The **Academy** *of* **Medical Sciences**

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

About the Academy of Medical Sciences

The Academy of Medical Sciences was established in 1998. It is an independent body with an elected Fellowship of 450, drawn from all the major disciplines in medical science. Its remit is to promote:

- *Excellence in medical sciences*
- *The transfer of new research findings to the practice of medicine*
- *Public understanding of the medical sciences and their impact on society*
- *Assessment of, and advice on, issues of public concern in medical sciences.*

Summary of this response

The House of Lords Select Committee has presented a heterogeneous list of diagnostic and therapeutic techniques that can usefully be divided into groups.

Some of the techniques listed are more or less within the mainstream of medicine: some others are potentially dangerous to the public.

The Academy advocates that all medical interventions should be underpinned by a scientific understanding of normal and pathological structure and function.

All medical and health care interventions should be evaluated using the same general approach and to the same standard of evidence about effectiveness and safety.

While measures of patient satisfaction are an important part of the evaluation process they need to be accompanied by more objective measures of quality of life.

There are an increasing number of complementary medicine practitioners, particularly in osteopathy, chiropractic and acupuncture, who are keen to establish the scientific basis of their work.

The lay literature is a very poor source of information for patients. Reliable and easily accessible sources of information, including on the worldwide web, should be made available to professionals and the public and their existence should be widely publicised.

Research money should not be spent on techniques already known not to work and should be allocated only through peer review to researchers likely to produce publishable and reliable results. There is no case for ring-fenced funding.

One area of particular concern is the use of unlicensed herbal remedies that may contain harmful substances.

Medical students are already taught about complementary medicine but should not be taught how to become complementary medicine practitioners.

All treatments available under the NHS should come under the same regulatory framework and be scrutinised by the National Institute for Clinical Excellence (NICE).

Public money should be spent only on those diagnostic and therapeutic techniques that have been shown to be effective.

Method of working

1. This response is based on the discussions of an Academy working group, chaired by Professor Peter Lachmann, which met on three occasions as well as a discussion at Council on 23 November 1999. The other members of the group were: Professor Alasdair Breckenridge, Sir Richard Doll, Professor David Gordon, Professor Stephen Holgate, Professor Tim Shallice, Professor John Swales, Professor Simon Wessely and Professor Lewis Wolpert.

2. The group also took evidence from Professor Edzard Ernst and Dr Charles Vincent.

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General comments

3. The Academy advocates that a distinction should be made between *complementary medicine*, which it considers embraces those techniques that are a legitimate adjunct to orthodox medicine and *alternative medicine*, which it regards as ignoring scientific principles.

4. The Academy has considered whether it possible to achieve a definition of complementary medicine but found it could only do so by exclusion. Because the Select Committee list contains so many diverse techniques, some of which are almost part of mainstream treatment, the Academy considers that they could be usefully grouped as follows:

Acupuncture (as an analgesic), chiropractic, osteopathy, the Alexander technique. These techniques are known to be effective treatments for certain conditions.

Aromatherapy, bodywork therapies including massage. These may be effective palliative and comfort therapies.

Faith healing, hypnotherapy, meditation, yoga, counselling. These are forms of psychological intervention which should be considered in a separate inquiry.

Anthroposophical medicine, Ayurvedic medicine, herbalism, traditional Chinese medicine, naturopathy. These are 'schools of medicine' which employ a variety of diagnostic and therapeutic techniques elements some of which use toxic substances.

Nutritional medicine is not a clearly defined discipline and overlaps with conventional medicine, particularly in the prevention of disease. However, extensive and fanciful claims for efficacy are common.

Crystal therapy: iridology, kinesiology, radionics, reflexology: these are valueless diagnostic techniques that are potentially dangerous if applied to patients who require proven diagnostic techniques.

Bach and other flower therapies, homeopathy: These are probably valueless but probably not harmful therapies unless applied to patients in place of proven therapies.

5. A principle that underpins the whole of the Academy's response is that of the level playing field for evaluation. This is encapsulated in the following quotation from a leading article in the *New England Journal of Medicine:* '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. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculation and testimonials do not substitute for evidence. Alternative medicines should be subjected to scientific testing no less rigorous than that required for conventional treatments'[1].

Responses to the Select Committee's questions

Evidence ***What is the role of patient satisfaction in evaluating the effectiveness of complementary and alternative treatments, and in determining availability? Do all medical and health care interventions have to be backed by the evidence of controlled clinical trials and by orthodox scientific thinking?***

6. The Academy prefers to answer the second of these questions first. It considers that all medical and health care interventions should ideally be backed by the evidence of controlled clinical trials and by scientific thinking, although it recognises that some orthodox medicine has not yet achieved this goal. Medical science has achieved enormous advances which are based on reliable discoveries and proven interventions. Although for scientists there is always an element of uncertainty, departing from the principles that underpin medical science and development would be extremely dangerous and wasteful.

7. The Academy further considers that all medical and health care interventions should be evaluated using the same general approach. Whereas not all interventions can be looked at using exactly the same techniques, there should be a 'level playing field' for evaluation, i.e. there should only be one standard for all. Evaluation cannot, however, always be achieved by double blind trial but requires a synthesis of evidence from every reliable source.

8. A commonly used tool for assessing efficacy in clinical trials is 'meta-analysis', a statistical technique for combining data from multiple trials which has considerable dangers (see Annex 1). Meta-analysis has been used to show that homeopathy is effective, despite the lack of any plausible explanation for its mode of action. However, the Academy is advised that an in-depth meta-analysis of many trials of homeopathy has shown negative results[2].

9. There is an important distinction that separates the scientific from the 'alternative' approach. Orthodox practitioners shouldand can be helped to change their clinical practice as new information comes to light (evidence-based practice) whereas many alternative and complementary practitioners, who operate on the basis of their belief systems, are less likely to be amenable to evidence-based change.

10. The Academy is encouraged, however, that there are an increasing number of complementary medicine practitioners, particularly in osteopathy, chiropractic and acupuncture (as an analgesic), who are keen to establish the scientific basis of their work. They should be encouraged and supported. Practitioners in complementary medicine need to participate fully in evaluations of their own techniques and this may help them alter their practice based on the findings.

11. The Academy considers that patient satisfaction is one important element in the evaluation of treatments. However, it not a reliable measure of therapeutic efficacy and, indeed, there are examples of where efficacy and patient satisfaction are not correlated. Measures of patient satisfaction are also vulnerable to the placebo effect, whereby the therapeutic benefit is due not to the treatment under investigation but to other factors in the treatment process. The placebo effect is not confined to complementary medicine, however, which is why properly controlled clinical trials are essential when evaluating all treatments. The Academy also points out that measures of patient satisfaction may not be the same as, or as reliable as, more objective measures of 'quality of life' which are used extensively in studies of orthodox treatments for chronic and disabling conditions.

12. This first question from the Select Committee also contains the issue of whether only those techniques and treatments that are biologically plausible should be evaluated. There is an argument that it is more important to show whether techniques work than whether their mode of action can be explained. However, in making judgements about whether to invest in expensive evaluations, such as controlled trials, there needs always to be credible evidence of efficacy; even more so when biological plausibility is absent.

Information ***What are the best sources of information for patients and doctors regarding complementary and alternative medicine? Is it desirable or possible to control the quality of public information available on such treatments?***

13. The Academy has been advised that the lay literature is a very poor source of information for patients[3] and, indeed, it has been termed a 'risk factor'. It is, however, not possible to control information available to the public although it is highly desirable for its quality to be improved.

14. Doctors should consult the Cochrane Collaboration field on

1 Angell M and Kassirer J. New England Journal of Medicine 1998, 339, 839-841

2 Ernst E. Are highly dilute homeopathic remedies placebos? Perfusion 11: 1998. 291-292

3 Ernst E, Armstrong NC. Lay books on complementary/alternative medicine: a risk factor for good health? International Journal of Risk and Safety in Medicine 11 (1998) 209-215

complementary medicine and there is a review journal *Focus on alternative and complementary therapies* which takes an evidence-based approach. The journal reviews all types of data sources, which are informative enough to be reported. There are also books which review the subject objectively such as *Complementary medicine: a research perspective* by C Vincent and A Furnham. It is important, however, that information for busy doctors and other health professionals should be easily accessible and relevant to their clinical practice.

15. It is probably the case, however, that most people do not get their information from journals or reports of controlled trials and so knowing how they obtain information would be valuable. The Academy is concerned about the increasing amount of information available on the worldwide web anis discussing ways in which medical information could be 'kite marked'. There is a need for sustained public education about all aspects of medicine and health care to help the public understand why and how they should look at research evidence. This is not an easy task.

16. In other countries there are funded groups and units that provide telephone services to the public about complementary medicine. A group of oncologists runs the service in Germany and the Office of Complementary and Alternative Medicine in Bethesda provides it in the USA. The Academy suggests that such a service would be useful in the UK.

Research ***Should research funding for evaluations of complementary and alternative medicine be increased? If so, where should the extra money come from? What types of additional research would be most useful?***

17. The Academy considers that research money should not be spent on techniques already known not to work. However, evaluation of untested techniques, even those that are biologically implausible, may be necessary to protect the public from exploitation.

18. The Academy further urges that money should be spent on further research only where the research protocols are of high quality and will lead to a publishable and reliable result. In this regard the Academy points out that the track record of exponents of alternative medicine is not encouraging. In 1992 the N.I.H. in the USA set up an Office of Alternative Medicines to evaluate alternative remedies. They gave 30 research grants, 28 of which provided final reports, but a *Medline* search revealed that only nine of the 28 resulted in published papers, and only five of these nine were in journals recognised in the Library of Medicine's collection. In most of these instances, the methodology used would not allow conclusions to be drawn about the efficacy of the alternative treatment.

19. The Academy has been advised that about 0.08 per cent of the NHS's funds on research and development was spent on complementary medicine in 1996[4]. It further under stands that there may be barriers to obtaining funds for high quality research because of lack of sympathy in review panels. This is not, however, an argument for ring-fenced funding but underlines the need for a plurality of funding sources.

20. The Academy understands that both the MRC and AMRC charities will support research into complementary medicine that meets their criteria. Further funds could be obtained from the manufacturers of complementary medicines.

21. Evaluations of complementary medicine techniques require the full co-operation of complementary medicine practitioners. Helping them to develop a sound research base for their education and practice may help take forward the complementary medicine research agenda in the longer term.

22. There may also be a need for good social science studies into the growing use of, and motives behind, complementary medicine. The Academy has considered whether shortfalls in NHS provision for some disorders may be one of the reasons behind more people seeking complementary treatments. This may be worth further study and recommendations sought about how orthodox medical practitioners, other health care professionals and perhaps society as whole can respondbetter to people's health needs.

23. Based on the Select Committee's list, the Academy considers that the treatments that most urgently need further study are those involving unlicensed herbal remedies.

a) With respect to herbal medicines, there are two regulatory routes by which these substances can reach the UK market.

- unlicensed herbal remedies which do not have to meet any set safety or quality standards.
- licensed herbal remedies which have to satisfy rigorous of evidence on safety, quality and efficacy - on the same basis as other licensed medicines.

b) The Government's stated objective is that the public should have continued access to a wide range of safe and high quality herbal remedies with appropriate information about the use of the products. The Academy supports the initiative taken by the Medicines Control Agency in holding informal discussions with a wide range of interest groups across the natural health sector to explore the possibility of moving towards regulatory arrangements which may provide a more effective balance between consumer safety and consumer choice. One problem is that any regulatory arrangement will have to depend on agreement with the European Union, in parts of which the alternative medicine lobby is extremely powerful; as are the forces to prevent change. Claims on the therapeutic properties of unlicensed remedies should be subject to the Trades Description Act.

c) There is a particular problem relating to issue of the quality of herbal medicines. There are several well-documented instances of adulteration of preparations which may have profound influences on both efficacy or safety[5], e.g.

- Heavy metals have been found in many preparations used in Ayurvedic medicine, resulting in both morbidity and mortality when taken.
- Traditional Chinese medicines are very frequently contaminated with poisonous extracts notably the contamination by Aristolochia of several preparations which have caused death from renal failure.
- Many herbal medicines that have claimed efficacy have been found to contain corticosteroids, which could have contributed to the therapeutic effect, claimed by the herbal preparation and are known to have side effects.

These examples emphasise the need for regulatory assessment of all types of herbal medicine, despite the underlying political difficulties.

Training ***Should the increased interest in complementary and alternative medicine be reflected in medical training and training of other healthcare professionals?***

24. There is already a requirement for medical students to be informed about complementary medicine but they should not spend more time learning how to use it. Doctors should certainly learn about their patients' health behaviour but this can be covered in a variety of subject areas and not limited to learning about complementary medicine. Learning about complementary medicine will be much more relevant to some doctors (e.g. GPs) than others and may best take place as part of vocational training and postgraduate and continuing professional education and development.

4 *Ernst E. Only 0.08% of funding for research in NHS goes to complementary medicine. British Medical Journal 1996; 313:882*

5 *Ernst E. Harmless herbs? A review of the recent literature. American Journal of Medicine 1998; 104: 170-178.*

Regulation and risk ***Are there areas of complementary and alternative medicine where lack of regulation causes unacceptable risk to the public? Are there practicable forms of regulation that would provide protection without unduly restricting patient choice?***

25. The Academy welcomes the move by some complementary medicine practitioners, such as the osteopaths, towards greater self-regulation. Other groups whose practice is known to be effective and which is also becoming part of orthodox medicine should be encouragedto do the same. Regulation of the remainder is probably best done through other statutory mechanisms that protect the public. The Academy is concerned about practitioners who use proven invalid diagnostic techniques such as reflexology and iridology as people with organic disease may be put at risk from faulty diagnosis.

26. The Academy considers that the public should certainly be protected from poisons, such as herbal remedies that contain heavy metals. All pharmacologically active substances should be brought within the same legislative framework if prescnbed by a doctor or by a complementary medicine practitioner working under the aegis of a doctor. Herbal remedies should not be allowed to contain substances that are normally regulated e.g. corticosteroids.

27. Complementary medicine practitioners and manufacturers should participate in the drive towards transparency and ensure that their compounds are labelled with their contents, in as far as they are known. It would also be helpful to the public for products to state at the point of sale if their composition is not known.

28. The Academy notes that it is forbidden by law for anyone other than a medical practitioner to offer treatment for venereal disease[6]. Other legislation[7] prevents advertising treatments for a wide range of diseases including cancer. Where there are complementary medicine practitioners providing treatments for these conditions, their activities should be reviewed. It would, however, be important to make a distinction between those offering treatments for these conditions and those offering legitimate palliative care.

NHS provision ***Should public healthcare attempt to integrate elements of complementary and alternative medicine into the mainstream of healthcare? How might this be done? Should access to complementary and alternative treatment through the NHS be limited to those areas that have (a) an established evidence base and (b) formal regulatory systems, and can minimum required standards of evidence and regulation be defined?***

29. The Academy considers that the NHS is already integrating complementary medicine into the mainstream of orthodox care. The Academy has been advised that up to 40 per cent of GPs are offering various types of complementary medical care, either directly or through other practitioners working under their aegis.

30. The Academy strongly supports the move towards all medical care in the UK having an established evidence base and would not support any departure from this principle for complementary medicine which might under mine the progress being made in orthodox medicine. All novel treatments, whether complementary or orthodox, should come under the same regulatory framework and be scrutinised by the National Institute for Clinical Excellence.

31. The Academy has considered whether shortfalls in NHS provision of orthodox treatments increase the need for complementary medicine in any way. There are, for example, only a few specialist clinics for diagnosing and managing allergies and chronic fatigue syndrome. However, back pain, depression and anxiety are the common conditions seen by complementary practitioners and NHS GPs should be equipped to deal with these conditions. Although there may be pressure to allocate a proportion of the NHS budget to complementary medicine, the money would be better spent on the NHS to provide better care for patients with some of these difficult conditions.

6 *Venereal Diseases Act 1917*

7 *Cancer Act 1939, The Medicines (Advertising) Regulations 1994.*

Annex 1

META-ANALYSIS IN EVIDENCE-BASED MEDICINE

Meta-analysis is a valuable tool, but like many such tools can be hazardous if misapplied. It is a simple statistical technique for combining the results of several studies that are individually inadequate to answer convincingly the questions they set out to answer. It was developed particularly to help interpret the results of multiple clinical trials, which were individually too small to give clear results. Its use requires that the trials should have been carried out in an unbiased way, that all trials that have been conducted should be included (or if not that the selection of trials should have been unbiased) and that the criteria for entry to the trials should have been broadly similar and the endpoints the same. It does **not** require that the types of patient in each trial should have been identical, as the object of the analysis is not to obtain a precise quantitative assessment of the effect of a given treatment, but to obtain a clear indication of the direction of any effect and an indication of its size.

False impressions can readily be obtained if all trials are not included, as unpublished trials (or trials overlooked because published in obscure journals) are more likely to have shown null effects than trials published in major journals. This is particularly the case when the analysis consists only of **small** trials. Large trials are much less likely to remain unpublished than small trials and the results of one really large well conducted trial may be more reliable than a meta-analysis of many small trials. The most reliable results are consequently obtained from a meta-analysis of large trials.

Meta-analyses are most reliable and most informative when they are conducted in the form of a collaborative re-analysis in which all investigators participate and ensure that all their results are reported in the same way, with the same rules for the exclusion of patients and rigid adherence to the principles of including all patients that were intended to be treated.

Meta-analysis is generally inappropriate for the combination of observational (non-experimental) studies as they are liable to be affected by different forms of bias and (possibly) confounding. If observational studies are to be combined, it is essential that it is in the form of a collaborative re-analysis when steps can be taken to take account of and, where appropriate, allow for such differences.

The **Academy** *of* **Medical Sciences**

The Academy of Medical Sciences
10 Carlton House Terrace
London SW1Y 5AH

Tel: 020 7969 5288
Fax: 020 7969 5298

Email: apollo@acmedsci.ac.uk
Web: www.acmedsci.ac.uk

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