Research in the field of biofeedback is not always effective for the development of the field. In particular, neurofeedback has had spotty success, with many studies failing to meet rigorous methodological standards. Many researchers are lacking in the basic understanding of neuromodulation and its inherent learning model. And many clinicians, while knowledgeable in clinical applications, lack understanding of the rigors of good research. However, the International Society for Neurofeedback and Research (ISNR) Foundation and the Association for Applied Psychophysiology and Biofeedback (AAPB) Foundation for Education and Research in Biofeedback are rich in expertise, yet that expertise is seldom tapped.

The following interview with the president of the ISNR Research Foundation, David Trudeau, will spotlight the foundation's impact on the field of neurofeedback. A second interview with Paul Lehrer, Chair of AAPB's Foundation for Education and Research in Biofeedback (FERB) will appear in the summer 2014 issue of Biofeedback. It is hoped that this interview series will provide insight to both foundations and facilitate future collaboration.

**Introduction**

Often researchers embarking on a project make lists and develop procedures they expect to follow. They organize their team, strategize about funding, plan the protocol and anticipate the outcome. However, once they begin to execute the project, more often than not unforeseen problems arise. Research is a nonlinear, nonsequential process that rarely adheres to the simplicity of research designs. And, that’s the fun of it.

When initially exploring the literature, it’s often the case that contradictory findings are found. How can we resolve this? Follow the ones that we believe to be true, while ignoring those that are also true? They were published, and peer-reviewed after all, and shouldn’t be set aside. Investigators can easily massage effect size, statistical power, correlations and causations, ad hoc findings, and alpha probabilities. In fact, John Ioannidis (2005) posits that more published research findings are false than true. This year, a paper was published that negated much of the recent research showing that we should take Omega 3 fatty acid supplements. Or is it Omega 6s? Or the combination of the two? I don’t recall, but I stopped my 4-year habit. Immediately. One study showed that Omega 3s may actually be one cause of prostate cancer. Read the fine print and you’ll see that these data were ad hoc (possible after-the-fact results). Yet, Time magazine, the Pharmacy Times, and The National Cancer Institute all reported on it (I’m sure there were others). These data may well be unsubstantiated; however, unsubstantiated or not, I’m still no longer taking Omega 3 supplements.

In our field, we recently witnessed three peer-reviewed papers with university and/or government funding that reported that neurofeedback didn’t stand out from sham treatment (Arnold et al., 2012; Lansbergen, van Dongen-Boomsa, Buiter, & Sluiter, 2010; von Dongen-Boomsma, Vollebregt, Sloos-Willems, & Buitelaar, 2013). From an expert neurofeedback perspective these studies are flawed. They used autotraining, not allowing for any
shaping centered upon the most basic operant conditioning models. Their neurofeedback protocols and equipment were not optimal. The Lansbergen et al. (2010) study actually trained sensory motor rhythm at F3 and F4. Minimal objective pre- and postcomparisons did not exist. Yes, these projects were funded, peer-reviewed, and published, and advised the scientific community as well as the public that neurofeedback doesn’t work.

Recently, this author interviewed David Trudeau, president of the International Society for Neurofeedback and Research (ISNR) Research Foundation, and Paul Lehrer, president of the Association for Applied Psychophysiology and Biofeedback’s (AAPB) Foundation for Education and Research in Biofeedback. In our highly specialized community, these individuals head the foundations that are responsible for promoting and subsidizing sound research and ultimately publications in our field. However, these men and their respective organizations are only infrequently consulted, but they should be, if not for funding, then maybe for the wealth of expertise the entities comprise. The interview with David Trudeau follows below. The interview with Dr. Lehrer will appear in the summer 2014 issue of Biofeedback.

Interview with David Trudeau, MD, President of the ISNR Research Foundation

Dr. Trudeau has been the editor of the Journal of Neurotherapy and Chair of the ISNR Research Fund Committee; he is now the president of the ISNR Research Foundation (ISNR-RF). His membership in ISNR began in 1991. His tenure as editor of the journal went from 1998 to 2004. He began the Research Committee in 2004, and in 2008 transformed it into the Research Foundation, a separate nonprofit dedicated to research that furthers the field of neuromodulation for central nervous system (CNS) disorders. He has earned the following awards: Fellow, International Society of Neuronal Regulation 2002; ISNR Career Achievement Award 2003; and Joel Lubar Award 2012.

CRK: In your role as head of the ISNR-RF what trend in research would you say has been most outstanding?

DT: LORETA neurofeedback1 and imaging has been the most exciting advance because it helps correlate information about brain electrical activity with other imaging techniques such as functional magnetic resonance imaging (fMRI) that are based on oxygen utilization/blood flow. Combining the high temporal resolution of electroencephalographic (EEG) and the high spatial resolution of fMRI lends more understanding to functional brain circuits. Another trend has been the use of event related potentials (ERP) to measure the effect of EEG biofeedback and other physiologic interventions on processing speed. I believe that studies combining neurofeedback with other interventions such as transcranial magnetic stimulation (TMS) will also increase understanding of electrophysiology-based therapies.

CRK: A recent look at the number of publications one can find in PubMed when searching for neurofeedback and EEG finds there to be an exponential growth of peer-reviewed and indexed papers. With this current interest in investigating neuromodulation, why do you think it is still considered experimental?

DT: I must tell you that what has been considered experimental vs. “fact based” clinical practice since I graduated from medical school in 1966 has been based more on perceptions than evidence. I think paradigms of practice are more anecdotally based than most people would think. I remember spending two entire mornings a week assisting at ulcer surgery in the ‘60s (the medical tower at my alma mater is named after one of the “giants” in ulcer surgery). Nowadays those vagotomies and pyloroplasties of the past are incredibly passé, but in 1968 the procedures were highly reimbursed and unquestioned. Today we are faced with overdiagnosis of attention deficit hyperactivity disorder (ADHD), with 12% of all children and up to 20% of boys being diagnosed with ADHD, and likely medication overtreatment of these children without enough questions being asked. And yet, physiologic interventions such as EEG biofeedback have failed to create a buzz despite their evidence.

I think part of the answer to this dilemma is to design more studies for those niches of the ADHD population that are hard to treat with drugs alone—those at risk for adverse effects from the use of stimulant drugs, or those whose response is inadequate. In my opinion the broad-brush battle of head-to-head studies of neurofeedback vs. stimulants is not where we should focus, but instead on studies that show neurofeedback can be useful where medications fail or can’t be used. Also, today we are in a bit of awakening to the risks of diversion and dependency for overprescribed drugs. Remember drug store amphetamines (very much like methamphetamine from meth labs) or methylphenidate (which hits the same receptors as cocaine) are big sellers on the street and often diverted.

I know we need more evidence regarding efficacy both in comparison studies and in studies that show changes in

1LORETA refers to low-resolution electromagnetic tomography. LORETA is a statistical technique to analyze surface EEG signals and determine which sites deeper in the brain are the sources of the surface electrical activity.
brain physiology. But we also need other persuasion to make the point that what we have is valuable clinically here and now.

CRK: How has funding (the presence or lack thereof) affected research in this area?

DT: Neurofeedback has not made inroads at the National Institutes of Mental Health (NIMH) or the National Institute on Drug Abuse (NIDA) or other sources of major governmental funding. There are not enough academic researchers interested in neurofeedback to make waves with lots of proposals for the big money requests for proposals, although there are proposals submitted regularly by some, such as Tato Sokhadze at the University of Louisville. And the old adage of “them that has, gets” may apply with neurofeedback proposals that are unable to break the ice.

CRK: Where do you hope the ISNR-RF will go?

DT: I can see the ISNR-RF growing over time with legacy support from ISNR and EEG section members. The largest foundations in the U.S.—those who are real shakers and movers—started small with legacy donors remembering these foundations with gifts of five to ten thousand dollars in their wills or retirement plans. Support of academics is essential for this field to grow. Someday I would hope the ISNR-RF could support a chair in clinical neurophysiology.

CRK: The ISNR-RF is involved as a collaborator/consultant on two projects. What is their status and do you see the Foundation pursuing more projects of this nature?

DT: Absolutely yes. The RF is looking for ways it can bring neurofeedback research expertise together with clinical needs. It is doing that today with the Collaborative Neurofeedback Project, which is aiming at the elusive, large, randomly controlled trial (RCT) of neurofeedback in ADHD, and with the Pathways Home neurofeedback project for returning warriors with minimal traumatic brain injury (mTBI) and posttraumatic stress disorder (PTSD).

CRK: How are FERB and ISNR-RF different than the ISNR and AAPB member organizations?

DT: The FERB and the ISNR-RF are both free-standing nonmembership 501(c)(3) organizations that are largely involved in funding research for, and raising money from, membership organizations. They must operate independently of the membership organizations so that there is no IRS question of using a foundation as a tax dodge for passing money through. Neither organization is restricted to awarding research to members of its respective membership organization or raising funds from those members. FERB is more focused on somatic biofeedback and ISNR-RF on CNS biofeedback, but of course both overlap. There are many ways in which these two research organizations could work together.

CRK: You and your coauthors rated neurofeedback for psychoactive substance abuse disorders (PSUD) as probably efficacious in 2006 and 2008. Would you maintain that position today, considering any newer publications?

DT: Like most complex clinical conditions, PSUD is fraught with comorbidities and one-size-fits-all treatments are limited. There is no magic bullet. There is every reason to believe that neurofeedback can be an effective part of a comprehensive long-term plan for many. Neurofeedback—like anticraving and aversive medications, cognitive–behavioral-based therapies, self-help and twelve-step group activities, longer term sober living support, and social rehabilitation—can and should be considered as part of a comprehensive treatment plan for PSUD recovery.

CRK: Another interest of yours—PTSD and mTBI—is an important area for neurotherapy due to returning war vets and the differing effect that brain blast injuries have in contrast to direct assaults. How do you think this affects the existing body of literature on mTBI?

DT: There is very little written on neurotherapy trials for diffuse brain injuries such as those that occur from acceleration/deceleration accidents, blast exposure, and repeated athletic trauma. The models for these injuries suggest microtrauma that disrupts neuronal pathways and produces inflammatory responses that are neurotoxic, especially to frontal brain areas. Neurotherapy may offer ways to reestablish pathways by first focusing on areas that are abnormally disconnected as seen with QEEG measures such as z-score LORETA coherence. Reestablished connectivity as measured by QEEG, changes in reactivity time as measured by ERP, changes in blood flow, and changes in white and grey matter volumes measured by fMRI are all things that can be studied as outcomes—as well as changes in neurometric tests and measures of quality of life. All of this will be important in both understanding and remediating mTBI. From my own work years ago with PTSD and TBI associated with blast, I have a hard time sorting out PTSD from the mTBI. They coexist clinically and their symptoms overlap. I suspect one of the risks for unremitting PTSD is an associated head injury like diffuse blast injury.

CRK: How has research affected the popular and professional views of neurotherapy?

DT: I think not nearly enough. Part of the problem, as I see it, is that overly enthusiastic marketing by a minority of neurofeedback advocates has lead to an impression of unsubstantiated therapeutic claims and has gotten a lot
more attention than the scientific efforts by AAPB and ISNR in their respective meetings, journals, and research organizations. I think this contributes to a credibility gap.

CRK: Some readers may not be aware of the details of the ISNR-RF’s work. Can you take a moment to highlight some past and ongoing research projects under ISNR-RF sponsorship?

DT: Currently the ISNR-RF sponsors minigrants for researchers that help them get a toehold. These grants are usually in the range of several thousand dollars and are supplemented by other grants and resources. This activity has been going on for a number of years, first under the research committee and now under the Foundation and has resulted in a number of published papers. This encouragement has had a modest but palpable effect on neurofeedback research overall.

In addition to sponsoring and administering grants, the RF brings together funding resources, research needs, and research expertise in collaborative projects that are ongoing. Some of these are more successful than others but the RF continues to look for and nurture opportunities to make important research happen. Some of the things in recent times that didn’t pan out were collaboration with a large brain-rehabilitation hospital to study and integrate neurofeedback for stroke and TBI rehabilitation, an attempt to establish a practitioner-to-practitioner collaboration network to do head-to-head studies in ADHD, and work to bring together a neurofeedback trial, epilepsy funding, and an epilepsy clinic. The RF is always ready to go back and revisit these projects, but for now they did not work out.

Some of the current and active projects include a collaboration with a rehabilitation program for returning warriors with PTSD to fund and implement a study design created by a panel of neurofeedback/PTSD experts. The neurofeedback track will use the Peniston protocol with pretreatment for anxiety disorder associated EEG phenotypes and incorporating heart rate variability (HRV) biofeedback training. Another project has gathered pilot data on IMRI and LORETA EEG validation of neurofeedback for ADHD to create an NIMH type of funding opportunity. Another project is to help bring together medical and neurofeedback expertise in ADHD to design a fundable and doable large scale RCT. Yet another and recent project involves interventions in early dementia using neurofeedback to improve quality of life in a collaboration between research centers in the United Kingdom and the United States.

Sometimes I think of this exploratory activity as analogous to drilling for oil back in the old days of wildcatting. The chances of hitting a dry hole were nine out of ten, but those who could garner the resources to persist made it big. Much of the financial support the RF gets helps the executive director, the board, and the advisory board pursue these exploratory projects. It costs the RF about $25,000 a year in administrative expenses to maintain these exploratory projects and the operation is as close to the bone as can be.

CRK: European neurofeedback research appears to be gaining a level of government sponsorship that has not yet been matched in the United States? Can you comment on this trend?

DT: There isn’t much I can say about this except it seems to me that there are many more academic opportunities in all of Europe. The U.S. university centers for graduate training in neurofeedback have all but disappeared. Joel Lubar’s former program trained some of today’s real leaders from European countries, now U.S. students are gravitating toward European centers. We need to do all we can to nurture our young academics in neurofeedback worldwide and the RF hopes to continue to play a role in this. One of my fantasies is that the RF could grow through modest endowments from ISNR and EEG section members and someday have the wherewithal to support academic positions in neurofeedback.

CRK: BCI, or brain–computer interface research, appears to be enjoying great interest as well as publicized successes in several research labs in the US and abroad, allowing disabled individuals to control their environments via “neurofeedback in action.” Will this have a positive impact for support of other areas of neurofeedback research?

DT: One would hope so. This is a clear demonstration of how brain electrical activity can be controlled volitionally by learned feedback through brain–computer interface. There should be no question in anyone’s mind that this is doable after seeing mobility and communication skills demonstrated in locked-in individuals using BCIs.

CRK: Recently an advisory committee of the American Academy of Pediatrics elevated neurofeedback to Level I efficacy status. Has ISNR-RF been involved in building the case for neurofeedback in treatment of ADHD?

DT: Yes—and in several ways. A good part of the issue for building the case for ADHD involves the question of which research approach will make the case best—RCT studies, head-to-head trials, or studies that show changes in brain physiology/anatomy as the result of neurofeedback. The common misconception is that, lacking RCT evidence, neurofeedback for ADHD cannot be shown to be efficacious. However, as I shall explain, there is an
argument that the RCT model for drug research does not lend itself to studies of operant conditioning. The RF has considered arguments for these approaches and has tried to facilitate them, not always an easy task. Our attempts at internally funding and executing a practitioner network-based head-to-head trial failed with lack of participation from the field of potential practitioners. Apparently it was just too much work to expect from those already preoccupied with clinical practice issues.

We have worked extensively hand in hand with the Collaborative Neurofeedback Project that brings together experts from both neurofeedback and ADHD fields to design and implement a large RCT with NIMH funding. That is, ongoing and to date there have been a number of rejected applications, but the CNP continues to go back to the drawing boards to respond to reviewers’ objections and resubmit. Coming up with a model that is therapeutic yet can be blinded to the therapist is one of the conundrums, another is the cost involved in doing many sessions in both groups (vs. the costs of simple interventions like comparing active pill to placebo.)

There are those who feel that it is not likely that it will ever be possible to design a truly double blinded study of neurofeedback and other approaches deserve our attention more. If the objective is to get neurofeedback accepted in lieu of supporting RCTs then some broader audience needs to hear why it may not be possible to double blind therapeutic operant conditioning of EEG signal, and why there is sufficient other evidence of efficacy and opportunities for developing more of this evidence. At last year’s ISNR meeting, Mario Beauregard presented his findings that sham normals show both functional improvement in attention and brain volume changes, but these are less robust and qualitatively different from those seen in active normals. When CPTs alone are used as outcome in clinical subjects both groups show improvements as compared to untreated and this paper gives a hint as to why. In any sham comparison where the subjects are asked to do something that requires attention, dedication, and lots of time there has got to be an effect.

In an RCT, if the therapists are blind to operant conditions, the “treated” group is getting very weak treatment, if any at all. In the RCT design it appears two shams are being compared—one that has slightly weaker effect to one that has slightly stronger effect—but neither is comparable to no-effect placebo or to actual treatment, respectively. With such weak effect sizes, one would need very large samples to show a difference and the findings may not be generalizable to actual interactive treatment anyway.

In my view, the mainstream views about neurofeedback for ADHD are more cultural than evidence-based. A big advertising budget could fix that, but I don’t see that happening. I think neurofeedback has to “go viral” to shift these perceptions.

At any rate the ISNR-RF keeps looking for better answers and solutions to the dilemma of research design to validate neurofeedback for ADHD.

CRK: Academic neuroscientists are now confirming with fMRI what has been known and practiced over the past thirty years using QEEG and neurofeedback: that human and animal subjects are able to voluntarily modify brain function when given feedback. Has ISNR-RF played a role in neurofeedback research projects featuring fMRI as an outcome marker?

DT: Yes, good question—the RF has done pilot study work using fMRI measures in ADHD adults and these data are now available for building a larger grant proposal. I think the really fertile areas of research in neurofeedback lie in the realm of demonstrating brain changes in response to interventions. Does lifting weights make your muscles bigger? Just look at those biceps! Does endurance exercise improve oxygen utilization? Look at the data. When we talk about functional improvements like these, based on direct obvious observation, we don’t normally think of designing RCTs to show that a physical fitness training paradigm has an effect. I expect the federal initiative to map the brain and its connectivities will rely on the high spatial resolution of fMRI techniques as much as the high temporal resolution of LORETA and magneto-encephalography (MEG) techniques, and will result in more cross validation. The more that people are able to see functional changes in graphic brain maps, the more apparent the changes brought about by operant conditioning will be. The bottom line—seeing changes in those images of the brain as the result of exercise and training—is the proof.

CRK: What are ISNR-RF goals for the future? Has the ISNR-RF prioritized any specific types or areas of research for future funding?

DT: The most immediate goal for the RF is to “keep on keepin’ on.” Without any direct support from ISNR or AAPB our meager existence is hand to mouth. The generosity of all those who make recurrent donations and support our fundraising efforts, such as book publishing and auctions, keeps the RF alive and makes it possible to do its mission.

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