

# PROFESSIONAL ISSUES

## AAPB Goes to Washington

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*Representatives of the Association for Applied Psychophysiology and Biofeedback (AAPB) met with a number of government officials April 21–22, 2005, to increase awareness of established clinical effectiveness and research potential of various biofeedback applications. The event was organized by the Federation of Behavioral, Psychological, and Cognitive Sciences. One day was devoted to a forum in which scholars and researchers from AAPB made presentations on empirical validation of biofeedback insurance reimbursement and outcome of pelvic floor, headache, attention deficit/hyperactivity disorder (ADHD), and heart rate variability applications. Peter Kaufmann and Margaret Chesney spoke from their perspectives as behavioral medicine researchers and National Institutes of Health (NIH) research administrators. The second day was devoted to congressional visits, during which AAPB representatives were well received and invited to provide further input to congressional deliberations on health care.*

### Introduction

On April 21–22, a delegation of Association for Applied Psychophysiology and Biofeedback (AAPB) members went to Washington to increase awareness and support for biofeedback. Our aims were (a) to inform Congress and administrators of federal health insurance programs (Medicare, CHAMPUS, the military, Medicaid, the Veterans Administration, etc.) and insurance regulators about the biofeedback applications that have strong empirical support for efficacy and evidence for cost-effectiveness and (b) to stir interest in supporting research initiatives for biofeedback applications that look very promising but have not yet been fully empirically supported. The event was organized by Jill Egeth of the Federation of Behavioral, Psychological, and Cognitive Sciences, of which AAPB is a member, and was sponsored by AAPB's Fund for the Future. The federation is a nonprofit science advocacy organization that represents the interests of researchers in the areas of behavioral, psychological, and cognitive sciences. Their efforts are focused on legislative advocacy, education, and the communication of information to scientists.

This was an auspicious time for such a mission. Because of the well-publicized findings of negative long-term effects of Cox-2 inhibitor drugs for arthritis, public wariness about taking medication is at an all-time high. Interest in complementary or alternative treatments is similarly strong. Also, the recent completion of AAPB-sponsored literature reviews and white papers has begun bearing fruit. These publications were written as critical and dispassionate analyses of biofeedback research results using the highest and most rigorous scientific standards; they were specifically *not* written as “promotion” pieces for the biofeedback field. This strategy paid off handsomely in Washington in terms of credibility. We were complimented as having among the highest scientific standards for any approach to health care. With the compliments came serious consideration of our ideas, our findings, and our critique of inequities in the health care system that pose barriers to patients' receiving biofeedback treatment. The ear of Washington was open to us, thanks in large part to the actions of AAPB in the past: promoting scientific rigor, transparent and high standards for biofeedback practice (through the creation of the Biofeedback Certification Institute of America [BCIA]), and explicit standards for biofeedback practice. Although this formula may have caused grumbling in some sectors of AAPB because of difficulties created for some practitioners, it created a *very* favorable impression in Washington. Indeed, we were asked to convey expressions of congratulations to AAPB and its members for taking this path.

### Who Went and What We Did

The following people went to Washington: myself, Frank Andrasik, Olafur Palsson, Robert Whitehouse, Vincent Monastra, Steven Baskin, and Francine Butler. We were joined by Margaret Chesney, deputy director of the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH), and Peter Kaufmann, leader of the Behavioral Medicine Research Group at the National Heart, Lung, and Blood Institute (NHLBI) of NIH.

Our first day comprised a series of talks on various aspects of biofeedback and a dialogue between representa-

tives of AAPB and NIH. It was a forum event held at the American Psychological Association's building near Union Station. Its format was similar to many other such forum events organized by the federation. It was attended by about 50 people, mostly representing various federal agencies including (but not limited to) NIH's Center for Scientific Review, the Association for HealthCare Research and Quality (AHRQ), the Office of Naval Research, the American Psychological Association, and the National Institute of Aging.

The first part of the program began with my introducing the field of biofeedback, presenting a brief biofeedback demonstration, and outlining our reasons for sponsoring such a meeting. I emphasized our impressions that biofeedback is often unavailable for the public, even after physician referral, because well-validated biofeedback methods may not receive third-party reimbursement. I also emphasized the orphan status of biofeedback research: it remains too conventional for NCCAM, but there are few opportunities outside NCCAM and the National Institute of Mental Health (NIMH) for support of pilot research, and there is little knowledge of or sympathy with biofeedback on study sections devoted to large-scale multicenter clinical trials.

After this, Andrasik spoke on the clinical effectiveness and cost-effectiveness of biofeedback, our standards for evidence, and standards of practice; Palsson spoke on pelvic floor applications and evidence for their effectiveness (now ranked by our literature as, essentially, the best treatment available for incontinence); and Whitehouse spoke about insurance reimbursement for biofeedback services, reviewing areas where it is strong and where it is weak, and pointing out disparities between the evidence for effectiveness and the reimbursement policies of various federal agencies and insurance companies, as well as inconsistencies among various third-party payers.

The later part of the program was devoted to talks on promising areas of biofeedback research: where controlled trials have already found evidence of effectiveness, but where a greater quantity and variety of randomly controlled trials is still needed. Andrasik spoke on headache pain, Monastra on attention deficit disorder, and I spoke on various cardiopulmonary and psychiatric applications.

This was followed by presentations by Chesney and Kaufmann. Both of these NIH attendees had listened carefully to our presentations and reacted to them in thoughtful and constructive, and sometimes pointed, ways.

Chesney indicated that NCCAM would be interested in novel applications of biofeedback, although it does not see its role as supporting biofeedback studies where a body of research data already exists. However, she left the door explicitly open for studies examining the mechanisms of other traditional healing methods where biofeedback effects might be quite relevant. She also mentioned the importance of "dose response" studies (i.e., how much training is necessary for good clinical effects?) and indicated that mind-body methods were widely used in the United States, and thus deserve empirical investigation for efficacy.

Kaufmann emphasized the importance of performing large-scale randomized-controlled trials.

He engaged us in a discussion of the double blind control problem and made a useful suggestion: using biofeedback methods targeted at the wrong system. He emphasized that outcome results must be evaluated by a blinded independent external expert for each subject, and that we not try to do too much in any one study (i.e., we should evaluate mechanism of action separately from evaluating clinical effects). It is worthwhile knowing whether a method is effective, even if we do not know why it works—although that also is an important issue that should be studied separately.

Both Chesney and Kaufmann were impressed by the degree of empirical support for biofeedback treatment of two biofeedback applications, headache and incontinence. They indicated that the proceedings of our meeting had convinced them that the time is ripe to conduct an NIH consensus conference on these topics. The results of such a conference could be a major boon to the biofeedback field.

Butler did not make a presentation but responded to questions about AAPB and the genesis and functioning of BCIA. She made the following observations:

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We had many questions and some of them not so friendly. Every question was answered with, "yes, we have done that." As you can guess, the questions were aimed at the concept that we can't make that claim because you have not.... fill in the blank... tested for this or that or run some kind of control. But to the presenters' credit, all the research presented had covered all the critical bases. What a sense of pride came over me to hear our presenters say, "yes, we did that and more." The efficacy document was referenced many times.

Peter Kaufman was particularly rigorous (as he should be) posing critical questions. He also asked how certification was instituted and when it was started. Then at the break he came up to me and said, "Fran, you have done everything right." What a compliment for AAPB.

Margaret Chesney is deputy director of NCCAM now, and is on leave from the Department of Medicine at the University of California, San Francisco. She referred to her roots in biofeedback research and the early work. Then Peter was the last speaker and he opened his talk with, "This is one of the most difficult talks I have ever had to present." He still advised cautions but was very complimentary to us.

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Kaufmann also had indicated to us that we had already addressed many of the comments and critiques that he had originally planned to make, and he was impressed by how similar our perspective on research approaches to biofeedback is to his own.

### *Congressional Visits*

Friday, April 22, was devoted to visiting several congressional offices: House of Representatives members Tim Murphy (Republican from Pennsylvania, and a psychologist as well); Grace Napolitano (Democrat from California); and Jeff Miller (Republican from Florida). We also visited the office of Senator Jim Bingaman (Democrat from New Mexico). Overall, we were received by knowledgeable staffers who took notes on our concerns and engaged us in meaningful conversations about our mutual concerns. Rep. Napolitano's health fellow specifically said she would like a biofeedback person to present information to the Mental Health Caucus. This represents a *major* opportunity to the biofeedback community. According to the federation's executive director, Barbara Wanchisen,

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You can imagine that LAs [legislative assistants] have to listen to lobbyists and constituents all day and that they almost

have to glaze over during some of those visits—I saw no evidence of that, and to get on the inside track of the Mental Health Caucus was enough to merit the costs of doing these events.... I actually think that, in general, the visits led to some amazing education for the staffers (or awareness raising), and follow-up will be received well by them.... Clearly this was all good and beyond perfunctory social norms.

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Senator Bingaman's health fellow said that the senator is very interested in low-cost solutions to health problems and, therefore, that biofeedback was of particular interest to her. She was very knowledgeable about our topic, having completed her MPH thesis on the topic of somatoform disorder. The federation intends to help us follow these meetings with further communications about our major concerns (particularly insurance reimbursement and establishment of NIH consensus conferences) to these and other congressional offices.

### *Overall Evaluation*

In general, we believe that our mission to Washington, DC, was a great success. We interested at least two important NIH officials in the idea of a consensus conference, and we sensitized them to several pregnant areas for biofeedback research. They responded with interest and support, and we expect that the results of this meeting will keep biofeedback higher in their own priority lists of worthy methodologies. We also made an initial foray to gain congressional support for biofeedback, for both financial and regulatory support. This is the beginning of a long process, but the federation has pledged its efforts to continue promoting the interests of biofeedback in Congress, to help follow up our visits to these specific offices, and to look for further opportunities. Our meeting also helped educate them about our field, so they can become more effective Washington, DC, advocates for us.

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# Abstracts of Forum Addresses

## How Can Biofeedback Improve U.S. Health Care?

Frank Andrasik, PhD, University of West Florida

A recent survey (Barnes, Powell-Griner, McFann, & Nahin, 2004) revealed that a sizable number of adults had used some form of mind-body/complementary and alternative medicine treatment within the year studied (2002). Among the explanations for this rapidly growing interest in alternative treatments are dissatisfaction with conventional (Western) medicine and a desire of patients to be more actively involved with medical decision-making and their subsequent care. A number of procedures that are typically combined with biofeedback were rated highly (such as deep breathing exercises and meditation), but biofeedback was not specifically listed among the top alternative choices. This is surprising because biofeedback has an extensive base of empirical support, certainly equal to that for the more highly rated alternatives (Andrasik & Lords, 2004; Schwartz & Andrasik, 2004). The presentation by Robert Whitehouse reviews the reasons for this puzzling state of affairs. In this era of evidence-based medicine, it is important to review what the literature has in fact shown about the clinical utility and cost-effectiveness of biofeedback. In short, the evidence is substantial. Biofeedback has been extensively reviewed from two vantage points: qualitative (examination by expert review panels, comprised of members both within and outside the profession) and quantitative (via the statistical method of meta-analysis, a way of comparing findings from diverse studies in a single analysis). A review recently completed by the Association for Applied Psychophysiology and Biofeedback (AAPB; Yucha & Gilbert, 2004) determined that six disorders met the two highest standards of efficacy: anxiety, attention deficit disorder, headaches, hypertension, temporomandibular disorders, and urinary incontinence in women. Biofeedback was judged as being probably effective for numerous other disorders, with many other disorders showing promise. AAPB, in conjunction with the International Society for Neuronal Regulation, has commissioned more in-depth follow-up efficacy reviews (Moss, LaVaque, & Hammond, 2004) for all appropriate disorders, and the first of these "White Paper Reviews" has now been published in a peer-reviewed journal (Palsson, Heymen, & Whitehead, 2004), as has a second (Monastra et al., 2005).

In order to be judged efficacious, large-scale clinical trials are needed, but funding for these biofeedback trials has been quite limited, which helps to explain why more disorders have not been placed into the higher evidence categories. Further, biofeedback clinical trials are often evaluated by conventional criteria, such as the rating system devised by Jadad et al. (1996), which requires double-blinding of conditions for the highest rating of empirical validation. This is inappropriate for biofeedback, where the therapist cannot be blinded to the treatment condition. Other considerations are important, too, such as the need for effectiveness trials for this type of treatment. Review panels look for studies yielding negative findings (nonsupport) as well as those reporting negative side effects. No major side effects have surfaced in the extant biofeedback clinical trials.

Clinical trials that have incorporated cost-effectiveness analyses provide further evidence of the value of biofeedback (these are summarized in Shellenberger, Amar, Schneider, & Turner, 1994). Preliminary findings from these studies have shown evidence for a number of favorable returns: reductions in medication, physician visits, medical costs, claims filed, costs of insurers/employees, hospital stays, rehospitalization, mortality, and morbidity and increases in quality of life. A recently completed investigation (Ryan & Gevirtz, 2004) examined the effectiveness and cost feasibility of offering biofeedback in the treatment of "functional" disorders presenting in a primary care setting. These types of patients have become a considerable liability in health care, as these patients tend to overutilize treatment and drain resources. The preliminary findings are encouraging, both with respect to patient improvement and cost savings.

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## **Biofeedback Issues: Access, Insurance, Cost, and Legislation**

*Bob Whitehouse, EdD, Colorado Center for Behavioral Health*

### ***I. BIOFEEDBACK—What Is It?***

Biofeedback is the use of biomedical instruments that monitor physiological responses that can be controlled to reduce symptoms of many medical and psychological disorders and/or optimize function. A therapist guides the process of awareness and then skill development. It is not just relaxation training, it does nothing to you, and it is not bio-rhythms. It is usually complementary to medical and psychological treatment. It is also used by astronauts and Olympic athletes to optimize function. It is also called applied psychophysiology and psychophysiological therapy.

### ***II. New Model of Self-Care***

Biofeedback has been here almost 40 years. It gathers objective measures of the signs and symptoms of stress, distress, disease, and injury. As a form of self-regulation, it helps individuals in prevention and treatment of these as well as marking improvement and outcome. It facilitates lifestyle changes for improved health and well-being.

### ***III. Complementary/Alternative Medicine (CAM) or Traditional***

Biofeedback has been in the Current Procedural Terminology (CPT) code books and reimbursed by some

insurances for many years, yet it also fits into the second of five CAM categories—mind-body interventions. The number of hospitals that have CAM programs has more than doubled since 1998.

### ***IV. Clinical Efficacy***

Biofeedback is used for over 40 medical and psychological disorders, varying in efficacy from treatment of choice to experimental, and recently rated on four levels, from “not empirically supported” to “efficacious.” Double-blind studies are not appropriate for biofeedback.

### ***V. Cost-Effectiveness***

Outcome studies have shown biofeedback treatment to be cost-effective in these six areas: (a) reduction in medication and/or physician usage, (b) decrease in medical care costs to patients, (c) decrease in number of claims and/or costs to insurers and employees, (d) reduction in hospital stays and rehospitalization, (e) reduction of mortality and morbidity, and (f) enhanced quality of life.

### ***VI. Access Issues***

Access to biofeedback is difficult because of inconsistent policies between government programs and major medical insurance companies, whereas workers' compensation and auto policies usually cover it. Many programs only allow physicians or psychologists and some licensed clinical social workers as the providers.

### ***VII. Insurance Coverage and Gaps***

CHAMPUS/Tricare covers biofeedback for about 28 diagnoses. Medicare covers 14 diagnoses (mostly incontinence), but not pain or psychological disorders. Aetna covers 10 medical conditions only. Medicaid does not cover biofeedback. The Blues now typically only cover incontinence (per Medicare) and deny others, citing biofeedback effects as nonspecific (i.e., not proven to be due to the instruments, and not proven to be more effective than other counseling/relaxation methods, and therefore considered experimental or investigational and not medically necessary). About 50% of major medical insurance companies reimburse for biofeedback for some diagnoses and by some providers licensed in medicine or mental health.

### ***VIII. Certifications and Requirements***

There is currently no licensure for biofeedback. There is voluntary certification. The most recognized is by the Biofeedback Certification Institute of America ([www.bcia.org](http://www.bcia.org)), which has three certifications: General

Biofeedback, EEG Biofeedback or Neurofeedback, and Pelvic Muscle Dysfunction Biofeedback. In addition to the prerequisite education in one of the above fields, there are biofeedback requirements in didactic education, personal and mentored practical training and case presentations, human anatomy and physiology, and a written examination covering the relevant Blueprint Knowledge areas.

## **EEG Biofeedback Treatments for ADHD: Rationale and Empirical Foundation**

Vincent J. Monastra, PhD, FPI Attention Disorders Clinic

Historically, pharmacological treatments for attention deficit/hyperactivity disorder (ADHD) have been considered to be the only type of intervention effective for reducing the core symptoms of this condition. These stimulatory medications appear to promote improved attention and behavioral control by increasing the availability of catecholamines (e.g., dopamine, norepinephrine) at the synaptic level, thereby increasing cortical activation in targeted brain regions (e.g., frontal lobes, rolandic cortex). Treatment response rates for stimulant therapy vary in the published research, with approximately 75% of patients responding positively to stimulant therapy.

Paralleling the emergence of stimulatory medications during the past three decades is a type of behavioral therapy called electroencephalogram (EEG) biofeedback. Like stimulant medication, this intervention seeks to treat symptoms of inattention, impulsivity, and hyperactivity by increasing cortical underarousal over frontal and central midline regions of the brain. During EEG biofeedback, patients are reinforced (via video and auditory stimuli) while producing half-second “bursts” of high-frequency brain waves (called beta or sensorimotor rhythm [SMR]) while simultaneously reducing the amplitude of slow frequency brain waves, thereby increasing levels of cortical arousal. The results of a series of case and controlled group studies examining the effects of EEG biofeedback indicate that children, teens, and adults diagnosed with ADHD are able to improve attention behavioral control, increase scores on tests of intelligence and academic achievement, demonstrate increased cortical activation on quantitative encephalographic (QEEG) examination, and exhibit increased activation of the cingulate gyrus, the caudate nucleus, and the lateral prefrontal cortex on functional magnetic resonance imaging (fMRI) following 20–50 minute sessions of this type of treatment. Similar to studies of medication effects,

approximately 75% of patients treated with EEG biofeedback have responded positively in controlled group studies. A current assessment of efficacy of EEG biofeedback rates it as “probably efficacious” for the treatment of ADHD, applying standards published by the AAPB and by the International Society of Neuronal Regulation (Monastra et al., in press). Hirshberg, Chiu, and Frazier (2005), using the American Academy of Child and Adolescent Psychiatry guidelines for recommending evidence-based treatments, considered EEG biofeedback to meet clinical guidelines for use of this treatment, indicating that a psychiatrist should anticipate positive responses in approximately 75% of patients. No other psychological or behavioral therapy meets this level of efficacy in treating the core symptoms of ADHD.

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## **Biofeedback for Pelvic Floor Disorders and Incontinence**

Olafur Palsson, PsyD, University of North Carolina, Chapel Hill

### *Functional Fecal Incontinence*

Functional fecal incontinence (FI) is a chronic disorder defined as recurrent uncontrolled passage of fecal material. About .7% of the overall adult population (and 2% of children) has severe FI, and 7% of adults have minor FI. Risk factors for developing FI include childbirth (pudendal nerve and sphincter damage); chronic diarrhea or chronic constipation; physical immobility; cognitive impairment; and physical injury or illness that leads to sphincter, nerve, or sensory damage. Fecal incontinence is a greatly underestimated problem because patients rarely discuss it with others because of its private and embarrassing nature. FI commonly has serious negative effects on patients’ lives, including social isolation, poor self-esteem, impairment of intimate relationships, reduction in mobility, and inability to travel freely. FI is one of the leading causes of nursing home placement of elderly

adults: 45%–47% of U.S. nursing home residents have FI vs only 3% of the community-dwelling elderly.

### *Chronic Constipation*

Chronic constipation affects about 3%–6% of the population. Women outnumber men two to three times. Risk factors include poverty, low-fiber diet, sedentary lifestyle, and race (more common in African American than white persons). There are three main types of constipation: pelvic floor dyssynergia (PFD; due to failure to relax, or paradoxical contractions of the pelvic floor muscles during defecation attempts); slow transit (due to biologically slow bowel); and constipation as a symptom of irritable bowel syndrome.

### *Biofeedback As a Treatment Option for Constipation and Fecal Incontinence*

Biofeedback is the treatment of choice for (a) PFD, one of the most common types of constipation (accounting for about one fourth to one half of adult constipation and one half of childhood cases), and (b) for FI cases that are due to neither serious anatomical defects nor the side effects of diarrhea. A recent comprehensive review of all relevant studies in the scientific literature in the past 30 years (Palsson, Heymen, & Whitehead, 2004) found that when biofeedback treatment is added to standard medical care, patients with fecal incontinence are 87% more likely, and constipation patients 39% more likely, to show improvement in their symptoms compared with patients only receiving standard medical treatment.

### *Advantages of Biofeedback for Chronic Constipation and Fecal Incontinence*

The following lists the advantages of biofeedback for chronic constipation and FI:

- Inexpensive (three to six sessions with a nurse or technician)
- Practically no adverse side effects
- Therapeutic benefit often lasts for years
- Complements standard medical care and significantly enhances clinical outcomes
- Sometimes makes surgery (an intervention causing permanent anatomical change with substantial risk of negative side effects) unnecessary
- Can reduce the serious negative psychological, social, and quality of life consequences of these disorders and help elderly people live independently in the community instead of needing nursing home care

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Palsson, O. S., Heymen, S., & Whitehead, W. E. (2004). Biofeedback treatment for functional anorectal disorders: A comprehensive efficacy review. *Applied Psychophysiology and Biofeedback*, 29(3), 153–174.

## **Heart Rate Variability Biofeedback: A New Approach to Fostering Cardiorespiratory and Emotional Control and Improving Human Performance**

*Paul Lehrer, PhD, UMDNJ—Robert Wood Johnson Medical School*

Heart rate variability (HRV) is highly correlated with health and fitness. It is negatively related to age and with most physical and mental illnesses. Depressed HRV is a strong predictor of death from all causes. Similar findings have been obtained for “baroreflex gain.” The baroreflexes are important mechanisms that help control blood pressure and emotional reactivity. They are triggered by sensors in the large blood vessels. When blood pressure changes, the baroreflexes act to restore the previous level, and thus help keep the body stable. When HRV is low or the baroreflexes are disordered, the body’s “control reflexes” do not work properly, so the body can no longer adapt normally to normal physical and mental stress. Illness or death may result.

HRV can be easily modified by biofeedback (Lehrer & Vaschillo, 2004). Also, HRV biofeedback greatly stimulates both HRV and the baroreflexes. Although great increases in these measures are easily seen within a few minutes of training in almost all people, the technique usually takes about four sessions of training to fully master. Regular practice of HRV biofeedback systematically exercises the baroreflexes and increases baroreflex gain (a measure of the strength of the baroreflexes) at rest (Lehrer et al., 2003).

HRV biofeedback also causes people to breathe at the specific rate at which respiration and heart rate vary in phase with each other, so that heart rate increases exactly when we inhale, and decreases exactly when we exhale (Vaschillo, Vaschillo, & Lehrer, 2004). This improves respiratory efficiency. More blood is circulating through the lung (from higher heart rate) exactly when the lung has the most oxygen in it (during inhalation). This allows the best absorption of oxygen from the lung. When people breathe at this rate their blood becomes maximally saturated with oxygen, and they

become more resistant to such respiratory stressors as exercise, high altitude, or high carbon dioxide concentration (as may occur in a crowded stuffy room).

We presented data showing that HRV biofeedback is clinically helpful for asthma (Lehrer et al., 2004), emphysema (Giardino, Chan, & Borson, 2004), hypertension (McCraty, Atkinson, & Tomasino, 2003), depression, and fibromyalgia. We also showed improvements in athletic performance, tolerance for altitude and exercise, and resistance to hyperventilation.

HRV biofeedback also allows a standardized and sensitive method for comparing HRV among various populations. By having people breathe at the rate that, for each individual, maximizes both respiratory efficiency and the baroreflex, we can develop a test that measures the aspects of health and adaptability in each person. We then can find out how specific diseases, stressors, etc., each affect health and the body's ability to adapt.

For convincing proof of our findings, we still need to do larger controlled clinical trials, as well as pilot trials for various populations who have not yet been studied. We believe that these methods may particularly help people whose autonomic nervous systems are not functioning properly. An example of this is persons with spinal cord injuries high in the spine who have no use of their bodies below the neck. In these persons, the brain's control of part of the autonomic nervous system is completely destroyed. We believe that HRV biofeedback can help train the remaining parts of the autonomic nervous system to compensate for this loss. We also need further studies of HRV biofeedback for improving athletic performance and exercise tolerance, for managing stress, for altitude tolerance, and for prevention of anxiety due to hyperventilation (overbreathing).

Further research is also needed to study the baroreflex itself. Previous research has measured the way that the baroreflexes affect heart rate. However, they also affect dilation and constriction of the arteries. This function of the baroreflexes is particularly important in controlling blood pressure, but it has been studied very little.

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## New Horizons in Pain Management: Headache As a Case in Point

Frank Andrasik, PhD, University of West Florida

Pain is a common complaint and accounts for considerable suffering, impairment, functional limitations, and disability. For example, migraine headache affects 20–25 million Americans and is underdiagnosed and undertreated. The American Migraine Study showed that migraine afflicts more people in the United States than many chronic conditions including diabetes, asthma, osteoarthritis, and depression. Over 80% of migraine sufferers have moderate to severe attacks, with most having some level of disability one or more days per month. Migraine prevalence is greatest during the peak years of productivity and has large direct and indirect costs. Direct costs are estimated at about \$1 billion per year. There is an estimated \$13 billion loss to employers because of absences from work or decreased work productivity.

Of the various recurrent pain conditions, headache has been investigated most extensively by biofeedback and related procedures (Andrasik, 2004; Andrasik & Walch, 2003; Holroyd, 2002; McCrady et al., 2000). This presentation reviews the status of research on headache treat-

ment and points out future avenues for investigation. Although the talk focuses on headache, many of the findings and suggestions apply to other pain conditions (and psychophysiological disorders). Biofeedback (chiefly electromyogram [EMG] and thermal), relaxation, and cognitive stress coping training are the most common nonpharmacological treatments for both pediatric and adult recurrent headache. Evidentiary reviews conducted by professional groups such as the U.S. Headache Consortium (composed of the American Academy of Family Physicians, American Academy of Neurology, American Headache Society, American College of Emergency Physicians, American College of Physicians—American Society of Internal Medicine, American Osteopathic Association, and National Headache Foundation); the American Psychological Association; the Canadian Headache Society; and AAPB; and statistical or meta-analytic reviews conducted by various authors beginning in 1980 document the clinical value of these treatments.

Outcomes for these procedures have been compared with those obtained with prophylactic medications as well. Consideration of these sources of evidence leads to the following conclusions: These treatments produce significant improvements in headache activity, although a sizable number of patients remain unhelped; improvements are similar among the treatments, including those obtained for pharmacological treatment; improvements exceed those obtained by various control conditions; and effects appear to endure well over time. There is some evidence to suggest that biofeedback can enhance medication treatment effects over time, particularly with difficult to treat patients (Grazzie et al., 2002). It is notable to point out that the U.S. Headache Consortium concluded that relaxation training, thermal biofeedback combined with relaxation training, EMG biofeedback, and cognitive-behavioral therapies yielded a consistent pattern of findings and were recommended as treatment options for migraine. All of these therapies were given Grade A efficacy, the highest rating that this evidence-based group gave for preventative therapies, including pharmacotherapy (Campbell et al., 2000).

The following are among the topics warranting further investigation.

1. Although a number of behavioral treatments have been shown to be valid from work conducted in specialized research or treatment centers, these treatments are not readily accessible to those most needing them. Translational research, applying these treatments in the settings where headache and pain patients first present (primary care), is sorely needed to evaluate the “effectiveness” of these approaches.
2. In a related fashion, consideration needs to be given to ways to make treatment more available and affordable by reducing the number of treatment sessions required and by reaching out to patients in more creative ways (limited contact, self-help with tailored messaging, mass communication, internet delivery, use of nontraditional providers, etc.).
3. Although nonpharmacological and pharmacological treatments are effective for a number of patients, many patients are not helped to a measurable degree. Research examining patient selection variables and the optimal sequencing of treatments, behavioral and medical, is also needed. Serotonin agonists are playing an increasing role in headache management. Integration of behavioral treatments with these medications has the potential to enhance outcomes and minimize medication doses.
4. It is likely that some of the patients who are not helped optimally by pharmacological or behavioral treatments may respond to nontraditional/conventional approaches such as acupuncture, pulsed magnetic fields, and nutritional therapies, to name just a few (e.g., Holroyd & Mauskop, 2003).
5. Even the most potent medication will not be effective if taken inappropriately. Behavioral strategies can help patients decide among possible medication options and employ methods to maximize adherence.
6. Greater attention needs to be given to mechanisms of treatment and development of biofeedback treatments that are more directly tied to underlying pathophysiology, such as EEG biofeedback.
7. A number of headache types are particularly difficult to treat or have been given insufficient attention in the literature to date (those with significant psychiatric comorbidity, posttraumatic headache, medication overuse, cluster headache, chronic forms of headache, and migraines related to the menstrual cycle). These also warrant an increased focus, as does the study of factors that contribute to headaches transforming from episodic to chronic forms.
8. The advantages of computers and the Internet for facilitating both assessment and treatment need further attention. Computers and information systems could be used to support headache management programs, identify when to use empirically derived treatment guidelines, and assist in their implementation.

9. The main outcome measures have focused on pain parameters and medication consumption. Greater attention needs to be given to impact and improvement in other domains that are important to patients, such as disability, affective distress, and quality of life.
10. Finally, future clinical trial investigations need to incorporate more rigorous methodology, adhering as closely as is possible to the guidelines prepared by the Behavioral Clinical Trials Workgroup of the American Headache Society (Penzien et al., 2005).

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## Brain, Body, and Behavioral Medicine Research: The NCCAM Perspective

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Among the domains within the area of integrative and complementary or alternative medicine (CAM), one of the most widely practiced is mind-body medicine, which involves the interplay of mind, brain, other body systems, and behavior. Research in this domain encompasses basic studies on how the mind and body interact and communicate, epidemiological studies of the key psychological characteristics and health of a given population, and clinical studies of how mind-body interactions affect health and disease. As with a variety of CAM practices, many mind-body techniques are ancient. Some remain intrinsic to Eastern systems of healing. In the West, they formed a part of the Greek and Roman tradition of medicine, which survived at least through the 17th century. Although dualism pervaded Western medicine, interest in more integrated approaches survived. Today, there is evidence that patients faced with chronic and even terminal illness—particularly conditions like heart disease and cancer—can learn and employ a variety of mind-body practices to achieve a level of symptom relief and a better quality of life, and in some cases, improvements in health outcomes. Among these practices are various forms of meditation, yoga, and tai chi and a range of other interventions for which there is not evidence sufficient to lead to their integration into mainstream medical or behavioral medicine practice. Important to the understanding of these practices, there is a growing body of basic research, much of it in the neurosciences, psychoneuroimmunology, and behavioral medicine. This research is aimed at elucidating the underlying mechanisms of action in mind-body techniques using a variety of biochemical markers and physiological measures, as well as advances in brain imaging technology. Together, this body of clinical and basic research is expected to lead to the integration of efficacious mind-body interventions into a new, more comprehensive approach to care.

NCCAM is committed to supporting research on the interactions between the mind, brain, body, and behavior and has identified four specific goals for this research in its new strategic plan:

Goal 1: Identify the common and specific features of widely used mind-body medicine practices

Goal 2: Discover means of enhancing and accelerating the healing process beyond the effects provided by conventional medicine.

Goal 3: Explore the value of CAM therapies to reduce the burden of stress-related chronic illnesses

Goal 4: Explore the value of CAM therapies to enhance resilience, positive affect, and coping in order to improve

health and well-being; prevent or slow disease progression; and treat disorders, diseases, and their symptoms.

### **Clinical Research in Biofeedback: Benefits of Developing Evidence-Based Practice**

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In spite of a long history of research and good evidence of effectiveness for treating several conditions, biofeedback interventions struggle for recognition. The issues facing biofeedback are not unique—they are faced by many other psychological treatments. In order to achieve greater acceptance and reimbursement for behavioral interventions, it is essential that we promote high standards for judging effectiveness, increase our expertise in design and conduct of randomized clinical trials (RCTs), and establish a process for continuous internal review of clinical practice guidelines. In the case of biofeedback, the process already under way should be continued and harmonized with third-party payers (Aetna, 2005; Yucha & Gilbert, 2004).

Based on successful experience with several large clinical trials at the National Heart, Lung, and Blood Institute involving psychological interventions such as stress management, biofeedback, and cognitive behavior therapy for cardiovascular disease patients, it is clear that a greatly expanded program of clinical research is needed if significant advances in clinical care are to be made. Of the 9 years that life expectancy increased in the United States between 1970 and 2000, the majority, namely 6 years, are due to a decrease in cardiovascular deaths. About half of that improvement is due to treatments developed through a vigorous program of RCTs—a record of proven success that can be emulated in behavioral interventions.

Evidence shows that in psychology too much emphasis is placed on mechanistic research before undertaking RCTs; that sample sizes in behavioral RCTs are too small, yielding unstable results (Yusuf, Peto, Lewis, Collins, & Sleight, 1985); and that high-quality RCTs are too few in number with insufficient replication and extension of initially promising results to encompass broader segments of the population (Eisenberg et al., 1993). Moreover, lack of agreement persists in review committees concerning the value of clinical outcomes as the primary, even the only, objective of an RCT; of the optimal choice of control group; and of the need to support a full

spectrum of trials including efficacy, effectiveness, and translation, depending on the level of development of an intervention and the specific objectives of a given trial. These issues can be resolved as experience accumulates through a vigorous program of randomized clinically important questions.

A broad base of support exists in the United States and internationally for conventional RCT methodology as the highest standard of evidence to support clinical decisions (Davidson et al., 2003). At stake is the confidence of research-funding agencies and third-party payers. Success of our efforts can be bolstered substantially by endorsing RCTs as the gold standard of evidence, training a cadre of sophisticated investigators thoroughly versed in RCT methods, and increasing the role of clinical practice guidelines for advancing psychological interventions.

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