

Complementary and Alternative Therapies Evidence Based Decision Making Framework

A broad range of treatments and practices that are not considered standard medical treatment

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1 Introduction

NHS Leeds will commission alternative therapy interventions if they are supported by adequate evidence of safety and effectiveness in the peer reviewed published medical literature.

2 Purpose

This Framework provides the evidence based framework for decision making by the Non Commissioned Activity Panel of NHS Leeds as described in the Individual Funding Requests Policy.

3 Scope

This Framework provides the supporting framework for decision making by the Non Commissioned Activities (NCA) Panel of NHS Leeds relating to decisions about funding complementary and alternative therapies. It is to be read in conjunction with the following related policies:

- Individual Funding Requests Policy
- Non Commissioned Activity Framework
- Cosmetic Exceptions and Exclusions Framework
- Non NICE non Tariff Drugs Framework

4 Framework operation

The following are some of the alternative medicine interventions that NHS Leeds considers appropriate for properly selected patients. These will only be funded for appropriately qualified, insured and registered therapists and it should be noted that it is the responsibility of the referrer to ensure, and provide evidence at the point of requesting funding, that this is the case.

- **Acupuncture** -- see Appendix B
- **Spinal Manipulation** -- see Appendix C

It should be noted that whilst NHS Leeds Musculo-Skeletal Service may provide acupuncture & manipulation as an adjunct to therapy, it does not accept prescriptive referrals which state that either acupuncture or manipulation is requested/required. Clinicians should refer to Appendices B and C for more information regarding referral for acupuncture and spinal manipulation.

There is little evidence beyond a modest placebo effect for other alternative interventions. Should a clinician wish to refer a patient for a therapy which is not covered by this framework, the request will be considered by the NCA panel on receipt of evidence of the therapy's effectiveness in peer reviewed journals.

Allergy and clinical immunology services will be funded according to local guidance available from the Leeds Health Pathways website.

However, NHS Leeds will consider requests for homeopathy in highly selected patients (see appendix D) but will not commission any of the procedures in appendix E because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness.

Prior approval is required from the NCA panel for any alternative therapy outside the MSK Service.

4.1 Referral Process

Refer to Individual Funding Requests Policy.

4.2 Exceptional circumstances

NHS Leeds does not offer treatment to a named individual that would not be offered to all patients with equal clinical need.

Consequently in making a case for special consideration, it needs to be demonstrated that:

- *the patient is significantly different to the general population of patients with the condition in question; and*
- *the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition.*

The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality.

4.3 Appeals

Refer to Individual Funding Requests Policy.

4.4 Panel TOR

Refer to Individual Funding Requests Policy.

5 Responsibility for Document Development

The Executive Director of Commissioning has overall responsibility for document development.

6 Equality Impact Assessment

The screening tool suggests that a full assessment is not required

7 Approval and Ratification Process

This Framework relates to the Individual Funding Requests Policy approved by NHS Leeds Board.

8 Process for Reviewing this Document

The Framework will be reviewed on an annual basis by the Primary Care Trust and its lawyers. The panels are not intended to be a mechanism for reviewing or developing policy.

9 Version Control

This is the final version and appendix F documents the Version Control Sheet.

10 Dissemination and Implementation

Appendix G documents the plan for the dissemination of this framework document. The final version will be stored in the Public Health Directorate Network Drive.

11 Monitoring Compliance and Effectiveness

The panel will maintain an accurate database of cases approved and rejected, to enable consideration of amendments to future commissioning intentions and to ensure consistency in the application of Primary Care Trust Commissioning Policies.

The Financial impact of approvals outside of existing Service Level Agreements will be monitored to ensure the Primary Care Trust identify expenditure and ensure appropriate value for money when commissioning outside of Service Agreements. PBC Consortia need to be aware that all referrals will ultimately be a call on their budgets.

See also Appendix H: Equality Impact Assessment Tool

12 References

See Appendices.

13 Associated Documentation

This framework should be read in conjunction with the associated NHS Leeds commissioning policies:

- Non Commissioned Activity Policy
- Cosmetic Exclusions and Exceptions Framework
- Individual Funding Requests Framework
- Non NICE Non Tariff Drugs Framework

Appendix A: Background to the Framework and Evidence Base

"Alternative medicine" is a term used for a broad range of treatments and practices that have not gained wide acceptance in the traditional medical community and so are not considered standard medical treatment. Other terms used to describe such procedures include "holistic", "unconventional", and "complementary."

Alternative therapies are based on no common or consistent ideology, therapy of illness, or treatment. They derive from a variety of sources: ethnic and folk traditions, mainstream medical practices, established religions or semi-religious cults, philosophies or metaphysical movements, and health-and-wellness groups.

The US National Institutes of Health's Office of Alternative Medicine classified alternative therapies into the following seven categories:

- Diet and nutrition - use of specific foods, vitamins, and minerals to prevent illness and to treat disease
- Alternative systems of medical practice - use of medicine from another culture (e.g., Ayurveda, Chinese medicine)
- Herbal medicine - use of plants as medicine
- Mind-body interventions - use of the mind to enhance health (e.g., hypnosis, meditation, yoga)
- Manual healing methods - use of the hands to promote healing (e.g., massage, chiropractic and osteopathic manipulation)
- Pharmacologic and biologic treatments - use of various substances (e.g., drugs, serums) to treat specific medical problems
- Bioelectromagnetic therapies - use of electrical currents or magnetic fields to promote healing (e.g., bone repair, electroacupuncture)

The efficacy of various alternative medicine regimens is generally unproven, and some alternative therapies have been shown to be ineffective or even harmful.

Active release technique (ART) is a patented soft tissue system that treats problems with muscles, tendons, ligaments, fascia and nerves (e.g., headaches, back pain, carpal tunnel syndrome, shin splints, shoulder pain, sciatica, plantar fasciitis, knee problems, and tennis elbow). Active release technique is similar to some massage techniques, albeit more aggressive. While ART may be utilised by some chiropractors, it is different from conventional chiropractic manipulation. Drover, et al. (2004) reported that ART protocols did not reduce inhibition or increase strength in the quadriceps muscles of athletes with anterior knee pain.

Bioidentical hormones (e.g., oestrogen, testosterone, dehydroepiandrosterone [DHEA], etc.) are manufactured to have the same molecular structure as the hormones made by one's own body, and have been used in conjunction with laboratory tests of salivary hormone levels. Proponents of bioidentical hormones state that they are better than synthetic hormones in that they are "natural" and that they are more easily metabolised by the body, minimising side effects. They state that synthetic hormones are stronger than bioidentical hormones and often produce intolerable side effects.

There is no scientific evidence to support claims of increased safety or effectiveness for individualized oestrogen or progesterone regimens prepared by compounding pharmacies. Furthermore, hormone therapy does not belong to a class of drugs with an indication for individualized dosing. Salivary hormone level testing used by proponents to 'tailor' this therapy isn't meaningful because salivary hormone levels vary within each woman depending on her diet, the time of day, the specific hormone being tested, and other variables.

Most compounded products, including bioidentical hormones, have not undergone rigorous clinical testing for either safety or efficacy. Also, there are concerns regarding the purity, potency, and quality of compounded products. In 2001, the United States Food and Drug Administration (FDA) analysed a variety of 29 product samples from 12 compounding pharmacies and found that 34% of them failed one or more standard quality tests. Additionally, 9 of the 10 failing products failed assay or potency tests, with all containing less of the active ingredient than expected. In contrast, the testing failure rate for FDA-approved drug therapies is less than 2%.

The above framework is based on the following references:

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Appendix B: Acupuncture Guidance and Evidence Base

NHS Leeds considers needle acupuncture (manual or electroacupuncture) may be medically necessary for any of the following indications:

- Postoperative and chemotherapy-induced nausea and vomiting; or
- Nausea of pregnancy; or
- Postoperative dental pain; or
- Temporomandibular disorders (TMD); or
- Migraine headache; or
- Pain from osteoarthritis of the knee or hip (adjunctive therapy); or
- Fetal breech presentation (with Obstetric advice)
- Chronic low back pain. (Maintenance treatment, where the patient's symptoms are neither regressing nor improving, is not medically necessary.)

Leeds considers acupuncture experimental and investigational for all other indications, including but not limited to any of the following conditions, because there is inadequate scientific research assessing the efficacy of acupuncture compared with placebo, sham acupuncture or other modalities of treatment in these conditions:

Addiction	Painful neuropathies
AIDS	Peripheral arterial disease (e.g., intermittent claudication)
Asthma	Phantom leg pain
Acute low back pain	Postherpetic neuralgia
Carpal tunnel syndrome	Psoriasis
Chronic pain syndrome (e.g., RSD)	Psychiatric disorders
Fibromyalgia	Raynaud's disease pain
Fibrotic contractures	Rheumatoid arthritis
Glaucoma	Rhinitis
Hypertension	Sensorineural deafness
Induction of labour	Shoulder pain (e.g., bursitis)
Infertility	Smoking cessation
Insomnia	Stroke rehabilitation
Irritable bowel syndrome	Tennis elbow / epicondylitis
Menstrual cramps/dysmenorrhea	Tension headache
Myofascial pain	Tinnitus
Neck pain / cervical spondylosis	Urinary incontinence
Obesity	Xerostomia
	Whiplash

Note: Further acupuncture treatment is not considered medically necessary if the patient does not demonstrate meaningful improvement in symptoms. Maintenance treatment, where the patient's symptoms are neither regressing nor improving, is considered not medically necessary.

Background

Acupuncture as a therapeutic intervention is widely practiced in the UK. The general theory of acupuncture is based on the premise that there are patterns of energy flow (Qi) through the body that are essential for health. Disruptions of this flow are believed to be responsible for disease. Acupuncture may correct imbalances of flow at identifiable points close to the skin. Findings from basic research have begun to elucidate the mechanisms of action of acupuncture, including the release of opioids and other peptides in the central nervous system and the periphery and changes in neuroendocrine function.

While there have been many studies of its potential usefulness, the vast majority of papers studying acupuncture in the biomedical literature consist of case reports, case series, or intervention studies. One of the difficulties with drawing conclusions from the existing literature is that the term acupuncture is used to describe a variety of treatments that differ in many important aspects according to level of effect (e.g., local, segmental, generalized) and type of acupuncture treatment (e.g., manual versus electrical acupuncture). Many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as placebos and sham acupuncture groups, and by absence of studies comparing acupuncture with conventional biomedical treatments. Some factors needing investigation include frequency, number, and duration of treatments, depth of puncture, number of acupuncture points used, combination with other therapies, sample size, setting, blinding factors, and needle size. Be that as it may, promising results have emerged on the efficacy of acupuncture in adult post-operative and chemotherapy nausea and vomiting and in postoperative dental pain.

The U.S. Department of Health and Human Services, Public Health Service, Agency for Healthcare Research and Quality (AHRQ) recently performed a technology assessment (2003) on "Acupuncture for the treatment of fibromyalgia", it stated that "At this time, therefore, there is insufficient evidence to conclude that acupuncture has efficacy for the treatment of fibromyalgia. Two randomised controlled clinical trials with a follow-up of at least 13 weeks are currently underway and should provide more useful data about this treatment for fibromyalgia."

Furthermore, an AHRQ technology assessment (2003) on "Acupuncture for osteoarthritis" concluded that "The currently available evidence is insufficient to determine whether acupuncture has a specific beneficial effect in osteoarthritis."

In a large randomised controlled study (n = 401), Vickers, et al. (2004) examined the effects of a policy of "use acupuncture" on headache (predominantly migraine), health status, days off sick, and use of resources in patients with chronic headache compared with a policy of "avoid acupuncture". Patients were randomly allocated to receive up to 12 acupuncture treatments over 3 months or to a control intervention offering usual care. Headache score, SF-36 health status, and use of medication were assessed at baseline, 3, and 12 months. Use of resources was assessed every 3 months. Headache score at 12 months, the primary end point, was lower in the acupuncture group (16.2, SD 13.7, n = 161, 34 % reduction from baseline) than in controls (22.3, SD 17.0, n = 140, 16 % reduction from baseline). The adjusted difference between means is 4.6 (95 % confidence interval 2.2 to 7.0; p = 0.0002). This result is robust to sensitivity analysis incorporating imputation for missing data. Patients in the acupuncture group experienced the equivalent of 22 fewer days of headache per year (8 to 38). SF-36 data favoured acupuncture, although differences reached significance only for physical role functioning, energy, and change in health. Compared with controls, patients randomised to acupuncture used 15 % less medication (p = 0.02), made 25 % fewer visits to general practitioners (p = 0.10), and took 15 % fewer days off sick (p = 0.2). The authors concluded that acupuncture leads to persisting, clinically relevant benefits for primary care patients with chronic headache, particularly migraine.

The results of the study by Vickers, et al., (2004) are in agreement with recent findings of Allais, et al., (2003) who reported that acupuncture is effective in reducing the frequency of migraine attacks as well as those by Melchart, et al., (2003) who reported that acupuncture and sumatriptan were more effective than a placebo injection in the early treatment of an acute migraine attack. Sok and colleagues (2003) stated that further investigation, using a randomised clinical trial design, is necessary to determine the effectiveness of acupuncture for the treatment of insomnia. Furthermore, additional work is also needed to promote the long-term therapeutic effects of acupuncture and to compare it with other therapies for insomnia. White (2003) performed a review of controlled studies of acupuncture for women's reproductive health care. The author concluded that in view of the small number of studies and their variable quality, doubt remains

about the effectiveness of acupuncture for gynaecological conditions. Acupuncture appears promising for dysmenorrhoea and infertility, and further studies are justified.

Acupuncture has also been employed to relieve pain and improve movement in people with osteoarthritis (OA) of the knee. In the largest clinical study of acupuncture reported to date, Berman, et al., (2004) studied 570 patients with an average age of 65 who had OA of the knee. Subjects were randomly assigned to receive one of three treatments for 26 weeks, in addition to standard care such as anti-inflammatory medications and pain relievers: (i) 190 received acupuncture, (ii) 191 underwent sham acupuncture and (iii) 189 participants attended six, 2-hour group sessions over 12 weeks based on the Arthritis Foundation's Arthritis Self-Help Course. Patients' progress was assessed at 4, 8, 14, and 26 weeks. At week 8, patients receiving acupuncture began showing a significant increase in function and by week 14 a significant decrease in pain, compared with the sham and control groups. Overall those who received acupuncture had a 40 % decrease in pain and a nearly 40 % improvement in function compared to baseline assessments. The authors concluded that acupuncture seems to provide improvement in function and pain relief as an adjunctive therapy for OA of the knee when compared with credible sham acupuncture and education control groups. This finding is in agreement with the recent observations of Vas et al (2004), Tukmachi, et al., (2004), as well as that of Stener-Victorin, et al., (2004).

In a randomised, controlled, single blind trial on the use of acupuncture as a complementary therapy to the pharmacological treatment of OA of the knee (n = 97), Vas and colleagues (2004) concluded that acupuncture plus diclofenac is more effective than placebo acupuncture plus diclofenac for the symptomatic treatment of OA of the knee. Tukmachi and associates (2004), in a randomised controlled trial (n = 30), reported that manual and electroacupuncture causes a significant improvement in the symptoms of OA of the knee, either on its own or as an adjunctive therapy, with no loss of benefit after one month. In a randomised controlled study, Stener-Victorin, et al., (2004) evaluated the therapeutic effect of electroacupuncture (EA) and hydrotherapy, both in combination with patient education or with patient education alone, in the treatment of OA in the hip (n = 45). These investigators found that EA and hydrotherapy, both in combination with patient education, induce long-lasting effects, shown by reduced pain and ache and by increased functional activity and quality of life, as demonstrated by differences in the pre- and post-treatment assessments. This finding is in agreement with that of Haslam (2001) who reported that acupuncture is more effective than advice and exercises in the symptomatic treatment of OA of the hip (n = 32) as well as that of Fink and co-workers (2001) who found that placement of acupuncture needle in the area of the affected hip is associated with improvement in the symptoms of OA (n = 67).

In a prospective cohort study, Kukuk, et al., (2005) ascertained the long-term effects 3 and 6 months after the end of a course of acupuncture treatment for chronic low-back pain (LBP) or chronic pain caused by gonarthrosis. A total of 1096 eligible patients with chronic LBP or gonarthrosis pain were identified (68.1 % female) and invited by letter to participate in the study. Ultimately 249 patients remained, with no loss of representativeness. Two telephone interviews were conducted 3 and 6 months after the last acupuncture session using standardized questionnaires, available as electronic case report forms. The primary target criteria were self-assessment of pain tolerability before the start of acupuncture and after the end of treatment, and pain intensity (GCPS) over time. Secondary target criteria were changes to functional impairment (HFAQ for chronic LBP, WOMAC for gonarthrosis), quality of life (SF12), depression (CES-D) and patient global assessment of treatment effectiveness (PGA). For the indication chronic LBP, pain-related fear avoidance beliefs (FABQ) were also queried. These investigators found that pain tolerability was significantly improved after acupuncture and remained so up to 6 months after treatment. The mean scores of almost all questionnaires did not change significantly between 3 and 6 months. They concluded that acupuncture had a long-term effect on important aspects of cognitive and emotional pain coping. In a multi-center, randomised controlled trial, Thomas, et al., (2005) examined whether patients with persistent non-specific LBP, when offered access to traditional acupuncture care alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost. Safety and acceptability of acupuncture care to patients, and the heterogeneity of outcomes were also tested. Patients in the experimental arm were offered the option of referral to the acupuncture service comprising 6 acupuncturists. The control group received usual care from their general practitioner (GP). Eligible patients were randomised in a ratio of 2:1 to the offer of acupuncture to allow between-acupuncturist effects to be tested. Patients were 18 to 65 years of age with non-specific LBP of 4 to 52 weeks' duration, and were assessed as suitable for primary care management by their general practitioner. The trial protocol allowed up to 10 individualized acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need. Main outcome measures included the Short Form 36 (SF-36) Bodily Pain dimension (range of 0 to 100 points), assessed at baseline, and 3, 12

and 24 months. Cost-utility analysis was conducted at 24 months using the EuroQoL 5 Dimensions (EQ-5D) and a preference-based single index measure derived from the SF-36 (SF-6D). Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, as well as safety and acceptability of acupuncture care. A total of 159 patients were in the acupuncture offer arm and 80 in the usual care arm. All 159 patients randomised to the offer of acupuncture care chose to receive acupuncture treatment, and received an average of 8 acupuncture treatments within the trial. These investigators found that traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific LBP. Acupuncture care and usual care were both associated with clinically significant improvement at 12- and 24-month follow-up. Acupuncture care was significantly more effective in reducing bodily pain than usual care at 24-month follow-up. No benefits relating to function or disability were identified. They concluded that GP referral to a service providing traditional acupuncture care offers a cost-effective intervention for reducing LBP over a 2-year period. In a meta-analysis, Manheimer, et al., (2005) evaluated the effectiveness of acupuncture for treating LBP. These researchers concluded that acupuncture effectively relieves chronic LBP. However, no evidence suggests that acupuncture is more effective than other active therapies. This is in agreement with the findings of a Cochrane review on acupuncture for LBP by Furlan, et al., (2005) who stated that the data do not allow firm conclusions about the effectiveness of acupuncture for acute LBP. For chronic LBP, acupuncture is more effective for pain relief and functional improvement than no treatment or sham treatment immediately after treatment and in the short-term only. Acupuncture is not more effective than other conventional and alternative treatments. They concluded that the data suggest that acupuncture may be useful adjuncts to other therapies for chronic LBP.

There is evidence that acupuncture, alone or in combination with moxibustion, may be effective in the treatment of fetal breech presentation. Moxibustion refers to a type of Chinese medicinal practice that involves burning a herb close to the skin of the acupuncture point – urinary bladder 67 (BL67, Chinese name Zhiyin), located at the tip of the 5th toe. Evidence based clinical guidelines from the New Zealand Guidelines Group (2004) state that "[m]oxibustion is an acupuncture technique that involves burning herbal preparations to stimulate the acupoint by the 5th toe. It may be offered to women with breech presentation". Cardini and Weixin (1998) assessed the safety and effectiveness of moxibustion on acupoint BL67 to increase fetal activity and correct breech presentation in a randomised, controlled, open clinical trial (n = 260). The 130 primigravidas in the 33rd week of gestation with normal pregnancy and an ultrasound diagnosis of breech presentation randomised to the intervention group received stimulation of acupoint BL 67 by moxa (Japanese term for *Artemisia vulgaris*) rolls for 7 days, with treatment for an additional 7 days if the fetus persisted in the breech presentation. The 130 subjects randomised to the control group received routine care but no interventions for breech presentation. Subjects with persistent breech presentation after 2 weeks of treatment could undergo external cephalic version (ECV) anytime between 35 weeks' gestation and delivery. The intervention group experienced a mean of 48.45 fetal movements versus 35.35 in the control group ($p < 0.001$). During the 35th week of gestation, 98 (75.4 %) of 130 fetuses in the intervention group were cephalic versus 62 (47.7 %) of 130 fetuses in the control group ($p < 0.001$). Despite the fact that 24 subjects in the control group and 1 subject in the intervention group underwent ECV, 98 (75.4 %) of the 130 fetuses in the intervention group were cephalic at birth versus 81 (62.3 %) of the 130 fetuses in the control group ($p = 0.02$). The authors concluded that among primigravidas with breech presentation during the 33rd week of gestation, moxibustion for 1 to 2 weeks increased fetal activity during the treatment period and cephalic presentation after the treatment period and at delivery.

Kanakura, et al., (2001) discussed their findings on the use of moxibustion or electrical stimulation for the treatment of breech. Only patients with breech pregnancies at the 28th week or later were entered into the study. With moxibustion treatment, the control group had a spontaneous correction rate of 165/224 (73.7 %), and the treatment group had a correction rate of 123/133 (92.5 %) ($p < 0.0001$). With low-frequency percutaneous electrical stimulation, the correction rate was 20/941 (83.9 %) in the control group and 171/191 (89.5 %) in the treatment group ($p = 0.094$). The controls in the moxibustion study did no exercises and received no external manipulation to correct breech presentation whereas those in the electrical stimulation study experienced both. Acupuncture stimulation, especially with moxibustion, is expected to serve as a safe and effective modality in the management of breech presentation in a clinical setting.

Habek et al (2003) evaluated the value of acupuncture in the conversion of foetal breech presentation into vertex presentation in a randomised prospective controlled clinical study that included 67 pregnant women with foetal breech presentation: 34 women with singleton pregnancies treated with manual acupuncture (Zhiyin) and a control group which included 33 women with singleton pregnancies without acupuncture

treatment. The acupuncture treatment lasted 30 minutes a day, and was conducted during and after 34 weeks of pregnancy with simultaneous cardiotocography. The success rate of the acupuncture correction of foetal breech presentation is 76.4 % (26 women), and spontaneous conversion without acupuncture in vertex presentation is observed in 15 women (45.4 %; $p < 0.001$). The authors concluded that acupuncture correction of foetal malpresentation is a relatively simple, efficacious and inexpensive method associated with a lower percentage of operatively completed deliveries, which definitely reflects in improved parameters of vital and perinatal statistics.

In a controlled study by Neri, et al., (2004), a total of 240 women at 33 to 35 weeks of gestation carrying a foetus in breech presentation were randomised to receive active treatment (acupuncture plus moxibustion) or to be assigned to the observation group. Bilateral acupuncture plus moxibustion was applied at the BL67 acupoint. The primary outcome of the study was fetal presentation at delivery. Fourteen cases dropped out. The final analysis was thus made on 226 cases, 114 randomised to observation and 112 to acupuncture plus moxibustion. At delivery, the proportion of cephalic version was lower in the observation group (36.7 %) than in the active-treatment group (53.6 %) ($p = 0.01$). Hence, the proportion of Cesarean sections indicated for breech presentation was significantly lower in the treatment group than in the observation group (52.3 % versus 66.7 %, $p = 0.03$). The authors concluded that acupuncture plus moxibustion is more effective than observation in revolving foetuses in breech presentation. Such a method appears to be a valid option for women willing to experience a natural birth.

While the majority of evidence supports the use of acupuncture/moxibustion in correcting fetal breech presentation, recent publications are less clear in its role for the management of this condition. In a single-blind randomised controlled study, Cardini, et al. (2005) assessed the effectiveness of moxibustion for the correction of fetal breech presentation in a non-Chinese population. Healthy non-Chinese nulliparous pregnant women at 32 to 33 weeks + 3 days of gestational age with the foetus in breech presentation were randomly assigned to treatment or observation. Treatment consisted of moxibustion (stimulation with heat from a stick of *Artemisia vulgaris*) at the Zhiyin for 1 or 2 weeks. Subjects in the control group received no moxibustion but were observed. Two weeks after recruitment, each participant was subjected to an ultrasonic examination of the fetal presentation. The main outcome measure was number of participants with cephalic presentation in the 35th week. The study was interrupted when 123 participants had been recruited (46 % of the planned sample). Intermediate data monitoring revealed a high number of treatment interruptions. At this point no difference was found in cephalic presentation in the 35th week (treatment group: 22/65, 34 %; control group: 21/58, 36 %). The authors stated that the results underline the methodological problems evaluating of a traditional treatment transferred from a different cultural context. They do not support either the effectiveness or the ineffectiveness of moxibustion in correcting fetal breech presentation.

In a Cochrane review, Coyle and colleagues (2005) examined the safety and effectiveness of moxibustion on changing the presentation of an unborn baby in the breech position, the need for ECV, mode of birth, and perinatal morbidity and mortality for breech presentation. These investigators concluded that there is insufficient evidence from randomised controlled clinical trials to support the use of moxibustion to correct a breech presentation. The authors stated that moxibustion may be beneficial in reducing the need for ECV, and decreasing the use of oxytocin; however there is a need for well-designed randomised controlled trials to evaluate moxibustion for breech presentation which report on clinically relevant outcomes as well as the safety of the intervention.

In women with a 3rd trimester breech presentation Caesarean section is the mode of delivery of 1st choice, especially when ECV has failed to turn the foetus to cephalic (RCOG 2006). According to the American College of Obstetricians and Gynecologists (ACOG, 2002), ECV may not be for some women and it can pose risks including pre-term labour, placental abruption, umbilical cord entanglement, premature rupture of the membranes, as well as severe maternal discomfort. Currently, neither Royal College of Obstetricians and Gynaecologists nor the ACOG have a policy statement/recommendation on the use of acupuncture/moxibustion for managing foetal breech presentation (RCOG, 2006). However, since ECV is complex, time consuming, and carries increased risk of Obstetric intervention, acupuncture/moxibustion may be a possible option for the management of foetal breech presentation with Obstetric advice.

Jedel (2005) evaluated the effectiveness of acupuncture in the management of xerostomia. Articles of controlled clinical studies assessing the effectiveness of acupuncture in the management of xerostomia were obtained by searching through the databases MEDLINE and Cochrane Central Register of Controlled Trials. Three articles met the criteria for inclusion and a criteria list was used to assess the quality of these studies.

The studies were considered to be of high quality or low quality in accordance with the criteria list utilized. The results of the trials were considered positive, negative or indifferent based on statistically significant between group differences. The criteria list utilized indicate that one of the three studies was of high quality and it presents indifferent results. One of the two studies of low quality presents positive results and one presents indifferent results. An analysis of the results degree of evidence resulted in no evidence for the effectiveness of acupuncture in the management of xerostomia. The authors concluded that this systematic review showed that there is no evidence for the effectiveness of acupuncture in the management of xerostomia, and there is a need for future high quality randomised controlled trials.

In a Cochrane review, Lim et al (2006) examined if acupuncture is more effective than no treatment, more effective than 'sham' (placebo) acupuncture, and as effective as other interventions used to treat irritable bowel syndrome. The authors concluded that most of the trials included in this review were of poor quality and were heterogeneous in terms of interventions, controls, and outcomes measured. Thus, it is still inconclusive if acupuncture is more effective than sham acupuncture or other interventions for treating irritable bowel syndrome.

Passalacqua et al (2006) noted that complementary-alternative medicines (CAM) are extensively used in the treatment of allergic rhinitis and asthma, but evidence-based recommendations are lacking. These researchers carried out a systematic review on CAM for these two indications. Meta-analyses provided no clear evidence for the effectiveness of acupuncture in rhinitis and asthma. Some positive results were described with homeopathy in good-quality trials in rhinitis, but a number of negative studies were also found. Therefore it is not possible to provide evidence-based recommendations for homeopathy in the treatment of allergic rhinitis, and further trials are needed. A limited number of studies of herbal remedies showed some effectiveness in rhinitis and asthma, but the studies were too few to make recommendations. There are also unresolved safety concerns. The authors concluded that the effectiveness of CAM (e.g., acupuncture) for rhinitis and asthma is not supported by currently available evidence.

The above framework is based on the following references:

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Appendix C: Spinal Manipulation Guidance and Evidence Base

Leeds considers spinal manipulation services medically necessary when *all* of the following criteria are met:

1. The patient has a neuromusculoskeletal disorder; *and*
2. medical necessity for treatment is clearly documented; *and*
3. Symptomatic improvement is documented within the initial 2 weeks of spinal manipulation care

NHS Leeds will fund a maximum of twelve treatments for any care episode. This may be provided by a registered osteopath or chiropractor.

If no improvement is documented within the initial 2 weeks, additional treatment is considered not medically necessary unless the treatment is modified. If no improvement is documented within 30 days despite modification of treatment, continued treatment is considered *not* medically necessary. Once the maximum therapeutic benefit has been achieved, continuing care is considered not medically necessary.

Spinal manipulation in asymptomatic persons or in persons without an identifiable clinical condition is considered not medically necessary.

Spinal Manipulation in persons, whose condition is neither regressing nor improving, is considered not medically necessary. Spinal Manipulation treatment for spinal pain will only be funded for acute onset (not chronic) back or neck pain.

Manipulation is deemed experimental and investigational when it is rendered for non-neuromusculoskeletal conditions such as dysmenorrhoea and epilepsy because its effectiveness for these indications is unproven. Manipulation is not considered medically necessary for treatment of idiopathic scoliosis or for treatment of scoliosis beyond early adolescence, unless the patient is exhibiting pain or spasm, or some other medically necessary indications for chiropractic manipulation is present.

Referral for spinal manipulation treatment according to this framework can be made by GPs or secondary care clinicians.

NHS Leeds considers the following procedures experimental and investigational:

Active Release Technique
Applied Spinal Biomechanical Engineering BioEnergetic Synchronization Technique Chiropractic Biophysics Technique
Cranial Manipulation
Coccygeal Meningeal Stress Fixation Technique
Directional Non-force Technique Manipulation for Internal (non-neuromusculoskeletal) Disorders (Applied Kinesiology)
Manipulation Under Anesthesia
Moire Contourographic Analysis
Network Technique
Neural Organizational Technique
Sacro-Occipital Technique
Spinal Adjusting Devices
Upledger Technique
Craniosacral Therapy.

Chiropractic Background

Chiropractic is a branch of the healing arts that is concerned with human health and prevention of disease, and the relationship between the neuroskeletal and musculoskeletal structures and functions of the body. The primary focus of chiropractic is the relationship of the spinal column and the nervous system, as it relates to the restoration and maintenance of health.

The primary focus of the profession is the vertebral column; however, all other peripheral articular structures and adjacent tissues may be treated.

Neuromusculoskeletal conditions commonly treated by chiropractic physicians include:

- Spondylosis
- Osteoarthritis - Intervertebral disc disorders of the spine such as disc protrusion, bulging, degeneration, and displacement
- Peripheral joint trauma
- Degenerative conditions of the joints
- Repetitive motion injuries
- Contractures
- Sprains and strains
- Headaches (including tension headaches, migraines, and vertebrogenic-type headaches)
- Noninfectious inflammatory disorders of the joints, muscles, and ligaments of the spine and extremities
- Myalgia, myofibrositis and fibrositis
- Neuralgias and radiculopathies
- Spinal facet syndromes
- Spondylolisthesis.

The chiropractor may treat multiple neuromusculoskeletal conditions during a single visit. Chiropractors use broadly accepted diagnostic procedures to assess diseases and adverse health conditions.

The primary mode of chiropractic treatment is manipulation or adjustment. Chiropractic manipulation is the application of a controlled force to re-establish normal articular function. The objective of manipulation is to restore the normal mobility and range of motion within the joint.

The chiropractor affects the body's physiology and promotes healing by locating and correcting mechanical disorders of joints or joint subluxations. In chiropractic, the term "subluxation" is used interchangeably with the term "spinal subluxation complex" or "vertebral subluxation complex". A subluxation may also be called a joint dysfunction, joint fixation, functional joint lesion, somatic dysfunction, or biomechanical dysfunction. A subluxation has been defined as a fixation, lack of motion, or aberrant motion of an articular joint, resulting in physiological changes within the joint that may cause inflammation of the joint and its capsule, which may result in pain, swelling, muscle spasm, nerve irritation, damage to joint cartilage, and loss of normal range of motion. Nerve irritation may cause pain and spasm to radiate. Vascular, sensory, and motor changes may accompany a spinal subluxation complex.

Some non-neuromusculoskeletal conditions may be managed by chiropractors when practicing within the scope of their licenses. In assessing the need for chiropractic treatment, both neuromusculoskeletal conditions and any related coexisting non-neuromusculoskeletal disorders should be considered.

Chiropractors treat disease without the use of medications or surgery. When medication or surgery is indicated, the chiropractor should refer the patient to an allopathic or osteopathic physician, as appropriate. Patients may receive medical treatment from an allopathic or osteopathic physician simultaneously or in conjunction with a chiropractic physician.

Chiropractors may diagnose disease and prescribe office-based treatments and home exercises. Chiropractors do not commonly make house calls.

In addition to manipulation, chiropractors may employ adjunctive nutritional, hygienic, and environmental modalities, physiotherapeutic modalities, rehabilitation, and therapeutic massage for the treatment of subluxation and related conditions. The use of adjunctive modalities must be appropriate for the diagnosis and must augment or enhance the manipulative treatment. The type of therapy used should be consistent with the status of the patient's condition (e.g., acute, subacute, rehabilitative or chronic).

Examples of adjunctive physiotherapeutic measures that have been used in chiropractic include:

- Acute phase: thermal (cold) therapy, electrotherapy, trigger point therapy;
- Subacute phase: thermal (heat), electrotherapy, ultrasound; and
- Rehabilitative phase: exercise.

Massage therapy and traction procedures are not considered to be manipulation.

Literature indicates that chiropractic treatment during pregnancy may be appropriate. Chiropractic therapy is often effective in reducing back pain and allowing the patient to function and perform her activities of daily living.

Experimental and Investigational Interventions:

Some diagnostic and therapeutic procedures are not considered medically necessary or essential to the treatment of an illness or injury and are not broadly accepted by the chiropractic profession. Manipulation is deemed experimental and investigational when it is rendered for non-neuromusculoskeletal conditions, because the effectiveness of chiropractic manipulation for this indication has not been proven by adequate scientific studies, published in peer-reviewed scientific journals. An example is the use of manipulation in lieu of antibiotics for treatment of suppurative otitis media. Manipulative procedures are not proven to be an effective substitute for childhood immunizations or for the treatment of infectious diseases, and are not covered for these indications. Chiropractic/manipulative management of scoliosis has not been shown to substantially alter the idiopathic scoliotic curve or progression of the curve in late adolescence or adulthood. Therefore, chiropractic manipulation is not considered medically necessary and is not covered for treatment of idiopathic scoliosis or for treatment of scoliosis beyond early adolescence, unless the patient is exhibiting pain or spasm or if some other medically necessary indication for chiropractic manipulation is present.

Scoliotic deviations may be a result of functional adaptations to lumbo-pelvic lower extremity dysfunction for which chiropractic care is appropriate. Manipulative procedures, in conjunction with electrical muscle stimulation and exercise, can significantly reduce the associated muscle spasm and resultant pain of scoliosis during the acute exacerbations and/or injury, and improve spinal mobility prior to an active exercise regimen. Chiropractic/manipulative management of scoliosis, however, has not been shown to substantially alter the idiopathic scoliotic curve or progression of the curve in late adolescence or adulthood.

The use of chiropractic to correct abnormal spinal curvature in asymptomatic persons is considered experimental and investigational. Chiropractic Biophysics Technique (CPB), also known as Clinical Biomechanics of Posture, is a variation of straight (subluxation-based) chiropractic whose overall goal is to restore posture. CBP advocates are reported to ascribe to the controversial position that decreased neck curvature is pathological and requires correction whether or not the patient has symptoms (Barrett, 2005).

Barrett (2005) critically evaluated the theory behind the Chiropractic Biophysics Technique. The CBP method is based on the idea that postural analysis is valid for diagnosing ligament contractures, muscle weakness, and proprioceptive deficits. The assumed deficits supposedly reduce blood flow, which decreases oxygen delivery and causes various diseases. To qualify for treatment, patients undergo a postural examination and are screened for contraindications to manipulation and cervical extension traction (Barrett, 2005). Therapy begins with relief care consisting of 1 to 12 sessions of spinal adjustments, cold or hot packs, trigger point therapy for muscle spasms, and/or massage with a motorized table. When relief care ends, CBP practitioners switch patients to rehabilitative care, which consists of weekly mirror image adjustments, neck and low back extension traction, as well as mirror image exercises intended to modify spinal curvature over a longer period of time. Initial rehabilitative plans often last 6 to 12 months, after which patients are switched to monthly visits for life (Barrett, 2005).

There is insufficient scientific evidence to support the use of CBP. The published peer reviewed literature focuses primarily on explaining the theoretical basis for the Chiropractic Biophysics Technique. Harrison, et al. (1996) discussed the theory underlying the Chiropractic Biophysics Technique, explaining how certain linear algebra concepts provide the theoretical basis for making postural corrections. The authors explained how Chiropractic Biophysics Technique uses these concepts in examination procedures, manual spinal manipulation, instrument assisted spinal manipulation, postural exercises, extension traction and clinical outcome measures. Jackson, et al. (1993) reported on the intra- and inter-rater reliability of the geometric line drawings used in CBP on lateral cervical radiographs. The investigators concluded that the reliabilities for intra- and inter-examiner were accurate enough to provide measurements for future clinical studies.

There is a paucity of published peer reviewed literature evaluating the effectiveness of the Chiropractic Biophysics Technique in improving clinical outcomes (e.g., reductions in pain and disability, improvements in function). Colloca & Polkinghorn (2003) described the use of CBP protocols in conjunction with other chiropractic techniques in two persons with Ehlers-Danlos

syndrome. In a 10-year follow-up study of neck x-ray findings in asymptomatic patients, Gore (2001) found no relationship between the loss of neck curvature and the development of pain or degenerative changes. Haas and colleagues (1999) noted that changes in spinal structure do not necessarily cause symptoms. They stated that CBP advocates have failed to (i) establish the biological plausibility of what they consider an ideal spine, (ii) show that their diagnostic tests enable better patient management, (iii) demonstrate meaningful outcomes such as decreased pain or disability, and (iv) validate the routine use of spinal x-rays to measure spinal displacement. Active release technique (ART) is a patented soft tissue system that treats problems with muscles, tendons, ligaments, fascia and nerves (e.g., headaches, back pain, carpal tunnel syndrome, shin splints, shoulder pain, sciatica, plantar fasciitis, knee problems, and tennis elbow). These conditions have one important commonality -- they often result from injury to over-used muscles. Each ART session is a combination of examination and treatment. The ART provider uses his/her hands to evaluate the texture, tightness and movement of muscles, fascia, tendons, ligaments and nerves. Abnormal tissues are treated by combining precisely directed tension with very specific patient movements. These treatment protocols - over 500 specific moves - are unique to ART. They supposedly allow providers to identify and correct the specific problems that are affecting each individual patient. Active release technique is similar to some massage techniques, albeit more aggressive.

While ART may be utilized by some chiropractors, it is different from conventional chiropractic manipulation. Furthermore, Drover, et al. (2004) reported that ART protocols did not reduce inhibition or increase strength in the quadriceps muscles of athletes with anterior knee pain. Further study is required.

In a Cochrane review, Proctor et al (2006) concluded that there is no evidence to suggest that spinal manipulation is effective in the treatment of primary and secondary dysmenorrhoea. In a review on the use of complementary and alternative medicine (CAM) including manipulative-based medicine such as chiropractic in the treatment of epilepsy, Ricotti and Delanty (2006) noted that in the available literature, there is a sense of the merit of these therapies in epilepsy, but there is a paucity of research in these areas. The authors stated that, in a science of double-blind, randomised controlled trials, appropriate designs and outcome measurements need to be tailored to CAM. More effort needs to be put into future trials, with the assistance of qualified CAM professionals to ensure conformation to their therapeutic principles.

The ProAdjuster is a hand-held device most commonly used by chiropractors for the diagnosis and treatment of back pain. The technology associated with this device entails the use of a piezoelectric sensing head/probe that is pressed onto the spine sending ultrasound to the vertebral column for measurements of movement of each vertebra or the lack of it. A series of signal waves, each representing an individual vertebra, appears on a computer screen beside digital bar charts, where longer, red bars indicate a mis-alignment in the lower spine. When the ProAdjuster identifies a problem, it then delivers a series of rapid and measured percussion taps that works like a traditional chiropractic adjustment. The sensing system will automatically stop the adjustment when normal motion is detected.

There is insufficient scientific evidence regarding the clinical value of the ProAdjuster for the management of patients with back pain or any other conditions (Barrett, 2005). Available published literature centers on the piezoelectric sensor technology. According to Zhang and Fu (2004), piezoelectric quartz crystal biosensor is a new sensor with the comprehensive utilization of the high sensitivity to mass and the surface characteristics of quartz crystal (e.g., conductance, density, dielectric constant, viscosity), as well as the high specificity of biologic identification molecules. The authors state that piezoelectric quartz crystal biosensors have been used in various settings such as environmental monitoring (e.g., detection of organophosphate levels in river water), foods sanitary control (e.g., detection of sulfamethoxazole residue or Salmonella in milk), as well as medical laboratory diagnosis (e.g., DNA biosensor, biosensor for estrogenic substances, and micro-array immunosensor for quantitative detection of serum or urine human chorionic gonadotropin). Beck and colleagues (2005) compared a piezoelectric contact sensor with an accelerometer for measuring the mechanomyographic (MMG) signal from the biceps brachii during sub-maximal to maximal isokinetic and isometric forearm flexion muscle actions. These researchers found that there were no significant relationships for normalized MMG mean power frequency (MPF, percent maximum) versus isokinetic and isometric torque for the contact sensor, but the accelerometer demonstrated a quadratic or linear relationship for the isokinetic and isometric muscle actions, respectively. There were also a number of significant mean differences between the contact sensor and accelerometer for normalized MMG amplitude or MPF values. The findings of this study

indicated that in some cases involving dynamic and isometric muscle actions, the contact sensor and accelerometer resulted in different torque-related responses that may affect the interpretation of the motor control strategies involved.

A number of other spinal adjusting instruments have been developed that share similarities to the ProAdjuster, including the PulStarFRAS. Similar to the ProAdjuster, the PulStarFRAS (Function Recording and Analysis System) can be used for diagnostic as well as therapeutic purposes. The PulStarFRAS is designed to generate an objective and repeatable analysis of the mobility (compliance) of the spinal structure. The resulting computerized differential compliance (CDC) scans are used as an aid in the identification of spinal joint dysfunction. The PulStarFRAS provides a low-force multiple impulse therapy to resolve joint fixation. There is a lack of adequate evidence regarding its clinical value of the PulStarFRAS.

The Activator is a spinal adjusting instrument that is similar to the ProAdjuster in that it provides low force. There is insufficient evidence that use of the Activator results in benefits equivalent to standard chiropractic manipulation. In a pilot study (n = 30), Wood et al (2001) found that both instrumental manipulation by means of the Activator II Adjusting Instrument and manual manipulation have beneficial effects associated with reducing pain and disability and improving cervical range of motion in patients with neck pain. They concluded that a randomised, controlled clinical trial in a similar patient base with a larger sample size is necessary to verify the clinical relevance of these findings. In a case series study (n = 9), Devocht et al (2003) reported that the symptoms of temporomandibular disease improved following a course of treatment using the Activator methods. The authors concluded that further investigation of this type of chiropractic treatment for patients with the articular type of temporomandibular disease is warranted. Moreover, Fuhr and Menke (2005) stated that the Activator Adjusting Instrument may be a clinically useful tool, but its ultimate scientific validation requires testing using sophisticated research models in the areas of neurophysiology, biomechanics, and statistical analysis. This is in agreement with the observation of Polkinghorn (1998) who noted that instrument-delivered adjustments (i.e., the Activator Adjusting Instrument) may provide benefit in cases of cervical disc protrusion in which manual manipulation causes an exacerbation of the symptoms or is contraindicated altogether. The author concluded that further study in this area should be made via large scale studies organized in an academic research setting.

Preventive or Maintenance Chiropractic Manipulation:

Preventive or maintenance chiropractic manipulation has been defined as elective health care that is typically long-term, by definition not therapeutically necessary but is provided at preferably regular intervals to prevent disease, prolong life, promote health and enhance the quality of life. This care may be provided after maximum therapeutic improvement, without a trial of withdrawal of treatment, to prevent symptomatic deterioration or it may be initiated with patients without symptoms in order to promote health and to prevent future problems.

Preventive services may include patient education, home exercises, and ergonomic postural modification. The appropriateness and effectiveness of chiropractic manipulation as a preventive or maintenance therapy has not been established by clinical research and is not covered.

Supportive care has been defined as treatment for patients who have reached maximum therapeutic benefit, but who fail to sustain benefit and progressively deteriorate when there are periodic trials of treatment withdrawal. Continuation of chiropractic care is considered medically necessary until maximum therapeutic benefit has been reached, when the patient fails to progress clinically between treatments, or when pre-injury/illness status has been reached. Once the maximum therapeutic benefit has been achieved, continuing chiropractic care is not considered medically necessary and thus is not covered.

Active corrective care is ongoing treatment, rendered after the patient has become symptomatically and objectively stable, to prevent a recurrence of a patient's condition by correcting underlying abnormal spinal biomechanics that appear to be the cause of the initial injury. The efficacy of active corrective care is not supported by scientific evidence and is not covered.

The above framework is based on the following references:

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Osteopathy Informationⁱ

Introduction

Osteopathy is a profession that has been regulated by statute since the passing of The Osteopath's Act (1993)¹. A new regulatory body, the General Osteopathic Council (GOsC)², was formed in 2000. Osteopaths practise throughout the UK and overseas; most osteopaths work in private practice but a growing number work within the National Health Service (NHS). Registration with the GOsC is renewed annually subject to certain requirements e.g. the retention of professional indemnity insurance and the meeting of mandatory continual professional development requirements.

Training

Osteopaths undergo four years training resulting in the award of BSc(Hons) Ost or BSc(Hons) Ost Med. There are now eight osteopathic training establishments in the UK which have met RQ status. An increasing number of osteopaths are undergoing postgraduate training for MSc, MRes and PhD awards.

Osteopathic practise

Osteopathic treatment employs a vast range of techniques and doesn't solely use spinal manipulation. Additional techniques include soft tissue work, spinal articulation, and appropriate exercise. A wide range of symptoms are treated in clinical practise; low back pain is the most common but pain to the cervical spine and shoulder joint are also very common. All other peripheral joints are treated and techniques are chosen so that they are suitable for a patient's symptoms, age, general health and morphology. Education relating to the patient's condition is also emphasised in their management to produce suitable coping strategies and to prevent the recurrence of injury. Initial screening takes place at first consultation and referrals are made where patients are not suitable for osteopathic treatment.

Osteopathy and safety

A number of studies are currently being undertaken to investigate the incidence of adverse events related to osteopathy. Episodes of soreness after treatment are short lived (24 hours) and are commonly found in many other therapies using a "hands-on" approach³. Anecdotally the profession has enjoyed an extremely safe reputation since it uses less high velocity manipulation than other

ⁱ Thanks to Carol Fawkes Research Development Officer Clinical Research Centre for Health Professions University of Brighton for providing the information for this section.

professions. The use of such high velocity manipulation techniques to the cervical spine has contributed to incidents of serious adverse events which have been reported by other manual therapy professions. The studies currently being undertaken for osteopathy are collaborative projects between osteopathic educational institutions and experienced researchers from Barts and The London, the University of Warwick and the University of Brighton. Further information concerning the studies can be found at www.brighton.ac.uk/ncor/research_opps/index.htm.

Osteopathy and Research

Research in osteopathy has taken place over a number of years but in an informal manner. In 2003, the National Council for Osteopathic Research (NCOR) was formed and is based at the University of Brighton under the direction of Professor Ann Moore. NCOR is involved in a number of projects including:

- The creation of a searchable online database of published osteopathic research
- The creation of a database of unpublished research
- The development of a standardised data collection tool for osteopaths
- The development of a network of research groups (hubs) throughout the UK each of which are involved in pilot studies

Low back pain.

In 2004 funding was awarded by the Medical Research Council for the United Kingdom Back Pain, Exercise and Manipulation (UK BEAM) randomised trial⁴. This looked at how one or a combination of treatment approaches could improve low back pain in patients. The study authors concluded that the combination of spinal manipulation and exercise was more beneficial than when the treatments were used in isolation, and when compared to “best care” offered through general practice. An economic evaluation⁵ was made for this study and this concluded that adding spinal manipulation to “best care” was a cost effective way to manage back pain in general practice.

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Appendix D: Homeopathy Commissioning Guidance

NHS Leeds recognises that there are a limited number of patients with complex needs who have exhausted all conventional therapies and represent a difficult clinical management challenge. They appear to derive some benefit from interventions such as Homeopathy. In this circumstance Homeopathy will only be funded on an outpatient basis and only when other avenues have been exhausted.

The PCT will not commission Homeopathy for patients who choose to avoid conventional treatments.

The PCT will commission the use of Homeopathy in this group for one cycle of 8 sessions. Additional sessions will only be considered where it can be clearly demonstrated the intervention has reduced reliance on medication, frequency of attendance at GP surgery or reduction in hospital outpatient attendance.

Any use of Homeopathy requires prior approval of the NCA panel.

The PCT regards the use of homeopathy in any other situation as medically unnecessary.

Appendix E: Interventions NHS Leeds will not Commission

Interventions NHS Leeds will not Commission. This list is not exhaustive and NHS Leeds reserves the right to decline interventions where there is no evidence of effectiveness.

Active release technique	Hyperoxygen therapy
Acupressure	Immunoaugmentive therapy
Alexander technique	Infratronic Qi-Gong machine
AMMA therapy	Insulin potentiation therapy
Antineoplastons	Inversion therapy
Apitherapy	Iridology
Applied kinesiology	Iscador
Aromatherapy	Kelley/Gonzales therapy
Art therapy	Laetrile
Auto urine therapy	Live blood cell analysis
Bioenergetic therapy	Macrobiotic diet
Biofield Cancell (Entelev) cancer therapy	Magnet therapy
Bioidentical hormones	Meditation/transcendental meditation
Carbon dioxide therapy	Megavitamin therapy
Cellular therapy	Meridian therapy
Chelation therapy for Atherosclerosis	Mesotherapy
Chung Moo Doe therapy	Moxibustion
Coley's toxin	MTH-68 vaccine
Colonic irrigation	Music therapy
Conceptual mind-body techniques	Myotherapy
Craniosacral therapy	Neural therapy
Cupping	Ozone therapy
Dance/Movement therapy	Pfrimmer deep muscle therapy
Digital myography	Polarity therapy
Ear Candling	(Poon's) Chinese blood cleaning
Egoscue method	Primal therapy
Electrodiagnosis according to Voll (EAV)	Psychodrama
Equestrian therapy	Purging
Essential Metabolics Analysis (EMA)	Qigong longevity exercises
Essiac	Ream's testing
Feldenkrais method of exercise therapy	Reflexology (zone therapy)

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Flower essence	Reflex Therapy
Fresh cell therapy	Reiki
Functional intracellular analysis	Remedial massage
Gemstone therapy	Revici's guided chemotherapy
Gerson therapy	Rolfing (structural integration)
Greek cancer cure	Rubinfeld synergy method (RSM)
Guided imagery	Sarapin injections
Hair analysis	Shark cartilage products
Hellerwork	Therapeutic Eurythmy-movement therapy
Hoxsey method	Therapeutic touch
Humour therapy	Thought field therapy (TFT) (Callahan Techniques Training)
Hydrazine sulfate	Trager approach
	Wurn technique/clear passage therapy
	Yoga

Appendix G: Plan for Dissemination of Framework Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Acknowledgement: University Hospitals of Leicester NHS Trust.

Title of Framework:	Complementary and Alternative Therapies Framework		
Date finalised:		Dissemination lead:	Matt Walsh
Previous framework already being used?	No	Print name and contact details	
If yes, in what format and where?	n/a		
Proposed action to retrieve out-of-date copies of the document:	n/a		
To be disseminated to:	How will it be disseminated, who will do it and when?	Paper or Electronic	Comments
Clinicians	Full policies on Leeds Health Pathways, September 2008	Electronic	
Clinicians	Summary of Policies September 2008	Electronic/ Paper	
Panel Members	In Person September 2008	Electronic and Paper	

Dissemination Record - to be used once framework is approved.

Date put on register / library of framework documents		Date due to be reviewed	
--	--	--------------------------------	--

Disseminated to: (either directly or via meetings, etc)	Format (i.e. paper or electronic)	Date Disseminated	No. of Copies Sent	Contact Details / Comments

Appendix H: Equality Impact Assessment Tool

To be completed and attached to any framework document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	Does the framework affect one group less or more favourably than another on the basis of:		
	• Race	no	
	• Ethnic origins (including gypsies and travellers)	no	
	• Nationality	no	
	• Gender	no	
	• Culture	no	
	• Religion or belief	no	
	• Sexual orientation including lesbian, gay and bisexual people	no	
	• Age	no	
2.	Is there any evidence that some groups are affected differently?	no	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	n/a	
4.	Is the impact of the framework likely to be negative?	yes	Some patients will be denied access to treatment on the NHS
5.	If so can the impact be avoided?	no	
6.	What alternatives are there to achieving the framework without the impact?	none	
7.	Can the impact be reduced by taking different action?	yes	By agreeing no restrictions to any intervention

Appendix A: Checklist for the Review and Approval of Framework Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Point of contact details concerning the main author/s

Name of Executive Director supporting the framework	Name of person responsible for the development of the framework
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	Title of Framework being reviewed: Complementary and Alternative Therapies Framework	Yes/No/ Unsure	Comments
1.	Title		
	Is the title clear and unambiguous?	yes	
	Is it clear that the document is a framework, ie does it fit the definition provided in Appendix G?	yes	
2.	Purpose		
	Are the reasons for development of the framework clearly stated?	yes	
3.	Development Process		
	Is the method described in brief?	yes	
	Are people involved in the development identified?	yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	yes	
	Is there evidence of consultation with stakeholders and users?	yes	
4.	Content		
	Is the objective of the framework clear?	yes	
	Is the target population clear and unambiguous?	yes	
	Are the intended outcomes described?	yes	
	Are the statements clear and unambiguous?	yes	
5.	Evidence Base		
	Is the type of evidence to support the framework identified explicitly?	yes	
	Are key references cited?	yes	
	Are the references cited in full?	yes	
	Are supporting documents referenced?	yes	
6.	Approval		
	Does the framework identify which committee(s)/group(s) will approve it?	yes	
	Does the document summarise the consultation process that it has been through and is this considered appropriate and adequate? Specifically consider whether consultation with formally constituted board	yes	

	Title of Framework being reviewed: Complementary and Alternative Therapies Framework	Yes/No/ Unsure	Comments
	sub committees have been consulted or approved for example, have the joint Human Resources/staff side committee (or equivalent) approved the framework?		
7.	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	yes	
	Does the plan include the necessary training/support to ensure compliance, and what will be the impact of this? e.g. training resources, staff time away from service provisions, new education commissioning required	yes	
	Does this document need to be available in languages and formats other than written or English?	no	
8.	Document Control		
	Does the document identify where it will be held?	yes	
	Have archiving arrangements for superseded documents been addressed?	n/a	
9.	Process to Monitor Compliance and Effectiveness		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	yes	
	Is there a plan to review or audit compliance with the document?	yes	
10.	Review Date		
	Is the review date identified?	yes	
	Is the frequency of review identified? If so is it acceptable?	yes	
11.	Overall Responsibility for the Framework		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	yes	

Individual Approval

If you are happy to approve this framework, please sign and date it and forward either to Julie Turner where discussion/approval at EMT if required, or to a Board sub-committee for their approval, prior to final ratification.

Name		Date	
Signature			

Committee Approval

If the committee is happy to approve this framework and recommend it for ratification, the Committee Chair must sign and date below. This form, together with the framework, must be forwarded onto the Board Secretary for adding to the next available Board meeting agenda.

Name		Date	
Signature			

Acknowledgement: Cambridgeshire and Peterborough Mental Health Partnership NHS Trust