The Role of Complementary and Alternative Medicine in the NHS

An Investigation into the Potential Contribution of Mainstream Complementary Therapies to Healthcare in the UK

Led by Christopher Smallwood

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DISCLAIMER

AUTHORS OF THE REPORT

The report was produced by Christopher Smallwood, with the support of a consultancy team from FreshMinds.

About Christopher Smallwood

Christopher Smallwood is a leading economist who has held a wide range of senior positions in government, industry, banking and media.

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About FreshMinds

FreshMinds is an innovative, full-service, research consultancy who work with 30% of FTSE 100 companies. Established in September 2000, FreshMinds is one of the fastest growing research companies in the UK and works in multiple sectors. Public sector projects include work for the DTI, the Engineering and Technology Board, the Metropolitan Police, the Corporation of London and GCHQ. Private sector projects cover a variety of industries including financial services, retail, professional services, new media, health and manufacturing.

The FreshMinds team for this Enquiry was led by Claudia Brendel.

Foreword from the President of the General Medical Council

The achievements of orthodox medicine over the last few decades have been quite remarkable. No one can question the benefits that immunisation, antibiotics, hip replacements and organ transplantation have brought to millions of people world-wide. These advances, however, also highlight those conditions where progress has been slower, with patients increasingly seeking help from complementary and alternative therapies. In general these are chronic complaints in which patient, illness and complex psychosocial factors so interact as to make standard therapeutic guidelines difficult to devise. In these instances, the care must be truly "patient-centred": care that is respectful of and responsive to individual patient preferences, needs and values and ensuring that patient values guide all clinical decisions. While the case for this type of holistic approach is no longer controversial, few robust scientifically-reliable studies have been undertaken.

All clinicians must be aware that many patients are interested in and choose to use a range of alternative and complementary therapies. Those practising orthodox medicine must be aware of the existence and range of such therapies, why some patients use them, and how these might affect other types of treatment that patients are receiving. Increasingly, complementary and alternative options are offered alongside conventional treatment in general practice, palliative care and elsewhere. Although not all medicine can be evidence-based we must ensure that any treatment is in the patient's best interests, and continue to assess and evaluate clinical options.

This report, commissioned by the Prince of Wales, is a welcome addition to that debate. The aim of the Enquiry, to assess the extent to which complementary and alternative approaches might help the NHS meet patient needs cost-effectively, is an important and relevant issue to address. The report itself indicates areas both of potential benefit and of overlap with conventional approaches. The conclusions will not be acceptable to all but focus much needed attention on the substantial costs of duplicating treatments for chronic conditions for which effective treatment remains elusive. Evidence-based clinical guidelines depend on robust research, and I support the recommendation made here that NICE should carry out a full assessment of the cost-effectiveness of the therapies which the report identifies as most likely to help close "effectiveness gaps" in the current range of NHS provision .

This report indicates a practical way forward and deserves serious consideration as part of this important and continuing debate.

Professor Sir Graeme Catto

President of the General Medical Council

SUMMARY AND GUIDE TO THE REPORT

Commissioning of Report and Remit

This report was commissioned by the Prince of Wales, with the objective of taking a fresh and independent look – within a reasonable timescale – at the contribution which complementary therapies can potentially make to the delivery of healthcare in the UK.

Its genesis lay in two observations. The first was that there are serious medical conditions which can often not be successfully tackled by the types of treatment generally offered by the NHS – chronic musculoskeletal conditions and psychosocial conditions such as depression are examples of these – and which complementary therapies claim to be able to alleviate.[1] The second was that, in view of the huge scale of the resources soaked up in attempting to treat illnesses of this kind, the possibility existed that greater use of complementary therapies, to the extent they were effective, might result in cost savings for the NHS, enabling more health-care to be delivered within existing budgets.

The purpose of the Enquiry was therefore to examine evidence relating first to the effectiveness and then to the associated costs of mainstream complementary therapies, and to assess whether there are therapies available which could help to meet "effectiveness gaps" in the current provision of health-care by the NHS in cost-effective ways. Subsequent questions then relate to the best ways of making such therapies widely accessible through the NHS.

It is important to recognise that, in view of the limited timescale of the Enquiry which took place over a period of nine months, this is an initial study, undertaken with the objective of reaching prima facie rather than definitive conclusions, and indicating the principal areas where more detailed research is likely to be worthwhile.

Our main conclusion is that there appears to be sufficient evidence to suggest that some complementary therapies, listed in the report, may be more effective than conventional approaches in treating certain chronic and psychosocial conditions, and that specific treatments offer the possibility of cost savings, particularly where they can be provided in place of, rather than in addition to orthodox treatments.

Our principal recommendation therefore is that Health Ministers should invite the National Institute for Health and Clinical Excellence (NICE) to carry out a full assessment of the cost-effectiveness of the therapies which we have identified and their potential role within the NHS, in particular in relation to the closing of "effectiveness gaps".

The Approach of the Enquiry

The phrase "complementary and alternative medicines" encompasses a very wide range of treatments, and it would have been impossible to attempt to scrutinise them all in the time available. The scope of the Enquiry has therefore been restricted to the first of the three groups of therapies defined in the House of Lords Science and Technology Committee's Sixth Report, comprising, in the Report's words, those therapies which are "principal disciplines" and "professionally organised alternative therapies." These include acupuncture, homeopathy, chiropractic, osteopathy and herbal medicine. These treatments, as the report says, "claim to have an individual diagnostic approach and … are seen as the 'Big Five' by most of the CAM world".[2]

1 Complementary Medicine was defined as non-conventional treatments, such as chiropractic and osteopathy, used in conjunction with conventional treatments. Alternative medicine includes techniques used in place of conventional medicine. See BMA, 2003.

2 The second group comprises therapies such as the Alexander technique, aromatherapy and massage therapy, which do not claim diagnostic skills and are mostly used to complement conventional medicine. The third group includes therapies which "favour a philosophical approach and are indifferent to the scientific principles of conventional medicine", such as ancient Indian and traditional Chinese medicine.

An important initial objective of the Enquiry, therefore, was to summarise the current state of knowledge relating to the relative effectiveness of treatments within these therapies, and to review evidence about the costs of treatments in these areas so that they could be compared with the costs of conventional alternatives. A fundamental problem, however, is that the appropriateness of much of the research which has been carried out into CAM is disputed. The randomised control trials (RCTs) which constitute the gold standard for conventional medicine are often difficult to apply to many CAM remedies. This is due to a number of factors: the individualised nature of the treatments; the difficulty of identifying genuinely comparable cases, where people receive identical treatments in identical clinical circumstances, which is exacerbated by the holistic approach adopted by many therapists; and the difficulty of finding appropriate placebos in areas such as acupuncture and chiropractic, especially in attempting to conduct double-blinded trials where neither the practitioner nor the patient knows whether the treatment being given is genuine.

Conclusive proof of effectiveness is difficult enough in relation to conventional medicines in clinical settings, without the added difficulties of personalised diagnoses and interactive treatments which are characteristic of many CAM therapies. So it rapidly became clear that, given the degree of disagreement which exists in this area about research methodologies, definitive answers to the questions facing the Enquiry could not be established simply by reviewing the relevant literature. Instead, the Enquiry adopted a three-fold approach – approaching the questions we had been set from three different angles in the hope that in some respects the outcomes might prove to be mutually reinforcing, which in fact they did.

The Plan of the Report

The first stage of the study was a literature review (Report, pages 35 to 79), aimed at drawing overall conclusions about the costs and benefits associated with CAM treatments from existing research. For the reasons already explained this was necessarily an imperfect exercise, as it was clearly unrealistic for us to attempt to adjudicate on technical disputes about the validity of research undertaken. Instead, we adopted a pragmatic approach, including in our review articles dealing with both cost and benefit aspects of CAM treatments which have been published in leading journals such as the BMJ and The Lancet, and medical databases such as PubMed, and the British Library medical journal database, or receiving regular citations in respected journals. In addition, systematic reviews of articles were consulted, and meta-reviews of systematic reviews held by the NHS Centre for Review and Dissemination at York University. On this basis, we have sought to identify CAM treatment options where the weight of evidence suggests that treatments have beneficial effects and where we also have some associated cost information.

Secondly, we conducted a series of interviews with stakeholders in the field (Report, pages 153 to 176) who were able to provide a range of perspectives and speak from different areas of expertise – leading researchers, policy-makers and healthcare professionals with insights into CAM. They advised us on key articles for inclusion in the literature review and discussed with us many of the issues explored in our report – effectiveness and costs, alternative methods of integrating chosen CAM therapies into the health system, issues of regulation and safety. The majority encouraged us to consider the costs and benefits of therapies in the widest sense, so as to include in our evaluations of effectiveness the patients' resulting sense of wellbeing as well as specific clinical outcomes and, on the cost side, wider economic and social costs such as the economic costs of time off work.

Thirdly, we undertook a number of case studies in order to discover what the experience of doctors, health practitioners and patients working with complementary and alternative medicines in different circumstances has been (Report, pages 81 to 121). These addressed such questions as: where GPs use CAM therapies, which are they? Are they administered by the GP practice itself or by reference to CAM practitioners, which constitutes the acid test as to which therapies doctors themselves believe to be effective. What is the experience of practitioners working with patients who in one way or another have been failed by conventional medicine? Not least, what has been the experience of patients treated with CAM, and how does this compare with their experience of conventional medicine?

In order to answer these questions, we had access to data relating to the effectiveness and costs of CAM treatments in three locations – the Newcastle PCT, the Glastonbury Health Centre and the Westminster PCT – including the most recent cost information currently available. Separately, we undertook a special case study of an innovative delivery model, the Get Well UK complementary services in the Laurels Healthy Living Centre in Haringey, London. Doctors, CAM practitioners and patients were interviewed to compare their experiences. The project was audited by Professor Nicola Robinson of Thames Valley University in May 2005, and a further cost-benefit analysis based on patients' records at the Laurels Centre was commissioned so that the comments of doctors and patients could be underpinned by systematic analysis.

Stepping back from these three lines of Enquiry, and comparing their outcomes, we found a strikingly consistent picture of the areas within which CAM therapies appear to make their most effective contributions. The outcome on the cost side was somewhat less clear cut, in the sense that while some of the chosen treatments appear to be cheaper than their conventional counterparts, others are not. Experience on the ground, as evidenced by our case studies, however, indicates that more widespread recourse to CAM therapies need not result in higher costs of healthcare overall, and that where it does, the health benefits generated seem, for a range of treatments, to be sufficient to justify the extra spending involved.

The last part of our analysis was then to map those areas of CAM where the best evidence of effectiveness and of cost-effectiveness exists against widely accepted "effectiveness gaps" in the current provision of healthcare through the NHS, so as to reach a final view on the areas of therapy where, according to the available evidence, CAM seems able to make its best and most efficient contribution (pages 131 to 142).

The final section of the Report (pages 143 to 149) lists our principal conclusions on the CAM therapies best placed to make a significant contribution to the provision of healthcare in the UK at reasonable cost. There follows a series of recommendations relating to barriers to the uptake of CAM – legal, regulatory, safety – which will need to be addressed if the CAM treatments we have identified are to be made available on a wide scale, particularly in the deprived communities which seem likely to benefit most.

The conclusions of each section of the Report will now be summarised in turn.

Literature Review

a) Acupuncture (Report pages 35 to 46).

As is common in research areas relating to CAM, studies of acupuncture treatments often use a wide range of treatment techniques and low sample sizes. Nevertheless, several systematic reviews were identified, as well as overviews of the effectiveness of treatments, for example provided by the NHS Centre for Reviews and Dissemination. Some studies (in some cases involving high quality RCTs) indicated not only clinical benefits in terms of symptom relief and more general health benefits in many cases, but also cost advantages, either in the form of pure cost savings or cost-effective additional benefits. In brief, the literature review indicates reasonably strong conclusions in relation to a number of areas.

There seems to be good evidence supporting the use of acupuncture in **post-operative and chemotherapy-related nausea, and post-operative pain.** We did not however locate any cost evidence in this area. Used as an alternative to conventional medicine, the studies examined suggest that acupuncture may increase benefits and reduce costs particularly in relation to **musculoskeletal conditions** in general practice. The requirement for hospital appointments and prescribed pharmaceuticals are both reduced when acupuncture is used as a treatment option in primary care. Used as a complement to conventional medicine, acupuncture increases direct costs, but the studies

suggest that the extra health benefits generated provide a good case for the additional spending in terms of wider economic implications. The main conditions in this category which appear to score well are **lower back pain, migraine** and **stroke rehabilitation.** However, it should be noted that for stroke rehabilitation the evidence of clinical efficacy appears to be significantly weaker than for the other two conditions. Recent work has also suggested that acupuncture generates beneficial effects in the treatment of **osteoarthritis of the knee.**

b) Homeopathy (Report pages 47 to 56).

Homeopathy is more challenged than other areas of complementary medicine in relation to its mechanism of action. Since remedies are often diluted to the extent that there are frequently no molecules of the preparation left in the prescribed solution, the grounds for scepticism that homeopathic preparations can have any effect on the body are clear. There is however a large literature on the costs and benefits of homeopathy, and many studies over the past 40 years – RCTs in humans and animals as well as cost-effectiveness studies – appear to suggest that homeopathy is better than placebo in trials, although these results are hotly contested.

Our survey of the evidence indicates that the best evidence for homeopathy, in terms both of improved health benefits and reduced costs, is associated with its use as an alternative to conventional medicine in relation to a number of everyday conditions in general care, particularly asthma. In addition, a small number of studies suggest that homeopathy may help in other areas including: post-dental surgery recovery and acute childhood upper respiratory tract and middle ear infections. The evidence is however fragmentary, and the most that can safely be said is that these are conditions commonly treated by homeopaths for which they report good results.

To the extent that homeopathic treatments are effective, they appear to offer the potential for substantial cost savings, particularly in drugs bills for primary care. The evidence also indicates fewer adverse effects than conventional remedies and a reduced need for follow-up appointments.

c) Manipulation Therapies: Osteopathy and Chiropractic (Report, pages 57 to 68).

These two therapies share many similar practices and in view of this overlap, and the proportion of studies which relate to manipulation in general, we have grouped them together under the heading of manipulation therapy. Manipulation therapies can be used as treatments for a wide range of conditions, including arthritis, shoulder pain, repetitive strain disorders and migraine. However, by far the largest evidence base for both therapies (including trials where the term manipulation is not further clarified) is in the treatment of back pain. This therefore has been the focus of this part of our Enquiry. This is not to deny that these therapies may be effective in treating other conditions, but the evidence base for them is much more sparse.

Our literature review indicates there is good evidence to suggest that, whether used as an alternative or a complement to conventional medicine, manipulation therapies offer advantages over conventional treatments for **lower back pain,** particularly **acute pain.** In particular, manipulation therapies appear to bring greater short-term pain relief for both acute and chronic back pain sufferers. Even when used as a complementary therapy, manipulation seems cost-effective in terms of NICE guidelines, and if we widen our scope beyond direct health costs, the wider benefits which could be generated by successful treatments in this area are potentially huge. There is the prospect not only of savings in benefit payments as patients return to work more quickly; but gains for the wider economy as output and productivity losses are avoided. Since back pain alone accounts for over 200 million days lost from work, costing the UK £11 billion in indirect costs – equivalent to 1% of GDP – it is not difficult to envisage benefits to the wider economy running into hundreds of millions of pounds as a result of improved treatments in this area.

d) Herbal Medicine (Report, pages 69 to 80).

The Report considers the Western rather than the traditional Chinese approach to herbal medicine, under which therapeutically active ingredients are extracted from plants, synthesised and incorporated into a manufactured drug. The literature scan for this section of the Enquiry suggests that there is evidence of clinical benefit relating to **musculoskeletal problems,** including rheumatoid arthritis (phytodolor, devil's claw), **viral infections and the common cold** (echinacea), **osteoarthritis** (chondroitin), **depression** (St. John's wort), Alzheimer's **disease and dementia** (gingko biloba), **heart problems** (hawthorn), **circulatory problems** (horse chestnut) and **benignly enlarged prostate** (saw palmetto).

Comparing the costs of herbal medicines with conventional medications is difficult because of varying dosages, potencies and the number of medications available. Our conclusions on herbal medicine are the most restricted of the five studied therapies. Moreover, the new EU Directive on Traditional Herbal Medicine Products scheduled to come into force in October 2005 may have some effects on availability due to licensing issues. However, much of the literature surveyed by this Enquiry compares the effectiveness of a herbal remedy against a specific conventional alternative, and where the conventional therapy is named, drug for drug cost comparisons are possible. In many cases, it is likely that where the herbal remedy is sufficiently effective, cost savings would be generated by its wider use. For example, in 2004 the NHS spent £400 million on anti-depressant drugs, at an average net ingredient cost of £13.82 per prescription. Compared with this, a weekly course of St John's wort costs just 82p. Similarly, non-steroidal anti-inflammatory drugs accounted for £247 million in 2004 at an average net ingredient cost of £11.82 per prescription. Phytodolor costs just 45p per week. The potential for cost savings cannot be ignored.

Case Studies: Costs and Benefits

a) Costed Primary Care Case Studies (Report, pages 87 to 100).

The next stage of the Enquiry was to look at the experience of a number of centres which make CAM therapies available on referral by GPs and where, in some cases, GPs and complementary practitioners work side by side. Several of these were examined by the Enquiry and provided interesting data on benefits and costs, although these were generally incomplete and uneven. The three offering the fullest data were Newcastle, Glastonbury and the Get Well UK services in Haringey.

i. Newcastle Case Study.

Newcastle PCT, together with a Health Action Zone, local GPs and CAM practitioners, piloted a complementary therapy initiative from 1999 aimed at assessing the contribution which CAM might be able to make in an area with a high proportion of low-income patients often unable to afford complementary treatment. The therapies offered were osteopathy, chiropractic and acupuncture. The objective was to focus on conditions requiring significant NHS care or responding poorly to conventional treatment. These were typically chronic conditions such as asthma, migraine, back and neck pain, eczema, hay fever, anxiety and insomnia. Musculoskeletal problems accounted for three quarters of referrals, the most common conditions being back and neck pain. Psychosocial problems relating to anxiety, stress or depression accounted for many of the rest.

Health improvement was measured by patients using Measure Yourself Medical Outcome Profiles (MYMOP). Evaluation of the CAM project at the end of 2004, utilising the MYMOP data, showed that three quarters of patients displayed clinically significant improvements. 40% of them showed a two point or greater improvement in their MYMOP score from pre-treatment measurements, well in excess of the 0.5 point change which is considered clinically and statistically significant.

On the cost side, several areas were identified where significant cost savings were achieved. Consultations with GPs following CAM treatment fell by 30% and there was a 40% drop in the number of prescriptions issued. Such identified reductions in spending on conventional care covered 40% of the pilot's costs. Other benefits such as reductions in specialist consultations with orthopaedic surgeons, psychologists and pain clinics, which can also be expected to have decreased, were however unquantified, as were the savings associated with the prevention of illness likely to have resulted from CAM counselling. The Glastonbury experience, set out next, suggests that savings in secondary care costs may have been substantial.

ii. Glastonbury Health Centre.

This centre has offered free access to CAM therapies in a three-partner GP practice for the last 13 years. Research into the contribution which CAM can make to primary care and the cost-effectiveness of treatments has been undertaken since the late 1990s. It provides good evidence both of health improvements, including reduced waiting lists, and of significant cost savings. Amongst those referred for CAM therapy, 60% had musculoskeletal complaints, a third were referred because their problem was not responding to conventional treatment and two-thirds described their health problems as severe. A team of practitioners in weekly CAM clinics based in medical practices provided treatment in five therapies: osteopathy, acupuncture, massage, homeopathy and herbal medicine.

In terms of health benefits, 85% of patients reported an improvement in their condition, with practitioners reporting that more than 50% had registered marked improvements. The results for patients suffering from short-term, more severe conditions, both musculoskeletal and psychosocial, were particularly good, and the CAM therapies were found to improve the health and wellbeing of those patients with milder conditions and to encourage positive changes in lifestyle.

These results have been underpinned by a recently-released analysis of clinical outcomes between May 2003 and October 2004 (18 months of data), again using the MYMOP seven-point scale, assessed at the beginning and end of courses of treatment in osteopathy and acupuncture. Patients were asked to measure their main symptom (e.g. pain), a second symptom (e.g. stiffness), activity level and well-being, and the results were then compounded into a fifth "profile" score. The scores indicated marked improvements in all areas (well above the clinically and statistically significant thresholds) and particularly in relation to the main symptom.
As for savings in conventional healthcare, visits to GPs dropped by about a third (the largest reduction being among patients who were the most frequent visitors to GPs prior to referral). Prescription use fell by almost 50%, and again those patients who were the heaviest users saw the greatest drop. There were also falls in the number of referrals to secondary care, especially for physiotherapy and X-rays. These were more difficult to quantify, but estimates made by the Glastonbury Centre suggested that on reasonable assumptions the CAM service could be expected to generate a sufficient reduction in conventional care expenditure to cover its costs. Analysis of the most recent data strengthens this conclusion. Referrals to secondary care were monitored for a sample of 144 patients for up to two years before treatment, and between six and 18 months afterwards. At the time of referral to CAM practitioners, these people would otherwise have been referred to secondary care: 64% to physiotherapy, 27% to orthopaedics and 9% to pain clinics. Following treatment by Glastonbury's CAM service, 8% of patients were subsequently referred to physiotherapy, 9% to orthopaedics and none to a pain clinic. Quantification of these secondary cost savings suggests that the CAM service has been associated with costs of treatment about a third below those which would have been incurred following the more orthodox route.

b) Get Well UK (Report, pages 101 to 118).

The Get Well UK project was chosen by this Enquiry as a special case study, and new work was

commissioned to analyse the effectiveness and costs of the treatments provided. This was because the service is aimed at providing CAM therapies to patients in disadvantaged socio-economic groups and amongst ethnic minority groups, who are least likely to have good access to CAM therapies at present. Since the Enquiry is considering the potential impact of more widespread provision of mainstream CAM therapies through the NHS, these groups could potentially benefit most, since their current level of usage is low and they frequently present with chronic health problems. Moreover, the therapies provided by Get Well UK, osteopathy, acupuncture, homeopathy, massage therapy and aromatherapy, have a good overlap with those of principal concern to the Enquiry, especially since osteopathy and acupuncture accounted for almost three quarters of the treatments provided.

The therapies are delivered at the Laurels Healthy Living Centre in Haringey, which also houses three GP practices. Local GPs refer to the service. They were asked which conditions they felt were not being satisfactorily treated by conventional medicine, and for which they would feel confident referring patients to CAM. The conditions identified for treatment at the Centre were asthma, back neck or shoulder pain, depression, stress and tension, headaches, hypertension, joint problems, arthritis or rheumatism, menstrual or menopausal complaints or sports injuries. In practice, most patients had conditions of a complex or chronic nature.

Analysis of the MYMOP scores reported by patients before and after CAM treatment found that three-quarters of patients experienced an improvement in their symptoms. There was, as in Glastonbury, a median reduction of two points, from five to three, which counts as a substantial improvement in patients' perceptions of their health and well-being. In MYMOP documents, many patients reported improved sleep following treatment, and some recorded reductions in addictive behaviour, including drugs and tobacco, as well as drops in anxiety, all of which contributed to improvements in family relationships. Some patients returned to work following treatment. In their interviews, practitioners commented that the patients they saw through Get Well UK were different from those seen in private practice, with a greater number of chronic cases and a greater prevalence of complex cases where patients reported multiple symptoms. Little or no knowledge of CAM therapies meant more education was needed. The opportunities for collaboration between practitioners and between practitioners and GPs were seen as particularly rewarding for all concerned.

22 local GPs were interviewed, of which 19 had referred patients to Get Well UK. Of these, 12 noted definite physical improvements and 14 a positive impact on the psychological health of their patients. Many saw the CAM model linking aspects of physical and psychological treatment into a single approach, and saw this as a key benefit in relation for example to the relief and management of pain and stress which requires improvement in both aspects. It also offered the possibility of avoiding the unpleasant side-effects associated with many conventional treatments. Interestingly, homeopathic treatments were the third most prescribed, even though some of the doctors thought they had "no basis in science whatsoever." Many stressed the important counselling role associated with these therapies and the link between improvements in patients' lifestyles and their physical and mental conditions.

In summary, the Get Well UK case study indicates that patients not generally in a position to purchase CAM therapies privately and suffering from chronic and complex conditions appear to have derived substantial benefit from the treatments provided, particularly in relation to the management of chronic pain. Interaction between all three groups, doctors, practitioners and patients, appears to have been beneficial for all concerned. Get Well UK, however, is a social enterprise with assistance from charitable sources and the New Deal for Communities; extending such treatments to deprived areas across the UK would require NHS funding.

c) Conclusions from case studies (Report, pages 119 to 121).

The case studies suggest that many patients have derived significant benefits from CAM therapies. In

the majority of cases, specific conditions have improved as have patients' general health and sense of well-being. The case studies were weighted towards disadvantaged communities, and CAM therapies appear to have been effective in ameliorating a range of psychological problems associated with anxiety, stress and depression. But specific physical conditions were also improved, especially chronic pain, and musculoskeletal problems.

On the cost side, CAM treatments resulted in reductions of around one third in consultations with GPs, and savings in the prescription drugs bill of up to 50%. The use of secondary care services, consultations with physiotherapists or orthopaedic surgeons or at pain clinics, also decreased markedly. Overall, the Newcastle service found that savings in conventional treatments covered 40% of its costs, but only primary care savings were quantified. At Glastonbury, where secondary care savings were also quantified, the introduction of CAM therapies appears to have resulted in overall savings in the costs of health care. In the case of Get Well UK, the conclusions on financial savings were inconclusive, but significant benefits for patient resulted.

It is important to keep in mind that only some of the relevant costs and benefits have been measured in these studies. Prevention of illness as a result of CAM consultations could be a source of large cost savings, particularly if patients are successfully weaned off tobacco, alcohol, drugs and junk food. In addition, wider economic benefits are not taken adequately into account in cost studies such as the budgetary and economic benefits of people returning to work more quickly.

CAM in the NHS

a) CAM Therapies as a Response to "Effectiveness Gaps" in the NHS

When the conclusions of our literature review are set alongside the experience of people in clinical situations "on the ground", as revealed in our three case studies, the two sets of evidence are remarkably consistent. The best evidence for the effectiveness of the mainstream CAM therapies which appeared to emerge from our literature review corresponds well with the experience of doctors, patients and practitioners in the three areas where we were able to examine data on benefits and costs and talk to the people involved. The major areas of treatment which emerge well from both types of evidence include musculoskeletal complaints, especially lower back pain and chronic arthritic conditions, psychosocial complaints such as depression, anxiety and stress, chronic pain and the management of pain generally, as well as important conditions in general care such as asthma and migraine .

This is not to say that other CAM therapies are not effective in treating different complaints. The case studies focused particularly on primary care, but the literature review indicated that CAM treatments appear to have an important role – at the least a palliative one – in relation to cancer conditions and post-surgery recovery. Moreover, the available literature is neither comprehensive nor of consistent quality, and our Enquiry has been restricted to particular therapies within CAM where there is sufficient evidence to support at least indicative conclusions. This evidence appears to us to suggest that there is a prima facie case for regarding the areas of treatment listed above as important priority areas when the NHS is considering the resources which it is prepared to devote to CAM therapies and to research into the field of complementary and alternative medicines.

This conclusion is further strengthened when the areas where CAM therapies seem to do best are mapped against the conditions which are currently poorly addressed by conventional medicine. Clearly, if particular CAM therapies can provide cost-effective additional benefits, they ought to be included in the range of health services provided by the NHS. Areas poorly served at present are known as "effectiveness gaps", though this is a little researched area of medicine. This Enquiry surveyed available studies of GPs and primary health care professionals, and consulted representatives of a range of medical organisations, in order to establish what they perceived as the principal gaps in conventional health care at the moment.

A large measure of agreement emerged about the main families of conditions where currently available treatments are unequal to the task. The main ones cited to us were: **musculoskeletal pain (including lower back pain), arthritis (rheumatoid- and osteo- arthritis) and its associated pain, pain complaints acute and chronic (such as headache and migraine), anxiety stress and depression, ill-defined chronic conditions, and skin conditions, especially eczema.** Comparing this list with the areas of CAM effectiveness listed above strengthens our prima facie view that these are the areas where CAM therapies may have the greatest potential to make a much needed contribution to the provision of healthcare in the UK.

b) Current Provision of CAM in the NHS: Geographical and Therapeutic Gaps

CAM therapies are provided through the NHS today and provision has steadily increased in recent years. Surveys suggest that ten years ago around 40% of general practices in England provided some access to CAM therapies, whether via a member of the primary care team or by a practitioner working in the practice. By 2001, this figure had risen to 50%, and the indications are that this proportion has continued to grow. In many cases, however, the range of CAM services on offer is narrow, perhaps only a single type of treatment, although by 2001 and in aggregate 33% of GP practices were offering provision or referral for acupuncture, 21% for homeopathy and 23% for manipulation therapies. Similarly, a 2004 estimate suggests that 43% of PCTs were by then offering some CAM service and that usage is growing slowly. Again, however, CAM seems to be a low priority for PCTs.

Access to the mainstream CAM therapies also varies greatly from one region to another. In 2003-4, with 67 CAM services across 31 PCTs, London had by far the greatest proportion of CAM services per PCT. With eight services across 21 PCTs, the Trent area had the lowest. Moreover, the evidence suggests that only 45% of PCTs which provide CAM services make them available PCT-wide so that there can be equitable access to CAM treatments within their districts. Plainly, if the view developed by the Report that there is strong prima facie evidence to suggest that certain mainstream CAM therapies have an important contribution to make to reducing effectiveness gaps in the NHS is correct, it should be a priority to remedy the disparities of access both geographically and in relation to individual therapies.

c) Cost Implications of Wider Use of CAM

The cost of providing CAM therapies varies greatly from one treatment to another. The Report draws on evidence of costs and benefits from the literature review in order to make comparisons with conventional treatments and identify where the CAM therapies are likely either to prove cheaper than conventional remedies or to be more cost-effective even if more expensive.

Broadly, where CAM treatments can be regarded as sufficiently effective to be regarded as alternatives to conventional treatments, the costs associated with the CAM options are likely to be lower. This is likely to be particularly true of herbal remedies. It may also be true for musculoskeletal complaints which can be treated successfully by acupuncture, where the savings in terms of GP time and conventional drugs are potentially large, and for homeopathy (for example for asthma) where the Report indicates that substantial savings in the prescription drugs bill may also be available, if the effectiveness of homeopathic treatments can be adequately established. As reported earlier, the case studies identified some significant sources of cost savings, with GP consultations down by about a third and prescription drug costs down by up to 50%. To put this in context, the national prescription drugs bill is £8 billion.

Where CAM therapies are employed as complements to conventional treatment, the presumption is that direct costs are likely to be higher, although if the treatment time is shortened in consequence this need not be the case. In addition, shorter treatment times may be associated with savings in social security payments and wider economic benefits, as in the case of lower back pain. Manipulation therapies used as an alternative to conventional treatments may be just as expensive as their conventional counterparts, and used as complements even more so. Taking a wider view, however, that expense may

be well worthwhile. The report suggests for example that economy-wide benefits running into hundreds of millions of pounds could result if a significant reduction in the time off work associated with lower back pain alone could be achieved as a result of the wider application of CAM therapies.

There is a paucity of data in this area: further research comparing conventional treatments and their CAM counterparts on the basis of full cost-benefit analyses should be a priority.

Conclusions and Recommendations

The key conclusions of this Report are as follows:

1. Evidence from the literature review and from our case studies indicates that many of the most effective CAM therapies correspond to recognised "effectiveness gaps" in NHS treatment, which suggests that they may have the potential to make an important contribution to the delivery of health care in the UK. The main areas identified comprise chronic and complex conditions, anxiety stress and depression, and palliative care relating particularly to pain and nausea;

2. Despite the fragmentary nature of the evidence, there seems good reason to believe that a number of CAM treatments offer the possibility of significant savings in direct health costs, whilst others, perhaps just as expensive as their conventional counterparts, can nonetheless deliver additional benefits to patients in a cost-effective way. In addition, the benefits to the economy (and hence to the Exchequer through enhanced tax revenues) of a wider application of successful complementary therapies in the key areas could run into hundreds of millions of pounds;

3. Our principal recommendation therefore is that Health Ministers should invite the National Institute for Health and Clinical Excellence (NICE) to carry out a full assessment of the cost-effectiveness of the therapies which we have identified and their potential role within the NHS in particular with a view to the closing of "effectiveness gaps";

4. There appears also to be a social case for extending the use of the CAM therapies which we have identified, since the psychosocial and chronic ailments where CAM seems to be able to make its best contribution are particularly prevalent in deprived communities where people lack the means to pay for such care. There will therefore be a strong case for giving priority to extending the availability of CAM in these areas, within the NHS, in the event that our provisional conclusions are confirmed by NICE.

5. It is also true (see CAM in the NHS pages 122-130) that there are substantial regional differences in the provision of CAM services across the UK, with London having much greater provision than other regions, particularly the North of England. These regional disparities will also need to be addressed.

There are a number of consequential recommendations. These include:

1. Funds available for research into the cost-effectiveness of CAM treatments should be increased. There is at present a paucity of financial support for CAM research, which commands no ring-fenced government funding and only 0.08% of the NHS research budget and in 2003, accounted for 0.3% of the research budget of UK medical charities.[3] Moreover, since CAM may have considerable potential in a wider range of applications than those which we have been able to consider, we urge the CAM research community to collaborate in order to develop a unified research agenda so as to establish a more rigorous evidence base relating to the costs and benefits of CAM therapies than exists at present.

3 See Ernst et al., 2005, p.21.

2. The GP's role as "gatekeeper" should be maintained as far as NHS provision of CAM therapies is concerned so that potential conflicts between CAM and traditional therapies can be minimised, and healthcare provided on an integrated basis. GP practices are increasingly responsible for commissioning and therefore for financial decisions in relation to this area.
3. It will be important to remove a series of barriers which may stand in the way of GP referrals.

    a. Firstly, the need for information about safety and side-effects needs to be addressed for all five therapies and specific treatments. Having said this, safety is a major factor motivating people to seek CAM treatments and generally speaking CAM appears relatively safe compared to conventional drugs. This of itself could be of considerable cost significance to the NHS.
    b. Secondly, the legal position of doctors making referrals to complementary practitioners needs to be safeguarded.
    c. Thirdly, statutory regulatory bodies for homeopathy, acupuncture and herbal medicine need to be set up as soon as possible (the latter two groups are already making good progress with help from the Foundation for Integrated Health) so that doctors can refer to statutorily registered practitioners.
    d. Finally, more education should be provided to doctors and other health care professionals and students in these disciplines, in order to familiarise them with the core CAM therapies and their applications.

Christopher Smallwood October 2005

GLOSSARY

Blinded trial: A study in which participants do not know whether they are in the experimental or control group in a research study. Those in the experimental group get the medications or treatments being tested, while those in the control group get a standard treatment or no treatment.

Cardiovascular disease: Any abnormal condition of the heart or blood vessels, for example, heart attack, stroke, high blood pressure, irregular heartbeat and hardening of the arteries.

Cochrane Systematic Reviews: The Cochrane Collaboration is an international non-profit organisation that makes information about the effects of healthcare available worldwide.

The Cochrane Library of evidence-based medicine databases is part of the collaboration and includes the Cochrane Database of Systematic Reviews.

Contraindications: Any symptom or circumstance indicating the inappropriateness of an otherwise advisable treatment for a patient.

Cross-over trial: A type of clinical trial in which the study subjects receive each treatment in a random order. In this type of study, every patient serves as his or her own control.

EQ-5D: A scale of patient satisfaction derived from questions on mobility, self-care, usual activities, pain/discomfort, anxiety/depression and imaginable health state.

Hamilton Rating Scale for Depression (HAMD): A scale obtained from scores given by patients on depression in 21 areas (including depressed mood, guilt, suicide, insomnia, loss of weight, agitation, anxiety, etc.)

Inclusion criteria: The criteria that studies must meet to be eligible for inclusion into systematic reviews or meta-analyses.

Measure Yourself Medical Outcome Profile (MYMOP): A patient questionnaire comprising questions on a few symptoms that bother the patient most on physical, mental or social problems, general well-being and use of medication.

Meta-analysis: A quantitative method of combining the results of studies in the literature. It synthesises summaries and conclusions in order to be able to make conclusions.

Musculoskeletal conditions: Conditions that affect the system of bones, joints, and surrounding soft tissue such as the skin, muscles, ligaments, and joint capsules.

Osteoarthritis: A type of arthritis that causes the cartilage in the joints to fray and wear. In extreme cases, the cartilage may wear away completely.

Oswestry Index Questionnaire: A patient completed questionnaire concerning back problems on 10 areas (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, changing degree of pain and travelling).

Pragmatic study: A study that asks whether an intervention works under real-life conditions and whether it works in terms that matter to the patient. It is concerned with whether the intervention works, not how or why.

Primary care: Health care provided by a health care professional in the first contact of a patient with the health care system.

Prospective study: A study designed to follow patients forward in time. Researchers plan and manage the treatment of interest in selected groups of patients and so do not know what the outcomes will be when they undertake the study.

Retrospective study: A study in which researchers select groups of patients that have already been treated and analyse data from the experiences of these patients.

Rheumatic disease: Any of the disorders that affect the musculoskeletal systems, including the different kinds of arthritis. Some are described as connective tissue diseases as they affect the supporting framework of the body and its internal organs. Others are known as auto-immune diseases as they occur when the immune system, which normally protects the body from infection and disease, harms the body's own healthy tissues.

Rheumatoid arthritis: A chronic and destructive form of joint inflammation caused by the body's own immune system attacking the tissues.

Roland Morris Disability Questionnaire: A patient completed questionnaire concerning neck or back pain with 18 possible descriptive sentences (e.g. “I stay at home most of the time because of my back”; “I sleep less well because of my back”; etc.)

Secondary care: After a referral from a GP or other primary health care professional, the care provided by medical specialists or hospital staff.

SF-6D: A scale of patient satisfaction derived from the SF-36 questionnaire on health which includes limits to carrying out activities (regular and particular), emotional problems, social activities, physical pain and general well-being.

Systematic review: A structured review that applies predetermined inclusion and exclusion criteria to the literature, critically appraises it and extracts and synthesises data in order to form conclusions.

Unio Homoeopathica Belgica: The Belgian National Homeopathic Union

Visual Analogue Scale: An instrument to measure a characteristic or attitude believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain a patient feels ranges across a continuum from none to extreme pain.

Abbreviations

CRD: The NHS Centre for Reviews and Dissemination at the University of York. It aims to provide research-based information about the effects of interventions used in health and social care.

DARE: The Database of Abstracts of Reviews of Effects compiled by the CRD.

NICE: National Institute for Health and Clinical Excellence

PCT: Primary Care Trust

RCT: Randomised Controlled Trial

INTRODUCTION

Complementary and Alternative Medicine (CAM) is growing rapidly in its use and uptake, with the homeopathic, aromatherapy and herbal remedies market alone valued at £147 million in 2004.[4] The Council of Europe recognises that such therapies are "growing in importance in Europe and throughout the world."[5] A 2002 White House report observes that up to 43% of Americans have used some form of CAM.[6] A study [7] by Simon Mills and Sarah Budd, for the Department of Health, estimates there were 50,000 CAM practitioners in the UK treating five million patients in 1999;[8] although more recent estimates places this at 19 million [9] patients, and an article by Ernst and White[10] reports predictions that this will rise steadily in the future.

Aims and Scope

This Enquiry investigates whether there is evidence that complementary and alternative medicines could enhance NHS provision of healthcare by reducing costs and/or providing treatment where conventional medicine currently fails to meet patients' needs. The Enquiry suggests there is a *prima facie* case that certain CAM therapies could provide cost-effective additional benefits in terms of healthcare or replacement benefits at lower cost. Its aim is not to advocate the full integration of CAM therapies into the NHS, but to provide a synopsis of the current level of integration, and to suggest the areas where there may be a case for further integration. The issues surrounding integration are both numerous and complex[11] and any decision further to integrate complementary and alternative therapies into NHS practices will require significant consultation between all interested parties. However, the hope is that by bringing cost and benefit issues to the foreground, this report will spur such consultation and further research in this field and thus make a useful contribution to the continuing debate on the integration of CAM therapies into the NHS and Primary Care Trusts.[12]

Determining effectiveness is of course a necessary condition for determining cost-effectiveness and the emphasis here is primarily on what is already known about the relative costs and benefits of CAM therapies and the implications for the potential role of such treatments in an integrated NHS. The Enquiry's Literature Review contains a summary of significant UK studies which have considered the benefits and costs of particular complementary therapies. We have also benefited from an extensive series of conversations with stakeholders in the field and we have reviewed a number of case studies of the impact of complementary medicine on the ground in different parts of the country. A new analysis of the provision of CAM therapies by Get Well UK in Haringey has also influenced our conclusions.

This Enquiry has taken the Sixth House of Lords Science and Technology report as a starting point for defining its scope. The Select Committee divided all complementary and alternative medicines into three groups. The first, defined as those therapies which are "principal disciplines" and "professionally organised alternative therapies", included:[13]

- Acupuncture
- Homeopathy
- Chiropractic
- Osteopathy
- Herbal Medicine

[4] Mintel, Complementary Medicines, 2005.
[5] Council of Europe, 1999.
[6] White House Commission, 2002, p.1.
[7] Budd & Mills, 2000.
[8] House of Lords, 2000, sec. 1.16.
[9] Interview with Dr Kate Thomas, who indicated that one in three people in the UK have used some form of CAM.
[10] Ernst & White 2000.
[11] Wilkinson et al., 2004.
[12] See Glossary.
[13] House of Lords, 2000, sec. 2.1.

The second group contained therapies such as the Alexander technique, aromatherapy and massage therapy, which do not claim diagnostic skills and are used mostly to complement conventional medicine. The third group included therapies which "favour a philosophical approach and are indifferent to the scientific principles of conventional medicine". This group also included the subgroups of traditional healthcare systems, such as ancient Indian (Ayurvedic) and Traditional Chinese Medicine, and of alternative disciplines which "lack any credible evidence base."[14]

This report examines the therapies in the first group identified by the House of Lords Select Committee. These treatments "claim to have an individual diagnostic approach and … are seen as the 'Big 5' by most of the CAM world."[15] These therapies have been chosen as the focus for this Enquiry as the House of Lords report is the most comprehensive and reputable general CAM study of recent years. Furthermore, these therapies might be expected to be at the forefront of any further wide-scale integration of CAM into the NHS.

Use of CAM in the UK

A way to look at the level of CAM uptake is to examine the market size and spend per capita. However, since no one source of information exists for such a figure, current figures have to be extrapolated from 1997 to 2000, more recent estimates not being available. Lewith (2000) suggests that spending per capita on CAM in the UK is on a par with the USA, which in 1997 spent $27 billion on such therapies.[16] An approximate estimate of this figure, assuming the UK population is approximately one-sixth of that of the US, would be £4.5 billion. A smaller figure was found by a 1999 BBC survey of 1204 adults which found that each CAM user in the UK spent £14 a month on CAM and estimated that nationwide expenditure on CAM per annum was £1.6 billion[17]. Indeed, the market for CAM therapies appears to be growing at 10-15% a year regardless of the economic climate[18]. On expenditures of £1.6 billion in 2000, this would indicate a possible level of £2.8-3.7 billion by 2005. These figures only reflect private CAM usage and so this figure would be considerably larger if NHS and charity-funded CAM usage was taken into account.

There are several strong motivators driving increased numbers of patients to CAM. These are[19]:

- Symptom relief, particularly in chronic illness
- Perceived effectiveness
- Safety and non-invasiveness
- Emphasis on the whole person - the "high touch low tech approach"
- Personal feeling of control over the treatment process
- Good therapeutic relationships and support
- Desire to be heard
- Accessibility
- Dissatisfaction with conventional medical care
- Few side effects

This suggests that people who consult CAM practitioners are seeking a different approach to healthcare than is offered by conventional medicine.[20] The lengthy and individualised CAM consultation process is seen as highly attractive. That practitioners are investing time by taking into consideration the overall health of the patient and their life circumstances, is

[14] Ibid.
[15] Ibid.
[16] Lewith, 2000, p.242.
[17] Ernst & White, 2000.
[18] Lewith, 2000, p.242.
[19] White, C., 2003.
[20] Lewith, 2000, pp.242-243.

viewed as providing the human element seen to be missing in modern conventional medicine, where it is the disease rather than the patient that is treated.[21]

While some critics have derided the use of CAM treatments, claiming the success of some therapies to be purely based on a placebo effect, CAM proponents see what Dr. Michael Dixon calls the "human effect"[22] as desirable in itself. However, as battles continue to rage over how best to allocate NHS funds, such arguments are not sufficient to convince many critics to recommend CAM treatments. Without scientific evidence of effectiveness beyond placebo, critics will continue to advocate that money would be better spent on something with a proven mechanism that confers similar benefits.[23]

Working Together

Despite previous mutual mistrust between CAM and conventional medicine, there is now a continuing trend towards closer cooperation. Not only is there an increasing evidence base for CAM therapies (the number of CAM effectiveness studies doubles every five years[24] and the publication of CAM medical research in mainstream peer-reviewed journals is rising)[25] but there is also a growing awareness of the need for convergence in regulatory, clinical and scientific standards, as well as organisational structures, between the two strands of medicine. Continued integration requires both convergence on the one hand, and agreement between conventional and CAM practitioners on the other, about the precise boundaries of their respective roles and the availability and access to CAM therapies.[26]

Acceptance by professional medical bodies of CAM therapies has increased in the UK and the US. The British Medical Association (BMA) has recommended increasing the use of acupuncture in the NHS;[27] the Royal College of General Practitioners has done likewise with the use of chiropractic and osteopathy;[28] and the National Institutes of Health (NIH) in the USA have recommended the use of hypnosis and acupuncture.[29] With the 1993 Osteopaths Act, osteopathy became the first complementary medicine to be accorded statutory recognition, followed by the 1994 Chiropractors Act. Furthermore, the General Medical Council has clarified that doctors may delegate treatment to non-medical complementary practitioners if satisfied of their competence and provided the general practitioner maintains overall clinical responsibility.[30]

Mutual awareness is on the rise: conventional medicine has become more aware of the value of CAM therapies and the value patients place on them; and CAM proponents have come to appreciate the need for more credible research and evidence.[31] This report seeks to clarify how this relationship could be most profitably taken forward.

[21] House of Lords, 2000, sec. 3.13-18.
[22] Dixon & Sweeny, 2000
[23] Ernst, *The Guardian*, 15th February 2005.
[24] Vickers, 2000, p.683.
[25] Lewith, 2000, p.243.
[26] Vickers, 2000, p.685.
[27] See Silvert, 2000
[28] See Waddell et al., 1999
[29] NIH, 1997
[30] Lewith, 2000, p.243
[31] Vickers, 2000, p.685

How this Report is Structured

This report is divided into three key areas:

Analytical Evidence

This section comprises our Literature Review. It covers articles examining the House of Lords (HOL) Group One therapies: acupuncture, homeopathy, manipulation therapies (which subsumes osteopathy and chiropractic) and herbal medicine. The aim of this section is to review evidence relating to the benefits and costs of complementary treatments for specific conditions and bring attention to evidence on the effectiveness or otherwise of CAM treatments. This part of the report represents the academic contribution to this field and the literature review is buttressed by interviews with stakeholders in CAM and related areas (see Appendix A and Appendix B for more information on the interviews) who have provided their views on these matters, and on key issues surrounding a broader uptake of CAM.

Practice

The next section concentrates on current applications of these therapies in practice. This includes the chapter Models of Integration and Methods of Delivery, which includes case studies of the benefits and costs associated with the delivery of CAM therapies in Newcastle, Glastonbury Health Centre and Westminster Complementary Health Centre. It also includes newly commissioned material of Get Well UK's experience in Haringey. The potential challenges faced in considering the further integration of CAM therapies in the NHS are then examined along with alternative ways of integrating effective CAM treatments into NHS care. Several examples of methods of delivery are provided along with their effectiveness in meeting the needs of their communities and associated costs and benefits.

This section concludes with a new case study conducted for this Enquiry of the Get Well UK delivery model in Haringey, London. The views of the three most important stakeholder groups, the practitioners, the GPs and the patients are set out. These highlight the benefits of CAM as well as the barriers to further uptake.

Conclusions

The outcomes of the Literature Review, interviews and case studies are then considered together and a series of overall conclusions and recommendations drawn.

To assess the potential future of scope of CAM provision in the NHS, the current level of provision and where it fits into the health service (see CAM in the NHS) has been examined and what appear to us to be the current "effectiveness gaps" defined. These are areas where conventional medicine is not meeting patient healthcare needs satisfactorily i.e. where treatments are mostly ineffective or no treatments exist for specific conditions. The evidence we have accumulated suggests to us that certain CAM therapies can start to fill some of these gaps.

In addition, there may be areas where CAM treatments are equally effective but cheaper than conventional treatments, or where, though more expensive, they are capable of generating health benefits in a cost effective way.

METHODOLOGICAL CONSIDERATIONS

The aim of this Enquiry is to examine the desirability of further use of complementary and alternative therapies by the NHS. This requires evidence on the effectiveness and associated costs of CAM treatments. We have reviewed academic literature on the effectiveness of treatments, with a focus on studies considering the costs as well as the benefits of specific therapies, since health policy is necessarily concerned with how best to allocate the limited resources available to the NHS. If policy makers, insurance companies, practitioners and patients are to be convinced of the value of incorporating some CAM therapies into conventional care models, accurate and trustworthy evidence needs to be compiled on the relative costs and benefits of both CAM therapies and the conventional treatments that currently represent "best care" practice in the NHS. Much work needs to be done in this area.

Conclusive proof of efficacy of conventional medicine is difficult enough to demonstrate. Evidence for its effectiveness and safety in a clinical setting (especially in the long term) is even harder to establish. The problems of testing CAM therapies may be even greater. This section discusses the general methodological considerations: distinguishing between efficacy and effectiveness, before considering best practice and then issues of particular pertinence to the examination of costs and benefits. The approach of this Enquiry is then set out in the following section.

Efficacy and Effectiveness

To perform economic evaluations of therapies, one must first determine their value in terms of improvement in patient health status, generally judged in terms of efficacy and/or effectiveness. In turn, this necessitates distinguishing between efficacy and effectiveness. The difference between these two concepts is outlined by Professor Nancy Devlin[32] as:

> […] *efficacy is a specific physiological response to either a therapy or a chemical entity, and how that would work under ideal circumstances if there was full compliance. Effectiveness is the outcome which can be observed and demonstrated where it is delivered, but where the circumstances for compliance might be less than ideal, or where people respond in different ways to the treatment, and so on. By evidence of effectiveness, I mean that you have got to be able to show to me what would happen in real life, if this therapy was available.*

Dr Kate Thomas[33] defined the difference (in an interview with this Enquiry[34]) as:

- Efficacy: Utilising a reductionist[35] scientific method to examine the specific effects of a specific intervention on a specific health outcome. This is a protocol driven approach, where you control for everything other than the intervention, similar to a laboratory experiment.
- Effectiveness: The intervention's effect in a clinical setting and measured by examining all aspects of the treatment's effect on a patient.

Deciding which type of study to undertake and subsequently how to measure the outcomes are contested and divisive issues. Efficacy and effectiveness research tackle different sets of questions and it is up to those responsible for setting guidelines for the choice between available treatments to decide when each set of questions is the more appropriate. In this report, we place weight on the perceived effectiveness as well as the efficacy of CAM therapies.

[32] White, C., 2003, p. 18.
[33] Dr Kate Thomas is Deputy Director of the Medical Care Research Unit at Sheffield University.
[34] The full interview is available in Appendix B.
[35] Reductionism refers to the attempt to break down complex systems into their constituent parts.

Best Practice Research Methodologies

There is no consensus on what constitutes the definitive set of research methods for CAM, and thus no agreed benchmark that CAM therapies must reach to gain acceptance. The "gold standard" for conventional medicine is the randomised control trial (RCT). Many contend that unless CAM therapies are analysed in this most rigorous manner, any claims of efficacy or effectiveness must be treated with scepticism. However, there are several CAM-specific considerations that several practitioners assert must be taken into account as part of any assessment mechanism:

Standardisation vs. Individualisation of Treatment

Extrapolating from a single trial to an entire therapy requires that therapy to be characterised by a uniform set of practices. However, one of the key components of most CAM therapies is the personalised diagnosis and individual hands-on interaction between therapist and patient, indicating a greater value of the holistic treatment of the patient. This makes any conclusions on efficacy from a single study very difficult to generalise. The demanded specificity of RCTs, where one product or treatment attempts to counter one ailment, is not relevant in many CAM contexts.

Variety of Treatments

Each of the five therapies comprises a wide variety of overlapping approaches bearing very little similarity to one another: contrast for instance the ideas and practices of homeopathy with those of osteopathy. The number and length of treatments may vary over the course of the therapy, and CAM practitioners' focus on the patients' experience rather than the pathology of the disease can lead to differing treatments for similar ailments.

Design Difficulties

All medical trials tend to encounter a common set of problems. On top of these, attempting to submit CAM therapies to medical testing would generate a further set of problems, each particular to CAM, as suggested by Nahin and Straus[36]:

- There is difficulty in gathering patients and reaching under-represented populations to undergo trials for CAM therapies, further limiting the ability to generalise from results.
- Patients with a strong preference for a specific CAM therapy may not accept the process of randomisation which might lead them to receive a conventional treatment they have been avoiding.
- Finding appropriate placebos, controls or sham treatments[37] for therapies such as acupuncture and chiropractic is especially difficult, and the interactive nature of CAM therapies makes it difficult to keep the trial double-blinded[38] as the practitioner will be aware of the difference between accurate and placebo treatment methods.

Process Preferences

As noted in the introduction, patients choose CAM for a variety of reasons. However, what is clear is that the holistic characteristics common to most CAM therapies enhance the desire for and the belief in the effectiveness of these treatments in certain patients. Patients appreciate the extra time that is spent on them, the individualisation of the diagnosis and treatment and the relative lack of side-effects. This implies that those patients that place

[36] Nahin and Straus, 2001.
[37] A 'sham treatment' is utilised as a placebo treatment, where it is necessary to perform a treatment on a patient in order that a patient will be unable to know whether they are receiving the therapy to be tested. It is used in cases such as acupuncture.
[38] In a double-blinded trial, neither the patient nor the doctor (or researcher) knows whether the treatment being received/given uses active ingredients or is a sham.

greater value on this more personal approach would tend towards this type of therapy and be more inclined to believe in its healing potential. The necessarily random assortment of patients for a RCT trial would fail to acknowledge this self-selection. RCTs may thus underestimate the impact a CAM therapy may have on those actively seeking out the treatment, and thus underestimate the overall benefits of a certain CAM treatment. In an NHS increasingly geared to respecting patient choice, this aspect of potential benefits should not be quickly discounted.

Restrictiveness of Conventional Qualitative Measures

Orthodox measures of health relating to quality of life, such as the Quality Adjusted Life Year (QALY), form a central component of any cost utility analysis of clinical treatments (see below for a discussion of economic evaluations of CAM therapies). Studies utilise one of a series of health-measuring patient response questionnaires to calculate QALYs. Those most commonly used include the EQ-5D questionnaire or the SF-36 questionnaire. However, such questionnaires may be considered overly restrictive to fully evaluate CAM's more holistic approach to healthcare. For example, Wilkinson, Peters & Donaldson, 2004, suggest that health benefits could probably be grouped into four areas:

- Health states: defined as the symptom relief and the point at which you finish up after treatment. This state would take into account any side effects.
- Wellbeing: empowerment, emotional wellbeing, coping strategies, and patients feeling good about themselves, despite perhaps having some measure of impairment.
- Process utilities: utility refers to a patient's wellbeing; it is a subjective valuation of the satisfaction gained. For example, assuming an equal improvement in health status, a patient might derive more utility from CAM than from conventional treatments because of the more personal approach. Other possible reasons include perceived empathy, the pleasure of receiving treatment, touch and a greater appreciation that time is being taken. Note that the concept of utility is also relative: a very ill patient would value a 1% improvement in health more than a perfectly healthy individual, much like an individual living on the streets would value an extra £1 more than a millionaire.
- Health behaviours: relates to health promotion, health maintenance, wellness generation.

The EQ-5D and similar measures may only take health states into account, thereby ignoring the importance patients and practitioners should place on the other three factors affecting benefit. CAM's more holistic approach to healthcare, which places a high premium on the relationship between therapist and patient, may subsequently be undervalued by conventional health state trials.

Length of Trial

RCTs are costly and time consuming, particularly if they are to be robust and rigorous enough to allow meaningful conclusions to be drawn. However, many CAM therapies deal with chronic ailments, and would need a substantial period of patient examination to measure long-term benefits that may take a long period to appear at all. The time constraints of RCTs additionally limit the ability to examine recurrence rates, where the condition may reappear in a patient.

Chronic, Complex Conditions

CAM therapies will often attempt to grapple with patients possessing chronic and complex conditions. This may be down to patients' dissatisfaction with conventional care driving them to seek alternatives, or, as Dr David Peters suggested when interviewed by the House of Lords Select Committee on Science and Technology[39], general practitioners may refer patients to CAM therapy when presented with patients with a set of inter-related and complex complaints. It would then be difficult to limit a RCT to examining a single treatment to deal with a single condition.

[39] House of Lords, 2000.

An additional list of the difficulties of utilising RCTs to measure efficacy (not just for CAM therapies) is outlined by Vincent & Furnham (1997) and reproduced as Appendix 1 in the House of Lords Report[40]. These authors highlight problems such as:

- Patients randomised to different treatment groups meeting and talking about their treatment (natural groups, for example school districts, may be preferable);
- Blinding may not always be possible, especially in non-pharmacological interventions;
- The very act of participating in a trial may affect the behaviour of the patients involved;
- Standardised treatments designed for comparability might bear little relation to clinical practice where individualised treatments are given;
- Individual response to treatment can be ignored in analyses of average group responses.

Ultimately, a resolution to this problem is not easily available, but we had to decide what our approach should be.

Many conventional researchers and practitioners will not be satisfied unless CAM therapies are treated and tested in an identical manner to conventional treatments[41]. Many CAM practitioners maintain that RCTs will always be too limiting for CAM treatments and hold that more appropriate measures to examine outcomes, efficacy and effectiveness must be constructed[42]. Between these two positions lies a growing acceptance, as expressed in the House of Lords Report, that modified and pragmatic RCTs may be utilised. A range of other methodologies may additionally be employed where appropriate, including "…sequential, longitudinal or cross-over trials"[43] as well as carefully selected qualitative research methods. Many conventional and CAM researchers acknowledge that correctly matching the methodology to the research question under investigation is of the greatest importance. This broader approach is supported by the Research Council for Complementary Medicine (RCCM), the House of Lords, the Foundation for Integrated Health and many of those interviewed by this Enquiry, and it is adopted by this Enquiry.

Cost-Benefit

There are five distinct approaches to the economic evaluation of healthcare:

Cost-description

The simplest and least valuable method of economic evaluation, cost-description lists the costs associated with a therapy. If there was a single therapy available (conventional or otherwise) to treat a particular ailment, then creating such a list would be of value. However, as this is rarely the case, cost-descriptions appear far too limiting for any conclusions to be drawn.

Cost-comparison (cost-minimisation)

This method assumes an identical outcome from two or more interventions, and then compares the cost of achieving this outcome. At the current time, given the debated state of the efficacy of some CAM treatments, it seems extremely unlikely that such an analysis could be carried out in any meaningful way. In addition, two interventions rarely engender identical outcomes, decreasing the possibility of robust conclusions being drawn using this method.

[40] Ibid.
[41] Ibid.
[42] Wilkinson, Peters, & Donaldson, 2004; Tonelli & Callahan, 2001.
[43] House of Lords, 2000, sec. 7.24.

Cost-effectiveness analysis

Frequently used to describe economic evaluations, cost-effectiveness is more narrowly and accurately defined as comparing costs of two (or more) interventions and relating them to a "common effectiveness outcome (e.g. heart attacks avoided.)"[44] The result will be a comparison of cost per unit of improvement between the examined treatments. As outlined in White, Resch & Ernst (1996), the choice of appropriate effectiveness outcome measures is a complex process, but one that should be carefully approached by those wishing to undertake research in this field.

Cost-utility analysis

A specific form of cost-effectiveness analysis, this method utilises a comparison between two (or more) interventions on cost and on a measure of the desirability or appreciation of the treatment by the patient. This is adjusted to gather a quality of life measure, most commonly the Quality of Life Year (QALY). The result is a measure of the relative cost per QALY of the analysed treatments. This should allow comparison between different treatments across the full range of ailments. The most useful measure would be a cost-utility ratio, where the incremental cost of treatment A over treatment B would be divided by the incremental QALYs of treatment A over treatment B. QALYs themselves are arrived at by using one of several qualitative patient questionnaires. The most widely used and examined questionnaires include the EQ-5D, the SF-36 (and accompanying SF-6D), the Nottingham Health Profile and MYMOP (the Measure Yourself Medical Outcome Profile).[45]

Cost-benefit analysis

The most comprehensive method (and most widely used in non-health related situations), cost-benefit analysis measures all costs and benefits in monetary values. Those undertaking the analysis determine which costs and benefits to include in the study. However, public involvement in defining NHS priorities would require the list of included variables to be expanded to incorporate all relevant cost and benefits, potentially on an economy-wide scale.

In any economic evaluation it is important to be aware of three factors. Firstly, the notion of opportunity cost, defined as the value of the next best use of the resources. For example, consider the choice between two therapies to treat migraine, treatment A and treatment B. If treatment A is selected, the cost of treatment B would be the cost of the foregone alternative, or the opportunity cost. As Devlin explains, opportunity cost answers the question "how do the benefits obtained from using resources in one way compare with the benefits foregone from alternative uses of them?"[46] Secondly, marginal costs and benefits are the most useful measures for economic evaluation. While averages and totals are important, analysis of what is happening at the margin provides a more useful tool for determining when a change in practice is worthwhile. For example, marginal benefit and marginal cost refer to how much benefit is gained for say a single additional pound spent. It is important to note, however, that changes at the margin may have knock-on effects elsewhere. Thus, if a new therapy is introduced, "what economists are interested in, with regard to resources, is not just the cost of delivering that new treatment, but the changes in resource use throughout the whole patient pathway."[47] Finally, understanding which costs and benefits one should calculate is a difficult process. Costs are often the easier to define and can be categorised into four distinct groups. Benefits are more difficult to outline, as the appropriate outcome measure will depend on the treatment, the ailment and the type of study to be conducted.

In the Literature Review to follow, a wide variety of cost and benefits are mentioned. Those most frequently cited are as follows:

[44] White, 1996, p.110.
[45] These questionnaires are considered below.
[46] White, C., 2003, p.8.
[47] Ibid.

Benefits

Clinical effectiveness measure

E.g. Reduced heart attacks, lowered blood pressure, attacking a certain pathogen, muscle flexibility, range of movement, etc.

Ailment-specific patient questionnaire

A questionnaire that examines the effect of the treatment upon a patient's ability to carry out everyday activities linked to the ailment. Areas covered include pain intensity, walking, lifting, sleeping, personal care, standing, reading, travelling, dressing, etc. For psychological ailments, areas would include anxiety, mood, guilt, insomnia, etc. Examples of ailment-specific patient questionnaires include:

a) Oswestry Index Questionnaire: examining back problems on 10 areas (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, changing degree of pain and travelling).
b) Neck Disability Index: examining neck problems on 10 areas (pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation).
c) Roland Morris Disability Questionnaire: examining neck or back pain with 18 possible descriptive sentences (e.g. "I stay at home most of the time because of my back"; "I sleep less well because of my back"; etc.)
d) Hamilton Rating Scale for Depression: examines depression on 21 areas (including depressed mood, guilt, suicide, insomnia, loss of weight, agitation, anxiety, etc.)
e) Glasgow Homeopathic Hospital Outcome Score: examines the effect of homeopathic treatment on a patient's health complaint.

Generic health questionnaire

This questionnaire is used to conduct cost-utility analysis and generate an overall understanding of health status. Questions are asked on physical and mental symptoms, function and mobility, emotional state, pain intensity, ability to perform certain activities, anxiety and depression. Examples of generic health questionnaires include:

a) EQ-5D: questions on mobility, self-care, usual activities, pain/discomfort, anxiety/depression and imaginable health state.
b) SF-36 (translated into SF-6D to calculate QALY): questions on limits to carrying out activities (regular and particular), emotional problems, social activities, physical pain and general well-being.
c) Measure Yourself Medical Outcome Profile (MYMOP): questions on a few symptoms that bother the patient most on physical, mental or social problems, general well-being and use of medication. [The case study carried out by this Enquiry will draw on MYMOP data in a later chapter – see Get Well UK Case Study]

Other possible benefits

These outcome measures may or may not include a consideration of well-being, process utilities, health behaviours or patient satisfaction. Whether or not to include these benefits and the methodology to be utilised will depend on the research question being analysed. Furthermore, wider social outcomes, for example the quality of life change for carers or family members, might also be included.

Costs

A table outlining the standard cost categories required for evaluation is presented in both White (1996) and White, Resch & Ernst (1996), and is reproduced here:

Direct costs

I. Medical
    i. Intervention costs: practitioner fees; diagnostic costs (X-rays, etc.); therapy costs (needles, remedies, etc.).

ii. Service costs: provision of clinic rooms and equipment; ancillary staff, including administrator, etc.; office costs including heat and light

II. Non-medical

i. Transportation costs; costs of accompanying relatives.

Indirect morbidity costs
Time off work, time off caring for family.

Intangible costs
Pain, suffering, grief.

"Induced" costs
Adverse reactions to additional treatments.

Economic evaluation attempts to judge the marginal benefit gained against the marginal cost incurred. In a medical context, this relates to determining first whether a treatment is clinically effective, and then whether the clinical results are worth the costs of treatment, namely whether it is cost-effective. Economic evaluations are thus subject to many of the same reservations that CAM practitioners express when attempting to gauge efficacy and effectiveness.

APPROACH OF THE ENQUIRY

This report intends to build on the House of Lords Select Committee on Science and Technology Sixth Report (2000), focusing on the costs and benefits associated with the delivery of complementary and alternative medicine and its possible further integration into the NHS. As is evident from the discussion in Methodological Considerations, much disagreement exists concerning both appropriate research methods and the most important questions to be answered.[48]

The Enquiry took place over nine months, a period of time far too short to attempt a scientific "meta-analysis" of the published material available. Instead, the literature scan, the interviews with stakeholders and the case studies were designed to provide an indicative rather than comprehensive sample of research and experience available.

Attempting to draw conclusions from economic studies of the respective costs and benefits of CAM therapies is not straight-forward. There is often a mismatch between evidence of the benefits of treatments examined in studies considering costs and benefits and clinical evidence regarding the efficacy of the treatment. In addition, cost-benefit studies can use very different conceptions of costs and benefits, some extending to social and other indirect factors, others concentrating purely on direct treatment costs. This Enquiry has conducted only a limited survey of the literature concerned purely with the efficacy of the five CAM therapies examined. It has concentrated instead on the costs and benefits which cost-benefit studies suggest may be associated with CAM treatments. And it seeks to provide some indications of the potential scope of their benefits, whether in the form of improved health care or reduced costs of treatment, which a wider take-up of CAM might be capable of generating.

Literature Review

As outlined in the Introduction, this report begins with a literature review examining the academic literature covering costs and benefits relating to the five selected therapies. This review informs the rest of the project, acting as a database for subsequent sections of the report.

To locate suitable academic studies on cost-effectiveness a generalised search was initially carried out of articles in leading journals and medical databases including:

- PubMed
- British Library medical journal database (AMED)
- *British Medical Journal*
- *The Lancet*

Multiple key word searches were further undertaken in order to reflect the different indexing criteria of various databases and online article archives: however, these were typically based around the five therapies in question. Through perusal of references and footnotes, accepted as a legitimate scholarly method of academic research, articles were included that received a weight of citation and were published in publications with high benchmarks for acceptance; references to academic texts by stakeholders interviewed by this Enquiry were also investigated, and were included when their relevance and reliability warranted. It should further be noted that all archives and databases consulted were in the public realm rather than specialist sources, and as such may be subject to bias. There may be some criticism that there is a positive-outcome bias on the part of the current study towards selecting and including materials dealing with CAM from these available sources, because a mainstream journal is far more likely to publish a well recommended study showing a positive result than a negative effect. But the data were intended as indicative of the field, rather than systematic or

[48] These methodological issues are discussed further in the interviews available in the Appendix A and Appendix B.

exhaustive: the review methodology was intended to offer as broad an overview as was possible given the finite scope and resources of the exercise.

Randomised Control Tests (RCTs) were the primary evidence examined as they represent the gold standard of scientific evidence, but bearing in mind the methodological considerations of assessing the effectiveness of CAM and the relative paucity of such trials in the areas under examination, other methodologies were also accepted, provided they were published in a credible source. Prospective trials[49] were of primary importance but other evidence on costs was additionally examined. All studies examined were in English.

Systematic reviews were consulted in order to check the veracity of trials where possible, and meta-reviews of systematic reviews found on the Database of Abstracts of Reviews of Effects (DARE), held by the NHS Centre for Review and Dissemination (NHS-CRD) at York University, were also consulted where appropriate.

To summarise: when selecting these studies we have relied on the reputation of the publications, reviews of the quality of the studies, and recommendations from the leading stakeholders involved in the field. The Enquiry has not conducted its own systematic review of effectiveness for the five therapies, which would not have been practical in the time available, but has instead identified indicative studies, which appear to have been well carried out, from which, when they are considered together, some reasonably robust conclusions appear to follow. The aim of this chapter is to identify CAM treatment options where the weight of evidence suggests that treatments have beneficial effects, and where related cost information is also provided.

Interviews with Stakeholders

Our conclusions have also been influenced by a series of interviews conducted with stakeholders in the field. Those interviewed cover a range of perspectives and areas of expertise, but constitute leading researchers, policymakers and healthcare professionals with insights into CAM. They come from the leading academic departments, healthcare organisations and governmental departments. Interviewees were identified by their citation in data, referrals as part of the process of research, and on the basis of their authority, relevance and availability. Given the time scale available for research, a fully representative range of opinions and could not be constructed, but the individuals eventually consulted were able to offer informed opinion of relevance to the main areas of study.

Each interview followed a common topic guide but allowed each participant to raise issues of interest or relevance to their research. Interviews were summarised and signed off by participants. The full interviews can be found in Appendix B and a summary in Appendix A. Where relevant the interview summaries have also been cited throughout this document.

Models of Integration and Methods of Delivery

As outlined in the Introduction, this section deals with the way in which services are currently being delivered in practice and the various models of integration that support them. The Enquiry outlines possible models of integration and methods of delivery developed by researchers, and then examines examples of actual delivery.

Service providers were chosen on the basis of their appearance in data, reputation and availability for comment and the time-constraints of the Enquiry. These service providers were chosen to illustrate the wide variety of CAM services currently available as well as indicate the

[49] A prospective trial refers to a study designed to prove or disprove a series of hypotheses. A retrospective study, in contrast, analyses existing data. See Glossary.

benefits and costs associated with these services where possible. They are not intended to provide a statistically representative cross-section of existing provision.

In the cases of Newcastle PCT, the Glastonbury Health Centre and the Westminster PCT, more in depth information was available on the cost-effectiveness of the primary care services. This was expanded by including the most recent cost information available from these trusts and gives three comprehensive examples of delivery. A fourth example of an innovative delivery model is provided in the form of a case study prepared by this Enquiry on the Get Well UK CAM Clinic in the Laurels Healthy Living Centre in Haringey, London. This case study highlights the needs of the three most important stakeholder groups: the general practitioners, the CAM practitioners, and the patients. This is presented in Get Well UK Case Study.

These chapters again indicate the potential for CAM to support conventional medicine in areas where it struggles to meet patients' needs. Our Enquiry seeks to indicate where treatments are potentially cheaper than but just as effective as conventional treatments or where they offer greater benefits at an equal or higher cost. In this section these conclusions should be considered indicative rather than definitive, as cost information is sparse.

CAM in the NHS and Effectiveness Gaps

These sections use publicly available sources and information gathered from interviews with stakeholders to sketch the current structure of funding and provision within the NHS as a whole. This serves to set the context within which integration is occurring although it should be noted that many public (i.e. not private) CAM services are in part charity funded and are to some extent running parallel to NHS-provided primary and secondary care.

As part of our assessment of the future potential of CAM treatments to support national health care provision, the Report outlines some important current "effectiveness gaps". These "gaps" are areas of healthcare where conventional medicine is not responding adequately to the needs of patients, and more specifically where NHS care has not been subject to research to assess its effectiveness or cost-effectiveness; normally, this relates to a range of interventions including issues of diagnosis, treatment and service delivery, especially with regard to the emergence of new technologies.[50] Although limited research has been carried out on defining these gaps, we set out the findings of two recent surveys[51] of general practitioners' and primary health care providers' views of where the effectiveness gaps are, the outcome of our interviews and the findings from the case studies in this area, and then map these against the areas where CAM treatments appear to be relatively effective (building on the Literature Review and other secondary sources). This part of the Report hopes to stimulate a debate on the potential contribution CAM can make to the NHS, providing patients with a broader and more cost-effective spectrum of treatment options.

Conclusions and Recommendations

Finally, the Enquiry presents its overall conclusions and a number of more detailed recommendations, and suggests areas where research should be taken further.

[50] Department of Health, 'NHS R&D Strategic Review: Primary Care', *Report of Topic Working Group* (June 1999), pp. 4 & 9.
[51] Fisher et al., 2004; van Haselen et al., 2003

LITERATURE REVIEW

Introduction

Given the broad spread of research material to be consulted, the Literature Review applies a common format to all therapies explored in this study in order to facilitate ease of comparison:

1. **The Treatment Process**
2. **Current Usage**
3. **Safety**
4. **Overview of Applications and Effectiveness**
5. **Costs and Benefits**
6. **Conclusions**

1. **The Treatment Process:** This describes the history of the therapy, process of treatment and defines the terms of the treatment as it is explored in the current study. This is necessary in some cases in which therapies traditional to one culture have been adapted and disseminated into a wider number of schools e.g. acupuncture.

2. **Current Usage**: The current provision of various therapies is described in this section, including, where possible, context and formats of delivery and estimates of market penetration.

3. **Safety**: Any information on safety considerations is presented.

4. **Overview of Applications and Effectiveness**: This section seeks to explore the evidence for effectiveness of the relevant therapy, as well as how this can be applied to various symptoms and conditions. In instances such as herbal medicine, the overview is segmented by individual treatment.

5. **Costs and Benefits**: The evidence base for costs and concomitant benefits is outlined in this section, which may segment the relevant data as appropriate.

6. **Conclusions**: This attempts to synthesise the existing data upon treatments, in order to provide a tentative conclusion as to the potential cost saving of treatments, as well as the specific conditions under which these savings could be made.

Acupuncture

The Treatment Process

> *"Acupuncture describes a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques. …The most studied mechanism of stimulation of acupuncture points employs penetration of the skin by thin, solid, metallic needles, which are manipulated manually or by electrical stimulation"*
>
> (NIH, 1997)

> *"Acupuncture involves the stimulation of particular points (acupoints) on the skin, usually by the insertion of needles"*
>
> (NHS-CRD, 2001b)

This therapy in its original form is based on the principles of Traditional Chinese Medicine, which sees health in terms of Qi[52] energy circulating meridians [53] linking parts of the body. Acupoints are sited on these meridians and are activated in order to regulate the strength and quality of the flow of Qi along the meridians.[54] There are, however, a number of types of acupuncture practised internationally. As well as the Chinese tradition there are Japanese and Western interpretations and combining two or more approaches gives rise to yet more types, such as Chinese acupuncture with Western influences. This Enquiry has also encountered studies that define treatment as tender spot injection therapy and micro-acupuncture. Like the House of Lords report, this Enquiry takes a pragmatic definition of acupuncture; evidence is considered wherever it is available.

Medical acupuncture, practised predominantly by medical practitioners additionally trained in acupuncture, uses the body's analgesic[55] mechanisms known as "trigger points" in its treatment of pain. These are areas of greater sensitivity in muscles that are supposed to cause referred pain in other areas of the body.[56] This is thought to be part of the "gate theory of pain" which describes acupuncture's action through the endocrine, nervous and immune systems[57]. Response to acupuncture can thus be local to the needling site or more distant, the effect being carried via sensory neurons.[58] The importance of endogenous opioids [59] (the body's own painkillers) in the analgesic effect of acupuncture is supported by considerable evidence.[60]

One recent study,[61] for example, examined the brain activity of patients while they were receiving acupuncture. The single-blinded randomised cross-over trial split fourteen patients suffering from painful osteoarthritis of the thumb into three groups. PET[62] scans monitored the brain function of the patients as they received treatment. One group received skin pricks which had no therapeutic value. Another group had sham acupuncture, which they believed to be genuine. The scans showed the area of the brain associated with the production of natural opiates was activated in the second group. The third group was given genuine acupuncture. It was found that acupuncture activated both the opiate parts of the brain[63] *and* a region of the brain thought to be involved in pain modulation (the *insula ipsilateral*). According to Linde et al. (2005) this means that "acupuncture has a specific physiological effect"[64] that exceeds the effect gained by expecting the acupuncture treatment (the placebo effect).

Current Usage

Acupuncture is used widely both in private and NHS settings. Of the three million acupuncture treatments received in the UK in 1998, one million were provided on the NHS at a total cost of nearly £26 million, more than the total of all other CAM therapies combined. Mike O'Farrell, Chief Executive of the British Acupuncture Council, stated last year that there are up to 12,000 acupuncturists in the UK, 2500 who belong to the British Acupuncture Council.[65] A BMA report in 2000 concluded that acupuncture should become more widely available on the

[52] The Chinese term for vital energy or life force.
[53] The invisible channels through which Qi circulates throughout the body. There are 12 main meridians, each related to, and named after, an organ or body function.
[54] NHS-CRD, 2001b.
[55] Defined as a pain-relieving medication that relieves or eliminates pain without producing anaesthesia or loss of consciousness.
[56] BMA, 2002.
[57] Ibid.
[58] Neurons that carry sensory information to the spinal cord and brain.
[59] Natural and synthetic substances such as morphine and codeine to control pain.
[60] NIH, 1997.
[61] Pariente et al., 2005.
[62] Positron Emission Tomography (PET) scanning acquires images of the body based on the detection of radiation from the emission of positrons. Positrons are tiny particles emitted from a radioactive substance administered to the patient.
[63] Those parts of the brain involved in releasing natural opioids.
[64] Linde et al., 2005.
[65] *The Times*, 19 May 2004.

NHS and a similar study in by the National Institutes for Health (NIH) came to the same conclusion for the USA.[66]

Safety

The safety record of acupuncture is considered high, with few examples of adverse effects;[67] the incidence of these adverse effects being lower than for many conventional drugs and medical procedures.[68] However, several cases of sudden death caused by needles puncturing the heart are recorded in the literature as are punctures to the lung. The most frequent serious risk of acupuncture worldwide is the transmission of infectious disease; there was an outbreak of hepatitis in West London within the last decade. These incidents are all avoidable by basic standards of good practice. In the UK the acupuncture profession is moving towards statutory regulation, already accorded the professions of osteopathy and chiropractic. The Acupuncture Regulatory Working Group was set up by the acupuncture professional bodies, the Department of Health and the Foundation for Integrated Health and has published proposals on the matter. Legislation is expected by 2007.

Overview of Applications and Effectiveness

> *"Acupuncture is a complex intervention that may vary for different patients with similar chief complaints. The number and length of treatments and the specific points used may vary among individuals and during the course of treatment. Given this reality, it is perhaps encouraging that there exist a number of studies of sufficient quality to assess the efficacy of acupuncture for certain conditions."*
>
> (NIH, 1997)

Given the focus of this Enquiry on cost-effectiveness, the information presented here on effectiveness is not a definitive overview: a more complete review would examine in detail all areas of application of acupuncture, incorporating a greater number of trials, systematic reviews and meta-analyses.[69] Instead, the information in this section is included to provide the reader with an introduction to conditions that can be treated with acupuncture.

The NHS Centre for Reviews and Dissemination (NHS-CRD) at the University of York provides overviews of the evidence for the effectiveness of treatments, including acupuncture. Its latest overview of acupuncture (2001)[70] finds that systematic reviews of acupuncture treatments for chronic pain, either for specific conditions such as low back pain or headache, or studies that have considered chronic pain across a range of conditions, vary in their conclusions. The studies compare groups receiving authentic acupuncture treatments with groups receiving sham acupuncture, no treatment at all, or waiting list control[71] (some studies include a combination of the three control groups). In this small survey, this document has been augmented by a search on the Database of Abstracts and Reviews of Effects (DARE) and other Cochrane databases for more recent systematic reviews. The following survey presents information under the following categories:

- **Acute Pain**
- **Chronic Pain**
- **Arthritic Conditions**

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[66] NIH, 1997.
[67] MacPherson et al., 2001.
[68] NIH, 1997.
[69] Meta-analysis is a quantitative method of combining the results of independent studies
[70] NHS-CRD, 2001.
[71] A control group is a group of patients with the symptom that do not receive the treatment to be tested. Waiting list control refers to a group of patients with the symptoms who will receive standard at a future date but are not receiving the treatment to be tested in the interim.

- **Nausea and Vomiting**

- **Other Conditions**

Acute Pain
The NHS-CRD suggests that post-operative dental pain, as a relatively straightforward research topic, provides a good framework for RCTs and reports that acupuncture is "probably effective"[72] for pain relief in this area. A subsequent systematic review also found acupuncture to be effective for the treatment of dental pain in comparison with other interventions.[73] However, the NHS-CRD finds that studies on other forms of post-operative pain use a wide range of treatment techniques and low sample sizes, making conclusions about effectiveness difficult.[74]

Chronic Pain
On the subject of chronic pain generally, the NHS-CRD cites two systematic reviews, both of 51 studies, (ter Riet et al., 1990 and Ezzo et al., 2000) which both come to the conclusion that the evidence for acupuncture in treating chronic pain in general is inconclusive and limited. In a subsequent review Leggett Tait (2002) came to the same conclusion. On back and neck pain, the NHS-CRD found seven systematic reviews[75] that found no conclusive evidence for the effectiveness of acupuncture and subsequent reviews[76] have been no more conclusive on the subject. Leggett Tait (2002) found evidence on neck pain to be unsupported by the evidence. In a systematic review, Furlan et al. (2005) also avoided firm conclusions due to lack of data, but found some evidence that acupuncture is more effective in relieving pain than no treatment or sham acupuncture over three months, and for improving function in the short term. Used as an alternative to conventional treatment they find acupuncture no more effective than conventional treatment, but when used as a complement found it slightly more effective than conventional therapy alone in pain relief and improving function.[77]

On shoulder pain, a systematic review by Green et al. (2005) finds only a small number of studies and inconclusive evidence, although they remark there may be short term benefits in pain and function. On headaches, the NHS-CRD cited four systematic reviews, of which the two largest (Linde et al., 2001 and Melchart et al., 2001) found evidence, though not fully convincing, of the effectiveness of acupuncture. Leggett Tait (2003) reported the evidence for acupuncture treating idiopathic[78] headaches as encouraging.

Arthritic Conditions
Vas et al. (2004) carried out a trial involving 97 participant outpatients with osteoarthritis of the knee in a pain management unit in a public primary care centre in southern Spain over a period of two years. The study comprised a randomised, controlled single blind trial with blinded evaluation and statistical analysis of results into the efficacy of acupuncture as a complementary therapy to the pharmacological treatment of osteoarthritis of the knee.[79] The study finds acupuncture used as a complement to conventional drug treatment using diclofenac to be superior to the drug treatment alone in terms of measures of pain, stiffness, physical capability and physical functioning. However, Ezzo et al. (2001) suggest a role for acupuncture in treating knee osteoarthritis, but finds no conclusive evidence. A similar conclusion of lack of conclusive evidence was found in the systematic reviews on acupuncture for rheumatoid arthritis.[80] A technology assessment [81] on the use of acupuncture

[72] NHS- CRD, 2001.
[73] Leggett Tait, 2003.
[74] NHS-CRD, 2001.
[75] For example, Ernst & White, 1998 and White & Ernst, 1999.
[76] Henderson, 2002, Leggett Tait, 2002 and Ernst et al., 2002.
[77] Furlan et al., 2005.
[78] Without a known cause
[79] Vas et al., 2004
[80] Lautenschlaeger, 1997 and ter Riet et al., 1989.
[81] AHRQ, 2003a.

to treat osteoarthritis, which considered systematic reviews and subsequent RCTs, found the evidence of the effectiveness of acupuncture sufficient to justify using it as a second or third-line treatment for patients not responding to conventional treatment, not tolerating medication or feeling recurrent pain, but not as a first line treatment.[82] However, for rheumatoid arthritis, a systematic review by Casimiro (2005) concluded that despite one positive study on the benefits of electro-acupuncture, it was of low methodological quality and there was no evidence for acupuncture improving any of the facets of rheumatoid arthritis, although the trials performed to date have been few and with low sample sizes.

Nausea and Vomiting

One systematic review on post-operative nausea,[83] which was reported by the NHS-CRD as consisting of high quality RCTs relating to nausea after surgery, chemotherapy and pregnancy,[84] found 11 of 12 studies showed acupuncture to be superior to sham. Whilst this review found data regarding post-chemotherapy nausea weaker than for post-operative nausea, subsequent trials reported by the NHS-CRD were positive. The review suggested a prophylactic[85] effect of acupuncture on pregnancy-related nausea, but found insufficient data for a conclusive result. Subsequent trials reported by the NHS-CRD were mixed in their findings.[86]

Another systematic review[87] on post-operative vomiting performed a meta-analysis on 19 RCTs and found a statistically significant reduction in both nausea and vomiting in adults given immediate post-operative acupuncture. Subsequent trials reported by the NHS-CRD were mixed in their conclusions.

Other Conditions

The effectiveness of acupuncture in stroke rehabilitation is found by the systematic review of Legget Tait (2002) not to be supported by the evidence. The systematic review of Kai-hoi Sze et al. (2002) finds no effect on motor recovery, and that the small positive effect on disability could have been due to placebo. However, it finds that the quality of trials was poor. Both Leggett Tait (2002) and an AHRQ report (2003b) found evidence for the effectiveness of acupuncture in the treatment of fibromyalgia as inconclusive. Holdcraft et al. (2003) in contrast found strong evidence for acupuncture improving symptoms.

Costs and Benefits

> *"Economic evaluation is a crucial aspect of health care if we are to make the best use of resources in the most equitable way. It is particularly relevant to acupuncture practitioners working in the health service because they need to know whether the service time they spend on acupuncture can be justified in terms of reduced drug costs, etc. and to show that acupuncture is not just an expensive hobby."*
> (White, 1996)

White (1996) points out that when it comes to persuading public health authorities or insurance providers to reimburse acupuncture practitioners' fees, "evidence of economic benefits would be essential."[88] He argues that recent improvements both in the quality of NHS data recording (thanks to computerisation) and in the methodology of economic evaluation has made such studies easier to perform. He advocates incorporating economic analysis into clinical studies, using the placebo control of sham acupuncture, but acknowledges that full rigour may not always be possible and acknowledges that uncontrolled trials can produce useful results. He provides a discussion of methodology and a framework for further studies of varying types, including setting out which costs and benefits can be considered.

[82] Ibid.
[83] Vickers, 1996.
[84] Note that acupuncture was found not to be effective when administered under anaesthetic.
[85] A preventative effect.
[86] NHS-CRD, 2001b.
[87] Lee & Done, 1999.
[88] White, 1996, p.110.

Presented below are studies from our literature search that specifically examine the costs and benefits of acupuncture as a treatment. This section has been split into two:

- Cost comparison studies (retrospective[89]) that examine the use of acupuncture compared to conventional treatment for a range of conditions in a general practice setting;
- Prospective studies that look at particular conditions and make direct comparisons of the benefits of acupuncture and conventional treatment as well as comparing costs.

The reason for the split is to draw a distinction between two sets of studies, which use quite different methodological approaches and have quite different subjects.

General Practice

Downey (1995) studied 50 patients with a range of ailments, mostly muscular-skeletal or pain problems (such as tennis elbow, neck pain, knee pain, back pain), in a GP practice in Herefordshire.

- The study compared the health outcomes, as expressed by two groups of patients: those given acupuncture (short needling treatments) and those who were not. Patients were assessed at their first treatment and given a score on a visual analogue scale. After treatment 80% of patients achieved an improvement of at least 10% in their score, with 50% experiencing an improvement in their score greater than 60% (classed as very good or excellent). Ten cases were cured. The author believes he showed that the introduction of short courses of acupuncture is useful for acute and short term conditions, but not for chronic ones: patients with problems of a year's standing or more had an improvement of 10% or more in only two of nine cases.
- The cost of providing acupuncture was compared with the likely cost of treatment had acupuncture not been administered. Comparator costs were identified as physiotherapy, with an average cost of £72 (six sessions at £12), monthly Ibuprofen 400mg treatment at £2, and an outpatient appointment at £70. The net saving over the whole sample of patients was estimated at £610 (a saving of £1,108 on physiotherapy, drugs and out-patient referrals against an increase in expenditure on surgery time and needles of £498).[90]
- White & Ernst (2000) in their systematic review of economic evaluation of complementary medicine, argue that a flaw in this study is that the costs of further treating the 50% of patients who did not receive a significant improvement from acupuncture were not taken into account.

Bourne (1996) studied a GP practice in Essex, comparing the total prescription costs of the partner (the author) that used tender-spot injection therapy (TSIT) with the partners who did not.

- Patients who the author felt could benefit from the treatment were administered the injection treatment. From clinical audits the author reported a relief from pain for five months in 54% of cases, a relief from between six weeks and five months in 23% of cases, and no relief in 2% of cases [the remaining 21% are unspecified].
- The annual prescription bill for the author was lower than the other partners, the author attributing the disparity to the use of TSIT. The cost of an average TSIT of four injections was £4 in 1979. The average monthly cost of conventional drugs for muscular-skeletal pain and anti-inflammation was between £2.70 and £5.45 (1979 prices). The saving for each patient treated with TSIT was around £4 for the first month and £8 per month thereafter (1979 prices). The author lists other cost savings, including reductions in: physiotherapy and support bandages; time off work; investigations such as x-rays; travelling costs; consultant time and inappropriate psychiatric referrals.
- The author concedes that there might have been patient selection bias as the doctor using TSIT could have treated most of the practice's muscular-skeletal patients who,

[89] See Glossary.
[90] This cost also included the cost to the practice of the initial acupuncture training (British Medical Acupuncturists Society basic course at £395). [0]

compared to those with cardiac or psychiatric disorders, are probably on average cheaper to treat. The author remarks that if one GP in each practice in the land (assuming one in four of the 28,000 GPs) were to adopt a similarly effective practice for treating muscular-skeletal pain an annual saving of £95 million (1979 prices[91]) could be realised.

Myers (1991) examined drug expenditure in a single GP practice in Yorkshire.

- 54 patients were studied, mostly suffering from back pain (including sciatica) or neck pain. Costs were compared between usual care and acupuncture allied to lifestyle advice (concerning diet, exercise, lifestyle and activities for daily living appropriate for each condition).
- The trial was retrospective and non-randomised, but gives an indication of reduced drug costs where a medical acupuncturist treated patients with conditions from which they had been suffering, and for which they had been taking medication, for at least a year.
- The costs of medication (taken from the British National Formulary) to treat patients for six months before and six months after the administration of the acupuncture treatment were compared, and showed that an average of £44 was saved in drug costs per patient (range £0 to £134) when acupuncture was used.

Lindall (1999) compared costs in a single practice and found acupuncture to be cheaper than hospital out-patient referral.

- 65 patients, all suffering from pain, mostly some form of musculoskeletal pain, and dissatisfied with initial drug treatment assessed their own health state after treatment on a ten-point scale (where 0 was their state of health before starting treatment and 10 perfectly normal). The average score for all patients after treatment was 7.6.
- Retrospective and imputed costs (what treatment would have been given in the judgement of the doctor had acupuncture not been administered) were analysed and an average cost saving of £232 per patient in total treatment costs across a large range of conditions reported (such as severe back pain, daily headache, shoulder pain and frozen shoulder). The total cost difference takes into account the reduction in cost saving of those patients who received acupuncture, but for whom it was unsuccessful and had an out-patient referral anyway.
- The study is not randomised, but according to White and Ernst (2000) is more rigorous than Myers (1991) or Downey (1995).

Ross (2001) studied the benefits of using micro-acupuncture[92] in general practice.

- Over four years one, then two partners in the practice administered this and similar acupuncture treatments, in all to 20% of the patient list of 6,700. The acupuncture was administered whenever suitable patient conditions were present and was performed in the usual GP appointment slot. This resulted in practice referrals to physiotherapy and outpatient rheumatology[93] falling by 86% and 51% respectively. Prescription of anti-inflammatory drugs also fell.
- No monetary values were assigned to the cost savings, but they were likely to be "considerable", and the treatment has the advantage of being able to be delivered in ten-minute GP consultations. Causation was not proven (through considered very likely) and increases in doctor workload not measured.
- The author does not claim to have found evidence of the cost-effectiveness of acupuncture in general practice, but adds to evidence that significant cost savings could be made.

Particular Conditions

[91] This article was published posthumously in 1996; the author had used 1979 costs when making calculations.
[92] Micro-acupuncture as developed by Felix Mann is a technique where (usually only one) needle is inserted on one side of the body, to a depth of about 3 mm, and withdrawn without stimulation after a few seconds.
[93] Hospital rheumatology departments diagnose and treat inflammatory diseases of the muscles and joints, including arthritis.

Wonderling et al. (2004) conducted a large trial with 401 patients, on the use of acupuncture in the treatment of chronic headache, mostly migraine.

- The comparison was made between the costs to the NHS and to that of society of treating migraine, which the authors estimate at £23-30m annually for the NHS and between £250 and £611m to the economy in lost production. It should be noted that estimates were made a decade ago and can be expected to have risen in the interim, partly due to the increase in prescription of more expensive drugs.
- The study used a net benefit approach to finding values for incremental costs per QALY gained, which requires a ceiling ratio with which to compare an increase in net benefit. The trial uses a ceiling of £30,000 per QALY on which to base its results, in line - according to the authors - with the benchmark used by NICE[94] in its decisions on cost effectiveness of treatment. It was a cost utility study, using the outcome measure of cost per QALY, thereby incorporating the range of clinical effectiveness benefits as included in the SF-6D, a health related quality of life index derived from patients' response to the SF-36 health questionnaire.[95]
- The study compared a control group which received normal care alone with an acupuncture group that received up to 12 treatments in three months. The study found that for a treatment of acupuncture, which in total lasted on average 4.2 hours (7.9 treatments),[96] a benefit of 0.021 QALYs (equivalent to eight quality-adjusted health days) accrued to each patient in addition to the benefits gained by patients receiving usual care; this result held under sensitivity analysis.
- The cost incurred by using acupuncture in addition to standard NHS treatment was £205 per patient, excluding reductions in patient expenditure on other appointments with CAM practitioners and over-the-counter medicines. The cost of a visit to the studied acupuncturist is £43 per hour. This leaves a net increase in cost of £189. The study finds that per patient the cost of an additional QALY is £9,180 if acupuncture treatment is undertaken by a study acupuncturist.[97]
- Using a statistical distribution the study finds that the probability of the acupuncture treatment being cost effective is 92%. The comparison can be altered to include different possibilities for treatment provider. For example the cost per QALY gained rises to £11,375 if a private acupuncturist is used (as her rate per hour is higher than would be paid to an NHS acupuncturist), but falls to £5,701 if an NHS physiotherapist trained in acupuncture who can treat three patients an hour is used (as her rate is lower).
- If a consideration of the reduction in work days lost is made than the cost is further reduced to £3,263 and when the long term benefits are considered over 2, 5 and 10 years the cost falls further. Even if the acupuncture were provided by a private practitioner, the probability that it would achieve cost effectiveness with a NICE ceiling of £30,000 per QALY is still greater than 85%.
- The study finds that not only is acupuncture cost effective when compared with the cost ranges set by NICE (see CAM in the NHS section of this report), but that in comparison to other possible interventions for migraine that have been analysed in a similar way, acupuncture also fares well. The authors recommend the use of acupuncture in the treatment of migraine as it is "relatively cost effective compared to other interventions offered by the NHS".
- This study has not been the subject of a systematic review, though the authors believe this paper to be the first rigorous economic evaluation of acupuncture.

A pragmatic RCT carried out by **Thomas (2003)** as a Health Technology Assessment tested the hypothesis that patients suffering non-specific lower back pain would gain more long-term pain relief at equal or lower cost if offered traditional acupuncture alongside conventional care, rather than conventional care alone.

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[94] National Institute for Health and Clinical Excellence. See CAM in the NHS for more details, including NICE cost effectiveness ranges and guidelines.

[95] See the Methodological Considerations section for a discussion of these terms and issues.

[96] Some patients (30 in the acupuncture group and two in the control group) attended further acupuncture appointments with another NHS, or a private, acupuncturist. These costs were added to the total for the acupuncture group.

[97] An acupuncturist used in the study (as distinct from a private acupuncturist).

- The study was undertaken in York in three non-NHS acupuncture clinics, with patients referred from 39 GPs. 241 patients were observed, each patient the acupuncture group were allowed up to ten (the average number used was eight) individualised acupuncture treatments, which included massage and advice on diet, rest and exercise. Usual care comprised physiotherapy, medication and back exercises. Patients' back pain was of between four and 52 weeks.
- The findings were that on the main benefit measure: SF-36 (0-100 scale) (see Glossary), there was a 5.6 point advantage to the acupuncture patients after one year of treatment and eight points after two years of treatment. No benefits for function or disability were identified. Patients also recorded a greater reduction in worry about their back pain after both one and two years of treatment. After two years of treatment those using acupuncture were significantly more likely to report a year of freedom from pain and less likely to use medication for pain relief. No major adverse effects were reported by patients using acupuncture; 16 patients left the acupuncture group, of whom four reported minor adverse effects such as pain at site of needling.
- The study found the acupuncture service to be cost effective after two years, with an estimated cost per QALY of £4,241 (using the SF-6D score, based on answers to the SF-36 health questionnaire). Using an alternative benefit measure, the EQ-5D cost per QALY is estimated at £3,598.
- The study concludes that commissioners of musculoskeletal services would be justified in considering short courses of traditional acupuncture (to which GPs would refer) available to a typical group of primary care patients with persistent non-specific lower-back pain.

Johansson et al. (1993) undertook a study of 78 patients in Sweden on the use of acupuncture after stroke.

- Benefits were measured on the mobility score measuring motor function and Barthel's Index[98] was used to measure physical disability. A broader quality of life index, the Nottingham Health Profile (a patient questionnaire), was also used. One group of patients received normal care (daily physiotherapy and occupational therapy) and the other received, in addition, acupuncture twice a week for ten weeks.
- The observed benefits were quicker to arrive and recovery was fuller for those patients receiving acupuncture than those in the control group. Not only were the measures of quality of life higher at three and six months after stroke, with higher scores for energy, mobility, emotional reaction and social isolation, the difference in mobility, balance and walking were statistically significant, as was the measure for overall quality of life (no estimate of monetary value is put on the quality of life or other wellbeing measures).
- Another benefit measure was the location of stroke survivors after three months and a year: a significantly larger number of patients receiving acupuncture were living at home at both intervals after stroke onset. While the number of days spent in neurological wards was the same for the two groups, the length of stays in geriatric rehabilitative units and nursing homes was significantly lower for the acupuncture than the control group.
- A cost saving of $26,000 ($56,000 compared to $30,000) per patient in the first year after stroke was observed for those using acupuncture compared to usual care. This figure was calculated by comparing the costs of hospital and nursing homes and rehabilitation facilities and excludes allowance for the costs of acupuncture.

[98] Includes nine items assessing the ability for self-care, and six items assessing the mobility, of a patient. Patients can score between 0 (complete dependency) and 100 (complete independence). A score between 80 and 100 is consistent with a mild impairment in physical independence.

Conclusions

The clinical effectiveness of acupuncture in the treatment areas covered in this review of cost-benefit literature has not been definitely established in many cases. However, several studies (in some cases high-quality RCTs) are indicative not only of clinical benefits in terms of symptom relief and more general health benefits, but also in many cases of the cost advantages, either in the form of pure cost savings or cost-effective additional benefits, of using acupuncture compared with conventional therapies.

There are uses of acupuncture for which there is good clinical evidence of health benefits, but no cost-benefit literature. While this Enquiry's survey of this branch of the literature was not exhaustive, it found strong evidence supporting the use of acupuncture in post-operative and chemotherapy-related nausea, and post-operative pain. Evidence on other treatment areas was found to be equivocal, and more work appears necessary to settle the questions raised. In this pursuit cost-effectiveness analysis is needed; as this survey shows, it is capable of offering some extremely useful results.

Used as an alternative to conventional medicine, the studies examined by this Enquiry suggest that acupuncture may have advantages in terms of costs and benefits in one main area:

- Musculoskeletal Conditions in General Practice

Used as a complement to conventional medicine, the studies examined by this Enquiry suggest that acupuncture may have advantages in terms of costs and benefits in relation to the following conditions:

- Lower Back Pain
- Migraine
- Stroke Rehabilitation

It should be noted however that for stroke rehabilitation the evidence of clinical efficacy independent of costs appears to be significantly weaker than for the other conditions for which there seems to be some good, though inconclusive, supporting evidence.

KEY for Literature Review Chapter Tables

Figure for CAM treatment is higher (up -arrow) or lower (down arrow) than conventional treatment based on a direct comparison in a study.

Indication that figure for CAM treatment is higher (up -arrow) or lower (down -arrow) than conventional treatment but not based on a direct comparison in a study.

Figure for CAM treatment is roughly equivalent to conventional t reatment.

(A blank space indicates that there is insufficient evidence for a judgement)

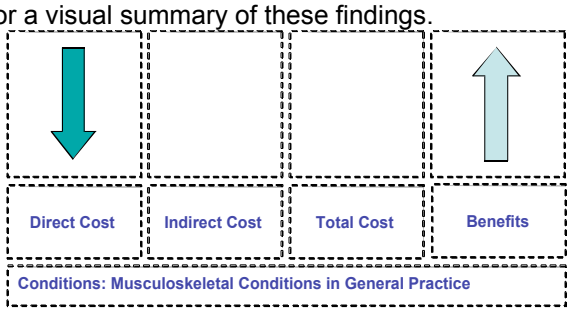
Acupuncture as an Alternative

The treatment by acupuncture of the diverse conditions of musculoskeletal conditions in primary care has been found to increase benefits and reduce costs compared to conventional treatment.

Musculoskeletal Conditions in General Practice

The requirement for hospital out-patient appointments and prescribed pharmaceuticals for musculoskeletal patients have both been shown to be reduced when acupuncture is used as a treatment option in primary care. If adopted nationwide, acupuncture in this setting could offer substantial cost savings to NHS purchasers of conventional treatments. One study

claims that if one GP per practice in the UK were to introduce short needling acupuncture treatments, primarily for musculoskeletal and pain complaints, savings of £95 million per annum (1979 prices) could be realised[99] (approximately £320m in today's prices). [100] These cost savings are allied to extra benefits in the form of increased scores in quality of life indices and other measures specific to an ailment (e.g. the physical disability associated with stroke). Some practitioners would argue that these savings undervalue the overall impact of acupuncture since more intangible benefits such as feelings of greater wellbeing and satisfaction with the treatment process are not captured by quality of life questionnaires used in these studies. Although these studies are in general not rigorous in their methodology, they do paint a consistent picture and describe acupuncture being successfully used for conditions for which there is evidence of its efficacy in the literature. The sources for this conclusion are: Downey, 1995; Bourne, 1996; Myers, 1991; Lindall, 1999 and Ross, 2001. Please see below for a visual summary of these findings.



Sources: Downey, 1995; Bourne, 1996; Myers, 1991; Lindall, 1999 and Ross, 2001

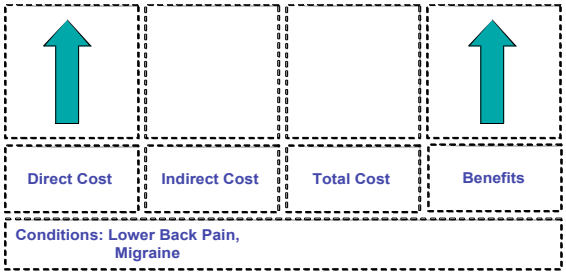
Acupuncture as a Complement

Used in conjunction with conventional care, acupuncture increases direct costs, but the extra benefits it provides can be cost-effective.

Lower Back Pain and Migraine

Conditions such as migraine and back pain have large economic costs to the UK; it was estimated in the early 1990s that the cost to the UK of the lost production caused by migraine was between £250 and £611 million per annum (approximately £340 - £840 million in today's prices)[101] and the economic cost of lower back pain is generally agreed to be very large (up to £11 billion[102]) While this Enquiry has found no full cost-benefit studies that took these indirect costs into account, it did find indications that as long as treatment costs are not too high, net benefits should accrue. A cost utility study[103] showed that administering acupuncture to migraine sufferers as a complement to normal care gives patients cost-effective extra benefits (given current NICE guidelines). Incorporating acupuncture into NHS migraine care would raise expenditure, estimated in the early 1990s to be £23 to £30 million (approximately £30 – £40 million in today's prices),[104] but economy-wide cost savings could be large. A similar result has been found in the use of acupuncture for lower back pain over two years.[105] The extra benefits of acupuncture are even more cost-effective than those relating to migraine. This is very encouraging for an ailment notorious for its ubiquity and its economic costs (see Manipulation Therapies, to follow in the Literature Review for more details). Although only backed by single studies (Wonderling et al., 2004 for migraine and Thomas, 2003 for lower back pain), they are of high methodological quality and the efficacy of acupuncture in the treatment of these ailments is supported in the literature. Please see below for a visual summary of these findings.

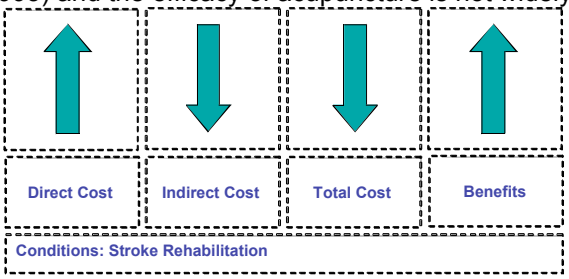
[99] Downey, 1995.
[100] Prices calculated using National Statistics retail price indices.
[101] Prices calculated using National Statistics retail price indices
[102] See Manipulation Therapies, for details
[103] Wonderling et al., 2004.
[104] Prices calculated using National Statistics retail price indices
[105] Thomas, 2003.



Sources: Wonderling et al., 2004 (migraine) and Thomas, 2003 (lower back pain)

Stroke Rehabilitation

In stroke rehabilitation, where the indirect benefits are not returning to work more quickly, but spending more time at home rather than in a rehabilitation facility or nursing home, acupuncture used in conjunction with normal physiotherapy and occupational therapy was found to be beneficial.[106] It could be ventured that this result has benefits to patients and their families unrecorded by the literature to date. Please see below for a visual summary of these findings. It should be noted that this result is drawn from only one study (Johansson et al., 1993) and the efficacy of acupuncture is not widely established in the literature.



Source: Johansson et al., 1993

Quantifying the potential cost savings on a nationwide scale is difficult. Since no patient-level data was available, extrapolation from individual studies to a national summary was not possible. Not only would data on individual patient treatments and costs have to be available, but also information on patient contraindication against acupuncture. However, the indications are that, although not quantifiable, the cost savings available in primary care due to reductions in GP time, referrals to secondary care and drug budgets are potentially large. The cost advantages in treating those patients suffering from stroke would be naturally more marginal to the wider NHS budget, though still potentially significant. The cost-effective additional benefits that acupuncture offers to sufferers of both lower back pain and migraine, two ubiquitous complaints, could on this evidence be substantial and highly cost effective. They should therefore attract a high funding priority.

[106] Johansson et al. (1993)

Homeopathy

The Treatment Process

Developed in Germany in the late eighteenth century by Samuel Hahnemann (1755-1843), homeopathy has spread throughout the world. The word itself is a compound of the Greek words homoios (similar) and pathos (suffering). It works on two basic principles: like treats like and even at very high levels of dilution the remedy remains effective. In practice this means that a substance that would produce symptoms in a healthy individual can be used (in great dilution) to treat a patient suffering from those same symptoms. For example, the homeopathic approach to treating hay fever is to give patients minute quantities of pollen. The approach is similar to that behind vaccination and anti-venom: a minute quantity of the substance that causes the ailment is used to heal it. The second principle means the active ingredient is used in a highly diluted form to avoid toxicity; remedies are still effective even after being diluted in water beyond Avogadro's number.[107]

A homeopathic consultation in a private practice often lasts an hour or more and would include a detailed patient history, a clinical examination of their symptoms and a discussion about "modalities". These are conditions that either aggravate or relieve the symptoms being presented, such as certain weather conditions or day-to-day activities (such as heavy lifting or smoking). The patient's symptoms are then matched to a remedy using a repertory.[108] After the initial diagnosis the patient attends follow-up appointments, their prescriptions being changed depending on the progress of their symptoms.[109]

The area of homeopathy that attracts most controversy is its mechanism of action. Since remedies are often diluted to the extent that there are frequently no molecules of preparation left in the prescribed solution, orthodox scientists are sceptical that the preparation can have an effect on the body. A study by Benveniste in the 1980s[110] seemed to prove the notion of water having a memory,[111] but the experiment proved irreproducible and struck a blow against the credibility of homeopathy. More recent work in the same area[112] has been seen by the homeopathic community as potential scientific proof of the therapy's mechanism of action, but it remains on the edge of orthodox science. A BBC Horizon experiment in November 2002 could not produce a trial proof of the water memory mechanism (although the methods of this experiment have been challenged by supporters of homeopathy). As Professor Ernst has concluded:[113]

> *"Few therapies have attracted more debate and controversy than homeopathy. Throughout its 200-year history, critics have pointed out that its very principles fly in the face of science, while proponents have maintained that it is narrow minded to reject an overtly helpful approach to healing only because one cannot explain how it might work."*

Current Usage

As with the other CAM therapies, most homeopathy in the UK is provided by the private sector. However, there has been provision in the NHS ever since its founding in 1948. There are five homeopathic hospitals in the UK; the largest, in London and Glasgow, both have in-

[107] NHS-CRD, 2002 and Ernst, 2002. Avogadro's number shows how many particles of a material are in a given mass of the material (the number is 6.02 _ 10^{23}). Homeopathic dilutions greater than about 24X (one X dilution is one part of material in 10 parts of water, a 2X dilution is one part of the first dilution in 10 parts of water) are virtually certain to contain not a single molecule of the initial substance.
[108] A repertory is an index of homeopathic remedies by symptom.
[109] NHS-CRD, 2002.
[110] Davenas et al. (including Benveniste), 1988.
[111] "Water Memory" is the notion that, even though in the average phial of homeopathic medicine no molecules of the original preparation remain, the water retains a "memory" of what it once contained. An analogy drawn is with a floppy disc, which contains detailed information undetectable by chemical analysis.
[112] Belon et al., 2004.
[113] Ernst, 2002.

patient facilities. In primary care,[114] according to a 1995 survey of general practices in the UK; half of all NHS referrals for complementary treatment were for homeopathy. Referrals for homeopathy, like other treatments, are made by GPs or other health professionals and rely on service agreements between PCTs and NHS homeopathy providers.[115] More detail on NHS provision is provided in CAM in the NHS and Effectiveness Gaps.

Safety

Homeopaths have not as yet followed the advice of the House of Lords Report[116] to form a single professional statutory body to regulate the profession; homeopathy is the only profession among those examined in this report that does not have and is not in the process of gaining this type of regulation. Dr Peter Fisher, Director of the Royal London Homeopathic Hospital, believes this might be due to inter-professional disagreements and is in favour of the formation of such a body[117]. However, it is among a group of CAM therapies working towards a system of voluntary regulation. The Foundation for Integrated Health in conjunction with the homeopathic professional bodies, using grants from the King's Fund and the Department of Health has been working on a model of voluntary self-regulation for the profession, including a timescale for its implementation.

It has been said that homeopathic remedies can have no side effects. Dr Fisher believes that the greater risk of adverse effects is found in the risk of indirect side-effects (see Appendix B). This is the (potentially life-threatening) danger of a patient being given homeopathy to treat a serious condition for which conventional treatment is clearly more effective (for example conditions such as HIV/AIDS or cancer).

A systematic review of information (published in English)[118] regarding adverse incidents connected to homeopathy between 1970 and 1995 (Dantas and Rampes 2000) found that whilst there may be underreporting of adverse incidents due to the assumption that homeopathic medicines are harmless (and the incidence of adverse effects in controlled clinical trials was low, and the effects minor and transient. Symptom aggravation and adverse reactions due to the mislabelling of homeopathic remedies were recorded, but overall the review concluded that:

> "Homeopathic medicines in high dilutions, prescribed by trained professionals, are probably safe and unlikely to provoke severe adverse reactions". (p.S37)

Overview of Applications and Effectiveness

Since the proposed mechanism of action for homeopathic remedies arouses controversy, it has been suggested that a "higher bar" of evidence, i.e. evidence of greater rigour, is needed to prove the effectiveness of homeopathy than for other treatments. This section provides an introduction to issues of effectiveness independent of costs, and allows the reader an overview of the possible applications for homeopathic treatments. The material in this section has been split into two sections: tests of homeopathy as a complete therapy system, and its use as such; and assessment of the ability of homeopathy to treat specific conditions.

Homeopathy as a treatment system

The NHS-CRD (2002) reports four systematic reviews examining the general effectiveness of homeopathic treatment, including patients with any disease (i.e. not targeted for specific complaints). The NHS-CRD reports that none of the reviews, due to methodological problems in the primary studies, could make firm conclusions about the effectiveness of homeopathy

[114] See Glossary.
[115] NHS-CRD, 2002.
[116] House of Lords, 2000.
[117] See Appendix A.
[118] A significant portion of the work on homeopathy is published in European languages other than English.

and urges caution in viewing the results of two of the studies (one of which was Linde et al., 1997), which pooled heterogonous data to carry out meta-analysis. However, in his review of systematic reviews of homeopathy, Ernst (2002) cites the "technically superb meta-analysis" of Linde et al. (1997), which concluded that while there is not sufficient evidence to prove the clinical effectiveness of homeopathy in the treatment of any particular condition, there is evidence that the action of homeopathy treatment is more than just placebo. Ernst reports that "homeopaths worldwide celebrated this publication as the ultimate proof of their treatment,"[119] but notes that some subsequent re-analysis of the same data has cast doubt on the original conclusion. A French meta-analysis found "some evidence that homeopathic treatments are more effective than placebo", but that "studies of high methodological quality were more likely to be negative than those of lower quality."[120] Most recently a comparative study in *The Lancet*[121] examined 110 studies of homeopathy and matched them with equivalent trials of conventional treatment. The report examined trials it deemed least likely to be subject to bias, which it acknowledged in the conduct and reporting of trials in both homeopathy and conventional medicine. Statistical analysis led the report to conclude that evidence for a specific effect of homeopathy was weak and for the effects of conventional interventions strong, meaning that the clinical effects of homeopathic remedies could be considered placebos. Dr Fisher, in his interview with this Enquiry, pointed out that the conclusions drawn from meta-analysis is highly dependent on the statistical methods used to analyse the data, and the criteria used to include or exclude studies and their data in the first place.[122]

These reviews assess the effect above placebo of homeopathy as a general system and therefore do not provide specific implications for clinical practice.[123] Overall Ernst (2002) concludes that "the best clinical evidence for homeopathy available to date does not warrant positive recommendation for its use in clinical practice" and NHS-CRD (2002) says that "There is currently insufficient evidence of effectiveness either to recommend homeopathy as a treatment for any specific condition, or to warrant significant changes in the current provision of homeopathy."

A forthcoming World Health Organisation (WHO) report[124] will acknowledge the implausibility of the underlying science of high dilution homeopathy from a pharmacological viewpoint. However, it will also report that the majority of research into homeopathy in the past 40 years, ranging from mechanism of action studies, to RCTs in humans and animals, to cost-effectiveness studies and practical research into service provision has shown homeopathy to be better than placebo in some placebo-controlled trials. It cites the Linde et al. study (1997) and also a report from the Homeopathic Medicine Research Group, a group of researchers in conventional medicine and homeopathy commissioned by the European Commission, which after selecting the highest quality RCTs, representing over 2,500 patients, performed a meta-analysis and concluded that homeopathy is in general superior to placebo.

Homeopathy treating particular conditions

On specific conditions, Ernst (2002) reports RCTs that provide evidence for the efficacy of homeopathy in the treating of postoperative ileus[125] and influenza, though in the latter case the effect was small and therefore of "debatable clinical relevance". Ernst (2002) finds RCT evidence on the efficacy of arnica,[126] the most frequently tested homeopathic remedy, "is not demonstrably different from placebo". According to the NHS-CRD (2002) there are RCTs that suggest homeopathic remedies may be successful in treating: otitis media (middle-ear

[119] Ernst, 2002.
[120] Cucherat et al., 2000.
[121] Shang et al., 2005
[122] See Methodological Considerations for more information on meta-analyses.
[123] Ernst, 2002.
[124] WHO Draft Report (to be published in 2005).
[125] The loss of adequate intestinal motility.
[126] A perennial herb with orange-yellow daisy-like flower heads. Used to reduce the inflammation and pain of bruises, aches, and sprains.

infections) and diarrhoea in children, mild traumatic brain injury, premenstrual syndrome and rheumatoid arthritis

Frei and Thurneysen (2001b) studied the use of homeopathic treatment individualised to each patient and the prescription drug methylphenidate (MPD, trade name Ritalin) in the treatment of attention deficit hyperactivity disorder (ADHD).[127] The study showed that homeopathy was very effective in treating ADHD, with three quarters of children responding after an average of three and a half months' treatment. Some children did not respond and had to go onto MPD and a few did not respond to either. The study found that when treatment is not urgent (it took some time and required trials of possible homeopathic medications), and especially in pre-school children, homeopathy is a very useful treatment option and one that does not carry the side-effects or abuse potential of MPD. The homeopathic remedy was also found to have a continuous positive effect over 24 hours (MPD has a duration of action of four hours or eight hours depending on its form). This implies that homeopathy can be used as either an alternative or a complementary medicine: when both MPD and homeopathy are used in conjunction the percentage of non-respondents fell to only 3%. The study points out that both treatments for ADHD are palliative (they ameliorate symptoms) rather than curative.

Riley et al. (2001) compared conventional and homeopathic approaches to treating patients with one or more of the following ailments: upper respiratory tract complaints, including allergies; lower respiratory tract complaints, including allergies; and ear complaints. 456 patients were observed across four countries; 281 received homeopathy and 175 conventional medicine. Response to treatment, measured by patient opinion on their improvement in health was found to be greater for patients using homeopathy than conventional medicine (83% against 68%), and a greater proportion achieved improvement within three days from homeopathic medicine (67% against 57%). Adverse effects were observed in just 8% of patients treated with homeopathy against 22% of those conventional treated. 79% of homeopathic patients reported being very satisfied with treatment compared to 65% of conventional medical patients. All these differences were found to be statistically significant.

A systematic review[128] of homeopathy used as a treatment for osteoarthritis[129] (OA) found four high quality trials comparing homeopathic to conventional treatment. One study, on patients with OA of the knee, found that injecting a homeopathic preparation into the knee was found to be just as effective as conventional injected treatment in pain reduction and just as well tolerated[130] by patients. The trial, also for knee OA, of a liquid homeopathic preparation, found that it was at least as effective as paracetamol and with fewer side effects. A crossover trial (see Glossary) of patients with hip or knee OA (or both) found the single homeopathic remedy rhus toxicodendron[131] (taken orally) to be no more effective than placebo, while a conventional non-steroidal anti-inflammatory drug was significantly more effective. The fourth trial found a homeopathic gel topically applied to the knee was at least as effective as the conventional non-steroidal anti-inflammatory drug (NSAID) gel in reducing pain and improving joint mobility in patients with knee OA (the gel has previously been shown to be as effective as ibuprofen in treating mild knee OA). The authors of the review state that the treatment of OA with conventional treatment is largely palliative and can have significant adverse effects, while homeopathic remedies are likely to have only few adverse effects and will appeal to those patients keen to do more than just alleviate symptoms. They also make the point that osteoarthritis is the most prevalent cause of joint pain in the middle-aged and elderly population and is destined to be the most prevalent disease in society, generating enormous costs.

[127] A condition that becomes apparent in some children in the preschool and early school years that makes it hard for these children to control their behaviour and/or pay attention.
[128] Long and Ernst, 2001.
[129] A type of arthritis that causes the cartilage in the joints to fray and wear.
[130] Toleration in this context refers to the incidence of side-effects on a patient of using a treatment
[131] A homeopathic remedy derived from the plant Poison Ivy.

Costs and Benefits

General Practice

Haidvogl et al. (2001) enrolled patients in Austria and Germany into a (non-randomised) large long-term observational study[132] of the effectiveness, safety and cost effectiveness of homeopathic and conventional medicine in primary care.

- Of the 665 patients recruited so far (the study eventually aims to recruit 1,000 patients), 70% suffered from chronic diseases known to be of "high economic burden", such as atopic dermatitis (eczema), asthma, bronchitis or migraine. In the homeopathy group, 63% of patients described their condition as "serious", compared to 35% in the conventional group.
- The project is ongoing though at last contact 24% of patients treated with homeopathy reported a complete recovery (patient outcome measured by Integrative Medicine Outcome Scale – IMOS), compared to 10% of patients that had received conventional medicines. Patients in the homeopathy group reported greater quality of life improvements, as well as more satisfaction with both their treatment and with their healthcare provider (patient satisfaction measured on the Integrative Medicine Patient Satisfaction Scale – IMPSS).
- Fewer adverse incidents were reported by patients in the homeopathic than in the conventional therapy group. The study also found homeopathic treatments to be more cost effective: to achieve a complete recovery) within the first six months, €86 had to be spent on homeopathic treatments compared to €173 on conventional treatments.

Wassenhoven & Ives (2004) studied 80 GP practices in Belgium in which doctors were member of the Unio Homoeopathica Belgica.[133]

- All patients that visited the practices on a particular day were invited to complete a questionnaire about their present homeopathic and past conventional treatment (on average the patients had been using homeopathy for just over nine years), its cost, and their satisfaction with it; their doctors completed an accompanying questionnaire. This approach captured 782 patients with a range of complaints covering all major organ systems, 78% of which were serious enough to interfere with daily living.
- The study showed that patients found that homeopathic consultations were much longer than conventional ones, but also that their annual expenditure on consultations was lower after switching to homeopathy. Just over half of patients discontinued at least one conventional drug treatment (the most common discontinued drugs were psychotropic,[134] those for respiratory conditions and antibiotics. The doctors prescribed conventional drugs to just over a quarter of patients, usually antibiotics, almost exclusively to treat respiratory infections, or cardiovascular medication (see Glossary).
- Prescription costs (including conventional drugs prescribed) were one-third of the GP average, 95% of patients declared themselves to be fairly of very satisfied (compared to 20% for their previous conventional treatment), and almost nine out of ten said homeopathy had improved their physical condition (8.5% said it had made no difference and 2.4% said it had worsened it). Under their previous treatments, 13% of patients recorded improvement, 32% no difference and 55% believed their condition to have worsened. Doctors' ratings of patient improvements were similar.
- The authors conclude that if extrapolated to the whole of Belgium, these figures would mean an annual saving of about two-thirds (€775m) in the Belgian drugs budget.
- Whitmarsh (2004) points out (and the authors acknowledge) that this figure should be treated with great caution as it is based on retrospective data, and relies on the memories of patients looking back at treatment costs and benefits sometimes from years ago. Furthermore, the positive observation of patient satisfaction might be overly optimistic as many of the patients surveyed were highly disaffected with their previous conventional treatment. However, the authors conclude that the results support the hypothesis that homeopathic treatment is cheaper than conventional medicine.

[132] Study in which variables of interest are observed, not manipulated.
[133] See Glossary.
[134] A drug that affects the mind, emotions, or behaviour.

Witt et al. (2005) performed a comparative cohort study on almost 500 patients in Germany.

- Patients with selected chronic conditions were selected for the trial and assigned to either conventional or homeopathic treatment groups.
- Results showed that both adults and children faired better in terms of their own assessment of treatment success when receiving homeopathic rather than conventional treatment.
- The assessment of physicians was also more positive for the homeopathic treatment, and costs were for the two groups found to be broadly similar.

Chaufferin et al. (2000) conducted a study using a general evaluation model of the French health system to assess the economic impact of homeopathic medicine on French health insurance expenditures and outlays.

- The study found that the cost of medicine reimbursements under the French public health insurance system fell to one quarter of the average. The paper reports that the average overall cost per year incurred by a homeopathic doctor in treating patients are half those of a conventional GP.
- The study finds that these differences cannot be explained by the profile of patients or of the diseases treated. It also cannot be explained by seeing homeopathic care as complementary to conventional treatments, as the study shows that in France 87% of patients for whom a doctor prescribed a homeopathic medicine did not consult another doctor for the same complaint.

Jain (2003) conducted a four-year comparative cost study in a GP practice in south London, comparing the costs of treating a patient homoeopathically with those of conventional treatments that would have been used instead.

- The most common patient complaints were skin conditions (eczema, dermatitis, psoriasis, urticaria,[135] warts, infection, acne), followed by allergies (asthma, hay fever, allergic rhinitis), women's problems, pain and other disorders. By the end of the trial, 64 of the 100 patients had reached +4 (cured or back to normal) on the Glasgow Homeopathic Hospital Outcome Measure and 10 were receiving ongoing treatment. No side effects were reported during treatment. Time off sick was not considered.
- The average cost saving per patient was £60.40 (range -£12.48 to £703.95) over the course of treatment. For the ten patients whose treatment was ongoing at the end of the study, two did not have a conventional medical alternative, and for the remaining eight the cost saving up to January 2002 was on average £68.40 (range -£3.21 to £349.82).
- The cost of the GPs' time was not considered, all costs were based on drugs. This could be significant as initial homeopathic appointments were one hour compared to 10 minutes for a conventional appointment (homeopathic follow up appointments were 15 minutes).

Swayne (1992) conducted a study of the prescription costs of 22 doctors who had taken part in a data collection survey by the Faculty of Homeopathy to test whether doctors practicing homeopathic medicine have lower prescription costs than their colleagues.

- On average practices with GPs using homeopathy were found to prescribe 12% fewer items of medication (including conventional and homeopathic) per patient than other practices in the area. Extrapolating this figure to a national level would find a reduction of 41.5 million items prescribed.
- The average ingredient cost *per prescribed item of medication* was lower for homeopathic doctors than for other doctors either in their practice or in their area, and the average ingredient cost for medications *per patient* was lower for doctors using homeopathy (by 20p, £4.59 compared to £4.39).
- The author quotes data from a practice in Somerset in which both doctors used homeopathy show prescription costs 31% lower than the national average (for the third

[135] Also called hives. A condition in which red, itchy, and swollen areas appear on the skin usually as an allergic reaction food or medication.

quarter of 1988), though it is not clear how these data were influenced by the use of homeopathy.

Particular Conditions

Trichard et al. (2005) conducted a six month study into acute rhinopharyngitis (a type of upper respiratory tract infection (URI) in a sample of 499 children between 18 months and 4 years old in France.

- The children were treated by allopathic and homeopathic GPs who used either an "antibiotic strategy" (i.e. those using conventional antibiotics) (group A) or a "homeopathic strategy" (group H). The strategies were compared in terms of medical effectiveness, quality of life and cost.
- Results showed that the superior medical effectiveness of the homeopathic strategy over the antibiotic strategy both in terms of the number of bouts of acute rhinopharyngitis (2.71 against 3.97 per patient), indicating the preventative effect of the homeopathic strategy, and the number of complications (1.25 against 1.95 per patient). There was no statistic difference in the incidence of side effects. Patients in group H required fewer intermediate consultations than those in group A. Group H also achieved significantly greater quality of life improvements, as measured on the Par-Ent-Qol scale[136].
- Overall direct costs of treatment, which include GP consultations, expenditure on drugs and on further tests, were found to be higher for the homeopathy strategy than the conventional strategy on average by €2 per patient (€174 for the homeopathic strategy compared to €172 for the antibiotic strategy).
- However, the indirect costs to parents of taking sick leave to care for their child was lower for those patients in group H, for which 9.5% of parents took at least one period of leave, than those in group A, for which 31.6% did so. The duration of this leave was similar between the two groups at around four days over the six month observation period.

Frei and Thurneysen (2001a) treated children suffering from acute otitis media (middle ear infection, from which an estimated 80% of 3 year olds suffer), with homeopathy in Switzerland and compared the costs against those of conventional interventions.

- Amelioration of pain was assessed (by the parents) six hours after the first treatment; if further treatment was judged (by the parents) necessary then they gave the child another, different homeopathic remedy. If the condition had not resolved itself within 12 hours of the original treatment then the patient was placed on antibiotics. 230 patients were included in the study over an eight month period and a total of 26 different homeopathic medicines were used. After six hours 39% of patients were free of pain, 33% after 12 hours (having received a second homeopathic treatment) and 28% needed antibiotics. This implies that homeopathy is 2.4 times faster in controlling pain than placebo. No complications were reported. Frei and Thurneysen used this treatment in their practice over a seven year period, during which time they treated an estimated 2,400 patients; just three suffered severe complications (0.125%).
- Both approaches required two medical appointments at a combined cost of 55.50sfr. The homeopathic appointments, being 5-10 minutes longer on average (necessary to find the right homeopathic remedy), cost an extra 20sfr. Both doses of the homeopathic remedy were reimbursed on social insurance at 4.60sfr each. The antibiotic alternative cost 46.80sfr on average and a decongestant nasal spray 7.20sfr. The average total cost of a homeopathic intervention was estimated at 94.60sfr (including the 28% of patients who were also prescribed antibiotics) and the antibiotic approach cost on average 109.50sfr. The homeopathic approach was therefore 14% cheaper.

Feldhaus (1993) conducted a study on the use of homeopathic arnica[137] for three days before and up to a week after surgical dental procedures in a German dental practice.

[136] A French questionnaire that evaluates the specific impairment of parents' quality of life brought about by their children (0-4yrs) developing ear, nose and throat (ENT) infections during a winter season.
[137] The arnica diluted to homeopathic strength (in this study a dilution of 12x was used).

- The study was undertaken in Germany, with the results expressed with reference to the compulsory insurance system operating at the time. The author started to use arnica in his dental practice from 1984 onward and compared the incidence of post-operative treatments (PT) in his practice to the average in his area.
- From the time the author started to use arnica (to reduce swelling) as an addition to the treatment involved in his procedures, he performed on average 54% fewer procedures (such as teeth extractions) (32 per quarter fewer) than the area average. Even after taking into account that the author was performing slightly fewer treatments than average before starting using arnica, the net decrease was 28 post-operative treatments per quarter. When the data were controlled for any natural decreases in surgical procedures over the time it was found that on average the author performed 40% fewer procedures than the area average from the start of 1985 to April 1986.
- The author calculated that if 250 dentists were to use arnica DM 600,000 (exchange rate of around DM 3 = £1 at the time) would be saved per year and that if each dental surgeon in Germany had to pay for just one fewer post-operative treatment per year DM 1.24 million would be saved.
- As a further indication of potential cost savings, the author considered whether the number of sickness certificates (SC) differed between practices. The study showed that the number of SCs issued by the author's practice fell from 7 per quarter to 2.6 after introducing the arnica treatment (3.85 fewer than the area average of 6.45). Reductions in SC writing can be financially significant when considering lost production in the economy. Assuming a sickness certificate lasts for two days of eight hours work at the minimum wage of DM 20, a reduction of one sickness certificate per year in each practice in the former West Germany would have led to an annual saving of DM 19.2 million.

van Haselen et al. (1999) analysed retrospective data on the costs of providing primary care for patients with rheumatoid arthritis (RA) as out-patients at the Royal London Homeopathic Hospital (RLHH).

- The aim of the study was to set out the marginal costs of providing complementary treatment (mainly homeopathic, but also some acupuncture and manipulation for certain patients) in terms of staff and medicines. Note that only operating costs were considered, rather than the sunk costs involved in setting up the service. The authors report the economic burden to the UK of RA to be £1.25 billion in 1992/3, half of which is lost production.
- Of the 427 patients attending RA outpatient clinics from April 1995 to March 1996 at the RLHH, a sample of 89 was taken. It was found that to treat the whole cohort cost £7,632, comprising fees for doctor time (£1,681, 29% of the total), drugs (£1,535, 22% of the total) and other costs such as a staff nurse (£1,259), a dietician (£400), a receptionist (£897), x-rays (£1,617) and blood tests (£272). Though not analysed, cost savings of reduced usage of conventional drugs (steroids and other anti-inflammatory drugs) in the patients were recorded. In a sub-sample of 25 patients, eight (32%) reduced their intake of conventional drugs to some degree during treatment at the RLHH.
- The authors encourage the results to be used to inform those interested in the cost effectiveness of homeopathic and complementary medicine, but acknowledge that a comparison with conventional costs would be necessary to fully inform health policy decision makers.

Homeopathy as an Alternative

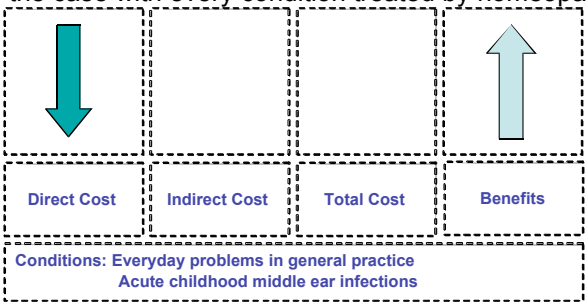
Several studies of the diverse conditions of common primary care concerns, and single studies on the specific conditions of childhood infections and recovery from dental surgery, have suggested that homeopathy may provide additional benefits and reduce costs compared to conventional treatment. (It should be noted that while homeopathy is used as a substitute for conventional treatment in the particular areas below, it is still used always used in conjunction with a conventional medical approach in the studies examined).

Everyday Conditions in General Practice

This Enquiry found several studies examining the costs of using homeopathy in general practice, including eczema, asthma and migraine, often comparing costs with conventional care (Haidvogl et al., 2001; Wassenhoven & Ives, 2004; Chaufferin et al., 2000; Witt et al., 2005; Jain, 2003 and Swayne, 1992). Patients reported greater satisfaction with their treatment, increased quality of life and greater contentment with their treatment provider. Studies, though not always of high methodological quality, consistently find that using homeopathy in primary care reduces the cost of achieving a given increase in patient satisfaction compared to conventional treatments[138]. The studies also point to fewer adverse effects, reduced need for follow-up appointments and positive clinical results for conditions that had not improved under conventional treatments. This Enquiry also found indications that the use of homeopathic remedies in GP surgeries lowered conventional drug prescription bills.

Acute Childhood Middle Ear Infections

Using homeopathy as an alternative to conventional antibiotic treatment (although keeping this in reserve if necessary) was found by a single study (Frei & Thurneysen, 2001a) to reduce treatment costs of a condition affected by acute middle ear infections. The efficacy of homeopathy in the treatment of this condition is supported in the literature, though weakly as is the case with every condition treated by homeopathy.



Sources: Haidvogl et al., 2001; Wassenhoven & Ives, 2004; Chaufferin et al., 2000; Witt et al., 2005; Jain, 2003 and Swayne, 1992 (everyday conditions in general practice and Frei & Thurneysen, 2001a (acute childhood middle ear infections)

Acute Childhood Upper Respiratory Tract Infections

A recent French study (Trichard et al., 2005) found convincing evidence that patients experienced greater quality of life and needed fewer doctor's appointments when homeopathy was used to treat a type of acute upper respiratory tract infections in children. Costs of treatment and the chance of parents taking time off work to care for their children were lower than for conventional treatment. The efficacy of homeopathy in the treatment of this condition is supported in the literature, though weakly as is the case with every condition treated by homeopathy.

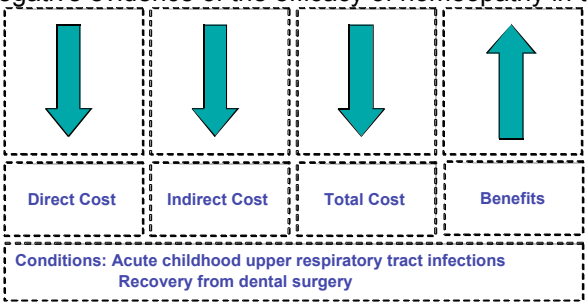
Recovery from Dental Surgery

A study from Germany (Feldhaus, 1993) on using a homeopathic preparation of arnica before and after dental surgery showed clear savings in costs to dentists and in time off for patients. The cost figures indicate that in early 1990s Deutsche Marks savings of DM 1.24 million (approximately £500,000 in today's prices)[139] would be saved if every dentist were to perform

[138] Haidvogl et al., 2001.

[139] Prices calculated using National Statistics retail price indices

one fewer surgical intervention per year (possible given the observed clinical benefits of arnica in the study) and DM 19.2 million would be saved per year in reduced days off work (approximately £9 million in today's prices)[140]. This Enquiry found no other supporting or negative evidence of the efficacy of homeopathy in the treatment this condition.



Sources: Trichard et al., 2005 (acute childhood upper respiratory tract infections) and Feldhaus, 1993 (recovery from dental surgery)

Conclusions

Despite a highly contested clinical evidence base, there is a relatively large literature on the costs and benefits of homeopathy. There appears to be potential for large savings in drugs bills if particular homeopathic treatments are effective options in primary care. All GPs are unlikely to offer homeopathy as a major frontline approach to treatment, but if 4% of GPs were to do so (the number of members of the Unio Homoeopathica Belgica[141] as a proportion of the number of GPs in Belgium)[142] a large saving (£190 million) would result. Evidence of efficacy is however a serious problem, and one with which homeopathy has much more difficulty than some other CAM therapies. We recognise that the evidence for efficacy is controversial for homeopathy as a whole and in relation to the treatment of particular conditions. This Enquiry cannot make a definitive judgement on the questions of medical efficacy.

We can however report that the literature on effectiveness presents some evidence that homeopathy may offer advantages in terms of both costs and benefits when used as an alternative to conventional medicine in a number of areas:

- Everyday conditions in general care, including asthma.

A small number of studies also offer evidence that homeopathy may help in the following areas:

- Post-dental surgery recovery
- Acute childhood upper respiratory tract infections
- Acute childhood middle ear infections

The evidence is however fragmentary and the most that can safely be said is that there are conditions commonly treated by homeopaths for which they report good results.

[140] Prices calculated using National Statistics retail price indices
[141] See Glossary
[142] Source: European Committee for Homeopathy

Manipulation Therapies

The Treatment Process

The two therapies of osteopathy and chiropractic share many similar practices and a common origin, and are frequently referred to as manipulation or manipulative therapy. Given the significant overlap between the two therapies, as well as a proportion of studies that employ general manipulation without further clarifying any exact details, manipulation therapies will be examined as a whole in this section.[143]

The founders of both schools (David Palmer for chiropractic and Andrew Taylor Still for osteopathy) met in the nineteenth century, in the USA, and the therapies have been linked since these early beginnings, with chiropractic developing as an offshoot of Still's original osteopathic medicine. Like most CAM therapies, a variety of subtly different treatment methods exist under each heading; however, both methods are therapies of the musculoskeletal system, "practitioners work with bones, muscles and connective tissue, using their hands to diagnose and treat abnormalities of structure and function."[144] Although the two therapies are very closely linked (in practice little if any difference is often experienced), historical underlying differences in philosophy do exist. As the House of Lords summarised in their 2000 report, "chiropractic was originally based on the idea that 'reduced nerve flow' led to disease" (Box 1) and osteopathy "historically differs from chiropractic in its underlying theory that it is impairment of blood supply and not nerve supply that leads to problems."

Chiropractors will often begin any diagnosis with the use of an x-ray examination, while osteopaths generally avoid x-raying unless they need to rule out a more serious pathology. Both sets of therapists will follow some form of the following diagnostic practices, outlined by Vickers and Zollman (1999):

> *Manipulative therapists take a history,* [feel] *for significant changes in muscle tension and skin circulation, and look for any restricted movements in order to diagnose musculoskeletal abnormalities and "neuromuscular dysfunction" (such as "trigger points" or signs of "pain spasm cycles").* (p. 1177)

The most recognisable technique is the "high velocity thrust": short and sharp applied to the spine. Chiropractors generally push on the spine with their hands; osteopaths will utilise the levered thrust, using the limbs of the patient. Both sets of practitioners may also utilise "functional techniques", a slower rotation or pressure on the limb or joint that is used to increase a joint's range of movement or to relieve muscle tension. These techniques rely on an understanding of neuromuscular behaviour. In addition, some osteopaths practice cranial osteopathy, gently handling the bones of the skull, most frequently in the treatment of infants.

Current Usage

Of the five CAM therapies examined in this report, chiropractic and osteopathy are the only practices regulated by statutory bodies. They are regulated by the General Chiropractic Council (GCC) and the General Osteopathic Council (GOC) respectively. These bodies have the power to remove practitioners who fail to maintain the high standards of care and safety required by both disciplines. The Royal College of General Practitioners has recommended the use of manipulative techniques for patients in the initial six weeks of lower back pain if they need additional pain relief or are taking a particularly long time to return to full functioning (RCGP 1999), and Europe-wide guidelines also support manipulation as a complementary treatment for lower back pain.[145]

[143] Where specific details about either osteopathy or chiropractic are available, they are analysed separately.
[144] Vickers & Zollman, 1999, p.1176.
[145] www.backpaineurope.org, 2001.

Current usage is difficult to measure. A 1999 telephone survey[146] of 1204 randomly selected UK adults saw chiropractic use at 3% of respondents and osteopathic care usage at 4%. A postal survey[147] of 2668 randomly selected adults presented almost identical figures, and outlined that 4.3% of respondents had visited an osteopath and 3.6% a chiropractor (2000, 1.19). In 2001, there were seven million consultations with osteopaths, a 14.3% increase on 1997 (GOC, 2005). Although there are currently no figures of this form for chiropractic, or current figures for osteopathy, it is very likely that the proportion of the UK population visiting these two CAM therapies has and is increasing since 1999. There are currently 2200 registered chiropractors working full-time in the UK (GCC, 2005) and 3600 registered osteopaths (GOC, 2005).

Safety

The debate on the incidence of serious side effects of manipulation therapies is ongoing. A report prepared by the NHS CRD for the NHS National Electronic Library for Health[148] reviews four studies on chiropractic and severe adverse effects including stroke and artery damage in the neck. The review found methodological problems with all the studies and recommends further, high quality research in this area. Non-serious adverse effects are more common, with several summaries[149] of the evidence suggesting 50% of patients experience some adverse reaction after the first treatment. These effects commonly include local discomfort, headache, tiredness or radiating discomfort. Contraindications do exist for such conditions as osteoporosis, cancer and some circulatory problems. However, the risk of adverse reactions is linked to the prudence of the practitioner, and the regulatory bodies for chiropractic and osteopathy will and do play a key role in this regard. Safety risks must also be viewed in comparison with those of conventional treatments, including medications and surgery.

Overview of Applications and Effectiveness

Manipulation therapies can be utilised as treatments for a wide range of ailments, including arthritis, sports injuries, shoulder pain, repetitive strain disorders and migraines. Cranial osteopathy is often used on children under six months old, treating infantile concerns such as behavioural problems and colic. However, the largest evidence base for both therapies (including trials where the term manipulation is not further clarified) is in the treatment of back pain. Therefore, manipulative techniques in treating problems of the back constitute the focus of this examination. While it may well be the case that these therapies are effective in the treatment of further conditions, the Enquiry has focused on specific conditions as part of their indicative approach.

The examination of cost-effectiveness combines an examination of costs and of effectiveness simultaneously. Therefore, the following overview of several systematic reviews should be considered as part of the overall evidence base that the Enquiry draws upon to make its conclusions.

Systematic reviews present a complex picture of the evidence for spinal manipulation treating acute and chronic lower back pain. Four extensive and well recognised studies give an idea of the disagreements that exist. These disagreements are found within the limits of conventional methodology, indicating that there is even more debate when strict RCT procedures are modulated for CAM therapies. In 1992, Shekelle et al. concluded in the Annals of Internal Medicine:

> *Spinal manipulation is of short-term benefit in some patients, particularly those with uncomplicated, acute low-back pain. Data are insufficient concerning the efficacy of spinal manipulation for chronic low-back pain.* (p.590)

[146] Ernst & White, 2000.
[147] Thomas et al., 2001.
[148] http://www.nelh.nhs.uk/hth/chiro.asp
[149] Including Stevinson & Ernst, 2002.

In 1996, Koes et al. found few trials of high quality under their rating system. Their review suggested they were as many trials with positive outcomes as negative outcomes, and that apart from some indications that manipulation may be effective for certain "subgroups" (unidentified) in treating acute and chronic pain, there was no conclusive evidence for its effectiveness.

In 1997, van Tulder et al. suggested that the Clinical Standards Advisory Group's (UK) decision to include manipulation as a key part of its approach to acute lower back pain was misguided as little evidence for its effect could be presented. The limited evidence for superiority to placebo did not necessarily mean that manipulation was the best and most effective treatment available. Yet the authors stated that manipulation possessed strong evidence for its use in treating chronic lower back pain, as it was strongly superior to placebo and moderately superior to general "best care" practices.

Finally, Assendelft et al. (2003) published a Cochrane Collaboration report, identifying (under their inclusion criteria) thirty-nine RCTs that suggest manipulation is superior to sham therapies on the Roland-Morris Disability Questionnaire[150] and a 100-point VAS [151] for pain. However, this treatment was only more effective for short-term pain when compared to therapies judged to be ineffective or "possibly even harmful" (p.5). Similarly, manipulation for chronic pain was only superior in a statistically significant degree compared to sham therapies. Nevertheless, the review does not indicate that chiropractic was any *less* effective, thus leaving open the door for cost-effectiveness trials to support a greater usage of manipulation in place of conventional treatments.

Costs and Benefits

The following review will present the current status of the research regarding costs and benefits of manipulation therapies. The studies analysed are divided into chiropractic, osteopathic or general manipulative care. Within these headings, the studies have been divided as to whether they analyse the CAM therapy as a complement or as an alternative to conventional treatment. The greater number of studies presented for chiropractic over osteopathy does not reflect a relative effectiveness or level of use in the UK. It is solely a reflection of the number of studies brought to our attention during the literature review.

It must be kept in mind that the results from an evaluation of the costs and benefits of a single study are very difficult to generalise from; however, it is from the *comparison* between the CAM therapy and either the placebo or conventional treatment over several studies that conclusions can be drawn. After illuminating the current state of manipulation therapies' costs and benefits, some initial conclusions will be drawn.

Chiropractic - Alternative Treatment

There have been several large scale retrospective[152] comparisons between chiropractic and conventional treatment for back pain conducted in the USA. These studies predominantly analyse insurance data, and provide data on the speed of patients returning to work and the comparative costs of treatment. In general, they highlight the advantage of chiropractic in returning acute back pain sufferers to work as quickly as possible. These trials are presented in Figure 1. It should be noted that given the different years and locations of the trials, there is a very restricted ability to compare costs across time periods. The valid contrast is within each study, where chiropractic and conventional treatment are compared.

[150] A patient completed questionnaire concerning neck or back pain, see Glossary.
[151] See Glossary.
[152] See Glossary.

Figure 1: Retrospective comparisons of chiropractic to conventional treatment in USA

Author	Year, Location	Average time lost from work (days) – chiropractic	Average time lost from work (days) – conventional treatment	Average treatment costs ($) - chiropractic	Average treatment costs ($) – conventional treatment	Average benefit payments ($) - chiropractic	Average benefit payments ($) – conventional treatment
Bergemann & Cichoke	1980, Oregon	18.88	41.16	181.48[153]	327.30[154]	276.59[155]	649.52[156]
Johnson et al.	1989, Iowa	11.26	13.63	222.72	351.96	263.66	617.85
Nyiendo	1991, Oregon	9.0	11.5	1,712[157]	1112		
Jarvis et al.	1993, Utah			527	684	68.38	668.39
Stano	1993, USA			3,799[158]	4,937[159]		
Stano and Smith	1996, USA			518	1020		
Phelan et al.	2004, North Carolina	25	175	634	3425	1,912	15,819

Source: FreshMinds, 2005

Several general points arise from these studies. Firstly, the average time lost from work is lower with chiropractic than conventional care. Secondly, these trials suggest lower treatment costs for chiropractic than conventional treatment. Thirdly, benefit payments are lower with chiropractic care. These conclusions are limited by the general lack of detailed diagnostic data on the patients that must form part of any more thorough analysis.

Certain interesting points were also highlighted by the authors. Firstly, Nyiendo (1991) highlighted that chiropractic seemed better at returning the very short-term claimants to work and in dealing with short-term problems of those with recurrent and chronic back problems: for those with chronic back problems, the median days off work was 34.5 for GP care and nine for chiropractic. Secondly, Stano and Smith (1996) concluded that total medical care payments were between 27% and 217% higher than those for chiropractic.

- A number of prospective[160] trials from the USA also compared chiropractic with conventional back pain treatments.

Shekelle et al. (1995) followed their work on the RAND Health Insurance Experiment (HIE) [a 5-year RCT in the USA that concluded that although the evidentiary quality was uneven, there was enough evidence to support the use of spinal manipulation to treat acute lower back pain in the absence of any lower nerve root problems] with a cost comparison of the patients involved in the trial. The mean cost per visit was lowest for chiropractic at $19.45 compared to $20.21 for a general practitioner. However, the mean total cost per episode of back pain saw general practitioner at $199 and chiropractic at $281. A key consideration in this study was

[153] This is the cost of visiting the practitioner.
[154] This is the cost of visiting the GP.
[155] Temporary Total Disability payments.
[156] Temporary Total Disability payments.
[157] The authors attribute the higher cost of treatment when utilising a chiropractor to five possible factors, including " *a higher proportion of claimants with chronic or recurrent low back conditions in the chiropractic group, resulting in more difficult cases"* (p. 295).
[158] Based on insurance data.
[159] Based on insurance data.
[160] See Glossary.

the dramatic difference in mean visits per episode (approximately five times more for chiropractic compared to general practitioner care) that may possibly be due to inappropriate over-treatment.

Stano et al. (2002) conducted a trial in Oregon, USA. There were no statistical differences in improvement for chiropractic patients and GP patients (who had not been referred on to secondary care). However, the study found greater costs for chiropractic than GP care. The mean for the chiropractic group was almost double ($214) that of the average GP cost ($123). This difference should be seen within the limitations outlined by the authors (for example, excluding costs for imaging and underestimating the use of prescription drugs by GP patients).

Carey et al. (1995) conducted a wide-ranging comparison between chiropractors, primary care practitioners, orthopaedic surgeons and care from a health maintenance organisation in treating acute lower back pain in North Carolina. Only 5% of all the patients did *not* report a full return to pre-injury functional status at the end of the six-month period. The study revealed no clinically significant differences in time to functional recovery across treatment groups. Similarly, there was no statistical difference in changes in disability across all groups. There was no difference in the mean number of days lost to work across the treatments, with over 95% of all patients back at work by the four-week interview. The average number of medications was lowest for chiropractic, and chiropractic patients were considerably more satisfied with their treatments than all other groups. Outpatient charges alone are presented, with average chiropractic costs per episode of acute back pain higher than the other treatments, the frequent visits offsetting the low cost per treatment session.

Finally, Cherkin et al. (1998) compared treatment of lower back pain by physical therapy, chiropractic and provision of an educational booklet in Washington State. Outcomes were measured with an 11 point "bothersomeness" of symptoms scale and a modified Roland-Morris Disability Questionnaire.[161] The "bothersomeness" of the symptoms was lower for both physical therapy and chiropractic than the booklet. Similarly, there were small differences in disability scores of the chiropractic and physical therapy care groups over the booklet at 12 months, but it was not significant. Twice as many patients were satisfied with their treatment in the chiropractic and physical therapy group than the booklet group. There was little difference in cost between chiropractic and physical therapy care, the average cost totalling $226.08 and $238.54 respectively. The cost of the educational booklet used was only $1 each, thereby making the crude cost-effectiveness comparisons firmly in the favour of the booklet.

- Two European trials also compared chiropractic as an alternative to conventional treatments.

Meade et al. (1990) carried out a study in the UK, dividing patients between chiropractic and hospital outpatient treatment. At two years, those treated by chiropractic had improved their Oswestry[162] scores by 7% more than hospital care. Those who had a history of back pain responded better to chiropractic than those without a history (13% difference at two years). Those treated with chiropractic showed greater improvements in back mobility, pain-free days and lowered drug use. 21% of those given chiropractic had time off work compared to 35% of hospital patients. In a 1995 extended follow-up, Oswestry scores were approximately 29% higher for chiropractic patients over hospital patients. Approximately 20% more chiropractic patients thought chiropractic had benefited them than GP patients thought hospital treatment had. Chiropractic patients showed greater improvements in both pain intensity and almost every secondary measure (including personal care, standing, walking, lifting, etc.) on the Oswestry scale. Although the chiropractic treatment cost per patient was greater than that for hospital care (in 1988-9 prices, £165 compared to £111), the £4 million that the NHS would have spent on chiropractic would have been more than offset by approximately £2.9 million

[161] See Glossary.
[162] See Glossary.

savings in social security payments and as much as £13 million savings from fewer days off work.

Skargren et al. (1998) carried out a RCT in Sweden to compare chiropractic and physiotherapy in treating back pain. On each outcome measure, both treatments brought significant health improvements and no statistical difference could be seen between the two treatments. At the subgroup level, chiropractic was better for patients with current pain episodes of less than a week, while physiotherapy was superior for those with episodes of longer than a month. The comparison of direct costs for physiotherapy and chiropractic (excluding those needing surgery) saw median costs of chiropractic care for the whole period at 4051 Swedish Krona (SKr) compared to 4010 SKr for physiotherapy. Statistically similar percentages of patients reported for sick leave in both groups: the median indirect cost difference was very small - 13797 SKr for chiropractic and 13326 SKr for physiotherapy.

Chiropractic - Complementary Treatment

- Two studies examined the costs and benefits of utilising chiropractic as part of a general package of care.

Manga et al. (1998) drew on their 1993 book and leading cost comparisons on chiropractic versus medical managed care (as presented in the report) to propose the possible cost savings for Ontario, Canada of altering its current co-payment scheme to pay for more chiropractic care under their national health system. The range of direct cost savings was from 769.8 million Canadian dollars to 199.5 million; the range of indirect cost savings varied between 3037 million to 795.2 million dollars. Therefore total cost savings to Ontario ranged from 3.8 billion Canadian dollars to 994 million Canadian dollars. In 2004, the Ontarian Government, having decided five years earlier to follow the advice of Manga and others, decided to de-list chiropractic from the national health system. Deloitte & Touche LLP (2004) examined what the implications of such a policy decision would be. They concluded that the shift from chiropractic to medical care for neuromusculoskeletal[163] conditions would actually increase the cost of healthcare in Ontario. Their three estimates range from an additional 225 million Canadian dollars to the more conservative 112 million Canadian dollars. This would equal an increase of approximately 1% in hospital operating budgets.

Legoretta et al. (2004) examined claims data in California for patients with and without chiropractic coverage. The expenditures of these groups for neuromusculoskeletal conditions is presented and compared. The per-member-per-year cost of those with chiropractic coverage was $2345 compared with $2706 for those without, a 13% reduction. Annual per capita hospital costs were $1224 for those with chiropractic coverage, compared to $1432 for those without. The average cost per back pain episode was $289 for those with chiropractic coverage, $110 lower than those without coverage (a 28% reduction). The annual added coverage cost per capita for chiropractic care was only $31. This analysis suggested an approximately 1.6% reduction in total healthcare costs if chiropractic care was available.

Osteopathy - Alternative Treatment

- Andersson et al. (1999) conducted a RCT to test osteopathy against standard medical care. All patients were screened to have had back pain for at least three weeks but less than six months, excluding those with serious nerve root problems, giving 72 patients to the GP group and 83 patients to the osteopath. Several questionnaires were utilised including the Oswestry,[164] Roland-Morris [165] and a visual analogue pain scale, [166] and measurements of straight-leg raising and range of motion were taken. Groups were controlled for similar demographic characteristics. They were examined for 12 weeks.

[163] Conditions that have a combined effect on the nervous system, the skeleton and the muscles of a patient.
[164] See Glossary.
[165] See Glossary.
[166] See Glossary.

On all primary outcome measures, there was no statistical difference between the two care groups, as both showed similar improvements at the final visit. Equal proportions of each group were satisfied with the care they received. In addition, the proportion of osteopathy patients who were prescribed medication was less than half as great as that for the GP group, indicating a possible source of cost savings given the equality of clinical outcomes, as well as avoiding the possible side-effects of drug use.

- Burton et al. (2000) performed a single-blind RCT for a very particular comparison of osteopathy and chemonucleolysis (a surgical procedure in which an enzyme is injected to dissolve a portion of the intervertebral disc) in treating symptomatic lumbar disc herniation[167] (where there is a clear indication that surgery was required, patients were excluded). This ailment results in back pain and associated leg pain. Patients were recruited from an orthopaedic department in the north of England, complaining of sciatica[168] due to herniation. Patients were questioned using traditional back measures (mobility, side bending, etc.), the Roland-Morris Disability questionnaire,[169] as well as distress and pain scales; they were questioned at two and six weeks, and at 12 months. Twenty patients were in each treatment arm.

  Both groups showed statistically significant improvements in baseline back pain, leg pain and disability measures at 12 months. Manipulation had greater improvements than chemonucleolysis at two and six weeks for back pain. Although slight, manipulation showed greater improvements in all outcome measures at 12 months. Osteopathy can be seen to be no less effective than traditional approaches to treat this back condition.

  Although very crude, the cost comparison between osteopathy and chemonucleolysis for lumbar disc herniation presented average number of treatment sessions for osteopathy at 11, at £20 per session, making the average cost £220 per patient for osteopathy. The average total cost of the chemonucleolysis was £800. When taking into account the costs for treating therapeutic failures (those not responding to osteopathy) the authors estimate that the use of manipulation could save approximately £300 per patient annually.

Osteopathy - Complementary Treatment

- Williams et al. (2003) conducted a pragmatic study of osteopathic manipulation in North West Wales of patients presenting with either neck or back pain from September 1997 to March 2001. 109 patients were randomly allocated to conventional general practitioner care only and 92 patients were additionally referred to an osteopathic clinic. Patients had indicated the presence of pain for between two and twelve weeks. Outcome measures were the Extended Aberdeen Spine Pain Scale (EASPS),[170] the Short-form McGill Pain Questionnaire (SMPQ)[171], as well as the generic SF-12 and EQ-5D.[172] Questionnaires were collected at randomisation, at two and at six months.

  At two months, both groups had seen improvements in all measures, with the osteopathy groups significantly better than the GP care group, especially on the EASPS and the SF-12 mental score. At six months the improvement had continued across measures and groups; however, the better performance of the osteopathy group on the EASPS was no longer significant, and there was a levelling off of the improvement for the osteopathy group on the SF-12 mental score and EQ-5D. Nevertheless, those receiving osteopathic care were better off than those limited to GP care on the outcome measures utilised in this study.

[167] The abnormal protrusion of a disc in the back and the accompanying problems.
[168] An irritation of the sciatic nerve resulting in pain or tingling running down the inside of the leg.
[169] See Glossary.
[170] A questionnaire designed for patients who are experiencing problems in the neck, upper and lower back, very similar to the other self-administered questionnaires outlined in Methodological Considerations.
[171] A short self-administered questionnaire examining pain experienced by the patient.
[172] See Glossary.

The authors utilised the gathered EQ-5D and cost data to carry out a cost-utility analysis for osteopathic care, calculating cost per QALY[173] estimates. There were 68 patients in each group with enough data to form part of the analysis. Given the greater improvements at six months on the EQ-5D for osteopathy, there was a mean QALY gain of 0.031 in the GP group and of 0.056 in the osteopathy group, a mean difference of 0.025 QALYs.

The differences in costs found between GP care and those additionally provided with osteopathic care is very similar to the cost of the osteopathy care itself. The difference in mean total costs of £22 was not significant.

When these costs were combined with the QALY data that were based on the EQ-5D responses presented above, the estimate of the mean incremental cost per QALY was £3560. Sensitivity analysis[174] reduced this to a median incremental cost per QALY of £1390, with spine-related median costs per QALY gained at £2870. These figures all compare favourably with the current incremental cost per QALY range with its upper limit of between £20,000 and £30,000 per QALY, above which more justification is required to recommend a treatment.[175]

General Manipulation - Alternative Treatment

- Koes et al. (1992) carried out a comparison between physiotherapy (exercises, massage and physical therapy), manipulation therapy (manipulation and mobilisation of the spine), treatment by general practitioners (drugs, advice about posture, home exercises and [bed]rest) and placebo treatment for dealing with persistent back or neck pain (persistent being more than six weeks). Each group was randomly assigned into the four groups, with 256 patients meeting the several selection criteria of non-specific complaint, duration of complaint (six weeks or longer), and the patient not having had either physiotherapy or manipulation therapy for either complaint in the past two years.

  A blinded research assistant assessed patients at three, six and 12 weeks and after randomisation, and at six and 12 months for long-term effects. The assessment was based on history-taking and physical examination, as well as severity of pain on a ten point scale, perceived effect on a six point scale, and physical functioning on a ten point scale.

  The manipulation therapy group showed the largest improvement after 12 months on the ten-point main complaint scale, an average increase of 4.5 (0.9 greater than physiotherapy). The manipulation therapy group was always above physiotherapy on physical functioning, an average 12 month difference of 0.6 (this difference was not statistically significant at 12 months, although it had been at the short-term follow ups). Even when adjusting for some missing values at the six and 12 month follow ups, the results show a greater improvement with manipulation therapy on every scale. The conclusion from the study can be simply stated as manipulation therapy being slightly but significantly superior to physiotherapy in treating persistent back pain, and both treatments being an improvement on placebo and GP care.

- Giles and Muller (2003) conducted a RCT to compare medication, needle acupuncture and spinal manipulation for the management of chronic back pain (defined as persisting for more than 13 weeks). The study was conducted from February 1999 to October 2001, with 115 patients randomised into one of three treatment groups. Outcome measures included the Oswestry Index,[176] the Neck Disability Index, [177] the SF-36 and VAS [178] of pain intensity and ranges of movement. Patients were questioned at randomisation, and then at two, five and nine weeks.

[173] See Glossary and Methodological Considerations.
[174] See Glossary.
[175] For greater detail please see the chapter CAM in the NHS.
[176] See Glossary.
[177] A self-administered questionnaire dealing with aspects of neck pain, including pain intensity, personal care, lifting, reading, headaches, concentration, etc.
[178] See Glossary.

On almost every outcome measure, manipulation was superior to other interventions. Early recovery was highest for manipulation (27.3%) compared to acupuncture (9.4%) and medication (5%). The 50% improvement on Oswestry scores highlights the impressive improvements manipulation provided. The authors conclude that manipulation results in greater short-term improvements for chronic spinal pain sufferers than either medication or acupuncture, although this does not apply to those contraindicated or as a long-term solution to chronic pain.

General Manipulation - Complementary Treatment

- The UK Back Pain Exercise and Manipulation (UK BEAM) Trial Team conducted a large RCT looking at both the effectiveness and cost effectiveness of manipulation. Manipulation (a package of techniques used by chiropractors and osteopaths) and exercise (a "back to exercise" programme) were separately combined with current "best care" practice (as suggested by UK national guidelines on acute back pain), as well as one group with all three treatments ("best care", manipulation, and exercise). 1334 patients who had consulted their GPs for lower back pain between March 1998 and April 2001 were selected for the study. They were randomly assigned to the different care packages, as well as dividing the manipulation groups into NHS and private treatments. The questionnaires used included two back specific measures, questions on back beliefs and fear avoidance, and the generic SF-36 and EQ-5D[179]. Patients completed these forms at randomisation, and at one, three and 12 months.

  The results showed that all three interventions improved a great many of the outcome measures at three or 12 months over "best care" alone. Exercise had the least effect, producing only statistically significant changes in the Roland Morris[180] questionnaire at three months. Other pain and back beliefs scored were improved at three and 12 months, with the mental score unchanged. Manipulation produced improvements on the Roland Morris at three and 12 months, and all other measures improved, most of them to a degree of statistical significance. Finally, manipulation followed by exercise was the most effective, with the largest disability, pain and back beliefs improvements. Three of the thirteen significant improvements were greatly above manipulation alone, but generally there was not a general statistical improvement on manipulation alone. The manipulation scores did not differ between NHS and private care.

  The EQ-5D questionnaire responses were used to calculate QALYs for the four treatment groups, which would finally be combined to calculate incremental cost per QALYs gained by the interventions over "best care". Mean QALYs gained for the 12 months of treatment were, in descending order, 0.659 for "best care" plus manipulation, 0.651 for "best care" plus manipulation and exercise, 0.635 for "best care" plus exercise and 0.618 for "best care" alone. Relative to "best care" therefore, manipulation generated a mean of 0.041 additional QALYs, combined treatment a mean of 0.033 additional QALYs and exercise a mean of 0.017 additional QALYs.

  The UK BEAM trial would perform a cost-utility analysis to compare current "best care" with manipulation and exercise interventions. The mean total costs of each group over 12 months were £346 for "best care", £486 for "best care" plus exercise alone, £541 for "best care" plus manipulation alone and £471 for "best care" plus manipulation and exercise. Therefore, for £125 extra, combined treatment provides 0.033 more QALYs, for an incremental cost-utility ratio of £3,800. Exercise generates 0.017 more QALYs than "best care", and thus produces an incremental cost-utility ratio of £8,300. Manipulation costs an additional £195 over "best care" for an extra 0.041 QALYs, totalling an incremental cost-utility ratio of £4,800. Relative to combined treatment, manipulation alone has an incremental cost-utility ratio of £8,700. Therefore, depending on the upper limits on the cost effectiveness ranges used, we are able to assess which intervention (if any) would be best. Unless the upper limit of the range is below £3,800 (and NICE currently uses an

[179] See Glossary.
[180] See Glossary.

upper limit of between £20,000 and £30,000[181]), an additional intervention would be better than current "best care". Additionally, as long as the upper limit of the range is above £8,700 per QALY, manipulation plus "best care" is likely to be the most appropriate treatment package. The possibility that manipulation could only be provided in private premises only increases the incremental cost-utility ratio of manipulation to conventional treatment to £10,600, still easily within the NICE cost effectiveness range, above which justification for recommendation of treatment becomes more stringent.

Conclusions

Taking the information above as the key current indicators, some initial hypotheses can be drawn. The available evidence is low in number, frequently below the most stringent demands of RCTs, often based solely on patient responses and sometimes lacking in diagnostic information. The comments are limited to the treatment of lower back pain, as this has been the body of the presented evidence. The possible effectiveness of manipulation in treating other conditions (for example neck pain, shoulder pain and other musculoskeletal disorders) has not been examined in the report but should form a part of any wider analysis of the proper role of manipulation therapies in the NHS.

In terms of lower back pain, the increased utilisation of manipulation therapies in the NHS may well generate significant cost savings for the UK economy once benefit payments, health spending and lost work/productivity are taken into account. One essential factor to remember when considering these conclusions is the limited scope of the Enquiry. Manipulation therapies have only been examined with respect to treating back pain, yet their application, and thus the possible benefit of greater usage, is much wider.

We find that the balance of the evidence from the literature review is that, used as an alternative to conventional medicine, chiropractic has advantages in terms of costs and benefits in the following condition:

- Lower back pain, particularly acute pain

Used as a complement to conventional medicine, the balance of the evidence is that manipulation therapies have advantages in terms of costs and benefits in the following condition:

- Lower back pain

Chiropractic as an Alternative

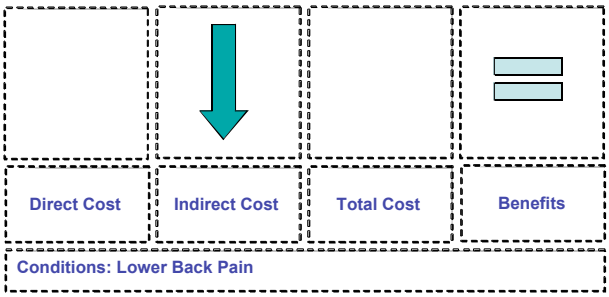
Lower back pain

On chiropractic care alone, it seems clear that manipulation returns patients to work at a faster rate than conventional treatments. A greater proportion of those utilising chiropractic than conventional medical care will return to work within less than a week's time, cutting the number turning to benefit payments. The difference in days missed for those utilising chiropractic and conventional treatment ranges from two to 150, but the studies suggest fewer work days lost when chiropractic is involved (the Enquiry understands that not all patients using chiropractic will be in employment).

The comparison of total cost for chiropractic versus conventional treatments is not clear from the available evidence. The direct costs of increasing the availability of chiropractic may well be greater than current direct costs for conventional treatments. There may be over-treatment by chiropractors; if there was a greater standardisation of care practices and a resultant reduction in the number of treatment sessions, the cost for chiropractic may reduce. Additionally, chiropractors frequently see patients with complex and chronic conditions, as patients who have not found conventional treatments beneficial often turn to CAM. Therefore, the costs are likely to be unfairly high if compared with conventional treatment in many cases.

[181] See CAM in the NHS.

The studies used to arrive at these conclusions are: Bergemann & Cichoke, 1980; Johnson et al., 1989; Nyiendo, 1991; Jarvis et al., 1993; Stano, 1993; Stano and Smith, 1996; Phelan et al., 2004; Shekelle et al., 1995; Stano et al., 2002; Carey et al. 1995; Cherkin et al., 1998; Meade et al., 1990 and Skargen et al., 1998. Please see below for a visual summary of these findings.



Sources: Bergemann & Cichoke, 1980; Johnson et al., 1989; Nyiendo, 1991; Jarvis et al., 1993; Stano, 1993; Stano and Smith, 1996; Phelan et al., 2004; Shekelle et al., 1995; Stano et al., 2002; Carey et al. 1995; Cherkin et al., 1998; Meade et al., 1990 and Skargen et al., 1998.

Manipulation as an Complement

Lower back pain

Manipulation therapies score at least as highly as conventional treatments on reducing scores of pain intensity, disability and function (physical, social and emotional) in a statistically significant degree for acute back pain sufferers. More emphatically, patient satisfaction with the treatment they received shows manipulation consistently rated far higher than conventional treatments.

In terms of sub-groups, manipulation therapies bring greater short-term (>6 weeks of treatment) pain relief for both acute and chronic lower back sufferers. This does not indicate that this treatment should be the sole or even initial course of treatment for those with lower back pain; however, short-term pain relief is an important component of overall treatment and must be a part of the overall guidelines in treating back pain (as echoed by the Royal College of General Practitioners, who recommended that chiropractic be made available as a treatment option for acute lower back pain). When utilised as an additional/complementary therapy, manipulation therapies produce an increase in quality-adjusted life years (QALY) to the patient. This increase varies between 0.006 and 0.041 QALYs and suggests incremental QALYs if "best care" is supplemented with manipulation.

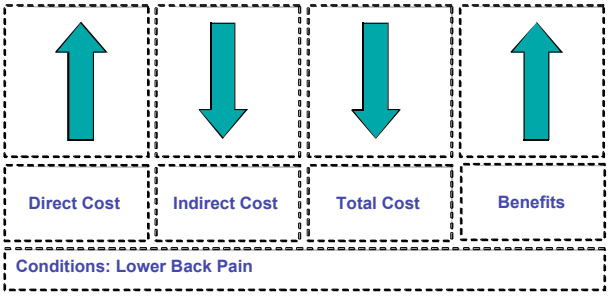
More concretely, even when utilised as a complementary therapy, manipulation is cost-effective at the limits outlined by NICE. The incremental cost to QALY ratio for manipulation as a complementary therapy compared to conventional treatment alone is between £3,000 and £10,000, far below the current NICE upper limit on its cost effectiveness range of between £20,000 and £30,000 (for more detail on this, please see CAM in the NHS).

Even if we accept the higher direct cost of manipulation for back pain compared with conventional treatment, two additional cost considerations indicate the possible cost savings of greater provision of these CAM treatments. Firstly, there are the savings from a reduction in benefit payments that would result from fewer claims, as patients are returned to work more quickly if utilising chiropractic as opposed to conventional care. Secondly, with the more rapid return to work with chiropractic care over conventional treatment, the savings from decreased output and productivity losses would be significant. Taking account of the fact that back pain alone accounts for over 200 million lost days from work,[182] costing the UK over £11 billion in indirect costs[183] (i.e. lost output) it is obvious that if more patients took advantage of

[182] Arthritis Research Campaign, 2003
[183] Maniadakis & Gray, 2000.

manipulative techniques and if these resulted in a speedier return to work, the resulting economic benefit could easily amount to hundreds of millions or even billions of pounds.

The studies used to arrive at these conclusions are: UK BEAM Trial Team, 2004a & 2004b; Williams et al., 2003; Manga et al., 1998 and Lagoretta et al. Please see below for a visual summary of these findings.



Sources: UK BEAM Trial Team, 2004a & 2004b; Williams et al., 2003; Manga et al., 1998 and Lagoretta et al., 2004.

Herbal Medicine

The Treatment Process

> *"A system of medicine which uses various remedies derived from plants and plant extracts to treat disorder and maintain good health"* House of Lords (2000, Box 1)
>
> *"Herbal Medicine is the use of plant remedies in the treatment of disease. It is the oldest known form of medicine."* National Institute of Medical Herbalists

Herbal medicine is also known as phytotherapy. This report considers the Western rather than traditional Chinese approach to herbal medicine. In more traditional approaches, complex mixtures of herbs are individually tailored to the patient, whereas the Western approach will more frequently designate which plant, part of plant or plant extract is to be used for a specific condition. Many modern pharmaceutical drugs are based on plant constituents. A therapeutically active constituent is extracted from the plant, synthesised and then incorporated into a manufactured drug. The difference between this and herbal medicine is that with the latter, extracts from whole plants are derived, which contain an unknown number of possibly significant plant constituents and it is these that are used to manufacture the herbal medicine. The Western approach will usually follow the conventional model of consultations, appointments and treatment.

Current Usage

There are three categories of herbal medicinal product: licensed herbal medicines, unlicensed herbal medicines and food supplements. The products are available over-the-counter at health food shops, supermarkets and pharmacies. In 2004, Mintel[184] calculated the market for herbal medicines reached £87 million in 2004, a 16% increase since 2002. From 2000-2, chemists accounted for 49% of sales, supermarkets 20% and health food shops 31%. The demographics of consumers of herbal products was weighed towards women, aged 45-54, in the higher income brackets (AB1) and living in Greater London and the South.

Safety

Each herbal product will have its own set of safety concerns. For example, the Medicines Control Agency (MCA) banned Kava Kava in the UK from 2003 (although the ban was subsequently overturned in Wales); the ban is currently under a planned review by the Medicines and Healthcare products Regulatory Agency (MHRA).

One major concern, as with all CAM therapies, is that the patient fails to use more appropriate conventional medical treatments. Second, herbal products may differ greatly in their strength and source. The products may have different active ingredients and differing amounts of these ingredients. This concern could be addressed with greater standardisation and regulation, as being implemented by the Medicines and Healthcare products Regulatory Agency (MHRA), the European Union and the Herbal Medicine Regulatory Working Group (HMRWG). In studies of the safety and effectiveness of herbal remedies standardised extracts are usually used (for example Trebonin produced by Schwabe for Ginkgo, and Kira produced by Lichtwer for St. John's wort). Third, the products may contain toxic ingredients that will need to be removed to allow the safe application of the treatments. The products may negatively interact with other medications and limit or even cancel out their effectiveness. Examples include St. John's wort or horse chestnut with anticoagulants[185] and ginkgo biloba

[184] Complementary Medicines, UK, 2003 and UK Essentials: UK Market Intelligence, 2005.
[185] A drug therapy used to prevent the formation of blood clots that can become lodged in cerebral arteries and cause strokes.

with anti-platelet[186] agents. This concern re-emphasises the need for herbal products to be used in conjunction with conventional medical consultation. Finally, herbal medicines may cause adverse effects, but the adverse effects caused by the remedies listed below are minor and usually more infrequent than the equivalent conventional treatment. All of the herbal medicines presented below have strong evidence of being safe. It is of course extremely important to recognise the necessity for patients to consult their primary medical practitioner before using these herbal products. Although all the discussed herbal medicines have good evidence for safety, interactions with other medications may be harmful.

As a further factor on the availability of over-the-counter tradition herbal medicine products, an EU Directive was agreed in April 2004, which will come into force in October 2005. The directive is designed to ensure that remedies are made to assured standards of safety and quality across the EU, and will achieve the concomitant effects of securing a legal basis for herbal medicine, as well as a rise in quality of available products. The MHRA have declared their intention to interpret the guidelines with sensitivity to traditional Chinese Medicine and Ayurvedic products. However, difficulties may arise regarding the licensing of previously exempt herbal products which may decrease consumer choice due to increased manufacturer costs, as well as the availability of some herbs to practitioners.

Regarding the profession of medical herbalism, it is, like acupuncture, in the process of attaining statutory regulation, already accorded to the professions of osteopathy and chiropractic. The Herbal Medicine Regulatory Working Group was set up by the herbal medicine professional bodies, the Department of Health and the Foundation for Integrated Health and has published proposals on the matter. Legislation is expected by 2007.

[186] Drugs that interfere with the blood's ability to clot. They're used to prevent blood clots from forming that can lead to heart attack or stroke.

Figure 2 below presents an overview of the general safety issues that should be considered when administering and using the herbal products examined below. The list is not comprehensive.

Figure 2: Safety of Herbal Products

Herbal Medicine	Contraindications[187]	Precautions	Adverse Effects	Overdose	Interactions with other drugs
St John's wort	Pregnancy, lactation[188]		Gastrointestinal symptoms, allergic reactions		Several prescription drugs, especially for HIV anti-retrovirals[189], anticonvulsants[190] and oral contraceptives
Echinacea	Pregnancy, lactation	AIDS[191], MS[192], autoimmune disease[193] sufferers avoid prolonged use	Uncommon allergic reactions		Lower effects of an immunosuppressant[194]
Ginkgo biloba	Pregnancy, lactation, hypersensitivity to ginkgo preparation	Effects on under-12s unknown	Gastrointestinal problems, including diarrhoea and vomiting	Childhood seizures	Anti-coagulants
Devil's claw	Pregnancy, lactation, gastric ulcer		Gastrointestinal symptoms	Cardiac effects	Anti-coagulants
Hawthorn	Pregnancy, lactation, allergic reactions	Hypotension[195] or arrhythmia[196]	Nausea, dizziness, fatigue	Respiratory failure	Antihypertensive drugs[197], nitrates[198]
Horse Chestnut	Pregnancy, lactation, bleeding disorders	Open wounds (external use)	Pruritus[199], nausea, stomach problems		Aspirin, anti-coagulants
Saw palmetto	Pregnancy, lactation		Gastrointestinal problems, constipation, diarrhoea		Oral contraceptives, hormone replacement therapy[200]

Source: Ernst et al., 2001

[187] See Glossary.
[188] The production and secretion of breast milk.
[189] Medication or substance that inhibits or destroys a retrovirus such as human immunodeficiency virus (HIV).
[190] Drugs given to prevent seizures.
[191] Acquired Immune Deficiency Syndrome.
[192] Multiple Sclerosis.
[193] A condition in which the body's immune system causes disease by attacking its own organs and tissues.
[194] An agent that acts to suppress the body's natural immune response.
[195] Low blood pressure.
[196] An irregular heartbeat.
[197] A medication that lowers blood pressure.
[198] A group of drugs that dilate blood vessels. They treat heart conditions in which blood is being pumped inefficiently.
[199] Severe itching.
[200] The substitution of naturally declining hormones with synthetic or artificial hormones in women during menopause.

Overview of Applications and Effectiveness

The herbal products examined are for specific remedies aimed at treating specific complaints. We have not included clinical evidence of systems of herbal medicine such as the traditional Chinese system. Below is a selection of those herbal medicines that have positive evidence of safety and efficacy.

Phytodolor

- Ernst, Soeken & Long (2001) conducted a systematic review into the treatment of osteoarthritis[201] with various herbal medicines. The authors selected RCTs (12) and two previous systematic reviews that met their inclusion criteria. Studies included in the review involved comparative examinations of one herbal treatment measured against one active drug. Herbal medicines and plant extracts reviewed included: Articulin-F, capsaicin cream, Devil's claw, ginger extract, Reumalex, ASU (avocado and soybean unsaponifiables) extract, Eazmov, Gitagyl, Phytodolor, stinging nettle leaf. The authors draw stronger conclusions than appear appropriate given the small number of RCTs that examine most of the treatments, and this is supported by the Centre of Reviews and Dissemination's (University of York) analysis of the systematic review. Nevertheless, six RCTs into Phytodolor (a fixed herbal preparation containing alcoholic extracts of Populus tremula, Fraxinus excelsior and Solidago virgaurea) indicate its superiority to placebo for pain, morning stiffness, immobility and joint mobility. There was no significant difference between Phytodolor and the active drug Diclofenac on pain, swelling, function, joint mobility and global symptom score.

- A further systematic review conducted by Ernst (1999) positively concluded that Phytodolor was efficacious in treating rheumatoid arthritis. The review concluded that the herbal product was both safe and effective in the treatment of musculoskeletal problems, as well as being as effective as conventional medications, non-steroidal anti-inflammatory drugs (NSAIDs). It can be concluded that suitable cost-benefit analyses of Phytodolor in treating osteoarthritis and rheumatoid arthritis[202] would be beneficial.

Echinacea

Echinacea is widely available and a popular choice of herbal remedy in the UK. It frequently is taken to alleviate symptoms from the common cold, give a boost to the immune system, combat viral infections and speed wound healing. In one survey (Turner, 2002), Echinacea was the most common herb taken by surgical patients, approximately 12.7%.

- Barrett, Vohmann & Calabrese (1999) examined placebo-comparing RCTs on the evidence of the efficacy of orally ingested Echinacea for upper respiratory infection (URIs), also known as the common cold. 13 RCTs covering 2416 participants met the inclusion criteria. The evidence for the *preventive* capacity of Echinacea was weak; however, 8 of 9 *treatment* efficacy RCTs supported the ability of Echinacea to decrease the severity and duration of acute URI. With strong safety data on the medicine, Echinacea could be cautiously recommended in the early stages of treatment for URIs.

- Melchart et al.'s (1999) systematic review also examined the treatment and prevention of the common cold through the taking of Echinacea. Its conclusions matched those Barrett, Vohmann and Calabrese, with good evidence to support the improvement in patient cold symptoms when taking Echinacea, but weaker evidence on its ability to prevent such symptoms.

St. John's wort

A significant body of randomised controlled trial (RCT) evidence supports the effectiveness and efficacy of St. John's wort in the treatment of mild to moderate depression. Two systematic reviews, a RCT meta-analysis and a very recent double-blinded RCT have set out a convincing case for the use of St. John's wort for mild and moderate depression.

[201] See Glossary.
[202] See Glossary.

Comparative efficacy to standard antidepressants is less clearly established although most of the major following studies do use prescription comparisons in efficacy investigations.

- The first review, published in 1999 by Kim, Streltzer and Goebert, examined six RCTs for the effect of St. John's wort (Hypericum perforatum) on depression, utilising the Hamilton Depression Scale (HAMD)[203] as an outcome measure. The two trials comparing St. John's wort to placebo showed more dramatic improvements in lowering HAMD scores for the herbal medicine, similar dropout rates and minimal if any side-effects. The four trials comparing St. John's wort to standard tri-cyclic antidepressants (TCA)[204] found similar effects in both groups, with lower rates of dropout from using the drug and side-effects for the herbal medicine.

- In a second systematic review, Gaster and Holroyd (2000) examined those RCTs passing their strict inclusion criteria and used HAMD measurements as the evidence base for their findings. Four trials comparing St. John's wort to placebo found much greater responder (a responder is defined as a patient whose HAMD score falls below 10 or whose score is 50% or less of their baseline score after treatment) rates for St. John's wort, three of the differences being statistically significant. There was no statistically significant difference in the four studies comparing St. John's wort to TCA drugs, with the low-dose of TCA still more likely to cause adverse effects in patients than St. John's wort.

- Szegedi et al. (2005) compared St. John's wort against the conventional medication, paroxetine, in a recent RCT from Germany. A total of 251 patients with acute major depression were given either St. John's wort extract three times a day or paroxetine once a day for six weeks. The HAMD score decreased by 56.6% with St. John's wort and only 44.8% for paroxetine, and the incidence of adverse reactions was 0.035 with St. John's wort and 0.060 with paroxetine.

- Whiskey et al. (2001) performed a meta-analysis and a systematic review of published trials consistently showing St John's wort is more effective than placebo. Twenty-two RCTs showed St John's wort to be significantly more effective than placebo but not significantly different in efficacy from active antidepressants. A sub-analysis of six placebo-controlled trials and four active comparator[205] trials satisfying stricter methodological criteria also suggested that St John's wort was more effective than placebo and of similar effectiveness to standard antidepressants.

- The rate of use of St. John's wort has fallen over the last few years. For example, St. John's wort used to outsell Prozac in Germany by approximately four to one. However, several well-publicised research studies laid out the possibly very serious consequences of mixing St. John's wort with certain other prescription drugs. St. John's wort sped up the breakdown and thus removal of these drugs, diminishing the effect of these prescriptions. Examples included affecting anticoagulants to avoid blood clots and reducing the effectiveness of oral contraceptives. Possibly this merely argues for a greater diligence in the advising of who should take St. John's wort, not in its eradication from the realm of possible treatments. Those advised not to take the extract should not do so: otherwise, it appears to be an effective and safe treatment for depression.

[203] See Glossary.
[204] Tricyclic antidepressants are used to treat depression, anxiety, and chronic pain.
[205] These trials compare two quantities and determine their equality by computational methods.

Ginkgo biloba

Ginkgo biloba can help patients with Alzheimer's disease[206] and vascular dementia [207], with evidence to suggest efficacy in slowing the progress of the disease and improving both the patient's ability to think clearly and relate better socially. Adverse effects are very rare and the over-the-counter price is comparable to conventional medications, although the "total costs may be lower, since Ginkgo biloba is associated with fewer adverse effects" (p. 421, Long, Soeken & Ernst, 2001). In addition there are a wide range of general complaints where herbalists recommend its use, including hearing loss, asthma, cardiovascular disease, memory loss, sexual dysfunction, stress and eye problems.

- Ernst and Pittler (2000b) ran literature searches of Medline, Embase, Biosis, AMED, CISCOM, and the Cochrane Library to identify RCTs for intermittent claudication.[208] Comment from commercial herb suppliers and literature authors were sought to corroborate findings. A meta-analysis of eight double-blind RCTs found a significant difference in the increase in pain-free walking distance when utilising Ginkgo biloba (weighted mean difference: 34 meters). These results suggest that Ginkgo biloba extract is superior to placebo in the symptomatic treatment of intermittent claudication. The analysis found Ginkgo biloba to be as effective as conventional medications.

- Several systematic reviews and meta-analyses suggest the effectiveness of the product in treating dementia. Ernst and Pittler (1999) systematically reviewed nine studies and tentatively concluded that Ginkgo biloba was safe and effective beyond placebo in treating dementia. A Cochrane meta-analysis by Birks et al. (2002) of 33 studies also concluded that ginkgo biloba gave patients improved cognition and function in the treatment of dementia.

Devil's claw

Devil's claw (*Harpagophytum procumbens*) is generally used for musculoskeletal problems, including inflammation, osteoarthritis and rheumatoid arthritis.[209] Research suggests improved mobility for osteoarthritis patients that are users of Devil's claw although relatively few studies have been conducted. These studies suggest that the use of Devil's claw may allow the dose of pain medications to be reduced.

- One clinical study suggests that Devil's claw may benefit patients with osteoarthritis of the hip or knee: Wegener et al. (2003) found Devil's claw preparations are successfully used in patients with rheumatic diseases, yielding a strong reduction in pain and the symptoms of osteoarthritis. The physicians reported a continuous improvement in typical clinical findings such as 45.5% for pain, 35% for limitation of mobility and 25.4% for joint "crepitus".[210] Although this was an open[211] clinical study, the results suggest that this Devil's claw extract has a clinically beneficial effect in the treatment of arthritic conditions of the hip or knee.

- Ernst and Chrubasik (2000) also present positive conclusions on the effectiveness of Devil's claw in the treatment of musculoskeletal conditions. In particular, while acknowledging that the area is under-researched, the authors conclude that such herbal anti-inflammatories as Devil's claw are effective above placebo in the treating of rheumatic disorders. However, the effectiveness compared to conventional medical treatments has not been established.

[206] A progressive form of presenile dementia that is similar to senile dementia except that it usually starts in the forties or fifties.
[207] An acquired loss of cognitive function that may affect language, attention, memory, personality and abstract reasoning resulting from brain damage caused by strokes or mini-strokes.
[208] Pain in the leg (thighs, hips or calves) mostly caused by build-up of cholesterol plaque in the arteries of the leg.
[209] See Glossary.
[210] A clinical sign in medicine characterised by a peculiar crackling, crinkly, or grating feeling or sound under the skin, around the lungs, or in the joints.
[211] A clinical trial in which researchers and participants know which drug or vaccine is being administered.

Hawthorn

Hawthorn has a long history of use in cardiovascular[212] problems, especially exhibiting cardiotonic activity (restoring the heart to a normal tone) for sufferers of congestive heart failure (CHF).[213] In addition to older research preceding the widespread use of hawthorn for the treatment of mild CHF in Germany, the Memorial Sloan-Kettering Cancer Center has produced valuable research papers on the efficacy of hawthorn extract. Hawthorn probably has a dual action: it increases the size of the smooth muscle in coronary[214] vessels thereby lowering their resistance and increasing blood flow; it also has positive inotropic[215] effects, leading to an increase in a patient's heart rate.

- Zapatero's systematic review on the effects of hawthorn (1999) used a Medline and EMBASE literature search to assess findings from a wide-range of studies. His thorough approach to qualifying a study's usefulness and detecting real effectiveness in the results make this piece of research one of the most informative in this area. He stated that the research showed that hawthorn decreases total cholesterol, low-density lipoprotein cholesterol[216] and triglycerides [217] in humans. It also increases the exercise capacity of patients with NYHA Class II[218] congestive heart failure. Further studies are needed to work out the mechanism of action for hawthorn. In recognition of the complexity of many extracts' activity, Zapatero stresses beneficial effects may come from several different compounds acting synergistically; their interaction should therefore also be addressed. The overall finding is that beneficial effects of hawthorn on the cardiovascular system are real and act by several different mechanisms, with few side-effects documented. However, the effectiveness of hawthorn compared to conventional drugs is not certain, with this review cautiously outlining that the effects are similar.

- Pittler, Schmidt and Ernst (2003) performed a meta-analysis of eight randomised, double-blind, placebo-controlled trials. In most cases hawthorn was used in combination with other medications. 632 patients with CHF provided the data. Hawthorn was seen to be more effective than placebo in treating problems with a patient's heart rate and heart pressure. Dyspnoea[219] and fatigue improved significantly.

- Tauchert et al. (2000) found a statistically significant improvement in cardiac performance in a RCT against placebo of 40 CHF sufferers in 2002. The role of hawthorn in aiding the treatment of hypertension, indigestion, angina and CHF is backed by strong evidence and good safety data.

Horse chestnut

Horse chestnut is widely used in Europe and appears to possess equivalent effectiveness to conventional treatments for chronic venous insufficiency (CVI) (prolonged problems with vein functioning), seeing marked reductions in leg pain and swelling. When used correctly it is safe and relatively cheap. Other uses suggested include: wider circulatory disorders, diarrhoea, haemorrhoids and varicose veins.

- Ulbricht et al. (2002) produced a multidisciplinary review of horse chestnut extract (aescin) examining activity in venous insufficiencies, the only condition for which there is strong supportive scientific evidence. Seven RCTs supported the superiority of horse chestnut over placebo, and suggested equivalent benefits to compression stockings and conventional medications.

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[212] See Glossary.
[213] A condition where the heart muscle weakens and can't pump blood efficiently throughout the body.
[214] Related to the arteries that supply blood to the heart.
[215] An inotropic heart drug is one that affects the force with which the heart muscle contracts.
[216] Often called the "bad" cholesterol because it carries cholesterol to the tissues of the body, including the arteries.
[217] Fatty substances in the blood that are a component of the "bad" type of cholesterol.
[218] New York Heart Association Functional Classification II (NYHA II) defined as: "Patients have cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain".
[219] Shortness of breath or difficulty breathing.

- Pittler and Ernst (2004) conducted a wide-ranging Cochrane review to examine horse chestnut compared to placebo or a conventional treatment in treating CVI. They concluded that overall horse chestnut was effective above placebo in treating the signs and symptoms of CVI. Leg pain and leg volume were both found to be dramatically improved with the herbal product in almost all the examined RCTs. One trial even found horse chestnut to be as effective as the conventional treatment of compression stockings in reducing leg volume. Thus, horse chestnut possesses strong evidence to indicate it is a safe and efficacious treatment for CVI.

Saw palmetto

Saw palmetto, from the American dwarf palm tree, has been approved by the NHS for treating benign prostatic hyperplasia (BPH). This condition, which involves non-malignant growth of the prostate gland, is very common and affects over 50% of men aged 60 or older and 90% of men aged 70 or older (Preuss et al., 2001). It is associated with problems in urination and of the urinary tract. Saw palmetto has so far proved safe throughout clinical trials and does not affect sexual function as Finasteride[220] does. Many trials, meta-analyses and systematic reviews show it to be efficacious, to be less costly and to have fewer side-effects than Finasteride, a leading conventional treatment. One example is the meta-analysis published in 2004 in the British Journal of Urology International, which pooled the results of 17 clinical trials on active saw palmetto extracts involving 4,280 patients and lasting from three weeks to two years. It concluded that use of the extract was positively associated with a mean reduction in the International Prostate Symptom Score (a questionnaire to rate how bad your symptoms are based on urination habits) and other measured symptoms of BPH compared to placebo (including urinary flow, urinary tract infections, incidence of urination during the night).

- Saw palmetto's mechanism of action is antiandrogenic[221] and is said to reduce inflammation, promote urination and aid in reducing the symptoms of prostate cancer. This wide spectrum of benefits is not matched by any single conventional drug therapy. One instance of a trial (Debruyne, 2002) comparing the effectiveness of saw palmetto to conventional drug treatment (Tamsulosin) in treating BPH found saw palmetto caused fewer side effects and maintained comparable clinical efficacy. These findings are supported in another analysis, Boyle et al. (2000), where the effect of saw palmetto on BPH in 11 RCTs and two open label[222] trials involving 2,859 patients was examined. This meta-analysis revealed a significant improvement in peak flow rate of urination and a reduction in the need to urinate at night in users of saw palmetto compared to placebo.

- Wilt, Ishani & MacDonald (2002) conducted a Cochrane review on the use of saw palmetto in the treatment of lower urinary tract symptoms caused by BPH. 3139 men from 21 trials (18 of which were double-blinded) were involved in the study. They conclude that compared with placebo, saw palmetto improved urinary symptom scores and flow measures. The results were almost identical for those of Finasteride, while adverse effects were very rare and mild. However, the authors do make it clear that these studies have not proved the long-term effectiveness, safety or ability to prevent BPH.

Others

This Enquiry has examined a selection of the most effective and potentially cost-effective herbal medicines. We recognise that there are many other remedies of this type that have compelling evidence for efficacy and others that do not. To widen the selection and give an indication of the range of herbal medicines available, we list below some of those medicines which in the judgement of Professor Ernst can be useful and safely prescribed[223]. The list is of course not exhaustive.

[220] An enzyme inhibitor medication used to treat urinary problems caused by enlargement of the prostate.
[221] This has the effect of slowing the creation of the hormones responsible for stimulating male sex characteristics.
[222] A clinical trial in which researchers and participants know which drug or vaccine is being administered.
[223] See Ernst, 2001

Aloe Vera:	Primarily for skin conditions, its topical use carries few risks and has well-documented benefits
Chaste Tree:	Has promising evidence of effectiveness and safety for use against injuries and inflammations
Chondroitin:	Likely to be effective and safe in treating osteoarthritis
Cranberry:	Good at preventing urinary tract infections with few adverse effects
Glucosomine:	Better than placebo in treating osteoarthritis and similarly effective to Ibuprofen (but with longer treatment periods). No safety concerns.
Melotonin:	Carries few risks and is worth considering for use against jet-lag and insomnia
Milk Thistle:	Few risks and some benefits (though inconclusively proven) for sufferers of chronic alcoholic liver disease
Phytooestrogens:	An alternative to hormone replacement therapy with fewer adverse effects
Tea Tree:	Evidence slightly in favour of use as an effective anti-bacterial treatment for skin conditions
Thyme:	Possibly superior to conventional treatment for bronchitis as part of a combination medicine

Costs and Benefits

In an introduction to the pharmacoeconomics (cost-benefit of medicines) of herbal medicine, De Smet et al. (2000) found only a single study, of "uncertain quality" on the costs and benefits of the prescription herbal medicines ginkgo, hawthorn, St. John's wort, horse-chestnut and saw palmetto. Comparing the costs of herbal medicines with other conventional medications is difficult due to varying dosages, potencies and the number of different medications available. Without conducting a rigorous clinical and cost comparison of herbal medicines to the appropriate conventional treatment, the ability to put figures on this possible cost saving is limited.

However, much of the herbal medicine literature analysed by this Enquiry compares the effectiveness of a herbal remedy against a specific conventional alternative. Where this conventional therapy is named, drug for drug cost comparisons are possible.

In 2004 the NHS spent £400m on anti-depressant drugs, at an average net ingredient cost of £13.82 per prescription. Two prominent conventional drugs cost £21.69 and £3.24 respectively per length of prescription. Although data on the length of prescriptions is not available, a weekly course of St John's wort costs just 82p. Considering the evidence that St John's wort appears to be both marginally more effective and produces fewer side effects,[224] dependent on prescription length, this sort of potential cost saving is potentially large.

Non-steroidal anti-inflammatory drugs also account for significant NHS drug expenditure: a total of £247m in 2004 at an average net ingredient cost of £11.82 per prescription. This Enquiry's literature review finds no significant difference between the herbal remedy Phytodolor and the usual conventional treatment diclofenac, on pain, swelling, function, joint mobility and global symptom score. Given that diclofenac costs £14.03 per prescription and phytodolor costs just 45p per week, the potential for cost savings cannot be ignored.

There are inherent problems in this analysis. Not only are dosage and prescription length unknown (an area about which this Enquiry has found very limited information), but practitioner skill also needs to be taken into consideration. Another consideration when assessing the extent of the savings to be made when comparing herbal remedies to conventional drugs is the patent status of the conventional drug: when still under patent they are far more expensive than their generic counterparts which are able to be produced once

[224] Szegedi et al., 2005.

the patent on the original drug has expired. For example, a generic version of Prozac (fluoxetin) is much cheaper than the original when it came on the market. We do not propose that herbal remedies could replace the use of their more conventional counterparts in every situation.

Conclusions

The lack of economic evaluations for herbal medicines is limiting, particularly given the focus of this report. In addition, significant changes are currently underway in the UK with respect to the regulation of herbal medicines: the Medicines and Healthcare Regulatory Agency (MHRA) is working on strengthening the regulation of herbal medicines, including a proposed regulatory agency; the Traditional Herbal Medicinal Products Directive and Food Supplements Directive should come into force in October 2005; the Herbal Medicine Regulatory Working Group (HMRWG) is working on the process of the statutory regulation of herbal medicines as proposed in the House of Lords Report in 2000. Whether these changes will spur the transformation of certain herbal medicines from being considered food supplements to prescription medications remains to be seen. Nevertheless, the above discussion highlights the possibility of cost savings: for example, St. John's wort compares favourably with many leading antidepressants on price, and the immense number of cold remedies is generally more expensive than echinacea. The need for economic evaluations of specific herbal medicines is evident.

Figure 3: Herbal medicines' clinical benefit and cost advantage data

Herbal Medicine	Condition	Published evidence of clinical benefit	Indication of cost advantage compared to conventional treatment
Phytodolor	Musculoskeletal problems (including rheumatoid arthritis)	YES	YES
Echinacea	Viral infections and common cold	YES	YES
St. John's wort	Depression (mild/moderate)	YES	YES
Ginkgo Biloba	Alzheimer's disease, Intermittent claudication, Dementia	YES	YES
Devil's Claw	Musculoskeletal problems (including arthritis)	YES	YES
Hawthorn	Heart problems (including congestive heart failure)	YES	YES
Horse Chestnut	Circulatory problems (including chronic venous insufficiency)	YES	YES
Saw Palmetto	Benignly enlarged prostate	YES	YES

Sources for conclusions on published evidence of herbal medicine effectiveness

Phytodolor: Ernst, Soeken & Long, 2001
Ernst, 1999

Echinacea: Barrett, Vohmann & Calabrese, 1999
Melchart et al,. 1999

St. John's wort: Kim, Streltzer and Goebert, 1999
Gaster and Holroyd, 2000

	Szegedi et al., 2005 Whiskey et al., 2001
Ginkgo Biloba:	Ernst and Pittler, 2000b Ernst and Pittler, 1999 Birks et al., 2002
Devil's claw:	Wegener et al., 2003 Ernst and Chrubasik, 2000
Hawthorn:	Zapatero, 1999 Pittler, Schmidt and Ernst, 2003 Tauchert et al., 2000
Horse chestnut:	Ulbricht et al., 2002 Pittler and Ernst, 2004
Saw palmetto:	Preuss et al., 2001 Debruyne, 2002 Boyle et al., 2000 Wilt, Ishani & MacDonald, 2002

MODELS OF INTEGRATION AND METHODS OF DELIVERY

Background

The Literature Review has introduced the wide variety of studies examining the costs and benefits of the individual CAM therapies. The Enquiry now turns to the practical considerations that the integration of CAM and conventional medicine must address.

The integration of CAM therapies into the NHS is a significant and complex topic, one that, in its entirety, lies outside the scope of this report. Research in this area is being carried out by the Foundation for Integrated Healthcare (FIH), the University of Westminster in collaboration with the King's Fund and Department of Health, the Research Council for Complementary Medicine (RCCM) and the Medical Care Research Unit (MCRU) at the University of Sheffield, amongst others. While referring interested readers to the in-depth work on integration and methods of delivery by the above organisations (see Appendix C), the Enquiry will: outline the key factors to be considered in the move towards integrating CAM with conventional care; the main methods of CAM delivery in the UK; summarise case studies of CAM services delivery; and finally, present and analyse a case study conducted by Enquiry on an example of CAM service delivery to a community that would otherwise not usually be able to buy these services privately.

The decision concerning which model of integration to utilise must precede the choice of methods of delivery. The philosophical perspectives regarding integration will be the primary consideration when selecting the range of delivery methods. For example, if the selected model is one of "side-by-side" practice, where CAM practitioners and general practitioners are located in the same practice and work together, the method of delivery would be different from a model of integration with limited referral opportunities and limited conventional and CAM practitioner interaction. In addition, the ease of access and cost of CAM services in the local setting will be a significant determining factor in the choice of delivery method. For most practices, a mix of delivery methods, corresponding to a mix of models of integration, will be most suitable.

General Considerations for Integration

It is important that any process of integration, however framed, will include close consideration of the following important factors:

Mechanism of Action, Efficacy and Effectiveness
As highlighted throughout this report, these three closely linked research areas must be considered by policy makers. Disagreement exists as to which of these research questions takes priority in working to further the provision of CAM within the NHS. Nevertheless, all parties appear to appreciate the importance of broadening CAM's evidence-base in all three areas. Priorities for research could be linked to the stated NHS priorities and "effectiveness gaps", defined as those areas where current conventional provision is inadequately meeting patients' needs (see Effectiveness Gaps).

In addition, it is necessary to have a regulatory body that will be able to make judgments on the quality of evidence so far collated and subsequently draw conclusions. NICE is the UK body designated to carry out critical appraisals of such results and it is important that the dialogue over appropriate standards for CAM therapies is coordinated with NICE. At the same time, there needs to be a greater willingness from those working in CAM to take evidence to NICE. NICE has stated that although it utilises a flexible approach in setting its guidelines, and involves a wide variety of interested parties,[225] it will need more than just effectiveness evidence to make strong recommendations when setting its clinical guidelines.[226] NICE also

[225] For further discussion of NICE, see CAM in the NHS.
[226] Interview with Peter Littlejohn, NICE.

requires data on the costs of therapies, as one of its key roles is assessing the cost-effectiveness of different treatments. Most CAM therapies are yet to be examined by NICE in a comprehensive way.

Cost-Effectiveness
The combined demands from patients for greater satisfaction and lower taxation make economic evaluations of all treatments of central importance to the NHS. CAM will necessarily be competing with other services for budgetary provision in the NHS and for this reason NICE must make the difficult decisions relating to the cost-effectiveness of treatments. Whichever type of economic evaluation is utilised (and NICE focuses on cost-utility ratios), proponents of CAM therapies will need to identify how the enhanced use of such services will affect NHS budgets and individual PCTs will equally require clear and objective guidelines as they grapple with their own budgetary constraints.

Safety
Regardless of whether CAM treatments are to be funded privately or from the public purse, it is self-evident that the safety of CAM therapies must be established. CAM practitioners and proponents need to demonstrate that the benefits of the treatment sufficiently outweigh its risks before public bodies can advocate its use. This is already taking place, and Prof. Edzard Ernst's group's study into the safety of acupuncture[227] is an example of this. The importance of safety concerns should not be dismissed by CAM practitioners; nor should it be forgotten that, as with many conventional treatments, adverse effects that are rare will only appear with very large samples. Hence CAM treatments may only be able to prove their safety when given the opportunity and the funding for studies that include sufficiently large numbers. An overview of safety is included in the literature review for acupuncture, homeopathy, manipulation therapies and herbal medicine.

Regulation and Legal Certainty
Both osteopathy and chiropractic have attained statutory regulation status, and acupuncture and herbal medicine are moving in that direction.[228] Other CAM therapies are also moving towards voluntary self-regulation. Whether or not voluntary self-regulation can achieve similar quality and safety assurances as statutory regulation is uncertain. It is however important that all therapies can show that the competency of practitioners is assessed, modes of practice are set out, complaints can be heard, and information can be disseminated to practitioners, policy makers and patients. Of equal importance is the certainty over who bears the legal responsibility for treating a patient. General Practitioners need to be certain about the scope of their responsibility after referring a patient to a CAM practitioner. This is an area of great concern to GPs and will be of paramount importance in any attempt to increase the rate of referrals to CAM.

Education and Training
Regulatory bodies could also play a central role in setting standards and accrediting professional training in their respective therapies. Education in CAM for undergraduate and graduate medical students is increasing, and could increase the interest in the use of CAM within the NHS. GPs are certain to be at the heart of any method of delivery, and this will require a greater prominence of CAM in medical curricula and in continuing professional development. Equally, non-medical CAM practitioners will need a greater understanding of orthodox medicine if they are to be able to adequately cooperate with and refer to other CAM practitioners and mainstream medical staff. If any model of integration is to become more widespread, the level of professional training will need to be increased and monitored.

Attitudes
A shift in attitudes may be necessary and beneficial to all sides. Many aspects of treatment that are associated with CAM therapies in fact find great support from orthodox practitioners,

[227] Ernst and White, 2001.
[228] See the work of the Acupuncture Regulatory Working Group [ARWG] and Herbal Medicine Regulatory Working Group [HMRWG]

including the need to spend more time with the patient and treat them individually. Equally, many of the concerns of orthodox medicine are present in much of the CAM community, such as those of regulation, safety and cost-effectiveness. Good communication and cooperation between all interested parties will assist those making the difficult decisions over integration.

The Process of Integration

There are certain key questions that must be examined, analysed and addressed as part of the integration process. This section draws heavily on the work of Dr David Peters that was presented in both the House of Lords Report[229] and on interviews with this Enquiry. It should be emphasised that, as above, each of these considerations could themselves form the basis of lengthy reports.

Healthcare Review

The first consideration must be an examination of the areas of healthcare that are not optimally served by conventional medicine in the area.[230] A first step in this process is to uncover the healthcare needs of the patient group served by the NHS or PCT, and conventional practitioners would be called upon to assess where opportunities exist to improve healthcare outcomes. Secondly, it will be important to assess patient preferences. A strong demand in the patient group examined should not automatically increase the provision of CAM therapies, but it would indicate the likelihood that any CAM therapies introduced would be utilised. Additionally, it should be taken into account that the identified gaps may vary across the country.

Resource Assessment

After identifying these healthcare gaps and needs, it will be important to understand whether or not the introduction of specific CAM therapies is feasible. The relevant healthcare authority (see CAM in the NHS) will need to make its own informed judgements as to the gains that introducing a CAM therapy may provide. The PCT too, must undertake feasibility studies on the costs of integration and whether or not the particular circumstances of each healthcare setting (for example its physical size or the number of patients it deals with) will make integration worthwhile.

Service Design

Although frequently overlapping, two broad underlying approaches exist on the form that integration could take, as outlined in *Models of Complementary Therapy Provision in Primary Care*:[231]

a) The Additive Model: "Offering a broader and more responsive range of provision, a "better" primary care service in which complementary therapies **are complementary to orthodox medicine** and address its gaps."
b) The Transformative Model: "The potential for a different type of ethos in primary health care, in which **conventional and "complementary" therapies are complementary to each other**, learning from and questioning each other's perspectives and practice."

On most occasions the integration model adopted will be a mixture of these two approaches. It is important to understand how the conventional practitioners will utilise the CAM services, as this will be one of the key variables determining the delivery method. For example, a greater willingness by the conventional practitioners to work in collaboration with CAM practitioners may lead to a delivery method that reflects closer working relations, including an understanding of the referral process that will be utilised, and the construction of core aims for the integration model selected.

[229] House of Lords, 2000, sec. 9.8.
[230] This topic is closely linked to the examination of "effectiveness gaps", to be discussed in greater detail in the chapter Effectiveness Gaps.
[231] Thomas & Luff, 1999, pp. 10-11.

Service Delivery
The main delivery methods available are outlined below. It should be clear that service design and delivery are closely linked. In fact, all three of the factors above (Healthcare Review, Resource Assessment and Service Design) will inform the delivery method chosen. In addition, the options available will be determined by the CAM services at the disposal of the PCT (i.e. the referral procedure has to be linked to the availability of referred-patient resources).

Management of the Service
Managers will be eager to measure outcomes and ensure the quality of the newly integrated services. Some of the major areas that should form the body of any evaluation are listed in *Integrated Healthcare: A Way Forward for the Next Five Years?*[232]

a) *Appropriateness* – are conventional practitioners and CAM practitioners correctly identifying patients and conditions that are best served utilising CAM treatment? Are CAM practitioners adequately trained and performing correct safety measures?
b) *Accessibility* – are the CAM services easily accessible within reasonable waiting times?
c) *Acceptability* – are patients satisfied with the results of the introduction of CAM therapies? Are local needs being addressed?
d) *Equity* – are the services reaching all socio-economic and ethnic groups?
e) *Efficiency* – are the services being provided and the resources allocated at an optimal level (i.e. over-treatment, missed appointments, etc.)?
f) *Effectiveness* – are the results clinically effective?
g) *Cost-Effectiveness* – does an initial analysis suggest the introduction of the services is cost-effective (or satisfies some other form of economic evaluation)?

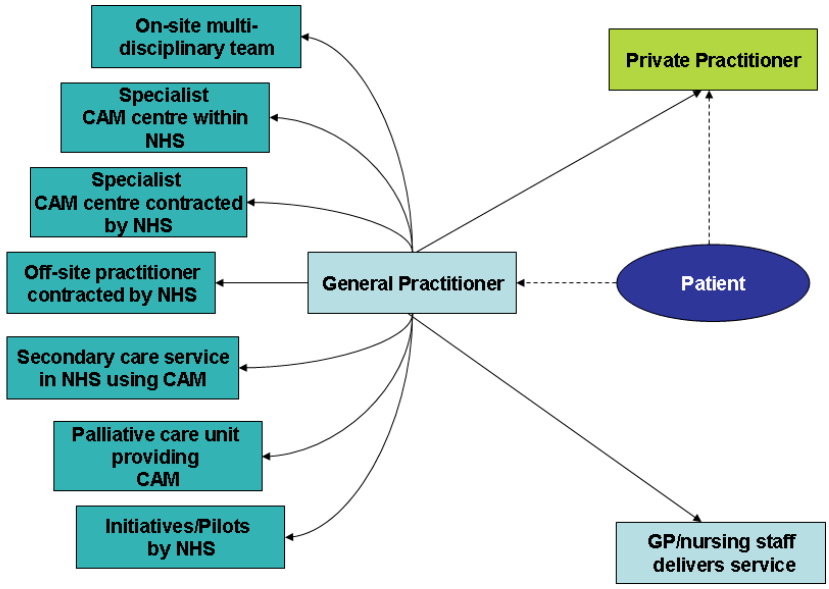
Modification of the Service
Once integration has been in place for a set period of time and has been analysed according to the set of outcome measures identified above, the integrated system should be adjusted to better serve patient needs. This process will be on-going, with the decision-makers always looking to be responsive to the needs and preferences of both patients and practitioners, as well as to changes in the available evidence for CAM treatments.

Methods of Delivery

The methods of delivery described in this section refer to the ways that patients can gain access to CAM treatments in the UK. It is important to understand that models of integration are closely related to methods of delivery (i.e. certain methods of delivery relate to specific models of integration). Decisions concerning the design and deliver of the service will be guided by both philosophical considerations of the role of CAM therapies and practical considerations of costs, effectiveness, and availability of local CAM practitioners. Figure 4 lays out the current ways that an individual can gain access to CAM therapies in the UK (with the headings explained below). This section draws on the work of the House of Lords Report,[233] *Integrated Healthcare: A Way Forward for the Next Five Years?,* [234] *Models of Complementary Therapy Provision in Primary Care*[235] and interviews conducted by this Enquiry.

[232] FIH, 1998, p.39.
[233] House of Lords, 2000.
[234] FIH, 1998.
[235] Luff & Thomas, 1999.

Figure 4: Methods of delivering CAM in the UK[236]



Source: FreshMinds, 2005

Private CAM Practitioner

a) Frequently a patient will make a self-referral to a private CAM practitioner. This can be funded by the patient directly or by some private health insurance plans.
b) Corporate services are available in several occupational settings, covering conditions that are common to those working in a particular field (for example manipulation or massage for jobs with frequent incidences of back pain).
c) A GP can refer a patient to a private practitioner if they believe that it may be of assistance, but the patient would still bear the full cost.
d) Patients can make self-referrals or be referred by a GP (or other primary care worker) to certain charitable projects. These may or may not be located on NHS premises. In this instance, the charity funds the treatment and neither the NHS nor the patient pay.

CAM Service delivered by GP/Nursing staff

Certain CAM treatments can be administered by GPs or health workers with appropriate training (for example, certain forms of acupuncture). As medical training (both university and continuing professional development) incorporates an enlarged curriculum on CAM, this option will become increasingly available.

On-site multi-disciplinary scheme

Primary care practitioners and CAM practitioners are located together, and opportunities for interaction and collaboration will be strong. An example of this delivery method is the Marylebone Health Centre.

Specialist CAM centre within NHS

A CAM centre can focus on one therapy or several. It is funded and administered like any NHS centre. An example of this delivery method is the Royal London Homeopathic Hospital (RLHH), which although focusing on homeopathy, also provides other therapies, including acupuncture and manipulation. The RLHH joined the University College London Hospitals NHS Trust in 2002.

Specialist CAM centre contracted by NHS

[236] This is just one example. Patients may access CAM practitioners through other healthcare professional, such as midwives, community nurses or in the hospital setting.

Independent CAM centres, utilising one or more therapies, are contracted by the NHS. The contract may stipulate a set number of treatments or it may be linked to treatment of specific conditions. An example of this delivery method is the Centre for Complementary Health Studies in Southampton.

Off-site CAM practitioner contracted by NHS
An individual practitioner is contracted to the NHS. These practitioners will utilise their own premises, where they would usually conduct private work as well. The number of treatments can either be set individually by cooperating primary care practitioners or through a set treatment course (e.g. 12 acupuncture sessions).

Secondary care service in NHS using CAM
Certain CAM therapies are utilised in secondary care departments as part of the treatment package for specific patients. Physiotherapy and orthopaedic departments are likely to be the most frequent providers of CAM services (for example, the use of osteopathy in physiotherapy clinics).

Palliative care unit providing CAM
For the long-term and terminally ill, CAM therapies can form part of a package of treatments in a palliative care unit. Touch-based CAM therapies are especially popular.[237] These units may treat cancer patients and several neurological conditions (for example motor neurone disease and multiple sclerosis).

Initiatives/Pilots by NHS
Any of the above may be piloted by health authorities in a national, regional, local or community setting.

Information on the current delivery of CAM in the UK is presented below in the chapter CAM in the NHS.

[237] FIH, 1998, p.38.

Case Studies: Costs and Benefits

Having discussed many of the philosophical and practical considerations concerning the integration of CAM and conventional treatment, several working examples are set out here. Three case studies offering both cost and benefit information are examined and evidence from the case-study conducted specially for this Enquiry is provided to give a further detailed example of the costs and benefits of delivery of CAM services.

This Enquiry was made aware of the existence of some costed case studies on the delivery of CAM service in primary care. These case studies, from Newcastle PCT, Glastonbury Health Centre, Westminster PCT, and the Get Well UK scheme in North London, provide some examples of how CAM can be, and is, provided in a primary care setting. As with other areas of the Enquiry, the case studies explored here cannot claim to be a comprehensive survey of models of existing provision. Centres were included due to the availability of data, referral from stakeholders and, in the case of Get Well UK, their willingness to co-operate with the Enquiry, which in any case was limited in terms of its time and scope. However, whilst the case studies are not wholly representative of CAM integration within the NHS, they can offer an indicative illustration of how integration works at ground level. There are numerous other models of CAM provision in New Deal for Communities (NDC) areas, focussed at specific needs such as mental illness, drug rehabilitation or refugee groups.[238] However, the studies chosen in the current study cover patients from the whole spectrum of socio-economic backgrounds, encompassing a range of ailments and variety in treatment frequencies:

- There are several practices in Newcastle offering complementary therapy, some of which receive PCT funding specifically for CAM, with acupuncture being the most common clinic type.
- The Glastonbury Health Centre offers an integrated service with a substantial selection of CAM practitioners running weekly clinics.
- The Cavendish and Marylebone practices share responsibility for CAM provision for Westminster PCT using nine complementary therapists.
- The Get Well UK service operates in a NHS centre in Haringey with twelve CAM practitioners providing treatment for the patients of 37 local GPs.

The Get Well UK and Newcastle projects place great importance on providing CAM at the primary care level to patients who would otherwise have restricted access to the therapies because of their socio-economic status. The selection is designed to represent a good cross-section of CAM therapy integration in terms of methods of delivery, conditions treated and evaluation of effectiveness.

[238] See Blank et al.

Newcastle Case Study

Introduction

Newcastle PCT Locality (formally Newcastle West PCG)[239] together with a Health Action Zone, funded the "Community Action on Health" (CAH) investigation into the feasibility of setting up a CAM service, funded by the NHS, in Newcastle West. The clear aim of the project was to evaluate CAM as an opportunity to address local health needs. In 1999, the CAH formed a group comprising members from the PCG, CAH, local GPs and CAM practitioners to pilot a complementary therapy initiative and assess its productivity and reliability. Newcastle CAH had some success in attracting voluntary CAM provision to an area with a high proportion of low-income patients who were often unable to afford complementary treatment. Due to its organised approach it acts as a good case study of cost-effectiveness for regional or national policy construction. Follow-up research was completed on particular CAM users in the PCT in 2003 and findings are integrated into this report.[240]

However, in 2004 there was a cut to the CAM budget for activities in West Newcastle. Although the PCT has continued to provide £15,000 annually for some services to continue, the backing for a wider CAM operation no longer exists, and restrictions on session repetitions were put in place. There have been changes in the management of the CAM service that have absorbed a lot of the available funds and this has resulted in the loss of some CAM services. Combined with an increased reliance on conventional specialist clinics, this reshuffle may have diminished the previous importance attached to the pilot scheme.

Objectives

The evaluation of the Newcastle services had two main objectives. First, to measure the savings in conventional healthcare from providing CAM therapies free at the point of delivery. Second, to evaluate the patient benefits and health improvements among those that adopted complementary therapy, using SF-36[241] and MYMOP[242] health surveys. The PCT's catchment area is characterised by high levels of social disadvantage, associated poor health, and a high incidence of chronic illness, resulting in increased demands on the PCT and this CAM service.

Benefits expected by the study

- Increased therapy options and shared knowledge between treatment providers.
- Establishing good referral relationships between GPs and a wide variety of CAM practitioners.
- More patients managing their own health and adopting successful, alternative treatments for previously acute and often expensive chronic conditions.
- Further patient education through pre-CAM adoption information packs that improve self-regulation in therapy and reduce GP visits and reliance on prescriptions.
- Proof that CAM reduces primary and secondary costs in conventional treatment to a level that justifies its inclusion into the activities of PCTs.

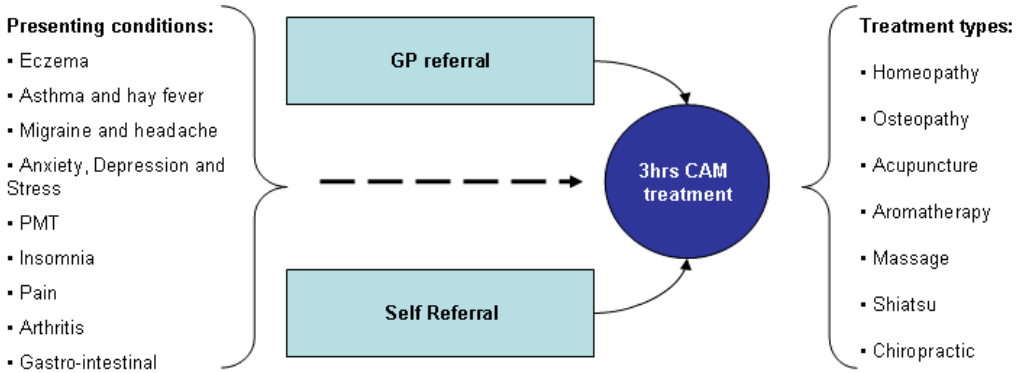
Description and measures

The therapies offered are osteopathy, acupuncture and chiropractic. One therapist from each CAM therapy provided weekly four-hour clinics based in local GP practices to which GPs could refer patients. Referrals were made for a range of conditions that were treated in clinical practice to varying degrees of success. The CAM clinic organisers used statistical information on NHS resource usage and repetition in consultation rates as two methods for identifying conditions that were requiring a lot of NHS care or were responding poorly to conventional treatment. Examples of chronic conditions for which conventional treatment was not meeting patients' needs well included: asthma, migraine, back and neck pain, eczema, hay fever, anxiety and insomnia. Figure 5 represents the original delivery model for the Newcastle

[239] PCG – Primary Care Group - this type of organisation preceded Primary Care Trusts.
[240] Solomon Dawn, Complementary Therapy Pilot, 2003.
[241] See Glossary.
[242] See Glossary.

project. For homeopathy, aromatherapy, massage and shiatsu, the PCT can no longer support the CAM practitioners and refers patients to private providers or SEARCH, a chronic condition alleviation organisation working in Newcastle. This decision involved a re-allocation of funds that were previously ear-marked to cover the wide range of treatments, resulting in a decrease in the number and diversity of CAM clinics available.

Figure 5: Overview of 2003 CAM provision in the Newcastle PCT case study



Source: Dawn Solomon, CAM evaluation April 2003

One aim of the Newcastle assessment was to consider the logistics and clinical governance issues of integration, including the clinical supervision of CAM practitioners and the responsibility placed on a GP when delegating to CAM practitioners with no statutory regulatory body. In addition, it was useful for measuring the level of patient demand for CAM. The assessment measured the following:

Monitored observed measures:
- Number of attendees
- Ethnicity
- Number of sessions attended
- Client satisfaction
- Use of conventional drugs.

In addition certain cost savings were expected:
- Reduced admission to hospital
- Reduced appointments with GPs
- Reduction in lost days from work
- Increased productivity at work.

Surveys
Health improvement was measured via sample patient groups who assessed their own pain, anxiety and depression using the SF-36 health survey in combination with the Measure Yourself Medical Outcome Profile (MYMOP).[243] Typically, measurements were taken from patients on referral at eight weeks and then again at six months. Practitioner and patient surveys and opinions all contributed to the findings below.

Reasons for referral
The initiative ran for thirty months with 41 GPs referring 650 patients. Musculoskeletal problems accounted for the majority of referrals (76%), and the most common conditions were back and neck pain. Psychosocial problems related to anxiety, stress or depression accounted for 13% of referrals.

[243] Carmichael, S. 2003

Figure 6: Reasons for referral

Referral reason as identified by GP referee	%[244]
Conventional treatments not working	80%
Conventional treatments causing side effects	20%
CAM would provide benefits to functioning conventional treatment	47%
Patient would have a better response to CAM	7%
Patient already used CAM and had a good response	47%
Seen a good response in another patient	13%

Source: Dawn Solomon, CAM evaluation, April 2003

The reasons for patients trying CAM, as identified by their GPs, are given in Figure 6. Some patients with debilitating chronic conditions reported they were "willing to try anything" or used CAM "as a last resort". 38% of patients requested CAM themselves and 62% were referred to CAM therapies by their GP. Self-referral at Newcastle accounted for a significant proportion of the total CAM appointments, and self-referred patients reported a lower level of satisfaction with treatments.

Costs

2005 Total annual project budget: £100,000
2005 Total PCT annual contribution to CAM services: £15,000

Cost per patient in 2005 was highest for shiatsu (>£250) and lowest for chiropractic (<£100). Chiropractic required fewer and shorter treatments, while acupuncture (>£150) often dealt with long term chronic conditions requiring longer treatments courses. Figure 7 gives details.

Figure 7: CAM therapy costs per patient

	Acupun.	Chiro.	Homeo.	Aromath.	Osteo.	Shiatsu
Number of patients	77	207	133	76	113	43
Appointments per patient	10	4	6	5	7	7
Cost per patient (£)	£182	£68	£127	£202	£140	£270

Source: Interviews with Newcastle Health Centre, 2005

Realised Benefits Including Savings in Avoiding Conventional Treatment

The benefits were divided into patient satisfaction, health improvement, reduction in GP consultations and prescriptions, and the positive opinions held by GPs involved in this project.

Patient Satisfaction

96% of patients were satisfied with their CAM treatment, while 62% were extremely satisfied. 42 positive comments were reported in the surveys; eight were negative and these concerned the short-term nature of the relief obtained and the desire for further treatment.

Health Improvement

Lifestyle benefits arising from CAM therapy are common; for instance, almost 40% of patients referred to CAM stated that they would or already do exercise more frequently. Findings were compiled using survey results plus the medical records of 70 patients, compared six months before the beginning of CAM treatment to six weeks and six months after referral. Health improvements are shown in Figure 8.

[244] Totals more than 100% due to questionnaire allowing multiple responses

Figure 8: Reported Health Improvements

Time	Improved	Same	Worse
Six weeks	68%	28%	4%
Six months	58%	37%	5%

Source: Dawn Solomon, Complementary Therapy Pilot, 2003

An evaluation of the CAM project in December 2004, utilising MYMOP data, stated that 76% of the 101 patients in the sample showed clinically significant improvement. 40% of the patients showed a two-point or greater increase in their MYMOP score from the pre-treatment measurement.

GP Consultations

The average number of consultations per person fell from 5.7 to 3.9 in the six months after CAM treatment; 30 patients reduced their number of GP visits, eight increased their visits. Overall, GP consultations fell by 31%. Extrapolating this percentage to all patients in the trials would represent a reduction in consultations of 666 per year, with an associated cost saving of £10,000 for the 650 patients in the pilot.

The Newcastle PCT finance director confirmed that specialist consultations with orthopaedic surgeons, psychologists and pain clinics are often many times more costly than CAM therapy sessions. Avoiding consultations by encouraging CAM that has proven efficacy counted as savings in secondary health provision, but these are still difficult to attribute directly to the adoption of complementary medicine.

Single individuals can make a very large difference to costs when finding trends in case studies concerning only a select number of practices in a PCT. A severely depressed patient using CAM, who might typically spend up to four months each year in hospital, may result in savings of tens of thousands of pounds if he/she responds well to CAM treatment instead of hospital admission. Dawn Solomon, a manager of the Integrated Complementary Therapies Project, comments in a later review of the work[245] that the incidence of such high resource users is low but of great significance; a particular case where an individual cost the NHS in excess of £15,000 is mentioned. The patient had on average been admitted every 10 weeks for five weeks at a time to manage her symptoms. Following a course of aromatherapy and massage the patient had not returned to hospital, saving 93 days of hospital care.

Prescriptions

There was a 39% reduction in the number of prescriptions issued to the sample of 70 patients, representing a cost saving between the two periods of £520; extrapolating to all 650 patients in the pilot would give an annual cost saving of £4,800. 31 patients reduced or stopped taking painkillers; eight did the same with anti-depressants.

GP opinion

There was a strongly favourable reaction by the clinicians to CAM adoption with 69% of GPs supporting continued CAM provision in the PCT. There were significant differences in the popularity of particular treatments however; 46% supported osteopathy, 53% chiropractic, 60% acupuncture and 6% homeopathy and shiatsu.

Conclusion

As an example of integrating general practice and complementary medicine, Newcastle PCT is an important case study in a region that places above average stresses on the local health providers. Consistent and expanding research into costs and benefits throughout the initiative support the credibility of the findings and help to identify conditions that are difficult to treat with conventional treatment alone.

The authors of the research carried out in Newcastle conclude that:

[245] White, C., 2003.

> *This pilot has clearly demonstrated that the complementary therapies provided are well tolerated, popular treatments, of which there is evidence of health improvement, and a cost offset for conventional care.* Dawn Solomon CAM evaluation, April 2003

The benefits in Newcastle ranged from changes in patient outlook regarding more healthy lifestyles to savings in primary and secondary care in conventional medicine. Psychological illness and its link with physical chronic conditions is just one of the areas where an integrated CAM and GP approach to therapy is likely to produce better results and savings to the NHS. Although the pilot project only covered 40% of its costs (indicating an overall cost increase to the trust), only savings in primary care were calculated, although savings in secondary care were also achieved. Has account been taken of them as they were at Glastonbury (below) a significantly higher proportion of the project's costs would have been covered. A full cost-benefit analysis, taking account of all the cost savings, would be well worthwhile in order to establish the cost-effectiveness of the treatment provided in Newcastle.

Glastonbury Health Centre

Glastonbury Health Centre offers a unique integrated complementary medicine service combining NHS General Practice with five mainstream complementary therapies.[246]

Introduction

The Glastonbury Health Centre has offered free access to CAM therapies in a three-partner GP practice for the last 13 years. For the first five years, Somerset Health Authority funded the scheme, initially as part of the Health Promotion Initiative, and then as a Health Authority research programme. In 1997 the research funding was redirected to the NHS Research Directorate, and from that time has been channelled through a practice-based charitable trust, the Somerset Trust for Integrated Health Care. Since 2001, the Glastonbury Health Centre has also received Mendip PCT funding for an osteopathy/acupuncture service (fully funded by the Mendip PCT) and an herbal medicine and massage service (part-funded by patient donations of up to £10 per treatment and part-funded by the Mendip PCT). The establishment of the service was partly due to patient demand: usage of CAM among the patient population of the GP practice was generally high, with half having some experience of CAM, and a third having had that experience at the GP practice itself.

Research in the late 1990s was commissioned by the Somerset Health Authority on the Glastonbury Health Centre to find out what contribution CAM could make to primary care and whether it could be cost-effective.[247] Since then further study into CAM integration and the benefits to complementary medicine users has built on the initial report. These reports are summarised in the section Initial Reports below. A more recent, fully costed review of the osteopathy/acupuncture musculoskeletal CAM service for the treatment period 2003-4 is dealt with separately, later in the section.

Initial Reports

Introduction

During the period of evaluation, 661 patients (17% of the practice population) had treatment in five CAM therapies, provided by a team of practitioners in weekly CAM clinics based in medical practices. Now supported by the Mendip PCT, Glastonbury is one of two general practices in the PCT area to offer professional osteopathy and acupuncture clinics. One in four people in the Mendip PCT had used a CAM[248] therapy by 2002. The research aimed to present the benefits of providing alternatives to conventional treatment as a valuable addition to social and patient care. To justify CAM inclusion, emphasis was placed on the resulting savings in conventional medical care.

Objectives

The research aimed to present the benefits of providing alternatives to conventional treatment as a valuable addition to social and patient care. To justify CAM inclusion, emphasis was placed on the resulting savings in conventional medical care.

Expected Benefits and Present Costs

- Equity of access to free CAM therapy, available through self-referral, but predominantly through GP referral.
- Establishing professional exchanges between GPs and CAM practitioners.
- Reduction in burden of chronic conditions by using alternatives to prescriptions and a possible reduction in adverse reactions to treatments.
- Reduction in waiting times for physiotherapy, orthopaedic and pain clinics.
- Psychosocial treatment as well as physical therapy, tackled with integrated approach.
- Proof that CAM reduces secondary and primary costs in conventional treatment to a level that justifies its inclusion into the activities of primary care trusts.

[246] Marketing material for the health centre.
[247] An evaluation into the provision of CAM by the Glastonbury Health Centre, 1994-1997.
[248] Dr R. Welford, Mendip PCT Paper for Executive Committee, July 2002.

The Glastonbury Integrated service has commented that positive indications of the following realised benefits have emerged:[249]

- Increased range of effective treatment options
- Improved health outcomes
- Eased waiting-list pressures
- Improved access for those unable to afford osteopathy or acupuncture
- Shorter-waiting lists for secondary care
- Eased staffing pressures
- Increased patient choice.

The overall costs of providing the service, including CAM practitioner time, administrative time and costs such as acupuncture needles and herbal medicines (but not overheads like room rent, heating etc.) were approximately £23,000 for 2003/2004, provided by Mendip PCT[250].

Description and Referral Procedure

- 60% of patients had musculoskeletal complaints
- 34% were referred because their problem was not responding to conventional treatment
- 66% stated that their health problems were severe or very severe
- Doctors recommended just over 25% of the patients.

Each patient was allowed treatment for up to three hours on each referral. The number of referrals depended on the practitioner, for example the osteopath - the most widely used practitioner (35% of patients) - would give a one-hour treatment followed by four half-hour appointments. The distribution of the referrals is outlined in Figure 9.

Figure 9: Referrals by CAM therapy

Therapy	Patients	Percentage
Osteopathy	229	34.6
Acupuncture	188	28.4
Massage	119	18
Homeopathy	30	4.5
Herbal Medicine	95	14.4
Total	**661**	**100**

Source: Glastonbury Complementary Therapy Service Research, 2004

The use of homeopathy was low because homeopathic treatment were less available than other therapies, and two of the GPs prescribed homeopathic remedies routinely in their practice anyway.

Benefits

The outcome of the CAM treatment was measured in three ways: patient self-assessment of improvement; practitioner's evaluation of the same; and several patient questionnaires concerning aspects of their general or specific health problems, including the SF-36, compared before and after treatment.[251] The patient self-assessment results correlated closely with the practitioner evaluations.

Practitioner survey

Practitioners concluded that 56% of patients had showed a marked improvement in their main symptom following treatment, with a further 27% experiencing a small improvement. 38% showed improvement in their overall well-being. Practitioners rated half of the patients as having a very positive reaction to treatment and a further 30% quite a positive response. Just fewer than 6% had a marked negative reaction or rejected the treatment.

[249] Dr R. Welford, Executive Committee, Mendip PCT.
[250] David Ward, Mendip PCT, 2005.
[251] Results from Glastonbury Complementary Therapy Service research, 2004.

Patient survey

Patients' own satisfaction scores showed that after treatment, 85% of patients reported some improvement in their condition, the majority of whom ascribed the benefit to the treatment itself. 85% also reported that they were very or mostly satisfied with the treatment and 95% found the treatment useful (there is a possibility that patients' modest expectations of success prior to treatment helps to explain the high levels of satisfaction).

SF-36 survey

SF-36 scores were measured on referral to CAM treatment, at the end of the treatment and six months after referral. In all outcome measures, patients showed significant improvement both at the end of treatment and six months after referral. However, the number of questionnaires returned to the researchers fell markedly at each of the intervals (425 on referral, 224 at the end of treatment, 93 six months after referral). A subgroup of patients with musculoskeletal complaints was large enough to perform analysis on; each completed a Functional Limitation Profile and Pain Index[252] and showed improvement in line with the SF-36 after treatment. However, the improvement was not consistent over time and deterioration back to baseline levels of pain was apparent after six months (although the number of respondents was low enough at this point to remove statistical significance).

Lifestyle and psychosocial benefits

The results found that patients suffering from short-term, more severe conditions had especially good results from the CAM treatment. The pain and discomfort caused by musculoskeletal problems was generally relieved and a contribution was made to the relief of the emotional and social distress of patients with psychosocial problems (for whom massage was most often prescribed). The CAM therapies were found to improve the health and wellbeing of those patients with milder conditions and to precipitate positive lifestyle changes which are detailed in Figure 10.

Figure 10: Lifestyle changes made after referral

Type of change made	Number	%
More attention to diet	62	27.7
More frequent exercise	82	36.6
More use of relaxation techniques	63	28.1
More use of meditation/prayer	34	15.2

Source: Integrated Medicine, Mendip Primary Care Trust Executive Committee Papers and Extracts

Costs

General savings in conventional healthcare

This cost of provision was set against the estimated reduction in use of other health services directly attributable to the provision of the CAM service. Usage of healthcare services by a sub-group of 41 patients referred to CAM for longer-term conditions were observed. It was found that following their initial CAM treatment, most of the group reduced their use of other health services for the problem for which they were referred. Those whose usage fell the most had been the heaviest users prior to receiving CAM treatments.

GP consultations and prescription use

Visits to GPs dropped by about a third (the largest reduction among those patients that were the most frequent GP visitors prior to referral). Prescription use fell by almost 50%, and again it was those patients who were previously the heaviest users that saw the greatest drop. In the year after CAM treatment, only five patients of the subgroup of 41 required more than four prescriptions for the problem treated. It was estimated this sub-sample of 41 patients had cost the NHS £4,000 in the year prior to them starting CAM treatment; after referral, costs fell to

[252] Two patient assessed pain and function questionnaires.

just over £1,500, a 62.5% fall. The total conventional care savings would increase if all 661 patients in the sample were analysed.

Secondary care savings
There were also drops in the number of referrals to secondary care, especially for physiotherapy and x-rays. Although these did not amount to substantial falls, figures for the referral patterns of health authorities comparable to Glastonbury were found to be increasing their referrals markedly during the same period. Therefore, if, as the authors hypothesise, this discrepancy was due to the introduction of the CAM service in Glastonbury, the service made savings of around £18,000, mostly due to savings in secondary care, meaning the service would cover its costs with a reduction in conventional care expenditure. The assumption that the £18,000 saving is entirely due to CAM activities is a loose one although patient numbers and other cost-influencing variables remained comparatively constant for that year.

Report on osteopathy/acupuncture musculoskeletal CAM service
The review of this service to patients treated between May 2003 and May 2004 has more up to date and detailed data on the savings realised by the reduction in referrals to secondary care than was available in the initial reports on the whole CAM service.

Benefits
Clinical outcome
In contrast to the initial reports which used the SF-36 patient satisfaction scale, this review used the MYMOP scale (See Glossary and Get Well UK for details). The MYMOP measures the criteria in Figure 11. A reduction in the score shows improvement, a reduction of 0.5 points is clinically and statistically significant. The results for the 276 patients were as follows:

Figure 11: MYMOP scores for osteopathy/acupuncture CAM service

	Osteopathy	Acupuncture
Symptom 1 (main symptom)	-1.8	-2.1
Symptom 2	-1.6	-1.5
Activity	-1.7	-1.8
Well-being	-1.1	-0.9
Profile score	-1.5	-1.5

Source: Glastonbury Health Centre and Surgery, 2005

Figure 11 shows a marked and significant reduction in all measure covered by the MYMOP for both therapies, especially in the main symptom.

Costs
Referrals to secondary care
Patient referrals to secondary care for the condition for which they were receiving treatment at the musculoskeletal CAM service were recorded up to two years before and between 6 and 12 months after the CAM treatment period. Data were available for a sample of 143 patients.

Of these patients 68 (47%) were referred to secondary care in the two years prior to CAM treatment. Of these patients 66% were referred to physiotherapy, 28% to orthopaedics and 3% to pain clinic. GP records on referring to the CAM service show the secondary service to which a patient would have been referred had he not been sent to the CAM clinic. This shows a similar profile in terms of the distribution of the 143 patient sample between secondary specialisations:

- 92 (64%) would otherwise have been referred to physiotherapy
- 39 (27%) to orthopaedics
- 12 (9%) to pain clinic

The referral record post CAM treatment was as follows:

- 11 (8%) subsequently referred to physiotherapy
- 13 (9%) to orthopaedics

- 0 (0%) to pain clinic

This post-CAM record shows that secondary referral rates were substantially lower after CAM treatment than before it, especially in physiotherapy; and lower than what would have been the case in the absence of the CAM clinic as a referral option.

Cost savings
The financial savings gained by these reductions in referrals to secondary care are shown in Figure 12.

Figure 12: Cost savings for osteopathy/acupuncture CAM service

Cost type	Cost per patient	Number of Patients	Total Cost
(1) Projected annual cost to NHS with no osteopathy/acupuncture CAM service			
Physiotherapy	£200 (four appointments)	92	£18,400
Orthopaedic clinic	£165 (two appointments)	39	£6,435
Pain clinic	£190	12	£2,280
Total		143 (sample)	£27,115
Total		**276 (all)**	**£52,000**
(2) Actual cost to NHS with the CAM service			
Annual cost of osteopathy/acupuncture CAM service		276 (all)	£24,000
Physiotherapy	£200 (four appointments)		
Orthopaedic clinic	£165 (two appointments)		
Total		276 (all)	£8,950
Total		**276 (all)**	**£33,000**
Total Overall Cost Saving (1) – (2)		**276 (all)**	**£19,000**

Source: Glastonbury Health Centre and Surgery, 2005

Conclusion
The Glastonbury Health Centre has been an integrated complementary health service and local GP practice since 1992. Surveys of patients, CAM practitioners and GPs report high levels of satisfaction and encouraging success rates for many alternative treatments, particularly in alleviating chronic conditions. The exceptionally high levels of satisfaction with complementary treatment might result in part from low expectations of CAM's curative abilities: only 15% expected a condition to be resolved.

Research into the cost savings of the practice including CAM clinics continues to suggest that, at a minimum, the cost of CAM provision is offset by savings in comparative conventional medical services for these patients. The research so far has not definitively demonstrated that the savings are all directly attributable to the CAM service implementation. However, in the case of the osteopathy/acupuncture CAM service, referrals to all relevant secondary care specialisms: physiotherapy; and orthopaedic and pain clinics, were found to fall markedly, particularly to physiotherapy, between 2003 and 2004. The cost saving of £19,000 accrued by these reductions represents a reduction of more than one third on the £52,000 cost of conventional treatment for the treatment group of 276 patients had CAM not been a treatment option.

This is a substantial saving and, when allied with the very positive scores on patient outcome measures it is difficult to argue with the assertion of Dr Welford of the Glastonbury Health Centre and Surgery that its CAM service is clinically effective, highly valued by patients and GPs, safe, offers the potential for significant cost savings, reduces waiting list pressure on other services and offers a model of innovative, forward-looking, integrated care.

Westminster Complementary Health Service

Introduction
Westminster PCT offers CAM therapy through a large number of providers to patients from most of the general practices under their jurisdiction. The funding for treatment from CAM practitioners comes from the PCT exclusively and offers new options to patients that potentially are unable to pay for private consultations. The prevalence and popularity of CAM London-wide are both high.

The Westminster PCT provided a budget of £125,000 for the Cavendish and Marylebone complementary therapy service for 2004.[253] The majority of the budget is spent on CAM practitioner salaries, particularly on osteopaths and acupuncturists who alleviate musculoskeletal conditions. After a three year pilot period, 2005 is the first year that the Westminster Integrated Health project is fully recognised and funded by the PCT. Figure 13 shows the number of practitioners involved and their specialisations.

Figure 13: Practitioners by therapy

Therapy	Practitioners
Osteopathy	3
Acupuncture	2
Homeopathy	1
Massage therapy	1
Naturopathy	1
Stress management	1

Source: Interviews with Rafra Baneera (2005)

Objectives
- To maintain and increase complementary therapy provision from the Cavendish and Marylebone practices
- To prove the cost-saving result of an integrated approach to primary health care at both the secondary and primary levels

Expected Benefits
- Free CAM therapy through existing general practices using weekly clinics
- Fostering and promotion of professional relationships between CAM and conventional medicine providers
- Reduction in the usage of prescriptions, GP consultations and referrals to medical specialists

Description and referral
Research into CAM Integration and Effectiveness
Westminster PCT funds a large proportion of the CAM activities in primary care for inner London. The King's Fund has supported the University of Westminster in its research into the effectiveness of an integrated approach to primary care provision working through referrals to regular CAM clinics. Although the Westminster PCT itself is not a research study for the University, very similar methodologies are being used to evaluate the costs and benefits of complementary therapy introduction into mainstream primary care in Cavendish and Marylebone practices.

Service providers are contacted with phone calls and questionnaires. Further research is gathered through email and follow-up calls that have provided data on clinical governance and service details:
- Referral frequency, nature and source;

[253] Beverley Toney, Cavendish Practice, CAM Manager, April 2005

- Types of integration and the ease of their adoption;
- Patient groups and types targeted by services;
- Funding and future structure of CAM integrated service;
- CAM clinical effectiveness;
- Staffing, education, training, risk management.

During 2005, a programme of MYMOP surveying is being conducted by the two practices that will yield important insights into patient satisfaction and therapy effectiveness. The data is not yet available but the interviews with staff and other reports give a very detailed overview of the acceptance and success of the programme. The Westminster Complementary Therapy Service enables patients in Westminster and Kensington and Chelsea to access up to six sessions in one year for each of the following therapies:

Referrals
A patient must be referred by his/her GP, who must have attended the Service's introductory course. There are three meetings annually between GP and CAM staff with the emphasis on doctors learning more about complementary therapy in order to be able to describe the benefits to potential patients in an accurate way.[254] Waiting lists are usually kept to within two months but it is not uncommon for patients to opt for private appointments.[255]

Realised Benefits
Benefits were measured by examining patient satisfaction, the effect of psychosocial healing, and reductions in GP visits and prescriptions.

Patient Satisfaction
The Cavendish and the Marylebone practices publish a frequent newsletter that documents some of the conditions that are often chronic and painful being cured effectively and promptly by CAM therapists. High levels of repeat treatments from particular CAM practitioners and the adoption of private appointments by patients that cannot wait, or do not want to wait, are testimony of the popularity and esteem that this population has in complementary therapists.

Psychological therapy
Psychosocial healing through alternative therapies is a key benefit of the Westminster Integrated Health pilot:

> *GP consultations are over in 10 minutes but for most of the CAM clinics the initial session lasts for at least 30 minutes and patients open up more. There are often underlying causes that would be missed by conventional consultations and prescription usage.* Beverley Toney, Cavendish CAM manager

Prescriptions and savings
There have been significant drops in the number of prescriptions per patient and a reduction in the frequency of visits from those patients that have the highest number of annual visits. However, the rapidly growing demand for complementary therapy encountered by the practices has made it difficult to attribute prescription usage falls and decreases in GP consultations directly to CAM clinics. (This is because sufficient time has not elapsed to see whether patients are just trying a new treatment and reducing their reliance on conventional drugs only to return to them later when CAM may not prove to be delivering lasting relief.) More detailed data on this topic will be available in 2006.

Conclusion
The findings from the 2005 MYMOP[256] study are expected to support the hypothesis that complementary therapy is having a very positive effect on patient healthcare levels in the two practices. The fact that the pilot scheme has now developed into a fully-fledged programme is

[254] Beverley Toney, CAM manager, Cavendish Practice, 2005.
[255] Rafra Baneera, CAM coordinator, Cavendish Practice.
[256] See Glossary.

testimony to the benefits over the last three years that have arisen from the integrated approach to primary health care.

There are few problems that have been voiced by staff and patients and the greatest object of dissatisfaction is the restriction to six sessions per treatment over a year. These restrictions arise from the limitations of the budget provided by the PCT.

GET WELL UK

Introduction

Get Well UK offers one way of integrating complementary medicine therapies into mainstream primary care, and is representative of many such programmes reaching out to disenfranchised communities in New Deal for Communities areas nation-wide.[257] It provides acupuncture, aromatherapy, homeopathy, massage therapy and osteopathy. The therapies are delivered at The Laurels Healthy Living Centre in Haringey, a centre that houses other NDC services and three GP practices. As part of the service's development strategy a second Get Well UK contract has been agreed in Islington. The aims of the service are to integrate complementary therapies into a conventional medical setting, and make CAM therapies available to all referred patients, particularly those who ordinarily lack access to CAM services. The service aimed to provide 1,100 complementary medicine treatments from April 2004 to April 2005, its pilot year; another contract has been agreed from April 2005 for a further 1,100 treatments.

Get Well UK's business model is to facilitate the provision of complementary medicine services by acting as a broker between the providers, funders and users of these services, as well as the gate-keepers to the service; the GPs. As a not-for-profit social enterprise Get Well UK re-invests its profits for the benefits of its stakeholders. It has received funding from: UnLtd, a company limited by guarantee with charitable status that is dedicated to making financial awards to social entrepreneurs; two networks of private individuals who invest money in projects for social change; and a loan facility from Futurebuilders, a Treasury funded initiative to improve the delivery of public services. Get Well UK recruited qualified CAM practitioners and negotiated a contract with the health board of the New Deal for Communities (NDC) in Haringey who agreed to fund a fixed number of treatments over 12 months (see above). Members of the local health community, including the PCT, sit on this board and contracts are awarded according to Treasury cost-recovery guidelines. Funding for the NDC is provided by the Office of the Deputy Prime Minister. The business model of Get Well UK is a reflection of the values of its founders and is formulated to correspond with the move by the present government to expand NHS capacity from the independent and voluntary sectors and to test the success of public service delivery by the experience of the "bottom 10%" of society.[258]

At Laurels Healthy Living Centre twelve practitioners provide complementary medicine treatments: four acupuncturists; an aromatherapy/massage therapist; three homeopaths; two massage therapists and three osteopaths (one practitioner is qualified in both acupuncture and massage therapy). 37 GPs in the Haringey area were identified as being able to refer to the service, based on the NDC boundaries: a roughly one-mile radius catchment area around the clinic, although a few GPs from further afield also referred as they had patients in the catchment area. In total 40 GPs referred their patients to the service. GP referral is the only route to treatment.

The conditions that the GPs were allowed to refer for are: asthma; back, neck or shoulder pain; depression, stress or tension; headaches; hypertension; joint problems, arthritis or rheumatism; menstrual or menopausal complaints or sports injuries. Get Well UK determined this list from an examination of the book *Integrating Complementary Therapies in Primary Care: A Practical Guide for Health Professionals* (Peters et al., 2001), looking for areas of healthcare with both gaps in conventional medical care and effectiveness in CAM (see Effectiveness Gaps). Additionally, a detailed survey of the GPs in the referral area was undertaken. The GPs were asked which conditions they would feel confident referring to CAM for and which conditions they felt were not being satisfactorily treated by conventional medicine. Under the first contract, patients were allowed 12 treatment sessions in total of any

257 See Blank et al.
258 See Department of Health, 2005, p.68 and Office of the Deputy Prime Minister, 2005, p.43

therapy, before being referred back to their GP to see if further sessions were required. Under the new contract, patients are allowed six treatment sessions, followed by a reassessment by the CAM practitioner, after which there is a possibility of a re-referral for a further six treatment sessions. Any further treatments need to be requested by the patient's GP.

Methodology

The Get Well UK project was chosen by this Enquiry for several reasons. The service is aimed at providing CAM therapies to those patients in low socio-economic groups and ethnic minorities, those groups least likely to have good access to CAM therapies, and as such is representative of a number of such schemes nationwide. Since the Enquiry is considering the potential costs and benefits of widespread integration of CAM into the NHS, these are the groups that should benefit most, as their base level of usage is low and they frequently present with chronic health problems. Furthermore, the project uses therapies that closely mirror those examined by the Enquiry.

The aim of this case study was to analyse the views of the three main stakeholder groups in the treatment model: the patients through their MYMOPs,[259] the CAM practitioners working at Get Well UK and the GPs who had referred patients to the Centre. These views were in the form of both qualitative and quantitative data, and concentrated on the groups' perception of the costs and benefits to all parties of the scheme. The information from these three groups was combined to arrive at a synthesis of opinions, identifying common themes.

Patients

Patients who had either completed their course of treatments or who had received 12 or more treatments were audited.[260] Forty-eight patients were identified as having completed Measure Yourself Medical Outcome Profiles (MYMOP) both before and after treatment. MYMOPs are a tool used to measure patient centred health outcomes. Published studies have shown that MYMOP is practical, reliable and sensitive to change. MYMOPs ask patients to rate the severity of their principal symptom, secondary symptom (if required), a daily living activity that the symptom impinges upon and their general wellbeing. Each of these items is measured on a seven-point scale running from 0 (as good as it could be) to 6 (as bad as it could be). An average of these strands is taken to arrive at an average MYMOP score. Average (median) scores were compared between pre- and post-treatment MYMOPs. This data was analysed in the nine-month audit carried out by Professor Nicola Robinson of Thames Valley University and the results made available to the Enquiry.

Practitioners

The Enquiry undertook structured face-to-face interviews at The Laurels with all 12 practitioners involved in the Get Well UK service. Each practitioner was interviewed for at least twenty minutes using a set of ten discussion points. Given the modest number of practitioners working at Get Well UK, the face-to-face approach was possible and had the advantages of seeing the environment in which treatment is carried out and to engage fully with the practitioners for a significant amount of time in a discussion of the issues. The questions asked of the practitioners in summary were:

- The advantages and disadvantages of the Get Well UK scheme, including its system of referral;
- Whether it has proved very different from working in private practice;
- What conditions have been most frequently treated through Get Well UK? What proportion of these was chronic and what proportion acute? Whether this is typical;
- Which conditions have been most successfully treated? How many sessions most patients need? Whether this is peculiar to Get Well UK;

[259] See Glossary.
[260] Robinson, 2005.

- What the practitioner sees as the main benefits to a patient of being referred and treated through Get Well UK and what the costs of equivalent treatment in private practice would be?

Regarding potential selection bias, it might be expected that only those practitioners in favour of providing CAM in the manner of the Get Well UK system will have applied to do so.

GPs

The Enquiry undertook structured telephone interviews with those GPs practising in London postal districts N15, N8 and N4, all in close proximity to The Laurels clinic, who had the opportunity to refer patients to the Get Well service. All twenty-two GPs in this area were interviewed for ten minutes and asked whether they had referred any patients to Get Well UK, or any other CAM service. The interviews with GPs were shorter than those with practitioners because of the extreme time pressure on the GPs. Despite the brevity of the contact, important broad themes were very clearly visible in GP opinions.

GPs were asked whether they had referred any patients to Get Well UK. If they reported doing so they were asked for which CAM therapy they had referred to and asked their opinion on what benefits and costs, or cost savings, they had noted. If they had made no referrals to Get Well UK they were asked whether they had referred to any other CAM service and if so what their view was on the associated benefits and costs as described above. If they had made no referrals to any CAM service they were asked why and whether they considered CAM therapies could afford any benefit to patients or cost savings to the NHS at all.

There is potential for selection bias in the sample of GPs interviewed in favour of those with a positive view of Get Well UK; some GPs contacted in the selected area around The Laurels clinic did not wish to answer the questionnaire because they did not believe the project to be of any value.

Summary of Patient Outcomes

MYMOP Statistics

Get Well UK has operated under a 12 month pilot contract at the Laurels, Haringey has been independently audited for 9 months by Thames Valley University.[261] The first Get Well UK contract ran from May 2004 to February 2005; the audit covered the months from when significant numbers of patients began to be referred to the service to when the quota of treatments had been reached, i.e. from May 2004 to February 2005. Over the nine-month audit period 124 patients were treated by the service.

Those patients who had both received 12 or more treatments or had completed their course of treatments were audited in detail with the Measure Yourself Medical Outcome Profiles (MYMOPs)[262] of these patients. Of the 58 patients that satisfied the above criteria for detailed audit, data on both pre- and post-treatment MYMOP profiles was available for 48. Analysis of the MYMOP scores for these patients showed that the median reduction in patient scores over the treatment period was two points, from a median score of five to a median score of three. This means that on average a patient who has recorded their health and wellbeing state as five on the seven point scale from 0-6, just below level six described as “as bad as it could be”, has improved to the level of perceived health and wellbeing of three, half way between the best and worst possible states. Statistically, these results show a highly significant improvement in the patient’s perception of his/her own health and wellbeing after CAM treatment. Statistical analysis shows that three-quarters of patients experienced an improvement in their symptoms.

[261] Robinson, 2005
[262] See Glossary

Further analysis showed that 44 other patients, who had received between three and eleven treatments, experienced a reduction in MYMOP scores similar to those patients detailed above; the mean difference in the MYMOP scores for these 44 patients from pre- to post-treatment was 1.5 points.

Patient Comments

In addition to scores relating to symptoms, wellbeing and daily living, MYMOP forms allow space for patient comment, and there were additional Quality Evaluation Forms which allowed further open-ended comment. Here, patients were able to express concerns or record benefits not covered in the scores, those that do not relate directly to symptoms or even to general wellbeing. In some cases, comments reveal the financial effects of the treatments, relating for example to reductions in conventional medication (and therefore personal prescription costs and those to the NHS) and the ability to work (with associated societal benefits).

General

Some patients reported improved sleep following treatment, and some recorded reductions in addictive behaviour, including drugs and tobacco, as well as drops in anxiety. These improvements could be classed as emotional benefits, which patients have also expressed in terms of an increased feeling of calm and confidence and in improvements in relationships with family members. Such benefits contribute directly to meeting public health targets.

Moreover, some patients commented that their recovery from medical conditions was hampered by damp, cold and noisy housing. This illustrates the importance of the idea of holistic healthcare, which encompasses not only symptomatic, or even general health, but all facets of wellbeing. Comments from patients have included the sentiments that they feel "more energised", "emotionally better" and "able to address my problems in a more active way than before". In some cases this has resulted in patients changing their diet. Patients appreciated the time the CAM practitioner spent with patients, the "warm and respectful" manner in which they were treated, and the encouragement and reassurance given to them.

Financial

Anecdotal evidence shows that patients are returning to work as a consequence of some CAM treatments. One patient presenting neck, shoulder and lower back pain as secondary symptoms to an occupational strain was given osteopathic soft-tissue treatment, mobilisation and manipulation, postural advice and exercises. The patient is now pain-free and able to return to working at full capacity. Another patient reported that he was unemployed and unable to work in May 2004, but after CAM treatment, returned to work by November of that year. Similarly, a health-care professional unable to work on health grounds (type I diabetes, hypertension chronic back pain and sciatica)[263] for over 10 years experienced relief after the first osteopathic treatment, having been referred from aromatherapy.

A patient reported not having taken any time off work due to back pain after receiving acupuncture treatment and that she stopped taking medication for her pain as the acupuncture had "completely controlled it". Another patient was able to stop taking conventional drugs to control acid reflux (excess acid in the stomach) after acupuncture treatment. Finally, although it cannot be used as a fair basis for wider cost evaluation, a patient with a history of depression stretching back to 1994 reported at the end of her course of homeopathic treatments that she had stopped taking anti-depressants. All patients who changed their medication did so by their own volition, or in consultation with their GPs and not on the recommendation of Get Well UK practitioners.

[263]Sciatica - A condition in which there is severe pain in the lower back and down the back of the thigh and leg.

Summary of Practitioner Views

Practitioners were generally very positive about the Get Well UK scheme and all thought it laudable that CAM therapies were being provided to patients who would not ordinarily have been able to afford them privately. Hands-on therapists – acupuncturists, osteopaths and massage therapists - generally reported a high level of referrals from GPs involved in the scheme, with doctors becoming more receptive to the benefits of treatment as the project continued. Homeopaths reported receiving few referrals (around five each), with no increase over the course of the project; the practitioners attributed this to a greater GP suspicion of homeopathy than of the hands-on therapies.

Referral and Administration

Some practitioners reported teething problems in the scheme such as arranging appointment times around practitioners' private practice commitments, but this difficulty was seen as having being solved by assigning a half-day to each practitioner for their appointments. Completing evaluation forms was seen as time-consuming by some, but the importance of evaluating the pilot stage of the project was recognised. The referral system at Get Well UK was praised as being very efficient. One osteopath remarked that there was less bureaucracy than in the NHS department in which she had worked, and another felt reassured about the suitability of a patient for treatment when they had been screened by a GP. Many practitioners recognised the benefit of Get Well UK taking care of administrative tasks such as booking treatment rooms. The move to the systems of six treatments followed by a re-referral from the GP was welcomed by one acupuncturist as it was thought to force the GP into greater engagement with the CAM therapy and the patient's progress through it.

Patient Type

As might be expected, practitioners reported that the patients they see through Get Well UK are very different from those seen in private practice. Many practitioners noted that they encountered few acute cases and a greater number of chronic cases, reflecting Get Well UK's focus as a service for chronic patients. A greater prevalence of complex cases where patients reported multiple symptoms was also in evidence. Practitioners noted the increased difficulty in treating such cases and the advisability of catching problems early; one acupuncturist reported using the rule of thumb that for every extra year a complaint has been present, a month of treatment is needed to address it.

Interpreters were needed in 15% of cases and some practitioners reported needing a longer time to build a treatment relationship with the patient, though this was often rewarded by good results and a revelatory experience on the part of the patient towards the CAM therapy.

Conditions Treated

The range of conditions for which patients were referred to Get Well UK practitioners was limited to specific areas by Get Well UK (see methodology section); the most commonly seen by the different therapists are listed in Figure 14 below:

Figure 14: Conditions frequently treated by CAM practitioners at Get Well UK

Therapy	Main Conditions Treated
Acupuncturist	pain, stress/depression
Homeopaths	stress/depression, menstrual problems, pain
Osteopaths	lower back and neck pain, arthritic conditions
(Aromatherapy) Massage Therapists	back/neck/shoulder pain, stress/depression

Source: Interviews with Get Well UK, 2005

Number of sessions

One homeopath reported that, as in private practice, children could require only one or two treatments, as opposed to more than twelve in chronic adult cases. Another homeopath reported that most Get Well UK patients needed between six and twelve sessions and there was disappointment that it was not possible to give patients more than the limit of twelve treatments. This feeling was also expressed by acupuncturists and an osteopath, who mentioned that maintenance appointments (appointments made for ongoing, less frequent treatments designed to maintain the benefit gained, for example in arthritic conditions) would be very beneficial and would reduce in frequency over time.

Comparison with Private Practice

One acupuncturist noted that not accepting money from the patient for treatment felt different. Another acupuncturist pointed out that stress was observed in patients in both private practice and through Get Well UK, but that it is the cause that differs (for example difficult family circumstances versus a high-powered job).

There were differing views on the motivation of patients coming through Get Well UK to continue treatment. Some thought the affordability of the treatment encouraged attendance at appointments, but others noticed a few more missed appointments than in private practice.

Several practitioners noted that most of the patients referred through Get Well UK have little or no knowledge of CAM therapies. This has meant that a period of education is needed, sometimes leading to a revelatory response from the patient who has committed to, and seen great benefit from, the treatment.

Collaboration

Collaboration between practitioners has been a key feature of the scheme. Many practitioners welcomed the opportunity to discuss particular complaints with other practitioners in the monthly clinical supervision meetings. Some practitioners were very impressed by the opportunity for therapists from different disciplines to learn from each other. There have been several cross-referrals between practitioners, and some patients were treated by a combination of more than one practitioner; these arrangements were usually based on a practitioner's knowledge of and preference for other therapies; acupuncture and osteopathy practitioners collaborated for more than one patient, though collaboration can be limited by the quota of twelve sessions in total per patient. The idea of having meetings between CAM practitioners, GPs and nurses was widely welcomed, although several practitioners have found it difficult to attend the meetings because of time constraints. One osteopath who had previously worked in the NHS believed putting the Get Well UK service under PCT control would improve CAM practitioners' feeling of being part of a primary healthcare team. Others agreed and felt that more contact between practitioners and GPs would be advantageous for both groups.

Benefits

One of the principal benefits to patients observed by practitioners was the reduction in worry about their state of health. The time spent with the patient is seen as a major benefit as it allows the whole patient to be treated rather than an individual ailment. The patient's wellbeing is worked on and improved. The patient is educated about their own health and body, and this is also of crucial importance. The reduction in use of conventional medicine, both medication and GP appointments, is also a very significant benefit to patients according to the practitioners. Practitioners also recognise that CAM therapies give GPs another treatment option, which can reduce the GPs' workload.

One acupuncturist interviewed mentioned that his treatment includes advice about diet and posture and habits, pointing out that the patient must commit to helping themselves to

improve their condition. Several practitioners were of the opinion that in the long-term, this prevention of illness through education and management of chronic conditions will reap large financial rewards.

Some practitioners had success with patients who were able to return to work as a result of their treatment. One osteopath treated a driver with a herniated disc causing shooting pain down his leg. The patient's GP had prescribed painkillers, but these were mostly ineffective. After five sessions of osteopathy, combined with some acupuncture from another practitioner, the patient had recovered and could drive again.

Other benefits were more financially intangible, but equally impressive. One patient could hardly sleep due to worry about herself and her family. A month after her first homeopathic treatment there was a drastic improvement, allowing her to sleep through the night and gain the associated benefits of improved function and wellbeing.

One acupuncturist treated a female patient for headaches. The headaches cleared and so did menstrual and fertility problems associated with the headaches. Two patients treated by practitioners were reported to reduce the number of cigarettes smoked and in one case give up smoking, an area with more clearly defined financial benefit to the NHS.

Costs

Costs for the CAM therapies in private practice ranged from £35 to £45+ for a session lasting 45-60 minutes, depending on whether it is a first consultation, which therapy is involved and where the practice is located (as this determines room rent). Some practitioners felt that the fee paid by Get Well UK was significantly less than the payment that would be received in private practice, even if costs such as room rent, booking administration and advertising are covered by Get Well UK.

However, others found that the £28 fee for a Get Well UK session, at the start of this contract, was approximately equivalent to that earned in private practice after the costs paid by Get Well UK were subtracted. In either case the practitioners cited the opportunity either to work in connection with the NHS or to provide their therapy to those who would otherwise not have access to it as a powerful incentive to be part of Get Well UK. The financial disparity did however limit the amount of time they were willing to commit to Get Well UK in a week.

Summary of Interviews with GPs

The Smallwood Enquiry interviewed a total of 22 General Practitioners (GPs) in the North London area, centred on N15, the site of the Haringey Get Well UK Clinic. Of the GPs interviewed, 12 were based within N15, and a further six in N8 and N4 combined. Finally, one GP from each of N6, N10, N17 and N22 was interviewed concerning the Get Well UK Clinic, and their general opinion on the role of CAM within their practice and personal experience.

What is striking is the very high level of general CAM referrals and recommendations, with 86% of GPs confirming that they had either referred a patient to the Get Well UK Clinic or another CAM practitioner. This reflects the generally positive attitude expressed by most GPs concerning the role of CAM, though it must be remembered that those who agreed to be interviewed were likely to be a relatively self-selecting group. This is not to detract, however, from the fact that the vast majority of GPs felt that CAM treatments were beneficial and effective. Although the catchment of Get Well UK may have limited GP referral, 9 GPs had referred their patients to other CAM practitioners, and their perceptions of the value of the treatments are included in the discussion below.

Of the 19 GPs (out of 22) who had referred patients to some form of CAM treatment, 12 noted definite physical improvements in their patients and 14 noted a positive impact on the psychological health of the patient. Taken together, GPs noted that CAM treatments offered a holistic approach to health (10 GPs) and stressed that it combined "mental, physical and spiritual health" into a concept of "complete wellbeing." Such a model of health linked aspects of psychological and physical treatment into a single approach. This helps explain why CAM appeared so effective: relief and management of pain and stress requires improvement in both aspects. 12 GPs highlighted this as a key benefit.

Acupuncture and osteopathy were the most commonly referred treatments, both being mentioned 13 times. Acupuncture was most often used as a pain management or stress relief treatment which, despite its less well understood scientific basis, was repeatedly noted for its effectiveness and supported by a large amount of anecdotal evidence. Osteopathy was regularly justified by the fact that many GPs "do not consider osteopathy remotely fringe", and that it "is not really seen as an alternative therapy anymore." The relatively conventional scientific rationale, comprehensive national oversight and regulation, as well as its demonstrable effectiveness ("comparable to physiotherapy"), made it an obvious choice for GPs.

Homeopathic treatments were the third most prescribed treatment, noted nine times. This was interesting, given that many GPs echoed the sentiment that homeopathy "has no basis in science or medicine whatsoever, and has no supporting evidence". Its popularity must, however, be understood in the context of the very important counselling role of CAM, with one GP commenting that "homeopathy may well be rubbish, but the practitioners are far more effective as counsellors than most conventional counsellors." Specific homeopathic treatments might rely largely on a placebo effect, but when combined with more lengthy consultations that examined a patient's entire life style, they were effective in generating positive improvements, both physical and mental.

Key Issues regarding CAM

Legal Protection

This was extremely important to most GPs: 54% mentioned is as a key concern and an issue that would have to be addressed before further expansion of CAM services was possible. One practice contacted had, for example, agreed collectively that no doctor would refer any patients to any kind of alternative or complimentary practitioner, following advice from the British Medical Association and the Medical Defence Union. They cited examples of common law cases where GPs had been found legally responsible for making a referral to a practitioner that was negligent, in spite of practitioners having full indemnity insurance. Another doctor cited an example of a patient whom they referred to an osteopath. Whilst the patient had received initial pain relief through the treatment, they had later suffered from a slipped disk. Although the practitioner was responsible for the treatment, the GP was sued as being responsible for the referrals. This was "simply not fair," and the issue urgently needed to be resolved so that the focus of responsibility and blame "is clearly with the practitioner."

GPs who were willing to explore CAM options need to be supported and legally protected, despite the fact that the chances of being sued are extremely remote (one doctor explaining that she had been referring patients for 20 years, and had only received three complaints, none of which reached court). Nonetheless, it was point out, often in the strongest terms, that whilst "one needs to know the practitioner is fully covered", GPs also required much more effective protection and clear guidelines about their legal situation. Overall, the current "legal grey-area" confused and dissuaded many GPs from exploring CAM, and proved to a "very substantial barrier" to their expansion and integration.

Regulation and Standardisation of CAM

Such anecdotal stories were also used by GPs to illustrate the need for greater regulation of CAM. Greater central regulation would lead to a standardisation of practice, and when

combined with more assessment and oversight, would go some way to resolving GPs current legal concerns by guaranteeing levels of service and professionalism, and at the same time providing a more empirical base from which to assess the effectiveness of any treatments.

In total, 68% identified increased regulation as a key issue in the CAM debate, though less pressing than the legal "grey area". A majority of doctors agreed that CAM had real benefits, but that there was too much discrepancy amongst different practitioners, hence "the necessary next step should be to regulate and standardise alternative treatments" to allow more people access to them. As a model, osteopathy was repeatedly cited as an example of CAM system of self-regulation and oversight which benefited both patients and aided doctors in making sound referrals. One GP summed up the situation by saying that the problem with CAM at the moment was "a legal, official and bureaucratic one, and *not* an issue of the value to patients' wellbeing or health." The lack of central regulation compounded existing legal concerns by GPs, undermined their trust and confidence in the therapies, and left them without a "centre of excellence" to consult or contact. At present, even those most positive about CAM felt somewhat frustrated with the existing framework with one stating "I will only refer patients to practitioners I know well" and have "a good personal relationship with." Such *ad hoc* arrangements and personal contacts are clearly not sufficient to support the widespread extension of CAM services.

Knowledge and Communication

A third equally interlinked issue was that of greater knowledge and communication between GPs and practitioners. Again, 68% of GPs highlighted this issue as a key point of consideration, though it was generally a lower priority. Many GPs described themselves as "keen to try anything that seems to work", but often felt severely constrained by their lack of knowledge concerning CAM treatments. The lack of centralised regulatory bodies, as a source of information and advice, means that GPs are more likely to refer to therapies of which they have direct knowledge. A central problem is that as general practitioners, doctors are expected to be "up to date in virtually every field" of conventional medicine, let alone developments in alternative fields. Their severe time pressures mean that "most traditional orthodox medical practitioners aren't informed" about the full range or scope of such therapies, even if they are sympathetic to them. This is combined with the "frustrating" attitude of some doctors (often older), who were described as trapped by their own "closed mindedness". One GP summarised by saying that "we don't know enough about [CAM] so we tend to fear it."

There is a need for much greater inter-professional contact to break down these divisions and antagonism. One GP stressed that "we should complement and not compete," and this will only be possible with greater communication. Many GPs stressed that they were very keen to see this happen: "we need this feedback so we can assess the benefits of any treatment so we can both understand each other's view of the patient." GPs also underlined their desire for more information, asking "what is out there, and who is eligible? We need to know what options there are." There was strong support for a range of clear-cut guidelines from practitioners on who they can treat, and how much they can help."

Finally, patients and the general public at large need to be brought more fully into the debate. One doctor who was strongly critical of CAM argued forcefully that "we need to educate the public to look at health in a rational sense." This certainly needs to be addressed, particularly with regards to "really quite worrying" therapies "such as coffee enemas or crystal healing", which found no support even amongst sympathetic GPs. The importance of engaging the public was highlighted by the "tragic case of a young man with potentially curable cancer" who had refused to continue his chemotherapy on the advice of a "quack practitioner" and subsequently died. The doctor concluded by saying, "we can't allow this sort of thing to happen again."

Non Referring GPs

In total, only three GPs had never referred a patient to any form of CAM. One practice had agreed collectively not to refer any patients to any form of practitioner, on the advice of the British Medical Association and the Medical Defence Union. The GP speaking on their behalf accepted that some approaches such as chiropractic or osteopathic treatments could be as effective as physiotherapy, and that there was certainly strong anecdotal evidence supporting massage and acupuncture. He stated that he felt they could be cost-effective, but simply felt that the legal risks were currently too great.

The second GP explained her situation: A young and newly qualified doctor, she had had few opportunities to refer patients to such treatments. At the same time, she felt poorly informed about them, to the point that she did not feel confident in making a recommendation. There was also an issue of limited availability in her area, combined with a lack of regulatory oversight that made her hesitant to make a referral – particularly as she was not convinced of the cost-effectiveness of the treatments. Finally, she pointed out that the legal grey area was "a very substantial barrier" to any referrals.

The third GP was the most strongly opposed to these therapies in general. His hostility stemmed from the fact that CAM treatments "do not sit with my sense of how things work …doctors practise medicine based on evidence and the scientific method," and most of these approaches were, according to him, "distinctly unscientific." What is more, he argued that it was important to bear in mind that "the vast majority of patients want traditional Western medicine, *not* alternative or complementary approaches." He was not prepared to "pander to people's superstition," and questioned the ethics of promoting treatments solely on the basis of a placebo effect. As a GP, he felt strongly that it was his duty "to be honest and treat my patients as mature adults."

Benefits

Whilst the large majority of GPs agreed that CAM treatments had either physical or psychological benefits, or a combination of both, there was a wide range of comments concerning their impact. Some cited "undeniable benefits," and expressed a clear belief that they could be "very beneficial and very helpful" for a range of conditions. Pain and stress relief and management were commonly cited as key benefits. Of course, as one admitted, "It's hard to know what the treatment is and what is the conventional medicine," but overall the impression was a strongly positive one, even in situations where GPs confessed not to understand how the treatment actually worked. One GP used as an example a patient who had suffered long term chronic back pain, to the point of being unable to work, and having had several relatively major operations. These had been ineffective, but a combination of osteopathy, massage and acupuncture had eventually allowed her to return to work. She summed up such treatments by noting that they "are popular, and generally reduce the need for medication - on the whole they do work, especially for chronic pain."

Equally importantly, they offered a wide range of options when dealing with patients. Such treatments were particularly valuable in cases where GPs were keen to send the patient for surgery, or for those patients who were intolerant of conventional treatments. As a more general observation, one GP who used extensive osteopathy pointed out that CAM was attractive as "you can't just keep giving people drugs forever," and it had to be remembered that with conventional "arthritis treatment and medicine, none of it is without side-effects."

Equally, the general holistic approach to individual patients was consistently highlighted as generating "great results," primarily because of their longer consultation sessions. As one GP pointed out, "what they have is time – and I do not have that, I only have a ten minute consultation, but they have half an hour…it is an extension of the support [patients] need," particularly those suffering from anxiety, depression or stress. Whilst osteopathy worked in a clearly physical way, less scientifically rigorous approaches such as aromatherapy or homeopathy were often suspected of working largely on a psychosomatic level; one GP felt

that they "seem to my mind largely about a placebo effect." That said, many admitted that their lack of knowledge meant that results "could be the power of placebo or the medicine or something else entirely." Irrespective of this, it was fundamental to remember that "the placebo effect is very important sometimes" and could be used to great effect in "fulfilling people's expectations." Equally, it was noted by doctors numerous times that "a sense of wellbeing is not a rigid science." One GP summed this up, commenting that "even if there is no scientific evidence, these [treatments] can still have a big impact on the happiness, health and wellbeing of the patient."

"The trouble with conventional medicine," one GP pointed out, "is that it's just one model of health. A holistic approach to health seems a very important way of viewing patients' problems," particularly those that involved anxiety, stress and pain. In such cases, CAM "practitioners are often the best people for patients to see" because "listening and touching therapies are very good at empowering patients to begin their own healing." An excellent example of the more radical and experimental uses of such approaches was provided by a GP who had used a combination of acupuncture and homeopathy to treat alcoholics. She also referred to a programme she helped organise in 1998 that treated psychiatric patients and their carers with a full spectrum of touch therapies including shiatsu, massage, acupuncture, as well as aromatherapy and homeopathy, with "fantastic results."

However, GPs also repeatedly stressed that "it is important to be realistic; you need to know the strengths and the limits of the particular therapy." Whilst it was hard to make generalisations across so many different treatments, (as "it all depends on the patient and their condition"), doctors were clear in stating that any single CAM therapy could be effective "only for limited aspects" of a condition. Many said they would usually refer a patient for "really just minor aliments, and a not major illness." As a whole, doctors would consider a CAM referral for "patients that do not have acute problems that need immediate orthodox Western medicine and treatment." Many expressed that they would be "very concerned if these tried to overcome and replace orthodox medical treatments." As one doctor pointed out, "if you need a hip replacement, no alternative practitioner in the world is going to be able to do that for you." Though some GPs remained fairly sceptical whilst willing to experiment with CAM, a very small minority expressed the view that "the benefits have not been proven, and I am not convinced" and that the "the benefits are thin to non-existent." Even those who were supportive of alternative therapies admitted of homeopathy and aromatherapy that often "there's nothing that shows benefit – other than anecdotal evidence."

Costs

Overall, a wider range of responses were recorded concerning the overall cost effects of CAM treatments. Those GPs who expressed the strongest support of the validity and impact of the treatments were, equally, those who consider the treatments most cost-effective, commenting that an extension of such treatments into the NHS would "save many, many millions of pounds." They argued that, in spite of the reservations of some doctors, it was increasingly clear that "these treatments are definitely cost-effective." This was particularly evident when they were compared with the cost of cumulative conventional approaches, with one doctor commenting that "you have no idea of the huge amount of money that is wasted on expensive tests and treatments whilst these alternatives are ignored" because of ignorance or close-mindedness. Equally, the cost of these treatments was justified by doctors with reference to their effectiveness in treating patients' symptoms and problems; as one put it, "if the patients' wellbeing is good, they don't need my help anymore." Amongst those who felt that CAM was cost-effective, the general feeling was that they "will definitely reduce the costs", but of course this was qualified by the fact that "it all depends on the service and the results" of specific treatments for specific patients.

Many doctors, however, felt unable or unwilling to try to make a costing assessment of CAM, mainly because of lack of knowledge. One commented "I simply haven't worked it out like that", and that "it has never been my aim to consider saving money, I am looking holistically at

my patient's health" first and foremost. Several GPs stated that in their opinion such treatments were "proven not cost-effective," and that they would only make the referral "as the practice doesn't have to pay for it."

One GP went so far as to state categorically that "these therapies are *not* cost effective". This, however, raised an important issue concerning access to these treatments by different economic groups; several stressed that "the most important concern for me as a GP is giving access to these treatments to poorer areas", and that it was "absolutely vital" that poorer communities also have access. Avoiding the emergence of a two-tier health system is a concern, but equally managing demand could be difficult; "I'm convinced more people would want access to them then the NHS could support," one stated.

Get Well UK Conclusions

Benefits

Get Well UK's three main stakeholder groups share opinions on several of the possible benefits of the service:

Equity of Provision
The aim of the project is to allow access to CAM therapies to all people. In the deprived NDC area where the service is being provided many of the patients are from ethnic minority communities, live on benefits, in council housing or temporary accommodation and have low educational attainment. The service is provided with no charge to the patient at the point of delivery, in line with the founding values of the NHS. It was agreed by the three stakeholder groups that this is a laudable aim.

Holistic Approach
The holistic treatment of patients' health was similarly seen by all three groups as valuable: GPs appreciated the time practitioners spent addressing a patient's overall wellbeing and practitioners saw this as an important feature of their treatment. Patients also commented on their satisfaction with this approach to their treatment.

Health Benefits
Improvements in both physical and emotional wellbeing were recognised by all three groups. Since the patients presented with chronic and complex conditions, the benefits in some cases were very marked and patients welcomed relief from their symptoms. However, some chronic cases were not always able to be treated entirely successfully due to the limit on the number of CAM sessions. GPs reported that the CAM intervention reduced demands on their time, especially in cases where progress through conventional medicine has proven difficult or ineffective. Pain conditions were particularly well addressed by all the therapies; practitioners and patients reported good results and GPs referred for these types of conditions readily.

Education
Members of the three groups appreciated the didactic component of the project: informing GPs about CAM therapies and how and when to refer to them; the education of practitioners about CAM therapies other than their own was facilitated by the multi-disciplinary nature of the service; and the education of patients was seen to be successful.

Barriers

There were however disagreements and marked differences in emphasis between the groups.

Legal
GPs interviewed by the Enquiry, including those who referred to Get Well UK or other CAM practitioners, were almost universally concerned with the legal position regarding the referral of patients to practitioners. They reported that this represents an impediment to referral due to uncertainties regarding legal culpability. This was, perhaps naturally, not a concern expressed by patients or practitioners.

Regulation
GPs commented on the need for regulation of CAM practitioners and the desire for regulatory bodies, as exist for osteopaths in the General Osteopathic Council and for chiropractors in the General Chiropractic Council. This would enable ready identification of competent practitioners to whom to refer. (For further information about the current movements toward regulation amongst CAM practitioners, see the relevant Safety sections in each therapy's entry in the Literature Review.)

Cost-Effectiveness
In many cases, even GPs who referred to CAM practitioners were dubious about the cost-effectiveness of CAM therapies. They were happy to refer to a non-NHS funded service, but more sceptical if NHS funds were to be involved. Anecdotal evidence from patients and practitioners (and some GPs) about reductions in GP appointments and consumption of prescription drugs by patients after receiving CAM treatment suggest some cost advantages; a more detailed analysis on costs has been conducted by Professor Nicola Robinson.

A Cost Analysis of Complementary Medicine Provision in Primary Care

Professor Robinson undertook a closer analysis of costs of conventional medicine treatment before, during and after complementary medicine in a study published in September 2005, funded by the Ann and Ian Marks Trust. Robinson argues that a combination of quantitative and qualitative data is necessary to analyse the costs of an integrated approach to CAM in primary care. Cost data for the analysis took into account prescription use, GP consultation costs and secondary care referrals and diagnostic tests for the periods.

Qualitative Data – Benefits

The analysis was based on consultation and prescription data collected retrospectively from GP records to which costs were subsequently applied. Information was also used from Robinson's independent audit of Get Well UK, as well as patient records accessed in co-operation from GPs within the Get Well UK ambit. A total of 58 patients referred by 22 individual GPs met the inclusion criteria in that they were registered patients, referred by their GP, over 18 years old, had been identified in the nine-month audit period and who had completed their course of complementary medical treatments. Of these 58 patients, 33 were accessible for the purposes of the cost analysis study. It was acknowledged that this was a small sample but representative of the total patients treated by the service. Due to the relatively brief timescale of Get Well UK's period of operation, the main limitation of the study was the short length of follow-up post treatment.

Robinson stresses that qualitative data must be incorporated when undertaking a cost comparison analysis of complementary medicine, which from the viewpoints of the patients and practitioners contacted in the study was very successful in addressing their symptoms, improving wellbeing and alleviating worry. No cost value was attached to this qualitative data, and in-depth analysis of patients' conditions will be imperative in assessing the effectiveness of complementary health care in further research.

On an analysis of pre- and post- MYMOP scores of the 28 patients for whom data was available, 90% demonstrated an improvement in their symptoms. For 9 patients this took place over two courses of treatment due to multiple morbidities and the development of new

symptoms. Over half of the patients increased their sense of wellbeing over their first course of treatment, and 78% after their second. Similarly, 85% of patients experienced a reduction in worry about their referred condition, which increased to 92% after their second course of treatment. Anecdotal references were also made to beneficial lifestyle and attitude changes as a consequence of treatment.

The study undertaken by Professor Robinson concluded that a far broader base of data and rigorous mixed-methods approach would be required to assess whether complementary medicine might be a cost-effective addition to GP care, especially given the short period of time available for the study.

GP Consultation and Prescription Costs

The complementary package at Get Well UK is offered at a total cost of £28 per appointment plus £1.50 for practitioner CPD and when Get Well UK administrative costs are included, the total cost of one treatment is approximately £50. This compares with the standard NHS GP consultation at £21 plus prescription costs of £30.52, leading to a total of £51.52; this is a standard prescription cost not specific to each patient, which was applied so that a standard cost could be compared.[264] However, from the evidence provided in the routine data, complementary medicine, despite its lower costs, may initially increase overall health costs as it may be used as an "add on" rather than a replacement, particularly if patients have to wait for other treatments. The greater frequency of GP consultations during the period of CAM treatment, based on the available data is given in the table below. All tables assume a mean of 4.3 months during and 5.7 months post treatment.

Figure 15: Cost analysis for GP consultations for referred and unreferred conditions at various times

Cost analysis for GP consultations for referred and unreferred conditions pre, during and post complementary medicine treatment		
	No. of GP consultations/ month/ patient	**Cost of GP consultations/ month/ patient**
Pre-complementary medicine treatment (2 years)	0.54	£11.27
During complementary medicine treatment	0.96***	£20.10***
Post-complementary medicine treatment	0.83**	£17.53**

Note: Table shows mean (95% CI derived from bootstrap analysis)
** p<0.01 compared to pre-treatment period (and significance maintained with bootstrap analysis)
*** p<0.001 compared to pre-treatment period (and significance maintained with bootstrap analysis)

It is evident that the number and therefore the cost of GP consultations were significantly higher during and post complementary medicine treatment.

[264] See Personal Social Services Research Unit, *Unit Costs of Health and Social Care,* University of Kent (2004).

Further analysis was undertaken, which attempted to quantify the cost of prescriptions per month per patient during the above time periods. However, two possible methods of costing were available; one by British National Formulary (BNF) category for actual drugs prescribed, for referred and other conditions;[265] the other using a standard prescription cost of £30.52, as stated in the unit costs of Health and Social Care 2004, and presumed a one consultation one prescription set-up. The results according to the BNF categories are presented in the table below.

Figure 16: Cost analysis for prescriptions/ month/ patient

Cost analysis for prescriptions/ month/ patient applying 2004 costs by BNF categories			
	Total cost of prescriptions/ month/ patient	**Cost of related prescriptions/ month/ patient**	**Cost of unrelated prescriptions/ month/ patient**
Pre-complementary medicine treatment (2 years)	£11.71	£3.24	£8.48
During complementary medicine treatment	£15.80	£2.26	£13.54*
Post-complementary medicine treatment	£19.67	£3.75	£15.92

Note: Table shows mean (95% CI derived from bootstrap analysis)
* $p<0.05$ compared to pre-treatment period (and significance maintained with bootstrap analysis)

Using the first method of BNF categorisation the total cost of medications/ months/ patient pre treatment for the referred condition was £3.24, during treatment it was £2.26 and post complementary medicine package it was £3.75. When the standard prescription cost of £30.52 was applied, the costs were £10.24, £7.53 and £11.68 for the same periods respectively; the same pattern was in evidence.

Prescription costs were slightly lower during the treatment period, but this difference did not achieve statistical significance.

17 of the 33 patients in the study had no prescriptions for their referred conditions post complementary medicine treatment. There was no change for 7 patients and an increase for 13 patients. This resulted in no difference being observed when the cost data were combined because of the skewed nature of the small sample.

Total prescription costs were somewhat higher during and post complementary medicine treatment compared with total prescriptions costs before complementary treatments, however these differences only achieved statistical significance post treatment, and only when standard cost per prescription was used.

Secondary Care Referrals

Costs of secondary care referrals and diagnostic tests (for the condition for which the patient was referred) did show a reduction in post-treatment referral and diagnostic costs but figures were not statistically significant.

[265] See Dept. of Health (2005) Prescription of Cost Analysis

Figure 17:Total number and cost of referrals and diagnostic tests and costs per patient per month

Total number and cost of referrals and diagnostic tests and costs per patient per month, pre, during and post complementary medicine treatment			
	Total number of referrals and diagnostic tests/ month	**Total cost of referrals and diagnostic tests/ month**	**Cost of referrals and diagnostic tests per patient/ month**
Pre-complementary medicine treatment (2 years)	1.38	£112.64	£3.41
During complementary medicine treatment	1.86	£133.07	£4.03
Post-complementary medicine treatment	0.7	£64.72	£1.96

Robinson points out that opportunity for evaluation and comparisons is limited since there was insufficient time between the end of the treatment period and the follow-up period post-treatment. The mean time between the end of the CAM package to the date when data was collected from the practice was 5.7 months (175 days). This is less than useful in the case of long-term chronic conditions. The space of time between end of treatment and referral, therefore, was not sufficient to make clear comparisons

Strengths and Vulnerabilities of Get Well UK

The example of integration that Get Well UK presents has both strengths and vulnerabilities. It is instructive to lay these out below.

Strengths

Get Well UK is a delivery model aimed at all people who could potentially benefit from its services, and due to its location and NDC funding helps particularly those patients who generally are not in a financial position to purchase these services privately. In this, it is representative of a number of services nation-wide which fulfil similar functions in NDC areas.[266] The MYMOP and practitioner data indicates that this group suffers from complex and chronic conditions and reportedly benefit greatly from the treatments provided. Specifically targeting groups that fit similar demographic profiles will enhance the possibility of recording significant patient benefits.

According to practitioners and MYMOP data, Get Well UK has become a central part of pain management for those patients referred to the service. The management of chronic pain sufferers has been identified by the GPs interviewed as an area of healthcare where CAM has a role to play. By beginning to fill this "effectiveness gap",[267] Get Well UK acts as a beneficial complement to conventional primary care.

Collaboration between the CAM practitioners has been extremely beneficial for both practitioners and patients. Practitioners have been able to refer patients to other therapies in-house, and to work together in treating individual patients (following a review, referrals internal to Get Well UK, i.e. between practitioners of different disciplines, now have to be signed off by a GP who remains responsible for the patients' care). This collaboration has also allowed practitioners to increase their knowledge of other therapies. This will increase

[266] See Blank et al.
[267] See Effectiveness Gaps.

the confidence of conventional practitioners that CAM can form part of an on-site multi-disciplinary team.

Some GPs indicated their concerns regarding the quality, accreditation and legal status of CAM practitioners. This is despite Get Well UK providing all 37 GPs identified as potential referrers to the service with information packs giving explanations of the CAM therapies being offered, the quality standards of the practitioners, information about liability and the journey the patient will have through the Get Well UK service. If this uncertainty can be overcome and Get Well UK becomes universally known as a safe and effective service, it will be able to leverage this trust when expanding its model to other locations beyond the current two contract areas – Haringey and Islington.

Get Well UK has an experienced Board of Directors. It is chaired by David Phillips OBE, the first chairman of the Professional Conduct Committee of the General Osteopathic Council, a former director of the Medical Protection Society and former chair of Wellhouse NHS Trust and advisor to the Health Select Committee.

Receiving funding from Futurebuilders indicates that the government is supportive of the delivery model offered by Get Well UK to provide CAM within the NHS. Indeed, Melanie Johnson, a Parliamentary Under Secretary in the Department of Health said in the House of Commons in reference to Get Well UK that: [268]

> *"We understand the benefit that many people get from complementary therapies. Local commissioning is a matter for local discretion, but we can see the benefits to local practices of an intermediary pulling together a range of service in the areas for alternative medical treatments."*

Vulnerabilities

Since funding for the Get Well UK contracts comes from local NDC funding rather than the NHS there seems a chance on the one hand that GPs and PCTs would be more willing to refer patients to the service, safe in the knowledge that they are not diverting funding away from other NHS expenditure, and on the other hand that these stakeholders might not recognise cost savings that stem from the provision of CAM services because they consider them a separate budget and disconnected from NHS spending. They are not making a budgetary choice; there is no conscious decision on the part of the local health authorities to divert funds to CAM because they believe it to be the best way to spend part of their limited budget.

Since HM Treasury appears ready to strengthen and stabilise funding of the voluntary and community sector in the delivery of public service[269], and assuming that this trend is sustainable and long-term, it would seem sensible to put in place a mechanism with which the health authorities could make a more active evaluation of CAM services, making a clear connection between the funding needs of CAM and conventional services. This would increase the stake of these authorities in evaluating the worth of CAM services and becoming aware of the cost savings to other services they can make.

Get Well UK and all other CAM service providers are vulnerable to perceptions of efficacy and effectiveness of the treatments. GPs are overworked and yet expected to be aware of all new developments in healthcare. Their relative lack of knowledge of new evidence on safety, efficacy and effectiveness for CAM will limit their ability to refer to CAM services. This Enquiry found that a multi-disciplinary set-up with GPs and CAM practitioners in the same building scheme encouraged interdisciplinary understanding and learning, but that there is still some way to go along this road to achieve the information sharing, collaboration and cooperation that is needed to address conventional practitioners' concerns and allow all medical

[268] Hansard, 22 February 2005
[269] HM Treasury, 2002, p. 29

practitioners to work together most efficiently. This perception cannot be entirely separated from the task of CAM practitioners to educate and support the GPs they work with.

Although Get Well UK practitioners are registered with their respective professional bodies and possess a minimum £2 million professional indemnity insurance plan, concerns remain over GPs' legal responsibilities when referring patients to CAM practitioners. While GPs quite rightly feel responsible for the full healthcare of their patients, they are likely to be hesitant to refer when there are possibilities of liability suits.

The Future of Get Well UK

If we consider the example of Get Well UK as one possible model that could be expanded nationally, several considerations should be kept in mind.

Having successfully completed two pilot projects with NDC financing Get Well UK now needs to secure contracts directly from health and social care purchasers. Get Well UK is well positioned to secure contracts with the changes in purchasing currently being made within the NHS. Get Well UK has developed its capacity as an organisation to be able to deliver services across the UK. Central to this is the development of bespoke software to manage the relationships of those involved with the service. The system allows for appointment booking, administration, management, quality assurance, clinical governance and standardisation across new services. The system is secure and online and able to plug into the NHS at a later date. This system allows for the growth of the service without increasing the bureaucratic burden on practitioners, GPs or patients.

Although it would increase the burden upon Get Well UK and other CAM centres to satisfy concerns over effectiveness and cost-effectiveness, becoming part of the NHS could promote co-operation between CAM practitioners and general practitioners, and increase the likelihood that general practitioners will refer and utilise CAM services. In addition, the move towards Practice Based Commissioning (PBC) in NHS primary care, whereby GP practices will have a greater involvement in commissioning health care services, may act as a driver for interest in the integration of CAM services. This devolution of power to a more local level is intended to enhance patient choice and support for people with long term conditions.[270] Improvements to the variety of services from a diverse number of providers in accessible settings are intended as the chief benefits of PBC, which can be seen to reflect aspects of the type of delivery model Get Well UK, and its nation-wide peers, offers.

Addressing some of the central concerns of the GPs will allow Get Well UK (and all CAM practitioners) to ease the integration process. Get Well UK's referral process and guidelines on treatment packages are clear, however, any improvement on regulation of treatments will instil further confidence in GPs. Further information and training is needed for GPs who use the service, and for practitioners who will work within the NHS. Get Well UK is positioning itself as a reliable and unbiased source of information on complementary therapies, and in so doing, intends to respond to changes in regulation law and the concerns of GPs. This will allow GPs to refer their patients not just to practitioners whom they know, but to practitioners in whom they are confident that they can deliver the services required because they are a part of the Get Well UK service.

[270] See Department of Health, 2004, *Practice Based Commissioning: Engaging Practices in Commissioning*.

Overall Conclusions Regarding the Delivery of CAM

This section has examined several instances of integration of CAM into NHS care in varying detail. It is difficult to generalise about the benefits gained by patients across therapies and across services due to differing measurement criteria, but some common points can be made.

Benefits

The case studies present a consistent picture of benefits to patients. First, patient satisfaction with their CAM treatments was very high. Patients would utilise CAM therapies again and often desired more treatments than they were able to access through the various schemes outlined.

Second, CAM practitioners, GPs and patients all identified the large number of patients who saw their general health and well-being improve after the introduction of CAM into the package of treatments available. This was supported by both qualitative surveys of the practitioners and the generic health questionnaires that can grasp general changes in the patient's perception of his/her well-being.

Third, CAM was effective in improving a series of emotional and psychological problems that affected the patients. The case studies examined by the Enquiry were weighted towards free service delivery, serving communities that are not traditional purchasers of CAM. These patients exhibited a range of psychological problems associated with anxiety, stress and depression. CAM was often very helpful in dealing with these persistent problems.

The specific health conditions that had originally motivated the patient's decision to seek any medical assistance were generally improved by the introduction of CAM. Areas that appeared to be particularly effectively served by CAM from the case studies include chronic pain management, musculoskeletal problems and emotional/psychological problems such as "worry", anxiety, stress and depression.

A significant long-term benefit of CAM that is of ever-increasing importance is the effect that CAM treatment has on transforming the patient's approach to lifestyle and looking after his/her own health. After treatment with CAM, patients showed marked improvements in their attitudes to their diets and exercising. The reduction in patients' use of medications is a benefit in and of itself. In general, the heightened awareness of health matters that CAM frequently gives to patients fits well with the increasing importance of public health issues (such as obesity and exercise) and health prevention.

Costs

The examples of integrated health services examined allow a preliminary analysis of the cost implications of integration.

The number of consultations with general practitioners for those patients introducing CAM into their treatment package dramatically dropped. In the Newcastle case study, consultations with GPs dropped 31% following the patients' use of CAM, saving approximately £15 per patient. In Glastonbury, the reduction was 33%.

Those utilising CAM reduced their use of prescription drugs. In the Newcastle case study there was a 39% decrease, representing approximately £7 per patient. In the Glastonbury Integrated Service, a 50% decrease in the use of prescription drugs gave a combined GP consultation and prescription drug use saving of approximately £60 per patient. To put this in a national context there were 686,139,000 prescriptions at a cost of over £8 billion in 2004.[271]

[271] Source: Department of Health.

The use of secondary care services also decreased for patients utilising CAM. These services included consultations with physiotherapists and orthopaedic surgeons, time spent at pain clinics and the utilisation of x-rays. This reduction will not only lead to cost reductions, but will also decrease the waiting time for those patients needing conventional secondary care.

The use of CAM allowed many patients to return to work after being unable to through injury or to return at a much faster rate than if the patient has been limited to conventional treatment. From the case study of Get Well UK, many patients and practitioners relayed several prominent examples of how using CAM had allowed a return to work and increased productivity while there after injury. Although the cost savings associated with this are not quantified in the case studies, it can be expected from the savings amounts identified in the literature review that any such figures will be very substantial.

A possible area of very large cost savings identified in the case studies focuses on prevention of illness, as outlined in the benefits section above. CAM practitioners were very keen to emphasise to their patients different ways to be in greater control of their own healthcare. In the very long-term, this could represent a very significant cost savings to the NHS and Department of Health.

The overall picture of costs is more complicated, as the difficulties facing an economic evaluation of Get Well UK faced by Professor Nicola Robinson attested. Similarly, Westminster PCT will be producing more concrete cost conclusions to link in with its study utilising MYMOP profiles in 2006. The examination of the integrated healthcare service in Glastonbury indicates that the cost of introducing the CAM therapies was matched by a reduction in costs in conventional medical care, therefore making the direct cost implications of the service as cost neutral (i.e. overall costs neither went up or down). There are added complexities though since the centre's funding was acquired in part from patient contributions and in part from the Somerset Health Trust and Mendip PCT. The integrated service in Newcastle was not as positive on a comparison of costs before and after the introduction of the CAM therapies. The savings from conventional medicine after patients began using CAM covered approximately 40% of the costs of the CAM service. However, without a greater analysis that would allow cost-effectiveness or cost-utility conclusions to be drawn, it is unclear at this stage whether or not the higher costs of the CAM services in Newcastle were within the ranges of cost-effectiveness used by NICE.[272]

In addition, all of the studies were limited in taking into account the full range of indirect costs, for example time lost from work and the costs of burdens placed upon family members and carers. The costs of adverse effects were also not calculated. These figures would increase the likelihood that the integrated clinics would prove to be cost-effective, justifying the increased costs of introducing CAM therapies with conventional care cost savings and significant additional benefits.

Effectiveness Gaps

The issue of "effectiveness gaps", referring to an examination of possible areas of healthcare where conventional medicine might not be responding fully to the needs of patients, is dealt with in detail in the chapter below entitled Effectiveness Gaps. However, information from the case studies allows an initial discussion of this area to be conducted.

In Newcastle, several key health areas were identified where conventional medicine was not meeting patient needs. These areas were: asthma, migraine, back pain, neck pain, eczema, hay fever, anxiety and insomnia. This list was determined by a statistical analysis of local NHS resource usage and repetition in the rates of consultation for these conditions. In addition, the GPs referring to the area identified that 76% of referrals were for musculoskeletal problems and 13% for anxiety, stress or depression; when this data is correlated with the information that 80% of referrals occurred because conventional

[272] See CAM in the NHS and the Glossary.

treatments were not working, we can infer that these conditions were not being adequately dealt with by the local conventional practitioners.

From the Glastonbury CAM service, another inference can be drawn on effectiveness gaps. Over 60% of those patients utilising the CAM therapies in the case study were referred with musculoskeletal problems and 34% of those referred were not responding to conventional treatments. This indicates that an effectiveness gap in the treatment of musculoskeletal problems may well exist.

Finally, the GPs interviewed for the Enquiry's case study of Get Well UK provided additional views on those ailments that were not being fully treated by conventional practitioners. Over 50% of the GPs referred to pain and stress management as requiring greater attention than was currently occurring with conventional care. The relatively small amount of time GPs get to spend with a patient highlighted an under-provision of counselling services, a factor identified as frequently very beneficial for many patients, pointing potentially to an effectiveness gap in treating stress, anxiety and depression. Many of the GPs surveyed outlined the areas where conventional treatment might more adequately deal with patients with chronic problems than at present. These chronic problems often lead to heavy use of medications and frequent visits to the GP. All of the conditions that GPs could refer to Get Well UK for were chosen as representing areas of healthcare that may be seen as effectiveness gaps. This includes asthma; back, neck or shoulder pain; depression, stress or tension; headaches; hypertension; joint problems, arthritis or rheumatism; menstrual or menopausal complaints or sports injuries.

This chapter has examined the practical and theoretical dimensions of an integrated approach to healthcare. The case studies provided a detailed examination of some of the possible cost and benefit implications of an integrated healthcare approach. The Enquiry now turns to the current framework of CAM and the NHS, and then outlines the current provision of CAM within the NHS. Any recommendations regarding an enhanced role for CAM must be set against an accurate picture of current situation.

CAM IN THE NHS

The possible models of integration of CAM into the NHS, discussed in the previous section, are closely connected with the organisational structure of the NHS. To determine the feasibility of, for example, an on-site multidisciplinary team of CAM practitioners working in an NHS general practice, demands an understanding of all these matters.

The first part of this section will outline the institutional and funding framework in the NHS in England; the roles and structures of the responsible bodies; how decisions are taken regarding the allocation of funds; and the principles by which this allocation is made. The structure of administering public healthcare is complex and its future is constantly open to change. This structure is at present in a period of transition and has experienced major reforms over the last decade.

The second part of the section will report on the latest information regarding the current provision of CAM on the NHS. According to Thomas et al. (2001), the NHS provided an estimated 10%[273] of the total provision of CAM services in 1998 in the UK, and this proportion is likely to be approximately accurate in 2005.[274] This information is only available by survey, as CAM treatments are non-statutory and so the keeping of records of NHS provision is not required. This unfortunately limits the Enquiry's ability to provide as up-to-date information and additionally suggests the benefits of such a database.

NHS Organisation and Funding

There is already some provision of CAM services paid for and administered by the NHS; in addition, patients may be referred to private-practice CAM therapists by NHS health professionals in primary care trusts (PCTs). The Department of Health notes that some NHS hospitals already make use of various CAM therapies. It cites the use of acupuncture in childbirth and in some pain clinics. Additionally some hospitals use CAM therapies in the palliative care of cancer patients and homeopathy and other therapies are used in the NHS homeopathic hospitals in London, Bristol, Tunbridge Wells, Liverpool and Glasgow, which are in some cases linked to outreach clinics.

The Department of Health states that PCTs can have individual policies regarding the provision of CAM to their patients, within which GPs have discretion to refer to therapies where and when they see fit. The decision to integrate CAM services into the NHS largely depends on whether they are seen by purchasers of primary care as satisfying national or local NHS primary care priorities, i.e. whether they are potential solutions to NHS problems.

NHS Funding Flows

Payment by Results

The NHS is in the process of reforming its financial framework. This reform implements the "Payments by Results scheme" (PBR). This is part of the 2002 NHS Plan and its aim is to let funding follow the patient to whichever hospital or other NHS organisation they choose to go to have treatment. PBR will be implemented from financial years 2003-4 to 2007-8. Under the initiative all providers of services to NHS patients, whether in the public, private or voluntary sectors should eventually be covered by the same overall financial framework. As of April 2005, PCT commissioning of elective care from NHS Trusts will be subject to the new funding arrangements. NHS Foundation trusts have used this system for a year already.

This new framework depends on a common nationwide tariff being paid to all providers of services (e.g. GPs for primary care and NHS acute trusts for secondary care) by those who

[273] 'Private' spending, accounting for 90% of CAM expenditure, includes the very limited funding of some voluntary organisations providing CAM by the NHS.
[274] Interview with Dr K. Thomas, see Appendix B.

commission them (PCTs). However, some flexibility will remain in the system. Under PBR the allocation of funding to a treatment provider will be increased if they have higher costs than usual because for instance they treat more patients with complex needs. Exceptions might also prove possible for specialised services or those with extra-high technology costs.

Allocation of funds
The allocation of funds to PCTs in different areas is determined by the relative need of their populations. This is first determined by the population size in the PCT area and is adjusted further for a number of factors, the most important of which is deprivation. Adjusting funding levels on this criterion (where greater deprivation leads to higher funding) aims to enable each PCT to match the level of healthcare provision to the needs of the population (deprived areas historically have greater health problems and so require greater NHS funding to meet these needs). Another consideration, known as the "market forces factor", takes into account the difference in the cost of providing healthcare due to geographic differences (for example providing ambulance cover in rural areas), but this is not expected to impact on CAM provision.

The boards of PCTs, and particularly their Chief Executives and Finance Directors, are the chief decision makers in how PCT funds are spent. Practice-based commissioning will, in time, allow general practices themselves to have more influence over their service provision; all GPs are expected to be involved by 2008. Regarding CAM this will clearly increase the importance of GPs' opinions.

The Department of Health suggests that since CAM is clearly attractive to some patients it could in principle be offered by all local NHS organisations. The Department notes that PCTs often have specific policies on the extent to which their patients can be given access to complementary medicines and within these policies it is open to GPs to provide access to specific therapies where they consider it in the interest of patients. Cost-effectiveness, availability and evidence in support of therapies are all issues taken into account when deciding which treatments to provide.

National Institute for Health and Clinical Excellence

The above explanation of NHS organisation and funding flows describes where decisions on treatment provision are made. Decisions about *which* treatments should be funded are based largely on the advice of the National Institute for Health and Clinical Excellence (NICE). To help purchasers of health services, NICE produces guidance on three main areas:

- **Technology appraisals –** which focus on the use of new and existing medicines and treatments within the NHS in England and Wales;
- **Clinical guidelines –** which set out the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales; and
- **Interventional procedures –** which consider whether procedures that are used for diagnosis or treatment are safe enough and work well enough for routine use. This programme has been recently extended to cover Scotland as well as England and Wales.

Recommendations from Technology appraisal form part of the "core standards" of the NHS. The Secretary of State has directed that the NHS should provide funding and resources for those medicines and treatments recommended by NICE in technology appraisals. Local NHS bodies have three months to provide this funding and these funding bodies (not NICE) have responsibility for the implementation within the time limit. The three-month limit can be extended or waived where it will be especially difficult to fulfil this requirement.

The clinical guidelines and interventional procedures programmes are part of the "developmental standards" of the NHS, standards that are to be implemented over time, appreciating the difficulty and time needed to implement significant changes that NICE may recommend. These guidelines are *not* subject to a mandatory funding time limit.

For all NICE guidelines it is the responsibility of local NHS bodies to ensure their implementation, with the Healthcare Commission playing the role of an overseer, working to ensure local NHS bodies are utilising NICE guidelines. NICE has increasingly opened up the opportunities for various parties to propose areas of investigation and to be part of the appraisal process. In addition, its guidelines are increasingly responsive to local considerations, appreciative of the differing needs of frontline NHS staff, patients and managers. In addition, NICE has begun to include information on the impact of its guidelines, including a focus on cost consequences, aiding the implementation of its guidelines and allowing easier budgetary calculations for PCTs and other NHS Trusts.

The central outcome of NICE clinical guidelines is a determination of the cost-effectiveness of each relevant treatment for each examined condition or ailment. The evaluation method utilised by NICE is a cost-utility analysis, comparing the cost per quality-adjusted life year (QALY) for each treatment. Although including other variables to test cost-effectiveness (for example fairness, the quality of the data, whether the intervention under examination is the only one available for a given condition), NICE considers cost per QALYs to be in a range which has a benchmark of between £20,000 and £30,000 per QALY, above which greater justification for the recommendation of a treatment is required. The cost per QALY value may then be compared to those of the other treatments for a condition. The benchmark will change according to assessments of the availability and desirability of differing levels of national healthcare funding. Please see the NICE website (www.nice.org.uk) for more detailed information on all aspects discussed in this section.

Current Provision of CAM in the NHS

As noted above, the extent of CAM provision in the NHS is much larger than generally believed. Having navigated the channels to NHS funding, PCTs and GPs are in a position to begin CAM provision. The remainder of this chapter examines the details of the current use of CAM by the NHS.

A national survey by Thomas et al. (2003) contacted a significant sample of GPs in one in eight practices in England, examining NHS patient access to CAM. It estimated that in 1995, approximately 39% of general practices in England provided some access to CAM therapies. This was in the form of delivery by a member of the primary care team, a CAM practitioner working in the practice or NHS referrals to external providers. A repeat of the same study in 2001 estimated that this figure had risen to nearly 50%. The increase was not due to increased referrals to NHS CAM practitioners by general practitioners – these stayed constant; instead it was provision by GPs themselves or other members of the PCT, and provision by CAM practitioners working in the practice that had risen (see Figure 18 below). The approximation that 50% of practices offer some CAM services may give a misleading impression. Firstly, a “lowest” estimate figure, in which all non-responding practices are assumed to have no CAM provision, indicates only 35.6% of practices have some form of CAM service in 2001. Secondly, any practice that had referred a *single* patient would be counted. As the survey by Thomas et al. (2003) was not looking at the volume of use of CAM services, readers may overestimate NHS CAM provision. Finally, general practitioners may underestimate their use of NHS referrals. This may occur when referring patients to secondary care clinics that may utilise CAM without the practice being fully aware of all the treatments available (e.g. palliative care).

Thomas et al. (2003) also conducted a survey with a sample of managers of Primary Care Organisations (PCO) - a general term covering both Primary Care Groups (PCG) [the predecessor of Primary Care Trusts] and Primary Care Trusts (PCT) - in 1999-2000. It estimated that by the end of 2000, 85% of PCOs had discussed CAM at board level, a 90% increase on the year before. The same study indicated that the dominant strategy of primary care providers towards CAM services was to “provide and review”, but CAM was a low overall priority.

Wilkinson et al. (2004) considered those CAM services provided free (or primarily free) to the patient through PCTs, excluding those CAM services provided by GPs, practice nurses, health visitors and physiotherapists *as part of their normal professional duties* (services provided by GPs were considered if they were carried out in time dedicated to CAM and paid for by a PCT separately from normal GP care). The survey contacted 73% of the 301 PCTs as of April 2004. Assuming a "worst-case scenario" - where none of the non-responding PCTs provided CAM services - an estimated 43% of PCTs were offering some CAM service. Thomas et al. (2003) had estimated that 37% of PCOs had at least one CAM service in place by the end of 2000. Therefore, the number of PCTs providing at least one CAM service is growing at a slow rate.

Figure 18 summarises the findings from Thomas et al.'s two surveys of GP practices and their use of CAM:

Figure 18: Trends in NHS access to CAM via primary care in England 1995-2001

	Proportion of practices offering any provision or referral (%)	Proportion with a provision by member of primary healthcare team[275] (%)	Proportion with provision by an independent CAM practitioner working in the practice (%)	Proportion offering access to CAM via NHS referral (%)
Estimated proportion of practices:				
2001	49.4	29.6	12.2	26.8
1995	39.5	21.4	6.1	24.6
"Lowest" Estimate				
2001	35.6	21.8	9.3	18.5
1995	30.3	17.5	4.9	18.1
Acupuncture				
2001	33.6	20.5	4.6	14.1
1995	21.2	12.5	1.8	9.0
Homeopathy				
2001	21.1	8.3	2.7	14.9
1995	16.8	6.7	<1	12.4
Osteopathy + Chiropractic				
2001	23.0	3.3	7.7	13.6
1995	7.1	2.0	3.4	5.3
Medical Herbalism				
2001	2.7	<1	<1	1.3
1995	1.5	<1	<1	<1
Other CAM				
2001	6.4	3.0	3.0	1.6
1995	5.1	1.8	2.8	<1

Source: Thomas, Nicholl et al., 2003

232 CAM services were reported as operational by those PCTs that had some CAM provision in 2003-2004, and by the end of 2003 almost 97% of these services were still active. The highest number of new and existing services being developed (38%) was in the region "Northern and Yorkshire". The picture in 2003-2004 therefore was one of a fairly static level of provision of CAM, illustrated in Figure 19.

Figure 19: Development of primary care accessed CAM services 2003-04

State of services	%

[275] The primary healthcare team includes the GPs in the practice, nursing staff and other primary care practitioners able to perform CAM.

Existing services maintained	87
Existing services developed	4
New services developed	3
New services planned	3
Services cut	3

Source: Wilkinson et al., 2004

The surveys by Thomas et al. (2003) suggest several factors influencing CAM provision. There was a positive correlation between the number of general practitioners in a practice and the provision of CAM services. This is especially marked for provision by a member of the primary care team or by an on-site CAM practitioner.

The location of the practice in either an inner city or rural environment appeared to make little difference except, as one might expect, in the number of practices utilising NHS referrals, which was significantly larger for inner city practices. The ability to refer patients to CAM services will be largely determined by the availability of local practitioners to refer to; this is likely to be easier in a city environment with greater population, and therefore CAM practitioner, clusters.

In 2001, those practices in receipt of deprivation payments (payments given to a practice for every patient on their list who is defined as deprived by the Secretary of State for Health) were more likely to utilise NHS referrals (29.9% of practices with deprivation payments compared to 18.9% without).

Regional/Geographical Variations

With 67 CAM services across 31 PCTs, London had by far the greatest proportion of CAM services per PCT in 2003-2004. With eight services across 21 PCTs, the Trent area (Trent Strategic Health Authority from 2002) had the lowest. The proportions across the four regions in England are shown in Figure 20.

Figure 20: England wide PCT survey: Regional primary care access to CAM

Region[276]	% PCTs reported access	% PCTs adjusted[277] figures
London	87	84
Midlands and Eastern Region	53	41
North Region	52	33
South Region	60	43

Source: Wilkinson et al., 2004

This is supported by the work of Thomas et al. (2003). Clustering the practices into a "northern" group (covering the former Health Regions of Trent, North West, West Midlands, Northern and Yorkshire) and a "southern" group (comprising Eastern, South East, London and South West) allowed a difference to be observed, with the "northern" cluster offering provision to CAM services in 42.9% of practices compared to 53.2% in the "southern" cluster in 2001.

PCTs in England are covered by twenty-eight Strategic Health Authorities (SHA).[278] The University of Westminster's study (Wilkinson et al., 2004) utilised the former areas of the Health Regions outlined above to examine the proportion of services delivered PCT-wide. On average, 57% of services are delivered PCT-wide, with 45% of PCTs who provide CAM services making them available PCT-wide. 60% of new and developing services are available PCT-wide. The import of providing services area-wide lies in equitable and widespread access to the services provided, attempting to ensure that as many individuals as possible

[276] These four regions represent the four directorates in the Department of Health that, for a brief period in 2002, each had a regional focus as listed in the figure.
[277] Adjusted for 'worst-case' scenario of all non-responding PCTs providing no access to CAM services.
[278] These are now in the process of merging

have access to CAM therapies. The percentage of services provided PCT-wide in each of the eight former Health Regions is presented in Figure 21.

Figure 21: PCT-wide access to CAM services

Area (former Health Region)[279]	% of CAM services provided PCT wide
London	61
Eastern	71
Trent	64
West Midlands	62
Northern & Yorkshire	64
North West	50
South West	29
South East	55
Total	**57**

Source: Wilkinson et al. 2004

Therapy types

The proportion of different CAM therapies offered in CAM services across England (Figure 22) provides an indicator of current PCT choices in the provision of CAM.

Figure 22: Proportion of CAM therapies for England-wide services

Therapy	%
Acupuncture	17
Osteopathy	13
Homeopathy	12
Therapeutic massage	10
Aromatherapy	10
Reflexology	9
Chiropractic	7
Nutritional therapy	7
Other (mainly cranial osteopathy, herbal medicine and yoga)	15

Source: Wilkinson et al., 2004

It is important to note that in 44% of services a bundle of three or more therapies was offered.

Figure 22 shows the changes in the proportion of practices that offered the various CAM services between 1995 and 2001. All five services increased over the time period, with the greatest increases for acupuncture and the manipulation therapies. Acupuncture was the most popular therapy in both 1995 (21.2% of practices offering CAM services) and 2001 (33.6%), with manipulation overtaking homeopathy as the second most popular by 2001 (23% for manipulation compared to 21.1% for homeopathy). Whereas the proportion of practices offering NHS referrals stayed approximately constant over the time period, referrals for manipulation went from 5.3% to 13.6% of practices. By 2001, an almost identical proportion of practices indicated provision by referral for the three main groups (acupuncture, homeopathy and manipulation), but a much greater proportion had provision by a member of the primary healthcare team for acupuncture (20.5%) than homeopathy and manipulation respectively (8.3% and 3.3%). This was a significant 8% increase in the proportion of practices offering provision of acupuncture by a member of the primary care team from 1995. By 2001, three-times as much provision of homeopathy was provided through a member of the primary care team than by an independent practitioner working in the practice, a proportion which is reversed in the case of osteopathy and chiropractic. Extracting the information from Figure 22 allows a comparison of the changing percentage of practices offering the various CAM services from 1995 to 2001 (see Figure 23).

[279] The eight areas, representing eight regional offices, were in place until March 2002.

Figure 23: Proportion of practices offering various CAM services

Therapy	% practices offering any provision or referral - 1995	% practices offering any provision or referral - 2001
Acupuncture	21.2	33.6
Homeopathy	16.8	21.1
Osteopathy or Chiropractic	7.1	23.0
Medical Herbalism	1.5	2.7
Other CAM	5.1	6.4

Source: Thomas et al., 2003

Referrals to CAM services

It is important to know how those referred to NHS-provided CAM services are arriving there. Figure 24 outlines the proportion of those being referred by different sources to a CAM service. The greatest proportion of referrals was made by GPs to CAM practitioners within their PCT (33%).

Figure 24: Referrals to services

Source of referral	%
GPs within practice	21
GPs within PCT	33
Designated group GPs	6
Self referrals	6
Other health professionals	34

Source: Wilkinson et al., 2004

Providers of CAM services

Although a detailed analysis of who is providing CAM services on the NHS - one that would allow an understanding of the proportion of provision by each delivery method outlined in the chapter above – is not yet available, there are some broad indications available from both Thomas et al. (2003) and Wilkinson et al. (2004). When patients are referred, there are several different providers who may currently perform the treatment. The proportion of CAM services delivered by different CAM practitioners is outlined by Wilkinson et al. (2004) in Figure 25. It is important to remember that this excludes services offered in the normal course of primary healthcare team work (i.e. time not specifically set aside for CAM).

Figure 25: Practitioners providing CAM on the NHS

Practitioners	%
Non–medical complementary practitioners	54
GPs	18
Practice nurse	2
Other	26

Source: Wilkinson et al., 2004

Thomas et al.'s (2003) analysis allows a comparison to be made over time (Figure 18). The number of practices offering treatment through independent CAM practitioners working in a GP practice doubled to 12% and by 2001, a greater proportion of practices provided services through a member of the primary healthcare team than offered referrals outside the practice. Extracting the information from Figure 18 provides a comparison of trends in access to CAM services.

Figure 26: Proportion of practices providing forms of CAM access, 1995-2001

Access Route	% of practices providing this service – 1995	% of practices providing this service - 2001

Provision by member of the primary healthcare team	21.4	29.6
Provision by an independent CAM practitioner in practice	6.1	12.2
Referral to CAM service	24.6	26.8
Total	**39.5**	**49.4**

Source: Thomas et al., 2003

The CAM services may be in primary care, secondary care or a variety of other settings. Figure 27 presents the proportion of treatments that were provided in the various treatment settings. For example, at the time of the survey, 59 PCTs (of the 301 in England) had a contract with either of the homeopathic hospitals in London or Bristol.

Figure 27: Location of the service

Treatment Setting	% of CAM services delivered in each setting
Primary care	48
Secondary care	28
Other (mainly community-based settings, including local community hospitals, hospices, training colleges, practitioners' own premises, premises owned by charities)	24

Source: Wilkinson et al., 2004

Payments for treatment

Although we are examining CAM provision in the NHS, services exist that require some payment from the patient. Those patients utilising CAM therapies through the NHS found 88% of the services totally free at the point of delivery. For the remaining 12%, some small additional contribution was required, with the highest proportion of patient burden at 50% of the total treatment cost (Wilkinson et al., 2004). To understand the number of services provided within general practice that is paid for by either the NHS or the patient, a comparison between the two at 1995 and 2001 is presented below. As Figure 28 shows, the proportion of CAM services offered through GPs that involved some level of patient payment increased from approximately 26% in 1995 to 42% in 2001.

Figure 28: Who pays for complementary therapies provided within general practice by therapy?

Therapy	NHS		Paid by patient	
	1995, N	2001, N	1995, N	2001, N
Acupuncture	87	116	21	43
Chiropractic	5	6	3	17
Homeopathy	47	51	8	20
Osteopathy	17	14	14	38
Herbal Medicine	5	3	1	7
Other	56	16	26	21
All	**217 (74.8%)**	**206 (58.4%)**	**73 (25.2%)**	**146 (41.3%)**

Source: Thomas et al., 2003

Additionally, the "northern" cluster (outlined above) had only half as many practices offering CAM services with patient payments as the "southern" cluster (6.5% compared to 13.2%). This may reflect the broader socio-economic differences between the North and the South of England. Wilkinson et al. (2004) also provide an indication of regional differences in payments for CAM in the NHS. Figure 29 shows the estimates of the proportion of CAM services that received PCT funding in each of the eight areas used by the study.

Figure 29: Percentages of CAM services with PCT funding

Area (former Health Region)	%
London	91
Eastern	80
Trent	55
West Midlands	30
North West	65
Northern and Yorkshire	92
South East	88
South West	67
Total	**80**

Source: Wilkinson et al., 2004

Conclusions

The organisational structure for the funding of CAM through the NHS is complicated. The new drive to decentralise responsibility for funding and service provision and the emphasis on patient choice will both contribute to changes in the process of providing CAM. Nevertheless, this chapter has navigated the reader through the process that must be followed if the appropriate body wishes to provide CAM to its patient body. The first part of the chapter should be taken in conjunction with Models of Integration and Methods of Delivery, providing the basic blueprint for beginning the introduction of CAM into an integrated model of healthcare.

The picture of the current provision of CAM in the NHS was necessarily limited by the lack of a central database maintaining up-to-date information on these topics; the Enquiry would recommend that such a database would be very beneficial for both CAM practitioners and the conventional medicine community. Nevertheless, the surveys analysed present some clear findings.

First, a far larger proportion of GPs and PCTs are providing some form of CAM than may be generally appreciated. These figures have also grown over the last ten years. Whether or not these proportions will continue to grow under the frequently changing systems of funding is uncertain.

Second, certain therapies are made available by many more providers than others. Acupuncture has been the most widely NHS-provided CAM therapy for the last ten years, with osteopathy and homeopathy the other widely provided therapies. The provision of each therapy should be correlated to the therapy's treatment of specific conditions and an analysis of local needs in relation to these conditions.

Third, wide regional variations exist in the NHS provision of CAM. London and the South-East provided the greatest percentage of PCT access to CAM therapies. This regional disparity will need to be addressed by any proposal to increase the use of CAM by the NHS.

The Enquiry has focused on the costs and benefits of the five major CAM therapies. Having examined the current situation of the NHS's use of CAM, we turn to an examination of how the conclusions reached on costs and benefits from the literature review and case-study sections can begin to help address healthcare needs that are not being fully met by conventional medicine at the current time.

EFFECTIVENESS GAPS

From a public policy point of view, the ultimate aim of studying the costs and benefits of CAM therapies and their use in treating certain conditions is to identify which of these conditions are at present poorly addressed by conventional medicine. If specific CAM therapies provide cost savings with equivalent or superior benefits or, at a minimum, cost-effective additional benefits, it would be beneficial to increase the use of CAM in the NHS. The areas of "gaps" in current conventional medical provision are known as effectiveness gaps (EGs). They fall into two categories:

- Those areas of clinical practice in which available conventional treatments are not sufficiently satisfactory to patients to constitute an acceptable level of effectiveness.

- Those areas in which as yet no treatment is available, for example in vaccination against HIV/AIDS.

This chapter will focus on the former. It will examine surveys of GPs and the opinions of stakeholders in the field to identify whether and, if so, where these effectiveness gaps exist. This examination will be followed by an indicative summary of the evidence of the effectiveness of CAM therapies in the treatment of particular conditions. This evidence stems from different sources and includes this Enquiry's statements on effectiveness as covered in its literature review. Finally, we bring these two sections together (a mapping of one onto the other) to offer tentative suggestions on those conditions where effectiveness gaps are present and a CAM therapy is capable of effective treatment, thereby filling or partly filling the gap. This section seeks to direct attention to the potential reduction in NHS financial and time pressures of using CAM therapies in areas of effectiveness gaps.

Studies

The subject of effectiveness gaps is a new and little researched area of medicine. A search of the same nature as carried out for the literature review section of this Enquiry found two studies on the subject.

In one study[280] 22 GPs in London were surveyed. The scale of the day-to-day problem represented by effectiveness gaps in their practice was assessed on a ten point scale, with zero representing no problem and ten the worst conceivable problem. The average score was 5.3. Of the reported problems stemming from effectiveness gaps, 45% caused the GP difficulty more than once per week and 40% between one and four times a month, suggesting that effectiveness gaps are consistent problems in general practice.

The problems most often cited (by 20 of the 22 GPs; 91%) are caused by musculoskeletal complaints including chronic back and neck pain, fibromyalgia,[281] osteoarthritis and rheumatoid arthritis. The next most common clinical problem area, cited by 10 GPs (45%), was depression; other conditions reported were eczema, chronic pain (excluding those conditions listed as musculoskeletal problems), irritable bowel system, anxiety, stress, headache and perennial rhinitis. Figure 30 displays the most commonly reported EGs.

[280] Fisher et al, 2004.
[281] A chronic pain illness characterised by widespread musculoskeletal aches, pain and stiffness, soft tissue tenderness, general fatigue and sleep disturbances. Its cause is unknown.

Figure 30: Effectiveness Gaps reported by GPs

Clinical problem area/diagnosis	Number of GPs reporting	Percentage (%) of GPs reporting[282]
Musculoskeletal problems	20	91
Depression	10	45
Eczema	8	36
Chronic pain	7	32
IBS	7	32
Anxiety/stress	4	18
Headache	4	18
Perennial rhinitis	4	18
Other	3 or less	14 or less

Source: Fisher et al. (2004)

The reason GPs most often gave for the existence of effectiveness gaps was the lack of effective conventional treatments (40%). The reasons in full were:

- Lack of effective treatments (40%);
- Adverse effects of available treatments (17%);
- Unacceptability to patients of available treatments (13%);
- Difficulty in defining a complaint (13%);
- Poor patient compliance with available treatments (potentially linked to adverse effects and unacceptability) (9%);
- Treatment interactions (1%);
- Cost (1%).

Another study[283] surveyed 370 GPs and 50 other primary health care professionals (PHCPs) in London. Responses were collected from 149 GPs, 24 nurses and 32 other PHCPs. 171 made, or in the case of nurses and other PHCPs influenced, a referral to CAM. Figure 31 shows how these referrals were distributed among the different CAM therapies.

Figure 31: Number of primary health care professionals making or influencing referrals to CAM therapies.

Therapy	Number
Acupuncture	125
Homeopathy	120
Manual therapies	101
Therapeutic massages	43
Reflexology	12
Nutrition	14
Other	12
Autogenic training	5

Source: van Haselen et al. (2004)

The opinions of the respondents on which conditions would benefit most from a referral to CAM (respondents could name any number of conditions) are illustrated in Figure 32. This is a good proxy for those conditions for which GPs think an alternative option could benefit their patients, indicating the presence of an effectiveness gap.

[282] As GPs could name multiple effectiveness gaps this column does not sum to 100%.
[283] van Haselen et al. (2004)

Figure 32: Number of Respondents (out of 171) who believe conditions are most likely to benefit from referral to CAM.

Condition	Number of Respondents
Musculoskeletal problems / rheumatology	127
Pain	118
Headache / Migraine	105
Skin Conditions	78
Chronic Fatigue Syndrome	70
Allergic conditions	69
Poorly defined conditions	62
Gastrointestinal disorders	40
I can't judge this issue	40
Gynaecological condition	26
Respiratory disease	25
Behavioural problems	24
Malignant disease	23
Neuro-disability	21
Mental illness	20
Substance abuse / dependence	15
Other	9
Dementia / Alzheimer's	4
None	2

Source: van Haselen et al. (2004)

Cost Implications

Respondents were also asked to assess whether they thought integrating CAM into primary care would lead to cost savings or cost increases (respondents could mention as many therapies and conditions in answer to these questions as they liked).

Therapies providing potential cost-savings

Acupuncture was the therapy for which the largest number of responses recognised potential cost savings, followed closely by manual medicine (manipulation) and homeopathy. Relaxation, therapeutic massage and hypnotherapy were also mentioned as potential cost saving options, but with fewer responses. More respondents believed that herbal medicine (and reflexology, nutrition and healing) would have cost increases than cost savings (a view contrary to most others in this report); additionally, the overall numbers of responses on these therapies was far less than for other therapies.

A ranking of the CAM therapies by the number of responses and their relative favourability to the opinion that they would represent a cost saving if integrated into primary care follows:

1. Acupuncture
2. Manual Medicine
3. Homeopathy
4. Relaxation
5. Therapeutic Massage
6. Hypnotherapy
7. Reflexology
8. Herbal Medicine
9. Nutrition
10. Healing

Conditions where CAM therapies potentially provide cost-savings

The condition cited by the greatest number of respondents as likely to offer cost savings if referred to CAM was pain. The majority of respondents also did not believe that such referrals would increase treatment costs. Musculoskeletal conditions and headache/migraine closely followed pain, both showing a large majority of respondents indicating potential cost savings. There was a smaller majority in the cases of skin conditions, allergic conditions, chronic fatigue syndrome, poorly defined conditions, gastrointestinal disorders and malignant disease. For the condition groups of mental illness, behavioural problems, substance abuse/dependency, respiratory disease, neurodisability and dementia/Alzheimer's disease more responses were of the opinion that referral to CAM would incur cost increases rather than savings.

A ranking of the CAM therapies by the number of responses and their relative favourability to the opinion that they would represent a cost saving if integrated into primary care is presented in the following list:

1. Pain
2. Musculoskeletal problems
3. Headache / Migraine
4. Skin conditions
5. Allergic conditions
6. Chronic Fatigue Syndrome
7. Poorly defined conditions
8. Gastrointestinal disorders
9. Mental illness
10. Malignant disease
11. Behavioural problems
12. Gynaecological conditions
13. Substance abuse / dependency
14. Respiratory disease
15. Neurodisability
16. Dementia / Alzheimer's disease

Opinions

In addition to the two studies in the above section, a full audit would need to be done to fully assess the current gaps in fulfilling patient healthcare needs. This Enquiry suggests that such an audit would take two parts: a survey of senior figures in the NHS and Department of Health, and a country-wide survey of PCTs and GPs.[284] This is, however, outside the remit of this Enquiry.

This Enquiry set out to consult a wide range of conventional medical organisations. However, few respondents were to comment on NHS effectiveness gaps. This was due to a variety of reasons, from a lack of research knowledge in the area to an unwillingness to talk about a potentially sensitive topic (that of areas in which conventional healthcare lacks effectiveness). However, we were able to garner opinions from people associated with the following organisations:

- Maggie's Centres (for cancer suffers and their families)
- Medical Research Council, Health Services Collaborative Research Unit
- Multiple Sclerosis (MS) Society
- Arthritic Research Campaign

[284] An important point to consider is the possibility that those inside the conventional medical establishment may not be in the best place to identify gaps in the effectiveness of the system in which they operate, where there are limitations that are absent in private healthcare. This would imply that it is the popularity of health services *outside* the NHS that could be more helpful in identifying areas where NHS care falls short of patient satisfaction.

- Arthritis Association
- King's Fund
- British Medical Acupuncture Society
- National Association of Primary Care

Our aim in consulting these stakeholders was to broaden our understanding of effectiveness gaps, and respondents were asked to comment on:

- Gaps in the effectiveness of conventional medicine as provided by NHS care at present;
- Conditions which are difficult to treat (in the sense that patients keep coming back for consultations because they do not find their condition satisfactorily treated).

The support groups for patients with terminal or chronic conditions are in a strong position to identify areas where NHS therapies are ineffective in the treatment of their conditions. A representative of the MS Society pointed to the prescriptions available for sleep quality, bladder control and pain management as gaps in the effectiveness of treatment presently on offer to MS patients.

Representatives from the Arthritic Association and the Arthritis Research Campaign commented that in a general sense the NHS approach to relieving arthritic symptoms is an area of its work where it falls far short. Controlling and minimising the pain associated with acute or inflammatory arthritis is the most important effectiveness gap for this group of patients. Maggie's Centres concentrate on the emotional healing of cancer sufferers and their families. A representative stated that managing pain, the nausea associated with prescriptions and fatigue were the three key areas where NHS falls short of patient and doctor expectations. In particular, the following areas were identified as gaps:

- Breathlessness arising from lung cancer is poorly managed.
- Pain induced by breast and prostate cancer, especially cases that spread to bones, is often addressed inadequately by conventional therapy.
- Nausea and hair loss induced by the aggressive chemotherapy and quite toxic drugs administered to young men with testicular cancer.
- Debilitating effects of fatigue (they are underestimated as they are difficult to quantify).

A representative from the British Medical Acupuncture Society stated that musculoskeletal pain accounted for most of the society's members' dissatisfaction with current NHS treatment.

An interviewee closer to the GPs who encounter effectiveness gaps day-to-day was Dr James Kingsland, Chairman of the National Association of Primary Care. Dr Kingsland identified chronic pain, palliative care and mental health as the three areas where the greatest evidence for gaps in effectiveness in the NHS lies. He stated that drug therapy has limitations, particularly in pain relief to enable patients to die comfortably. Dr Kingsland also pointed out that minor mental health problems such as reactive depression and severe anxiety are those that benefit most from therapies beyond those on offer in the NHS. He also pointed out that relief from chronic musculoskeletal conditions, especially lower back pain, occupies a significant proportion of NHS pain relief efforts and that patients often feel this treatment could be improved. Dr Kingsland mentioned patients suffering from conditions that have very real physical symptoms but arise from a complex range of causes, but for which the patient has never received satisfactory treatment (somatising conditions). The attempt to address these conditions is responsible for most of the high-resource users in the NHS. These patients do not fit into any category and typically have seen three or more NHS consultants only to end up at their GPs again.

Dr Paul Dieppe, director of the Health Services Collaborative Research Unit of the Medical Research Council (MRC) had a different view of the subject. He indicated that that almost all areas of the NHS have effectiveness gaps. He said it is almost easier to identify areas where the present medical approach is rapidly improving and patients are given good levels of

attention, notably cancer care, acute medical crises, infectious disease and coronary/vascular improvement. Dr Dieppe was of the opinion that it is unhelpful to measure gaps in effectiveness by condition type or in terms of organ-specific treatment. He stated that the NHS is failing those with chronic disorders, which usually present multiple causes and symptoms. He maintained that conventional treatment is stuck in a non-inclusive observation-to-diagnosis-to-therapy framework that does not consider the patient's total wellbeing.

The case studies provided additional views on those ailments that were not being fully treated by conventional practitioners. The Newcastle integrated pilot has identified the following areas as possible effectiveness gaps through statistical analysis of local NHS referral rates: asthma, migraine, back pain, neck pain, eczema, hay fever, anxiety and insomnia. Both the Glastonbury and Newcastle case studies indicated effectiveness gaps in the treatment of musculoskeletal conditions and psychological conditions (anxiety, stress and depression). Get Well UK determined its list of conditions that GPs could refer to the clinic for by looking for effectiveness gaps. These conditions were: asthma; back, neck or shoulder pain; depression, stress or tension; headaches; hypertension; joint problems, arthritis or rheumatism; menstrual or menopausal complaints or sports injuries. Over 50% of the GPs from the Get Well UK case study referred to pain and stress management as requiring greater attention. The relatively small amount of time GPs get to spend with a patient highlighted an under-provision of counselling services, a factor identified as frequently very beneficial for many patients, pointing potentially to an EG in treating stress, anxiety and depression. Finally, many of the GPs surveyed outlined the areas where conventional treatment might more adequately deal with patients with chronic problems than at present. These chronic problems often lead to heavy use of medications and frequent visits to the GP.

Safety

The safety of CAM treatments needs to be explored fully to ensure patients and health authorities are aware of the risks and can weigh them against the benefits of treatment. Indeed a major motivating factor for patients' choosing CAM is improved safety compared to conventional interventions, a survey showed that this reason was given more than any other, including that other treatment had failed.[285]

The existing evidence is that CAM is relatively safe, especially compared to conventional drugs.[286] The cost savings to the NHS of using safer treatments is potentially very large. Even disregarding the bill to the NHS for compensation of patients harmed by conventional treatment, which is rising steeply, other costs are even more prohibitive. For example, the recent finding that the use of non-steroidal anti-inflammatory drugs (NSAIDs), used in the treatment of a range of musculoskeletal conditions, increases the risk of heart attack by between 24% and 55% (depending on the type of NSAID)[287] is of considerable cost significance to the NHS. Heart attacks are by no means the only adverse effect of NSAIDs: 2,000 deaths and 12,000 hospitalisations per year are attributable to them.[288] The costs of these adverse effects must run into millions of pounds per year. It could reasonably be concluded that at least a portion of these costs, both in money and suffering, could be saved by the use of CAM where is provides an alternative to NSAIDs (see Acupuncture, Homeopathy, Manipulation Therapies and Herbal Medicine). This could be seen as one of the reasons that certain musculoskeletal conditions are gaps in the effectiveness of conventional care.

Similar concerns have been unearthed about the antidepressant drug Paroxetine[289] and the case of Vioxx is well known.

[285] Sharples et al., 2003
[286] Prof. P. Fisher in correspondence with this Enquiry
[287] Hippisley-Cox and Coupland., 2005
[288] Blower, 1996 and Tramer et al. 2000
[289] Aursnes et al. 2005

Conclusion

From the studies and opinions we have gathered, albeit from a limited number of sources, this Enquiry finds a large measure of agreement about the main families of conditions that the NHS treats in a manner unsatisfactory to patients and practitioners, i.e. effectiveness gaps. The main gaps are:

- Musculoskeletal pain (including lower back pain);
- Arthritis (rheumatoid arthritis and osteoarthritis) and its associated pain;
- Pain complaints, acute and chronic (such as headache and migraine);
- Anxiety, stress and depression;
- Ill-defined chronic conditions and somatising[290] conditions;
- Skin conditions, especially eczema.

Other conditions were mentioned by some sources:

- Nausea (post-operative, post-dental);
- Fatigue, including chronic fatigue syndrome;
- Allergic conditions (such as hay fever).

Effectiveness of CAM Therapies

The section so far has examined surveys and opinion on the effectiveness gaps in conventional care. In order to determine whether CAM therapies can fill any of these gaps, evidence of their effectiveness must be examined in parallel. This evidence can then be considered in the light of the gaps and a process of mapping performed.

Several summaries exist of the evidence for the effectiveness of CAM therapies in treating certain common conditions. Figure 33 presents one such summary, as constructed by Professor David Peters of the University of Westminster:

Figure 33: Effectiveness Grid

[290] Patients presenting a variety of physical problems but where the cause is unclear.

Condition	Acupuncture	Homeopathy	Manipulation	Herbal Medicine
Colds and Flu		3		4 (Echinacea)
Asthma	3	3	0 Chiropractic	
Rhinitis and Hayfever	2	4		
Headache	3	2	3 Osteopathy / Chiropractic	
Migraine	3 (prevention of attacks)	3	1 Chiropractic	
Ezcema		2		
Irritable Bowel Syndrome	3	2		
Ischaemic heart disease	3 (reduces pain)			
Intermittent claudication [1]				4 (Gingko)
Benign prostatic hyperplasia [4]				5 (Saw Palmetto)
Chronic fatigue syndrome	2	3	2 (with hyperventilation)	3 (St. John's Wort for depression)
Anxiety		2		
Mild to moderate depression	3 Electro-acupuncture [5]	2		5 (St John's Wort)
Dementia				4 (Gingko)
Cancer related problems	5 (chemo-nausea)	3 (chemoRx Stomatitis)		

DEFINITELY (good evidence from systematic reviews or meta-analyses)

PROBABLY (evidence from one or more sound randomised and or controlled study)

POSSIBLY (some evidence from RCTs available: results inconclusive, studies conflicting or methods open to question)

OPINION (practitioner conviction, expert opinion or clinical experience, but no reliable research)

RUMOUR ('traditional use', but effectiveness doubted or research suggesting complementary therapy ineffective)

ANTI (some research derived evidence suggesting that this therapy is not useful in the condition)

Medical definitions:

[1] Pain in the leg (thighs, hips or calves) mostly caused by bu ild-up of cholesterol plaque in the arteries of the leg.

[2] A chronic pain illness characterised by widespread musculosk eletal aches, pain and stiffness, soft tissue tenderness, general fatigue and sleep disturbance. Its cause is unknown.

[3] The time before menopause (45 -56 years of age in women) and its associated problems such as feelings of bloating, dry skin, fati gue, not flushes, irritability, night sweats, vaginal dryness and itching, and red uced libido.

[4] A benign (not caused by infection or cancer) swelling of the prostate gland, possibly leading to difficulty in passing urine.

[5] The application of a pulsating electrical current to acupunc ture needles as a means of stimulating the acupoints .

These scores come from a hierarchy of sources, from clinical case reports to systematic reviews. The original document presents at least one source for each conclusion reached, listing over 120 references. Additionally, the table reproduced here focuses only on those therapies examined in this Enquiry's literature review: therefore, columns examining nutritional therapies and mind-body methods and hypnotherapy have been removed, as have those therapies falling under the headings of manipulation and herbal medicine that do not form part of the literature review.[291]

The grid from Prof. Peters is not the only opinion on the effectiveness of CAM therapies across conditions. There is a wide variety of such syntheses of evidence and we do not take Prof. Peters' grid as definitive. Another grid, published by the Foundation for Integrated Health in 1997, includes only about half the number of conditions as the Peters grid, but for example does include "glue ear",[292] which the Peters grid does not. Furthermore, the ratings of the quality of the evidence, which is on the same 0-5 scale, sometimes differ. For example, the FIH grid gives a five rating for evidence for herbal medicine in treating eczema, whereas the Peters grid shows a three (this could be explained by the different dates of the two grids; some evidence could have come to light in the time between the compilation of the grids).

Another view is offered in the book *The Desktop Guide to Complementary and Alternative Medicine: an evidence based approach* (edited by Prof. Edzard Ernst, 2001). The book presents evidence-based clinical evaluations of a large number of CAM therapies. There are examples of both general agreement and disagreement between the conclusions of this book and the grids above. General agreement is found about many conditions, including the following:

- Post-operative nausea — Acupuncture
- Hay fever — Homeopathy
- Lower back pain — Osteopathy and Chiropractic
- BPH — Herbal Medicine (saw palmetto)

There is less agreement about the following:

- Menopausal problems — Acupuncture
- Migraine — Homeopathy

Such differences of opinion on the state of evidence for CAM therapies stem from differences in the process of appraising the evidence. This highlights that interpretation of the same evidence is possible, even among stakeholders.

The findings of this Enquiry's literature review can also be added to the opinions on the effectiveness of CAM treatments.

Figure 34 summarises the findings from the above surveys and includes evidence from sources gathered from interviews with this Enquiry and its literature review. This summary does not address the safety of treatments, nor does it claim to be an exhaustive survey of the existing evidence in these areas, rather a short overview of the subject.[293] The focus on costs of this Enquiry report means that it has not performed a systematic analysis of the issue of efficacy/effectiveness.

[291] For example, tai chi and yoga in manual therapies

[292] Glue ear (otherwise known as otitis media) is an inflammation of the middle ear.

[293] Evidence for the effectiveness of manipulation therapies was exclusively concentrated on the treatment of back pain, and most frequently on lower back pain. Effectiveness evidence of herbal medicine is in the form of individual herbal remedies rather than the over-arching approach of Traditional Chinese Medicine. Evidence for the effectiveness of acupuncture and homeopathy is taken from the NHS Centre for Reviews and Dissemination reports on these two therapies (CRD 2001 & 2002) and from some subsequent systematic reviews, along with this Enquiry's review of literature examining the costs and benefits of these therapies.

The colours of the boxes refer to the confidence the Enquiry has of its conclusion in each area. Blue indicates a lower confidence than yellow. This Enquiry's conclusions in this area arise from a consideration both of the number of studies surveyed on each ailment and therapy combination, and the quality and strength of results presented in these studies.

Figure 34: Summary Table of Effectiveness of CAM Therapies by Condition

Condition	Therapy
Attention Deficit Hyperactivity Disorder (ADHD)	Homeopathy
Middle ear infections	Homeopathy
Lower back pain	Manipulation Therapies[294]
Lower back pain (persistent)	Acupuncture
Upper Respiratory Infections (URIs)	Homeopathy
Upper Respiratory Infections (URIs)	Herbal Medicine (echinacea)
Osteoarthritis	Herbal Medicine (Phytodolor)
Osteoarthritis	Acupuncture
Rheumatoid arthritis	Herbal Medicine (Phytodolor)
Rheumatoid arthritis	Homeopathy
Depression (mild/moderate)	Herbal Medicine (St. John's wort)
Dementia and Alzheimer's disease	Herbal Medicine (ginkgo biloba)
Benign Prostatic Hyperplasia (BPH)[295]	Herbal Medicine (saw palmetto)
Chronic Venous Insufficiency (CVI)[296]	Herbal Medicine (horse chestnut)
Cardiovascular problems	Herbal Medicine (hawthorn) for e.g. angina and congestive heart failure
Acute pain	Acupuncture
Persistent (chronic) pain management	Acupuncture
Headache/Migraine	Homeopathy
Headache/Migraine	Acupuncture
Stroke rehabilitation	Acupuncture
Post-operative conditions	Homeopathy for post-operative ileus[297] and post-operative dental recovery
Post-operative conditions	Acupuncture for post-operative nausea and pain
Post-chemotherapy nausea	Acupuncture
Skin conditions - eczema	Homeopathy
Respiratory conditions – bronchitis and asthma	Homeopathy

Mapping

The aim of this section is to combine the preceding sections on where there are gaps in conventional provision and where there is evidence of the effectiveness of CAM treatments – mapping one to the other.

In their study, Fisher et al. (2004) performed such a mapping by conducting a literature search on the effectiveness of CAM treatments in the areas in which they had found effectiveness gaps. The search found evidence from systematic (including Cochrane) reviews, meta-analyses and RCTs. The study did not formally assess the quality of the evidence found, but the authors suggest that the following treatments fill the following effectiveness gaps:

- St. John's wort in depression;
- Glycosaminoglycans (glucosomine and chrondroitin)[298] in osteoarthritis;

[294] Specifically, there is strong evidence to support the use of chiropractic and osteopathy in the treatment of acute back pain and in dealing with short-term complaints of chronic back pain sufferers
[295] A benign (not caused by infection or cancer) swelling of the prostrate gland, possibly leading to difficulty in passing urine.
[296] Pain and swelling in the leg caused by prolonged problems with vein function.
[297] A partial or complete non-mechanical blockage of the small and/or large intestine.

- Fish oil in rheumatoid arthritis;
- Psychological treatments in irritable bowel syndrome.

Figure 35 shows the mapping of evidence of CAM effectiveness taken from this Enquiry's literature review to effectiveness gaps.

Figure 35: Mapping of Effectiveness Gaps to Evidence of Effectiveness

Condition	Acupuncture	Homeopathy	Manipulation	Herbal Medicine
Musculoskeletal Pain				3
Lower back pain				
Osteoarthritis				1
Rheumatoid Arthritis				1
Post-dental pain				
Acute pain			4	
Headache Or Migraine				
Eczema				
Depression				2
Nausea (post-chemotherapy)				

1. Phytodolor
2. St. John's Wort
3. Devil's Claw
4. (Acute lower back pain)

[298] Natural substances found in and around the cells of cartilage.

Conclusion

There is general agreement from surveys of GPs and interviews with others in the conventional medical profession that gaps in the effectiveness of the conventional medical approach exist, often in chronic and ill-defined conditions. This Enquiry concludes that while some EGs are unavoidable due to a lack of effective treatment of any type (conventional or CAM), other EGs can be filled at least partly by CAM therapies, particularly in areas of musculoskeletal complaints and pain.

Since chronic complaints burden the NHS with large costs for little return in terms of patient satisfaction, it might be assumed that any effective CAM treatment would automatically provide a cost saving. However, an analysis of the relative cost-effectiveness of the present conventional treatment and the suggested CAM therapy is still required: the central focus of this Enquiry.

It could be the case that a CAM therapy could either:

- Fill an effectiveness gap, but be less cost-effective than the existing conventional treatment and on cost and benefit grounds still be considered undesirable to integrate into the NHS.

- Not fill an effectiveness gap, but be more cost-effective than a conventional treatment and on cost-benefit grounds be considered desirable to integrate into the NHS.

More research needs to be done on effectiveness gaps, where they occur, and to what extent they represent serious failures in addressing patient healthcare needs. This could lead to a targeting of research into treatments that could fill these gaps, whether conventional or CAM. This is especially important for chronic and ill-defined conditions as they have such a high economic burden. An analysis of the costs and potential benefits of the treatments to fill each gap could assist in finding where resources would best be targeted.

This chapter has emphasised the very important role that CAM could play in meeting those healthcare needs that conventional is currently not fully addressing. The Enquiry will now draw on all the chapters of the report to make conclusions and recommendations that have arisen from the literature review, the interviews and the case studies.

CONCLUSIONS

1. Effectiveness Gaps can be reduced

This Enquiry concludes that many of the most effective CAM therapies correspond to gaps in the effectiveness of conventional treatment (see Effectiveness Gaps). While rigorous cost-benefit analysis of CAM treatments for these conditions does not always exist, the very fact that conventional treatment is ineffective means that the opportunity is there for CAM treatments to improve patient health outcomes. Since patients absorb many conventional medical resources attempting to gain relief from an intractable medical problem, CAM treatments can often provide cost savings.

The main effectiveness gaps which have been identified are:

- **Chronic and complex conditions:** the most evident gaps are in the treatment of chronic musculoskeletal pain. There is evidence to support the hypothesis that CAM can offer improvements in relation to conditions where conventional treatments are either less effective or cause more side-effects than their CAM counterparts;

- **Anxiety/stress/depression**, fatigue, ill defined conditions and other conditions in primary care;

- **Palliative care:** CAM can provide a complementary role in the sense that it can provide relief from symptoms and side-effects (e.g. nausea, pain) caused by conventional care. It can provide a holistic approach to health and increase the quality and sometimes the length of life of seriously ill patients.

2. Cost savings are possible

Despite the fragmentary nature of the evidence, there exist a number of treatments for specific ailments where the implementation of CAM therapies may offer significant cost-savings to public health bodies, and to the economy more widely, and others in which additional benefits to patients may be obtained cost effectively (see Acupuncture, Homeopathy, Manipulation Therapies and Herbal Medicine for details).
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The costs:

- **Direct costs** (which would accrue to the NHS);
- **Indirect costs** (public finance costs such as unemployment benefit and time lost from work);
- **Benefits** to the patient in symptomatic relief, the ability to self treat, health improving behaviour and a range of other health benefits such as wellbeing (see Methodological Considerations).

This Enquiry has found quantifying cost savings difficult due to a lack of information. However, we have identified a number of areas where cost savings or wider benefits to the economy may result from the adoption of CAM therapies.

Manipulation Therapies

- Savings in “indirect costs”, as defined above, could be very large since the value of lost output associated with lower back pain is officially estimated at £11bn per year. The benefits to the economy and to the social service budget of returning people to work more quickly are potentially substantial although impossible to quantify at this stage.

- As an alternative to conventional treatment chiropractic has equivalent benefits but unclear costs.[299]
- As a complement to conventional treatment manipulation therapies (taken to include both chiropractic and osteopathy) have higher direct costs but generate cost-effective additional benefits according to NICE guidelines.[300]

Herbal Medicine

- Potential savings in expenditure on expensive conventional drugs.

  Examples include:
  - The average net ingredient cost of prescription anti-depressant drugs per patient in 2004 was £13.82; a weekly course of St. John's wort costs just 82p.
  - The same cost for non-steroidal anti-inflammatory drugs in 2004 was £11.82; phytodolor costs only 45p per week.

- The published evidence for the effectiveness of a number of herbal medicines is strong. The following (among many others - see Herbal Medicine) may be effective for a range of conditions:
  - St. John's wort
  - Echinacea
  - Phytodolor
  - Ginkgo biloba
  - Devil's claw
  - Hawthorn
  - Horse chestnut
  - Saw palmetto

Acupuncture

- Savings in both GP time and conventional drugs relating to the treatment of musculoskeletal conditions in primary care.[301]

- Used as a *complement* to conventional care in the treatment of the ubiquitous complaints of lower back pain and migraine acupuncture represents an increase in direct treatment costs, but additional benefits that are cost-effective according to NICE guidelines.[302]

- Acupuncture is effective in the treatment of post-operative and chemotherapy related nausea and post-operative pain, and there are strong indications of usefulness in a range of other conditions, such as osteoarthritis of the knee. Cost effectiveness data is lacking for these areas and should be undertaken.[303]

Homeopathy

- Savings in the prescription drugs bill would accrue if GPs made more use of homeopathy as a treatment option in primary care.[304]

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[299] See Bergemann & Cichoke, 1980; Johnson et al., 1989; Nyiendo, 1991; Jarvis et al., 1993; Stano, 1993; Stano and Smith, 1996; Phelan et al., 2004; Shekelle et al., 1995; Stano et al., 2002; Carey et al. 1995; Cherkin et al., 1998; Meade et al., 1990; and Skargen et al., 1998.

[300] See The UK BEAM Trial Team, 2004a & 2004b; Williams et al., 2003; Manga et al., 1998; Lagoretta et al. 2004, and CAM in the NHS for further explanation of NICE guidelines.

[301] The indications are that benefits are as good or better than conventional treatment, but no direct comparison of benefits between the CAM and conventional treatment were found. See Downey, 1995; Bourne, 1996; Myers, 1991; Lindall, 1999; and Ross, 2001.

[302] See Wonderling et al., 2004 and Thomas, 2003 and CAM in the NHS for further explanation of NICE guidelines.

[303] See Acupuncture for details.

[304] To put these savings in a national context there were 686 million prescriptions in the UK in 2004 at a cost of over £8 billion (source: Department of Health).

Safety

Although there are safety issues, CAM is relatively safe compared to conventional drugs; there may therefore be additional cost savings to the NHS due to the avoidance of additional treatments and compensation payments for patients harmed by conventional treatments. Certain musculoskeletal conditions and depression may be areas where CAM provision may replace potentially harmful conventional treatment (See Safety).

Case Studies

The case studies we reviewed also revealed some significant cost savings.

- Reduction in the number of **GP consultations**. In the Newcastle case study, consultations dropped 31% following the patients' access to CAM, in the Glastonbury case study the reduction was 33%.
- Reduction in the number of **prescription drugs**. In the Newcastle case study a 39% decrease was recorded, in the Glastonbury case study it was 50%.
- Reduction in the use of specialist **secondary referrals**. The osteopathy and acupuncture service in the Glastonbury case study showed that for musculoskeletal conditions secondary referrals fell from 47% of patients before CAM treatment to 17% after. This reduced costs by a third.

Such savings however need to be set against the costs of delivery of CAM care. Overall the picture which emerged from the case studies was a mixed one with Glastonbury for example delivering extra health benefits for reduced overall costs whereas Get Well UK and Newcastle improved patient outcomes but at additional overall costs. In conclusion, the cost picture appears to be that where CAM treatments can be supplied as an alternative to conventional medicines they will for a number of treatments as listed above result in cost savings. But, where treatments are complementary, a higher level of spending will result and the question there is whether this is cost effective in light of the extra health benefits generated. It is not possible to argue therefore, and this Report does not do so, that a general expansion in CAM will necessarily lower the overall costs of health care in the UK.

3. Regional differences are undesirable

This Enquiry has found substantial regional differences in the provision of CAM services across the UK (see CAM in the NHS). London particularly has a much greater provision of CAM services per patient and there is unevenness in coverage elsewhere too. Pockets of provision exist in certain areas, prompted, for example, by enthusiastic CAM practitioners and enlightened GPs or other health professionals, or the availability of a source of charitable funding. This points to a lack of a concerted national strategy on CAM provision, a state of affairs we find undesirable bearing in mind the benefits to patients and reduction in NHS costs CAM can provide. We do not believe the complete eradication of local differences in provision either necessary or desirable, as such differences could exist legitimately, due for example to differences in patient demands and the availability of CAM practitioners.

4. Areas of deprivation

Results from this Enquiry's case studies of non-NHS funded CAM services at Get Well UK and Newcastle PCT (see Models of Integration and Methods of Delivery) reveal the benefits of providing CAM services to the most deprived sections of society, ordinarily unable to afford such treatment when it is only available from the private sector. The benefits of CAM to people with low income and poor health are more marked, as is the reduction in the NHS cost burden of complex and chronic diseases which are more common in these groups.

5. A full assessment of the cost-effectiveness of the most promising therapies is needed

In view of the evidence which we have reviewed suggesting that mainstream CAM therapies may be able to make an important contribution to closing effectiveness gaps in NHS health care, with some attendant cost-savings, we conclude that health ministers should invite the National Institute for Clinical Excellence to carry out a final assessment of the cost-effectiveness of the therapies which we have identified, and their potential role in the NHS.

RECOMMENDATIONS

1. Prioritise Effectiveness Gaps

Effectiveness gaps need to be audited comprehensively. This Enquiry recommends that this audit be carried out in consultation with external bodies representing patient groups (such as organisations for sufferers of rheumatoid arthritis or cancer) which may in many cases be better placed to assess patient needs and the shortcomings in treatments currently available. Having identified the effectiveness gaps, a coherent research programme needs to be implemented into the effectiveness of potential treatments and their costs. It is the opinion of this Enquiry that this approach offers the best chance of driving forward the uptake of effective therapies (in line with actual demand) and helps make the most of limited research resources. The lack of a unified research agenda is currently working contrary to the interests of both patients and the research community.

Musculoskeletal and psychosocial conditions appear to represent the effectiveness gaps where greatest potential benefit to the economy could accrue and yet much work is needed to clarify exactly which therapy works best for each particular condition. The absence of conclusive, credible and comparable data (particularly on lower-back pain), producing fully costed evidence continues to hamper the adoption of CAM treatments. This Enquiry recommends that medical research councils and other funding bodies prioritise research in this area as a matter or urgency.

2. Focus future reseach

Future research into the cost-effectiveness of CAM treatments should initially be focused on the key therapeutic areas identified in this Report. Thereafter, since CAM may have considerable potential in a wider range of applications than those we have been able to consider, we urge the CAM research community to collaborate to develop a unified research agenda in order to establish a more rigorous evidence base relating to the costs and benefits of CAM therapies than exists at present. In this, the recommendations of the House of Lords report regarding research should be implemented, especially the need to foster a strong CAM evidence base through infrastructure support from higher education and companies providing CAM services, with research finance pump-primed by the NHS R&D directorate and MRC.[305]

There is currently no consensus on a base standard for carrying out research into effectiveness of CAM therapies. In order to remedy this situation this Enquiry recommends using the RCT “gold standard” where possible, but recognises the difficulties inherent in separating research from pragmatic, real-life situations. For this reason this Enquiry would support pragmatic research with demonstrable outcomes which can be trusted by all stakeholders. This would include comparative research into the effectiveness and benefits of competing (conventional/CAM) therapies. The range of costs and benefits of treatments should be the widest possible within the bounds of practicality and should include, for example, the effect on returning people to work, reducing their dependence on carers and improving their sense of wellbeing and that of their families.

A consistent, agreed set of research approaches will foster a sense of trust in the PCT community and provide information which will allow both patients and GPs to make informed decisions. NHS resources are limited. Research resources are similarly constrained. Only through the development of a structured research schedule will stakeholders be in a position to reap the huge potential that this report has highlighted.

[305] Ernst et al. (2005)

3. Target deprived communities

The weighting towards private delivery of CAM tends to disadvantage patients from more deprived social groups. Arguably these groups are more in need of CAM as they tend to present more complex, chronic conditions than the average patient. Equitable access to therapies (especially where demonstrable benefits or cost-savings can be derived) should be encouraged, and service providers like Get Well UK are showing the way. In the case of limited CAM resources in an area it is to these groups that services should be aimed first.

Case studies examined and carried out by this Enquiry suggest that innovative ways of achieving provision of CAM to deprived areas are being developed. These projects have typically been sustained through non-NHS funding. This Enquiry believes that a greater financial commitment from national health funding bodies should be encouraged. Such funding will increase commitment to CAM at all levels and demonstrate the value of CAM therapies and establish their place in the NHS.

4. Promote regional equality

Health authorities and GPs in under-provided regions should consider increasing their provision of mainstream CAM therapies in those regions of the UK, particularly in the North of England, where access is largely denied to people, and where deprivation is more widespread than in the South.

5. Keep GPs as gatekeepers

The GP's role as "gatekeeper" should be maintained as far as NHS provision of CAM therapies is concerned so that potential conflicts between CAM and traditional therapies can be minimised, and because of the NHS strategy of channelling budgetary decisions through a practice-based commissioning system.

The GP role as gatekeeper is crucial to maintain cohesion in national health provision by allowing GPs to recommend appropriate treatment. Patients referred through their GPs report higher levels of satisfaction (see the Newcastle Case Study in Models of Integration and Methods of Delivery). This Enquiry fully supports the current referral system, and recommends that this should become the established route to CAM treatments. This referral path increases public confidence while minimising contraindications and potential conflicts between CAM and traditional therapies (for example, drug interference in the case of herbal medicine). Given the NHS strategy to channel budgetary decisions through a practice-based commissioning system by 2008, buy-in from GPs is likely to become an increasingly important driver of CAM provision (See Allocation of Funds, CAM in the NHS).

6. Remove barriers to GP referral to CAM

It will be increasingly important to remove a series of barriers which may stand in the way of GP referrals, including:

Clarity
Lack of clarity regarding CAM treatments is a significant barrier to GP referral and PCT support. GPs and patients need clear and unambiguous information regarding the CAM evidence base, the validity of CAM stakeholder claims, and safety. As the NHS continues to support the agenda of increasing patient choice, clear and responsible information sources become increasingly necessary.

Safety

Safety fears remain significant barriers to CAM uptake and should not be underestimated. Large scale RCTs need to be done to determine the unusual side effects that will only become manifest in trials with very large sample sizes. Established safety figures and contraindications need to be available for all five therapies and their specific treatments. However, it should be noted that a significant factor motivating patients towards CAM is a higher level of safety compared with existing interventions.

Legality

There needs to be clarification of who is liable if patients decide to sue as consequence of injury or dissatisfaction. GPs are currently concerned that as "gatekeepers" they are legally liable, even if practitioners carry indemnity insurance. In fact they can only "delegate care" to a non-statutorily registered practitioner and retain some of the responsibility for that patient when doing so; how much is unclear. Bodies like the Medical Defence Union and the British Medical Association need to issue clear guidelines once this legal "grey area" is cleared up. Otherwise, statutory regulation would solve the main difficulty and allow GPs to refer completely care and legal responsibility to a CAM practitioner.

Regulation

The formation of statutory bodies for homeopathy, acupuncture and herbal medicine[306] is very desirable and should occur as soon as possible, as recommended in the House of Lords report.[307] These regulatory bodies at their best would serve to drive up and maintain professional standards.

Education

The increased introduction of CAM in undergraduate and graduate medical degrees helps to familiarise GPs with the therapies and their applications and should be encouraged. Additionally CAM courses are being offered as part of some continued professional development courses and this should be extended.

[306] Both osteopathy and chiropractic have gained statutory regulation.
[307] Recommendations 6, 7 & 8 in House of Lords, 2000

APPENDIX A: SUMMARY OF INTERVIEWS

Introduction

The Enquiry conducted interviews with leading stakeholders in the field of complementary and alternative medicine. The interview sample cannot claim to be a comprehensive and representative cross-section of opinion but, like the literature review, a pragmatic approach was taken; a shortlist of around ten interviewees were approached having been identified from their frequency of appearance in initial research and referral by other stakeholders. Again, the constraints of time and scope limited the composition of the sample which, had it been intended as representative, would have included a body of neutral, sceptic and anti-CAM opinion. However, the stakeholders contacted were useful in their primary function, in allowing the Enquiry to gain a broad and informed picture of the CAM field more rapidly than a more forensic approach would allow.

These caveats aside, the interviews covered a variety of topics, but focused on the following:

- The evidence base for CAM
- Appropriate methods for analysis of costs and benefits
- Opinions of models and methods of integration
- Regulation of CAM and issues of safety
- The future for CAM research
- Effectiveness Gaps and the relevance of CAM

The Enquiry interviewed the following individuals:

- Dr Peter Fisher, Clinical Director, Research Director, Royal London Homeopathic Hospital
- Dr Kate Thomas, School of Health and Related Research, University of Sheffield
- Professor David Peters, University of Westminster, School of Integrated Health
- Dr Sharma, The Diagnostic Clinic
- Professor Mike Saks, Pro Vice Chancellor, University of Lincoln and Chair of the Research Council for Complementary Medicine (RCCM)
- The Lord Colwyn, House of Lords
- Professor Peter Littlejohns, Clinical Director, National Institute for Health and Clinical Excellence
- Dr John Appleby, Chief Economist, King's Fund
- Dr Michael Dixon, Chair, NHS Alliance
- Professor Nicola Robinson, Centre for Complementary Healthcare and Integrated Medicine, Thames Valley University

This section summarises the main opinions from the interviews. Readers interested in a more detailed summary of each interviewee's viewpoints will find this information in Appendix B.

Clinical Evidence

There was general agreement that three separate research questions could be posed for every treatment. First, mechanism of action, describing the science of how the treatment works on a particular condition. Second, its efficacy, examining the specific effects of a treatment on a specific health outcome. Third, its effectiveness, examining the treatment in a real-life setting and measuring a fuller set of health-related outcome measures. One opinion was that the concept of effectiveness has been utilised by the CAM community to avoid proper examination of its treatments. On the other hand, another view was that the distinction is meaningless, both questions attempting to test whether a treatment has a beneficial effect on a patient.

Opinion on the relative importance of the different research questions was divided. It was generally agreed that an analysis of the mechanism of action, while beneficial, was less important at this stage of the evaluation of CAM therapies. While some interviewees believed that efficacy was the only question worth examining, and thus promoted the necessity of RCT data, others advocated a more pragmatic approach that would not discard good evidence that may be of a different sort, for example more qualitative data.

Cost Effectiveness

The general opinion expressed was that clinical evidence needs to be examined before costs and benefits are considered. There was general agreement that the costs and benefits of health interventions should (where applicable and if possible) be analysed in their widest possible sense, including the effects on a full range of patient health outcomes, as well as their wellbeing and satisfaction with treatment. Additionally, many interviewees emphasised the importance of including the wider impact on a patient's carers and family, as well as the effects on society, for example, the economic costs of time off work. Considering the wider costs and benefits to society led some interviewees to advocate a realigning of public funding from treatment of disease to prevention of illness, many believing that CAM therapies could have a role in this change.

Several interviewees stated that using CAM treatments would reduce expenditure on health, saying that CAM treatments predominantly treat patients with chronic conditions for which conventional medicine is either expensive, ineffectual or absent. A minority believed that while this conclusion seemed likely to be correct, the time taken by CAM practitioners to treat patients and its associated costs might negate any cost savings. What was universally accepted was that there is at present a paucity of research on the economic evaluation of CAM therapies. However, one interviewee suggested that for a remedy such as St. John's wort, where clinical evidence of efficacy is strong and the cost of production below comparable pharmaceutical products, cost- effectiveness is almost assured.

Integration

There was some considerable disagreement on the topic of integration. Some interviewees insisted that in a health service using evidence-based medicine, a treatment is either backed by evidence and considered the most appropriate to use (in terms of efficacy and cost) or not, and that this should apply equally to CAM and conventional treatments, rendering the idea of "integrating" the two meaningless. Others accepted the distinction and suggested ways to reconcile different approaches to healthcare within one system. Others saw a need to transform the healthcare system, with a greater onus placed on issues of diet, diagnostic prevention and natural remedies, creating a holistic approach that makes explicit use of people's self-healing processes. CAM therapies could help move the health system towards this direction.

The difference between a "transformative" model of integration (whereby the conception of holistic healthcare would become central to the health system) and an "incorporative" model (which sees CAM treatments offered simply as other treatment options) was frequently stressed by the interviewees. Most of those interviewed believed that integration would be advisable and achievable if carried out slowly, starting with "side-by-side" provision of CAM and utilising referrals to CAM practitioners. They said that integration of CAM into mainstream healthcare would increase mutual understanding of treatment possibilities and also counter the belief by any discipline that it can cure everything. The majority proposed a flexible approach to integration, with the method of delivery and model of integration dependent on the treatment, the condition and local institutional factors.

The importance of practical considerations was frequently stressed. Practice-based commissioning was proposed as a potential way of letting GPs provide access to CAM where they and their patients see fit. This would enforce the GP's role as "gatekeeper" to CAM

therapies, changing the present situation in primary care where the patient conducts his/her own referrals. It was also noted that cross referrals between disciplines, conventional to CAM and vice-versa, and between CAM therapies, are rare. Another idea put to the Enquiry was of a "third sector", brokering treatment agreements between CAM practitioners and health service administrators. The sector would be run as a network, with a central body overseeing matters such as the regulation of practitioners and the setting of standards. Providing information and training on the workings of the NHS to graduates in CAM subjects was also put forward as a useful addition. A further suggestion by some interviewees was that integrated CAM practitioners should be salaried, so as to begin to remove any incentive to treat patients more than is required.

Regulation and Safety

There was substantial agreement on the issues of regulation and safety. It was recalled that the recommendations of the House of Lords report in 2000 had not led to statutory regulatory bodies for homeopathy, acupuncture or herbal medicine, even though the report has led to a developing programme on regulation. Many interviewees believed that the march to increased regulation, both of practitioners and of remedies, should be supported, and local difficulties overcome. The view was put forward that regulatory bodies should have the ability to strike off a member for malpractice or for making outlandish claims; similar powers are held by the regulatory authorities for homeopathy in Germany.

The view was expressed by several respondents that while CAM treatments in themselves are usually low risk, the greater danger is the indirect risk of patients not receiving suitable conventional treatment due to their use of CAM. The desirability of including safety as a component of studies of effectiveness or efficacy was pointed out, and it was suggested that RCTs are often not the most appropriate vehicle for this, as very large sample sizes are needed. It was pointed out that there is no yellow card system for CAM treatments like that for pharmaceutical products.

Future Research

Almost all interviewees expressed the belief that the funding of CAM research was inadequate. While some interviewees felt that those working in the field have too frequently focused their efforts away from examining efficacy and safety in favour of effectiveness, the general feeling was that CAM was eager to be examined in the appropriate ways, once the methodological concerns that are especially relevant to CAM were considered. Many interviewees highlighted the important role that NICE will play in any future attempts to increase the utilisation of CAM therapies on the NHS. Finally, there were several suggestions that greater coordination of research into CAM should occur, as too frequently the research is patchy and determined by the funding body's goals, not the interests of either those in the field or (more significantly) patients' healthcare.

APPENDIX B: INTERVIEW SUMMARIES

Dr John Appleby, Chief Economist, King's Fund, 6th May 2005

Clinical Evidence

Dr Appleby started by pointing out that there is not enough clinical evidence in the field of conventional medicine, and researchers would do better filling the gaps here first before turning to more minor concerns such as CAM. He remarked that the clinical evidence base for CAM is poor and that even when RCTs have been performed they are often statistically underpowered. He pointed out that the quality of the journal in which a study is published is very important, there being many studies published in less reputable journals, which can reduce their credibility almost to zero.

Dr Appleby remarked that a reason for the lack of high quality clinical evidence for CAM is the lack of opportunity to patent any of the treatments, in contrast to pharmaceutical products for which there are many more financial incentives to attract those funding research. Dr Appleby did not recognise a difference between efficacy, which RCTs test, and effectiveness. He noted that evidence on the mechanism of action of a treatment is desirable, for example when researching different uses of the drug and its side-effects. This evidence is not however necessary for the treatment to be used (the mechanism of action of aspirin for example has only just been fully explained). Dr Appleby thought that the level of evidence for CAM treatments should be same as for any other.

Evaluation of Costs and Benefits

SI pointed out that public money could be profitably used to fund CAM research if the benefits of CAM treatments were to reduce NHS spending significantly. Dr Appleby acknowledged that a judgement depends on the limit set on the benefits to be considered. This limit could be set to include only those benefits that accrue to the NHS directly (reduction in medication expenditure for example), it could include social security transfers like sick pay (though these payments are transfers from one part of the social security system to another), or it could include benefits to the whole economy, i.e. reduction in lost output (though this raises the issue of equity: including these benefits values the health of the working population more than the retired or unemployed).

Dr Appleby stressed that benefits need to be transferred into QALYs in order to compare the effectiveness, and cost effectiveness, of different treatments and therefore make judgements about where to target NHS expenditure. SI pointed out that in some cases CAM treatments provide small measurable relief of symptoms, but large increases in wellbeing. Dr Appleby stressed that the different benefits: from biological, symptomatic relief; to increases in psychological wellbeing; to fewer sick days; need to be assessed according to society's valuations, i.e. if people value complete symptomatic relief more than a week more of productive work, this should be reflected in the relative values used in calculation of QALYs and therefore of NICE recommendations on cost effectiveness.

Benefits to Include

A related point on the benefits obtained from CAM treatments, not from symptomatic relief, but from increases in wellbeing was made by Dr Appleby, who noted that process utility, where patients gain benefit purely by the process of treatment rather than its outcome, has been studied, though he is sceptical about its veracity.

Dr Appleby remarked that the boundaries of what is considered a matter for healthcare have widened. Dementia is now seen as a disease to be treated rather than an accepted part of the ageing process. Dr Appleby considered that this widening might allow CAM into the health

system more readily as they might bring benefits in these areas previously not strictly covered by health.

The Lord Colwyn, House of Lords, 23 March 2005

Introduction

After the interviewers introduced themselves and the Smallwood Enquiry, Lord Colwyn gave a short history of his involvement in the CAM field which started after his conversion from medical to dental training, treating nervous dental patients and using nutritional therapy. The interest expanded into treating migraine and other stress related conditions using the same methods, working with George Evershall, and then onto homeopathy and acupuncture, also taking in cranial osteopathy. Lord Colwyn recalled the 18 month project leading to the publication of the Sixth Report of the House of Lords Scientific Committee in 2000, remarking that he and Earl (Edward) Baldwin were co-opted to the committee for their CAM expertise in the House of Lords, but that the present president of the All Party Group concerned with CAM, David Treddinick MP, is the parliamentarian with the greatest knowledge on the subject. Lord Colwyn suggested that SI would profitably consult on their project Earl Baldwin and Mr Treddinick, and also Simon Mills, a CAM practitioner the House of Lords Committee appointed as a specialist advisor.

Regulation and Integration

The conclusions of the House of Lords report were discussed, SI having taken it as a starting point for its research. Lord Colwyn remarked that the report had not achieved as much as he would have liked, for example the moves of the acupuncture and herbal medicine communities towards single statutory regulatory bodies are still not complete, despite the report's recommendations. Lord Colwyn said he believed all CAM therapies should be statutory regulated (like chiropractic and osteopathy are at present). On another House of Lords report recommendation - on increasing the funding of research into CAM - Lord Colwyn suspected that he felt the situation has not changed markedly since publication of the report five years ago.

Lord Colwyn highlighted the danger of therapists believing they can treat all complaints, without referring to other CAM practitioners or conventional medicine, recalling a personal experience of chiropractic treatment he received for a neck injury that a neuro-surgeon later judged dangerously inappropriate. Lord Colwyn maintained that the integration of CAM into conventional care, with GPs acting as gatekeepers to well-evidenced CAM therapies, would counter this tendency. Another plank of a well-integrated health service would be the education of medical students at undergraduate level in CAM therapies to enable GPs of the future to make use of CAM where appropriate. Lord Colwyn said GPs should know of the CAM practitioners in their area and should consider them early in the treatment deliberation for a patient.

Effectiveness and Cost Effectiveness

SI introduced the subject of cost-effectiveness as the main focus of their report. In Lord Colwyn's opinion CAM therapies should be cost effective, especially in the area of back pain for example, but are probably not, due to the extra time taken over treatment compared with conventional care. SI brought up the question of the clinical evidence of CAM, which it sees as a necessary precursor to cost effectiveness work. Lord Colwyn made it clear that much of this evidence is anecdotal, and that the nature of CAM, with its treatments individualised to each patient, does not lend itself to the classic double-blinded RCTs. However, he conceded that it is just this sort of trial that could determine whether a treatment is cost effective.

Holistic Healthcare

Lord Colwyn suggested that health could be seen in terms of stresses on a person. If the accumulated stress, expressed in social, skeletal, nutritional, environmental, dental and other stresses, exceeds a threshold the person will experience symptoms; preventing this is an

important medical aim. Diagnostic screening such as kinesiology,[308] which Lord Colwyn uses in his own dental practice, can be very useful in detecting problems, but research into its mechanism of action is under resourced. Lord Colwyn mentioned that the Natural Medicine Authority, of which he was the president, has unfortunately folded due to lack of funds.

Lord Colwyn saw nutrition as hugely important in health, with its link to cancer for example very strong; so important in fact that Lord Colwyn speculated that the effect of Jamie Oliver's recent campaign for healthier school dinners could be the most influential piece of health policy in the last thirty years, providing as it does an impetus to put into effect changes in children's diet that have been known to be beneficial for many years, but never concertedly addressed.

Political Considerations

The discussion turned to the political situation regarding CAM and what this could mean for the Smallwood Enquiry. Lord Colwyn advocated the de-politicisation of healthcare in the UK. Since governments of any colour rarely look beyond the five-year period of a parliament they do not act in the long term interest of health policy which needs changes that will bear fruit in decades to come (for example altering childhood nutrition to reduce adulthood diseases). Lord Colwyn acknowledged the need in the end to change the current approach to healthcare with a more holistic approach to health, but did not consider the political impetus for this as strong. Lord Colwyn predicted that the funding of UK healthcare would change, with a greater role for insurance schemes. He advocated an approach that would allow CAM to be provided on a sliding-scale, with the poor paying less or none of the treatment costs.

Lord Colwyn advised the Enquiry that their report should not necessarily endorse what is seen as the more extreme forms of alternative healthcare, such as kinesiology, but that to advocate integration into the NHS of therapies classed as group-one by the House of Lords would be advantageous. He agreed that evidence on efficacy/effectiveness should precede cost-effectiveness, which could in the end lead to increased provision in the NHS.

[308] The use of muscle testing to identify imbalances in the structural, chemical, emotional or other energy of the body.

Dr Michael Dixon, Chair, NHS Alliance, 10th May 2005

Under the new funding arrangements for the NHS control of budgets has moved from Health Authorities to PCTs: large, conservative organisations which are strapped for cash (as new funding has been soaked up by wages? etc.) and bound by centrally set targets, often regarding secondary care.

The NHS Alliance set up a hypothetical PCT board, including a CEO and CFO of existing PCTs. When questioned individually about the desirability of funding CAM therapies they were positive; however when making a collective decision, imagining they were controlling a PCT budget, they came to the opposite view.

Payment by Results

There is now a fixed, national price for secondary care procedures on the NHS. This provides at last clear opportunity costs of secondary care items, i.e. what could be saved by not purchasing the secondary care service and treating the patient in primary care instead. This clarity could lead to some hospital out-patient appointments being forgone in favour of primary care treatment.

Foundation Trusts already have commissioning power for emergency care and elective secondary care, but with other PCTs, who do not yet have this autonomy, the balance of power is with the provider of services (NHS acute trusts and similar), which has led to large increases in the costs charged to PCTs for secondary care.

An article, “Caveat Emptor”, published on the NHS Alliance website details how easy it is for acute trusts to game the present system, meeting targets by apparently perverse behaviour (such as admitting A&E patients to hospital just before the target A&E waiting time). There are anomalies in the system (such as the payment for a patient with a DVT being hardly higher that for a similar but harmless cyst that requires no treatment); these will have to be cleared up before PBR can be extended to all PCTs. When it is the system should give more clout to PCTs in purchasing negotiations.

Practice Based Commissioning

There are two elements to this initiative. One is to trim budgets for existing services by making efficiency savings such as purchasing services locality-wide and thereby making economies of scale.

The other is to redesign services and their pathway, perhaps including an element of CAM, in order for the whole approach to be more cost effective that the original.

Patient Participation

Patient Participation Forums, which have a say in PCT decision making, are fairly ineffectual, with NICE recommendations about treatment provision trumping their views. But Patient Participation Groups at practice level should have more influence, especially under PBC. The new GP contract will give GPs an incentive for a strong patient contribution as under the contract GPs will be rewarded financially by more/happier patients?

In practice a solution to any differences in opinion between patients and NICE recommendations will be to offer a range of choices along the treatment pathway.

Structure of PCT decision making apparatus

The Clinical Executive of the PCT is made up by two parts: non-executive directors (like a public company) and the PCT itself (run by a management board headed by the Chief

Executive?). The Statutory Committee of the PCT is made up of local Clinicians (mostly GPs, also nurses and others) which is fairly ineffective at the moment, but should come into its own with the advent of PBC.

Effectiveness Gaps

Chronic conditions most clearly fall into this category; by definition they cannot be cured and CAM can often manage them more effectively (and cheaply). Particularly: musculoskeletal pain (mostly back, neck); all the types of arthritis; migraine and headache; irritable bowel syndrome (IBS); a number of skin conditions, particularly eczema; depression/anxiety/stress; ME; and those patients with a long list on symptoms, apparently unrelated, and probably with a psychological cause.

Conclusion

PCTs want to see evidence that CAM treatments will *reduce* their budgets (not provide better treatment at extra cost, even if the treatment is in the range of cost per QALY in which NICE requires less justification to recommend a treatment). The Department of Health is worried that CAM will increase NHS costs; it needs to be convinced that in fact it has the potential to reduce strain on primary care. The Wanless Report on the future of the NHS, and particularly its scenario of patients “fully engaged” in managing their own health, should be consulted on this subject as it puts figures on the costs savings to the whole NHS if patient were to act this way.

Suggestions for the Smallwood Enquiry

To suggest a simple process/methodology that can be followed by researchers to gather the evidence required by PCTs, i.e. that CAM treatments reduce costs compared to conventional care.

To explain why the research on the cost effectiveness of CAM has not yet been done, identifying any obstacles past or present, and suggest ways to overcome them.

Dr Peter Fisher, Clinical Director, Royal London Homeopathic Hospital, 7 March 2005

After an introduction to the Smallwood Enquiry from SI, Dr Fisher noted that in spite of the UK focus of the Enquiry, there are good quality French and German studies on the cost-effectiveness of homeopathy (including a recent French study by Trichard published in the journal Homeopathy). Dr Fisher was of the opinion that it is currently difficult to examine the cost-effectiveness of integrated healthcare projects given the lack of clear and easily available cost data.

RLHH background

Dr Fisher reported that the RLHH is moving back to Queen's Square in late May 2005 as a full part of University College London Hospital (NHS foundation trust). (The RLHH joined UCLH in 2002.) He noted that the RLHH has been part of the NHS since its inception in 1948 and is the biggest public sector provider of CAM in the world. It does not just provide homeopathy – it also provides other CAMs. A recent focus has been on manipulation and acupuncture. Herbal medicine is likely to be the biggest growth area for the RLHH in the near future. It was the first NHS centre to offer complementary cancer treatments (since the 1960s), acupuncture (since the 1970s) and musculoskeletal treatment since 1995. There has been rapid and friendly integration with the UCLH.

Individual studies

Acupuncture

SI asked about current evidence on CAM therapies. Dr Fisher cited the recent trial by Wonderling/Vickers, a pragmatic study of acupuncture for headache/migraine, as a good example of CAM cost effectiveness literature. He reported that the acupuncture led to big improvements in patient benefit and was highly likely to be cost effective given reduced medication usage, fewer referrals and less time off work. The costs compared were approximately £300 for conventional treatment against £600 for acupuncture. Dr Fisher acknowledged that this trial has been criticised for lacking placebo control (it was a pragmatic trial).

Homeopathy

Dr Fisher pointed to a series of French studies on childhood upper respiratory tract infections (URTI) that showed that homeopathy shifted co-payments in reimbursements from doctor to patient, which the French government might like (but the result might be difficult to compare with the UK situation as the systems are so different). The French government has recently cut public spending on homeopathy. Dr Fisher suggested this may be because the French health system, although rated by the WHO as the best in the world, is very expensive. Homeopathy might be seen as a soft target for cuts. There are about 10 times as many homeopathic GPs in France as in the UK (and more doctors overall) but in France homeopathy is rigidly excluded from hospital practice and academic medical system.

Dr Fisher also mentioned studies by Walach & Güthlin at Freiberg University and Becker-Witt in Berlin as useful examples of the literature on the cost effectiveness of homeopathy. The French and German studies agree that integrating homeopathy into primary care leads to better outcomes for the same cost.

Types of evidence (homeopathy)

SI began a discussion on the different types of evidence for homeopathy, their present state, and where they lie in relation to the Smallwood Enquiry.

Mechanism of Action
In Dr Fisher's opinion the Benveniste affair was a setback to homeopathy, because it associated homeopathy with "pseudoscience". Although Benveniste's method proved irreproducible, subsequent studies have shown that, a similar method produces reproducible positive results (Belon et al 2004). The water memory idea is physical rather than chemical; this can be illustrated by the floppy disk metaphor: chemical analysis of a floppy disc would find only chemicals (vinyl and ferric oxide) the information it carries is in a physical form – the alignment of the dipoles of ferric oxide. The methods used by the Horizon experiment are unknown – they have not been published or subject to peer-review, although it is known (from a Brazilian TV programme!) that it involved 80 repetitions of the experiment compared to 6,000 in the positive study of Belon et al. The Belon experiments were published in a scientific journal (Inflammation Research), following rigorous peer review. Dr Fisher noted that homeopathy is the most difficult of all CAM therapies to accept from a traditional scientific standpoint, because of its use of "ultramolecular" dilutions.

Efficacy
PF cited two global meta-analyses that have shown that homeopathy has a benefit above that of placebo (Linde 1997 and Cucherat, European Commission 2000). These were conducted independently but came to similar, positive, conclusions.

Effectiveness
In discussing the contested evidence regarding the mechanism of action and efficacy of homeopathy, Dr Fisher averred that the key in research is to prioritise the question the study is trying to answer. He recommended that SI steer clear of tackling the issues of efficacy and the mechanism of action, and instead concentrate on questions of effectiveness (where efficacy is defined as a "specific physiological response to either a chemical entity or therapy and how that would work under ideal circumstances", while effectiveness is the "outcome that can be observed and demonstrated where it is delivered"). Dr Fisher maintained that the question of whether homeopathic "ultramolecular" dilutions have real biological effects is better settled by laboratory experiments than by RCTs.

Complementary vs. Alternative

Dr Fisher explained that whether or not CAM therapies are substituted for conventional treatments varies from disease to disease. From evidence collated at the RLHH, use of CAM for those with skin disease is almost entirely alternative. For musculoskeletal problems, rheumatoid conditions and respiratory diseases it is mainly alternative. For cancer, it is entirely complementary.

Current Integration

SI turned to the concept of integration of CAM and conventional treatments. Dr Fisher noted that integration of CAM within the NHS is increasing. The contracts with PCTs and payments by patients (i.e. zero for prescriptions if you qualify on means-tested standards) are exactly the same as those for conventional treatments, when they are used by health professionals working for the NHS. The difficulty with herbal medicine is that GPs are unwilling to prescribe them and patients buy the remedies themselves from shops. In addressing the question of models of integration, Dr Fisher identified three models:

1. A CAM doctor would sit in primary/secondary care consultations, for example in a cancer clinic. (SIDE-BY-SIDE)
2. Education: i.e. GPs train to be able to administer certain CAM treatments or to better understand when and to whom to refer patients. This includes teaching CAM to midwives and a five-day CAM treatments course April 2005 at RLHH. The RLHH, in partnership with the Research Council for Complementary Medicine is to provide the CAM section of the NHS National Electronic Library for Health (NELCAM) website.

Although primarily aimed at medical practitioners this library is linked to NHS Direct. (EDUCATION)

3. A fully-integrated CAM and conventional service for a condition, which would be a significant change in the approach to healthcare. For instance the proposed integrated pain clinic involving the National Hospital for Neurology and Neurosurgery (the UK's leading centre for Neurology) and the RLHH (INTEGRATIVE)

Dr Fisher felt the ideal model of integration would incorporate all three of these elements, culminating in a situation in which GPs would be able to administer CAM themselves and knowledgeably refer to independent CAM practitioners.

Safety
Dr Fisher emphasised the importance of safety issues: while direct side effects of CAM might be less serious than for conventional medicine, there may be indirect side-effects (the risk of patients achieving a lower health outcome by virtue of not taking conventional treatments). Dr Fisher noted that homeopaths, unlike the other big-five CAM therapies, have not followed the House of Lords' advice to form a professional statutory body and said they should. That they have not may be due to disagreements between different bodies representing homeopaths who are not registered health professionals Dr Fisher compared the UK situation with Germany, where it is illegal to practice medicine without a licence. "Heilpraktikers" (health practitioners) are permitted to practice after a fairly basic training, but they are licensed and registered can be struck off in the event of malpractice etc. The problem with voluntary self-regulation as currently proposed for instance by the UK non-medical homeopaths, is that it has no such "teeth". Where there is more regulation of the profession it is better able to counter untenable claims by some homeopaths who for example oppose vaccination (incidentally this goes against the tenets of homeopathy and vaccinations were embraced by Hahnemann, originator of homeopathy).

Academic Research

Dr Fisher saw this as very important for CAM and the partnership of the RLHH with the UCLH/UCL will advance this cause. He alerted SI to an increase in hostility towards homeopathy in recent years due to people's perception of the underlying science and some of the exaggerated claims of some practitioners. It is very important for Dr Fisher to define the difference between the credible and the non-credible claims of homeopathy.

In evaluating CAM therapies, Dr Fisher thought it important to consider the full range of benefits, i.e. the humanistic considerations that exceed the pure clinical benefit, for example a trial that saw increasing parents' quality of life and peace of mind by averting the need for Ritalin in children with ADHD by using homeopathic treatment (Frei and Thurneysen, 2001b) (see Homeopathy for more details of this study).

Effectiveness Gaps
The Smallwood Enquiry (SE) asked about future progress and Dr Fisher advised scanning for effectiveness gaps in conventional treatment and mapping them to the areas in which CAM treatments can be effective. Chronic pain for example is a fast growing problem: conventional drugs can be dangerous and have substantial side-effects. The RLHH conducted a research project identifying effectiveness gaps – ailments GPs have trouble treating and for which CAM therapies can be helpful (mainly chronic complaints, e.g. musculoskeletal complaints and URIs in children) (Fisher 2004).

The RLHH would recommend identifying niches for certain therapies in the House of Lords therapy groups 2 and 3. For example, aromatherapy has proved very useful in calming elderly patients with dementia. This highlighting of niches was seen as important in setting NHS spending priorities.

Professor Peter Littlejohns, National Institute for Health and Clinical Excellence, 19th April 2005

Introduction

Professor Littlejohns was contacted in his capacity as a private individual with expert knowledge; he wished to make it clear that opinions were his own, and did not reflect the will of NICE, which would have required extensive consultation to establish. SE outlined its integrated health project and how talking with NICE fitted into the project framework. Prof. Littlejohns outlined the role of NICE. The final decision on what NICE assesses is determined by the Department of Health and the Secretary of State for Health. However, all interested parties (health committees, professional bodies, members of the public, etc.) can bring items to the attention of the DOH. Once NICE is given its work programme it functions independently of the DOH and Government. The core responsibility of NICE is to develop systems of analysis in order to issue guidance to the NHS on the clinical and cost-effectiveness of health care interventions. This guidance is in three main areas: technology appraisals (use of new/existing drugs, healthcare interventions, etc.), clinical guidelines (scope to look at a broader approach to the appropriate treatment and care for specific ailments) and interventional procedures (looking at the safety and efficacy of procedures). Prof. Littlejohns highlighted NICE's future intention to examine public health interventions, for example in obesity and smoking prevention and cessation.

Efficacy and Effectiveness

SE brought up the differing concepts of efficacy and effectiveness. Prof. Littlejohns defined efficacy as showing a treatment that works in a trial setting (that does "what it says on the packet"). For example, if it aims to lower blood pressure, it does that specifically. Effectiveness is defined as working in a real-life setting. For example, if a tablet is efficacious but tastes awful and is never taken by patients, it is not effective.

Prof. Littlejohns explained that key difficulties in assessing effectiveness data in developing clinical guidance is the placebo effect and minimising bias , hence the emphasis on using RCT data. However trials are often not appropriate to assess long term outcomes or side-effects.. Prof. Littlejohns expressed the view that RCTs were not the only form of acceptable data..

Making Judgments

SE asked about the process for making judgments in developing guidance . Prof. Littlejohns stated that first there are criteria for working out the quality of studies (inclusion criteria), and that NICE would balance the strengths and weaknesses of different studies. However, there is no rigid approach to the number or type of study that must be met to be positively assessed. Secondly, NICE separates the assessment of evidence from the appraisal. The appraisal committee will incorporate ideas and viewpoints from a wide variety of stakeholders, including professional groups, patient groups, health economists, public health experts, etc. Thirdly, any guidance document will include a consideration section outlining how the evidence was balanced and how decisions were arrived at. Finally, a consultation process exists whereby interested parties can have their say on the guidance and further discussion can occur.

Cost-Effectiveness

Prof. Littlejohns explained that one of the most important tasks carried out by NICE was making recommendations on cost-effectiveness of treatments. The main approach used is a cost-utility analysis, examining cost per quality adjusted life year (QALY) as an outcome. In addition, consideration is given to issues of fairness, equity, to the quality of the data, to whether or not the intervention is the only one available for a certain ailment. Although there

is no threshold Prof. Littlejohns outlined that as the cost of an intervention rose above £20,000- £30,000 per QALY considerations other than cost-effectiveness would need to be demonstrated to make it acceptable for use in the NHS

Ramifications of NICE decisions

SE enquired what happens once NICE has made decisions as outlined above. Prof. Littlejohns outlined that the appraisal program information was sent direct to the NHS which must make sufficient funding available to implement the decision within 3 months. However , it is still just guidance at the professional-patient interface: as long as the practitioner records explicit/rational reasons for utilizing different treatments, that is fine. The guidelines are expected to be taken into account by local planning authorities but there is no 3-month rule. The guidelines form part of the NHS Development standards program while the rest of NICE's recommendations form part of the NHS Core standards program. Additionally, appraisals and guidelines form part of post-graduate training and continuing professional development exercises, and the Health Commission has the ability to check whether or not NICE guidelines are being implemented at the local level.

Safety

SE moved to issues of safety. Prof. Littlejohns explained that the interventional procedures program was focussed on safety issues and was the only programme doing so. For drugs however, there is a separate regulatory authority – the Medicines and Healthcare products Regulatory Agency (MHRA) which as the statuary responsibility for assessing safety and efficacy . NICE takes side-effects into account in its appraisals.

CAM Therapies

SE began a discussion dealing specifically with CAM therapies. With respect to the possibility that the differing philosophies may suggest differing standards for evidence, Prof. Littlejohns expressed the need for evidence to fit the purpose of the study and acknowledged the difficulties of size and cost for many possible RCTs, for example in NICE's future work on public health. Nevertheless, it is still important to go beyond effectiveness data alone. NICE will look for convergence and consistency in study results . Although studies in English generally form the majority of those analyzed by NICE, international evidence is utilized in deliberations.

Prof. Littlejohns acknowledged the large amount of public support and use of CAM therapies, and made it clear that quality of life issues were already a large part of the guidance NICE issues). Ultimately, NICE makes recommendations for the NHS and thus must focus on issues of cost-effectiveness in addition to public health concerns. It was Prof. Littlejohns' personal view that at this time, when there is already great debate within areas with known safety and efficacy, it was unwise to add in new areas with a less strong evidence base at this time.

Prof. Littlejohns acknowledged that one of the reasons for the lack of movement on CAM in NICE was that there has been a lack of incentive for funding research in the area. The major sources of funding are both limited and frequently emanate from pharmaceutical companies. Lacking a sponsor for studies has meant a lack of evidence, but Prof. Littlejohns did not feel this was due to any lack of desire on behalf of CAM researchers or practitioners for their therapies to be examined.

Professor David Peters, School of Integrated Health, University of Westminster, 10 March 2005

Introduction

An introduction to the aims and methods of the Smallwood Enquiry was followed by a discussion on the overall objective of the project. Agreement was reached that three areas could be investigated in the work:

- Available research into the effectiveness of CAM in practice
- Effectiveness gaps
- Reliable ways of delivering CAM into the mainstream and their cost.

These can be triangulated - like in a Venn diagram - to find areas of CAM treatment where there exists potential in all three areas.

Nature of Evidence

Professor Peters hoped the Enquiry would help provide a rationale for integrating cost-effective elements of complementary therapies (CT) into mainstream care. His experience as a GP who is also a complementary practitioner has led him to believe that CTs can augment conventional medicine in ways that patients and primary care teams find very valuable. However, there is a startling lack of good (in the sense of RCT) evidence that CTs actually work. He believes that this dissonance between research and practice may be largely due to the way CTs have been investigated: methods that tell us whether a drug is better than a placebo pill will not be appropriate for many types of CTs. Humanistic-holistic, skills-based approaches to healthcare, are not the equivalent of a tablet. Professor Peters voiced his concern that RCTs may be an inappropriate way of studying CTs because their outcomes are so greatly influenced by "human factors": the practitioner's skill, therapeutic alliance, the patient's will and capacity to change. CTs – rather like physiotherapy or psychotherapy act largely by boosting the capacity for self-healing. But in a standard RCT such self-healing processes, though profoundly important aspects of recovery, will become just "noise in the system" – something to be bracketed out by experimental randomisation and blinding. Although it would be possible to re-design RCTs (and expensive to conduct them) so as to avoid throwing out the baby with the bathwater, few such high quality studies had been done as yet. Therefore when the available, very limited studies are collected together and subjected to a Cochrane style statistical analysis, the evidence for efficacy seems to disappear. So there is a huge gap between experience (what practitioners and patient say about CAM's *clinical effectiveness*) and experiment (what researchers tell us about CAM's *efficacy*).

As an example of such a gap he mentioned a recent article in the *BMJ* reporting that routine physiotherapy seems no more effective than one session of assessment and advice from a physiotherapist.[309] Various RCTs also suggest that psychotherapy is ineffective. It seems that unmodified RCTs may fail to capture all subtle differences and benefits associated with such skill- and relationship-based treatments (and by implication CAM treatments too). Professor Peters recommended the Enquiry should therefore seek out comparative and pragmatic studies which more accurately reflect real (as opposed to experimental) practice. He citied the example of a long-term study of traditional acupuncture for low back pain.[310] This research

[309] Frost H et al. Randomised controlled trial of physiotherapy compared with advice for low back pain . BMJ 2004;329:708

[310] Thomas KJ, Macpherson H et al. Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain. Health Technol Assess. 2005 Aug;9 (32):1-126

comparing individualised acupuncture with “usual care” found that both were associated with clinically significant improvement at 12- and 24-month follow-up. However, acupuncture care was significantly more effective at 24-month follow-up. This study (unusual in that it embraced “real” rather than formulaic acupuncture, and followed up over a long period) commented that acupuncture could be a highly cost-effective intervention for reducing low back pain (which very commonly recurs, becoming a long-term problem) over a 2-year period. Prof Peters felt that more such pragmatic, long-term studies would be needed before the true cost-benefits of CAM could be properly assessed, but that these finding seemed to suggest that the experience-experiment gap in CAM research could in time be narrowed.

SE found this sort of study very interesting and noted the example of homeopathic treatment for ADHD that indicated it could reduce the need for Ritalin. This example highlighted the disparate range of benefits that might accrue from CAM treatments, for example increased quality of home life and less disruption at school, although these benefits would be extremely difficult to measure in an economic evaluation.

SE brought up the gaps in the evidence found in the literature survey for the effectiveness of homeopathy and the cost effectiveness of herbal medicine. Professor Peters drew attention to animal trials of homeopathy, where the placebo effect was unlikely to be at work. On herbal medicine, Professor Peters said that research is more prevalent in continental Europe where its use is more widespread and more commonly incorporated in mainstream care (and that Professor Ernst might be a good source of advice about this). Professor Peters acknowledged there is little cost effectiveness evidence on herbal medicine but pointed out that in any case cost-effectiveness evidence is insufficient on its own: clinical evidence for effectiveness/ or at the very least patient satisfaction would be needed first and there is a danger of putting the cart before the horse when this is not available.

Effectiveness Gaps and Holistic Healthcare

DP reported that Dr Peter Fisher of the Royal London Homeopathic Hospital had done work on “effectiveness gaps” revealing that GPs perceived gaps in the effectiveness of conventional medicine for e.g. mild to moderate depression, skin complaints, irritable bowel syndrome and musculoskeletal disorders. A very important category of complaints identified by Professor Peters in this connection was so-called “medically unexplained symptoms.” Distress can manifest itself as chronic pain and dysfunction, but even where no psychological disorder is present, many patients have long term symptoms that cannot be attributed to an objectifiable disease. Professor Peters confirmed that consultations for medically unexplained symptoms, expend many resources in primary care, outpatient time, investigation costs and days off work. Professor Peters thought that CAM might have a role to play in plugging this and other expensive gaps. He said that even if we are not sure that CAM therapies do any good by themselves – and they should certainly not be seen as magic bullets – if they can improve patients’ sense of wellbeing then this might be sufficient to trigger a self-healing process that was likely to be powerfully cost-effective in many chronic conditions.

SE mentioned an example of a piece of social entrepreneurship that had won an award from the charity of which he is a trustee. It involved women with non-specific ailments setting up a nursery. The act of organising and running the nursery reduced their need to consult doctors about their minor ailments. Professor Peters said this was a true example of an holistic approach to health that tackles the issues of lifestyle, relationships, working life etc. The holistic approach takes into account all the factors that affect a person’s health, and aims to support normal processes of self-healing and aims to help people learn how best to trigger these processes. Professor Peters saw CAM as a possible staging post along the way towards the mainstream’s adopting a more holistic approach because CAM operates in a manner more sympathetic to this paradigm than conventional medicine. Professor Peters said that in the long term an holistic approach is going to have to be considered by all publicly

funded systems, for they face ever increasing costs for medical care in the face of an aging population, accelerating technology and ever-increasing public expectations.

Integration and Organisation

SE said that they had come across different models of integration, ranging from education of practitioners and patients, to the referral of patients to outside professionals, to in-house provision by GPs. Professor Peters said that in his opinion a "third sector" would be very useful, if it could be a broker between PCTs or GP practices and experienced CAM practitioners. He cited the example of Westminster PCT which offers a community based centre for CAM provision. SE spoke about Boo Armstrong and her brokering of treatment hours through Get Well UK.

Models of Integration

- The Marylebone Health Centre (this is now changing as the founding generation of staff leaves);
- University of Westminster Polyclinic (university training centre) - this works at a low-cost provider in the private sector (final year students provide the treatments);
- Other training colleges;
- Westminster PCT community centre (contact: Derek Chase);
- Get Well UK: acts as intermediary between PCTs and CAM therapists (contact: Boo Armstrong).

Professor Peters stressed the importance of the practical considerations when achieving integration of CAM into the NHS. In answer to SE inquiries about clinical and cost-effectiveness evidence Professor Peters concluded that although the NHS national priorities are at the top of PCTs' "to do" lists, and while evidence derived from RCTs strongly influenced PCTs' spending decisions, that nonetheless many PCTs were funding CAM treatments: about 1 in 3 according to his School's recent survey of England PCTs.[311] Therefore it would seem that such developments must have been driven not necessarily by research evidence, but at least as much by local enthusiasts, patient or GP needs and particular local development opportunities. So far, this organisational dimension rather than a strong evidence base for efficacy may have played the largest part. Effectiveness is perhaps the most important factor: what patients say about what helps them, what reduces demand for GP consultations and hospital referrals, what cuts down the number of drug-prescriptions and investigations needed and the rate of serious side-effects from conventional treatment.

Professor Peters suggested that NHS managers need to feel confident about CAM practitioners' accountability and ability to comply with NHS standards. Improving the education and registration of practitioners was part of this process, and is well underway. In the medium term though, CAM practitioners who want to work in the public sector will need to understand how the NHS works, the challenges it faces and the objectives it has set. They will have to grasp the notion of clinical governance - the NHS's chosen way of developing higher standards through quality assurance. But CAM in the UK is still largely a loose community of independent self-employed professionals with little experience of the public sector. Perhaps, given the increasingly corporate way NHS decisions are made, the CAM field needs to develop new kinds of commercial and social businesses to act as management intermediaries between the NHS bureaucracy and CAM practitioners.

Turning to the practical considerations of improving GPs access to CAM services, Professor Peters said solution would tend to arise once practice-based commissioning (PBC) and Alternative Providers of Medical Services (APMS) initiatives get underway. PBC is a new "ethical version of GP fund-holding" whereby practice savings can be ploughed back into service development. The objective of this new Dept of Health policy is to localise particular healthcare services and locate them in primary care. Such services could feasibly include e.g. CAM back pain clinics. The uptake of such a scheme would require a number of GPs with

[311] Wilkinson J, Peters D, Donaldson J. full ref needed

knowledge and experience of CAM to lead the way in a PCT in order to create a service staffed appropriately, and shared by several practices.

Professor Peters said that the School of Integrated Health in the University of Westminster had been providing advice about working in the NHS; advice based on a study of CAM clinical governance undertaken for the Dept of Health in 2003-4, but also driven by the experience of staff who had spent many years bringing CAM into the NHS. Further funding would develop the infrastructure and provide an internet-based network. In addition, CAM graduates will need support if they want to explore ways of making their services available through the NHS and voluntary sector: social entrepreneurship models could be especially important for instance. The School would be aiming in the near future to provide opportunities for workplace learning and its "I-CAM" unit would be looking into ways of sharing experiences and information about CAM in the NHS. Professor Peters suggested that it would be very valuable to bring the best available economic research on CAM as well as pragmatic trials and effectiveness studies together, alongside systematic reviews of RCTs. Practice development will need all of these disparate types and sources of CAM research.

Professor Peters said that the incorporation of CAM into the NHS might well begin as "bolt-on" services brokered by third parties, but this stage should be seen as only a first step towards more effective integration which would on the one hand entail medical practitioners knowing more about CAM, and on the other, the development of more in-house primary care provision. This in turn would encourage a cross-fertilisation of ideas between conventional and complementary practitioners: the sort of inter-professional learning Professor Peters believes will be crucial to the integration of CAM into mainstream practice, along with a gradual shift towards the provision in the NHS of "the best of both worlds". The challenge will be for 21st century healthcare to find a balance between applied bio-technology, and more human-centred, holistic ways of practicing healthcare. CAM, he said is a signpost in this direction, but it is not the destination.

Professor Peters said that he would be happy to help the Smallwood Enquiry as its work continues, for which SE were very grateful.

Professor Nicola Robinson, Centre for Complementary Healthcare and Integrated Medicine, Thames Valley University, London, 31 March 2005

Clinical and Cost Evidence

SE asked Prof. Robinson's opinion on the state of clinical evidence for CAM and how it relates to current evidence on cost-benefit. She said the nature of scientific evidence is often to standardise and to rigorously compartmentalise interventions. The whole point of CAM treatments is that they are individualised to each patient and so cannot be assessed by the traditional RCT. A pragmatic RCT approach could be employed so that outcomes can be compared and used as a basis to investigate cost savings/benefit. The problem she acknowledged was the lack of cost-benefit analysis of CAM treatments so far.

Prof. Robinson stressed that there may be a potentiating[312] effect of CAM therapies, particularly in her own field of acupuncture. This is very important to their effectiveness. She pointed out that the York study RCT on back pain[313] had demonstrated that the acupuncture group had better outcomes two years after treatment compared with the group receiving standard care. Anecdotally, from her own research team a similar effect has been found in treating night sweats, a side-effect of the cancer drug Tamoxifen, with acupuncture. The potentiating factor necessitates the use of long term trials to capture all the effects over time.

Efficacy and Effectiveness

Prof. Robinson pointed out that there will always be difficulties in finding evidence for the efficacy of CAM therapies due to the individualisation of treatment which demands that a mix of methods are needed to measure outcomes, including qualitative data in order to capture the different types of benefit. The nature of the outcome measures will depend on the type of illness. For example, a before/after analysis may not be suitable for acute conditions.

Prof. Robinson mentioned her own research on spiritual healing, for which she reported that there was some evidence and that it increases the perceived quality of life (measured using scales such as the MYMOP), while not necessarily improving the disease prognosis. In Prof. Robinson's view this represents a health benefit to the patient and the mechanism of action causing it is not understood. The important requirements are that treatment is delivered safely and competently and that patients are made aware of its limitations.

Integration

Prof. Robinson drew attention to the expert patient programme operating in the UK. In the case of people with HIV disease, patients have become very well informed about the interventions that are available to treat their symptoms. Patient demand is the biggest driver in the usage of CAM.

Prof. Robinson reported that the Cochrane reviews of clinical trial evidence are now starting to look at qualitative evidence as well as traditional clinical data and that the Medical Research Council (MRC) has recognised the importance of complex interventions (it published a discussion document on the subject in 2000). There has been work published in the *BMJ* in January this year (Devereaux et al., 2005) on an alternative to traditional RCTs for non-pharmacological interventions that makes use of expert doctors for specific interventions. The preventative aspect of CAM is also being much more developed – Prof. Robinson reported that chiropractic treatment is regularly given to children in Canada. Prof. Robinson cited these developments as indications that integration is proceeding.

[312] The ability of a medical treatment to improve the effectiveness of the same or a different subsequent treatment, so that the combined effect is greater than the sum of the individual effects.
[313] MacPherson et al., 2001

In response to an enquiry by SE about an ideal form of integration Prof. Robinson said that good models of integration of CAM and western medicine are found in mainland China. She had visited 32 institutions (academic, hospitals etc) as part of a Winston Churchill Fellowship last year. The first year of medical training is common for those studying Traditional Chinese Medicine (TCM) and those who study western medicine. All western style hospitals have TCM departments and so there is great common understanding and cross-referral between the traditions. Prof. Robinson pointed out that consultations for CAM in this system are not like private consultations in the UK where a lot of time is taken over one patient on their own. Instead, due to inevitable cost pressures, more patients are seen for shorter periods. It is this sort of arrangement that Prof. Robinson envisages occurring in the UK if integration into the health service was to move forward.

Prof. Robinson said that information for patients and practitioners is a key factor in the successful integration of CAM into conventional healthcare. This information ideally leads to patients being able to make informed decisions as to their treatment. She acknowledged that inter-referral between CAM practitioners is desirable.

Regulation and Future Prospects

Prof. Robinson supported the regulation of complementary medicine. However, she said that the EU directives on supplements and herbal remedies could result in banning safe remedies along with the unsafe.

SE brought up the possibility of a larger scale shift in priorities of the NHS to focus more on health and prevention rather than illness. Prof. Robinson said that this was happening gradually, prompted by the House of Lords report. However, the loss of ring-fencing of the Department of Health funds for CAM research is a set-back. Prof. Robinson mentioned that in the USA usage of CAM is increasing more quickly.

For the future of CAM, Prof. Robinson said that the education of medical staff in CAM is limited (due to curriculum constraints) within nurse and doctor training. Increasing the awareness of CAM research should lead in the next ten years to a substantial change in the provision of CAM in the UK, including in the health service.

Professor Mike Saks, Pro Vice Chancellor, University of Lincoln and Chair of the Research Council for Complementary Medicine (RCCM), 17th March 2005

Current RCCM Work

SE outlined the focus of the project it is working on in CAM, and Prof. Saks drew attention to the very closely linked work currently being done by the RCCM for its *NHS Priorities* project, a systematic review of selected CAM therapies in the area of key NHS priorities of cancer, coronary heart disease, mental health and chronic conditions. The focus is more on the clinical side than the cost side, but Prof. Saks did recommend SE talk to Janet Richardson (Uni. of Plymouth) as she is the research director for the RCCM. This work, done with NHS funding, will be publicised in stages. The focus of the RCCM project will hopefully allow the NHS to invest in further research into the most promising forms of CAM; CAM research is also being coordinated through the NCRI Clinical Studies Group of which Prof. Saks is a member.

Research Methods

SE began a discussion on the different ways in which one can conduct research into CAM therapies. Prof. Saks explained that presently there was an eclectic approach to research methods, with some advocating that RCTs must be the sole source of evidence utilised in making decisions and others not wanting the placebo effect to be removed when conclusions on CAM are drawn. Prof. Saks stated that we would be foolish to ignore qualitative evidence. Many in the bio-medical field are besotted by RCTs, of searching for physiological indicators and chemical changes instead of concerning themselves with "wellness". This is the strength and the weakness of the RCT, and the subjective measure of progress in patient perceptions which is often utilised in measuring CAM therapies is in fact very much in accordance with the growing NHS philosophy of putting the patient first. Prof. Saks also outlined that RCTs can be more flexible than many in the CAM community believe.

The Evidence Base

Alluding to his background, Prof. Saks broadened the discussion into the philosophy of science, and whether we could ever prove anything conclusively (in both conventional and non-conventional medicine). All knowledge can be seen as provisional, awaiting falsification. Many individuals have used a certain limited concept of "hard" science as a weapon against CAM therapies. Prof. Saks brought up the example of the lawsuit in the US concerning attacks on the chiropractic profession. There is a limited evidence base for CAM at this point but that is to be expected given that CAM receives less than 1% of the research funding for medicine.

Prof. Saks stated that it was very hard to draw a line and decide when cases have been made conclusively or not, but one should certainly stay clear of quasi-religious beliefs. There are advantages to having an independent body playing a watchdog role, which in the UK is illustrated by NICE. However, the committees that attempt to deal with economic evaluation as part of examining changes in the NHS can lack clarity when it comes to choosing measurements and research questions. On the CAM practitioners' side, there is often an assumption that CAM will be cost-effective because it costs less than many conventional therapies (fewer drugs, etc.), but this ignores the disparity in labour time - CAM therapists can spend up to seven times as much time with patients than general practitioners.

Finally, Prof. Saks stated that even when positive conclusions for CAM have been drawn, many practitioners do not want to integrate and become highly regulated. Such individuals often feel this would put up too many barriers between practitioner and patient.

Integration

SE moved the discussion to focus on the issue of integration. For Prof. Saks, the critical factor was that whoever is coordinating the care is cognizant of current research and can deliver an appropriate and beneficial set of therapies to a patient in an integrated fashion. Presently, integration is through the consumer and not the practitioner. Many CAM practitioners see themselves as providing a holistic treatment, and while this may be true philosophically, in practice it is rare for a CAM therapist to refer patients to other therapists, conventional or otherwise. This reinforces the importance of the question “who is the gatekeeper?”

Classically, this role has been carried out by the GP. Prof. Saks recognized that there has been a revolution in the use of CAM by GPs (pointing to the work of Kate Thomas showing that 49% of practices provide CAM on the NHS in some form) and that 1 in 5 GPs practice a CAM therapy themselves (although the definition of CAM is sometimes very broad). The issue is whether the GP has adequate knowledge to refer patients.

In the long-term, the education of GPs will be very important. Prof. Saks referred to work by David Morgan of the British Medical Association (BMA) into medical education in the UK, examining how universities have progressed in incorporating CAM into their curricula. He concluded that there was great improvement and CAM was now being mentioned, but it was still quite limited.

However, Prof. Saks stressed the need for interim measures. While referrals do occur between GPs and CAM (non-medical) therapists, it is not as extensive as one might believe. Prof. Saks stated that about 10% of CAM is paid for through the NHS, but the vast majority was still privately acquired. Prof. Saks explained that any top-down approach will not be effective, but that changing the culture of both conventional medicine and CAM communities (regarding particularly the openness of each to the views of the other) will be the most helpful policy to implement (for more information on this Prof. Saks referred to his latest book *Orthodox and Alternative Medicine*).

Finally, in discussing economic evaluation, Prof. Saks referred to his role on the DoH CAM Capacity Development Steering Group. He noted that, while there were proposals for economic evaluations, this was an area where existing expertise is limited. Greater funding in future needs to be given to commissioned work in this and other key areas of CAM research.

Dr Rajendra Sharma, Diagnostic Clinic, New Cavendish Street, London, 10 March 2005

Introduction

Dr Sharma gave a brief run-through of his CV and his reasons for entering the CAM field. He noted that when he was training such medicine was dubbed “fringe” and that over the years the term has changed to “complementary”, “alternative” and now “integrative”.

In answer to the SE question of what the clinic does and how it fits into the CAM industry, Dr Sharma remarked that CAM in the UK is a cottage industry, with 50,000 practitioners (of whom only 1,000 are doctors). He traced the history of the Diagnostic Clinic (TDC), which grew out of another similar clinic two years a go and was co-founded by Alex Oates, himself and the Chairman and main shareholder the businessman Hans Snook. SE inquired whether the clinic has any link to the NHS, but Dr Sharma explained that it is entirely private, although NHS referrals are possible.

Screening and Protocols

Dr Sharma explained that the principle of TDC was to integrate orthodox and pioneering as well as Eastern diagnostic tests removing the dangers of unqualified and unproven analysis from the public domain. One aim of the centre for example is to offer a much higher quality alternative to the “bio-resonance” diagnostic method employed for example at high street health food shops. The screening the clinic offers can spot conditions prospectively, rather than just finding present ailments in the manner of conventional scanning. The clinic offers screening for free radicals and also performs live-blood analysis, which uses an advanced form of microscopy to determine a person’s state of health.

TDC uses a system of triage that assess where the first port of call for treatment should be for a particular ailment. Then a series of protocols is followed, which are different and more detailed than those offered by NICE. They include the use of naturopathic, dietetic, life-style changes, homeopathic, structural medicine such as osteopathy and herbal remedies and other supplements as well as a full range of orthodox tests The sources for these protocols include such data bases as the company Clinical Pearl’s Prescription 2000 information and that listed on vitasearch.com.

Paradigms

In Dr Sharma’s opinion a great problem at the moment is the patient flow through the system. Instead of going to an osteopath first, a patient with a bad back might see a GP several times, take drugs, be seen by a specialist and maybe a physiotherapist, and only end up at the osteopath as a last resort. The screening and protocols in the clinic are aimed to avoid this inefficiency in care.

Dr Sharma argued that a change in paradigm in healthcare is needed, especially in the face of an ageing population and greater prevalence of chronic diseases. However, he saw a barrier in the form of the present arrangement of medical schools and medical research departments at universities being funded, directly or indirectly, by pharmaceutical companies. Research institutes wanting to do research into CAM therapies are discouraged to do so by the pharmaceutical companies who promise not to send their research contracts to the laboratory – on which they might depend financially. Dr Sharma maintained that for financial reasons the pharmaceutical companies have no interest in drugs that cure a condition, rather in those that alleviate its symptoms, because this approach maximises patient expenditure on drugs. Dr Sharma cited as an example a scientifically examined cure for allergic asthma: neutralisation (work at the Radcliffe Hospital, Oxford has found a similar result using a technique known as EPD) that is currently not accepted by the medical establishment, which

is in the pocket of pharmaceutical companies will not provide funds for research to enable the evidence base to grow.

SE asked how this stranglehold could be broken. Dr Sharma thought that research alone will not shift the NHS. The key is for people to take more responsibility for their own health and this is rare, especially amongst the under-30s. The way to target this particular group would be through schools.

To illustrate the point that people's attentiveness to their own health is generally low, Dr Sharma identified five groups of people in the UK according to their attitude to health:

Generally Middle Class and above (some interest in their own health)

- Health Consumer (have the most interest)
- Those who become ill and know why (e.g. smoking) and know they should be avoiding the reason for their ill health, but have poor response to their cry for help from the NHS
- Those who are well and have little interest in their own health

Majority (very little interest)

- Those with no interest until those who become ill
- Those who are well, but have no concern for their own health

Supplements

Dr Sharma explained that a large part of the clinic's work is in naturopathy, non-drug treatments which include dietary supplements. He disagreed with the EU's decision to ban high potency supplements. He felt this is misguided because people need to take supplemental vitamins and minerals, as even a balanced diet cannot provide all that is required nowadays when much fruit and vegetables do not contain the nutrients they should due to the way they are grown. Dr Sharma predicted that in the future it would be accepted that many of the important and widespread diseases reported (such as arthritis, asthma, etc.) are deficiency diseases. He was also of the opinion that lower risk standards should be applied to naturopathic medicines than to conventional drugs. He also questioned if today's standards for drug medicine were acceptable at all considering recent failures as shown by the withdrawal of Co-proxamol and a brand of COX-II inhibitor. These had passed the "rigorous" safety margins required by current authorities who are frequently swift to ban herbal medicine on scant evidence – Kava Kava and Tryptophan being examples.

Models of Integration

SE explained that they had come across several models of integration of CAM into the NHS, ranging from increased education of practitioners and patients to in-house CAM provision. Dr Sharma saw an ideal arrangement of integration as one where GPs with knowledge of (or access to suitable data) and access to practitioners of CAM acting as gatekeepers to therapeutic and diagnostic services. Dr Sharma highlighted pay as an important issue – both to pay doctors enough, and make the therapists salaried so they do not have an incentive to hold onto patients and treat them beyond what is really required.

The ideal way forward would be for the leading practitioners (Dr Sharma plus 5 others) to set up a few centres (10 at first) on the model of The Diagnostic Clinic. Patients or insurance or local PCTs should pay for the diagnostics and treatment, but should be given a tax/national insurance rebate if they do (a tax relief for the healthy). Then it could expand nationwide.

Cost Effectiveness

SE was interested in Dr Sharma's opinions on cost effectiveness, the focus of the Smallwood Enquiry. Dr Sharma said that in general a CAM approach reduced a doctor's drug bill but increased his wage bill, with these two usually cancelling each other out (Lewith has shown a

£70k example of this). Dr Sharma maintained that practitioners should make a margin on the naturopathic remedies they prescribe.

Dr Kate Thomas, School of Health and Related Research (ScHARR), University of Sheffield, 9th March 2005

Defining CAM

The discussion began with Dr Thomas highlighting how large the field of CAM truly is, and how difficult it is to examine any part of it in isolation. There are no standard definitions of each CAM therapy, and therefore any comparison between two studies with treatment types may not be too meaningful. For example, many varying practices and theories fall under the acupuncture heading, e.g. Japanese, Western, medical, traditional Chinese, western-influenced traditional Chinese. Acupuncture is in the process of being more clearly defined in work by Volker Scheid, University College London. Dr Thomas felt this was due to a wish by CAM professionals to define practices before they are defined for them by those providing it in the NHS.

Level of use of CAM

SE relayed their surprise about the higher than expected level of usage of CAM in the NHS. Dr Thomas agreed that the decision whether or not to provide on the NHS was made 5-10 years ago, and that the issues now revolve around how, when and who should provide as part of the NHS. Many health departments had reacted to discovering the level of CAM usage by capping referral and spending amounts, claiming that the lack of a clear evidence base removed the need to provide CAM. Dr Thomas stated that it is vital to grapple with what is happening presently and not be entirely removed from the daily reality of patient use.

Public Policy Priorities

Dr Thomas outlined that in the area of public policy towards CAM, when the provision is solely privately-funded, the Government's guidance is motivated by a public health concern, and their duty to ensure safety (i.e. regulation). However, once public (NHS) funding is introduced, an additional consideration is cost-benefit appraisal and making fund-allocation choices.

Types of Evidence

SE brought up that in order to analyze cost-effectiveness, one had to examine the evidence base, and on the back of earlier conversations, were attempting to separate the concepts of efficacy and effectiveness. Dr Thomas outlined her view on the three types of evidence:

- *Mechanism of action:* How the process involved in the treatment can be explained scientifically. The National Institutes of Health, having been burnt by certain questionable efficacy and effectiveness they funded, are devoting their funding in this area. In Dr Thomas' view, this will be the focus of funding in the USA for the next ten years.
- *Efficacy:* Utilizing a reductionist scientific method to examine the specific effects of a specific intervention on a specific health outcome. This is a protocol driven approach, where you control for everything other than the intervention, similar to a laboratory experiment. However, this is NOT how most CAM treatments are delivered in practice. The CAM community has been pushed too fast to follow an evidence-based approach in this form, and has jumped through hoops in order to play much of the associated politics.
- *Effectiveness:* The intervention's effect in a clinical setting and measured by examining all aspects of the treatment's effect on a patient. The most important consideration here is the NHS priorities in order to make any studies in line with NHS goals.

Direction of Future Research

Dr Thomas outlined that she believes that any future research must start from how people are using CAM at the moment. She said that approximately one in three of the population uses or has tried CAM in some form. The research agenda should be set with this in mind. The key questions to patients should be:

- What are you using?
- Why are you using it?
- How does this fit into you health needs?
- What do you perceive the benefits to be?

The current direction of research is very ad hoc, with no clear long-term agenda. Dr Thomas suggested that the main medical charities should form a vanguard and set an agenda for research that follows patient priorities. An example of agenda setting was provided by the National Cancer Research Institute which coordinates research priorities for 18 cancer charities in the UK (including Cancer UK). They performed an audit of their research, finding that there were gaps in their research for lung cancer, cancer prevention and for palliative care (including CAM).

A key concern for Dr Thomas was the approach of the research. If a researcher is looking at it from a position of pushing CAM therapies, the NHS commissioners will not be open. However, if the research is examining CAM as part of the solution, part of the overall picture in treating a certain patient group (for example, cancer patients), the reception will more welcoming.

Dr Thomas discussed her recent study of acupuncture for back pain in York, published as a HTA monograph (Thomas 2003, see Acupuncture for more details). She explained how it was fortunate the study fit into an area of perceived interest In the face of 13 Cochrane reviews on back pain stating no strong conclusions for any treatment, Dr Thomas expressed the view it was important to focus on offering discrete packages early on, and show how this early intervention changed recurrence later on. This evidence would allow provision of a CAM therapy as an option of care, and then the costing of these short-term interventions would help persuade those whose framework is the most important: NICE.

Integration

SE asked Dr Thomas about her views on the topic of integration. She outlined that there were two broad schools of opinion. Some GPs have expressed their view the focus on CAM could be part of transforming the approach to primary care, touching the whole healthcare system. Others see CAM as purely (theoretically) instrumental tools to form part of the treatment options. These two different conceptions of healthcare were not seen as stages (integrative vs. side-by-side), but as opposing ideas that cannot be easily dragged together. Dr Thomas stated that currently it was easier to get practices to allow a side-by-side/referrals model to form part of their approach.

APPENDIX C: BIBLIOGRAPHIES

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