

DEPARTMENT OF HEALTH

GOVERNMENT RESPONSE TO THE HOUSE OF LORDS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY'S REPORT ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

Presented to Parliament by the Secretary of State for Health By command of Her Majesty March 2001

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INTRODUCTION

This Report publishes the results of the first ever comprehensive Inquiry into Complementary and Alternative Medicine (CAM) in the UK by a Parliamentary Select Committee.

There has been increased public interest in and use of CAM in recent years. CAM is a thriving feature of the private healthcare sector, and may owe some of its commercial success to the fact that it currently enjoys relatively light regulation. The Government's overall policy towards better regulation is that it should be both proportionate and effective. In other words, the regulation should give customers adequate protection, without stifling the commercial services they want.

CAM must, of course, start with the basic healthcare precept "First do no harm". But a commercial provision which contributes to our caring services should share the same accountability: practising to high levels of professional competence, guided by strong professional ethics, honest about its boundaries and limitations, collaborating with all its professional peers.

CAM can also play a part in treating NHS patients. But if it aspires to be an equal player with other forms of NHS treatment, it must meet the same standards required of them. And it must be clear and realistic about the contributions it can make. Many of the CAM professions have begun making the changes they need to secure a more lasting place in broader health provision. But those changes must now be driven forward more decisively. All the professions need to adapt and improve and, in doing so, they must work together more.

The Committee's Report articulates the changes that are needed. The Government welcomes the Report, and believes its main recommendations will help protect the interests of patients and other consumers. If taken seriously by both orthodox and complementary medicine, the Report could also bring significant benefits to medicine as a whole.

This document reproduces each of the Report's recommendations in turn, and provides the Government's response to them.

GROUPING OF THERAPIES

- 1. The Report began by organising therapies into three separate groups. These were described as follows:
 - The first group embraces what may be called the principal disciplines, two of which, osteopathy and chiropractic, are already regulated in their professional activity and education by Acts of Parliament. The others are acupuncture, herbal medicine and homeopathy. Each of these therapies claims to have an individual diagnostic approach and are seen as the 'Big 5' by most of the CAM world.
 - The second group contains therapies which are most often used to complement conventional medicine and do not purport to embrace diagnostic skills. It includes aromatherapy; the Alexander Technique; body work therapies, including massage; counselling, stress therapy; hypnotherapy; reflexology and probably shiatsu, meditation and healing.
 - The third group embraces those other disciplines which purport to offer diagnostic information as well as treatment and which, in general, favour a philosophical approach and are indifferent to the scientific principles of conventional medicine, and through which various and disparate frameworks of disease causation and its management are proposed. These therapies can be split into two sub-groups: Group 3a includes longestablished and traditional systems of healthcare such as Ayurvedic medicine and Traditional Chinese medicine. Group 3b covers other alternative disciplines which lack any credible evidence base such as crystal therapy, iridology, radionics, dowsing and kinesiology.

The Government believes that, in general, patients, consumers and healthcare practitioners will find it helpful, at least for the time being, to differentiate between therapies in the way the Report proposes. It could help identify approximately the stage various therapies have reached in their professional organisation, the roles they may be able to play in healthcare generally, and what is known of the relative risks involved in their practice.

However the Government accepts that the categorisation is necessarily broad in nature, and it need not imply that all therapies in each category have identical features.

In some circumstances there may also be scope for some therapies to be allied for a specific purpose across the boundaries of the proposed groupings. For example the Government considers that, for the purposes of professional self-regulation, those aspects of the traditional therapies listed in Group 3a which include the use of herbal remedies could come together within a federal grouping of therapies in Group 1 under the general heading of herbal medicine, while still retaining their individual identities and traditions. It may also be possible to bring within Group 1 those aspects of traditional therapies which practise acupuncture. Under the general headings of herbal medicine and acupuncture, there would therefore be scope to protect the public by affording statutory recognition to large parts of these more traditional therapies (See also Recommendation 8).

Introduction (Chapter 1)

2. More detailed quantitative information is required on the levels of CAM use in the United Kingdom, in order to inform the public and healthcare policy-makers, and we recommend that suitable national studies be commissioned to obtain this information (para 1.21).

The Government accepts that more knowledge of the extent to which various CAM therapies are used in the UK, and the reasons why people use them is desirable although perhaps not strictly essential. For practical reasons, any national survey would inevitably be limited to a sample of the population.

The Government has decided to test the issue from several different perspectives. The Department of Health has commissioned the Foundation for Integrated Medicine to conduct an assessment of existing reports on consumer preferences in CAM. As part of its annual survey of NHS patients, the Department has also asked NHS cancer patients to identify their use of complementary therapies. Finally, the Department has commissioned the Office of National Statistics to include questions on the use of complementary medicine in its National Statistics Omnibus Survey in March 2001. The results of these three pieces of work will help determine the need for and design of any further surveys in future years.

Evidence (Chapter 4)

3. Diagnostic procedures must be reliable and reproducible and more attention must be paid to whether CAM diagnostic procedures, as well as CAM therapies, have been scientifically validated. We agree that this is an issue that should always be kept in mind when doing research in this area (para 4.16).

The Government recognises that CAM diagnostic procedures are used for diagnostic purposes and considers that these should be subject to the same standards of evidence required for treatment.

The NHS Research and Development Health Technology Assessment Programme has a Diagnostic Technologies and Imaging Panel which prioritises research in this area. The programme has prioritised and commissioned CAM research in the past and could consider CAM topics in the area of diagnostics. However, as with all research programmes, funding is limited and all topics submitted are subject to a process of prioritisation.

4. In our opinion any therapy that makes specific claims for being able to treat specific conditions should have evidence of being able to do this above and beyond the placebo effect. This is especially true for therapies which aim to be available on the NHS and aim to operate as an alternative to conventional medicine, specifically therapies in Group 1. The therapies in our Groups 3a and b also aim to operate as an alternative to conventional medicine, and have sparse, or non-existent, evidence bases. Those therapies in our Group 2 which aim to operate as an adjunct to conventional medicine, and mainly make claims in the area of relaxation and stress management, are in lesser need of proof of treatment-specific effects but should control their claims according to the evidence available to them (para 4.18).

The Government agrees with the need for strong evidence beyond the placebo effect to support the use of any complementary therapy in Groups 1 and 3 on the NHS. The test proposed - i.e. that any treatment that makes specific claims

should have evidence of benefit above and beyond the placebo effect – is a tough one. However this is the right standard to set for therapies in Groups 1 and 3, especially as the report goes on to accept that therapies which are mainly about relaxation and stress management and make only limited claims, need not satisfy this particular test. NICE will obviously comment on the type and quality of the evidence available in cases which come before it.

The Government understands that traditional herbal medicine systems from outside the western tradition can be supported by very substantial bodies of research data but that in many cases the studies purporting to demonstrate efficacy have not so far been replicated under the rigorous conditions that would be required in order to gain wide credence in orthodox western medicine.

The Government expects CAM practitioners in all disciplines to be realistic about the claims they make for their therapy. If need be, action can be taken under consumer protection legislation against practitioners who make blatantly unjustifiable claims for their therapy. However it would be better if their regulatory bodies set guidelines that helped avoid such action. The Government therefore urges CAM regulatory bodies to put in place codes of practice to limit claims made by practitioners, and to ensure that their members recognise and follow them.

5. We recommend that if a therapy does gain a critical mass of evidence to support its efficacy, then the NHS and the medical profession should ensure that the public have access to it and its potential benefits (para 4.37).

As already mentioned, the Government agrees with the need for strong evidence beyond the placebo effect to support the use of therapies on the NHS. However in the final analysis it must be for the NHS clinician or healthcare practitioner with lead clinical responsibility for the individual patient to judge whether, when and how an individual patient could benefit from the use of a particular therapy. Wherever possible the patient should be actively involved in this process and in any agreed plan for his or her treatment or therapy. (See also the response to recommendations 43 and 44).

The National Electronic Library for Health and NHS Direct Online will in due course make evidence concerning CAM therapies as widely available as possible to clinicians and managers, patients and the public, carers, patient representatives and advocates. The Government will also continue to be open to opportunities for NICE to evaluate individual CAM therapies as a supplementary or alternative treatment for specific conditions.

Regulation (Chapter 5)

- 6. We recommend that, in order to protect the public, professions with more than one regulatory body make a concerted effort to bring their various bodies together and to develop a clear professional structure (para 5.12).
- 7. We recommend that each of the therapies in Group 2 should organise themselves under a single professional body for each therapy. These bodies should be well promoted so that the public who access these therapies are aware of them. Each should comply with core professional principles, and relevant information about each body should be made known to medical practitioners and other healthcare professionals. Patients could then have a single, reliable point of reference for standards, and would be protected

against the risk of poorly-trained practitioners and have redress for poor service (para 5.23).

The Government believes professional self-regulation works best when it operates as an open and transparent partnership between the profession, patients and the wider public. These stakeholders clearly deserve better than the current fragmented regulation of certain CAM therapies. The Government therefore strongly encourages the regulating bodies within each therapy to unite to form a single body to regulate each profession. We believe this approach will be in the best interests of patients and the wider public, as well as potentially enhancing the status of individual professions.

8. It is our opinion that acupuncture and herbal medicine are the two therapies which are at a stage where it would be of benefit to them and their patients if the practitioners strive for statutory regulation under the Health Act 1999, and we recommend that they should do so. Statutory regulation may also be appropriate eventually for the non-medical homeopaths. Other professions must strive to come together under one voluntary self-regulating body with the appropriate features outlined in Box 5, and some may wish ultimately to aim to move towards regulation under the Health Act once they are unified with a single voice (paras 5.53 and 5.55).

The Government accepts that, at this point in their development, and bearing in mind certain public health risks, it would be desirable to bring both acupuncture and herbal medicine within a statutory framework as soon as practicable. The Government has held preliminary discussions with organisations representing each therapy.

The Government is prepared to consider the possibility of extending statutory regulation for other therapies if there is a case for it, and there is a unified professional body which has the support of most members of its profession for pursuing that option. Representatives of the aromatherapy profession have already expressed an interest in statutory regulation, and others may wish to do so.

As the Report concludes, therapies outside Group 1 are likely to function in a different way. The case for statutory regulation of those therapies may be therefore harder to establish and may follow a different course.

Before inviting Parliament to exercise the powers of the Health Act 1999 to recognise any CAM profession, the Government will undertake wide and detailed consultation on its proposals, including consultation with interested professional and regulatory bodies and discussion with the devolved administrations. However, as has been stated on other occasions, the Government reserves the right to take its own initiative to invite Parliament to invoke Section 60 of the 1999 Act where it considers this step necessary as a last resort.

9. We recommend that each existing regulatory body in the healthcare professions should develop clear guidelines on competency and training for their members on the position they take in relation to their members' activities in well organised CAM disciplines; as well as guidelines on appropriate training courses and other relevant issues. In drawing up such guidelines the conventional regulatory bodies should communicate with the relevant complementary regulatory bodies and the Foundation for Integrated Medicine to obtain advice on training and best practice and to encourage integrated practice (para 5.79).

The Government agrees that each statutory regulatory body in the conventional healthcare professions which make significant use of CAM therapies should develop clear guidelines for its members on both the competences and training required for the safe and effective practice of the leading CAM therapies, in consultation with the relevant CAM regulatory bodies and the Foundation for Integrated Medicine.

10. We encourage the bodies representing medical and non-medical CAM therapists, particularly those in our Groups 1 and 2, to collaborate more closely, especially on developing reliable public information sources. We recommend that if CAM is to be practised by any conventional healthcare practitioners, they should be trained to standards comparable to those set out for that particular therapy by the appropriate (single) CAM regulatory body (para 5.83).

The Government also wishes to encourage all bodies which represent practitioners who provide one or more of the CAM therapies in Groups 1 and 2 to work together to develop reliable public information which conforms to the quality standards publicised by the National Electronic Library for Health and NHS Direct Online. NHS Direct Online and the National Electronic Library for Health will, over time and where authoritative research is available, include information on CAM treatments and therapies alongside information on conventional medicine.

The Government supports the training of conventional healthcare practitioners to standards agreed with the appropriate CAM regulatory body. In some cases there may need to be a gradation of standards which reflect both training and practice at different levels. This recommendation should be reinforced with Recommendations 16 to 18 and 29.

11. We recommend that the MCA find a mechanism that would allow members of the public to identify health products that had met the stringent requirements of licensing and to differentiate them from unregulated competitors. This should be accompanied by strong enforcement of the law in regard to products that might additionally confuse the customer with claims and labelling that resemble those permitted by marketing authorisations (para 5.93).

The Government agrees that it is desirable that the public should have clear information on the regulatory status of products. For all medicines which are the subject of a marketing authorisation it is a legal requirement under European law that the product licence number is stated on the labelling. In European discussions about the proposed directive on traditional medicinal products, the Medicines Control Agency has advocated that there should be a requirement for consumers to be given explicit information about the significance of a registration under the proposed directive. As currently envisaged this may take the form of a label marking. The Government will continue to pursue these issues within Europe with a view to providing clarity to the public. The Medicines Control Agency will continue to enforce medicines law in relation to the presentation of medicinal products.

12. We strongly recommend that the Government should maintain their effective advocacy of a new regulatory framework for herbal medicines in the United Kingdom and the rest of the European Union, and urge all parties to ensure that new regulations adequately reflect the complexities of the unregulated sector (para 5.95).

The Government welcomes the recognition of its work to advocate the case for an improved European regulatory framework for safe, traditional herbal remedies. The European Commission recently circulated to member states a preliminary draft of a directive on traditional medicinal products. The Medicines Control Agency, as a priority, will continue to participate actively and constructively in continuing development work on this issue at both European and domestic level with a view to putting in place a national scheme for these remedies within a secure European legislative framework.

The Government takes the view that any single legislative or other measure is unlikely to address the full range of issues and problems presented by the unregulated sector. However, an effective directive on traditional medicinal products would represent a major step forward.

13. We are concerned about the safety implications of an unregulated herbal sector and we urge that all legislative avenues be explored to ensure better control of this unregulated sector in the interests of the public health (para 5.97).

The wide range of herbal products on the market span a number of regulatory categories including foods and cosmetics as well as medicines. The Government accepts that for products classified as medicines there is a weakness in the regulatory arrangement for unlicensed herbal remedies provided for under Section 12(2) of the Medicines Act 1968. The best prospects for resolving this problem lie with the introduction of a national scheme within the framework of the proposed European directive on traditional medicinal products. Potentially, this could provide a legally secure regime effectively balancing consumer choice and public safety. The Government is currently encouraged by progress on the directive but will keep the position under review and in the event that this initiative founders will consider what alternative approaches may be available.

The Government's view is that in principle the cover of a European directive would be necessary in order to replace the provisions of Section 12(2) with systematic regulatory arrangements within medicines law. The Government welcomes the Committee's support for the position that herbal medicines should be regulated under medicines law rather than in a less regulated environment.

The MCA is consulting on proposals to make permanent the prohibition in unlicensed medicines of the toxic ingredient *Aristolochia* and of other herbal ingredients at risk of confusion with *Aristolochia*. The Government will take any further action necessary to protect the public from specific health risks of this kind. In addition, to promote an understanding of, and compliance with, the current medicines law relating to unlicensed medicines the MCA has established an information base (*Traditional ethnic medicines*, *public health and compliance with medicines law*) on its website.

14. We support the view that any new regulatory regime should respect the diversity of products used by herbal practitioners and allow for simplified registration of practitioner stocks. Nevertheless, any such regime must ensure that levels of quality and assurance of safety are not compromised (para 5.98).

The Government agrees that future regulatory arrangements relating to the ingredients and products used by individual herbal practitioners should safeguard quality and safety standards while recognizing the diversity of practice.

We aim to clarify and if necessary improve regulatory arrangements covering the varied situations which can arise, ranging from the practitioner using crude or partially processed herbal ingredients to make up individual remedies to the situation where the herbalist buys in mass produced finished products. Regulatory arrangements should in particular reflect the extent to which the practitioner is in a position to take personal responsibility for the safety and quality of the remedy supplied to the consumer.

The Government will hold discussions with herbal interest groups to consider the way forward. In the light of this we will consider whether any changes in domestic legislation would be required in order to reach a satisfactory regulatory position and the extent to which requirements for responsible good practice attaching to the herbalist profession could play a greater role in ensuring the safety and quality of materials practitioners use.

Professional Training and Education (Chapter 6)

15. Establishing an independent accreditation board along the lines of the British Acupuncture Accreditation Board is a positive move. Other therapies with fragmented professional representation may wish to use this as a model (para 6.20).

The Government agrees that the use of accreditation boards can be an effective way of bringing together representatives of fragmented professions to establish robust common standards of education for their profession. Where several regulatory bodies are involved, it will be important to ensure that any accreditation board is completely independent of the institutions being accredited and is part of a move towards regulation of that therapy by a single body.

16. We recommend that CAM training courses should become more standardised and be accredited and validated by the appropriate professional bodies. All those who deliver CAM treatments, whether conventional health professionals or CAM professionals, should have received training in that discipline independently accredited by the appropriate regulatory body (para 6.33).

17. We suggest that the CAM therapies, particularly those in our Groups 1 and 2, should identify Continuing Professional Development in practice as a core requirement for their members (para 6.34).

The Government considers that all qualifications in CAM should be assessed by the regulatory body which grants the licence to practise the CAM therapy concerned. To facilitate both accreditation and recognition, and to make it easier for members of the public to judge the qualifications practitioners claim to offer, the Government would welcome more standardisation of training in CAM therapies.

The Government would like all CAM regulatory bodies to promote lifelong learning amongst their practitioners by setting standards of clinical practice and by promoting effective systems of continuous professional development. Greenwich University has, funded by Government, provided to all CAM regulatory bodies a model Continuing Professional Development pack for practitioners.

18. We consider that it is imperative that higher educational institutions and any regulatory bodies in CAM liaise in order to ensure that training is adequate for registration. If extra training is required after academic qualifi-

cation to ensure fitness to practise, this should be defined by the appropriate professional body, which should then implement appropriate mechanisms in order to see that this objective is achieved (para 6.40).

The Government supports this recommendation.

- 19. We recommend that training in anatomy, physiology and basic biochemistry and pharmacology should be included within the education of practitioners of therapies that are likely to offer diagnostic information, such as the therapies in Groups 1 and 3a. (para 6.43).
- 20. We recommend that every therapist working in CAM should have a clear understanding of the principles of evidence-based medicine and healthcare. This should be a part of the curriculum of all CAM therapy courses. (para 6.49).
- 21. We recommend that all CAM training defines the limits of the particular therapist's competence as clearly as possible in the state of current knowledge. Training should also give students clear guidance on when a patient should be referred to a primary care physician or even directly to secondary hospital care (para 6.52).
- 22. We recommend that all CAM therapists should be made aware of the other CAM therapies available to their patients and how they are practised. (para 6.54).

The Government supports these recommendations. It is Government policy to encourage the inclusion of certain core elements in every vocational qualification, and this feature is being developed for health professional programmes in the NHS Plan. The above recommendations would apply that general principle to CAM.

It is a basic function of all healthcare regulatory bodies to concern themselves with the competence of those who practise their profession. This will mean defining standards of competent practice and encouraging all providers of education and training in CAM to reflect those standards in their qualifications. The above common elements could help delineate the minimum standards expected of CAM qualifications which permit graduates to practise a therapy in a professional capacity. (See also recommendations 24 and 25).

- 23. We conclude that there should be flexibility for training institutions to decide how to educate practitioners. It is the relevant professional regulatory body of a specific CAM therapy that should set objectives of training and define core competencies appropriate to their particular discipline, and we so recommend. We do not advocate a blanket core curriculum (para 6.61).
- 24. We recommend that, whether subject to statutory or voluntary regulation, all healthcare regulatory bodies should consider the relevance to their respective professions of those elements set out in paragraph 6.55 (para 6.62).

The Government concurs with these recommendations.

25. We recommend that therapies with a fragmented professional organisation work with Healthwork UK to develop National Occupational Standards, and we encourage the Department of Health to further support Healthwork UK's activity with such therapies; we believe that this would be of long-term benefit to the public (para 6.70).

The Government welcomes the work that Healthwork UK has done in developing National Occupation Standards in CAM. It has commissioned Healthwork UK to do further work in this area, and also to develop the concepts in recommendations 19 to 22 above.

A strong health sector National Training Organisation is important in delivering the Government's modernisation agenda. In the light of the NHS Plan, the Government is working with Healthwork UK to better align its functions with the structures for education, training and workforce development in healthcare in each UK country.

- 26. We recommend that familiarisation should prepare medical students for dealing with patients who are either accessing CAM or have an interest in doing so. This familiarisation should cover the potential uses of CAM, the procedures involved, their potential benefits and their main weaknesses and dangers (para 6.77).
- 27. We recommend that every medical school ensures that all their medical undergraduates are exposed to a level of CAM familiarisation that makes them aware of the choices their patients might make (para 6.79).
- 28. We recommend that Royal Colleges and other training authorities in the healthcare field should address the issue of familiarisation with CAM therapies among doctors, dentists and veterinary surgeons by supporting appropriate Continuing Professional Development opportunities (para 6.85).
- 30. We recommend that the UKCC work with the Royal College of Nursing to make CAM familiarisation a part of the undergraduate nursing curriculum and a standard competency expected of qualified nurses, so that they are aware of the choices that their patients may make. We would also expect nurses specialising in areas where CAM is especially relevant (such as palliative care) to be made aware of any CAM issues particularly pertinent to that speciality during their postgraduate training. The Royal College of Nursing and the UKCC, as they do not provide CAM training themselves, should compile a list of courses in CAM that they approve, in order that nurses who wish to practise in this field can obtain guidance on appropriate training (para 6.106).

A later section of the Report makes recommendations about the provision of information on CAM to healthcare professionals and patients. The Government agrees that it will be important to ensure that healthcare professionals and patients have access to proper information and that the regulatory bodies, Royal Colleges and other training authorities work together to provide greater familiarisation in CAM in approved under-graduate and post-graduate training programmes. In order to increase clinical awareness of CAM therapies, the NHS will offer clinicians and medical undergraduates access to the most authoritative information available on the safety and efficacy of CAM therapies via the National Electronic Library for Health (and its specialist Virtual Branch Libraries) and other NHS library and information services.

However the Government believes that courses which aim to give healthcare practitioners some familiarisation in CAM for the purpose of advising patients will be at a different level to courses that are intended to equip practitioners to practise specific therapies themselves. In the latter case, the Government considers that Recommendation 10 of the Report should apply.

29. The General Osteopathic and Chiropractic Councils, and any other regulatory bodies, should develop schemes whereby they accredit certain training courses aimed specifically at doctors and other healthcare professionals, and which are developed in conjunction with them. Similar schemes should be pursued by dentists and veterinary surgeons (para 6.95).

The General Osteopathic and General Chiropractic Councils are empowered under their respective Acts to formally recognise qualifications. The General Osteopathic Council already recognises a qualification for doctors. The Government would encourage other CAM regulatory bodies to do the same.

Research (Chapter 7)

- 31. To conduct research into the CAM disciplines will require much work and resources, and will therefore be time-consuming. Hence, we recommend that three questions should be prioritised and addressed in the following order:
 - To provide a starting point for possible improvements in CAM treatment, to show whether further inquiry would be useful, and to highlight any areas where its application could inform conventional medicine does the treatment offer therapeutic benefits greater than placebo?
 - To protect patients from hazardous practices is the treatment safe?
 - To help patients, doctors and healthcare administrators choose whether or not to adopt the treatment how does it compare, in medical outcome and cost-effectiveness, with other forms of treatment? (para 7.7)

The questions the report identifies are important questions to address when considering research on a particular CAM intervention. However there is also a need to identify priorities across CAM interventions to ensure effort and resources are invested in the most productive areas.

Given the limited research capacity in this area and the barriers to developing a research culture in CAM, the feasibility of the research should be an important consideration, for example where there are opportunities to develop high quality research programmes which can act as "models" or "beacons" of research excellence in CAM. The identification of priorities for research should also take account of whether the nature of a treatment, the condition being treated, or the scale of use, creates an exceptional public health need to gain evidence of safety or efficacy.

32. We recommend that CAM practitioners and researchers should attempt to build up an evidence base with the same rigour as is required of conventional medicine, using both Randomised Controlled Trials and other research designs (para 7.26).

The Government agrees that an evidence base for CAM needs to be built up. We also recognise that there are barriers to developing a culture of evidence-based CAM. Principal among these may be the risks of research results undermining the product or services being sold, and the absence of pressure for evidence from regulators or bodies accrediting training. Another barrier is limited awareness of

scientific method, and the difficulty of working in partnership with those who have such expertise, but who have worked mainly within a conventional environment.

Enhancing the evidence base in an area such as CAM can prove challenging methodologically. The NHS R&D Methodology Programme has commissioned research of relevance to those working in this area, for example a systematic review of literature comparing the use of randomised controlled trials and quasi-experimental or observational methods for assessing the effectiveness of interventions and comparing the quality of care has been funded

33. To achieve equity with more conventional proposals, we recommend that research funding agencies should build up a database of appropriately trained individuals who understand CAM practice. The research funding agencies could then use these individuals as members of selection panels and committees or as external referees as appropriate (para 7.45).

The Government has recognised the need to involve appropriate experts on relevant panels and committees or through the peer review process. For example in commissioning projects covering CAM the Health Technology Assessment programme invited comments from appropriate peer reviewers through the Research Council for Complementary Medicine.

The Medical Research Council (MRC) will be developing databases of research experts who are familiar with the issues raised by CAM research. At present the pool of CAM practitioners who are expert in research is limited; and many of these experts will be people whose primary experience is in non-CAM medical research.

- 34. We recommend that universities and other higher education institutions provide the basis for a more robust research infrastructure in which CAM and conventional research and practice can take place side-by-side and can benefit from interaction and greater mutual understanding. We recommend that a small number of such centres of excellence, in or linked to medical schools, be established with the support of research funding agencies including the Research Councils, the Department of Health, Higher Education Funding Councils and the charitable sector (para 7.57).
- 37. We recommend that the NHS R&D directorate and the MRC should pump-prime this area with dedicated research funding in order to create a few centres of excellence for conducting CAM research, integrated with research into conventional healthcare. (para 7.102).

Recommendations 34 and 37 seem to address the same issue.

The current capacity for research in this field and the scale of current research make it premature to talk of setting up separate centres of excellence. Research capacity cannot be created simply by forming academic posts – clinical trials, as in conventional medicine, depend also on commitment, attitudes and competence of practitioners in the field.

We recognise the need to develop the research capacity in this field. It is important that high quality researchers are developed and the Department is considering the best way to achieve this objective. We will be asking the NHS R&D Workforce Capacity Implementation Group to consider research capacity development needs in CAM and how these might be met. One of the options to be

explored includes the provision of funding for Fellowships within the Department's priority areas, with funding for pilot projects included.

Proposals for CAM research can be considered through the usual funding mechanisms of the Department of Health and the MRC, and some CAM research has been funded through existing schemes, in competition with other research. In the short term a ring-fenced scheme would be unlikely to succeed in adding substantially to the volume of research in this area, given the need to increase the research base in this field.

The Department welcomes proposals for CAM research in response to the stated priority areas it is currently taking forward. The NHS Cancer Plan identifies the need to review the evidence of complementary therapies in relation to supportive and palliative care and the Department will be seeking high quality proposals for work in this area.

However it is important that links should continue to be made between researchers already working in or interested in this area with a view to developing and strengthening research networks, which in turn will encourage the production of high quality research into CAM.

35. Bodies such as the Departments of Health, the Research Councils and the Wellcome Trust should help to promote a research culture in CAM by ensuring that the CAM world is aware of the opportunities they offer. The Department of Health should exercise a co-ordinating role. Limited funds should be specifically aimed at training CAM practitioners in research methods. As many CAM practitioners work in the private sector and cannot afford to train in research, we recommend that a number of university-based academic posts, offering time for research and teaching, should be established (para 7.67).

The Government is aware of the need both to promote better understanding of research in the complementary medicine field, and to develop better quality research conducted by practitioners in this field. We are also aware that there are a number of qualified and experienced researchers interested in research into CAM therapies, whose background is in both conventional and complementary medical areas.

The Government has started to promote a research culture by forging links between CAM practitioners and research experts. The new division developing within the MRC Clinical Trials Unit will increase the opportunities for collaboration with CAM and other areas where expertise in trials and other evaluative methodologies are weak. As well as being the quickest way to develop a body of research evidence, the promotion of research partnerships between CAM and non-CAM groups is a good way of ensuring rigour and objectivity in research. The MRC also offers help to those interested in conducting CAM studies to assist in developing expertise in relevant research methods.

The development of workforce capacity in healthcare research is an important element of the NHS R&D Strategy. The NHS R&D Workforce Capacity Implementation Group has addressed research capacity development needs in a number of different professions and relevant disciplines, including the therapy professions. NHS R&D support for research capacity development ranges from research training courses and bursaries to high level awards for research leaders of the future and is being provided through a mix of regional and national

schemes. These are open to a wide range of professions including CAM practitioners. The Department will ensure that these opportunities are made more widely known to the CAM community.

We do not consider that separate University posts devoted to CAM research and teaching would be the most effective way ahead. Recommendations 34 and 37 state that CAM research should be carried out alongside high-quality conventional research, and we consider this integrated approach to be most effective. The Department will ask the NHS R&D Workforce Capacity Implementation Group to consider research capacity development needs in CAM.

36. We recommend that companies producing products used in CAM should invest more heavily in research and development (para 7.81).

The Government considers that, since CAM is a private-sector endeavour, it should take financial (and legal) responsibility for research and standardisation, safety and efficacy of its own products. In areas where product safety has not been scientifically established, or where the competent administration of a treatment could not be assured, the Department of Health or MRC or any other responsible funding body would be unable to support clinical trials without a great deal of costly preliminary work.

Information (Chapter 8)

38. We recommend that the NHS Centre for Reviews and Dissemination work with the Research Council for Complementary Medicine (RCCM), the UK Cochrane Centre, and the British Library to develop a comprehensive information source with the help of the Centralised Information Service for Complementary Medicine (CISCOM) database, in order to provide comprehensive and publicly available information sources on CAM research, and that resources be made available to enable these organisations to do so (para 8.21).

As stated earlier, the Government expects the National Electronic Library for Health and NHS Direct Online to be the main conduits through which information on the most authoritative CAM research is made more widely available.

In common with findings elsewhere in this report, the Government is more concerned to identify the soundest CAM research findings than to bring all existing research findings together into a single database. Both the Cochrane Library and the Database of Abstracts of Reviews of Effectiveness (complied by the Centre for Reviews and Dissemination (CRD)) contain references to research on complementary medicine. These databases are available online to practitioners, the NHS and the public. The CRD also provides an enquiry service for those who are interested in undertaking systematic reviews of research. Additionally the CRD is charged with maintaining external links including the necessary networking with other review organisations, the Department of Health and MRC to ensure good communication, prevent duplication of effort and to explore opportunities for co-operation.

International initiatives also provide useful sources of information. The National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health in the USA (NIH) is dedicated to exploring complementary and alternative healing practices in the context of rigorous science; training CAM researchers; and disseminating authoritative information. They have

recently launched a complementary component to their website with a database of over 220,000 abstracts, reference and articles.

The Department of Health will initiate discussions with the CRD about this recommendation although any resultant proposals requiring additional resourcing will need to be considered alongside other priorities for research and development.

- 39.Consequently we support the plans of the Department of Health to make information on CAM available through NHS Direct, and we urge that they be carried out in the very near future. We recommend that the information should contain not only contact details of the relevant bodies and a list of NHS provision of CAM in each local area, but also some guidance to help patients (and their doctors) evaluate different CAM therapies (para 8.31).
- 40. We are aware that the National electronic Health Library and NHS Direct Online plan to have information available about CAM in the future and we support these plans and recommend that they are carried forward (para 8.48).

There are plans for NHS Direct Online to issue a feature on complementary medicine in the near future. The exact content of this feature has yet to be determined, but the possibility of including electronic links to reliable sources of more detailed information will be considered. The NHS will, over time, develop local information services which will include details of registered practitioners and clinics. In due course the National Electronic Library for Health and NHS Direct Online will also signpost statutory registers of healthcare practitioners, including statutorily registered CAM practitioners.

To complement this work, the Department has also commissioned the Foundation for Integrated Medicine to produce an information leaflet for patients and the public, and provide supporting electronic information.

41. We recommend that CAM regulatory bodies, whether statutory or voluntary, remind their members of the laws concerning false claims in advertisements and take disciplinary action against anyone who breaks them. Information leaflets produced by such bodies should provide evidence-based information about a therapy aimed at informing patients, and should not be aimed at selling therapies to patients (para 8.57).

The Government sees CAM regulatory bodies as the main source of expert advice to their practitioners, and of objective information to patients.

Legal action can be taken under consumer legislation against practitioners who make blatantly unjustifiable claims for their therapy. However it would be better if their professions set guidelines that helped avoid such action. The Government therefore urges CAM regulatory bodies to be active in ensuring that their members recognise and adhere to codes of conduct that provide proper safeguards for their patients and their profession.

Delivery (Chapter 9)

42. We recommend that those practising privately-accessed CAM therapies should work towards integration between CAM and conventional medicine, and CAM therapists should encourage patients with conditions that have not been previously discussed with a medical practitioner to see their GP. We also urge CAM practitioners and GPs to keep an open mind about each

other's ability to help their patients, to make patients feel comfortable about integrating their healthcare provision and to exchange information about treatment programmes and their perceptions of the healthcare needs of patients (para 9.20).

The Government agrees that there is scope for closer integration of CAM and conventional medicine. This is in the interests of all relevant disciplines and, above all, in the interests of their patients.

- 43. We recommend that all NHS provision of CAM should continue to be through GP referral (or by referral from doctors or other healthcare professionals working in primary, secondary or tertiary care) (para 9.37).
- 44. We recommend that only those CAM therapies which are statutory regulated, or have a powerful mechanism of voluntary self-regulation, should be made available, by reference from doctors and other healthcare professionals working in primary, secondary or tertiary care, on the NHS (para 9.46).

The Government supports these recommendations. The Government agrees with the need for strong evidence beyond the placebo effect for therapies in Groups 1 and 3 and the practise of effective professional self-regulation to the standards recommended in *Supporting Doctors, Protecting Patients* to support any use of therapies on the NHS. However, even when these two conditions are met, it must be for the NHS clinician or healthcare practitioner with lead clinical responsibility for the individual patient to judge whether, when and how the patient could benefit from the use of a particular therapy.



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