

**A BRIEF HISTORY OF THE CURRENT GOVERNMENT DIRECTIVES FOR
REGULATION OF COMPLEMENTARY ALTERNATIVE MEDICINE
(CAM)**

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In all areas of public life the dragnet of government regulation trawls nearer and draws tighter. In a litigious society, where accountability, demand for service and insufficient funding confuse and threaten the NHS, even complementary and alternative medicine (CAM) is now targeted. This is because the public are voting with their feet, and using and benefiting from it. There are considerations of cost effectiveness that have impelled the government to accept its eventual and inevitable inclusion into the NHS.

However, the government operates within a western paradigm of scientific thinking, and finds it very difficult to rationalise payment for therapies that have no apparent scientific basis. Therefore it is seeking to filter and redefine these therapies within a contemporaneous scientific paradigm, even to the extent of admitting the effectiveness of the placebo effect.

At the heart of this new ferment of activity, is the **6th Report of 21st November 2000** of the **Select Committee** appointed to consider **Science and Technology** (Select Committee on Science and Technology, 2000). In its summary of the criteria for regulation of CAM, it emphasised the need for evidence-based practice, research and adequate training. It also accentuated the fact that CAM therapies are '*based on theories about their mode of action that are not congruent with current scientific knowledge*'. While acknowledging that there was some evidence base for some

'efficacy in treatment of a limited range of ailments' by osteopathy, chiropractic and herbalism, the report expressed scepticism about the modes of action of most other CAM therapies. This desire to only endorse CAM that has some scientific basis is encapsulated in the statement:

'we therefore emphasise that in recommending the regulation of training in CAM, we specifically exclude training in the asserted modes of action of many CAM therapies. We do so because regulation could lead to a misleading public perception of improved status. Such regulation is in fact an attempt to safeguard the public.'

It is obvious from this statement that the official government view is to regard alternative paradigms as heretical and unsafe, and dangerous to the public mind-set, and it is anxious to distance itself from any training in, for example, 'ki projection' or 'hara diagnosis' or 'yin and yang organs.' The report stated that *'only a concerted partnership between higher education institutions and properly regulated professions as validating bodies will ensure that CAM practitioners are well trained.'* This statement paved the way for approval and increased status for CAM courses sponsored by universities and colleges of further education. The report recommended pump-priming research funding for certain therapies, to help them build on their evidence base. This funding would be distributed through the NHS, R&D Directorate. The report recommended that randomised controlled trials (RCTs) should be the favoured research technique.

In order to be selective about those therapies that would be worth supporting, the report categorised the various CAM therapies into 3 groups, according to their current evidence base and research potential. Group 1, which was recommended for support by the majority of the pump-priming research funding, consisted of the following

therapies: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy. These therapies were also recommended for statutory regulation, as they are more invasive and potentially harmful. Group 2, which was recommended for a small amount of research funding, subject to preliminary studies, before any large scale studies were approved, and a system of voluntary self-regulation, consisted of the following: Alexander technique, aromatherapy, Bach, massage and body work, counselling, hypnotherapy, meditation, reflexology, Shiatsu, healing, ayurvedic medicine(TM) nutritional, yoga. Group 3 consisted of those therapies that were considered to have no research base, and consist of: anthroposophical, ayurvedic, chinese herbal, eastern meditation, naturopathy, traditional chinese, crystal therapy, dowsing, iridology, kinesiology and radionics.

The report recommended that access to CAM should be through GP referral, or from other healthcare professionals within NHS primary, secondary or tertiary care. It recognised a reversing trend towards provision of CAM due to the need to equalise access. Previously GP practice could support CAM by using savings and 12% of practices, prior to 1995, did this. However, as GP practices became part of PCGs (primary care groups), new factors affected provision of care, including information on effectiveness and cost effectiveness, knowledge of accreditation procedures and standards, wider resource implications of decisions. It was seen that there was a need for doctors and healthcare professionals to be aware of CAM availability and to advise on existing evidence. This need for 'informed advice' and 'informed consent' underpins professional codes of conduct in the health professions, and therefore requires a strong and accessible evidence base for CAM.

It was predicted that CAM may come under the auspices of the Health Improvement Programmes (HIMPs) which can constitute long-term service arrangements. The GP would provide gate-keeper access to these programmes, and would need to be sure that any CAM contribution to the programmes were safe and effective and cost effective. Therefore CAM would need to communicate within a multi-disciplinary framework, and provide evidence of safety and efficiency.

One question considered in the report was what level of evidence was needed to justify CAM on the NHS. Various members of the Committee considered this. The Royal London Homeopathic Hospital suggested that it may be necessary to introduce new CAM therapies, even though they have a weak evidence base, in order to facilitate research base development: *'systematically appraising the evidence and emerging evidence.'* They suggested that the National Institute for Clinical Excellence (NICE) should take a lead in such appraisals. *'Where an appraisal is promising, yet sufficient evidence is not available, supporting further research and development work'*. It suggested research into cost effectiveness of CAMs as there was already evidence that integrated healthcare could be cheaper.

The report indicated that there might be a problem in trying to subsume the best of CAM therapy into a western scientific paradigm, as this could leave much of what CAM sees as important (its philosophy) out in the cold. *'Witnesses have suggested that there is a non-pragmatic, deep seated prejudice held by some members of the conventional scientific establishment against the entire CAM field and its philosophy'*. The report suggested that the opposite is also true. It writes *'the different philosophical approaches may make it hard to design trials with methods that are*

acceptable to both conventional and CAM practitioners '. However, it discusses in Chapter 7, development of various novel methods that would be acceptable to conventional science and take into account concerns of both paradigms.

Most importantly the committee considered the placebo effect, postulating: *'it could even be suggested that the placebo effect is a legitimate form of psychotherapy.'* And *'in addition, there is increasing evidence of a neuroeffector mechanism (mind over matter) which can influence significantly the immune system.'* *'In drug action trials, there are sometimes even difficulties in differentiating placebos from the active agents they are being compared with., several studies have shown parallel time-effect curves and dose-response relationships* ' *'Despite a lack of understanding of the exact mechanisms through which the placebo effect may operate, research clearly shows that the effect exists and can have a significant effect on health. This work has important implications for anyone who has identified a therapy which appears to be efficacious but which does not have a clearly identified mode of action and it is important that all research on such therapies takes account of the placebo effect.'*

However, the report emphasised that *'the idea that the placebo effect might be something worth using as a treatment was not a majority opinion'* Professor Timothy Shallice of the Academy of Medical Sciences suggested that there was probably little justification for supporting the wider advocacy of any technique that relies on the placebo effect within the NHS, *'since it depends so critically on the particular beliefs of that particular person at that particular time.'* Professor Lewis Wolpert of the Academy of Medical Sciences asserted *'medicine aims to base itself upon science. I*

am sorry that any complementary alternative medicine procedure for which one can see no reasonable scientific basis should be supported.'

One of the recommendations in the conclusion of the report was:

“that CAM should attempt to build up an evidence base with the same rigour as is required of conventional medicine, using both randomised controlled trials (RCTs) and other research designs which we discuss (see paras 7.10-7.30).”

The outcome of this lengthy report, has been the development of the PFIH (The Prince's Foundation for Integrated Health) regulation programme and its funding by the Department of Health, to facilitate statutory regulation of group 1 CAM therapies, and voluntary self-regulation of group 2 therapies. Group 1 therapies have almost completed their process, and group 2, including Shiatsu, are now in progress.

The Shiatsu Regulatory Group (SRG) is the group set up and constituted to prepare the whole Shiatsu profession in U.K. for regulation, and is now officially part of the PFIH programme working towards this goal. It comprises a committee composed of representatives from a number of different Shiatsu associations and organisations representing Shiatsu practitioners. The Shiatsu Society is represented by three members, including a director, on this committee.

The Shiatsu Society participated in the recent PFIH consultation concerning the federalist model of voluntary self-regulation, proposed by Professor Julie Stone, following a study commissioned by the PFIH. The General Shiatsu Council and a

few individual members also responded. All these responses were taken into account in the final analysis.

The results of the consultation, prepared and presented by Abi Masterson of Abigail Masterson Consulting Ltd., showed a majority in favour of a voluntary federal regulatory body for complementary healthcare professions. 83 professional associations responded, and there were also individual practitioner responses from the 12 main therapies involved in the PFIH programme:

Alexander Technique,

Aromatherapy

Bowen Technique

Cranial Sacral Therapy

Homeopathy

Massage Therapy

Naturopathy

Nutritional Therapy

Reflexology

Yoga Therapy

Reiki

Shiatsu.

Two therapies, however, were not in favour of the proposals for a voluntary federal regulator. These were Homeopathy and Alexander Technique.

There was a strong recommendation from the professional associations for working in partnership with the regulator. A high percentage of the responses outlined the need for strong professional associations working in partnership with a strong regulator, and non-duplication of roles, requiring a two-tiered system.

The feasibility study, prepared by Maggie Wallace, explored a number of models, out of which only 2 met the criteria for the federal approach to regulation:

The model described in the consultation document ,

The Ontario Model.

The former model requires a larger and representative council with many subcommittees. The latter model requires a leaner, more stream-lined central council, which is not representative, but with specific professional boards advising it. This Ontario model could be a good model for the 2-tier system.

Kim Lavelly, the Chief -Executive of the PFIH, presented her schedule 'Next Steps' for the next year, following this consultation and feasibility study. The schedule she outlined was based on the clear mandate for the federal approach for complementary healthcare regulation, and aims to explore the two identified approaches through a working group. The working group has now been established, and will meet monthly until Sept 07. The report of their decisions will be published in October 07. The PFIH has committed to prepare budget, terms of reference and scope of the regulator, recruitment of chair and lay members, identify secretariat and provide project management. It will also explore funding options and liase with the Department of Health with regard to reprioritisation.

The working group represents all the professions involved in the PFIH regulation programme and each profession has delegated one representative and one alternate representative, to ensure that they are always represented at every meeting. Each profession has committed to set up a mechanism for representatives to communicate with the members. It is anticipated by the PFIH that a regulatory body for

complementary healthcare can be established within two years, which will be able to accommodate a range of professions, both large and small. The PFIH is facilitating the development and inclusion of many of these professions, by providing the support for uniting the individual therapy associations under the banner of their own representative regulatory groups. Many of the groups already have common standards of professional practice and training, based on National Occupational Standards. These provide codes of practice and competency common to all the professions, and identify those that are individual to the specific disciplines. A similar process facilitated the establishment of the Health Professions Council as a regulator for the various medical health professions.

Two new reports have been published, furthering the debate and requirements for regulation: the Donaldson Report ('Good Doctors, Safer Patients') and the Foster Report on the regulation of non-medical healthcare professions, (government publications, 2006.) Also, the National Institute for Health and Clinical Excellence, (NICE) has been commissioned to undertake a new programme of work to help the NHS identify and stop ineffective interventions. The new reports advise on limiting the number of regulators and standardisation. They urge a requirement to record post-registration qualifications and standardise pre-employment English language testing, and require a Lay majority in regulation governing bodies. There are proposals for a 'spectrum of revalidation' across all the healthcare professions. The emphasis is on CPD (continuing professional development) and NOS (National Occupational standards) and appropriate standards of proof and public representation. It is advocated that some elected members of regulatory bodies be replaced by appointed

professional members, and that patient feedback should be a component of assessment for non-medical healthcare, and should take place every few years.

New rules for the regulation and registration of homeopathic products has been instituted via the Medicine and Healthcare Products Regulatory Agency (MHRA). New rules state that a product may be registered if its traditional use is long-established. The first product to be registered has been Arnica gel (New Scientist, 2006).

In conclusion, it may be appreciated from this sketch of the government directed overview of CAM regulation, that there are some key areas for Shiatsu to consider:

- Research: providing an evidence base using RCTs (randomised controlled trials) among other models.
- Cross-referencing of paradigms: communicating effectively within a paradigm with reference to another; intellectual development, understanding Western science.
- CPD: a framework for post graduate studies, and recording progress.
- NOS: a consideration of what criteria in Shiatsu training can be framed within the generic NHS, health-care related occupational standards.
- Liason with Universities and Colleges of Further Education.
- Interdisciplinary working: training needs to support the awareness of NHS work, the work of other health-care professions, allopathic medicine and effective communication within a team.

- Training in ‘evidence-based’ practice and scientific techniques: use of research awareness as part of the curriculum.

If the Shiatsu profession is willing and able to take all this on board, then it will be plain sailing into a streamlined future and a free-flowing partnership in the health of the nation.

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