

# AAPB NEWS AND EVENTS

## From the President: Issues in Establishing the Efficacy of Biofeedback-Based Interventions

The evidence supporting the efficacy of biofeedback techniques is often criticized based on the paucity of studies acceptable to mainstream medicine. The major criticisms usually center around the studies being too small to be certain of response variability; the follow-ups being too short to ensure that the intervention works longer than a placebo would to maintain its effect; and, supposedly most damning, the lack of good controls or appropriate comparisons to other treatments. Although these criticisms are frequently accurate, there are other methodologies that demonstrate the efficacy of biofeedback-based interventions nearly as well as large controlled studies. It is up to us to do the kinds of studies within our means and show the medical community that they do show efficacy.

### *Study Size and Duration versus Cost*

Relatively small studies with 20 to 40 patient subjects are within the financial means of many practice groups and graduate students, as long as they do not need to pay for data gathering beyond the scope of normal practice and do not require lengthy follow-ups. The vast majority of studies supporting the efficacy of biofeedback techniques fall into the category of small studies with brief follow-ups because of cost and time available. Small individual studies simply do not have the power to establish response variability. Follow-ups need to be between 6 months and 1 year in duration before the duration of effect can be estimated. Unfortunately, small studies with brief follow-ups are only considered to be indicators that a technique may be effective enough to warrant formal study, rather than providing useable evidence of efficacy. In other words, they are a first step in a process. Committees evaluating effectiveness studies are used to seeing hundreds, or even thousands, of participants in an efficacy study using the traditional “baseline, intervention, baseline” design. Such studies provide sufficient data to clearly establish actual levels of response variability, including dropout rates. However, although huge studies of this variety are very easy to plan, they are impossibly costly and time consuming for any one practitioner. The current alternative to trying to

have any one group perform a huge study is to combine the data from many similar small studies through power analysis techniques. These require that all of the studies use similar patients who have a very clearly diagnosed condition, very similar interventions, and very similar outcome measures. Unfortunately, few biofeedback studies can be combined because finding any two—let alone three or more—that are similar on the above factors is rare.

There is no reason the biofeedback community cannot do simple studies with large numbers of subjects if groups of practitioners will agree to enter data from patients into a joint database and permit students to do the long-term follow-ups. Several such studies have been tried in the past but have failed because of a lack of interest and complexity of the data required. There always seems to be attempts at performing such studies, but they have yet to produce publishable data.

The Association for Applied Psychophysiology and Biofeedback (AAPB) and AAPB’s surface electromyography (SEMG) division have begun one such multipractitioner study in which practitioners seeing patients with tension headaches, lower back pain, and a few other conditions can enter just a few bits of data at the start and end of treatment. For more information about this study, please go to the Members’ Only section of the AAPB web site and click on study section. Weaknesses of this approach are that the patients and interventions are frequently dissimilar and the impact of concurrent interventions are difficult to account for.

### *Adequate Controls/ “Gold Standard” Comparisons*

Adequately controlled studies are very rare in biofeedback, not only because they are incredibly costly and time consuming but also because meeting the currently acceptable criteria for a good comparison or control are difficult. Waiting list controls are no longer considered viable comparisons because people on a waiting list have no expectations of improving and, of course, make no therapist-patient bond. Thus, all of the nonspecific effects are not accounted for. Our controlled studies of chronic migraine patients frequently have a 50% placebo

bo effect, with most of the participants showing at least modest benefits during and shortly after participation in the placebo arm. These are usually patients who have had every medical intervention. Most other studies of migraine show 30% to 50% of responses as well. Comparison with “gold standard” medications is no longer considered adequate because there is far less patient-therapist contact, and the incredibly high level of patient action (frequent sessions, homework, learning expectations, etc.) is thought to lead to a strong desire to get better so that all of that work is worth it. Thus, the placebo is not adequate unless it requires a similar level of patient-therapist interaction and level of work on the part of the patient. The best route to go seems to be using a type of biofeedback not likely to affect the condition in question. It certainly does not need to be the same type of biofeedback.

### **Alternative Ways of Demonstrating Effectiveness Acceptable to the Mainstream Medical Community**

There are two main, usually acceptable, ways of demonstrating effectiveness that do not require huge groups and difficult, costly controls:

1. Longitudinal studies. These studies follow groups of patients over a very long span of time. This permits solidly establishing variations in symptom severity and the long-term effects of several interventions. There is no need for huge groups, as the details of each patient’s history are known over a long period of time. This technique is now being employed by insurance companies to determine whether a wide variety of interventions are effective or whether individual practitioners just think they are effective without realizing that the vast majority of patients simply move on to the next practitioner when the previous one did not help. Huge studies (such as ours of over 10,000 amputee patients) have shown that many patients have never given the preceding practitioner any indication that the treatment was not effective. Many insurance-based studies have resulted in clear demonstrations of ineffectiveness for numerous commonly accepted interventions. These studies can not readily be performed by clinicians in a busy private practice, but they can be performed by graduate students or others who are given access to the records of patients who are treated with biofeedback in large care systems.

The U.S. military and veterans health care systems are among the few in the United States that have longitudinal files on a sufficient number of people who have received biofeedback at one time or another that would be useful in performing longitudinal evaluations, as both pre- and postbiofeedback patterns of care can be established. We used the longitudinal technique to demonstrate that a now defunct group who employed a “minimal” biofeedback intervention system (a maximum of four biofeedback sessions with a “one size fits all” intervention) was generally ineffective.

2. Changes in psychophysiological markers of disease. When an intervention is being tested, a very well-accepted approach is to show that the cause of the disease is present only among those with the disease and that the cause is gone at the end of treatment. For example, people who have a specific bacterial disease only show symptoms (come down with the disease) when there is a sufficient density of the right bacteria able to act under the right conditions. When the bacteria are reduced below a critical mass of numbers/activity, the symptoms abate. For better or worse, nobody seriously questions this model any longer. Therefore, any treatment shown to eliminate the underlying problem as well as its symptoms is generally accepted as efficacious without the requirement for controlled studies. This is not to say that subsequent studies of dose/response, response rate, safety, etc., are not required.

We are unique among the professions applying behavioral interventions and performing training, in that we are the only ones who regularly make physiological recordings as an intrinsic part of our work. These recordings can be used to demonstrate that psychophysiological functions are abnormal or less than optimal prior to our interventions and that they normalize along with resolution of symptoms and improvement of function. In fact, we can readily demonstrate that the problems do not change unless the physiology changes first and that the symptoms stay away only for as long as the underlying physiology remains correct. We have done this with both physical stress urinary incontinence and posture-related tension headaches. We first demonstrated the physiological deficit causing the symptoms and then showed that the symptoms only subsided when the underlying physiological problem was reduced to a parallel extent. We then went on to demonstrate that only

those people who learned to change the underlying physiological problem succeeded in ameliorating their symptoms. People who did not learn the skills needed to change the underlying physiology, and people who did not apply those skills showed no changes or minimal changes of brief duration. The “minimal” changes of brief duration beyond the normal variation in underlying physiology permitted us to estimate the extent of the placebo effect. The placebo/nonspecific effects were accounted for by the minor amount of change in symptoms beyond the change in physiological levels—especially when there was no physiological change at all. Obviously, this technique is useless for conditions in which there is not a solid relationship between the underlying physiological dysfunction and the symptoms. In other words, the technique can only be used when all of the symptoms are reliably accounted for by the physiology.

This is the most direct approach we can use to demonstrate efficacy of our techniques. It requires little more expense and effort than we are already putting in, because we are already doing the recordings. All we need to do is follow-up with the patients at 6 months and 1 year to have incredibly powerful evidence supporting the efficacy of our interventions.

—Richard Sherman, PhD

### **From the President-Elect: A Window of Opportunity for Biofeedback**

As mentioned in an earlier column, I have been working on forging an agreement with a major Complementary Alternative Medicine (CAM) HMO to include biofeedback as an offered service. The good news is that the people in charge of the business of CAM see biofeedback as an attractive offering to go along with chiropractic, acupuncture, and nutrition. This speaks well for the public’s perception of our field. At this point the HMO is willing to set up an affinity program. The HMO in question only wants licensed practitioners (Biofeedback Certification Institute of America [BCIA] certified as well). Practitioners can join a panel (at no cost) and, in exchange for seeing patients at a reduced fee, they will be listed on a massive provider list (the HMO covers 15 million people). Practitioners will get the referral and charge at the designated rate, and a simple reporting mechanism lets them keep track of the numbers.

In the meantime we are working on a true HMO panel just for biofeedback. This might operate in con-

junction with chiropractors, medical doctors or other providers, or be a separate service offered to all employees at a workplace plan. I am hoping to get some feedback from our membership regarding the following:

- Fees: What is the minimum fee that would tempt you to partake in a panel?
- Services: What symptoms should be covered?
- Sessions: What is the range of sessions you would need to have covered?
- What practitioners should be eligible (BCIA, PhD, MD, LCSW, etc.)?
- Settings: Would you be interested in going to medical facilities or work sites to deliver services?
- Modalities: What modalities should be included (Temperature biofeedback [TEMP], surface electromyography [SEMG], heart rate variability [HRV], electroencephalography [EEG], etc.)?

We may be able to set up a meeting at the national conference in April in Portland. Would you be able to come to give the HMO feedback?

As you can see, we seem to be on the verge of breaking into the massive CAM and/or traditional health care system in the United States. This company also carries some weight with third-party payers and might help us gain acceptance of billing codes such as 96152, which is ideal for many of the services we provide, but is difficult to get paid.

I hope you will help by spreading the word and giving me some feedback on how these sorts of plans would work for you.

—Richard Gevirtz, PhD, BCIAAC  
rgevirtz@alliant.edu

### **From the Executive Director: Impressions from the Meeting of the American Psychological Association (APA)**

#### *AAPB As an Exhibitor*

For the past few years the AAPB Board has discussed whether AAPB should have a booth at the American Psychological Association (APA) meeting. After all, some 65% of our members are psychologists. At the most recent Board meeting we approved the funding and off we (meaning me) went. Note that at the same time Judy Crawford was in Seattle representing the

Biofeedback Certification Institute of America (BCIA) at the National Council of State Legislatures. Both of us copromoted the other organization. At the AAPB meeting, we have about 30 booths from long-time colleagues. We spend a lot of time with booth layout and exhibit hours to make the experience positive. Now I was on the other side of the fence.

I arrived in Washington, DC, on Wednesday at 4 p.m. and went directly to the convention center to set up the booth. Given that we made our decision to take a booth comparatively late (compared with the other long-term exhibitors), the booth location was quite excellent. Most folks want to have a booth near the door where attendees access the exhibit area. In a room with about 150 booths, there were several walkways and the posters and food station were located at the opposite side from where the attendees entered. Our booth was located on the walkway from the entrance and anyone going for food and to the posters had to walk by us.

We were located next to a company demonstrating virtual reality equipment to be used with phobia patients. They had constant traffic, and many attendees stopped to talk with us as well. The owner was quite familiar with our work, and we are hoping they will take a booth at our Portland meeting.

It was nice to have a visit from Paul Lehrer and Frank Andrasik. Both were on the APA program. Those of you who have been AAPB members for a long time will share my pleasure at having a visit from pioneer member Hal Musiker, who in his mid-eighties looks wonderful and sends regards to all. Ray Folen and the group from Honolulu also stopped by.

### *Impressions*

Given the estimate of 14,000 meeting attendees, the number of attendees in the exhibit hall seemed a small percentage. In talking with veteran attendees from past exhibits, they said this was very typical. It was also a surprise to find jewelry and luggage salesmen among the booths. Did you know that psychologists bring their small children to the exhibits? The general makeup of the exhibitors was over 50% book publishers, many of the National Institutes of Health (NIH) institutes, equipment service providers, and about 10 associations.

It was surprising to me that so many people did not know about biofeedback. The primary inquiry from anyone who did know about biofeedback was, "I am interested in neurofeedback and I want to be certified."

Membership was seen as a source of education and training. When we see that many inquiries from people (i.e., psychologists) who know nothing about AAPB, we need to pay attention. There were a large number of students; they were great and asked excellent questions.

On Thursday, Friday, and Saturday we had at least 100 visitors per day who asked questions and/or took materials. Time will tell, of course, if we see concrete results, such as new members or meeting attendees. About 250 order forms and membership applications went to individuals who showed any interest in books and publications. The fall workshops brochures were also a hit, and the teleseminars seemed to evoke a lot of interest.

For giveaways (you always need giveaways), we gave out 250 pencils that have AAPB and our web site address on them. The pencils react to hand temperature, and everyone was fascinated that they could make the pencil change color. These were a real hit and served to start a conversation. I also brought 50 copies of past issues of *Biofeedback* and 100 copies of the most recent issue of AAPB's journal, *Applied Psychophysiology and Biofeedback*, which contains the Vince Monastra white paper about neurofeedback for attention deficit/hyperactivity disorder (ADHD).

### *Other Contacts*

One new company made their business debut at the opening of the meeting. The product is called Stresseraser. Their booths were directly across from us and, again, the flow of traffic was helpful. This is a handheld device that records a number of measures. The business representatives took our information, and I feel certain we will have a new corporate member. Other biofeedback booths were Thought Technology, Vivometrics, and Alpha Stim.

One outcome was the opportunity for expanding our publications marketing efforts via distribution through an existing small publisher; participation in regional APA meetings; and participation in large state APA meetings (Texas, Florida, California, New York, etc.), as well as participation in the combined title book booth where different groups can have their books and materials displayed for a fee.

### *Other Opportunities*

I met with Carol Bischoff, our editor at Springer. She has secured permission for the Monastra article to be made available through our web site for open access (i.e., there is no charge for readers to see the full article). In gener-

al the abstract is free, but the article is not available without a \$25 charge.

At the NIH booth I picked up a pamphlet on headache and pain. In it is a very strong statement in support of biofeedback. We need to make that known as well. Separately, one group that was particularly interested in our material was the Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) group. Their division on AD/HD is funded by the Centers for Disease Control and Prevention (CDC), and they have a ton of literature. They clearly state that neurofeedback is an alternative treatment but needs more research. I made sure they had the Monastra article. They did invite us to provide further information to them.

All in all it was an interesting physical and mental challenge. I have a new appreciation for exhibitors. Standing and being cordial for 9 hours at a time for 3.5 days gives one a whole different perspective. I'm looking forward to receiving all those applications and registration materials from new members.

—*Francine Butler, PhD*

### **Launch Date Set for New BCIA Web Site**

February 1, 2006, is the scheduled launch date for BCIA's new web site. Enhanced design and functionality will usher in a user-friendly interface that will include several long-awaited changes. The web site will address the needs of the consumers, BCIA-certified professionals, and other professionals.

Highlights of the new site include the following:

- A new design that will offer a more appealing graphic presentation
- Navigational elements throughout the site in a standard, logical format
- The ability for members to update their demographic and contact information online in real time
- Online payment of recertification and other fees
- An enhanced "find a practitioner" service
- Establishment of online mentoring services
- Easily accessible information on how to become certified for noncertified professions.

Watch for more details as the site development progresses at [www.bcia.org](http://www.bcia.org).