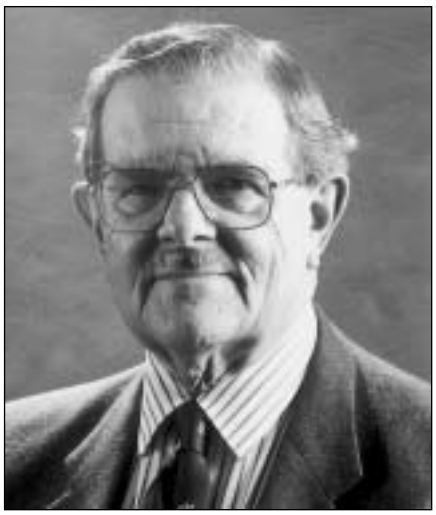
MEETING OF THE PARLIAMENTARY AND SCIENTIFIC COMMITTEE ON MONDAY 17TH OCTOBER 2005

Some 40 per cent of GPs recommend CAM therapies to their patients – indeed, 20 per cent offer them on their premises. Although many doctors accept that CAM has much to offer their patients, others are not so sympathetic. Nevertheless CAM is increasing in popularity with many patients who claim to have benefited. Is the evidence base for the efficacy of any of the twenty-five recognised CAM therapies good enough to justify the taxpayer paying for this treatment as part of the NHS?

Complementary and Alternative Medicine – should it be provided on the NHS?



Lord Walton of Detchant

For ten years I served as a Member of the House of Lords Select Committee on Science and Technology, and chaired three Sub-Committee Enquiries, producing Reports which were accepted by the parent Committee and eventually debated in the House. The last enquiry which I chaired was into Complementary and Alternative Medicine (CAM). To assist the enquiry, two specialist advisors were nominated, namely Professor Stephen Holgate, who will speak later, and Professor Simon Mills, Director of the Centre for Complementary Health Studies at the University of Exeter.

Our first task was to try to achieve a definition of terms. We concluded that alternative medicine normally refers to a number of professions or disciplines which claim to offer systems of diagnosis, prognosis or management using approaches different from those employed in conventional Western medicine.

Complementary medicine we accepted as embracing a number of other professions or disciplines which do not usually offer diagnostic information, but which are more often used to complement the treatment offered by conventional medical practitioners. We broadly accepted the definition provided by the Cochrane Collaboration as "A broad domain of healing resources that encompasses all health systems, modalities and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health systems of a particular society or culture in a given historical period."

Having issued a public call for evidence, we received 185 written submissions, and held 21 oral hearings, interviewing 44 representatives of many organisations in the conventional medical field, in science and in CAM. Several individuals also gave oral evidence. One witness was Dr Stephen Straus, Director of the Office of Complementary and Alternative Medicine in the USA, an organisation funded by the National Institutes of Health in order to undertake research in CAM. In our enquiry we were not primarily concerned with efficacy, but were required to consider evidence, regulation, training and education, research and development, information availability and the delivery of CAM, including the question as to whether it should be provided by the NHS.

It soon became clear that the uptake of CAM in the UK had increased steadily. More than 15% of people in the UK had consulted CAM practitioners and more than 30% had bought over-the-counter remedies used in CAM, with a total annual expenditure approximating to £1.6 billion. In the USA expenditure was estimated at some US$27 billion.

Eventually, we classified the CAM professions and disciplines into three groups. In the first group were those known as "the big five", namely osteopathy, chiropractic, herbal medicine, acupuncture and homeopathy. The professions of osteopathy and chiropractic are individually regulated by Acts of Parlament. Herbal practitioners in the UK are also to some extent a cohesive group, who have developed a powerful method of voluntary self-regulation and who subscribe to scientific principles. Very many powerful drugs in common used in Western medicine are of herbal origin. We also learned that, through the British Acupuncture Registration Board, practitioners using acupuncture,

some of whom are doctors and nurses but many of whom hold no other professional qualification, had begun to develop a mechanism of self-regulation. There is good physiological evidence to show that acupuncture can induce an increased output of endorphins (the body's own analgesics) from the central nervous system. We also included homeopathy, a long-established method of diagnosis and treatment used in the UK by many medical practitioners, but also by non-medical homeopaths, in Category 1.

In our Category 2 we included disciplines such as aromatherapy, massage, counselling, reflexology, shiatsu, hypnotherapy, meditation and different varieties of healing. We found that these disciplines were complementary in being used, generally, but not invariably, to complement conventional medical treatment.

Category 3 gave us the greatest difficulty. In Category 3a we included ancient Chinese medicine and Ayurvedic medicine; we were concerned by some principles employed in Chinese acupuncture and Chinese herbal medicine, not least because the large combinations of herbs, widely used in both ancient Chinese medicine and, to a lesser extent, in Ayurvedic medicine, have sometimes included harmful components such as aristolochia, which can cause serious renal damage, while some preparations also contain combinations of heavy metals which may be deleterious. We also feel that many of the concepts upon which these disciplines rely (the elements, ying and yang and the five doshas, for example) which date from antiquity, are totally outdated. We therefore classified them in Category 3a, implying that, when practised according to traditional concepts, they seemed to us to lack validity. Nevertheless, we discovered later that some practitioners of ancient Chinese medicine and many of Ayurvedic Medicine take part in scientifically valid research, exploring the value of individual herbal preparations as distinct from massive combinations. In Category 3b we classified several disciplines for which we could find no credible supportive evidence, including crystal therapy, radionics, dousing and kinesiology.

While much evidence we received stressed, very properly, the role of the therapist and of the placebo response, which has been shown, in conventional medicine, to have profound effects upon many bodily organs and especially upon the body's immune system, we did receive evidence to indicate that several of the CAM disciplines, especially those in our group 1, do have specific effects which could not be wholly accounted for by the placebo response. We also noted that many alternative and complementary practitioners were able to offer much more time for consultations than can busy doctors. The Cochrane Collaboration reviewed 154 trials, 40% of which revealed some benefit. The recent Smallwood Report felt that CAM in the NHS would be cost-effective, a point disputed by Ernst and his colleagues in a recent paper in the British Medical Journal.

Accepting that the practice of osteopathy and chiropractic is controlled by Acts of Parlament, we recommended that herbal medicine and acupuncture should seek for statutory regulation under the Health Act 1999, alongside other healthcare professions; we took the view that this might become possible for homeopathy, once differences of opinions and practice, as between medically qualified homeopaths and those without medical qualifications, are resolved. We also recommended that the many organisations representing the disciplines in Category 2 should seek to develop a system of rigorous voluntary self-regulation for each , with a view perhaps ultimately to becoming registered by Statute.

In relation to education and training, we recommended that each profession should define a core curriculum including elements of anatomy, physiology and clinical medicine, as well as statistics and the accumulation and analysis of evidence. We felt it imporrtant that conventional medical practitioners, nurses and others working in the healthcare field should develop some understanding of the CAM disciplnies so as to be aware of the principles underlying the systems which many of their patients may consult. We also recommended simple familiarisation courses for undergraduate medical students.

We also discussed the crucial importance of randomised controlled trials, sequential trials and many other research techniques designed to collect evidence on the validity and efficacy of the various CAM disciplines, with particular reference to being able to demonstrate which had effects superior to placebo. We also recommended the establishment of Centres of Excellence in UK universities, where CAM practitioners could undertake research programmes in collaboration with scientists, doctors and others already well versed in research techniques. We were pleased to note that the NHS R&D organisation has now supported several such research projects in the CAM field. We also considered mechanisms by which high quality information about CAM could be made available, not only to the public, but also to healthcare professionals, and recommended that NHS Direct might be a useful source of information. We also recommended that health authorities should work with representatives of the well-regulated CAM professions to produce information about well-qualified CAM practitioners in their respective areas and regions.

Finally, in relation to the provision of CAM in the NHS, we recommended that primary care groups and trusts should be willing, in appropriate circumstances, to fund consultations and treatment using well-established, well-regulated and well-founded CAM methods, but that all such consultations paid for by public funds (ie through the NHS) should be by referral from doctors or other healthcare professionals, working in primary, secondary or tertiary care. Our Report was accepted without significant modification by the parent Committee, and was debated in the House of Lords early in 2001. Our recommendations were accepted, virtually entirely, by the Government. I and all those who served on the enquiry look forward to seeing whether, how and when our recommendations will be implemented.

Integrated Health Care; What can be learned from Complementary and Alternative Medicine

Professor Stephen Holgate, Medical Research Council Clinical Professor of Immunopharmacology, University of Southampton

The House of Lords report on complementary and alternative medicine (CAM) published in 2002 has led to the wider recognition of complementary approaches for the delivery of health care with improvements both in regulation and in research. However, the recent Smallwood Report "The Role of Complementary and Alternative Medicine in the NHS" and recent articles in the premier medical journals have once again brought this field of medicine to the forefront. It is, therefore, worth exploring some of the issues that fuel this debate.

Features of Conventional Medicine and CAM

Practitioners of CAM often say that they do things differently and have a special connection with the patient (or client). The Parliamentary Select Committee on Science and Technology that reported on complementary and alternative medicine in 2002 stated *"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"*. However, in a recent editorial in the Lancet[1], Vandenbroucke commenting on continued controversy over the use of homeopathy and the growth of truth quoted William Osler in his Harvean Oration of 1906 *"Truth may suffer all the hazards incident to generation and gestation….. all scientific truth is conditioned by the state of knowledge at the time of its announcement"*. There are clearly some fundamental differences in the way that orthodox and complementary medicine deliver their practice. Orthodox medicine is focused on specific disease causation, is divided into specialties and delivers treatment specific to the diseased organ(s) (one disease, one target, one cure). In contrast, CAM addresses distributed cause, is not divided into specialties and treats the whole person with multiple therapies that are not necessarily disease-dependant.

It is increasingly recognised that there are some problems which currently afflict conventional medical practice. These include the management of chronic disease and pain and unexplained symptoms eg chronic fatigue syndrome; being able to take full account of changing behaviour eg housing, diet, stress and life style; patients sense of fragmentation, disempowerment and dehumanisation; concerns about drug side effects and the cost of adverse events and a lack of time for communication between patients and health care professionals. Thus a legitimate question to be asked is whether CAM represents a signpost for modern medicine's missing elements.

The Prince of Wales' Foundation for Integrated Health defines integrated healthcare as incorporating integrated medicine as its core component, but is a broader concept that goes beyond the treatment of illness to emphasise the importance of improving health and wellbeing, views the living person as more than a collection of molecules, cells and organs which may or may not be working properly and sees the human as an integrated self-correcting whole. Thus it views good health not simply as the absence of illness, but as a self regulating state that involves interacting complex systems. Professor Michael Hyland, a psychologist from the University of Plymouth, views health as a complex system in which parts form wholes, with everything being interconnected and the whole behaviour not being predictable from the behaviour of the individual parts[2]. As a consequence new properties of the component parts and the whole system emerge. He states that changing a part will lead to a change in the whole and that changing the whole will lead to the part changing. Based on this health concept represents the behaviour of the whole system which has the capacity to self- organise and adapt to constant change. Integrated health care is directed towards supporting this adaptation. Hyland emphasises the important of networks with the brain at the centre of a self-regulating, self-organising pattern recognition system that is intimately connected to immune and endocrine systems functions. Two types of error in this complex system may lead to human disease. The first is an organic error leading to abnormalities in sequential processing involving molecules, cells and organs and against which conventional treatments operate. The second is to an information error which is more closely linked with alterations in lifestyle and involves network processing and an imbalance against which CAM is directed.

The Role of Specific and Non-Specific Treatment Effects

It is stated by some that the placebo or dummy treatment effect underlies much of the therapeutic benefit that patients experience with medical intervention and that this non-specific (incidental or placebo) effect differentiates CAM from orthodox medicine. In conventional randomised placebo controlled trials (RCT) designed to investigate a specific therapeutic intervention, the placebo effect is also often large and not infrequently exceeds 50% of the total treatment response eg analgesia and depression. In RCTs the placebo is subtracted to isolate the specific therapeutic response of the actual intervention (efficacy). Thus, the components of therapeutic response comprise the sum of the specific effect (efficacy) and the non-specific effect (placebo). In the "real world" the therapeutic response (or effectiveness) of a treatment equals the sum of efficacy and placebo. With different forms of therapy the relative contributions of the specific and non-specific responses will differ. In seeking to characterise the incidental or placebo effects in complex interventions used in CAM such as acupuncture Patterson and Dieppe[3] made the following four points:

1. The RCT developed to test new drugs is based on bio-medical assumptions alone.
2. In a drug trial talking and listening to patients are often defined as incidental (placebo) factors separate from the drug effect.
3. In CAM interventions the characteristic and incidental factors are intertwined.
4. Use of placebo or sham controlled trial designs for complex interventions may lead to false negative results.

This publication led to an extensive debate in the British Medical Journal correspondence column with a wide range of views being expressed about the relative importance of non-specific responses with different types of treatment. Possible factors that make up the placebo effect include improved adherence to concomitant treatments, Pavlovian conditioning, expectation and a physical (or "organic") response. Use of functional brain imaging such as PET, MRI and SRI has now demonstrated that placebos can indeed mimic drugs in activating the same brain areas as some specific treatments eg in Parkinson's disease, pain relief, depression and the use of stimulants[4]. These findings greatly enrich the debate regarding the relative benefits of specific and non-specific treatment responses.

It is now known that sustained pain results in the release of endogenous opioides that stimulate opioide mu receptors in cortical and subcortical regions of the brain, and that activation of these receptors reduces sensory and affective ratings of the pain experience[5]. By applying functional magnetic resonance imaging (fMRI) of the brain, placebo analgesia decreases activation in the pain sensitive regions – the thalamus, insula and anterior cingulate cortex. The placebo also increases fMRI activity in the prefrontal cortex during anticipation of pain. Of great interest was the finding that both placebo induced analgesia and altered perception of pain were effectively blocked by naloxone an opioid receptor antagonist.

Implications for CAM

The recent study investigating the effect of acupuncture on pain in osteoarthritis has revealed 12% specific effect versus a more than 30% placebo effect. Based on findings described above expectancy and belief could modulate the therapeutic response of pain relief by acupuncture. In a trial of patients with osteoarthritis, Pariente et al[6] undertook PET scans of the brain (that reflect local blood flow) before and after "real" acupuncture, Steitberger needle placebo and sham placebo (skin prick distant from the acupuncture point). They demonstrated that the various treatments each gave increased brain PET signals in the right prefrontal cortex, anterior singular cortex and thalamus the treatment order effect being real acupuncture > Steitberger placebo >> sham placebo. These findings reinforce the view that real acupuncture has both a specific effect on the pain centres in the brain but also a non-specific effect also via the brain's reward system. Thus, at least in the case of pain relief, active treatment and different types of placebo may have effects on the brain that may truly complement each other. This might indicate that every effort should be made to enhance the non-specific effects of a treatment eg by practitioner interaction and the health care setting and, by doing so, this can add to or enhance the effect of a specific treatment. The fact that CAM is conducted in a way that maximises the non-specific response may help account for a substantial portion of the treatment effect beyond any specific action, and that in conventional medicine insufficient attention is given to this aspect of health care in focusing only on unitary solutions in the form of drugs or surgery.

The challenge of integrated health care

Recognising that the human organism is a complex system, it is apparent that each level of the system speaks a "different language" and yet communicates continually, the levels being entangled and self organising[2]. Integrated health care that interacts with this complex system entails more than simply combining conventional with complementary approaches. It emphasises health promotion, self-care and patient practitioner partnership. It aims to trigger, support or remove constraints on the ability of the mind and body to heal itself and it sees the humanisation of health care as a central issue. There is already ample evidence that when doctors use communication skills effectively, their patients and they benefit. Integrated health care means not using reductionist approaches alone, but being aware and understanding the importance of body intelligence and the impact of the lived experience, triggering adaptation and self healing processes, tailoring treatment to individual needs and circumstances, optimising the human factor, encouraging participation and empowerment. Thus, such whole person care requires practitioners who utilise both the science and the art of medicine.

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Integrated Healthcare for better Health and Happiness

David Tredinnick MP

I am honoured to address this audience and follow on after two such illustrious speakers and with all the Doctors in the House of Commons present. I have been involved with Complementary Medicine for 30 years. I fell off a horse in 1976 and then had to turn to Chiropractors and Osteopaths to help straighten out my spine. Subsequently my wife had allergies and headaches, resulting in visits to Jean Munro in Hemel Hempstead for treatment and she has never had a headache since. Homeopathy has helped my family with treatment for asthma, colds, and I have had crippling pain that has been successfully treated using acupuncture, that is the one component of Chinese Medicine listed in the first category in the House of Lords report. Our group, the All-Party Parliamentary Group for Integrated and Complementary Healthcare has two objectives:

1) to bring Complementary practitioners together and

2) briefing Members of Parliament on the benefits of Complementary Medicine.

When the Government changed from Conservative to Labour I changed strategy and have taken every opportunity to question the Health Minister on Complementary Medicine at every single Health Questions in order to get the matter up in lights. According to Tony Benn, "first they say you are mad, then they agree with you, then they want to own the idea." This resulted in me being dubbed "the Member for Holland and Barrett". Ironically their headquarters are in my constituency.

This talk focuses on the past, present and future for Complementary Medicine. There has been an exponential growth in demand for Complementary Medicine to the extent that half of the population have now had some experience of it. People are not fools and tend to buy things that work. The first major attempt to improve CAM acceptance and regulation was in the 1987 Parliament. In the 1992 Parliament the two Private Members Bills on Osteopaths and Chiropractors both became law, bringing them into mainstream medicine with the establishment of regulatory bodies. The next stage was the House of Lords report in 2002 with definable categories. I would disagree with some of the categories, but overall it was a brilliant piece of work that gave us a benchmark to work around. There are some out there that say that some of the categories are wrong. I don't see personally that you can claim that Chinese Medicine that has been around for 2,000 years should be divided into two different categories. With 60,000 hospitals in China delivering Chinese Medicine perhaps these methods delivered over 2,000 years have some credibility? On some of the zanier treatments, ignoring Crystal Therapy which we are not going to discuss further this evening, I would say that 20 years ago, what is now seen as mainstream Complementary Medicine was then seen as wacky and off-the-wall. I put it to this distinguished Committee that they should bear in mind that things do change and that it is possible that some of these treatments that have not been given much credibility may in the end turn out to be quite helpful.

Where are we now in the political world? There have been some very important developments; first of all the Government has brought in practice-based permission for healthcare which means that doctors now have almost got their GP Fundholders status back that the Conservatives brought in. It

is giving them more purchasing power and the ability to choose where and what services they buy. I understand that 50 per cent of GP practices are now using Complementary Therapy to some extent and that there will be a huge increase in demand through these practices.

The second interesting development will be the third major change, namely Stephen Smallwood's report which is very helpful as it identifies the so-called effectiveness gap in the health service where there is not enough treatment available. In the past the Complementary Therapies were given the really hopeless patients that doctors call privately the "heart-sink patients". They are the ones that were farmed out to the Complementary Therapists. Amazingly, about 75% of heart-sink patients get relief in the Complementary Medical sector.

Now we have these clearly identified effectiveness gaps which is jargon for saying that there is not enough treatment around for back pain, knees or stress and nausea. What is now needed is for these to be linked up with Complementary Therapies and the recommendation that the National Institute for Clinical Excellence (NICE) performs further studies on this is welcomed. But what has not been picked up from the Smallwood report is that it also stated that Complementary Medicine is more effective than Mainstream Medicine.

So what about the future? Are Complementary Medicine and Integrated Healthcare here to stay? The whole thrust is towards better regulation, awareness and knowledge.

Regulation of acupuncture and herbal medicine is now almost complete. There are many clinics nationwide with useful research studies, such as the Glastonbury Clinic the Get Well UK Clinic in Camden that offers advice to doctors by helping them to find suitable Complementary Practitioners.

I would like to finish by emphasising that the risks of Complementary Medicine are overemphasised, especially since there are many cases in Mainstream Medicine where the use of drugs such as aspirin can cause death, and even travelling around by London transport is not risk-free.

There are 50,000 Complementary Therapists and huge gaps in our National Health Service. Let us have better regulation and interfaces with our doctors. This is a hugely exciting time and if we go down the route of Integrated Healthcare we will have a healthier and happier population.

In discussion the following points were made:

Variations in genotype affect the sensitivity and responses to both the placebo and to conventional and integrated medical therapies and the whole genome should be considered when treating chronic fatigue syndrome. Medical approaches to disorders of the prostate in the UK differs from those in the EU where herbal medicines are the treatment of choice and which have also been successfully used to extend longevity. The increase in conventional medical treatments has also grown enormously starting from a very restricted base in the early days. Intercomparisons between integrated and conventional medicine therefore should be continually updated. Integrated medicine emphasises the importance of the individual, in preference to the general application of a more conventional medical system. Delivery of the latter may be unduly constrained by a single, undifferentiated approach to population studies, based on systematic drug treatment hierarchies, with pressure on doctors to conform and subject to legal issues, with hospitals where pharmacists apply drug regimes based on external criteria, and doctors who don't know their patients. For example, pooling the results of research on asthma studies on 3 year olds with those of young adults is anti-science and provides unusable data. An open mind is needed, based on direct observation, resulting in various differing explanations.

The culture base for Chinese medicine is 2,000 years old which accounts for some of the differences from a more reductionist conventional medicine that tends to consider human health issues in isolation from one another. Nevertheless evidence is still needed for proper regulation of integrated medicine, to help inform sceptical doctors and to assess the science base for diagnostic procedures, using the pulse and tongue and therapies such as acupuncture for example. The human body needs to be put back together and considered holistically. Many modern treatments are based on ancient herbal remedies. For example, Indian scientists have recently provided scientific interpretations that support traditional Ayurvedic medicine that can also benefit from both placebo and and cultural effects. GPs can currently only afford 10 minutes per patient. How can this be extended to 45 minutes to match that of integrated therapists? The main benefits of medical research in the last 50 years have arisen from randomised, controlled trials and the production of high quality efficaceous medicines. In summary, don't subtract the placebo effect as it may be one of the benefits of integrated medicine, for example, thought alone may provoke change. Whole person medicine giving help and comfort to the patient should be provided by the NHS.