

Acupuncture

NIN Consensus Development Panel on Acupuncture

Objective.—To provide clinicians, patients, and the general public with a responsible assessment of the use and effectiveness of acupuncture to treat a variety of conditions.

Participants.—A nonfederal, nonadvocate, 12-member panel representing the fields of acupuncture, pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, family practice, internal medicine, health policy, epidemiology, statistics, physiology, biophysics, and the representatives of the public. In addition, 25 experts from these same fields presented data to the panel and a conference audience of 1200. Presentations and discussions were divided into 3 phases over 2½ days: (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that were part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. The conference was organized and supported by the Office of Alternative Medicine and the Office of Medical Applications of Research, National Institutes of Health, Bethesda, Md.

Evidence.—The literature, produced from January 1970 to October 1997, was searched through MEDLINE, Allied and Alternative Medicine, EMBASE, and MANTIS, as well as through a hand search of 9 journals that were not indexed by the National Library of Medicine. An extensive bibliography of 2302 references was provided to the panel and the conference audience. Expert speakers prepared abstracts of their own conference presentations with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience.

Consensus Process.—The panel, answering predefined questions, developed their conclusions based on the scientific evidence presented in the open forum and scientific literature. The panel composed a draft statement, which was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference. The draft statement was made available on the World Wide Web immediately following its release at the conference and was updated with the panel's final revisions within a few weeks of the conference. The statement is available at <http://consensus.nih.gov>.

Conclusions.—Acupuncture as a therapeutic intervention is widely practiced in the United States. Although there have been many studies of its potential usefulness, many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as placebos and sham acupuncture groups. However, promising results have emerged, for example, showing efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations, such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma, in which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful.

JAMA. 1998;280:1518-1524

ACUPUNCTURE is a component of the health care system of China that can be traced back for at least 2500 years. The general theory of acupuncture is based on the premise that there are patterns of energy flow (Qi) through the body that are essential for health. Disruptions of this flow are believed to be responsible for disease. Acupuncture may correct imbalances of flow at identifiable points close to the skin. The practice of acupuncture to treat identifiable pathophysiological conditions in American medicine was rare until the visit of President Nixon to China in 1972. Since then, there has been an explosion of interest in the United States and Europe in the application of the technique of acupuncture to Western medicine.

Acupuncture describes a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques. There are several approaches to diagnosis and treatment in American acupuncture that incorporate medical traditions from China, Japan, Korea, and other countries. The most studied mechanism of stimulation of acupuncture points uses penetration of the skin by thin, solid, metallic needles, which are manipulated

NIH Consensus Development Conferences are convened to evaluate available scientific information and resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public.

NIH Consensus statements are prepared by a nonadvocate, nonfederal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session, (2) questions and statements from conference attendees during open discussion periods that are part of the public session, and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the federal government.

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manually or by electrical stimulation. The majority of comments in this report are based on data that came from such studies. Stimulation of these areas by moxibustion, a technique that applies heat to an acupuncture point by burning a compressed, powdered, combustible substance at or near the points to be stimulated, pressure, heat, and lasers is used in acupuncture practice, but because of the paucity of studies, these techniques are more difficult to evaluate.

Acupuncture has been used by millions of American patients and performed by thousands of physicians, dentists, acupuncturists, and other clinicians for relief or prevention of pain and for a broad spectrum of health conditions. After reviewing the existing body of knowledge, the US Food and Drug Administration recently removed acupuncture needles from the category of "experimental medical devices" and now regulates them just as it does other devices, such as surgical scalpels and hypodermic syringes, under good manufacturing practices and single-use standards of sterility.

Over the years, the National Institutes of Health (NIH) has funded a variety of research projects on acupuncture, including studies on the mechanisms by which acupuncture may produce its effects, as well as clinical trials and other studies. There is also a considerable body of international literature on the risks and benefits of acupuncture, and the World Health Organization lists a variety of medical conditions that may benefit from the use of acupuncture or moxibustion. Such applications include prevention and treatment of nausea and vomiting; treatment of pain and addictions to alcohol, tobacco, and other drugs; treatment of pulmonary problems such as asthma and bronchitis; and rehabilitation from neurological damage such as that caused by stroke.

To address important issues regarding acupuncture, the NIH Office of Alternative Medicine and the NIH Office of Medical Applications of Research organized a 2½-day conference to evaluate the scientific and medical data on the uses, risks, and benefits of acupuncture procedures for a variety of conditions. Cosponsors of the conference were the NIH's National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Dental Research, the National Institute on Drug Abuse, and the Office of Research on Women's Health of the NIH, all in Bethesda, Md. The conference brought together national and international ex-

perts in the fields of acupuncture, pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, family practice, internal medicine, health policy, epidemiology, statistics, physiology, and biophysics, as well as representatives from the public.

After 1½ days of available presentations and audience discussion, an independent, nonfederal consensus panel weighed the scientific evidence and wrote a draft statement that was presented to the audience on the third day. The consensus statement addressed the following key questions:

1. What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?
2. What is the place of acupuncture in the treatment of various conditions for which sufficient data are available, in comparison or in combination with other interventions (including no intervention)?
3. What is known about the biological effects of acupuncture that helps us understand how it works?
4. What issues need to be addressed so that acupuncture can be appropriately incorporated into today's health care system?
5. What are the directions for future research?

1. WHAT IS THE EFFICACY OF ACUPUNCTURE, COMPARED WITH PLACEBO OR SHAM ACUPUNCTURE, IN THE CONDITIONS FOR WHICH SUFFICIENT DATA ARE AVAILABLE TO EVALUATE?

Acupuncture is a complex intervention that may vary for different patients with similar chief complaints. The number and length of treatments and the specific points used may vary among individuals and during treatment. Given this reality, it is perhaps encouraging that there exist a number of studies of sufficient quality to assess the efficacy of acupuncture for certain conditions.

According to contemporary research standards, there is a paucity of high-quality research assessing efficacy of acupuncture compared with placebo or sham acupuncture. The vast majority of studies on acupuncture in the biomedical literature consist of case reports, case series, or intervention studies with designs inadequate to assess efficacy.

This discussion of efficacy refers to needle acupuncture (manual or electroacupuncture) because the published research is primarily on needle acupuncture and often does not encompass the full breadth of acupuncture techniques and practices. The controlled trials usu-

ally have involved only adults and did not involve long-term (ie, years) acupuncture treatment.

Efficacy of a treatment assesses the differential effect of a treatment when compared with placebo or another treatment modality using a double-blind controlled trial and a rigidly defined protocol. Articles should describe enrollment procedures, eligibility criteria, description of the clinical characteristics of the subjects, methods for diagnosis, and a description of the protocol (ie, randomization method, specific definition of treatment, and control conditions, including length of treatment and number of acupuncture sessions). Optimal trials should also use standardized outcomes and appropriate statistical analyses. This assessment of efficacy focuses on high-quality trials comparing acupuncture with sham acupuncture or placebo.

Response Rate

As with other types of interventions, some individuals are poor responders to specific acupuncture protocols. Both animal and human laboratory and clinical experience suggest that the majority of subjects respond to acupuncture, with a minority not responding. Some of the clinical research outcomes, however, suggest that a larger percentage may not respond. The reason for this paradox is unclear and may reflect the current state of the research.

Efficacy for Specific Disorders

There is clear evidence that needle acupuncture is efficacious for adult postoperative and chemotherapy nausea and vomiting and probably for the nausea of pregnancy.

Much of the research focuses on various pain problems. There is evidence of efficacy for postoperative dental pain. There are reasonable studies (although sometimes only single studies) showing relief of pain with acupuncture on diverse pain conditions such as menstrual cramps, tennis elbow, and fibromyalgia. This suggests that acupuncture may have a more general effect on pain. However, there are also studies that do not find efficacy for acupuncture in pain.

There is evidence that acupuncture does not demonstrate efficacy for cessation of smoking and may not be efficacious for some other conditions.

Although many other conditions have received some attention in the literature and, in fact, the research suggests some potential areas for the use of acupuncture, the quality or quantity of the research evidence is not sufficient to provide firm evidence of efficacy at this time.

Sham Acupuncture

A commonly used control group is sham acupuncture, using techniques that are not intended to stimulate known acupuncture points. However, there is disagreement on correct needle placement. Also, particularly in the studies on pain, sham acupuncture often seems to have either intermediate effects between the placebo and “real” acupuncture points or effects similar to those of the “real” acupuncture points. Placement of a needle in any position elicits a biological response that complicates the interpretation of studies involving sham acupuncture. Thus, there is substantial controversy over the use of sham acupuncture in control groups. This may be less of a problem in studies not involving pain.

2. WHAT IS THE PLACE OF ACUPUNCTURE IN THE TREATMENT OF VARIOUS CONDITIONS FOR WHICH SUFFICIENT DATA ARE AVAILABLE, IN COMPARISON OR IN COMBINATION WITH OTHER INTERVENTIONS (INCLUDING NO INTERVENTION)?

Assessing the usefulness of a medical intervention in practice differs from assessing formal efficacy. In conventional practice, clinicians make decisions based on the characteristics of the patient, clinical experience, potential for harm, and information from colleagues and the medical literature. In addition, when more than 1 treatment is possible, the clinician may make the choice by taking into account the patient's preferences. Although it is often thought that there is substantial research evidence to support conventional medical practices, this is frequently not the case. This does not mean that these treatments are ineffective. The data in support of acupuncture are as strong as those for many accepted Western medical therapies.

One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted medical procedures used for the same conditions. As an example, musculoskeletal conditions, such as fibromyalgia, myofascial pain, and epicondylitis (tennis elbow) are conditions for which acupuncture may be beneficial. These painful conditions are often treated with, among other things, anti-inflammatory medications (aspirin, ibuprofen) or with steroid injections. Both medical interventions have a potential for deleterious side effects but are still widely used and are considered acceptable treatments. The evidence supporting these therapies is no better than that for acupuncture.

In addition, ample clinical experience, supported by some research data, suggests that acupuncture may be a reasonable option for a number of clinical conditions. Examples are postoperative pain, myofascial pain, and low back pain. Examples of disorders for which the research evidence is less convincing but for which there are some positive clinical trials include addiction, stroke rehabilitation, carpal tunnel syndrome, osteoarthritis, and headache. Acupuncture treatment for many conditions such as asthma or addiction should be part of a comprehensive management program.

Many other conditions have been treated by acupuncture; the World Health Organization, for example, has listed more than 40 conditions for which the technique may be indicated.

3. WHAT IS KNOWN ABOUT THE BIOLOGICAL EFFECTS OF ACUPUNCTURE THAT HELPS US UNDERSTAND HOW IT WORKS?

Many studies in animals and humans have demonstrated that acupuncture can cause multiple biological responses. These responses can occur locally, ie, at or close to the site of application, or at a distance, mediated mainly by sensory neurons to many structures within the central nervous system. This can lead to activation of pathways affecting various physiological systems in the brain as well as in the periphery. A focus of attention has been the role of endogenous opioids in acupuncture analgesia. Considerable evidence supports the claim that opioid peptides are released during acupuncture and that the analgesic effects of acupuncture are at least partially explained by their actions. That opioid antagonists such as naloxone hydrochloride reverse the analgesic effects of acupuncture further strengthens this hypothesis. Stimulation by acupuncture may also activate the hypothalamus and the pituitary gland, resulting in a broad spectrum of systemic effects. Alteration in the secretion of neurotransmitters and neurohormones and changes in the regulation of blood flow, both centrally and peripherally, have been documented. There is also evidence of alterations in immune functions produced by acupuncture. Which of these and other physiological changes mediate clinical effects is at present unclear.

Despite considerable efforts to understand the anatomy and physiology of the “acupuncture points,” the definition and characterization of these points remain controversial. Even more elusive is the scientific basis of some of the key traditional Eastern medical concepts, such as the circulation of energy flow, or Qi, the meridian system, and other related theo-

ries, which are difficult to reconcile with contemporary biomedical information but continue to play an important role in the evaluation of patients and the formulation of treatment in acupuncture.

Some of the biological effects of acupuncture have also been observed when “sham” acupuncture points are stimulated, highlighting the importance of defining appropriate control groups in assessing biological changes purported to be due to acupuncture. Such findings raise questions regarding the specificity of these biological changes. In addition, similar biological alterations, including the release of endogenous opioids and changes in blood pressure, have been observed after painful stimuli, vigorous exercise, and/or relaxation training; it is at present unclear to what extent acupuncture shares similar biological mechanisms.

For any therapeutic intervention, including acupuncture, the so-called non-specific effects account for a substantial proportion of its effectiveness and thus should not be casually discounted. Many factors may profoundly determine therapeutic outcome, including the quality of the relationship between the clinician and the patient, the degree of trust, the expectations of the patient, and the compatibility of the backgrounds and belief systems of the clinician and the patient, as well as a myriad of factors that together define the therapeutic milieu.

Although much remains unknown regarding the mechanism(s) that might mediate the therapeutic effect of acupuncture, the panel is encouraged that a number of significant acupuncture-related biological changes can be identified and carefully delineated. Further research in this direction not only is important for elucidating the phenomena associated with acupuncture but also has the potential for exploring new pathways in human physiology not previously examined in a systematic manner.

4. WHAT ISSUES NEED TO BE ADDRESSED SO THAT ACUPUNCTURE CAN BE APPROPRIATELY INCORPORATED INTO TODAY'S HEALTH CARE SYSTEM?

The integration of acupuncture into today's health care system will be facilitated by a better understanding among providers of the language and practices of both the Eastern and Western health care communities. Acupuncture focuses on a holistic, energy-based approach to the patient rather than a disease-oriented diagnostic and treatment model.

An important factor for the integration of acupuncture into the health care system is the training and credentialing

of acupuncture practitioners by the appropriate state agencies. This is necessary to allow the public and other health practitioners to identify qualified acupuncture practitioners. The acupuncture educational community has made substantial progress in this area and is encouraged to continue along this path. Educational standards have been established for training of physician and non-physician acupuncturists. Many acupuncture educational programs are accredited by an agency that is recognized by the US Department of Education. A national credentialing agency exists for nonphysician practitioners and provides examinations for entry-level competency in the field. A nationally recognized examination for physician acupuncturists has been established.

A majority of states provide licensure or registration for acupuncture practitioners. Because some acupuncture practitioners have limited English proficiency, credentialing and licensing examinations should be provided in languages other than English when necessary. There is variation in the titles that are conferred through these processes, and the requirements to obtain licensure vary widely. The scope of practice allowed under these state requirements varies as well. Although states have the individual prerogative to set standards for licensing professions, consistency in these areas will provide greater confidence in the qualifications of acupuncture practitioners. For example, not all states recognize the same credentialing examination, thus making reciprocity difficult.

The occurrence of adverse events in the practice of acupuncture has been documented to be extremely low. However, these events have occurred on rare occasions, some of which are life threatening (eg, pneumothorax). Therefore, appropriate safeguards for the protection of patients and consumers need to be in place. Patients should be informed fully of their treatment options, expected prognoses, and relative risks, as well as informed of safety practices to minimize these risks before their receipt of acupuncture. This information must be provided in a manner that is linguistically and culturally appropriate to the patient. Use of acupuncture needles should always follow Food Drug Administration regulations, including use of sterile, single-use needles. These practices are already being performed by many acupuncture practitioners; however, these practices should be uniform. Recourse for patient grievance and professional censure are provided through credentialing and licensing procedures and are available through appropriate state jurisdictions.

It has been reported that more than 1 million Americans currently receive acupuncture each year. Continued access to qualified acupuncture professionals for appropriate conditions should be ensured. Because many individuals seek health care treatment from both acupuncturists and physicians, communication between these providers should be strengthened and improved. If a patient is under the care of an acupuncturist and a physician, both practitioners should be informed. Care should be taken to ensure that important medical problems are not overlooked. Patients and practitioners have a responsibility to facilitate this communication.

There is evidence that some patients have limited access to acupuncture services because of inability to pay. Insurance companies can decrease or remove financial barriers to access depending on their willingness to provide coverage for appropriate acupuncture services. An increasing number of insurance companies are either considering this possibility or already providing coverage for acupuncture services. Expansion of appropriate acupuncture coverage for populations served by state health insurance plans and by Medicare and Medicaid would also help remove financial barriers to access.

As acupuncture is incorporated into today's health care system and further research clarifies the role of acupuncture for various health conditions, it is expected that dissemination of this information to health care practitioners, insurance providers, policymakers, and the general public will lead to more informed decisions about the appropriate use of acupuncture.

5. WHAT ARE THE DIRECTIONS FOR FUTURE RESEARCH?

The incorporation of any new clinical intervention into accepted practice faces more scrutiny now than ever before. The demands of evidence-based medicine, outcomes research, managed care systems of health care delivery, and a plethora of therapeutic choices make the acceptance of new treatments an arduous process. The difficulties are accentuated when the treatment is based on theories unfamiliar to Western medicine and its practitioners. It is important, therefore, that the evaluation of acupuncture for the treatment of specific conditions be carried out carefully, using designs that can withstand rigorous scrutiny. To further the evaluation of the role of acupuncture in the management of various conditions, the following general areas for future research are suggested.

What Are the Demographics and Patterns of Use of Acupuncture in the United States and Other Countries?

Currently limited information on basic questions exists about who uses acupuncture, for what indications is acupuncture most commonly sought, what variations in experience and techniques used exist among acupuncture practitioners, and what differences in these patterns by geography or ethnic group exist. Descriptive epidemiologic studies can provide insight into these and other questions. This information can in turn be used to guide future research and to identify areas of greatest public health concern.

Can the Efficacy of Acupuncture for Various Conditions for Which It Is Used or for Which It Shows Promise Be Demonstrated?

Relatively few high-quality randomized controlled trials have been published on the effects of acupuncture. Such studies should be designed in a rigorous manner to allow evaluation of the effectiveness of acupuncture. Such studies should include experienced acupuncture practitioners to design and deliver appropriate interventions. Emphasis should be placed on studies that examine acupuncture as used in clinical practice and that respect the theoretical basis for acupuncture therapy.

Although randomized controlled trials provide a strong basis for inferring causality, other study designs, such as those used in clinical epidemiology or outcomes research, can also provide important insights regarding the usefulness of acupuncture for various conditions. There have been few such studies in the acupuncture literature.

Do Different Theoretical Bases for Acupuncture Result in Different Treatment Outcomes?

Competing theoretical orientations (eg, Chinese, Japanese, French) currently exist that might predict divergent therapeutic approaches (ie, the use of different acupuncture points). Research projects should be designed to assess the relative merit of these divergent approaches and to compare these systems with treatment programs using fixed acupuncture points.

To fully assess the efficacy of acupuncture, studies should be designed to examine not only fixed acupuncture points but also the Eastern medical systems that provide the foundation for acupuncture therapy, including the choice of points. In addition to assessing the effect of acupuncture in context, this would

also provide the opportunity to determine if Eastern medical theories predict more effective acupuncture points.

What Areas of Public Policy Research Can Provide Guidance for the Integration of Acupuncture Into Today's Health Care System?

The incorporation of acupuncture as a treatment raises numerous questions of public policy. These include issues of access, cost-effectiveness, reimbursement by state, federal, and private payers, and training, licensure, and accreditation. These public policy issues must be founded on high-quality epidemiologic and demographic data and effective research.

Can Further Insight Into the Biologic Basis for Acupuncture Be Gained?

Mechanisms that provide a Western scientific explanation for some of the effects of acupuncture are beginning to emerge. This is encouraging and may provide novel insights into neural, endocrine, and other physiological processes. Research should be supported to provide a better understanding of the mechanisms involved, and such research may lead to improvements in treatment.

Does an Organized Energetic System That Has Clinical Applications Exist in the Human Body?

Although biochemical and physiologic studies have provided insight into some of the biologic effects of acupuncture, acupuncture practice is based on a very different model of energy balance. This theory might or might not provide new insights to medical research, but it deserves further attention because of its potential for elucidating the basis for acupuncture.

CONCLUSIONS

Acupuncture as a therapeutic intervention is widely practiced in the United States. There have been many studies of its potential usefulness. However, many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as creating placebo and sham acupuncture groups.

However, promising results have emerged for the use of acupuncture in treating the nausea and vomiting related to chemotherapy, adult postoperative surgery pain, and postoperative dental pain. There are other situations such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low

back pain, carpal tunnel syndrome, and asthma for which acupuncture may be useful as an adjunct treatment or an acceptable alternative or may be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful.

Findings from basic research have begun to elucidate the mechanisms of the action of acupuncture, including the release of opioids and other peptides in the central and peripheral nervous system, and changes in neuroendocrine function. Although much needs to be accomplished, the emergence of plausible mechanisms for the therapeutic effects of acupuncture is encouraging.

The introduction of acupuncture into the choice of treatment modalities readily available to the public is in its early stages. Issues of training, licensure, and reimbursement remain to be clarified. There is sufficient evidence, however, of its potential value to conventional medicine to encourage further studies. There is sufficient evidence of acupuncture's value to expand its use into conventional medicine and to encourage further studies of its physiology and clinical value.

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Speakers: Abass Alavi, MD, "The Role of Physiologic Imaging in the Investigation of the Effects of Pain and Acupuncture on Regional Cerebral Function"; Brian M. Berman, MD, "Overview of Clinical Trials on Acupuncture for Pain"; Stephen Birch, LicAc, PhD, "Overview of the Efficacy of Acupuncture in the Treatment of Headache and Face and Neck Pain"; Hannah V. Bradford, MAc, "Late-Breaking Data and Other News From the Clinical Research Symposium (CRS) on Acupuncture at NIH"; Xiaoding Cao, MD, PhD, "Protective Effect of Acupuncture on Immunosuppression"; Daniel C. Cherkin, PhD, "Efficacy of Acupuncture in Treat-

ing Low Back Pain: A Systematic Review of the Literature"; Patricia Culliton, MA, LAc, "Current Utilization of Acupuncture by United States Patients"; David L. Diehl, MD, "Gastrointestinal Indications"; Kevin V. Ergil, LAc, "Acupuncture Licensure, Training, and Certification in the United States"; Richard Hammerschlag, PhD, "Methodological and Ethical Issues in Acupuncture Research"; Ji-Sheng Han, MD, "Acupuncture Activates Endogenous Systems of Analgesia"; Joseph M. Helms, MD, "Acupuncture Around the World in Modern Medical Practice"; Kim A. Jobst, DM, MRCP, "Respiratory Indications"; Gary Kaplan, DO, "Efficacy of Acupuncture in the Treatment of Osteoarthritis and Musculoskeletal Pain"; Ted J. Kaptchuk, OMD, "Acupuncture: History, Context, and Long-term Perspectives"; Janet Konefal, PhD, EdD, MPH, CA, "Acupuncture and Addictions"; Lixing Lao, PhD, LAc, "Dental and Postoperative Pain"; C. David Lytle, PhD, "Safety and Regulation of Acupuncture Needles and Other Devices"; Margaret A. Naeser, PhD, LicAc, Dipl Ac, "Neurological Rehabilitation: Acupuncture and Laser Acupuncture to Treat Paralysis in Stroke and Other Paralytic Conditions and Pain in Carpal Tunnel Syndrome"; Lorenz K.Y. Ng, MD, "What Is Acupuncture?"; Andrew Parfitt, PhD, "Nausea and Vomiting"; Bruce Pomeranz, MD, PhD, "Summary of Acupuncture and Pain"; Judith C. Shlay, MD, "Neuropathic Pain"; Alan I. Trachtenberg, MD, MPH, "American Acupuncture: Primary Care, Public Health, and Policy"; Jin Yu, MD, "Induction of Ovulation With Acupuncture."

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BIBLIOGRAPHY

The consensus conference speakers identified the following key references in developing their presentations. A more complete bibliography prepared by the National Library of Medicine at NIH, along with the references below, was provided to the consensus panel for its consideration. The full NLM bibliography is available at: <http://www.nlm.nih.gov/pubs/cbm/acupuncture.html>.

Addictions

Bullock ML, Culliton PD, Olander RT. Controlled

trial of acupuncture for severe recidivist alcoholism. *Lancet*. 1989;1:1435-1439.

Bullock ML, Umen AJ, Culliton PD, Olander RT. Acupuncture treatment of alcoholic recidivism: a pilot study. *Alcohol Clin Exp Res*. 1987;11:292-295.

Clavel-Chapelon F, Paoletti C, Banhamou S. Smoking cessation rates 4 years after treatment by nicotine gum and acupuncture. *Prev Med*. 1997;26:25-28.

He D, Berg JE, Hostmark AT. Effects of acupuncture on smoking cessation or reduction for motivated smokers. *Prev Med*. 1997;26:208-214.

Konefal J, Duncan R, Clemence C. Comparison of three levels of auricular acupuncture in an outpatient substance abuse treatment program. *Altern Med J*. 1995;2:8-17.

Margolin A, Avants SK, Chang P, Kosten TR. Acupuncture for the treatment of cocaine dependence in methadone-maintained patients. *Am J Addict*. 1993;2:194-201.

White AR, Rampes H. Acupuncture in smoking cessation. In: *Cochrane Database of Systematic Reviews* [database on CD-ROM]. Oxford, England: Update Software; 1997. Updated November 24, 1996.9 The Cochrane Library; No. 2.

Gastroenterology

Cahn AM, Carayon P, Hill C, Flamant R. Acupuncture in gastroscopy. *Lancet*. 1978;1:182-183.

Chang FY, Chey WY, Ouyang A. Effect of transcutaneous nerve stimulation on esophageal function in normal subjects—evidence for a somatovisceral reflex. *Am J Chin Med*. 1996;24:185-192.

Jin HO, Zhou L, Lee KY, Chang TM, Chey WY. Inhibition of acid secretion by electrical acupuncture is mediated via β -endorphin and somatostatin. *Am J Physiol*. 1996;271:G524-G530.

Li Y, Tougas G, Chiverton SG, Hunt RH. The effect of acupuncture on gastrointestinal function and disorders. *Am J Gastroenterol*. 1992;87:1372-1381.

General Pain

Chen XH, Han JS. All three types of opioid receptors in the spinal cord are important for 2/15 Hz electroacupuncture analgesia. *Eur J Pharmacol*. 1992;211:203-210.

Patel M, Gutzwiller F, et al. A meta-analysis of acupuncture for chronic pain. *Int J Epidemiol*. 1989;18:900-906.

Portnoy RK. Drug therapy for neuropathic pain. *Drug Ther*. 1993;23:41-53.

Shlay JC, Flaws B, Shaloner K, et al. *The Efficacy of a Standardized Acupuncture Regimen Compared to Placebo as a Treatment of Pain Caused by Peripheral Neuropathy in HIV-Infected Patients*. *JAMA*. In press.

Tang NM, Dong HW, Wang XM, Tsui ZC, Han JS. Cholecystokinin antisense RNA increases the analgesic effect induced by electroacupuncture or low dose morphine: conversion of low responder rats into high responders. *Pain*. 1997;71:71-80.

Ter Riet G, Kleijnen J, Knipschild P. Acupuncture and chronic pain: a criteria based meta-analysis. *J Clin Epidemiol*. 1990;43:1191-1199.

Zhu CB, Li XY, Zhu YH, Xu SF. Binding sites of mu receptor increased when acupuncture analgesia was enhanced by droperidol: an autoradiographic study. *Chung Kuo Yao Li Hsueh Pao*. 1995;16:311-314.

History and Reviews

Helms JM. *Acupuncture Energetics: A Clinical Approach for Physicians*. Berkeley, Calif: Medical Acupuncture Publishers; 1996.

Hoizey D, Hoizey MJ. *A History of Chinese Medicine*. Edinburgh, Scotland: Edinburgh University Press; 1988.

Kapchuk TJ. *The Web That Has No Weaver: Understanding Chinese Medicine*. New York, NY: Congdon & Weed; 1983.

Lao L. Acupuncture techniques and devices. *J Altern Complement Med*. 1996;2:23-25.

Liao SJ, Lee MHM, Ng NKY. *Principles and*

Practice of Contemporary Acupuncture. New York, NY: Marcel Dekker Inc; 1994.

Lu GD, Needham J. *Celestial Lancets: A History and Rationale of Acupuncture and Moxa*. New York, NY: Cambridge University Press; 1980.

Lytle CD. History of the Food and Drug Administration's regulation of acupuncture devices. *J Altern Complement Med*. 1996;2:253-256.

Mitchell BB. *Acupuncture and Oriental Medicine Laws*. Washington, DC: National Acupuncture Foundation; 1997.

Porkert M. *The Theoretical Foundations of Chinese Medicine*. Cambridge, Mass: Massachusetts Institute of Technology Press; 1974.

Stux G, Pomerantz B. *Basics of Acupuncture*. Berlin, Germany: Springer Verlag; 1995:1-250.

Unschuld PU. *Medicine in China: A History of Ideas*. Berkeley: University of California Press; 1985.

Immunology

Cheng XD, Wu GC, Jiang JW, Du LN, Cao XD. Dynamic observation on regulation of spleen lymphocyte proliferation from the traumatized rats in vitro of continued electroacupuncture. *Chin J Immunol*. 1997;13:68-70.

Du LN, Jiang JW, Wu GC, Cao XD. Effect of orphanin FQ on the immune function of traumatic rats. *Chin J Immunol*. In press.

Zhang Y, Du LN, Wu GC, Cao XD. Electroacupuncture (EA) induced attenuation of immunosuppression appearing after epidural or intrathecal injection of morphine in patients and rats. *Acupunct Electrother Res*. 1996;21:177-186.

Miscellaneous

Medical devices: reclassification of acupuncture needles for the practice of acupuncture. *61 Federal Register*. 1996;61(236):64616-64617.

NIH Technology Assessment Workshop on Alternative Medicine. Acupuncture. *J Altern Complement Med*. 1996;2:1-256.

Bullock ML, Pheley AM, Kiresuk TJ, Lenz SK, Culliton PD. Characteristics and complaints of patients seeking therapy at a hospital-based alternative medicine clinic. *J Altern Complement Med*. 1997;3:31-37.

Cassidy C. A survey of six acupuncture clinics: demographic and satisfaction data. In Programs and abstracts for the Proceedings of the Third Symposium of the Society for Acupuncture Research; September 16-17, 1995; Washington, DC. Pages 1-27.

Diehl DL, Kaplan G, Coulter I, Glik D, Hurwitz EL. Use of acupuncture by American physicians. *J Altern Complement Med*. 1997;3:119-126.

Musculoskeletal

Naeser MA, Hahn KK, Lieberman B. Real vs sham laser acupuncture and microamps TENS to treat carpal tunnel syndrome and worksite wrist pain: pilot study. *Lasers Surg Med Suppl*. 1996;8:7.

Nausea, Vomiting, and Postoperative Pain

Christensen PA, Noreng M, Andersen PE, Nielsen JW. Electroacupuncture and postoperative pain. *Br J Anaesth*. 1989;62:258-262.

Dundee JW, Chestnutt WN, Ghaly RG, Lynas AG. Traditional Chinese acupuncture: a potentially useful antiemetic? *BMJ*. 1986;293:583-584.

Dundee JW, Ghaly G. Local anesthesia blocks the antiemetic action of P6. *Clin Pharmacol Ther*. 1991;50:78-80.

Dundee JW, Ghaly RG, Bill KM, Chestnutt WN, Fitzpatrick KT, Lynas AG. Effect of stimulation of the P6 antiemetic point on postoperative nausea and vomiting. *Br J Anaesth*. 1989;63:612-618.

Dundee JW, Ghaly RG, Lynch GA, Fitzpatrick KT, Abram WP. Acupuncture prophylaxis of cancer chemotherapy-induced sickness. *J R Soc Med*. 1989;82:268-271.

Dundee JW, McMillan C. Positive evidence for P6 acupuncture antiemesis. *Postgrad Med J*. 1991;67:47-52.

Lao L, Bergman S, Langenberg P, Wong RH, Berman B. Efficacy of Chinese acupuncture on postoperative oral surgery pain. *Oral Surg Med Oral Pathol Oral Radiol Endod.* 1995;79:423-428.

Martelele M, Fiori AMC. Comparative study of analgesic effect of transcutaneous nerve stimulation (TNS), electroacupuncture (EA), and meperidine in the treatment of postoperative pain. *Acupunct Electrother Res.* 1985;10:183-193.

Sung YF, Kutner MH, Cerine FC, Frederickson EL. Comparison of the effects of acupuncture and codeine on postoperative dental pain. *Anesth Analg.* 1977;56:473-478.

Neurology

Asagai Y, Kanai H, Miura Y, Ohshiro T. Application of low reactive-level laser therapy (LLLT) in the functional training of cerebral palsy patients. *Laser Ther.* 1994;6:195-202.

Han JS, Chen XH, Sun SL, et al. Effect of low- and high-frequency TENS on Met-enkephalin-Arg-Phe and dynorphin A immunoreactivity in human lumbar CSF. *Pain.* 1991;47:295-298.

Han JS, Wang Q. Mobilization of specific neuropeptides by peripheral stimulation of identified frequencies. *News Physiol Sci.* 1992;7:176-180.

Johansson K, Lindgren I, Widner H, Wiklung I, Johansson BB. Can sensory stimulation improve the functional outcome in stroke patients? *Neurology.* 1993;43:2189-2192.

Naeser MA. Acupuncture in the treatment of paralysis due to central nervous system damage. *J Altern Complement Med.* 1996;2:211-248.

Naeser MA, Alexander MP, Stlassny-Eder D, Galler V, Bachman D. Acupuncture in the treatment of paralysis in chronic and acute stroke patients: improvement correlated with specific CT scan lesion sites. *Acupunct Electrother Res.* 1994;19:227-249.

Simpson DM, Wolfe DE. Neuromuscular complications of HIV infection and its treatment. *AIDS.* 1991;5:917-926.

Reproductive Medicine

Yang SP, He LF, Yu J. Changes in densities of hypothalamic μ opioid receptor during cupric acetate induced preovulatory LH surge in rabbit [in Chinese]. *Acta Physiol Sinica.* 1997;49:354-358.

Yang QY, Ping SM, Yu J. Central opioid and dopamine activities in PCOS during induction of ovulation with electro-acupuncture [in Chinese]. *J Reprod Med.* 1992;1:6-19.

Yang SP, Yu J, He LF. Release of GnRH from the MBH induced by electroacupuncture in conscious female rabbits. *Acupunct Electrother Res.* 1994;19:9-27.

Yu J, Zheng HM, Ping SM. Changes in serum FSH, LH and ovarian follicular growth during electroacupuncture for induction of ovulation. *Chin J Integrated Traditional West Med.* 1995;1:13-16.

Research Methods

Birch S, Hammerschlag R. *Acupuncture Efficacy: A Compendium of Controlled Clinical Trials.* Tarrytown, NY: National Academy of Acupuncture and Oriental Medicine; 1996.

Hammerschlag R, Morris MM. Clinical trials comparing acupuncture to biomedical standard care: a criteria-based evaluation of research design and reporting. *Complement Ther Med.* 1997;5:133-140.

Kaptchuk TJ. Intentional ignorance: a history of blind assessment and placebo controls in medicine. *Bull Hist Med.* In press.

Singh BB, Berman BM. Research issues for clinical designs. *Complement Ther Med.* 1997;5:3-7.

Vincent CA. Credibility assessment in trials of acupuncture. *Complement Med Res.* 1990;4:8-11.

Vincent CA, Lewith G. Placebo controls for acupuncture studies. *J R Soc Med.* 1995;88:199-202.

Vincent CA, Richardson PH. The evaluation of therapeutic acupuncture: concepts and methods. *Pain.* 1986;24:1-13.

Adverse Effects

Lao L. Safety issues in acupuncture. *J Altern Complement Med.* 1996;2:27-31.

Norheim AJ, Fønnebo V. Acupuncture adverse effects are more than occasional case reports: results from questionnaires among 1135 randomly selected doctors and 197 acupuncturists. *Complement Ther Med.* 1996;4:8-13.