A Technology Assessment

Assessment and Evaluation of the Efficacy of Acupuncture

Medical Background Information:

Acupuncture is defined in RCW 18.06.010 as a health care service based on a traditional Oriental system of med4ical theory utilizing Oriental diagnosis and treatment to promote health and treat organic or functional disorders by treating specific acupuncture points or meridians.

The Chinese has used acupuncture for several thousand years to cure disease and protect health. According to ancient Chinese philosophy, a balance of two forces, yin (negative) and yang (positive), exists in the universe and in the human body. Illness and pain are caused by an imbalance of these forces, which interrupts the normal flow of qui (pronounced "chee") through 12 meridian channels located in the human body. These meridians, located just under the skin, allegedly represent the organs. While it is the view of most Western researchers that the meridian system does not exist nor represent a correct interpretation of the physiology of the human body, some researchers do concede that meridians provide a good system of noting the location of acupuncture points.

When the balance between yin and yang is skewed and the flow of qui is interrupted, restoration is achieved by placing needles, either stainless steel, silver or gold, at acupoints. Rotation or other movements at different speeds manipulate the needles. Electrical stimulation through the needles may also be applied, a process called electro-acupuncture. An acupuncturist may also place a tiny piece of moxa, a flammable substance obtained from the leaves of Chinese or Japanese wormwood plants (*artemisia vulgaris*), on the skin or the outer end of the needle and set it afire; this procedure is called moxibustion.

Western researches have postulated several theories about how acupuncture "works." In general, the scientific community accepts that acupuncture produces physiological changes in the human body. However, two specific theories are more accepted than others: one relates to the production of endorphins and enkephalins, and the other is known as the gate theory.

First Theory:

Endorphins and enkephalins are opioid neurotransmitters. Like morphine, they have the ability to suppress pain. Acupuncture seems to activate the production of these endorphins and enkephalins, thus acting as painkillers. It has also been hypothesized that acupuncture may impact hormone secretion via the hypothalamus, which may also impact the immune system.

Second Theory:

Researchers have proposed that the spinal cord, and perhaps the brain, have gates through which pain impulses are allowed to pass to the brain or are blocked. Nerve impulses can either open or close these gates. Large diameter nerve fibers close the gates, while small diameter fibers open them. It has been suggested that acupuncture helps close the gate, thus preventing painful sensations from passing.

As will be discussed later, much of Western hesitation to accept these two theories stems from a lack of clinical studies on acupuncture's effectiveness. A study in 1995 concluded that only 28 out of 2,500 acupuncture studies published in English since 1960 offered meaningful information about the efficacy of acupuncture.

MEDICAL CONDITIONS FOR WHICH ACUPUNCTURE IS TYPICALLY USED

Musculoskeletal	Acute or chronic strains, sprains, spasms and/or pain. Myofacial syndromes, torticollis, low back pain, tendentious, bursitis, and arthritis
Neurological	Carpal tunnel syndrome, sciatica, rehabilitative phase of traumatic nerve injuries, and post CVA hemiplegia
Acute and Chronic Pain	Headache, low back, and pain associated with industrial injuries
Anesthesia	Pain control during major and minor surgeries

1. How has it come to the Office of the Medical Director for coverage consideration?

The Office of the Medical Director (OMD), on its own initiative, decided to review the efficacy of acupuncture. As it currently stands, WAC 296-20-03002 (2) lists acupuncture as a treatment that the department will not authorize for payment.

In 1986, OMD reviewed this exclusion. After reviewing published scientific evidence regarding the efficacy of acupuncture, the department found that the evidence to support the long-term effectiveness of acupuncture was insufficient and determined that this form of treatment was experimental. This decision has been upheld despite subsequent articles and information forwarded in 1994 to OMD by Karen Boyd, past president of the Acupuncture Association of Washington.

2. What is the regulatory status of the device?

In March of 1996, the FDA, in a somewhat historic move, reclassified acupuncture needles, after a team of lawyers and acupuncturists formally asked the FDA to re-evaluate its position in December of 1994. Formerly a Class III medical device, a category in which clinical studies are required to establish safety and effectiveness, the FDA reclassified the needles to Class II, a category which involves less stringent controls by the FDA but requires good manufacturing and labeling practices. Therefore, the FDA has determined that the current investigational use labeling requirements no longer apply to acupuncture needles intended for general use by qualified practitioners.

In their December 1994 solicitation of the FDA, the group of lawyers and acupuncturists asked the FDA to approve the needles as treatment for five conditions: pain, nausea and vomiting, substance abuse, asthma and other respiratory problems, and stroke and paralysis. In reviewing the scientific studies supporting their petition, Bruce Burlington, director of the FDA's Center for Devices and Radiological Health said, "there is some suggestion that acupuncture works for these specific claims but it does not reach the level of proof we generally require."

Burlington went on to say, "We did conclude that a substantial number of states regulate acupuncture as a healing art, and within that context ... we ask, do these needles break, do they cause infection, and do they work as a tool for the art of acupuncture?" Burlington also noted that the FDA decided that acupuncturists themselves - not the needles they use - should be the main focus of regulatory efforts. "We don't ask, 'Does gall bladder surgery work?' We ask, 'Can a knife make an incision?' So it did not require us to establish that acupuncture works, but that needles work in acupuncture."

3. Evaluation of literature:

Rather than evaluate acupuncture literature for one particular indication, such as low back pain, a more general approach was taken.

The chief objection cited in many of the articles that evaluated the use of acupuncture is that there is no proof -- beyond anecdotes and testimonials -- that acupuncture works. The critics argue that the research is methodologically flawed; it does not consist of double-blind, placebo-controlled studies, the gold-standard in medical research methodology. However, it is estimated that half of today's traditional medical practices have never been subjected to such studies either.

Typical problems in design studies of acupuncture include: use of a placebo is not possible (sham acupuncture is still considered acupuncture as needles are merely inserted at different meridians), therapies cannot be masked, outcome variables are not reliable, therapy is highly individualized, and studies on the efficacy of the procedure require many patients and long treatment periods, something many of the studies lacked.

Complicating the picture further is that in Western medicine, patients with the same diagnosis usually receive the same treatment. Acupuncturists, however, believe that every patient is unique, and details of the needle placement and manipulation must be adjusted individually. This makes comparison of treatment effects difficult.

One of the leading meta-analysis articles (Ter Reit et al, 1990) compared the overall quality of the different published controlled clinical trials using weighted methodological criteria. These criteria included such study elements as randomization, blind patient, blind evaluation, number of patients per group, and adequate presentation of data, including statistical calculations. The study found that the study designs were generally poor and that the quality of the studies which gave negative results (i.e. acupuncture not effective) were slightly higher than the quality of the studies which gave positive results. These conclusions were based on 37 studies on chronic pain - 22 studies on low back and neck pain, 3 studies on rheumatoid arthritis, 10 studies on migraine and tension headaches, and 2 studies on facial pain. The study concluded that "acupuncture should not be considered as proven, remains doubtful, or, in the alternative, definite conclusions cannot be drawn."

A 1995 meta-analysis (Resch KL, Ernst E., 1995) examined controlled clinical trials of acupuncture listed in MEDLINE from 1987 to March 1994 (n = 39) that met certain baseline criteria. These clinical trials addressed a wide variety of diseases and/or symptoms with no major focus apart from the symptom of pain. In agreement with the findings of other meta-analyses, most of the more recent clinical trials have been found to be still of indifferent quality, according to the authors. The two problems noted were in attaching too little importance in choosing an appropriate control model, and inadequacies of study design.

Another meta-analysis was conducted by Patel et al (1989) which pooled the results from 14 studies using acupuncture on chronic pain. The 14 studies were randomized controlled trials of chronic pain that measured outcome in terms of number of patients whose conditions improved. Not all of the 14 published studies used the "standard extent" of acupuncture treatment (i.e. using both the suggested number of needles and length of treatment). The meta-analysis concluded that:

- Acupuncture compared favorably to conventional treatment of chronic pain or placebo;
- Traditional acupuncture protocol (where treatment points vary from treatment to treatment) was more effective than formula acupuncture (fixed points);
- Blind studies were less favorable to acupuncture than non-blind studies;
- Trials with large numbers of patients were more favorable to acupuncture than small trials; and
- There may be publication bias, as evidenced by articles published in journals with the words “acupuncture” or “Chinese” being more favorable to acupuncture than those in traditional western medical journals.

The FDA, during the recent reclassification petition, "heavily considered" Stephen Birch's paper submitted in anticipation of completing a doctoral degree. (Stephen Birch, doctoral candidate, University of Exeter, An evaluation of the adequacy of treatment in the clinical trial evaluation of acupuncture for low back pain, neck pain and headache, 1996). Birch is a Board member of the Society for Acupuncture Research.

In his paper, Birch attempts to evaluate the adequacy of the acupuncture treatments, as opposed to the methodological quality of the studies. His conclusion is that the actual acupuncture that has been tested and used in treating low back pain, neck pain and headaches is inadequate, which "profoundly" impacts the clinical results of these tests.

In comparing the clinical acupuncture literature describing appropriate acupuncture treatment for low back, neck and head pain, and the actual acupuncture used in clinical trial studies of the same conditions, Birch found that the tested treatments were almost always significantly inadequate in terms of quantity (treatment points) and number of treatment sessions compared to what the literature specifies as necessary. "This problem is equivalent to conducting a pharmaceutical study where only a fraction of the dose of the drug is prescribed for an inadequate amount of time," Birch said. "Consequently we should not be surprised to find negative results in these studies." Birch's literature review included: 18 Chinese, Japanese and English-language sources for low back pain, 12 Chinese, Japanese and English-language sources for neck pain, and 15 Chinese, Japanese and English-language sources for headaches.

Birch concludes from his literature review that "there is a pervasive problem with the inadequacy of the tested acupuncture treatment." He goes on to conclude however, that where an "adequate" number of treatments are administered and where the practitioner is allowed to make individualized judgments about selection of treatment points and/or the number of treatments at the time of each treatment, there is a tendency towards positive results.

And finally, in a 1993 acupuncture analysis produced by Hayes, Inc, an organization that sells technology assessments, a literature summary was conducted for 15 indications for which acupuncture is used. As a generalization, Hayes found many of the same limitations that other researchers have encountered: no control group, limited and poorly designed studies, and poorly reported findings.

4. Economic Issues:

In 1993, the Food and Drug Administration reported that Americans were spending $500 million a year on an estimated 9 to 12 million patient visits for acupuncture treatments. The cost to visit an acupuncturist is as follows. Typically one will pay $45-$100 for the initial consultation and treatment session. Follow-up sessions range from $30-$70 per session. The number of follow-up sessions depends on the severity of the condition being treated.

In a literature review, only one biostatistical profile of individuals seeking acupuncture treatment at one clinic was found. In a four-year period, the clinic received approximately 3,600 new patients for acupuncture treatment. Approximately 70% of the patients went for treatment of pain symptoms, 17-18% for smoking withdrawal, and 5-8% for weight reduction. Of the patients seeking acupuncture for pain relief, 97.8% had been diagnosed and treated by a licensed physician without satisfactory results.

Acupuncture in California: a quasi-economic analysis:

In December of 1995, the Department of Industrial Relations - Division of Workers' Compensation completed a report which evaluated the participation of acupuncturists in the medical treatment of workers' compensation cases between January 1988 and December 1995. (*Evaluation of the participation of acupuncturists in the medical treatment of workers' compensation cases*, Department of Industrial Relations, Division of Workers' Compensation, State of California, December 31, 1995). It is estimated that over half of the nation's acupuncturists practice in California.

In 1988, the California legislature passed into law a provision that allowed acupuncturists to be considered as "physicians" for workers' compensation purposes until January 1, 1997. This legislation eliminated the referral requirement that was necessary for an acupuncturist to treat an occupational injury prior to 1988.

The impact of this change in the law was gauged in this report through interviews and surveys of acupuncturists and claims administrators; i.e. those who provide the service and those who pay for them. The underlying assumption of the study was that there would be friction between providers and payers if significant issues had arisen concerning the frequency or appropriateness of acupuncture treatments since employees were permitted to directly select an acupuncturist without referral.

The two most significant findings of the study are discussed below. Surprisingly lacking in the study were specific numbers from before and after the 1988 legislation reflecting the number of acupuncture treatments administered and amounts paid.

1. Treatment by Acupuncturists:

Over the seven year evaluation period, it was found that acupuncturists treated more occupational injuries than before, but it was still a very small portion of the overall workers' compensation cases.

Of the 99 claims administrators responding to the survey, 80% of them estimated that less than 1% of the bills they processed in a given month involved acupuncture. The average number of bills processed each month per claim administrator was approximately 500-1000.

Eighty-four percent (808) of the acupuncturists responding to the survey reported treating occupational injuries, and half of the respondents reported commencing the treatment of workers' compensation patients just within the past 5 years. Most of the acupuncturists responded that workers' compensation patients constitute a small part of their practice. Over half reported it constituted less than 10% of their practice and approximately 80% reported it constituted less than 20% of their practice.

The responding acupuncturists report self-referral of patients as the most common (85%) reason for a patient to see them, with referral from other licensed practitioners a close second (70%). The most common reason for seeking treatment, according to the acupuncturists, is that the patient has exhausted other forms of treatment.

2. *Disability evaluations*:

There was strong disagreement expressed over whether acupuncturists should be allowed to do disability evaluations. The law disallows them now.

Eighty percent of acupuncturists believe they should be able to perform such an evaluation arguing that it is convenient for the patient and less costly. As expected, 91% of claims administrators believe that acupuncturists should not be allowed to perform these evaluations. Specifically the claims administrators question the adequacy of the educational training of an acupuncturist to do such an evaluation.

5. Other Health Insurers' positions

As of 1993, 27 states plus the District of Columbia recognize the practice of acupuncture by non-physicians, and 22 have administrative bodies that regulate acupuncturists.

In the **State of Washington**, before being allowed to practice acupuncture, an individual must be licensed. This entails successfully completing a course of didactic training in basic sciences and acupuncture over a minimum period of two academic years. The training must include such subjects as anatomy, physiology, bacteriology, biochemistry, pathology, hygiene, and a survey of western clinical sciences. Furthermore, an acupuncturist must also successfully complete a course of clinical training in acupuncture over a minimum period of one academic year. The training must include a minimum of: (i) twenty-nine quarter credits of supervised practice, consisting of at least 400 separate patient treatments involving a minimum of 100 different patients, and (ii) one hundred hours or nine quarter credits of observation which must include case presentation and discussion.

In addition to the training requirements, there are examination requirements. Individuals must pass the National Commission for the Certification of Acupuncturists exam as well as the Practical Examination of Point Locations Skills. Additionally, individuals must enroll in the Clean Needle Technique course.

Acupuncturists are required to refer the patient out to an MD for specific acute problems. If the patient declines the referral, the acupuncture treatment must not be continued. MD's and D.O.'s can practice acupuncture with no additional training. Osteopathic physician acupuncture assistant is a unique designation that requires completion of a minimum of two academic years of undergraduate college education in the general sciences and humanities plus 700 hours of acupuncture theory, diagnosis and treatment techniques plus acupuncture clinical training of one year with a minimum of 400 separate patient treatments. There are 144 licensed acupuncturists in Washington.

California's Workers' Compensation (Dr. Linda Rudolph):

The statute in California specifically allows for the coverage of acupuncture treatment. Coverage of acupuncture was mandated from the legislature in 1984. Although an acupuncturists is not allowed to do disability evaluations, they are considered to be treating/attending physicians

(*Please see page 8, Economic Issues, for a detailed discussion of California's acupuncture program and results*).

Colorado's Workers' Compensation (Carolyn Boyd - legal and Dr. Kathryn Mueller - medical)

Acupuncture is a covered service as of September 1995. Previous to this date acupuncture was blanketly excluded, however lost court battles mandated the change in policy. The Colorado courts felt it was not the medical director's charge to determine what was reasonably necessary to cure and relieve the effects of an injury. There are approximately 115 licensed acupuncturists, and there is no specific referral requirement before a patient may see an acupuncturists.

Oregon's Workers' Compensation (Jean Zink - Medical Review Unit)

Acupuncture is allowed if prescribed by an attending physician, and so long as it is a part of an overall treatment plan. The rationale behind this decision is that historically it has always been a covered service, and in terms of efficacy, Oregon believes that the evidence available substantiates the use as a part of a physician treatment plan. There are approximately 168 licensed acupuncturists.

Medicaid:

In some states Medicaid will cover acupuncture treatment by both physicians and non-physicians alike. However, the Medicaid coverage is limited in many cases to acupuncture treatment for substance abuse. States that provide Medicaid payment for acupuncture treatment include California, Florida, Massachusetts, and New York.

In Washington, those Medicaid recipients in the fee-for-service program (approximately 100,000) are denied acupuncture service. The rationale behind this

denial, according to acting Medical Director, Dr. Eric Houghton of the Medical Assistance office, is that there is a lack of substantiated evidence supporting the efficacy of acupuncture. Because the federal government will not help pay for acupuncture treatment, allowing acupuncture would be prohibitively expensive according to Dr. Houghton. Despite the NIH consensus conference on November 3-5, 1997, the decision to deny acupuncture services remains.

For those Medicaid recipients who are in the managed care - capitated fee program (approximately 450,000), it is up to the managed care provider to decide how moneys will be spent.

(Current contact: Dr. Nancy Fisher, medical director, 360-664-9419)

Medicare:

According to Barbara Riley of HCFA, Medicare has specifically excluded acupuncture as a covered service. This is spelled out in Guideline 35-8 in the *Coverage Issue Appendix*. The rational behind this decision is that HCFA believes there is no medical evidence that substantiates the efficacy of acupuncture and therefore it is not considered medically reasonable nor a necessary service in maintaining the health of their patient population. No change in policy has occurred despite the NIH consensus conference on November 3-5, 1997

(Current contact: Fay Baier, 206-615-2347)

Blue Cross / Blue Shield Association:

Based on Blue Cross / Shield's **Technology Evaluation Center's** assessment of acupuncture in September 1996, the Association has not recommended covering acupuncture because the scientific evidence did not show improved health outcomes. Their findings were based on analysis of literature from 8/95 – 9/96.

Summary:

There is little evidence that acupuncture improves the perception of pain over placebo. The fact that only the smaller studies show positive findings, while larger ones do not, suggest weakness or bias in study design or random differences.

Because all pain treatments are subject to placebo effects, efficacy must be demonstrated in randomized placebo-controlled trials. Since pain is subjective, and self-reported, it is likely to be influenced by research protocols; careful controls are essential to adequate assessments.

Four different types of controls have been used in studies: needle vs. no needle; correct location vs. wrong location; adequate needle depth vs. inadequate depth; and stimulation vs. no stimulation. Studies were

included if the were randomized clinical trials (RCT) with some form of placebo or control included.

Needles outside the meridian: 10 RCTs included studies for stable angina (Ballegaard 1986 n=26, 1990 n=49), low back pain (Edelist 1976 n=30), osteoarthritis (Gaw 1975 n=40), (Takeda 1994 n=40), rheumatoid arthritis (Man 1974 n=20), mixed disorders (Ghia 1976 n=40), (Lee 1975 n=128), musculoskeletal complaints (Godfrey 1978 n=193), dysmenorrhea (Helms 1987 n=43), tension headache (Tavola 1992 n=30). Eight studies reported that acupuncture was no more effective than needles used elsewhere. Of the two studies reporting significant differences, Ballegaard found benefit for acupuncture on cardiac work, but not for pain or exercise. Man's study on rheumatoid arthritis reported consistent findings across various parameters. It is relevant that the two smallest studies reported positive findings, while the larger ones were all negative.

Low needle insertion: Skin pressure, pricking or shallow needle insertion was used as controls. Conditions included: tension headache (Hanse 1985 n=18), migraine (Vincent 1989 n=30), oral surgery (Lao 1995 n=19), tennis elbow (Molesberger 1994 n=48), shoulder pain (Moore 1976 n=117), (Moore and Berk 1976 n=42), osteoarthritis (Thomas 1991 n=44), low back pain (Mendelson 1983 n=77), and mixed (Junnila 1982 n=44). Molesberger found acupuncture superior to control in pain reduction. Vincent found acupuncture superior to low-insertion control for self-reported pain, but not on more objective outcomes. Junnila reported acupuncture superior to fingernail pressure in terms of self-reported pain. Blinding procedures were not addressed in these reports. Two studies where needles did not break the skin reported negative findings (Moore, Moore and Berk); this includes the largest study. Thomas found acupuncture superior to a placebo pill, low-insertion control was comparable to the normal acupuncture group. Mendelson's study was also negative. Again, the larger studies yielded negative results.

No or low stimulation: Mao (1986 n=26) varied stimulation in mixed patients, reporting that higher stimulation was associated with greater pain relief than lower levels. High stimulation was also correlated with higher serum levels of serotonin.

Comparison to TENS: Three studies compared acupuncture with TENS. In two studies, there were no differences. The Lehman study (1983 n=48) found a significant effect, but failed to reproduce these findings three years later (Lehman 1986). Seven studies compared acupuncture with sham TENS. Three found a significant difference, and four found no differences. The studies with positive findings were small. Conditions

treated in these studies included: musculoskeletal complaints, headache, low back pain, post-herpetic neuralgia, neck pain, and mixed complaints.

6. Medical profession's opinion

The American Medical Association has not formulated a position on acupuncture. In 1993, it advised members that a substantial number of patients use it but added that there is not sufficient scientific evidence to support the recognition of acupuncture as the standard of practice of medicine. However, last year the Association "grudgingly" passed a resolution suggesting that its 300,000 members become better informed regarding the practices and techniques of alternative or unconventional medicines.

The World Health Organization recognizes the use of acupuncture for 41 diseases and conditions such as bronchitis, back pain, sprains, stress, and tendentious.

In 1992, the National Institute of Health opened an Office of Alternative Medicine, which has awarded modest grants to study 26 therapies including the use of guided imagery to control asthma, hypnosis to treat back pain, and acupuncture to treat pain of various origins and alcoholism.

Acupuncture Association of Washington

Letters were sent on three separate occasions in September 1996, November 1996, and April 1997 to the current and past president of the Acupuncture Association of Washington inviting comments, opinions, and information to be sent to OMD that would be helpful in evaluating the efficacy of acupuncture. Nothing to date has been submitted.

National Professional Acupuncture Organizations

American Association of Oriental Medicine (AAOM):

Founded in 1981, the association is organized for the further development of Oriental medicine with acupuncture as a complementary field of health care in America. Of the two major membership organizations, the AAOM has the largest number of acupuncture practitioners with over 1,000 practicing members in the United States. In conjunction with the National Council of Acupuncture Schools and Colleges, the AAOM established the National Commission for the Certification of Acupuncturists with the purpose of standardizing acceptable levels of training and credentialing of acupuncturists.

American Academy of Medical Acupuncture (AAMA):

Founded in 1987 by a group of physicians who were graduates of the "Medical Acupuncture for Physicians" training programs sponsored by University Extension, UCLA School of Medicine, the AAMA is the sole physician-only professional acupuncture society. The AAMA follows WHO's World Federation of Acupuncture-Moxibustion Societies' guidelines for physician training as requisite for full membership.

Beyond the medical degree, qualifications include a minimum of 220 hours of formal training, plus two years of practice experience in acupuncture. The AAMA organizes and presents medical acupuncture symposia and courses accredited by the Accreditation Council for Continuing Medical Education.

National Commission for the Certification of Acupuncturists (NCCA):
Established in 1984 to set and maintain national standards for competence in acupuncture.

7. Comparison with established technologies

In comparing other established technologies, procedures and medicine, Owen Wilson, assistant professor of medicine at Baylor College of Medicine in Houston captured the heart of the issue. In Wilson's view, the first question is whether the real physiological changes produced by acupuncture actually turns into something that is clinically useful, "No doubt you can get some analgesia from acupuncture. But if you can get the same thing for less with aspirin, why not take aspirin?" However, many acupuncture specialists stress that it is most effective when combined with other treatments.

Alternative treatments to acupuncture include: massage and physical therapy, rest, exercise, behavioral and attitudinal training, chiropractic, surgery, medications, trigger point injections, dry needling, and transcutaneous nerve stimulators.

One comparable technology employed by physicians, and approved for reimbursement at the department, is dry needling. Considered as a variant of trigger point injections rather than of acupuncture, dry needling is a technique performed by physicians who insert a needle directly into trigger points (sometimes with medication) as opposed to the distant points that are used in acupuncture. The department allows such a procedure to be billed under the trigger point CPT codes, limiting the injections to 3 with written justification required if an additional 3 injections are to be administered.

Another comparable technology is transcutaneous nerve stimulators (TENS). This non-invasive, self-administered therapy is one physical modality for which there is some support in the literature in terms of its efficacy. TENS therapy has been effective in reducing self-reported pain and analgesic use following abdominal surgery, orthopedic surgery, thoracic surgery, mixed surgical procedures and cesarean section, according to the FDA.

Also according to the FDA, TENS therapy has improved physical mobility following thoracic and orthopedic surgery. Both TENS therapy and sham-TENS therapy significantly reduced analgesic use and subjective pain after the surgeries. No significant differences were found between the TENS and sham-TENS therapy. Despite these findings suggesting that a placebo effect underlies the reduction of perceived pain and

analgesic use, the FDA claims that beneficial effects do in fact result from use of TENS, and the department has subsequently allowed for payment of these devices.

8. Additional Considerations

Prevalence of acupuncture use:

In determining whether acupuncture has reached a level commiserate with being considered standard of care, one element that should be considered, in addition to the medical community's opinion, is that of the general populous. In 1990, the New England Journal of Medicine conducted a national survey to determine the prevalence, costs and patterns of use of unconventional therapies such as acupuncture and chiropractic. Thirty-four percent of the 1,539 respondents reported using at least one unconventional therapy in the preceding year. The highest use group was non-black persons from 25-49 years of age who had relatively more education and higher incomes.

The majority of the respondents used unconventional therapy for chronic as opposed to life threatening medical conditions. Eighty-three percent of these respondents also sought treatment for the same condition from a medical doctor. Extrapolating from this sample of 1,539 respondents, it is estimated that in 1990, Americans made an estimated 425 million visits to providers of unconventional therapy, which exceeds the number of visits to all U.S. primary care physicians (388 million visits). Expenditures associated with use of unconventional therapies in 1990 amounted to approximately $13.7 billion, 75% of which ($10.3 billion) was paid out of pocket. This figure compares to $12.8 billion spent out of pocket in 1990 for all hospitalizations in the U.S.

As for the Journal's findings in regards to acupuncture, less than 1% of the 1,539 respondents saw an acupuncturist in the prior twelve months before the survey. Of those who did, the mean number of visits per user in the past twelve months was 38. Furthermore, 91% of those who did see an acupuncturist also saw a traditional medical doctor.

As mentioned earlier in this report, it is estimated that 9-12 million patient visits are made to acupuncturists around the country, translating into $500 million being spent on treatment.

Acupuncture Education:

Beginning in the mid-1980's, an increasing number of medical schools began offering acupuncture training to their students or as a part of their continuing education programs. Schools such as Stanford, University of Arizona, UCLA, and Washington School of Medicine have, and still continue, to offer such programs.

Two major academic institutions in Europe have developed academic programs in the study of acupuncture: University of Heidelberg in Germany, and University of Exeter in Great Britain.

Acupuncture in other countries:

In 1991, it was estimated that there was approximately 9,000 practicing acupuncturists (mostly non-physicians; certified and uncertified) in the U.S. equating to 35-40 acupuncturists per million. The numbers in other countries amount to more acupuncturists per millions of people. In China, it is estimated that there are 1.5 million acupuncturists, equating to 1,500 per million of people. Japan boasts 42,000 acupuncturists or 350 per million of people.

In Europe, both France and Italy require that a certified and trained physician administer acupuncture treatment, and in France such services are covered by the French National Health Insurance. In Germany pain clinics, it is estimated that 90% of them use acupuncture in their treatment of chronic pain.

Conferences:

A consensus panel convened by the National Institute of Health (NIH) met from November 3 – 5, 1997, to address the current state of acupuncture, and draft a corresponding consensus statement.

The consensus statement addressed the following 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 with or in combination with other interventions (including no interventions)?
3. What is known about the biological effects of acupuncture that helps understand how it works?
4. What issues need to be addressed so that acupuncture may be appropriately incorporated into today's health care system?
5. What are the directions for future research?

The consensus panel concluded that "promising results have emerged showing the efficacy of acupuncture in postoperative and chemotherapy nausea and vomiting, nausea of pregnancy, and postoperative dental pain."

The 12-member panel also concluded in their consensus statement that there are a number of other pain-related conditions for which acupuncture may be effective as (1) an adjunct therapy, (2) an acceptable alternative, or (3) as part of a comprehensive treatment program, but for which there is less convincing scientific data. Typically the scientific data and conclusions are based on clinical experience, supported by some research data. These conditions include addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, low back pain, carpal tunnel syndrome and asthma.

Sampling of abstracts from conference:

Acupuncture and Pain[1]:

Many of the biological effects of acupuncture for chronic pain are well documented. Unfortunately, the clinical efficacy question is not as clear cut. The literature is confounded by sham controls that produce analgesia and by heterogeneity of designs using diverse stimulation parameters (many of which are now know not to work). Failing to make the parameters of acupuncture treatment homogeneous is like doing a meta-analysis on a drug that was given at vastly different doses.

Acupuncture and Post Operative Pain[2]:

Four randomized studies on the effects of acupuncture on post operative pain after general surgery were identified. Overall, the research shows positive trends suggesting that acupuncture is a promising method of providing relief from postoperative pain, despite many methodological design insufficiencies. In the four studies, the results indicated that the analgesic effect of acupuncture is equivalent to the analgesic effect of medication; one study concluded that acupuncture was superior to medication or TENS units in terms of lessening pain intensity and duration. However one study reported that the analgesic effect of acupuncture is no better than the effect of a placebo medication.

Acupuncture and Low Back Pain[3]:

The objective of the study was to review the literature to determine if acupuncture is more effective than a placebo, sham acupuncture or reference treatments (e.g. exercise or medication) for nonspecific low back pain with regard to pain intensity, overall improvement, functional status and return to work. Although the findings are in draft form, the following was concluded:

1. Acupuncture vs. no treatment: Three studies were identified comparing acupuncture to no treatment for chronic back pain. All 3 studies were of a low methodological quality and the conclusions were contradictory. Therefore there was no evidence that acupuncture is more effective than no treatment

2. Acupuncture vs. conventional treatment: Two studies were identified with the reviewers concluding that there is strong evidence that acupuncture is equally effective as trigger point injection or TENS.

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[1] Pomeranz, Bruce, *Summary of Acupuncture and Pain*, NIH Acupuncture Consensus Conference, November 3-5, 1997.

[2] Lao, Lixing, *Dental and Postoperative Pain*, NIH Acupuncture Consensus Conference, November 3-5, 1997.

[3] Cherkin, Daniel C., Efficacy if Acupuncture in Treating Low Back Pain: a systematic review of the literature, NIH Acupuncture Consensus Conference, November 3-5, 1997.

3. Acupuncture vs. placebo or sham acupuncture: Eight studies, all of high methodological quality, were identified of which 6 had an overall conclusion being neutral as to whether acupuncture was more effective than a placebo or sham acupuncture. The authors, however, concluded that there was strong evidence that acupuncture is equally effective as placebo or sham acupuncture in the treatment of low back pain.

9. Conclusion

As of March 1998, the Department of Labor and Industries, believes there is no substantial evidence proving the efficacy of acupuncture in the recent technology assessment performed by OMD staff and the NIH consensus conference. The Washington State Medical Association's Industrial Insurance Committee agreed with such a recommendation. OMD will continue to monitor the situation, work closely with those involved, and remain open to looking at new data as it becomes available.