Complementary and Alternative Therapies
Evidence Based Decision Making Framework

A broad range of treatments and practices that are not considered standard medical treatment by NHS Leeds North CCG, NHS Leeds South and East CCG and NHS Leeds West CCG

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Name & Title of originator/author(s):	Dr Simon Stockill, Medical Director, NHS Leeds West CCG Dr Manjit Purewal, Medical Director NHS Leeds North CCG Dr David Mitchell, Medical Director NHS Leeds South and East CCG Dr Fiona Day, Consultant in Public Health Medicine, Leeds City Council
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On behalf of NHS Leeds North Clinical Commissioning Group, NHS Leeds South and East Clinical Commissioning Group and NHS Leeds West Clinical Commissioning Group

1 Introduction

Leeds Clinical Commissioning Groups (CCGs), NHS Leeds North CCG, NHS Leeds South and East CCG and NHS Leeds West CCG do not routinely commission alternative therapy interventions unless they are supported by adequate evidence of safety and effectiveness in the peer reviewed medical literature. "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".

2 Purpose

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

3 Scope

This document is intended as an aid to decision making. It should be used in conjunction with Leeds CCG policies on Individual Funding Requests and associated decision making frameworks.

4 Framework operation

The following are some of the alternative medicine interventions that the CCGs consider appropriate for properly selected patients. Appendix A summarises the background evidence. These will only be funded when provided by 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 the Leeds Musculo-Skeletal (MSK) 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.

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

The CCGs will not commission any of the procedures in appendix D because there is inadequate evidence of their effectiveness in the peer-reviewed medical literature.

Prior approval is required from the Non Commissioned Activity panel for any complementary or alternative therapy outside the MSK Service. Providers will not be paid for any activity with regards this framework which has not been approved in advance.

4.1 Endpoints

Following completion of the agreed treatment, a proportionate follow up process will lead to a final review appointment with the clinician where both patient and clinician agree that a satisfactory end point has been reached. This should be at the discretion of the individual clinician and based on agreeing reasonable and acceptable clinical and/ or cosmetic outcomes.

Once the satisfactory end point has been agreed and achieved, the patient will be discharged from the service.

Requests for treatment for unacceptable outcomes post treatment will only be considered through the Individual Funding Request route. Such requests will only be considered where a) the patient was satisfied with the outcome at the time of discharge and b) becomes dissatisfied at a later date. In these circumstances the patient is not automatically entitled to further treatment. Any further treatment will therefore be at the relevant Leeds Clinical Commissioning Group's discretion, and will be considered on an exceptional basis in accordance with the IFR policy.

Appendix A: Background to the Framework and Evidence Base

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 7 categories:

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

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 in Europe. 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

The CCGs consider needle acupuncture (manual or electroacupuncture) may be medically necessary for any of the following indications:

- Chronic low back pain. (Maintenance treatment, where the patient's symptoms are neither regressing nor improving, is considered not medically necessary. A suitably qualified acupuncture practitioner could consider delivering a maximum of 10 sessions of acupuncture over 12 weeks for chronic low back pain (as per NICE))
- Migraine headache (as per NICE);
- Post-operative and chemotherapy-induced nausea and vomiting;
- Post-operative dental pain;
- Temporo-mandibular joint (TMJ) disorders

The CCGs consider 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:

Acne
Acute low back pain
Addiction
AIDS
Amblyopia
Asthma
Autism spectrum disorders
Bell's palsy
Burning mouth syndrome
Cancer-related dyspnoea
Carpal tunnel syndrome
Chemotherapy-induced leukopenia
Chemotherapy-induced neuropathic pain
Chronic pain syndrome (e.g., RSD, facial pain)
Chronic obstructive pulmonary disease
Diabetic peripheral neuropathy
Dry eyes
Erectile dysfunction
Facial spasm
Foetal breech presentation
Fibromyalgia
Fibrotic contractures
Glaucoma
Hypertension
Induction of labour
Infertility (e.g., to assist oocyte retrieval and embryo transfer during IVF treatment cycle)
Insomnia
Irritable bowel syndrome
Menstrual cramps/dysmenorrhea
Mumps
Myofascial pain
Myopia
Neck pain/cervical spondylitis
Obesity
Painful neuropathies
Parkinson's disease
Peripheral arterial disease (e.g., intermittent claudication)
Phantom leg pain
Polycystic ovary syndrome
Post-herpetic neuralgia
Psoriasis
Psychiatric disorders (e.g., depression)
Raynaud's disease pain
Respiratory disorders
Rheumatoid arthritis
Rhinitis
Sensorineural deafness
Shoulder pain (e.g., bursitis)
Smoking cessation
Stroke rehabilitation (e.g., dysphagia)
Tennis elbow / epicondylitis
Tension headache
Tinnitus
Urinary incontinence
Uterine fibroids
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 not considered 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. Use of Acupuncture in this situation is supported by NICE.

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 remainsbout 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 electro-acupuncture (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.

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.

In a prospective, randomized, controlled, cross-over trial, Lam et al (2011) evaluated the safety and adjunctive effect of acupuncture added to refractive correction for anisometropic amblyopia in younger children. A total of 83 children aged 3 to less than 7 years with untreated anisometropic amblyopia and baseline best-corrected visual acuity (BCVA) of 20/40 to 20/200 in the amblyopic eye were included in this study. Participants were randomized to receive spectacles alone (group 1; n = 42) or spectacles + acupuncture (group 2; n = 41) for 15 weeks, and were then crossed-over to receive the other regimen for another 15 weeks. The BCVA in both eyes was measured at baseline and every 5 (+/- 1) weeks for the initial 45 weeks and at 60 (+/- 1) weeks. Main outcome measures were BCVA in the amblyopic eye at 15, 30, and 60 weeks. The mean baseline BCVA in the amblyopic eye was 0.50 and 0.49 logarithm of the minimum angle of resolution (logMAR) in groups 1 and 2, respectively. After 15 weeks of treatment, the BCVA had improved by a mean of 2.2 lines in group 1 and 2.9 lines in group 2. The mean difference in BCVA between groups was 0.77 lines (95 % CI: 0.29 to 1.3; p = 0.0020) with baseline adjustment. BCVA of less than or equal to 0.1 logMAR was achieved in 14.6 % of the patients in group 1 and 57.5 % in group 2 (p < 0.00010). After the regimens were crossed-over at 30 weeks, group 1 had a mean of 1.2 (95 % CI: 0.98 to 1.48) lines additional improvement from the 15-week BCVA, whereas in group 2 the mean improvement was 0.4 (95 % CI: 0.19 to 0.63) lines. The proportions of responders, resolution, and participants achieving a BCVA of less than or equal to 0.1 logMAR at 30 weeks were similar between groups. After completion of acupuncture, only 1 participant had greater than 1 line of VA decrease to 60 weeks. Acupuncture was well-tolerated by all children, and no severe adverse effect was encountered. The authors concluded that acupuncture is a potentially useful complementary treatment modality that may provide sustainable adjunctive effect to refractive correction for anisometropic amblyopia in young children. They stated that acupuncture has good potential to become a complimentary therapeutic modality for amblyopia, and further large-scale studies seem warranted.

In a Cochrane review, Cheuk et al (2011) examined the effectiveness of acupuncture for people with autism spectrum disorders (ASD) in improving core autistic features, as well as communication, cognition, overall functioning and quality of life, and established if it has any adverse effects. These investigators searched the following databases on September 30, 2010: CENTRAL (The Cochrane Library, 2010, Issue 3), MEDLINE (1950 to September 2010 Week 2), EMBASE (1980 to 2010 Week 38), PsycINFO, CINAHL, China Journal Full-text Database, China Master Theses Full-text Database, China Doctor Dissertation Full-text Database, China Proceedings of Conference Database, Index to Taiwan Periodical Literature System, metaRegister of Controlled Trials and the Chinese Clinical Trials Registry. They also searched AMED (February 26, 2009) and Dissertation Abstracts International (March 3, 2009), but these were no longer available to the authors or editorial base at the date of the most recent search. TCMLARS (Traditional Chinese Medical Literature Analysis and Retrieval System) was last searched on March 3, 2009. These researchers included RCTs and quasi-RCTs. They included studies comparing an acupuncture group with at least one control group that used no treatment, placebo or sham acupuncture treatment in people with ASD. They excluded trials that compared different forms of acupuncture or compared acupuncture with another treatment. Two review authors independently extracted trial data and assessed the risk of bias in the trials. They used relative risk (RR) for dichotomous data and mean difference (MD) for continuous data. The authors included 10 trials that involved 390 children with ASD. The age range was 3 to 18 years and the treatment duration ranged from 4 weeks to 9 months. The studies were carried out in Hong Kong, mainland China and Egypt. Two trials compared needle acupuncture with sham acupuncture and found no difference in the primary outcome of core autistic features (RFRLRS total score: MD 0.09; 95 % CI: -0.03 to 0.21, p = 0.16), although results suggested needle acupuncture might be associated with improvement in some aspects of the secondary outcomes of communication and linguistic ability, cognitive function and global functioning. Six trials compared needle acupuncture plus conventional treatment with conventional treatment alone. The trials used different primary outcome measures and most could not demonstrate effectiveness of acupuncture in improving core autistic features in general, though 1 trial reported patients in the acupuncture group were more likely to have improvement on the Autism Behavior Checklist (RR 1.53; 95 % CI: 1.09 to 2.16, p = 0.02) and had slightly better post-treatment total scores (MD -5.53; 95 % CI: -10.76 to -0.31, p = 0.04). There was

no evidence that acupuncture was effective for the secondary outcome of communication and linguistic ability, though there seemed to be some benefit for the secondary outcomes of cognitive function and global functioning. Two trials compared acupressure plus conventional treatment with conventional treatment alone and did not report on the primary outcome. Individual study results suggested there may be some benefit from acupressure for certain aspects of the secondary outcomes of communication and linguistic ability, cognitive function and global functioning. Four trials reported some adverse effects, though there was little quantitative information, and at times both intervention and control groups experienced them. Adverse effects included bleeding, crying due to fear or pain, irritability, sleep disturbance and increased hyperactivity. None of the trials reported on quality of life. There are a number of problems with the evidence base: the trials were few in number and included only children; 6 of the trials were at high-risk of bias; they were heterogeneous in terms of participants and intervention; they were of short duration and follow-up; they reported inconsistent and imprecise results, and, due to carrying out large numbers of analyses, they were at risk of false positivity. The authors concluded that current evidence does not support the use of acupuncture for treatment of ASD. There is no conclusive evidence that acupuncture is effective for treatment of ASD in children and no RCTs have been carried out with adults. They stated that further high quality trials of larger size and longer follow-up are needed.

In a Cochrane review, Wei et al (2011) evaluated the safety and effectiveness of acupuncture in slowing the progression of myopia in children and adolescents. These investigators searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2011, Issue 7), MEDLINE (January 1950 to July 2011), EMBASE (January 1980 to July 2011), the Allied and Complementary Medicine Database (AMED) (January 1985 to July 2011), Latin American and Caribbean Health Sciences Literature Database (LILACS) (January 1982 to July 2011), the metaRegister of Controlled Trials (mRCT) (http://www.controlled-trials.com/), ClinicalTrials.gov (http://www.clinicaltrial.gov/), the National Center for Complementary and Alternative Medicine (NCCAM) (The first issue to August 2010), the Chinese Biological Medicine Database (CBM) (1978 to April 2011), China National Knowledge Infrastructure (CNKI) (1994 to April 2011) and VIP (1989 to April 2011). There were no date or language restrictions in the electronic searches for trials. CENTRAL, MEDLINE, EMBASE, AMED, LILACS, mRCT and ClinicalTrials.gov were last searched on 9 July 2011. NCCAM was searched up to August 2010 and CBM, CNKI, and VIP were last searched on April 6, 2011. These researchers included RCTs that included any type of acupuncture treatment for myopia in children and adolescents. Two authors independently evaluated the search results according to the inclusion and exclusion criteria. Two authors extracted and assessed data independently. They contacted the study investigator for missing data. The authors included 2 RCTs conducted in Taiwan with a total of 131 participants. They did not perform a meta-analysis as the trials were assessing different outcomes. Neither trial met the pre-defined primary outcome criteria of myopia progression defined as 1 diopter mean change. Only 1 trial reported the changes of axial length without non-significant difference among groups and both trials reported that several children experienced mild pain during acupuncture stimulation. Two trials were included in this review but no conclusions can be drawn for the benefit of co-acupressure for slowing progress of myopia in children. The authors concluded that further evidence in the form of RCTs are needed before any recommendations can be made for the use of acupuncture treatment in clinical use. These trials should compare acupuncture to placebo and have large sample sizes. Other types of acupuncture (such as auricular acupuncture) should be explored further as well as compliance with treatment for at least 6 months or longer. Axial length elongation of the eye should be investigated for at least 1 year. The potential to reduce/eliminate pain from acupuncture experienced by children should also be reviewed.

The Canadian Thoracic Society's clinical practice guideline on " Managing dyspnea in patients with advanced chronic obstructive pulmonary disease" (Marciniuk et al, 2011) noted that dyspnea is a cardinal symptom of chronic obstructive pulmonary disease (COPD), and its severity and magnitude increases as the disease progresses, leading to significant disability and a negative effect on quality of life. Refractory dyspnea is a common and difficult symptom to treat in patients with advanced COPD. There are many questions concerning optimal management and, specifically, whether various therapies are effective in this setting. These investigators addressed these important clinical issues using an evidence-based systematic review process led by a representative inter-professional panel of experts. The evidence supported the benefits of oral opioids, neuromuscular electrical stimulation, chest wall vibration, walking aids and pursed-lip breathing in the management of dyspnea in the individual patient with advanced COPD. Oxygen is recommended for COPD patients with resting hypoxemia, but its use for the targeted management of dyspnea in this setting should be reserved for patients who receive symptomatic benefit. There is insufficient evidence to support the routine use of anxiolytic medications, nebulized opioids, acupuncture, acupressure, distractive auditory stimuli (music), relaxation, hand-held fans, counseling programs or psychotherapy. There is also no evidence to support the use of supplemental oxygen to reduce dyspnea in non-hypoxemic patients with advanced COPD.

Williams et al (2012) stated that acne is a chronic inflammatory disease of the pilo-sebaceous unit resulting from androgen-induced increased sebum production, altered keratinization, inflammation, and bacterial colonization of hair follicles on the face, neck, chest, and back by Propionibacterium acnes. Although early colonization with P acnes and family history might have important roles in the disease, exactly what triggers acne and how treatment affects the course of the disease remain unclear. Other factors such as diet have been implicated, but not proven. Facial scarring due to acne affects up to 20 % of teenagers. Acne can persist into adulthood, with detrimental effects on self-esteem. There is no ideal treatment for acne, although a suitable regimen for reducing lesions can be found for most patients. Good quality evidence on comparative effectiveness of common topical and systemic acne therapies is scarce. Topical therapies including benzoyl peroxide, retinoids, and antibiotics when used in combination usually improve control of mild to moderate acne. Treatment with combined oral contraceptives can help women with acne. Patients with more severe inflammatory acne usually need oral antibiotics combined with topical benzoyl peroxide to decrease antibiotic-resistant organisms. Oral isotretinoin is the most effective therapy and is used early in severe disease, although its use is limited by teratogenicity and other side-effects. Availability, adverse effects, and cost, limit the use of photodynamic therapy. New research is needed into the therapeutic comparative effectiveness and safety of the many products available, and to better understand the natural history, subtypes, and triggers of acne. Moreover, the authors stated that complementary and alternative medicine (including acupuncture) can not be recommended for the treatment of acne because it is not supported by good evidence.

Yan et al (2012) noted that burning mouth syndrome (BMS) is a common chronic pain condition that lacks a satisfactory treatment approach. These researchers examined the effects of acupuncture or acupoint injection on the management of BMS and evaluated the evidence supporting the use of acupuncture therapy for BMS in clinical practice. The following databases were searched for relevant articles: Cochrane Oral Health Group Trials Register (July 2011), Cochrane Central Register of Controlled Trials (issue 7, 2011), MEDLINE (1966 to June 2011), and electronic medical database from the China-National Knowledge Infrastructure (1979 to June 2011). Articles were screened, and the quality of the included trials was assessed independently by 2 reviewers. After screening, 9 studies with 547 randomized patients were included in this review. All 9 articles were published in Chinese and were clinical trial studies with a Jadad score of less than 3. Their results showed that acupuncture/acupoint injection may benefit patients with BMS. The evidence supported the efficacy of acupuncture/acupoint injection therapy in reducing BMS pain and related symptoms. The authors concluded that in light of the positive outcomes reported, the use of acupuncture therapy for BMS patients warrants further research.

Bo and colleagues (2012) evaluated the reports' qualities which are about RCTs of acupuncture treatment on diabetic peripheral neuropathy (DPN). A total of 8 databases including The Cochrane Library(1993 to Sept.,2011), PubMed (1980 to Sept., 2011), EMbase (1980 to Sept.,2011), SCI Expanded (1998 to Sept.,2011), China Biomedicine Database Disc (CBMdisc, 1978 to Sept., 2011), China National Knowledge Infrastructure (CNKI, 1979 to Sept., 2011), VIP (a full text issues database of China, 1989 to Sept., 2011), Wan Fang (another full text issues database of China 1998 to Sept., 2011) were searched systematically. Hand-search for further references was conducted. Language was limited to Chinese and English. These investigators identified 75 RCTs that used acupuncture as an intervention and assessed the quality of these reports with the Consolidated Standards for Reporting of Trials statement 2010 (CONSORT2010) and Standards for Reporting Interventions Controlled Trials of Acupuncture 2010(STRICTA2010). A total of 24 articles (32 %) applied the method of random allocation of sequences. No article gave the description of the mechanism of allocation concealment, no experiment applied the method of blinding. Only 1 article (1.47 %) could be identified directly from its title as about the RCTs, and only 4 articles gave description of the experimental design. No article mentioned the number of cases lost or eliminated. During 1 experiment, acupuncture syncope led to temporal interruption of the therapy. Two articles (2.94 %) recorded the number of needles, and 8 articles (11.76 %) mentioned the depth of needle insertion. None of articles reported the base of calculation of sample size, or has any analysis about the metaphase of an experiment or an explanation of its interruption. One (1.47 %) mentioned intentional analysis (ITT). The authors concluded that the quality of the reports on RCTs of acupuncture for diabetic peripheral neuropathy is moderate to low. They stated that the CONSORT2010 and STRICTA2010 should be used to standardize the reporting of RCTs of acupuncture in future.

In a meta-analysis, Wang et al (2012) evaluated the effectiveness of acupuncture in facial spasm. The research team categorized results from each of the reviewed studies in 2 ways: (i) the number of participants who showed a positive response to therapy (total effectiveness rate), and (ii) the number of participants who made a full recovery (clinical cure rate). The research team reviewed a total of 13 studies involving 1,262 participants with facial spasm. Researchers in China had conducted all studies, and most studies were poor

in methodological quality. All studies reported that acupuncture was superior to other treatments, including carbamazepine, mecobalamin, and massage, and the meta-analysis on these low-quality studies yielded similar results. The authors concluded that present trials evaluating the effectiveness of acupuncture in treatment of facial spasm are mostly poor in methodological quality. These studies showed that acupuncture was superior to other treatments for facial spasm; however, in its meta-analysis, the research team could not draw an affirmative conclusion as to the benefits of acupuncture due to the poor methodological quality and localized population of the included trials. The authors concluded that the field needs large international, well-conducted RCTs.

In a Cochrane review, He and colleagues (2012) evaluated the safety and effectiveness of acupuncture for children with mumps. These investigators searched CENTRAL (2012, Issue 4), MEDLINE (1950 to April week 4, 2012), EMBASE (1974 to May 2012), CINAHL (1981 to May 2012), AMED (1985 to May 2012), the Chinese BioMedicine Database (CBM) (1979 to May 2012), China National Knowledge Infrastructure (CNKI) (1979 to May 2012), Chinese Technology Periodical Database (CTPD) (1989 to May 2012) and WANFANG database (1982 to May 2012). They also hand-searched a number of journals (from first issue to current issue). These researchers included RCTs comparing acupuncture with placebo acupuncture, no management, Chinese medication, Western medication or other treatments for mumps. Acupuncture included either traditional acupuncture or contemporary acupuncture, regardless of the source of stimulation (body, electro, scalp, fire, hand, fine needle, moxibustion). Two review authors independently extracted data and assessed the quality of included studies. They calculated risk ratios (RR) with their 95 % CI for the effective percentage and standardized mean differences (SMD) with 95 % CIs for the time to cure. Only 1 study with 239 participants met the inclusion criteria. There were a total of 120 participants in the acupuncture group, of which 106 recovered, with their temperature returning back to normal and no swelling or pain of the parotid gland; the condition of 14 participants improved, with a drop in temperature and alleviation of swelling or pain of the parotid gland. There were 119 participants in the Western medicine group, of which 56 recovered and the condition of 63 improved. The acupuncture group had a higher recovery rate than the control group. The relative RR of recovery was 1.88 (95 % CI: 1.53 to 2.30). However, the acupuncture group had a longer time to cure than the control group. The mean was 4.20 days and the standard deviation (SD) was 0.46 in the acupuncture group, while in the control group the mean was 3.78 days and the SD was 0.46. There was a potential risk of bias in the study because of low methodological quality. The authors concluded that they could not reach any confident conclusions about the safety and effectiveness of acupuncture based on 1 study. They stated that more high-quality research is needed.

The above framework is based on the following references:

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Appendix C: Spinal Manipulation Guidance and Evidence Base

Leeds CCGs consider 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

The CCGs 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, maintenance 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.

The CCGs consider s the following procedures experimental and investigational:

Active Release Technique
Active Therapeutic Movement (ATM2)
Applied Spinal Biomechanical Engineering
Atlas Orthogonal Technique
Bioenergetic Synchronization Technique
Biogeometric Integration
Blair Technique
Chiropractic Biophysics Technique
Coccygeal Meningeal Stress Fixation Technique
Cranial Manipulation
Directional Non-force Technique
FAKTR (Functional and Kinetic Treatment with Rehab) Approach
Gonzalez Rehabilitation Technique
Koren Specific Technique
Manipulation for infant colic
Manipulation for internal (non-neuromusculoskeletal) disorders (Applied Kinesiology)
Manipulation under anesthesia
Moire Contourographic Analysis
Network Technique
Neural Organizational Technique
Neuro Emotional Technique
Sacro-Occipital Technique
Spinal adjusting devices (ProAdjuster, PulStarFRAS, Activator)
Upledger Technique and Cranio-Sacral Therapy
Webster Technique (for breech babies)
Whitcomb Technique
Computerized radiographic mensuration analysis for assessing spinal mal-alignment
Neurocalometer/Nervoscope
Para-spinal electromyography (EMG)/Surface scanning EMG
Spinoscopy
Thermography

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. A practitioner of chiropractic is referred to as Doctor of Chiropractic (D.C.), Chiropractic Physician or Chiropractor.

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

Although chiropractors often use physical modalities with spinal manipulation, there is a lack of evidence that modalities yield additional benefits over spinal manipulation alone. The UCLA Back Pain Study examined the net effect of physical modalities on low back pain outcomes among chiropractic patients in a managed-care setting (Hurwitz et al, 2002; Hurwitz et al, 2006). Half of the 681 patients participating in this clinical trial of low back pain treatment strategies were randomized to chiropractic care with physical modalities (n = 172) or without physical modalities (n = 169). The other half of the study subjects were assigned to medical care with or without physical therapy modalities. Subjects were followed for 6 months with assessments at 2, 4, and 6 weeks and at 6 months. The primary outcome variables were average and most severe low back pain intensity in the past week, assessed with numerical rating scales (0 to 10), and low back-related disability, assessed with the 24-item Roland-Morris Disability Questionnaire. Almost 60 % of the subjects had baseline low back pain episodes of more than 3 months' duration. The 6-month follow-up was 96 %. The investigators reported, comparing groups assigned to chiropractic alone to chiropractic plus physical therapy modalities, the adjusted mean differences between groups in improvements in average and most severe pain and disability were clinically insignificant at all follow-up assessments (Hurwitz et al, 2002). The investigators reported that clinically relevant improvements in average pain and disability were more likely in the modalities group at 2 and 6 weeks, but this apparent advantage disappeared at 6 months. Perceived treatment effectiveness was greater in the modalities group. The investigators concluded that physical modalities used by chiropractors in this study did not appear to be effective in the treatment of patients with low back pain, although the investigators noted that a small short-term benefit for some patients cannot be ruled out. In a subsequent report on the 18-month outcomes of the UCLA Back Pain Study, 89.6 % of the original cohort were followed through 18 months (Hurwitz et al, 2006). Among study subjects assigned to chiropractic care, assignment to physical therapy modalities in addition to chiropractic was not associated with improvement or remission (adjusted RR = 0.98; 95 % confidence interval [CI]: 0.62 to 1.55) compared to chiropractic care alone. The investigators concluded that physical modalities appear to have no benefit in chiropractic care.

In another publication, Haas et al (2004) reported on a randomized controlled pilot study conducted in the faculty practice of a chiropractic college outpatient clinic examining the effects of the number of chiropractic treatment visits for manipulation with and without physical modalities on chronic low back pain and disability. The study involved 72 patients with chronic, non-specific low back pain of mechanical origin. All patients received high-velocity low-amplitude spinal manipulation. Half received one or two of the following physical therapy modalities at each visit: soft tissue therapy, hot packs, electrotherapy or ultrasound. The investigators reported that, at 4 weeks, there was no effect of treatment regimen (chiropractic or chiropractic plus physical therapy modalities) on pain or functional disability at 4 weeks or 12 weeks follow-up.

In another randomized controlled clinical study, joint manipulation plus myofascial therapy was found to be no more effective than joint manipulation alone for persons with subacute low back pain. Hsieh et al (2002) reported on the results of a randomized, assessor-blinded clinical trial to investigate the relative effectiveness of 3 manual treatments and back school for patients with subacute low back pain. Two hundred patients with subacute low back pain were randomly assigned to one of four treatments for 3 weeks: back school, joint manipulation, myofascial therapy, and combined joint manipulation and myofascial therapy. The investigators reported that all 4 groups showed significant improvement in pain and activity scores after 3 weeks of care, but did not show further significant improvement at the 6-month follow-up assessment. No statistically significant differences were found among treatment groups at either at the 3-week or 6-month reassessments. The investigators concluded that, for subacute low back

pain, combined joint manipulation and myofascial therapy was no more effective than joint manipulation or myofascial therapy alone.

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.

The above framework is based on the following references:

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Osteopathy Information

Introduction

Osteopathy is a profession that has been regulated by statute since the passing of The Osteopath's Act (1993). A regulatory body, the General Osteopathic Council (GOsC) 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 reviewed 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 a t 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" approach. Anecdotally the profession has enjoyed an extremely safe reputation since it uses less high velocity manipulation than other 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. (Accessed July 2013)

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 data base 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 trial. 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 evaluation 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.

Osteopathy References

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Appendix D: Interventions Leeds CCGs will not commission

These are interventions Leeds CCGs do not routinely commission because of lack of evidence of safety or effectiveness in peer reviewed scientific journals. This list is not exhaustive and the CCGs reserve the right to decline any interventions where there is no evidence of effectiveness.

(Poon's) Chinese blood cleaning 714-X (for cancer)
Active Release Technique
Active Therapeutic Movement (ATM2)
Actra-Rx
Acupressure
Alexander technique
AMMA therapy
Antineoplastons
Anti-oxidant function testing (e.g., Spectrox™)
Apitherapy
Applied kinesiology
Applied Spinal Biomechanical Engineering
Aromatherapy
Art therapy
Atlas Orthogonal Technique
Aura healing
Auto urine therapy
Autogenous lymphocytic factor
Bioenergetic Synchronization Technique
Bioenergetic therapy
Biofield Cancell (Entelev) cancer therapy
Biogeometric Integration
Bioidentical hormones
Biomagnetic therapy
Blair Technique
Bovine cartilage products
Brain integration therapy
Carbon dioxide therapy
Cellular therapy
Chakra healing
Chelation therapy for Atherosclerosis
Chiropractic Biophysics Technique
Chung Moo Doe therapy
Coccygeal Meningeal Stress Fixation Technique
Coley's toxin
Colonic irrigation
Color therapy
Computerized radiographic mensuration analysis for assessing spinal mal-alignment
Conceptual mind-body techniques
Cranial Manipulation
Craniosacral therapy
Crystal healing
Cupping
Dance/Movement therapy
Digital myography
Directional Non-force Technique
Ear Candling
Egoscue method
Electrodermal stress analysis
Electrodiagnosis according to Voll (EAV)
Equestrian therapy
Essential Metabolics Analysis (EMA)
Essiac
FAKTR (Functional and Kinetic Treatment with Rehab) Approach
Feldenkrais method of exercise therapy (also known as awareness through movement)
Flower essence
Fresh cell therapy
Functional intracellular analysis*
Gemstone therapy
Gerson therapy
Glyconutrients
Gonzalez Rehabilitation Technique
Graston technique
Greek cancer cure
Guided imagery
Hair analysis
Hako-Med machine (electromedical horizontal therapy)
Hellerwork
Herbalism or Medical Herbalism
Hivamat therapy (deep oscillation therapy)
Homeopathy
Hoxsey method
Human placental tissue
Humor therapy
Hydrazine sulfate
Hydrogen peroxide therapy
hydrolysate injections
Hyperoxygen therapy
Hypnosis
Immunoaugmentive therapy
Infratronic Qi-Gong machine
Insulin potentiation therapy
Inversion therapy
Iridology
Iscador
Juvent platform for dynamic motion therapy
Kelley/Gonzales therapy
Koren Specific Technique
Laetrile
Live blood cell analysis
Macrobiotic diet
Magnet therapy

Manipulation for infant colic
Manipulation for internal (non-neuromusculoskeletal) disorders (Applied Kinesiology)
Manipulation under anesthesia
MEDEK therapy
Meditation/transcendental meditation (except as part of IAPT services)
Megavitamin therapy (also known as orthomolecular medicine)
Meridian therapy
Mesotherapy
Micronutrient panel testing
Millimeter wave therapy
Mirror box therapy
Moire Contourographic Analysis
Moxibustion (except for foetal breech presentation)
MTH-68 vaccine
Music therapy
Myotherapy
Network Technique
Neural Organizational Technique
Neural therapy (neural tension technique/electro-neuromodular medicine)
Neuro Emotional Technique
Neurocalometer/Nervoscope
NUCCA procedure
Ozone therapy
Para-spinal electromyography (EMG)/Surface scanning EMG
Spinoscopy
Pfrimmer deep muscle therapy
Polarity therapy
Primal therapy
Psychodrama
Purging
Qigong longevity exercises
Ream's testing
Reflex Therapy
Reflexology (zone therapy)
Regenokine therapy
Reiki
Remedial massage
Revici's guided chemotherapy
Rife therapy/Rife machine
Rolfing (structural integration)
Rubenfeld synergy method (RSM)
Sacro-Occipital Technique
Sarapin injections
Shark cartilage products
SonoKinesthesia treatment
Spinal adjusting devices (ProAdjuster, PulStarFRAS, Activator)
Telomere testing
Therapeutic Eurythmy-movement therapy
Therapeutic touch
Thermography
Thought field therapy (TFT) (Callahan Techniques Training)
Traditional Chinese Medicine
Trager approach
Traumeel preparation
Trichuris suis ova therapy
Tui Na
Upledger Technique and Cranio-Sacral Therapy
Vascular endothelial cells (VECs) therapy
Vibrational essences
Visceral manipulation therapy
Webster Technique (for breech babies)
Whitcomb Technique
Whitcomb technique
Whole body vibration
Wurn technique/clear passage therapy
Yoga

Appendix E: Version Control Sheet

Version	Date	Author	Status	Comment
Draft 1.0	12.7.13	Jon Fear	Updated previous policy	Updated
Draft 1.1	9.9.13	Fiona Day	Draft	Updated cover
Draft 1.2	18.11.13	Fiona Day	Draft	Addition of endpoints section. Review date april 2016.
Draft 1.3	21.11.13	Fiona Day	Draft	Homeopathy now not routinely commissioned- feedback from LWCCG CCC
Draft 1.4	29.11.13	Fiona Day	Draft	Addition of Providers will not be paid for any activity with regards this framework which has not been approved in advance. Addition of dissemination plan.
Final amended & reviewed	18.5.15	Fiona Day, Jamie OShea, Steve Laville	Final amended and reviewed	Low back pain acupuncture - Additional specific text concerning what the suitably qualified practitioner may consider; Removed reference to use on OA Knee and Hip (no longer NICE indicated); Removed reference to use on nausea in pregnancy (no longer NICE indicated). Whole Policy reviewed.

Appendix F: 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.

Title of Framework:	Complementary and alternative therapies		
Date finalised:	29.11.13	**Dissemination lead:**	CCG x3 Medical Directors
Previous framework already being used?	**Yes**	**Print name and contact details**	
If yes, in what format and where?	Electronic and paper		
Proposed action to retrieve out-of-date copies of the document:	Official launch of new policies in Feb 2014, with request to delete any previous versions.		
To be disseminated to: **General Public**	This has been shared with: All 3 CCG intranet & extranets LTHT Intranet & Extranets Leeds Health Pathways 3rd sector via Voluntary Action Leeds bulletins and website and Healthy Lives Leeds LLMC Leeds GPs at Target events (one in each CCG) Links to this document on the relevant section of each CCG website will be sent to: All 3 CCG intranet & extranets; LTHT, LCH and LYPFT Intranet & Extranets; Leeds Health Pathways; 3rd sector via Voluntary Action Leeds bulletins and website and Healthy Lives Leeds; LLMC; Healthwatch; LCC scrutiny; LCC Lead Member for Health and Wellbeing; LCC Director of Public	**Paper or Electronic** **Electronic**	**Comments**

Clinicians	Links to the final versions will be circulated to all Practice Managers and local provider Medical Directors plus relevant Clinical Directors in LTH, LYPFT, LCH, independent providers. Specific clinicians where relevant eg cosmetics, plastics, dermatology, breast. Also to be discussed at primary care TARGET or similar events	Electronic	
Panel Members	Final versions will be circulated to Panel Members	Electronic	

Acknowledgement: University Hospitals of Leicester NHS Trust.

Appendix G: Equality Impact Assessment

To ensure the Individual Funding Requests Policy and associated decision making frameworks for the Clinical Commissioning Groups in Leeds reflects due process for identifying the effect, or likely effect, of the policy on people with Equality Act protected characteristics – age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation - and that the policy demonstrates due regard to reducing health inequalities, addressing discrimination and maximising opportunities to promote equality the following steps have been taken.

The update to the policy results from the iterative refresh process, and the requirement to make changes to care as indicated by an evolving evidence-base. This means that access is broadened as more treatments and interventions become available without the need for an IFR. There is no change to the underlying principles of the policy. In order for an IFR to be approved according to the core principles for managing Individual Funding Requests, it must be demonstrated that the patient's case is exceptional.

The following consultation and engagement activities have been undertaken. The evidence-based policy has been circulated to all GPs and secondary care consultants for comment, and has been made available on the internet to the public, along with Plain English patient information leaflets. The core principles for managing Individual Funding Requests in Leeds have been made available online for twelve weeks and disseminated through Patient Advisory Groups and Patient Reference Groups along with a cascade through the Community and Voluntary Service network. Feedback from all these sources has been collected by the Clinical Commissioning Groups. There is also an open and transparent approach to the processes of the decision making panel with an established mechanism for appeals.