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Complementary and alternative medicine

Response to the House of Lords inquiry into complementary and alternative medicine

The Science and Technology Committee of the House of Lords launched an inquiry in July 1999 requesting comments on complementary and alternative medicine (CAM). The inquiry brief was wide-ranging, encompassing diverse issues such as evidence, education, training, regulation and NHS provision. The Royal Society welcomes the opportunity to comment and has chosen to concentrate its submission largely on scientific evidence since that is our area of expertise, addressing what is known and not known about specific therapies. We have taken as examples acupuncture, chiropractic, herbalism, homoeopathy, and osteopathy, but many of the issues raised apply across the broad spectrum of CAM. The Society recognises that the debate surrounding any assessment of efficacy for such therapies must address wider issues than the science alone, but would nevertheless like to stress the importance of informing debate with sound scientific advice.

The Society has previously produced statements on the medical uses of cannabis (June 1998), the scientific advisory system (June 1998) and science and society (June 1999) which have relevance to this inquiry. This response has been endorsed by the Council of the Royal Society, and was prepared by a group chaired by Professor Patrick Bateson (Biological Secretary and Vice-President, Royal Society). The other members were Dr Simon Campbell (formerly Pfizer Central Research), Professor Tom Meade (MRC Epidemiology and Medical Care Unit), Mr Simon Mills (Centre for Complementary Health Studies, University of Exeter), Sir Keith Peters (University of Cambridge), Professor Patrick Wall (University College London), Professor Lawrence Weiskrantz (University of Oxford), Dr Steven Lipworth (Secretary) and Miss Sarah Teather (Secretary).

The four main points to which the Society draws attention are as follows:

- Careful evaluation of the effectiveness and safety of CAMs in health care is needed. Authoritative information is lacking for the most part and properly designed clinical trials must be carried out.
- Some CAM therapies are based on empirical knowledge built up over generations and grounded on practical experience. The Society endorses the Resolution of the recent ICSU General Assembly which supported the values and methods of verifiable science in contrast to approaches that promote anti-scientific attitudes and pseudo-science¹.
- The Society welcomes regulation of therapies shown by clinical research to be effective and recommends that the Government investigates the most appropriate mechanism for such regulation.
- The Society recommends that NHS provision for CAM, as for conventional treatments, be confined to procedures supported by adequate diagnosis together with evidence of both efficacy and safety. This issue should ideally be evaluated by the new National Institute of Clinical Excellence (NICE).

In the remainder of this document we address the scientific evidence for a range of therapies. Attention is drawn to the need to distinguish between the theory underlying a therapeutic technique and its effectiveness. The theory may be wrong and yet the technique may work.

Acupuncture

The theory behind acupuncture supposes that invisible energy channels (meridians) run in the skin. The acupuncturist inserts a needle into points along these supposed channels. Much of the acupuncture practised is a form of analgesia (pain relief). Acupressure, which is acupuncture without the needles, and moxibustion which involves burning a herb, *Artemisia vulgaris* (called moxa in Japan), in the vicinity of an acupoint, make use of the same meridians as acupuncture².

Meta-analyses (a method for reaching conclusions about treatments by combining the results from all the relevant trials) of published studies on the effectiveness of acupuncture have largely shown beneficial effects for the treatment of pain. However, these studies have been unable to draw firm conclusions about the efficacy of acupuncture as many trials were of poor quality and it was not possible to ascertain the extent of any publication bias³⁻⁷. Publication bias may arise in areas of research when researchers tend only to report studies which show positive results. Acupuncture increases endogenous endorphin and enkephalin levels in the cerebrospinal fluid and this may be involved in any analgesic effects⁸⁻¹².

The British Acupuncture Council represents a unification of five professional groups and is associated with the British Acupuncture Accreditation Board which, under an independent chair, works with the relevant training colleges to set verifiable standards of education and training^{13,14}. Membership of these professional organisations is voluntary and not covered by statute.

Chiropractic

Chiropractic is based on the theory that illness is caused by spinal-column maladjustments, known as subluxations². Chiropractors use joint-adjusting procedures, manipulation, massage and other techniques to treat musculo-skeletal complaints¹³.

A Medical Research Council (MRC) funded multi-centre randomised controlled trial has demonstrated that for some conditions chiropractic was more effective than hospital out-patient treatment, not only in the short-term but also at three years^{15,16}. However, it is important to note that the trial demonstrated that the 'package' of chiropractic was beneficial (manipulation, other treatment such as massage, and the patient-practitioner interaction), rather than any particular aspect of treatment, although by far the most frequent component of the 'package' was manipulation.

This first trial is now being followed by a second MRC sponsored trial carried out through general practice. Its primary objective is to establish whether the therapists taking part (chiropractors, osteopaths, physiotherapists) collectively achieve the same or different outcomes in various settings, including private and NHS practice.

A literature search by Koes and colleagues published in 1991¹⁷ evaluated published trials on the efficacy of spinal manipulation (including both osteopathy and chiropractic techniques) for the treatment of back and neck pain. The authors concluded that results were promising but that more research was needed in order to show convincingly that this treatment was efficacious.

The General Chiropractic Council and General Osteopathic Council were established under Acts of Parliament (Chiropractic Act 1994, Osteopaths Act 1993) and have statutory self-regulatory status. The Acts make it a criminal offence to practice as an osteopath or chiropractic unless registered with the appropriate council. Such regulation is to be welcomed for therapies shown by clinical research to be effective.

Herbalism

It is estimated that some sixty per cent of the world's population use herbal medicine¹⁸. This is based on knowledge accumulated over generations of practical experience. While such information is important, it must be distinguished from the values and methods of verifiable science.

Of all the CAM therapies available herbalism is the one most amenable to explanation and evaluation by orthodox science. Herbal treatments have for many years contributed to orthodox medical practice, the best known example being digitalis from the fox-glove which has been used to treat heart conditions for hundreds of years. Artemesinins based on traditional Chinese remedies for fever may yet prove to be useful in the treatment of malaria as the malarial parasite becomes increasingly widely resistant to conventional treatments¹⁹⁻²¹. Clinical trials have been carried out on herbs subject to licensing as medicinal products in the European Union. Most of these trials are unfamiliar to English-speaking audiences as they are often published in German and French in European journals. For example, a meta-analysis by Linde and colleagues²² published in the British Medical Journal evaluating the use of St John's Wort for depression concluded that extracts of this herb are more effective than placebo for the treatment of depression. However, they noted that none of the articles would have been found had they have confined their literature search to English language publications as is often done for meta-analyses.

In addition to these clinical trials, the ESCOP Monographs (European Scientific Cooperative on Phytotherapy) have reviewed around 3000 papers looking at pharmacological *in vivo* and *in vitro* studies on plants and their extracts. These monographs have been submitted to the European Agency for the Evaluation of Medicinal Products as a basis for new harmonised data requirements and regulatory procedures for drug authorisation across the European Union. Once harmonisation is complete, any new licence for a medicine containing a herb would then need to be consistent with an agreed summary of product characteristics.

However, further and more intensive research on the efficacy of these medicines is needed. Results of trials are available, but meta-analyses of published trials on these traditional medicines have generally been inconclusive owing to poor methodological quality and the problems of accounting for publication bias^{22,23}. Evaluation of the safety of herbal medicines is urgently needed as continuing, not infrequent, reports in the medical literature point to serious and sometimes fatal adverse effects of some herbal remedies²⁴⁻²⁷. Sometimes patients suppose that because herbal medicines are derived from plants they will have fewer side effects than conventional medicines. However, just because a product is natural does not mean that it will not be toxic. Indeed, plants commonly protect themselves with poisons. The effectiveness of herbal remedies relies on pharmacological activity and these agents may be prone to the same problems of lack of specificity and toxicity as synthetic agents.

A privately funded herbal authentication centre is expected to open at the Royal Botanic Gardens at Kew, London in collaboration with physicians from Guy's Hospital London. In addition, companies have been funded in both Europe and the US to evaluate well characterised herbal products in controlled clinical trials. The Society broadly welcomes these new initiatives to evaluate the safety and efficacy of these medicines. However, their use should be tied to proper and explicit diagnosis.

A number of professional organisations for herbalists are constituent organisations of the umbrella body: the British Herbal Practitioners Association (BHPA): the National Institute of Medical Herbalists (NIMH), the General Council and Register of Consultant Herbalists and the Register of Chinese Herbal Medicine. The College of Practitioners of Phytotherapy (CPP) is a more recent body which does not fall under the auspices of the BHPA. The NIMH and the CPP are both associated with university degree courses¹³.

While self-regulatory bodies exist for herbal practitioners, many herbal remedies are available in health food shops. This market is largely unregulated. We recommend that the Government considers this as part of a review of the regulation of CAMs.

Homoeopathy

In homoeopathy, treatment consists of administration of highly diluted forms of natural substances that in a healthy person would bring on symptoms similar to those which the medicine is prescribed to treat¹⁴. The theories behind any possible effect of homoeopathy have been reviewed elsewhere²⁸.

The evidence so far on homoeopathy has been confusing and inconclusive. A survey of 107 controlled trials worldwide by Kelijnen and colleagues in 1991²⁹ and a more recent report by the Homoeopathic Medicine Research Group in its report for the European Commission in 1997³⁰ both appeared to show positive results, but found the evidence to be insufficient for definitive conclusions because most trials were of low methodological quality. It is to be hoped that the trials of high quality that are currently in progress will resolve any uncertainty.

Homoeopathy is alone among CAM professions in achieving recognition in the National Health Act of 1950 and five hospitals in the UK have provided specialist homoeopathic wards. However, the title of homoeopath is not protected by statute (i.e., anyone may call themselves a homoeopath). Doctors who practise homoeopathy may belong to the Faculty of Homoeopathy. For non-physicians, the main organisation is the Society of Homoeopaths, which is a member of the European and International Councils for Classical Homoeopathy¹³. In common with herbal medicines, these medicines are available in health food shops and this market is unregulated.

Osteopathy

Osteopathy is a system of diagnosis and treatment whose main emphasis is on conditions affecting the musculo-skeletal system. Treatment is mainly by gentle manual and manipulative methods¹⁴. It is likely if not certain that osteopathy achieves any benefits by the same general means as chiropractic and trials of osteopathy are covered in references already cited for chiropractic¹⁷.

As mentioned earlier, the title of osteopath is regulated by statute.

Placebo effect

Patient satisfaction is self-evidently a major factor in any therapeutic intervention and the beneficial effects of most, if not all, CAMs include a 'tender loving care' element. The question, however, is whether they exert treatment-specific beneficial effects over and above this element. The placebo effect occurs in all treatment regimes be they alternative or conventional, and the number of people who exhibit an improvement in symptoms in response to a placebo varies widely in clinical trials, but is often as high as one in three³¹. Indeed, a recent paper in *Science*³² suggested that up to seventy-five per cent of the effectiveness of standard antidepressants may in fact be caused by the placebo effect. A strong therapist-patient interaction is known to increase the rate of placebo responses³¹ and this factor should be taken into account when designing trials.

In addition to this tender loving care element, other methodological difficulties are inherent in defining appropriate controls for trials investigating CAM, particularly when investigating procedures as opposed to substances. For example, use of sham acupuncture as a control in acupuncture trials, where needles are inserted in to sites proximal to presumed active sites, may also elicit responses in patients. The complexities of trial design in CAM have been reviewed in a recent article in the *Journal of the American Medical Association*³³ and in a publication by the Royal College of Physicians³⁴.

Recent publications have suggested strong links between the psychological environment, the brain and the immune system indicating that, for example, a cancer patient's state of mind can affect their rate of recovery³⁵. Possible interactions between a therapy and belief about its effectiveness need to be considered in designing adequate trials. Observed outcomes, beneficial or otherwise, may be the result of patient expectations as well as of

treatment in both the active and placebo treatment groups. Careful planning beforehand enables these modifying effects to be detected.

Discussion

The distinction between orthodox and CAM treatments is increasingly hard to define as, for example, manipulative therapies and acupuncture are now being provided by many NHS Trusts and as many as thirty-nine per cent of general practices provide access to CAM for NHS patients³⁶. In an environment of increasing uptake of these therapies it is important to debate openly the role of these treatments in health care and certainly knee-jerk reactions against the potential of at least some CAMs should be avoided. It should be noted that many advances in orthodox medicine have grown from traditional therapies and traditional herbal remedies may still offer leads for the development of new drugs, such as the treatment for malaria referred to earlier.

Despite the increased integration of these therapies into the NHS, CAMs remain available mostly through private practice. Patients have a right to expect that their choices are informed by readily available information on whether they are spending money on safe and effective remedies. Authoritative information on the effectiveness of many CAMs is lacking, largely reflecting a paucity of scientific enquiry.

At least two bodies have looked at the main research requirements in CAM: the Office of Alternative Medicine (OAM) in the US and the South and West Health Authority Research and Development (R&D) Directorate in the UK. They have concluded that the main priority is for randomised controlled trials on effectiveness and safety³⁷. In addition, the OAM concluded that choice of research design is independent of the therapy under investigation and CAMs may be evaluated by the same methodology as for conventional treatments. We have already made the point that care must be taken in defining appropriate controls for evaluation of procedures in CAM. If trials are to produce high quality conclusive data the design of the trial is crucial, particularly where it is necessary to disentangle placebo effects from treatment specific effects. Quality of life and patient satisfaction should be outcomes for these trials as well as the more familiar clinical endpoints.

The Society has written much of late on the need for respect for experimental evidence and peer review³⁸ and would like to stress that refutable claims of therapeutic efficacy should be scrutinised by randomised controlled clinical trials. While these trials are expensive to fund, in a rationed health care service placing increasing emphasis on evidence based medicine, we recommend that NHS provision for CAM, as for conventional treatments, should be confined to those supported by adequate evidence of efficacy and safety. This issue should ideally be evaluated by the new National Institution of Clinical Excellence (NICE) in conjunction with other information on cost-effectiveness.

The Medical Research Council and the NHS R&D programme are both sympathetic to research submissions evaluating CAM. However, funding is not often won by these proposed projects and this in part reflects the poor scientific quality of many proposals. The high quality research that is necessary in this area is not possible without increased training of CAM practitioners in research skills and a greater willingness by those in orthodox medicine to collaborate in such trials. Many medical schools are increasingly offering courses on CAM as part of the curriculum³⁶. While this should be encouraged, therapy must be tied to diagnosis.

A huge disparity exists between the regulation of different CAM therapies, from the totally unregulated (herbal remedies available in health food shops) to those whose regulation is enshrined in statute (osteopathy and chiropractic). We recommend that this issue be investigated by the Government.

There is a need for authoritative information to inform the debate on the role of CAMs in health care. The main requirement is for high quality randomised clinical trials. Sources of funding for these trials already exist within the established funding framework, but training

in and acceptance of research methods is needed if proposed projects are to be funded. The issue of NHS provision for these therapies should ideally be addressed by NICE in the light of published research.

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