

1 **Clinical Practice Guideline: Homeopathy**
 2
 3 **Date of Implementation: February 9, 2006**
 4
 5 **Product: Specialty**
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7
8 **GUIDELINES**

9 American Specialty Health – Specialty (ASH) considers homeopathy as unproven because
10 it lacks credible scientific evidence to show its clinical efficacy is similar to or better than
11 standard means of treatment or diagnosis. Homeopathy should not be used as a substitute
12 for a treatment of known effectiveness in cases where its use would place the patient at
13 risk.
14

15 **DESCRIPTION/BACKGROUND**

16 Homeopathy is a system of treatment that uses infinitesimal amounts of animal, vegetable,
17 and mineral preparations to treat health conditions. Homeopathic substances are extremely
18 dilute preparations of the original substance.
19

20 Developed by the 18th century physician and chemist Samuel Hahnemann, homeopathy is
21 built on two basic premises. First, the “law of similars” or “like cures like” principle states
22 that a remedy that causes a certain symptom (e.g., a headache) in healthy volunteers can
23 be used to treat a headache in individuals who suffer from it. The second principle is the
24 “law of infinitesimals.” This principle provides that the substance being used must be
25 subjected to successive dilutions and that the remedies become stronger rather than weaker
26 when submitted to these dilutions. After each dilution the compound is subjected to
27 “potentization,” (i.e., vigorous shaking of the mixture).
28

29 Homeopathy defines the potency of its remedies according to how diluted they are; the
30 more diluted, the stronger the remedy. The potency is defined in terms of a number and a
31 letter indicating the dilution factor and number of dilutions.
32

33 The principle of infinitesimals is contrary to current conventional scientific principles and
34 therefore lacks credibility in that discipline. The principle of infinitesimals is counter to the
35 well-established principle of dose-response which holds that the more of an active
36 ingredient is present, the more effect it will have. This relationship of dose to response has
37 been demonstrated in clinical trials and through the biochemical actions of conventional
38 therapeutic agents.
39

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

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

3
4 When Samuel Hahnemann, the creator of homeopathy, developed this homeopathic
5 dilution system in the late 18th century Avogadro’s number (6.023×10^{23}) was unknown,
6 Per Avogadro’s number, homeopathic preparations more dilute than 12c would no longer
7 contain any of the original substance and are purely placebos (Mahata, 2017). Homeopathy
8 theorizes, based on quantum electrodynamics, that there are structures called coherent
9 domains in water that carry information after serial dilutions and are influenced by other
10 molecules, electromagnetic fields, etc. Electron microscopy, diffraction, and DNA array
11 results are consistent with the presence of nanoparticles in homeopathic remedies.
12 Homeopathic theories purport that disturbances of the human organism affect the spin on
13 electrons of different elements within the body. Using homeopathic preparations of an
14 agent similar to the electromagnetic force that created the problem may serve to reset the
15 disturbance and thus restore the good health of the organism.

16
17 The mechanism of how homeopathic healing effects are produced is unknown, but there
18 are theories involving multiple mechanisms including such possibilities as epigenetic
19 influences on gene expression, and alterations of the microbiome.

20
21 In the United States, homeopathic remedies are subject to regulation by the Food and Drug
22 Administration (FDA). Although regulated, the FDA treats homeopathic remedies
23 significantly differently from other products. Homeopathic remedies are not required to be
24 approved by the FDA prior to sale, not required to prove either safety or effectiveness prior
25 to being sold, not required to label their products with expiration dates, and not required to
26 undergo finished product testing to verify contents and strength. Homeopathic drugs have
27 their own imprints that, unlike conventional drugs, do not have to identify their active
28 ingredients on the grounds that they have little or no active ingredients. In many other
29 countries (e.g., the United Kingdom), homeopathic medicines are sold over the counter. In
30 the U.S. only homeopathic medicines that claim to treat self-limiting conditions may be
31 sold over the counter, while homeopathic medicines that claim to treat a serious disease
32 can be sold only by prescription.

33 34 **EVIDENCE REVIEW**

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

38
39 A meta-analysis by Linde et al. published in the journal *The Lancet* (Linde et al., 1998)
40 reviewed 89 different RCTs that met the inclusion criteria. The investigators calculated the
41 odds-ratio that the clinical effects of homeopathy were greater than that of placebo. The
42 analysis found the resultant odds ratio was 2.45:1 in favor of there being effects greater

1 than that of placebo. There are several reasons to be cautious about these findings. The
2 authors themselves conclude the following: “The results of our meta-analysis are not
3 compatible with the hypothesis that the clinical effects of homeopathy are completely due
4 to placebo. However, we found insufficient evidence from these studies that homeopathy
5 is clearly efficacious for any single clinical condition” (Linde et al., 1998). In other words,
6 although overall there appeared to be affects greater than placebo, this cannot be said of
7 any specific treatment and disease state. This in fact is the greatest technical criticism of
8 this meta-analysis: it is not a valid use of meta-analytic technique to aggregate studies of
9 different conditions and different interventions. Finally, the authors of the study also make
10 this concluding remark relative to the theoretical foundations of homeopathy, “Even if
11 positive findings from similar trial sets were found in the future, pharmacologists and other
12 scientists are likely to remain doubtful unless plausible mechanisms are discovered.”
13

14 Three separate systematic reviews have evaluated the overall quality of homeopathic trials
15 and found them to be generally of low quality. Most importantly, one analysis found that
16 most of the positive results attributed to homeopathy are to be found in the studies of lowest
17 quality (Linde et al., 2001; Jonas et al., 2001; Cucherat et al., 2000).
18

19 Weiner and Ernst (2004) carried out a critical review of the literature on acupuncture and
20 related modalities, herbal therapies, homeopathy, and spinal manipulation. Included in the
21 review were 798 cases within two systematic reviews of homeopathy. Some evidence
22 exists to support the superiority of homeopathic remedies over placebo for treating
23 osteoarthritis and rheumatoid arthritis. The authors concluded that while the use of
24 complementary and alternative modalities for the treatment of persistent musculoskeletal
25 pain continues to increase, rigorous clinical trials examining their efficacy are needed
26 before definitive recommendations regarding the application of these modalities can be
27 made.
28

29 An analysis done for the National Health Service in Great Britain was even more cautious
30 (Center for Reviews and Dissemination, 2002). It also noted the relative low quality of
31 studies and made this observation, “All conclusions about effectiveness should be
32 considered together with the methodological inadequacies of the primary studies and some
33 of the systematic reviews.” Its ultimate conclusion relative to inclusion of homeopathic
34 services in the health care system was, “There are currently insufficient data either to
35 recommend homeopathy as a treatment for any specific condition, or to warrant significant
36 changes in the provision of homeopathy.”
37

38 Ernst (2010) evaluated the evidence for and against the effectiveness of homeopathy. All
39 Cochrane reviews were discussed narratively due to the heterogeneity that existed in the
40 studies, precluding meta-analysis. The findings did not show that these medicines have
41 effects beyond placebo. One other Cochrane review was published since then and found
42 similar results. In 2013, Hahn did a meta-analysis of pooled clinical data on homeopathy.

1 His conclusion was that many of the clinical trials demonstrated a statistically significant
2 effect of homeopathy. This prompted academicians to perform alternative analysis to
3 demonstrate lack of effect leading to flawed results as diseases were inappropriately pooled
4 for analysis. The author suggests that further meta-analysis should focus on a specific
5 disease or group of diseases and the use of homeopathy to reduce error in statistical
6 interpretation. To this effect, Boehm et al. (2014) studied homeopathy in the treatment of
7 fibromyalgia. The results of the studies as well as the case reports define a sufficient basis
8 for discussing the possible benefits of homeopathy for patients suffering from fibromyalgia
9 syndrome although any conclusions based on the results of this review have to be regarded
10 as preliminary. Mathie et al. (2014) completed a review on RCTs that used individualized
11 homeopathic treatments. Thirty-two eligible RCTs studied 24 different medical conditions
12 in total. They concluded that medicines prescribed in individualized homeopathy may have
13 small, specific treatment effects. Findings are consistent with sub-group data available in
14 a previous 'global' systematic review. Caution when interpreting the results should be taken
15 given the low or unclear overall quality of the evidence.

16
17 Stub et al. (2016) studied the adverse effects of homeopathy via a systematic review and
18 meta-analysis of randomized controlled trials. A total of 28 trials (68%) reported adverse
19 effects and five trials (12%) reported homeopathic aggravations. The meta-analysis
20 (including six subgroup comparisons) demonstrated that no significant difference was
21 found between homeopathy and control with OR 0.99, 95% CI 0.86-1.14, I² =54%.
22 Authors concluded that adverse effects including the concept of homeopathic aggravations
23 are commonly reported in trials. The meta-analysis demonstrated that the proportion of
24 patients experiencing adverse effects to be similar for patients randomized to homeopathic
25 treatment compared to patients randomized to placebo and conventional medicine. Perry
26 et al. (2017) completed an overview of systematic reviews of complementary and
27 alternative therapies for fibromyalgia. The individual studies had to be randomized
28 controlled trials where the intervention was compared to placebo, treatment as usual or
29 waitlist controls to be included. The primary outcome measure was pain, and the secondary
30 outcome measure was adverse events. There was low-quality evidence that acupuncture
31 improves pain compared to no treatment or standard treatment, but good evidence that it is
32 no better than sham acupuncture. The evidence for homeopathy, spinal manipulation and
33 herbal medicine was limited. Mathie et al. (2017) completed a rigorous systematic review
34 and meta-analysis focused on randomized controlled trials (RCTs) of non-individualized
35 homeopathic treatment. Authors tested the null hypothesis that the main outcome of
36 treatment using a non-individualized (standardized) homeopathic medicine is
37 indistinguishable from that of placebo. An additional aim was to quantify any condition-
38 specific effects of non-individualized homeopathic treatment. Authors concluded that the
39 quality of the body of evidence is low. Reliable evidence is lacking in condition-specific
40 meta-analyses, precluding relevant conclusions. Better designed and more rigorous RCTs
41 are needed in order to develop an evidence base that can decisively provide reliable effect
42 estimates of non-individualized homeopathic treatment.

1 A commentary on the continued discussion around the research approach used in meta-
2 analysis of homeopathic research was authored by Vithoulkas in 2017. The article
3 discussed the immanent problems of meta-analyses selecting a number of independent
4 trials in homeopathy, within which, the purpose was to examine the effectiveness of
5 homeopathic treatment. The author sought to clarify that the complex effects of
6 homeopathic treatment known from history and day-to-day practice have not been
7 respected so far. The examination of most of the homeopathic trials showed that studies
8 rarely account for homeopathic principles, in order to assess the effectiveness of the
9 treatment. The main flaw was that trials reflect the point of view that the treatment with a
10 specific remedy could be administered in a particular disease. However, homeopathy aims
11 to treat the whole person, rather than the diseases and each case has to be treated
12 individually with an individualized remedy. Furthermore, the commonly known events
13 during the course of homeopathic treatment, such as "initial aggravation" and "symptom-
14 shift" were not considered in almost all the studies. Thus, only few trials were eligible for
15 meta-analyses, if at all. The author concludes that a better understanding of homeopathic
16 principles would provide guidelines for homeopathic research, which are more acceptable
17 to both homeopathy and conventional medicine.

18
19 Cukaci et al. (2020) analyzed and summarized the evidence and plausibility of
20 homeopathic treatment effectiveness. Authors compiled results systematically to support
21 their conclusion that there is no evidence that homeopathic remedies have any therapeutic
22 effect, which goes beyond that of a placebo.

23
24 A systemic review and meta-analysis were completed by Stub, et al. (2020) evaluating the
25 adverse effects of homeopathic treatments. Forty-one studies were included, and a separate
26 eighteen studies were specifically reviewed for comparison of adverse events during the
27 use of homeopathy vs. control (conventional medications and herbal preparations). Eighty
28 seven percent of the studies reported adverse events. The incidence of adverse effects was
29 significantly higher for the control groups using conventional medicines and herbs than for
30 the homeopathy group. Homeopathic aggravation, a transient worsening of symptoms
31 when starting homeopathic remedies, is not generally considered a side effect, and was less
32 often documented. The authors noted, "development and implementation of a standardized
33 reporting system of adverse effects in homeopathic studies is warranted in order to facilitate
34 future risk assessments."

35
36 Kass, et al. (2020) studied the effectiveness and cost-effectiveness of the addition of
37 homeopathy to care contracts in Germany. Information from 2524 participants was
38 included. There was significantly better clinical effectiveness and cost-effectiveness in the
39 homeopathy participants who suffered from migraine, asthma, atopic dermatitis, and
40 depression. Authors urged caution in interpretation due to study design and other
41 limitations.

1 Scatiota (2021) completed a Cochrane evaluation of nine systematic reviews of treatment
2 for irritable bowel syndrome. Four randomized controlled trials with 307 participants
3 included treatment with homeopathy. Homeopathic treatment showed a small
4 improvement in symptoms of irritable bowel compared to placebo, but evidence level was
5 low to very low. When individual data was analyzed from the RCTs there was no difference
6 between homeopathy and conventional treatments. Certainty of evidence was classified as
7 very low because of methodological limitations, small sample size and short follow-up
8 periods. One meta-analysis of 197 participants showed very low-quality evidence for
9 homeopathy when compared to placebo. There was no report of abdominal pain or stool
10 character in these studies. No adverse events reported.

11
12 A meta-analysis of homeopathic *Arnica montana* for reducing post-operative pain,
13 bleeding, motion limitation, and swelling was performed by Gaertner (2021). Twenty-two
14 studies and 28 comparisons including those comparing arnica to placebo, active control or
15 no treatment were reviewed. The overall effect size was small and not quite at the level of
16 statistical significance. The authors noted that the heterogeneity of the studies likely caused
17 the lack of significance of the results. The heterogeneity included the types of surgical
18 procedures, measures of pain management, type of control used, dosage, whether
19 homeopathic rationales were used, and if the arnica was used as a preventative or
20 therapeutic agent. The author states, “If only those studies that used placebo-controls and
21 VAS measures of pain are considered descriptively, then the effect of Arnica can be
22 quantified as lying between a reduction of 5 and 9 mm visual analogue scale (VAS) pain
23 rating.” Per the authors, when evaluating only the studies comparing arnica with
24 prescription NSAIDs or paracetamol, overall effects of arnica and medications are largely
25 comparable. However, many studies were not randomized.

26
27 Wagenknecht et al. (2022) performed a systematic review of eighteen studies with 2016
28 patients to evaluate the effectiveness of homeopathy on the toxicity of cancer treatments,
29 time to drain after mastectomy, survival, quality of life, global health, and subjective well-
30 being in patients with cancer. Results were heterogeneous with some studies demonstrating
31 significant differences in quality of life or toxic effects of treatments and some showing no
32 difference or worsening with homeopathic remedies. The studies were mostly of low
33 methodological quality.

34
35 Gartlehner et al. (2022) used a cross-sectional study and meta-analysis to study reporting
36 bias in trials of homeopathy. Nearly 38% of registered trials of homeopathy were not
37 published and 50% of published RCTs were not registered. One quarter of the primary
38 outcomes were altered after the trial was registered. There were substantially larger
39 treatment effects reported in unregistered trials. These findings were said by the authors to
40 likely affect the validity of the homeopathic evidence.

1 **PRACTITIONER SCOPE AND TRAINING**

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

7
8 It is best practice for the practitioner to appropriately render services to a member only if
9 they are trained, equally skilled, and adequately competent to deliver a service compared
10 to others trained to perform the same procedure. If the service would be most competently
11 delivered by another health care practitioner who has more skill and training, it would be
12 best practice to refer the member to the more expert practitioner.

13
14 Best practice can be defined as a clinical, scientific, or professional technique, method, or
15 process that is typically evidence-based and consensus driven and is recognized by a
16 majority of professionals in a particular field as more effective at delivering a particular
17 outcome than any other practice (Joint Commission International Accreditation Standards
18 for Hospitals, 2020).

19
20 Depending on the practitioner’s scope of practice, training, and experience, a member’s
21 condition and/or symptoms during examination or the course of treatment may indicate the
22 need for referral to another practitioner or even emergency care. In such cases it is prudent
23 for the practitioner to refer the member for appropriate co-management (e.g., to their
24 primary care physician) or if immediate emergency care is warranted, to contact 911 as
25 appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice
26 guideline for information.

27
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