Homeopathic Medicine Should Have a Role in Managed Care
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BACKGROUND
The formularies of nearly all managed care organizations (MCOs) and pharmacy benefit managers (PBMs) share the near-total absence of homeopathic drugs. The authors explore the possible use of homeopathic drugs in a managed care setting and make some suggestions for formulary committees’ consideration. The broad research question is whether there is a role for homeopathic medications in contemporary clinical practice in a managed care environment.

Pharmacy and therapeutics (P&T) committees regularly convene to review the safety, efficacy, and value of the drugs placed on the formulary. Given the lack of safety, efficacy, and value data for homeopathic preparations, these forms of alternative medicine are often overlooked during formulary reviews.

INTRODUCTION
Alternative medicine is defined as health care practices “neither taught widely in medical schools nor generally available in hospitals” (Eisenberg 1993). Treatments with alternative medicine fall outside of mainstream Western (conventional) medicine. Alternative treatment regimens include complementary treatments — a non-traditional treatment approach used with a conventional treatment, an approach often referred to as integrative care, and treatments that are purely alternative and outside the realm of traditional Western medicine.

Homeopathy is one of the most popular branches of complementary and alternative medicine (CAM). It was pioneered in Germany approximately 200 years ago by Samuel Hahnemann and it has been practiced continuously around the world since the 19th century (Ballard 2000). The principle that Hahnemann used is the law of similes — a drug that can cause symptoms in a healthy individual can, when used in a highly diluted form, cure the same symptoms when they appear as a disease state. Hahnemann and his assistants conducted studies observing and recording administered plants and mineral substances. These recordings were compiled and named the Materia Medica. When a patient presented to the treating physician with symptoms, these symptoms were compared to the Materia Medica and matched with a substance that produced the same symptoms in a healthy individual. Homeopathic treatment regimens treat a specific ailment or symptom(s). They are not used as prophylaxis, a point that is sometimes ignored or not known.

Although research into homeopathic treatments is on the rise, their clinical utility in managing disease is questioned because of limited robust safety and efficacy studies. Homeopathic agents are regulated by the United States Food and Drug Administration (FDA) under the Homeopathic Pharmacopeia of the United States (HPUS), but robust clinical testing is not a requirement for marketing approval. In fact, homeopathic preparations fall into a relative gray zone within the scope of the Center for Drug Evaluation and Research (CDER). CDER regulates prescription drugs, generic drugs, and over-the-counter preparations. Given that homeopathic treatments do not fall into any of these categories concisely, they remain relatively unregulated with regard to safety, efficacy, and value.

When a pharmaceutical agent comes to market, it has already gone through animal testing, testing in healthy volunteers, safety studies, and efficacy studies. Furthermore, postmarketing studies are conducted to determine the long-term safety and efficacy of each pharmaceutical agent. Homeopathic treatments are only required to meet the standards for strength, quality, and purity set forth in the HPUS (FDA 2010). These agents are not required to show safety and efficacy data for approval for use in the United States. Thus, some manufacturers of homeopathic agents have claimed efficacy for treating an infinite number of conditions such as acne, arthritis, bronchial and respiratory problems (including colds and asthma), bruises, cramps, cystitis, depression, diarrhea, diabetes, digestive problems, insomnia, menstrual problems, psoriasis, stress, toothache, varicose veins, and even worms.

Efficacy or placebo effect?
It has long been debated whether homeopathy shows efficacy in the management of symptoms and disease or is merely a result of the placebo effect. Placebos and the placebo effect can be viewed in two different lights. On one hand, placebos can be viewed as means to satisfy a patient without any reasonable expectation of
symptom improvement. On the other hand, the placebo effect has been touted as a tool to produce symptom improvement in a host of medical conditions (Brody 2011).

At the heart of the placebo effect are two psychological mechanisms: expectancy and classical conditioning (Finniss 2010). Expectancy refers to the patient’s expectation of response following the receipt of a placebo preparation (Kirsch 1985). Classical conditioning is the result of the repeated association between a neutral stimulus (placebo) and active drug that results in the placebo being able to elicit a response similar to that of the active drug (Finniss 2010). Not surprisingly, the expectations of treating clinicians also play a role in the placebo response. One small dental pain study found that the placebo response was dramatically reduced in the treatment group in which clinicians believed no active treatment was administered, although active treatment was administered (Gracely 1985). Thus, numerous factors play into the potential for placebo response and lead to the efficacy paradox — placebo can be more powerful than proven, evidence-based treatments (Walach 2011).

The use of placebo plays an important role in controlled clinical trials and in some clinical practices. One study that looked at the use of placebos in clinical practice found that the rate of use of pure placebos (those without efficacy in any clinical situation, eg, sugar tablets) varied from 17% to 80%, and the rate of impure placebo use (those with efficacy but not in the clinical situation of interest, eg, antibiotic treatment for viral infection) varied from 54% to 57% (Fässler 2010).

Homeopathic preparations are often thought of as placebos because the solutions taken by patients are so dilute that they contain only a few molecules — if any — of any active ingredient. Hahnemann’s usual practice was to serially dilute the initial solution by 1/100 at each stage according to his centesimal scale (C scale). Other practitioners developed a decimal scale (X scale, sometimes called the D scale), in which the dilution at each stage is 1/10. Other scales exist. On the X scale, 1X is equivalent to 1/10 of the original dose, 2X is equivalent to 1/100, and so on — a dilution of 12X would be 1,000,000,000,000 of the original dose.

Some reports from the literature suggest that homeopathic preparations are more than simply placebo.

In 2004, for example, one group of researchers reported on a randomized trial that homeopathy was better than placebo at improving patient pain and quality of life in a cohort of fibromyalgia patients (Bell 2004). Specifically, a statistically significantly higher proportion of patients in the homeopathy group had ≥25% improvement in tender-point pain vs placebo (P=.008), and at the 4-month follow-up, patients reported significantly greater helpfulness of the homeopathic treatment versus placebo (P=.004) (Bell 2004).

Another report found that the homeopathic efficacy of some products was attributable to something more than the placebo effect among a group of subjects with allergic rhinitis (Taylor 2000). Taylor and colleagues conducted a randomized, placebo-controlled trial of a homeopathic preparation vs placebo in allergic rhinitis patients. Patients aged ≥16 years receiving the oral homeopathic preparation had a statistically significant objective improvement in nasal airflow compared with the placebo group (P<.001) (Taylor 2000). Another report in allergic rhinitis patients found that participants taking homeopathic remedies were more than twice as likely to see symptom improvement as those taking placebo (Linde 1998).

The validity of such findings has been challenged. Most recently, a draft report from Australia’s National Health and Medical Research Council looked at homeopathy versus placebo in 55 conditions. The council found that study designs limited the conclusions that could be drawn with regard to homeopathy demonstrating superior efficacy to placebo preparations (NHMRC 2014).

Thus, the use of homeopathy and the potential for the placebo effect may play an important role in the management of difficult-to-treat patients who present with symptoms of unknown etiology. For example, a patient may present with a generalized sense of anxiety but not be a candidate for treatment with a traditional pharmacologic agent because of 1 or more mitigating factors. Such a patient could be prescribed a homeopathic treatment for anxiety. In such a situation, the patient may feel satisfied with the holistic treatment approach and also may experience the placebo effect manifesting as a reduction in anxiety.

**Homeopathy in the U.S.**

In 1993, Eisenberg and colleagues set out to define the use of unconventional medicine in the United States (Eisenberg 1993). They looked at demographic, socioeconomic, and regional differences among CAM users as well as the overall rate of CAM use. More people 25 to 49 years of age were CAM users than those who were younger or older (P<.05). The use of CAM was lower among blacks (23%) than among other racial groups (35%; P<.05). People with some college education were more likely users of CAM than people without some college education (44% vs. 27%, respectively; P<.05). Geographic variation was also a factor, with subjects living in the western United States reporting greater use of CAM than those living in the rest of the country.
(44% vs. 31%; \(P<.05\)). Overall, 23% to 53% of all respondents reported using some form of CAM in the prior 12 months. In this early survey, homeopathy accounted for only 1% of CAM use reported by respondents. In 1998, however, 3% of persons in the United States reported using homeopathic preparations in the prior 12 months (Eisenberg 1998). Furthermore, the number of Americans using forms of CAM rose from 1990 to 1997 from 34% to 42% (Eisenberg 1998).

In 2009, a nationwide survey (N=4,001) conducted by the Deloitte Center for Health Solutions found that about 20% of health care consumers in the United States preferred homeopathic, chiropractic, or naturopathic alternatives to traditional medicine (Keckley 2009).

**Pharmacy perspective**

In the United States, medications in the Homeopathic Pharmacopoeia are regulated as drugs under the Food, Drug, and Cosmetic Act, but they are exempt from a 1962 amendment requiring that all new drugs provide clinical trial data to the FDA to support safety and efficacy. Despite the lack of these reporting requirements, it is clear that the United States recognizes homeopathic preparations as drugs.

Homeopathic preparations represent a growing market in the United States. From 1990 to 2000, the sale of homeopathic preparations rose 1,000% (Sayner-Flusche 2000), with that trend continuing to present. In 1994, 69% of all chain drugstores and more than 3,000 independent pharmacy retailers reported stocking homeopathic preparations (McDermott 1995). Furthermore, a 2000 study estimated CAM sales to be more than $34 billion in the United States (MacLennan 2002), up from $21 billion in 1998 (Eisenberg 1998).

Pharmacists have an obligation to their patients to provide unbiased reports on drugs that are dispensed within their pharmacy. An American Pharmaceutical Association survey in 2000 on homeopathic preparations found that pharmacists wanted to increase their knowledge of these preparations so that they could improve personal understanding (31%) and provide accurate information to patients (7%) (Sayner-Flusche 2000).

With the number of pharmacies selling homeopathic preparations and the number of patients seeking alternative treatments on the rise, pharmacists need to be informed about the use of these alternative medications and be prepared to provide unbiased advice to their patients and other health care providers.

**Implications for managed care**

CAM appears to be solidly entrenched in American society, enjoying support from politicians and health care professionals as well as the general public. Political support for CAM became manifest in 1992 when a controversial bill passed both houses of Congress to create the Office of Alternative Medicine within the National Institutes of Health. Dismayed by the office’s meager resources, in 1995 Congress transformed it into the National Center for Complementary and Alternative Medicine (NCCAM) and increased its budget to $50 million in 1999 (Jonas 2013). According to the NCCAM’s third strategic plan, which extends through 2015, 1 of its 5 strategic objectives is to advance research on CAM natural products, a category that includes homeopathic products, with a focus on mechanistic research that provides a scientifically sound hypothesis for these products (NCCAM 2011).

At the same time CAM has garnered some political support, so have health care providers expressed greater interest in CAM. For example, a large HMO in Northern California looked at the extent of CAM use and the interest of primary care practitioners and adult members in having such treatments incorporated into a HMO-delivered care model (Gordon 1998). In the 12 months prior to the study, 25% of adult members reported using some form of CAM. Ninety percent of obstetrics and gynecology practitioners reported the recommendation of at least one form of CAM to their patients. They reported recommending herbal and homeopathic medications, particularly for the management of premenstrual syndrome and symptoms associated with menopause. Approximately 33% of primary care physicians serving adults and 75% of obstetric-gynecology clinicians were interested in using CAM with their patients. When the young and middle-aged adult members were surveyed, nearly 70% reported interest in having CAM incorporated into their health care paradigm, with approximately 50% of people beyond middle age responding similarly. Behavioral and manipulative treatments, but not homeopathy, were cited as the most desirable CAM methods that adult primary care practitioners were interested in having the HMO provide coverage for (Gordon 1998).

Another large survey of community physicians, in New Mexico and Washington, reported that >60% of physicians had referred ≥1 patient for CAM in the past 12 months. Among those, 12% included some form of CAM in their present practice patterns and 42% had utilized CAM for themselves or family members (Borkan 1994). Another survey, in the Chesapeake region, found that 70% to 90% of physician respondents considered complementary medical treatments to be legitimate medical practices (Berman 1995). In this study, however, homeopathy was not a favored treatment modality of the practitioners surveyed.

More recently, a study based on National Health Interview survey data...
found that 76% of health care workers (vs. 63% of the general population) said they had used at least one kind of CAM therapy in the past year (John-son 2012). In addition, a survey con-ducted by the Samueli Institute and a subsidiary of the American Hos-pital Association in 2010 found that 42% of responding hospitals (N=714) reported offering ≥1 CAM therapy in 2010, compared with 27% of re-spondents 5 years earlier. In all, 85% of the hospitals said patient demand was their primary reason for offering CAM therapies (Ananth 2011).

Despite the paucity of data on the use of homeopathy, specifically in a managed care environment, homeo-pathy represents a growing market in the United States. Historically, there has been an absence of coverage for homeopathic remedies by insurers in the United States. Over the last 2 decades, there has been some inter-est by insurers in favor of paying for these naturopathic remedies (Montoya 1998). With the popularity of CAM on the rise among subscribers in the United States, some insurers are taking a closer look at alternative treatments as a means to boost their enrollment numbers in a new marketplace that is now extremely com-petitive because of the advent of the Affordable Care Act. Some insurers, however, are still reluctant to pay for homeopathy because of the lack of standardization of care by clinicians and conflicting outcomes in programs designed to provide evidence-based medicine. CAM is not approved by the FDA, and thus the treatments offered are not eligible for payment under federal drug benefit programs (Medicare, Medicaid, etc.). Since CAM is not covered under this umbrella, managed care plans have no means by which to recapture costs and thus have been historically reluctant to offer benefits for any type of CAM. Some plans offer “affinity benefits,” which amount to an out-of-pocket cost reduction to the patient for using a particular vendor, but the patient is still fully responsible for the expense. An increase in public and private sector funding for research may lead to increased interest in establishing the safety and effectiveness of homeo-pathic preparations. This may help drive the number of MCOs that are paying for homeopathic treatments (Ullman 1999).

At present, it looks as though we are faced with an all-too-frequent dilemma of having to make decisions with insufficient information. It is not likely that any further full-scale clinical trials will be conducted, because the number of homeopathic agents was capped by the grandfather clause permitting homeopathic drugs to be included among the United States FDA approved list. Moreover, if insur-ers were to argue for the permitted use of homeopathic drugs, they might go onto a list for over-the-counter (OTC) status, and as we know, MCOs and health insurers do not typically pay for OTC drug products.

For P&T committees, there is little solid evidence from which to inform policy, from the body of knowledge surrounding homeopathic prepara-tions. It would probably be the sugges-tion of the authors that P&T commit-tees should ascertain the feelings of plan members and use that information to assist in determining a status for homeopathic drugs within that plan. We posit that when no organic source of some symptoms can be de-termined, the use of some nonspecific homeopathic agent might be consid-ered when the patient clearly expects a medication prescription. Perhaps, some brave P&T committees might monitor outcomes from homeopathic drug studies and, at least, report their experience in the literature.

REFERENCES


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