

## The Practitioner's Need-To-Know Overview of Homeopathic Research

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### Introduction

As are practitioners in most other areas of health care, homeopaths in clinical practice are often too busy with patient care to keep up with much of the research literature in their field. Furthermore, even in conventional medicine, clinicians often point out that they find research papers irrelevant to their everyday work with patients. Even large-scale clinical trials of drugs that they prescribe daily seem not to provide much useful information about what to do for a specific patient. Homeopaths already know this, as their field is already so intensively focused on individualized care involving both the non-specifics of the patient-provider relationship and specifics of the individualized remedy (T. D. Thompson & Weiss, 2006), and patients respond with complex multidimensional changes (Bell, Koithan, Gorman, & Baldwin, 2003; M. Oberbaum, Singer SR, Vithoulkas G., 2005).

Life – also known as “extenuating circumstances” - seems to make the seemingly ideal treatment not quite right for a given person – because of side effects, interactions with drugs, complications from co-morbid conditions not allowed in the original clinical trials, high cost, poor access, reduced willingness or ability to take the treatment on the recommended schedule, cultural, family, or personal beliefs against the treatment, and so on. Overall, real-world clinical practice is usually vastly different from what medical researchers spend most of their time studying (Freeman & Sweeney, 2001).

To add even more confusion to the situation, even in conventional medicine, the results of large scale real-world observational trials and the results of controlled, double-blind clinical trials can lead to opposite conclusions. For example, hormone replacement therapy (HRT) was touted as a way to reduce menopausal symptoms and various health care risks for women – until new data raised serious concerns that HRT actually increases those same risks.

Homeopaths encounter similar dilemmas with treatments such as Arnica. That is, clinical experience tells them the remedy is helpful in many first aid situations, but the research literature shows mixed results (for many reasons, especially involving study design), with many negative studies showing Arnica of no benefit (Ernst & Pittler, 1998; W. Jonas, Lin, Y., Williams, A., Tortella, F., Tuma, R., 1999; Oberbaum et al., 2005; Ramelet, Buchheim, Lorenz, & Imfeld, 2000; Stevinson, Devaraj, Fountain-Barber, Hawkins, & Ernst, 2003). When clinicians have the opportunity to look at the details of each study, they usually can point out glaring problems with a mismatch between clinical practice and the actual study design – in terms of choice of clinical condition, remedy, and dosing schedule. Data suggest that Arnica may be useful in certain bruising conditions (e.g., facial plastic surgery), but not necessarily all type of surgical procedures (e.g., carpal tunnel repair) or sports injuries.

When the data contradict personal experience, many practitioners and patients choose to act on the side of their own experience with a treatment – in both conventional and alternative health care. Skeptics just use such behavior as further “proof” that proponents of homeopathy are irrational and unscientific.

However, it is possible to be rational and scientific – and find logical ways to evaluate articles with findings that do - or do not - coincide with strongly-held beliefs, to make sense of conflicting information. Often methodological design or analysis problems contribute to the divergence between clinical impressions and randomized clinical trial findings. The appropriate response is

to revise study design to better reflect clinical practice, not to ignore or attack results globally that are counter to expectation.

### **Reasons for Homeopathic Research**

So, why bother with research at all (Bell, 2003)? There are two major pragmatic reasons for paying attention to research in homeopathy:

#### **(1) Developing the Evidence Base on Homeopathy (aka Survival of the Field) –**

Western drug-oriented medicine still holds immense political, legal, and financial power in the health care arena. People in power do not always understand or care about alternative medicine practices; sometimes they see these practices as risky for patients in terms of physical safety or “unnecessary” expenses. They can find ways to squeeze practitioners out of practice by legal actions against providers and financial actions (restricting practice and payment).

Establishing homeopathy as an evidence-based health care system is one essential element in a viable offense and defense against such attacks. Homeopaths who need to give talks on homeopathy in their local communities or to defend their own practice when skeptics come calling will find this type of information vital.

Types of research that fall into this broad category include placebo-controlled randomized clinical trials, large scale observational outcomes studies, and cost-effectiveness studies.

**(2) Improving Clinical Care for Patients –** Even purists in any field agree that the ideal stated in the textbooks and the reality in practice can differ. Any practitioner who is honest about their field and their own practice will acknowledge that there is always room for improvement. Research can provide ways to know where to begin in this process.

Here, we can ask questions like:

“Are combination remedies and individual remedies comparable or different in clinical effectiveness for treating certain acute illnesses?”

“When do patients benefit from LM dosing versus C potency dosing?”

“What is the ‘right’ potency to use in a given patient?”

“Does zigzagging to cure through a series of remedies have the same benefits and downsides for a patient as does finding a single remedy that covers the whole case early on?”

“What individual differences between people make them better or worse responders to homeopathic treatment?”

“How do the clinical outcomes of people treated with homeopathy versus allopathic drugs differ for a specific clinical picture?”

“Which allopathic drugs interfere with homeopathic treatment – and in what ways?”

“What factors do antidote remedies and under what circumstances – and which patients?”

“Under what circumstances does one system of finding the remedy work better than another?”

“Are there cultural and/or biological differences between patient populations that impact applying the teachings of various master homeopaths from different countries in your own home town?”

“How can we improve the reliability and clinical applicability of provings so that we obtain good remedy pictures on which to base prescriptions?”

These and many more questions relate to improving care for patients at a practical level. Homeopaths should want to know answers to these types of questions in order to make

changes in their practice and improve patient outcomes. There are many opinions on most areas of homeopathic practice – research findings can help inform the decisions that each practitioner ultimately has to make for each patient.

The bibliography resources below provide some starting points for addressing these two main reasons why practitioners might want to learn more about the research literature. Just as any good homeopath keeps up with new case reports in clinical journals, at conferences, and on the internet and becomes familiar with new ideas about practice, the research literature can make us think even harder about cases in ways we currently might not do – all for the advancement of the field and better outcomes for patients.

Incorporating homeopathic research helps reduce our uncertainty, add professionalism to the way we present homeopathy in our communities, and identify the important questions that need answers (beyond opinions). Ultimately, this effort will help homeopathy to strengthen and grow as a health care discipline.

### **(1) Developing the Evidence Base on Homeopathy Papers**

#### **Allopathic Conditions in which Homeopathy has been studied**

<b>Condition</b>	<b>Reference(s)</b>
Allergies	(Kim et al., 2005; D. Reilly, Taylor, M.A., Beattie, N.G.M., Campbell, J.H., McSharry, C., Aitchison, T.C., Carter, R., Stevenson, R.D., 1994; D. T. Reilly, Taylor, McSharry, & Aitchison, 1986; Taylor, Reilly, Llewellyn-Jones, McSharry, & Aitchison, 2000)
Asthma	(G.T. Lewith et al., 2002; Linde & Jobst, 2000; White, Slade, Hunt, Hart, & Ernst, 2003)
Chronic headache	(Walach et al., 1997; Walach et al., 2000; Walach, Lowes et al., 2001)
Chronic fatigue syndrome	(Geraghty, 2002; Weatherley-Jones et al., 2004)
Depression and anxiety	(I.R. Bell, 2005; Bonne, Shemer, Gorali, Katz, & Shalev, 2003; Davidson, Morrison, Shore, Davidson, & Bedayn, 1997; Katz, Fisher, Katz, Davidson, & Feder, 2005; K. Pilkington, Kirkwood, Rampes, Fisher, & Richardson, 2005; K. Pilkington, Kirkwood G, Rampes H, Fisher P, Richardson J., 2006)
Childhood Attention Deficit/Hyperactivity Disorder	(H. Frei, Everts R, von Ammon K, Kaufmann F, Walther D, Hsu-Schmitz SF, Collenberg M, Fuhrer K, Hassink R, Steinlin M, Thurneysen A., 2005; H. Frei, Thurneysen A., 2001; H. Frei, von Ammon, & Thurneysen, 2006; J. Jacobs, Williams, Girard, V.Y., & Katz, 2005; Lamont, 1997)
Vertigo	(Morawiec-Bajda, Lukomski, & Latkowski, 1993)
Minimal Brain Trauma	(Chapman, Weintraub, Milburn, Pirozzi, &

	Woo, 1999; Chapman & Wilson, 1999)
Fibromyalgia	(Bell et al., 2005; Bell, Lewis, Brooks, Schwartz, Lewis, Caspi et al., 2004; Bell, Lewis, Brooks, Schwartz, Lewis, Walsh et al., 2004; Bell, Lewis, Lewis et al., 2004; Bell, Lewis, Schwartz et al., 2004; P. Fisher, Greenwood, A., Huskisson, E.C., Turner, P., Belon, P., 1989)
Osteoarthritis	(Breuer et al., 2005; R. A. van Haselen & Fisher, 2000)
Rheumatoid arthritis	(Andrade, Ferraz, Atra, Castro, & Silva, 1991; P. Fisher & Scott, 2001; Gibson, Gibson, MacNeill, & Buchanan, 1980; W. B. Jonas, Linde, & Ramirez, 2000)
Sepsis	(Frass et al., 2005)
HIV/AIDS	(Rastogi, Singh, Singh, Dey, & Rao, 1999)
Influenza	(A. J. Vickers, Smith C., 2006)
Childhood Upper Respiratory Infections	(Steinsbekk, Bentzen, Fonnebo, & Lewith, 2005; Viksveen, 2003)
Childhood diarrhea	(J. Jacobs, Guthrie BL, Montes GA, Jacobs LE, Mickey-Colman N, Wilson AR, DiGiacomo R., 2006; J. Jacobs, Jimenez, Gloyd, Gale, & Crothers, 1994; J. Jacobs, Jonas, JimAnez, & Crothers, 2003)
Otitis media	(Harrison, Fixsen, & Vickers, 1999; J. Jacobs, Springer, D.A., Crothers, D., 2001; Steinsbekk, Bentzen, Fonnebo, & Lewith, 2004)
Cancer and treatment complications	(Biswas & Khuda-Bukhsh, 2004; Buettner, 2006; Clover & Ratsey, 2002; Ernst, 2001; J. Jacobs, Herman, Heron, Olsen, & Vaughters, 2005; MacLaughlin et al., 2006; Molassiotis et al., 2005; Montfort, 2000; Oberbaum et al., 2001; Schlappack, 2004b; E. A. Thompson, Montgomery, Douglas, & Reilly, 2005)
Menopausal symptoms	(Clover & Ratsey, 2002; J. Jacobs et al., 2005)
Premenstrual syndrome	(Yakir et al., 2001)

Most studies have been on small samples and receive criticism for various methodological shortcomings including sample size per se. Nonetheless, these papers may provide some guidance to practicing homeopaths on how to approach treatment of individual patients with similar allopathic diagnoses.

### **“Lumping” Approaches to Research**

#### ***Allopathic Gold Standards – Meta-Analyses and Systematic Reviews***

<b>Systematic Review Papers</b>
(Cucherat, Haugh, Gooch, & Boissel, 2000)
(Kleijnen, Knipschild, & ter Riet, 1991)

(Linde et al., 1997)
(Ernst, 2002)
(Shang et al., 2005)
(Caulfield, 2005)
(K. Pilkington et al., 2005; K. Pilkington, Kirkwood G, Rampes H, Fisher P, Richardson J., 2006)
(J. Jacobs, Jonas, Jimenez-Perez, & Crothers, 2003)
(A. J. Vickers & Smith, 2004)
<b>Editorials/Letters about Recent Meta-Analyses, etc.</b>
(Vandenbroucke, 1997)
(Lancet, 2005)
(Weissmann, 2006)
(P. Fisher, Berman B, Davidson J, Reilly D, Thompson T. , 2005)
(R. van Haselen, 2005)
(M. Oberbaum, Singer SR, Frass M. , 2005)
(Aickin, 2005)
(I. R. Bell, 2005)
(Ullman, 2006)

### Take-Home Points:

Meta-analyses are a formalized type of systematic review in which the results of different, multiple randomized controlled trials are systematically assessed and rated numerically for allopathic study quality, then combined to draw general conclusions about a particular treatment in a specific allopathic condition.

Notably, the highest profile meta-analyses (Linde et al 1997 and Shang et al 2005) combined trials of homeopathically-prepared remedies prescribed homeopathically, isopathically, and allopathically across multiple allopathic conditions. They do not and cannot address the efficacy of usual care homeopathy by any one practice approach (classical, complex, clinical, isopathic) in any single allopathic condition or for any single homeopathic remedy. The analogy would be for someone to take all of the best clinical trials done on all types of allopathic drugs to run one big meta-analysis in order to ask the question – “Does allopathic medicine work?”

Even without elegant statistics, obviously the answer for allopathic medicine is – sometimes, under certain experimental conditions, allopathic medicine produces certain good outcomes, certain bad outcomes, and sometimes no change at all. It also depends how you define a “good” or “bad” outcome. From a homeopathic perspective, a suppressive effect would be a bad outcome, but allopathic rating systems would consider a suppressive outcome as “good.” At present, it is probably fair to draw the same kind of conclusion about “homeopathy” from existing metaanalyses, i.e., that it produces certain good outcomes, certain bad outcomes (though fewer than with allopathic medicine, based on available data), and sometimes no change at all.

In conventional medicine, the meta-analysis would be restricted to a specific medication or surgical procedure for a specific diagnosis. At best, some of the earlier meta-analyses examined isopathically-prescribed allergens in rhinitis patients. Other methodological problems with the actual statistical procedures are also a major issue with accepting the validity of most meta-analyses on homeopathy as a whole field.

Another important point to make about these meta-analyses is that the quality ratings for studies derive from standards relevant to studies of allopathic drugs. Quality ratings for reporting studies in homeopathy to date have never established or included any standards for quality of the homeopathy given (including experience of practitioner(s), prescribing method, confidence of practitioner in remedy prescription, ability to change remedy choices for non-response, management such as use of LM potencies or dose repetition to deal with possible antidoting effects of concomitant allopathic drugs, etc), study duration adequate to expect change in the allopathic condition, and so on (Dean, Coulter, Fisher, Jobst, & Walach, 2006).

Finally, one systematic review found that conventional medical journals show a bias toward publishing negative studies about homeopathy, whereas CAM journals show a bias toward publishing positive studies. However, for meta-analyses, to date, the bias is more evenly distributed between positive and negative studies in mainstream medical and complementary medical journals (Caulfield, 2005).

### ***Observational Outcome Studies***

Observational studies can vary in quality, from case-control and cohort designs to simple chart reviews or audits of case series. Skeptics will often object to observational data, saying that it is not as “good” as the controlled studies – but the evidence does not support this claim. In fact, well-designed observational studies using comparison groups (to compare treated patients with those receiving standard care or no care, thereby controlling for the natural course of the disease) generate findings of at least equivalent capacity to detect significant treatment effects (J. Concato, 2004; J. Concato, Horwitz, R.I., 2004; Concato, Shah, & Horwitz, 2000).

Observational studies are particularly valuable for homeopathy research because of a) the relative lack of academically-based researchers and major research funding worldwide; b) the relevance of real-world context, including complex and multiple diagnoses/symptoms, and longer-term periods of evaluation for assessing homeopathic outcomes; and c) theory-driven models for mediators of change in homeopathy (Milgrom, 2006b). Observational studies rely on case data from real patients in real practice settings and can involve large numbers of patients treated for short- or long-term periods. This permits determination of outcomes that may be much more relevant to clinical practice than most controlled clinical trials (with typically durations of 12-16 weeks) or meta-analyses that depend on randomized controlled trials.

Of note, observational studies on homeopathy have reported consistently highly favorable outcomes, typically at rates of 70-80% improvement, along with high levels of patient satisfaction and low rates of adverse effects. Obviously, especially in studies without comparison groups, skeptics could point to potential bias of the authors in favor of homeopathy to discount such findings. However, one recent observational study did include a control group (see Witt et al 2005). Studies on cost of homeopathic care vs allopathic care also have suggested that, depending on the fiscal structure of the health care system in which the homeopathy is given, the overall costs either decrease or are equivalent (Frenkel & Hermoni, 2002; van Wassenhoven & Ives, 2004; C. Witt, Keil T, Selim D, Roll S, Vance W, Wegscheider K, Willich SN., 2005).

In complementary medicine generally, studies of safety and cost in the face of equivalent or better outcomes to conventional care may be even more useful in making the case for using and insurance reimbursements for alternative therapies, including homeopathy (Bornhoft, 2006; Maxon-Bergemann, Wolf, Bornhoft, Matthiessen, & Wolf, 2006). Reports of safety (adverse reactions) with homeopathy are generally low in most controlled trials, although one clinical

audit study suggested that homeopathic “aggravations” are fairly common (approximately ¼ of patients) (E. Thompson, Barron, & Spence, 2004). We need much more research of this type to make the case at this point in time.

<b>Observational Studies</b>
(Sevar, 2005)
(Relton & Weatherley-Jones, 2005)
(Sevar, 2000)
(Anelli, Scheepers, Sermeus, & Van Wassenhoven, 2002)
(Riley, Fischer, Singh, Haidvogel, & Heger, 2001)
(van Wassenhoven & Ives, 2004)
(Goldstein, 1998)
(Frenkel & Hermoni, 2002)
(Steinsbekk & Ludtke, 2005)
(Schlappack, 2004a)
(Spence, Thompson, & Barron, 2005)
(Trichard, Chauferin, & Nicoloyannis, 2005)
(Witt et al., 2005; C. M. Witt, Luedtke R, Baur R, Willich SN., 2005)

### ***Basic Science Papers on the Nature of Remedies***

The single most important argument that skeptics of homeopathy raise is that the remedies, at least those potencies above 24x or 12c, are diluted so much that there are no more physical molecules of the original source substance remaining (diluted past Avogadro’s number of  $6 \times 10^{23}$ ) (Mastrangelo, 2006). Being prepared to cite some of the papers mentioned below and provide references is critical for homeopaths who encounter skepticism from patients, family members, and allopathic physicians.

The research is showing that it is the succussion process that is essential for generating persistent changes in solvent, even when remedy source material molecules are no longer present (Elia, 1999, 2004; Rey, 2003). Several different research groups have documented differences from control solvents of the remedies themselves or of remedy effects at above-Avogadro number dilutions (with succussions) in animals, plants, or cell preparations (Belougne-Malfatti, Aguejouf, Doutremepuich, Belon, & Doutremepuich, 1998; Doutremepuich, Aguejouf, Pintigny, Sertillanges, & De Seze, 1994; Hamman, Koning, & Lok, 2003; W. Jonas, Lin, & Tortella, 2001; W. B. Jonas, 1999; Marotta et al., 2002; N. C. Sukul, Bala, S.K., Bhattacharyya, B., 1986; N. C. Sukul, Ghosh, Sinhababu, & Sukul, 2001; Van Wijk & Wiegant, 1997; Werkman, 2006).

Theories of mediation include changes in hydrogen bonding and/or van der Waals forces between the dynamical interactive network of water/solvent molecules (not the structure of any single water molecule). Other documented phenomena such as epitaxy are also testable hypotheses (Roy, Tiller, Bell, & Hoover, 2005). Silica contaminants released from the walls of glass containers during succussion may contribute to the generation and/or stabilization of remedies, but not necessarily to explaining the unique signatures of specific individual remedies in comparison with succussed solvent controls or other remedies (Ives et al. presentation at the North American Research Conference on Complementary and Alternative Medicine, Edmonton, AB, Canada, May 24-27, 2006).

Another key aspect of remedy response is potentially the phenomenon of hormesis, or nonlinear dose-response relationships that occur below the lowest observed level for adverse effects of many different agents, including radiation, toxins, and various drugs (E. J. Calabrese, 2005; E. J. Calabrese, Baldwin, L.A., 2001). Low doses of agents under certain conditions can cause effects on a biological system opposite in direction to those of high doses of the same agent. For homeopathy, this well-documented phenomenon is likely relevant to the healing responses of people, plants, and animals to remedies, but little research on hormesis per se has addressed homeopathically-prepared remedies.

In addition, the timing of the dose relative to an injury may contribute to nonlinear dose-response relationships in homeopathy. One study in animals, for example, found that giving a mineral remedy mixture lessened experimentally-induced swelling in paws when given after the injury occurred, but the same remedy and potencies worsened the swelling when given before the injury occurred (Bertani, Lussignoli, Andrioli, Bellavite, & Conforti, 1999). Such research deserves much additional study of state-dependent effects to determine the circumstances under which it is helpful – or potentially harmful – to administer remedies.

Several different homeopathic research groups have converged on suggesting that modern complex systems and network theory may assist in translating homeopathic theory and practice into a scientifically accessible framework (Bell, Baldwin, & Schwartz, 2002; Bell & Koithan, 2006; Bell, Lewis, Lewis et al., 2004; P. Bellavite, 2003; P. Bellavite, Signorini, A., 2002; M. Hyland, 2003; M. E. Hyland & Lewith, 2002; Milgrom, 2002; Torres, 2002; Torres & Ruiz, 1996). Systems theory may provide a bridge between the basic science research and clinical observations in homeopathic practice that can advance the field in both broad areas.

## **(2) Improving Homeopathic Practice Papers**

### ***Provings Research***

Provings are the foundation of drug development in the field of homeopathy, but systematic research has raised concerns about the reliability and reproducibility of the information generated. In some studies, the issue is that conventional statistical approaches in which symptom tallies are used show no differences between active (verum remedy) and placebo under controlled conditions.

Some investigators have said that such data analysis is inappropriate for studying homeopathy, as it is patterns of change, not lists of changes, that the more qualitative aspects of provings generate. It is also important to acknowledge that conventional health psychology research has consistently shown that even generally “healthy” people generate a low level of symptoms on a regular basis, thereby making some observation of symptom patterns in the absence of remedy essential in order to avoid confusing spontaneous symptoms with those related to remedy action.

Any novice homeopath can attest that the remedies all seem to blur together and seem all alike, if he/she is looking for a treatment for an isolated symptom. Thus, both the symptom pattern and time course pattern may be critical in ecologically valid provings research. Use of qualitative research methods may also be essential for improving the quality of the generated information.

Other investigators have raised more fundamental theoretical concerns, i.e., that the remedy, the remedy symptoms, the placebo, and provers are all entangled in a macro- way in the real world, just as quantum physicists have demonstrated entanglement at the quantum level of

analysis. Such a possibility offers one explanation why leading homeopaths who do provings research report seeing unique symptoms of the active/verum remedy occurring in persons receiving placebo or just in participating in the same training workshop where other people are taking the remedy.

Therefore, it is important for any homeopath who undertakes provings research to educate him/herself about the issues and consider design options for dealing with both the issue of patterns and the possibility of macro-quantum entanglement as confounders of the work.

References to inform homeopaths who choose to work on provings are listed below.

<b>Provings Studies</b>
(Dominici, 2006)
(Milgrom, 2006a; Walach, 1993, 2000; H. Walach, 2002; Walach, 2003; H. Walach, Jonas, W.B., 2002; Walach, Koster, Hennig, & Haag, 2001; Walach et al., 2004)
(T. D. Thompson, 2004)
(Milgrom, 2004, 2005; Milgrom, 2006a)
(G. T. Lewith, Brien, & Hyland, 2005)

### **Clinical Practice Studies**

One of the most noticeable lacks in the homeopathic research literature is studies addressing how to improve clinical practice. Most of the clinical literature is concerned with presenting individual case reports in detail, but rarely do clinical investigators look at how to optimize patient outcomes during homeopathic treatment as a broad question.

One recent and notable exception has been a series of papers by Frei et al. on attention deficit disorder, in which they looked at strategies for improving patient outcomes (H. Frei et al., 2006). Their paper opens the door on a huge need in the field of homeopathic research that could begin to lessen opinion-based homeopathic practice and strengthen evidence-based and clinically-relevant homeopathic practice. Any one system from any particular master homeopath likely has internal validity, but when should practitioners apply one approach versus another? Do allopathic diagnosis, patient characteristics, homeopath characteristics, specific remedy kingdom or remedy family etc. influence outcomes? These are pressing questions that research can and should address.

### **Conclusions**

The research literature on homeopathy is growing and improving in quality. However, for various reasons, the field is still young in terms of developing appropriate methodologies for the unique nature of homeopathy as a complex intervention and whole system of care. Advances in both theory and empirical work are bringing us closer to useful data for application in everyday homeopathic practice. In the meantime, serious students of homeopathy and practitioners need to monitor developments on the research front that may help them carry out their difficult challenge of meeting Hahnemann's original charge to the profession, i.e., "...to make the sick healthy, to cure as it is termed."

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