Clinical Practice Guideline: **Homeopathy**

Date of Implementation: **February 9, 2006**

Product: **Specialty**

GUIDELINES

American Specialty Health – Specialty (ASH) considers homeopathy as unproven because it lacks credible scientific evidence to show its clinical efficacy is similar to or better than standard means of treatment or diagnosis. Homeopathy should not be used as a substitute for a treatment of known effectiveness in cases where its use would place the patient at risk.

DESCRIPTION/BACKGROUND

Homeopathy is a system of treatment that uses infinitesimal amounts of animal, vegetable, and mineral preparations to treat health conditions. Homeopathic substances are extremely dilute preparations of the original substance.

Developed by the 18th century physician and chemist Samuel Hahnemann, homeopathy is built on two basic premises. First, the 'law of similars' or 'like cures like' principle states that a remedy that causes a certain symptom (e.g., a headache) in healthy volunteers can be used to treat a headache in individuals who suffer from it. The second principle is the 'law of infinitesimals.' This principle provides that the substance being used must be subjected to successive dilutions and that the remedies become stronger rather than weaker when submitted to these dilutions. After each dilution the compound is subjected to 'potentization' (i.e., vigorous shaking of the mixture).

Homeopathy defines the potency of its remedies according to how diluted they are; the more diluted, the stronger the remedy. Potency is defined in terms of a number and a letter indicating the dilution factor and number of dilutions.

The principle of infinitesimals is contrary to current conventional scientific principles and therefore lacks credibility in that discipline. The principle of infinitesimals is counter to the well-established principle of dose-response which holds that the more of an active ingredient is present, the more effect it will have. This relationship of dose to response has been demonstrated in clinical trials and through the biochemical actions of conventional therapeutic agents.

Also contributing to low credibility is that many of the dilutions that are used in homeopathy (e.g., those greater than 12c) contain no molecules of the original substance. Further, the theory of infinitesimals raises the issue of why the minute impurities that are

inevitably present in any solution do not themselves become 'potentized' and therefore clinically active during the successive dilutions and shakings.

When Samuel Hahnemann, the creator of homeopathy, developed this homeopathic dilution system in the late 18th century Avogadro's number (6.023×10^{23}) was unknown, Per Avogadro's number, homeopathic preparations more dilute than 12c would no longer contain any of the original substance and are purely placebos (Mahata, 2017). Homeopathy theorizes, based on quantum electrodynamics, that there are structures called coherent domains in water that carry information after serial dilutions and are influenced by other molecules, electromagnetic fields, etc. Electron microscopy, diffraction, and DNA array results are consistent with the presence of nanoparticles in homeopathic remedies. Homeopathic theories purport that disturbances of the human organism affect the spin on electrons of different elements within the body. Using homeopathic preparations of an agent similar to the electromagnetic force that created the problem may serve to reset the disturbance and thus restore the good health of the organism.

The mechanism of how homeopathic healing effects are produced is unknown, but there are theories involving multiple mechanisms including such possibilities as epigenetic influences on gene expression, and alterations of the microbiome.

In the United States, homeopathic remedies are subject to regulation by the Food and Drug Administration (FDA). Although regulated, the FDA treats homeopathic remedies significantly differently from other products. Homeopathic remedies are not required to be approved by the FDA prior to sale, not required to prove either safety or effectiveness prior to being sold, not required to label their products with expiration dates, and not required to undergo finished product testing to verify contents and strength. Homeopathic drugs have their own imprints that, unlike conventional drugs, do not have to identify their active ingredients on the grounds that they have little or no active ingredients. In many other countries (e.g., the United Kingdom), homeopathic medicines are sold over the counter.

EVIDENCE REVIEW

There are numerous randomized controlled trials (RCTs) on homeopathy. There are also several meta-analyses and systematic reviews of these trials. Below is a summary of these reviews.

A meta-analysis by Linde et al. (1998) reviewed 89 different RCTs that met the inclusion criteria. The investigators calculated the odds-ratio that the clinical effects of homeopathy were greater than that of placebo. The analysis found the resultant odds ratio was 2.45:1 in favor of there being effects greater than that of placebo. There are several reasons to be cautious about these findings. The authors themselves concluded the following: "The results of our meta-analysis are not compatible with the hypothesis that the clinical effects of homoeopathy are completely due to placebo. However, we found insufficient evidence

from these studies that homoeopathy is clearly efficacious for any single clinical condition" (Linde et al., 1998). In other words, although overall there appeared to be affects greater than placebo, this cannot be said of any specific treatment and disease state. This in fact is the greatest technical criticism of this meta-analysis: it is not a valid use of meta-analytic technique to aggregate studies of different conditions and different interventions. Finally, the authors of the study also make this concluding remark relative to the theoretical foundations of homeopathy, "Even if positive findings from similar trial sets were found in the future, pharmacologists and other scientists are likely to remain doubtful unless plausible mechanisms are discovered."

Three separate systematic reviews have evaluated the overall quality of homeopathic trials and found them to be generally of low quality. Most importantly, one analysis found that most of the positive results attributed to homeopathy are to be found in the studies of lowest quality (Linde et al., 2001; Jonas et al., 2001; Cucherat et al., 2000).

Weiner and Ernst (2004) carried out a critical review of the literature on acupuncture and related modalities, herbal therapies, homeopathy, and spinal manipulation. Included in the review were 798 cases within 2 systematic reviews of homeopathy. Some evidence exists to support the superiority of homeopathic remedies over placebo for treating osteoarthritis and rheumatoid arthritis. The authors concluded that while the use of complementary and alternative modalities for the treatment of persistent musculoskeletal pain continues to increase, rigorous clinical trials examining their efficacy are needed before definitive recommendations regarding the application of these modalities can be made.

An analysis done for the National Health Service in Great Britain was even more cautious (Center for Reviews and Dissemination, 2002). It also noted the relative low quality of studies and made this observation, "All conclusions about effectiveness should be considered together with the methodological inadequacies of the primary studies and some of the systematic reviews." Its ultimate conclusion relative to inclusion of homeopathic services in the health care system was, "There are currently insufficient data either to recommend homeopathy as a treatment for any specific condition, or to warrant significant changes in the provision of homeopathy."

Ernst (2010) evaluated evidence for and against the effectiveness of homeopathy. All Cochrane reviews were discussed narratively due to the heterogeneity that existed in the studies, precluding meta-analysis. The findings did not show that these medicines have effects beyond placebo. One other Cochrane review was published since then and found similar results. In 2013, Hahn did a meta-analysis of pooled clinical data on homeopathy. His conclusion was that many of the clinical trials demonstrated a statistically significant effect of homeopathy. This prompted academicians to perform alternative analysis to demonstrate lack of effect leading to flawed results as diseases were inappropriately pooled for analysis. The author suggests that further meta-analysis should focus on a specific

disease or group of diseases and the use of homeopathy to reduce error in statistical interpretation. To this effect, Boehm et al. (2014) studied homeopathy in the treatment of fibromyalgia. The results of the studies as well as the case reports define a sufficient basis for discussing the possible benefits of homeopathy for patients suffering from fibromyalgia syndrome although any conclusions based on the results of this review have to be regarded as preliminary. Mathie et al. (2014) completed a review on RCTs that used individualized homeopathic treatments. Thirty-two eligible RCTs studied 24 different medical conditions in total. They concluded that medicines prescribed in individualized homeopathy may have small, specific treatment effects. Findings are consistent with sub-group data available in a previous 'global' systematic review. Caution when interpreting the results should be taken given the low or unclear overall quality of the evidence.

Stub et al. (2016) studied the adverse effects of homeopathy via a systematic review and meta-analysis of RCTs. A total of 28 trials (68%) reported adverse effects and 5 trials (12%) reported homeopathic aggravations. The meta-analysis (including 6 subgroup comparisons) demonstrated that no significant difference was found between homeopathy and control with OR 0.99, 95% CI 0.86-1.14, I (2) =54%. Authors concluded that adverse effects including the concept of homeopathic aggravations are commonly reported in trials. The meta-analysis demonstrated that the proportion of patients experiencing adverse effects to be similar for patients randomized to homeopathic treatment compared to patients randomized to placebo and conventional medicine. Perry et al. (2017) completed an overview of systematic reviews of complementary and alternative therapies for fibromyalgia. The individual studies had to be randomized controlled trials where the intervention was compared to placebo, treatment as usual or waitlist controls to be included. The primary outcome measure was pain, and the secondary outcome measure was adverse events. There was low-quality evidence that acupuncture improves pain compared to no treatment or standard treatment, but good evidence that it is no better than sham acupuncture. The evidence for homoeopathy, spinal manipulation and herbal medicine was limited. Mathie et al. (2017) completed a rigorous systematic review and meta-analysis focused on RCTs of non-individualized homeopathic treatment. Authors tested the null hypothesis that the main outcome of treatment using a non-individualized (standardized) homeopathic medicine is indistinguishable from that of placebo. An additional aim was to quantify any condition-specific effects of non-individualized homeopathic treatment. Authors concluded that the quality of the body of evidence is low. Reliable evidence is lacking in condition-specific meta-analyses, precluding relevant conclusions. Better designed and more rigorous RCTs are needed in order to develop an evidence base that can decisively provide reliable effect estimates of non-individualized homeopathic treatment.

A commentary on the continued discussion around the research approach used in meta-analysis of homeopathic research was authored by Vithoulkas in 2017. The article discussed the immanent problems of meta-analyses selecting a number of independent

trials in homeopathy, within which, the purpose was to examine the effectiveness of homeopathic treatment. The author sought to clarify that the complex effects of homeopathic treatment known from history and day-to-day practice have not been respected so far. The examination of most of the homeopathic trials showed that studies rarely account for homeopathic principles, in order to assess the effectiveness of the treatment. The main flaw was that trials reflect the point of view that the treatment with a specific remedy could be administered in a particular disease. However, homeopathy aims to treat the whole person, rather than the diseases, and each case has to be treated individually with an individualized remedy. Furthermore, the commonly known events during the course of homeopathic treatment, such as 'initial aggravation' and 'symptom-shift' were not considered in almost all the studies. Thus, only a few trials were eligible for meta-analyses, if at all. The author concludes that a better understanding of homeopathic principles would provide guidelines for homeopathic research, which are more acceptable to both homeopathy and conventional medicine.

Cukaci et al. (2020) analyzed and summarized the evidence and plausibility of homeopathic treatment effectiveness. Authors compiled results systematically to support their conclusion that there is no evidence that homeopathic remedies have any therapeutic effect, which goes beyond that of a placebo.

A systemic review and meta-analysis were completed by Stub et al. (2020) evaluating the adverse effects of homeopathic treatments. Forty-one studies were included, and a separate eighteen studies were specifically reviewed for comparison of adverse events during the use of homeopathy vs. control (conventional medications and herbal preparations). Eighty-seven percent of the studies reported adverse events. The incidence of adverse effects was significantly higher for the control groups using conventional medicines and herbs than for the homeopathy group. Homeopathic aggravation, a transient worsening of symptoms when starting homeopathic remedies, is not generally considered a side effect, and was less often documented. The authors noted, "development and implementation of a standardized reporting system of adverse effects in homeopathic studies is warranted in order to facilitate future risk assessments."

Kass et al. (2020) studied the effectiveness and cost-effectiveness of the addition of homeopathy to care contracts in Germany. Information from 2,524 participants was included. There was significantly better clinical effectiveness and cost-effectiveness in the homeopathy participants who suffered from migraine, asthma, atopic dermatitis, and depression. Authors urged caution in interpretation due to study design and other limitations.

Scaciota et al. (2021) completed a Cochrane evaluation of nine systematic reviews of treatment for irritable bowel syndrome. Four randomized controlled trials with 307 participants included treatment with homeopathy. Homeopathic treatment showed a small

improvement in symptoms of irritable bowel compared to placebo, but evidence level was low to very low. When individual data was analyzed from the RCTs there was no difference between homeopathy and conventional treatments. Certainty of evidence was classified as very low because of methodological limitations, small sample size and short follow-up periods. One meta-analysis of 197 participants showed very low-quality evidence for homeopathy when compared to placebo. There was no report of abdominal pain or stool character in these studies. No adverse events reported.

A meta-analysis of homeopathic Arnica montana for reducing post-operative pain, bleeding, motion limitation, and swelling was performed by Gaertner et al. (2021). Twenty-two studies and 28 comparisons including those comparing arnica to placebo, active control or no treatment were reviewed. The overall effect size was small and not quite at the level of statistical significance. The authors noted that the heterogeneity of the studies likely caused the lack of significance of the results. The heterogeneity included the types of surgical procedures, measures of pain management, type of control used, dosage, whether homeopathic rationales were used, and if the arnica was used as a preventative or therapeutic agent. The author stated, "If only those studies that used placebo-controls and VAS measures of pain are considered descriptively, then the effect of Arnica can be quantified as lying between a reduction of 5 and 9 mm visual analogue scale (VAS) pain rating." Per the authors, when evaluating only the studies comparing arnica with prescription NSAIDs or paracetamol, overall effects of arnica and medications are largely comparable. However, many studies were not randomized.

Wagenknecht et al. (2022) performed a systematic review of eighteen studies with 2,016 patients to evaluate the effectiveness of homeopathy on the toxicity of cancer treatments, time to drain after mastectomy, survival, quality of life, global health, and subjective well-being in patients with cancer. Results were heterogeneous with some studies demonstrating significant differences in quality of life or toxic effects of treatments and some showing no difference or worsening with homeopathic remedies. The studies were mostly of low methodological quality.

Gartlehner et al. (2022) used a cross-sectional study and meta-analysis to study reporting bias in trials of homeopathy. Nearly 38% of registered trials of homeopathy were not published and 50% of published RCTs were not registered. One quarter of the primary outcomes were altered after the trial was registered. There was substantially larger treatment effects reported in unregistered trials. These findings were said by the authors to likely affect the validity of the homeopathic evidence.

Gaertner et al. (2023) set out to establish standardized recommendations for analyzing evidence from homeopathic intervention studies (HomIS). The authors reported five recommendations for systematic reviews and meta-analyses: "1) A broad literature search including special archives and consideration of so-called grey-literature; 2) The inclusion

of controlled observational studies alongside randomized controlled trials; 3) The choice of a clear clinical research question in the terms that, if possible, the review project includes studies with predominantly homogeneous populations, interventions, comparators and outcomes (PICOs); 4) The use of a global quality assessment including the assessment of external, model and internal validity; 5) A summary of evidence using the GRADE-approach if the body of evidence is sufficiently large and homogenous or a descriptive summary if it is not so."

Schulz et al. (2023) reviewed common criticisms of homeopathy in literature from 1950 to 2020 and evaluated the Introduction, Methods, Results and Discussion (IMRaD) characteristics of the publications. Fifteen articles that had a focus on criticizing homeopathy met inclusion criteria. There were five basic groupings of criticism proclaiming that homeopathy: 1. Contradicts current laws of physics, chemistry, and modern medicine; 2. Lacks a scientific basis; 3. Is based on faith and ideology such as a religion or sect; 4. Is dangerous, deceptive, wastes resources, and is ethically unjustifiable; and 5. Lacks clinical empirical evidence. Only four out of the fifteen articles met the majority of IMRaD criteria scoring a seven on an 11-point scale.

Six meta-analyses of homeopathic studies met inclusion criteria for evaluation by Hamre et al. (2023). Studies were from 1943 to 2014, included individualized and non-individualized treatments, and averaged sample sizes of 45-97 patients in between 16 to 110 studies. Significant positive effects were noted for homeopathy compared with placebo. The individualized homeopathy showed the highest positive outcomes.

In a randomized controlled trial, Kaur et al. (2023) evaluated 129 patients with moderate and severe Covid-19 who received either only standard of care per the study hospital's protocols or standard of care and homeopathic treatment. Standard care included remdesivir, corticosteroids, antibiotics, Ivermectin, multivitamins and anticoagulants. The homeopathic treatments were chosen after a detailed evaluation of patient symptoms and personal history. Homeopathic remedies were administered orally except for patients who were intubated and received the treatment through a feeding tube. The treatment groups who received homeopathic care had fewer days requiring oxygen therapy (primary outcome), shorter hospitalizations, faster conversion of positive to negative polymerase chain reaction testing, lower mean score on the Clinical Outcome Ordinal Scale, and more rapid normalization of laboratory markers.

Freire de Carvalho et al. (2024) performed a systematic review of 15 articles and 1,459 patients involving treatment of rheumatic diseases with homeopathy. Conditions included rheumatoid arthritis, osteoarthritis, fibromyalgia, ankylosing spondylitis, hyperuricemia, and tendinopathy. The homeopathic treatments varied from a single, fixed agent to an individualized combination homeopathic preparation. Nine out of the 15 studies showed improvement. Five didn't show any significant difference with treatment. One study

demonstrated that the relationship with the practitioner was therapeutic, but the homeopathic preparation was not. Side effects either didn't occur (6 studies) or were not reported (6 studies). In the other 3 studies, side effects were mild and comparable to the control groups.

Toma et al. (2024) conducted a systematic review of the use of arnica products to treat pain. Products included phytotherapeutic and homeopathic remedies with arnica alone or in combination with other substances. Forty-two studies were included in the review. Homeopathic oral arnica resulted in less pain and swelling following knee arthroscopy, cruciate ligament reconstruction, and artificial knee joint implantation. Pain, edema and mouth opening after third molar extraction was reduced after arnica homeopathic tablet administration without significant difference compared with corticosteroids or ibuprofen. A small, but significant reduction in pain after tonsillectomy was observed when using homeopathic arnica compared with placebo. A homeopathic ointment containing arnica among other ingredients was used in a study of 357 patients with tendinopathies and demonstrated that the homeopathic was non-inferior to diclofenac gel for pain relief and improvement in motility. For pain management after knee ligament reconstruction, arnica granules were not superior to placebo. Arnica sublingual pellets were not effective in eliminating delayed onset soreness after exercise. Arnica homeopathic preparations are generally considered safe, however some side effects such as rash, dry skin, and itching were reported. The authors noted that an appropriate safety evaluation is difficult due to the multitude of ingredients in preparations and lack of standardization of preparations and dosages.

Herman et al. (2025) reviewed 99 research studies of homeopathy. Eighty-five studies were controlled trials with about two-thirds having high or unclear risk of bias. Seventy-nine studies were randomized. Forty percent of the studies did not report on safety. Overall, higher quality research and better reporting was recommended.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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