

## **Expanding the Paradigm of Acupuncture Research**

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"Let one hundred flowers bloom. Let one hundred schools of thought contend and flourish." So begins one of Mao Tse Tung's treatises following the Cultural Revolution. In the spirit of these sentiments, we would like to discuss the variety of research models and approaches to evaluation that are available to the acupuncture community.

An essential element of public health is the evaluation of treatments and programs. Although there is always an interest in improving individual health or well-being, examining changes on a community or state level is also valuable.

Public health takes a holistic view, because it appreciates the role of the individual in the context of that person's membership in a larger social unit. Public health research focuses on the factors that influence health in a society. Some of the earliest investigations in the 17th and 18th centuries examined whether giving British sailors citrus fruit on long voyages would prevent scurvy, or whether drinking from certain wells could prevent cholera. These research efforts were valuable, and formed the beginnings of epidemiological research. Epidemiology assesses factors that impact health, such as lifestyle habits or genetic predisposition. Epidemiological techniques include a variety of study approaches designed to accurately and scientifically evaluate the effects of interventions, treatments, or other environmental factors.

Although the model of the randomized clinical trial is relevant to our profession, it has the same drawbacks evident in other types of health-related research. For example, there can be ethical issues with trials (we can't assign study participants to an intervention we know is harmful), or trials can be prohibitively costly in terms of the numbers of participants needed or resources of the research team. Lastly, logistical concerns in terms of timing or other factors may be problematic. (Do we know enough about a new intervention to test it? Are other interventions less invasive or associated with fewer side-effects?)<sup>1,2</sup> Despite these caveats,

acupuncture investigators have produced numerous trials that honor the biomedical model of research and the traditional Asian art and science that form the foundation of our profession.

Other areas of valid science exist without being able to draw on the paradigm of the trial approach: In astronomy, for example, we could never repeat the experiment of the creation of the universe. In the field of psychotherapy, the concepts of double-blinding or using a placebo are meaningless, yet researchers and clinicians are continually striving to improve and refine techniques to aid individuals' psychological well-being.

Acupuncture researchers have an array of study designs from which to choose, depending on the research questions of interest. We would like to encourage researchers to consider nonexperimental approaches when appropriate, to nurture and fortify the growing body of knowledge about acupuncture's effects. Although our focus in this article is on clinical issues that can be examined through rigorously designed observational inquiries, we acknowledge the value of trials, as well as physiological research, in enhancing our understanding of Asian medicine.

Observational studies can be used to monitor, evaluate and improve treatment, thus making important contributions to our understanding of acupuncture's role in health care. Examples of observational research methodologies include cohort studies; case-control approaches; formative research; program evaluation; and outcomes research. In cohort studies, individuals are followed over time to ascertain the effects of health-related behaviors or lifestyle practices. Case-control studies evaluate the effects of specific characteristics, practices or exposures to factors that may influence health. Formative research is often qualitative, and provides preliminary information needed to set the stage for future investigation, while program evaluation examines the processes inherent to health care delivery. Outcomes research is often used to evaluate the actual effectiveness of an intervention as it is practiced, rather than in a research environment.

None of these designs can address the question of precisely how well acupuncture works in a given situation, but each can meaningfully describe aspects of the integration of acupuncture into treatment. Study designs that examine changes within individuals over time, without comparing changes between different individuals, can also reveal important clinical information. Most importantly, observational techniques can evaluate "real-world" conditions in which clinical trials would be unfeasible, making it possible to gain maximal knowledge and expertise from our clinical experience.

For example, Fairfield and colleagues used a survey research approach to learn valuable information about utilization, cost and perceived efficacy of a variety of CAM techniques from a group of individuals diagnosed with HIV/AIDS.<sup>3</sup> An innovative assessment of acupuncture in the treatment of headache, performed by Lewith and colleagues in the U.K., followed patients for a year and documented reduction of symptoms over time.<sup>4</sup> For a more detailed description of outcomes research, readers are invited to peruse articles by Walach<sup>5</sup> and Kane.<sup>6</sup>

In other examples of observational research, Robinson and her colleagues in London investigated the correlation between use of acupuncture and improved adherence to medication therapies among people with HIV/AIDS.<sup>7</sup> Researchers from Italy, Germany and France developed a case-control study that compared characteristics between individuals who used complementary therapies and those who did not.<sup>8</sup> These types of studies provide crucial understanding of a variety of elements related to treatment, including outcome. Along with appropriate clinical trials, observational research offers the possibility of deeper comprehension of the overall treatment process. As such, they can edify our practice on a number of levels (for example, broadening the scope of who we treat, or integrating health information and referrals into our best practices).

When we have access to data from large numbers of patients (either from our own clinics or from collaborating institutions), or from groups of patients followed over a period of years, we can contribute to acupuncture research by creatively posing questions that can be addressed by the information we have. Working in conjunction with statisticians or other experienced public health investigators, we can co-create studies that benefit consumers, ourselves as clinicians, and the ever-expanding body of knowledge about Asian medicine. The "one hundred flowers" of our efforts have the potential to bring increased knowledge and healing into the world.

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