be demonstrable change as understood within scientific physiological terms? Is placebo effect a valid healing modality? Does it involve the patient coming to terms with or accepting the illness, possibly with the symptoms remaining the same, but the person relating to them differently? Does it involve the patient feeling empowerment in relation to the 'illness', or in their life in general? Does it involve the patient increasing their richness of experience, for example by feeling that there is more to the universe than accepted by conventional materialistic science? Does it involve enriching the patient's experience by resonating with what Jung termed 'unconscious archetypes', such as magical thinking in relation to illness, which may be involved in the healing process, even if such magic doesn't exist from a scientific point of view? Or if magical thinking does alter the course of illness, does this mean that magic in this sense actually does exist? Does society have a right to insist that the only medical modalities that can be practised must accord with the conventional scientific worldview?

2. How does it work?

Must this be determined in biomedical terms? Many scientists and philosophers, such as Fritjof Capra, David Bohm, Andrew Weil and Thomas Kuhn, have profoundly questioned the mainstream scientific paradigm as an exclusive basis for knowledge and practice¹. Mainstream science has been criticised for its reductionist, mechanistic and materialistic outlook. For example, reductionism is, in principle, an inappropriate methodology for studying systems, in which feedback mechanisms operate (see Capra, 1982 and

1997). Most aspects of life have systems properties. Is the explanation offered by the CAM modality valid, even if this makes no sense from a biomedical point of view? For example, Chinese medicine does offer an explanation of how acupuncture works, but this is within a separate and incommensurable paradigm from the biomedical (for elaboration of this, see discussion below). Many scientists believe that the scientific paradigm has absolute truth value, but philosophers such as Thomas Kuhn reject this. If no paradigm does have absolute value, there is no absolute basis with which to judge another paradigm. Any paradigm will appear limited or incorrect from the perspective of a different paradigm, so Chinese medicine will seem incorrect from a biomedical point of view, and vice versa.

3. *Is it safe?*

This is in some ways a much easier question to answer. Issues relating to sterilisation, or to not doing obvious damage such as penetrating the lungs with an acupuncture needle, are straightforward. Although this question is often asked about alternative medical modalities, in many ways it is more relevant to biomedicine. Studies have identified preventable biomedical accidents and adverse drug reactions as the third, and fourth to sixth, greatest causes of death in Australia² and the US³ respectively. Biomedicine has a high rate of iatrogenesis, which is often ignored by exponents of biomedicine who question alternative medicine. There are a number of less obvious questions one can ask about medical safety. For example, are short-term gains of using drugs like antibiotics to treat non-serious disease outweighed by the long-term disadvantage of breeding more pathogenic micro-organisms? Also, a considerable amount of disease is associated with diet, lifestyle, and the environment. Epidemiologists estimate that these factors account for about 75% of cancer⁴. Would a higher proportion of limited financial resources have been better spent on preventative measures? And when it is questioned whether people lose valuable time from receiving conventional treatment by using alternative medicine, which is, undoubtedly, sometimes true, it could also be asked if on other occasions the reverse is the case.

4. *How does one determine 'Does it work?' and 'How does it work?'*

Obviously, this will in part depend on how one has answered the above questions. Furthermore, research results must be interpreted, and this introduces the problem of bias. Biomedical proponents have been shown in studies to be prejudiced against research relating to alternative medical modalities. For example, Resch, Ernst, and Garrow concluded in their study 'Does Peer Review Favor the Conceptual Framework of Orthodox Medicine?', *European Journal of Clinical Nutrition* "Despite a remarkably large within-group variation in both groups, there seems to be a relevant reviewer bias against papers dealing with unconventional medical concepts". In our present society, regula-

tory authorities and the media delegate decisions on medical issues to biomedical authorities, who may adversely judge CAM research simply because of their prejudices.

5. *Should a form of medicine be permitted until 'Does it work?', 'How does it work?', and 'Is it safe?' have been determined?*

Again, this has a great deal to do with one's point of view, comprising issues such as the individual's freedom of choice in health issues and paradigm choices. A person who believes that the scientific paradigm is limited, incorrect, or not absolute, will justly feel that any attempt to make the biomedical paradigm the basis for decision-making violates their rights.

Many people who advocate evidence based medicine are biomedically trained and committed to that paradigm. They may feel threatened by alternative medical practices. It is apparent that in deciding how research should be conducted, many judgements need to be made which will profoundly alter the implications and outcomes of the research. Research needs to be interpreted, and bias and prejudices can influence this. In fact, research cannot be devised and interpreted without assumptions being made that influence the results. Since biomedical adherents are likely to be involved, CAM professions take a serious risk of opening themselves to appropriation by the biomedical paradigm.

Another problem exists for evidence based medicine. High quality research (the only type that is ultimately worthwhile) is very costly, is often inconclusive, and may have to be replicated. Drug companies pay for research by being able to patent their products, but for complementary medicine there is no such financing option. Once CAM consents to or endorses the idea of research as the basis for approving CAM modalities, it may be digging its own grave, because research that is unfavourable can be used against it, whereas positive results can be challenged or ignored as unworthy, as is currently the case for much Chinese research on TCM.

At the turn of this century, allopathic and 'natural' forms of medicine had equal importance (see Weil, 1995). The ascendancy of biomedicine was associated with commercial investment, coupled with political lobbying making use of the idea that biomedicine was 'scientific'. The 'biomedicine is scientific' argument has been used continuously and mainly successfully in this century to suppress competition, and one can suspect that the call for evidence based medicine is the latest manifestation of this. Out of interest, despite biomedicine's claims, the US Office of Technological Assessment estimated that only 20% of biomedical treatments are 'proven'⁵. Add to this the high level of damage biomedicine causes, and the many conditions it cannot treat or cure, and its claims to authority are greatly attenuated, but biomedical critics of CAM, regulatory authorities, and the media, rarely acknowledge this.

Two matters that have particular relevance to CAM being

subjected to EBM, the incommensurable nature of paradigms and placebo effect, will now be considered in detail.

The Incommensurability of Paradigms

In his monumental work *The Structure of Scientific Revolutions*, Thomas Kuhn, the philosopher and historian of science, discusses the nature of paradigms at great length. Most forms of CAM have a different paradigm from biomedicine, yet biomedicine and many aspects of society feel that it is valid to judge CAM from the biomedical viewpoint. Understanding the nature of paradigms, including the appropriateness of assessing one by another, which I will call 'inter-paradigm issues', is essential.

Kuhn shows that no paradigm is complete, being unable to answer all the questions that can be asked of it. A paradigm is not associated with truth; it involves a methodological approach towards problems. Furthermore, different paradigms are incommensurable, meaning that their frames of reference are different so that the world depicted in one paradigm cannot be translated into another, just as not everything that can be said in one language can be said in another. For example, Newton's Laws are not simply a special case of Einstein's theories of relativity; 'the physical referents of these Einsteinian concepts [i.e. space, time, and mass] are by no means identical with those of the Newtonian concepts that bear the same name.' (Kuhn, 1996) The specific meaning of concepts can elude precise definition, and emerge within the entire context of their use. The world described or evoked by Einstein's Theory of Relativity is a different one from Newton's Law of Gravitation, and the fundamental concepts of each reflect this. It is impossible to construct Einstein's world using Newton's conceptual building blocks. The same applies to traditional Chinese medical and biomedical theories.

Biomedical researchers often ignore this problem. For example, Dr. Adrian White, co-editor of *Medical Acupuncture*⁶, writes, in justification of traditional Chinese theories being jettisoned in favour of the biomedical approach towards acupuncture, "Despite detailed research, there is simply nothing can be found to suggest that energy really does circulate in meridians." 'Research' here is within the biomedical context; since Chinese medical concepts are concerned, inter-paradigm issues are involved. White uses the terms 'energy' and 'meridians' as if the Chinese concepts to which they refer can be translated directly into biomedical concepts. He makes the assumption that the term 'energy', understood in its Western scientific sense, is equivalent to 'qi', which is to make the elementary error that the concepts 'qi' and 'energy' (or even additional scientific concepts) are commensurable and can be equated. Qi (like yin or yang) is a fundamental (and complex!) concept which cannot be understood without taking account of the totality of the theoretical foundation and practice of Chinese medicine in addition to the Chinese worldview. As far as 'meridians' are concerned, as Dan Bensky writes in the Introduction of *Acupuncture - A Comprehensive Text*⁷: "The channels are

regarded as three-dimensional passageways through which the Qi and Blood [note that 'Blood' is capitalised because it cannot be equated with the 'blood' of biomedicine] flow at different levels of the body. Therefore, it is inappropriate to refer to the channels by using the two-dimensional term 'meridian,' as is common in English translation." White's statement involves a fundamental misrepresentation of Chinese theoretical concepts in the simplistic and invalid superposition of biomedical concepts over traditional Chinese theory. Similarly, Prof. Ernst, Professor of Complementary Medicine at Exeter University, has asserted that the existence of Yin and Yang have not been substantiated by scientific research⁸. In these examples, the edifice of Chinese theory has not been destroyed, only the sandcastles built of biomedical researchers' misunderstandings.

Statements such as White's and Ernst's, respected academic specialists in complementary medicine, show the danger to CAM of the incommensurability of paradigms not being taken into account. Very little human understanding or endeavour is possible without utilising paradigms, and understandably people want to feel that the paradigm they use has universal applicability. Kuhn's insights take one into an initially uncomfortable world in which all understanding is relative, limited and provisional. Living with this is an aspect of the intellectual maturity required in the post-industrial, post-Cartesian, multicultural world.

Because of the incommensurability of paradigms, any CAM practised its original way cannot be the same as its biomedical version - they must remain two separate worlds. If the biomedical paradigm is adopted, the system will have the characteristics of that paradigm - materialistic, mechanistic, reductionist, linear-causal, and deterministic (many of the characteristics that inspire people to use complementary medical therapies). Biomedical research into that discipline will reflect the biomedical worldview. Statements such as 'Yin and Yang do not exist' will follow as unavoidably as night follows day.

Not only are paradigms incommensurable, but the questions they can answer are different. Experienced CAM practitioners will recognise that, often, conditions that are hard to diagnose in biomedical terms can be diagnosed straightforwardly in the CAM paradigm. If the original CAM paradigm is replaced by the biomedical, this understanding of conditions will disappear as well.

Placebo effect

Placebo effect is a significant issue in biomedicine. The success of CAM modalities is often attributed to it, and it is relevant to most research. Biomedicine's goal is to identify physiological mechanisms of illness that can be treated with specific, rationally applied methods. Placebo effect violates this ethos, and makes it difficult to determine why a treatment is effective. Despite its negative image in conventional medicine, placebo healing has great power. The invocation

of a saint can cure intractable cancer; a voodoo curse can kill⁹.

Placebo and how it is regarded are paradigmatic issues. It is a term generally applied to healing outside the therapeutic parameters acknowledged by biomedicine. A shaman applying a curse does not consider it to be a placebo, nor does his victim. To them, real magic is involved. To interpret it otherwise is to make a culturally, paradigmatically-biased judgement. We can never prove the shaman wrong, only offer an alternative explanation.

Even if one accepts the concept of placebo, it can be regarded positively or negatively (See Weil, 1995 and 1997). In his books, Andrew Weil emphasises the importance of natural healing capability. Enhancing natural healing is central to most CAM modalities, but of low priority in biomedicine, which we have seen is concerned with rationally utilising specific physiological mechanisms. Placebo effect is a form of natural healing, sometimes par excellence.

In evaluating a study, one should ask "could what this study assumes to be placebo effect be a healing modality not recognised in the biomedical framework", and "does this study implicitly assume that what it calls placebo is something negative?" Hidden assumptions are the most insidious. These considerations are essential in appreciating the true significance of research. Initial assumptions govern end results.

Conclusion

Evidence based medicine, while an attractive concept because it appears to be a method of simply determining if a treatment works, is not neutral insofar as the outcomes of research will reflect the initial assumptions of the researchers, and the biases of the interpreters and those who promulgate the results. Since biomedicine and its sympathisers dominate this arena, there is a significant danger that EBM will be used to gain biomedical control over CAM modalities. Even if EBM is initially concerned with determining whether a CAM modality 'works', as research progresses, more energy will be put into determining the biomedically conceived 'mechanisms' involved¹⁰. With success in this area, biomedicine will argue that the discipline has been put on a 'firm scientific foundation', and that science is the appropriate methodology, with the original paradigm at best empirical but flawed and redundant.

CAM professions must be aware that their paradigms and perspectives are very seldomly represented or respected by the media or medical authorities with regards to medical research. The result is to make it appear that the biomedical paradigm is the automatic basis with which to consider medical issues, and subsequent usurpation of the CAM modality within the biomedical framework is a distinct possibility. It is therefore essential for CAM professions to determine whether inter-paradigm issues enter research, and if so, whether the integrity of the original CAM paradigms are respected or transgressed, recognising that the superposition of the biomedical paradigm over a

CAM paradigm easily leads to a violation of the latter. CAM professions should insist that their own paradigms be given full recognition and acceptance. They should not casually consent to EBM as the basis of regulatory decisions, and should question its ethos and possible implicit intention to subjugate CAM disciplines to the biomedical agenda.

Notes

- 1 See David Bohm: *Wholeness and the Implicate Order*, London 1980; Fritjof Capra: *The Turning Point*, London, 1982; Fritjof Capra: *The Web of Life*, London, 1997; Thomas Kuhn: *The Structure of Scientific Revolutions*, London, 1996; Andrew Weil: *Health and Healing*, London, 1995; Andrew Weil: *Spontaneous Healing*, London, 1997.
- 2 Reported in *New Scientist*, 10 June, 1995.
- 3 Jason Lazarou, MSc; Bruce H. Pomeranz, MD, PhD; Paul N. Corey, PhD: Incidence of Adverse Drug Reactions in Hospitalized Patients - A Meta-analysis of Prospective Studies, *JAMA*, April 15, 1998.
- 4 See Trichopolis, Li and Hunter: "What Causes Cancer", *Scientific American*, September 1996.
- 5 Quoted in Walter A. Brown: 'The Placebo Effect', *Scientific American*, January 1998.
- 6 Ed. Jaqueline Filshie and Adrian White: *Medical Acupuncture*, Edinburgh, 1998.
- 7 Trans. John O'Connor and Dan Bensky: *Acupuncture - A Comprehensive Text*, Seattle, 1981.
- 8 "What's the Point?", *The Independent*, 20 October, 1998.
- 9 See Weil (1995) for detailed discussion of this.
- 10 Many studies of a CAM modality that shows its usefulness, allude to the need for the mechanisms to be determined, almost as an apology to the biomedical profession. A recent case is in the Reuter's report of evidence that Therapeutic Touch can alleviate knee pain: "[The researchers] also conclude that 'it may well be that therapeutic touch works in a different way than by manipulating energy fields,' and they urge further studies aimed at investigating underlying mechanisms." (Reuters, October 26, 1998)