

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR COMPLEMENTARY
AND ALTERNATIVE MEDICINE**

**NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY
AND ALTERNATIVE MEDICINE
MINUTES OF THE FORTY-NINTH MEETING
June 7, 2013**

NACCAM Members Present

Dr. Brian Berman, Baltimore, MD
Dr. David Borsook, Waltham, MA
Dr. Daniel Cherkin, Seattle, WA
Dr. Gary Curhan, Boston, MA
Dr. Steven DeKosky, Charlottesville, VA¹
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Susan Folkman, San Francisco, CA
Dr. Tracy Gaudet, Washington, DC
Dr. Jane Guiltinan, Seattle, WA
Dr. Scott Haldeman, Santa Ana, CA
Dr. Frances Henderson, Jackson, MS
Dr. David Kingston, Blacksburg, VA
Dr. John Licciardone, Fort Worth, TX
Dr. Richard Niemtzw, Clinton, MD
Dr. Philippa Marrack, Denver, CO¹
Dr. Lloyd Michener, Durham, NC
Dr. Lynda Powell, Chicago, IL
Dr. Chenchen Wang, Boston, MA

¹ Telephone

SPEAKERS

Dr. Paul Coates, Bethesda, MD
Dr. Julia Finkel, Washington, DC
Dr. Randy Gollub, Charlestown, MA
Dr. Russell Glasgow, Bethesda, MD
Dr. Joel Greenspan, Baltimore, MD
Dr. Francis Keefe, Durham, NC
Dr. Barbara Sorkin, Bethesda, MD

NACCAM Members Not Present

Dr. Deborah Powell, Minneapolis, MN

NIH Staff Present

Diane Hannemann, OSP, OD, NIH
Wendy Smith, OSP, OD, NIH

Members of the Public

Toyin Adewolf
Miles Braun
Keith Egan
Ed Kennelly
Victoria Menus
Michelle Rodrigues
Amita Shukla
Jay Sirois
Ucchan Sitak
Angela Starhweather

I. Closed Session

The first portion of the forty-ninth meeting of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

A total of 137 applications were assigned to NCCAM. Of these, 43 were reviewed by NCCAM, 94 by Center for Scientific Review. Applications that were noncompetitive, not discussed, or were not recommended for further consideration by the scientific review groups were not considered by Council.

Council agreed with staff recommendations on 78 applications requesting \$40,413,476 in total costs.

II. Open Session—Call to Order

The open session convened at 10:35 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

The minutes of the February 1, 2013, NACCAM meeting were approved unanimously.

III. NCCAM Director's Welcome and Overview of the Meeting

NCCAM Director Dr. Josephine Briggs welcomed Council members and guests and briefly summarized the agenda items. She welcomed the four new Council members, Dr. David Borsook, Dr. Stephen Ezeji-Okoye, Dr. Deborah Powell, and Dr. Chenchen Wang, and the new ex officio member from the Veterans Health Administration, Dr. Tracy Gaudet.

Dr. Briggs welcomed NCCAM's incoming Deputy Director, Dr. David Shurtleff. Dr. Shurtleff is an NIH veteran, with 18 years of experience at the National Institute on Drug Abuse (NIDA), most recently as Acting Deputy Director. He has extensive experience in the oversight of research that is very relevant to NCCAM's portfolio. Prior to joining NIDA, Dr. Shurtleff worked as a research psychologist; his research included studies of dietary supplements that are of particular interest with respect to NCCAM's mission.

Dr. Briggs drew Council's attention to *Genome: Unlocking Life's Code*, a new exhibit at the Smithsonian that was produced collaboratively by the National Museum of Natural History and NIH's National Human Genome Research Institute.

The sequester has reduced NCCAM's budget from \$128 to \$120.6 million. For the current year, NCCAM's policy is to award new and competing grants with a 5-percent reduction from the recommended level in most instances. NCCAM's renewal grants are being awarded with a 3-percent downward revision. Inflationary increases for future-year commitments will be discontinued for all competing research grant awards issued in Fiscal Year 2013. Overall, the sequestration is having a major impact at NIH. Cuts are being made across all programs, projects, and activities, so every area of medical research is affected. NIH expects to award about 700 fewer competitive research project grants and must absorb a 5-percent cut in intramural programs as well. NIH does not anticipate furloughing employees but may not fill vacancies, including some vacancies at NCCAM.

Notable recent and upcoming events include the following:

- **Publications.** Two major studies for which NCCAM was a cofunder—a trial of dietary supplements for macular degeneration and a trial of chelation therapy for heart disease—were recently published.
- **Symposium.** The 8th Annual NIH Pain Consortium Symposium on Advances in Pain Research, which focused on integrated self-management strategies for chronic pain, was held on May 29–30.
- **Twitter chat.** NCCAM recently participated in a Twitter chat on yoga and meditation led by Dr. Richard Besser of ABC News, which reached more than 3 million people.
- **Lectures.** Dr. Aniruddh Patel presented an NCCAM lecture on the impact of music on brain function, and Dr. Barbara Fredrickson lectured on the relationship between positivity and healing.
- **Facebook chat.** NCCAM's first Facebook chat, which will focus on dietary and herbal supplements, will be held on June 13, 2013.

IV. Concepts for Management of Clinical Research

Dr. Briggs updated Council on a September 2012 NIH leadership meeting on challenges in the management of clinical research. Much of the discussion at this meeting focused on the failure to publish the results of many clinical trials.

An analysis published in the *British Medical Journal* showed that of 635 NIH-funded trials registered in ClinicalTrials.gov after September 2005 and completed by 2008, only 46 percent

were published within 30 months. Even after longer followup, almost 40 percent of trials remained unpublished.

Selective and delayed publication of clinical trial results violates the ethical commitment to trial participants and the commitment to funders. It distorts clinical research by failing to inform future research efforts. It may also distort clinical practice, leading to slower uptake of effective therapies and slower reduction in the use of unsafe or ineffective therapies.

NCCAM has performed a detailed analysis of its own publication rates, focusing on 43 trials that completed patient accrual in 2008 and 41 that completed accrual in 2009. Publication rates, although better than those for NIH as a whole, were unacceptably low. The primary results of 12 (28 percent) of the 2008 studies and 19 (46 percent) of the 2009 studies have not been published. NCCAM contacted the majority of investigators with unpublished results; many had not submitted manuscripts for publication. None of the investigators reported that negative findings had impeded publication of their results.

Discussion. Dr. Daniel Cherkin commented that with the current financial situation, researchers may need to prioritize the preparation of grant applications over the preparation of manuscripts reporting on completed work. Dr. Lynda Powell observed that delays in recruitment of study participants may have contributed to difficulties in completing and publishing research. Dr. Briggs agreed and explained that NCCAM tracks patient accrual closely in the studies it funds. Dr. Lloyd Michener pointed out that failure to publish may relate to a lack of community and patient group involvement in trials. If people were deeply involved, the idea that the researchers did not share their results would be untenable. Dr. Gaudet suggested that a system should be created that includes an explicit commitment to publish and incentivizes publication.

V. Update on the Botanical Research Working Group and Concept Clearance

Dr. Paul Coates, Director of NIH's Office of Dietary Supplements (ODS), summarized NIH's investment in botanical research and reported on the findings of the ODS-NCCAM Botanical Research Expert Panel.

The National Cancer Institute (NCI) funds more botanical research than any other NIH agency, with NCCAM funding the second-largest component. Cancer is the greatest area of focus, but substantial numbers of projects involve other diseases, including neurological, immune, infectious, and cardiovascular conditions.

The Expert Panel, which convened on April 29, 2013, addressed questions ranging from botanical research priorities for NIH to barriers to and incentives for interdisciplinary collaboration. The panel concluded that botanical research urgently needs methodological innovation and discussed the creation of a scientific "scaffold" that would provide investigators with improved access to materials, tools, and techniques. The panel emphasized the need to encourage further training in this field and recognized that the traditional use of botanical materials can help guide future research. The panel also recognized that botanicals may play a role in health maintenance, as well as in the treatment and prevention of disease.

The panel's next steps are to move forward as quickly as possible in identifying areas where resources can best be used. The concept clearance for the Botanical Research Centers is one part of this process, but other implementation mechanisms will also be considered.

Speaking by telephone, Dr. Steven DeKosky, who chaired the panel, reported that the panel's meeting had provided opportunities for frank and informative discussion and that he was more than satisfied with the panel's accomplishments. Dr. David Kingston, who also served on the panel, explained that panel members emphasized the importance of safety. He also expressed agreement with the panel's emphasis on the need for increased training. With large pharmaceutical companies deemphasizing natural products research in recent years, training opportunities have diminished, and new ones are needed.

Dr. Lynda Powell raised the issue of botanical synergy, and Dr. Briggs explained that NCCAM has supported some basic studies on this topic. However, studying complex mixtures is difficult, especially those that contain components also found in food. Dr. DeKosky explained that safety is the first priority for research, followed by mechanisms of action, and then by studies that determine whether botanicals are useful for particular purposes.

Dr. Barbara Sorkin, Director of the Botanical Centers Research Program at ODS, presented the concept for renewal of the Botanical Centers research initiative. Through this initiative, ODS and NCCAM propose to support cutting-edge research efforts, including:

- Improved approaches to product identification and characterization
- Elucidation of bioactivities and inter-component interactions
- Assessment of modulation of bioactivity by individual host differences.

The proposed initiative would include interdisciplinary, multiproject collaborations applying state-of-the-art approaches or developing new methodologies and would provide a suitable environment for training and contributing to a scientific scaffold for the botanical research community. If the concept is approved, a funding opportunity announcement would be published in late 2013, with submission of proposals in mid-2014. The initial funding plan would be brought back to Council in early 2015, allowing for continuity of funding if any current Centers successfully recomplete.

A motion to approve the concept was made, seconded, and passed unanimously with 15 votes.

VI. Council Working Group Report

NCCAM Deputy Director Dr. John (Jack) Killen, Jr. presented a report from an ad hoc working group that considered changes in the Center's name. The working group comprised Dr. Cherkin, Dr. Susan Folkman, Dr. Deborah Powell, Dr. Michener, and Dr. Gert Bronfort.

The working group agreed that the Center's current name does not accurately reflect its scientific agenda. The phrase "alternative medicine" means different things to different people and may imply use in place of proven therapy. Both "complementary" and "alternative" are usually defined in opposition to conventional medicine, which does not reflect current research on the

integration of practices of non-mainstream origin into comprehensive health care. The word “for” in the Center’s name may incorrectly imply advocacy for complementary approaches rather than scientific investigation of them.

The working group agreed that concerns about the Center’s name do not reflect a desire or need to alter the Center’s legislative mandate. Instead, possible name changes should be considered in the context of the larger challenge of communicating about the Center’s priorities and the current science in this field. The working group did not make a specific proposal for a name change at this time.

Discussion. Dr. Haldeman observed that internationally, what Americans refer to as complementary medicine is often described as traditional or natural healing and may be considered mainstream.

Alyssa Cotler, Director of NCCAM’s Office of Communications and Public Liaison, commented that the Center’s name is an easy target because it is highly visible. However, explaining the Center’s interests, priorities, and values to the research community is more important than changing its name. Communication should be the outward-facing element of all of the Center’s activities, and NCCAM must ensure that all its actions and words reflect its priorities.

Dr. Briggs added that in the year and a half since Ms. Cotler became the Center’s communications director, she has been reshaping NCCAM’s public message. NCCAM was one of the first NIH agencies to recognize the value of being NIH-branded. The Center’s goal is to make science and safety central to all its activities. Dr. Briggs asked Council members to provide feedback on NCCAM’s outreach materials.

Dr. Cherkin commented that adopting a new name might provide an opportunity to highlight NCCAM’s strategic priorities. Dr. Brian Berman said that this discussion is timely and important and has been going on for about 20 years. NCCAM has focused on individual modalities, but research in the field is evolving to focus on an integrated approach to care of the whole person. Dr. Berman said that any change in the Center’s name should reflect this newer focus.

VII. Pragmatic Trials and PRECIS Criteria: Rationale and Examples

Dr. Russell Glasgow, Deputy Director, Implementation Science, Division of Cancer Control and Population Sciences, NCI, described the benefits of pragmatic research and explained the key differences between pragmatic studies and traditional randomized clinical trials (RCTs).

Traditional RCTs are slow and expensive, and they rarely produce findings that are easily put into practice. Because RCTs study the efficacy of treatments delivered to carefully selected populations under ideal conditions, translating their findings to the real world is difficult. Despite the completion of thousands of RCTs every year, systematic reviews consistently find that evidence is insufficient to effectively inform clinical decisions.

Pragmatic studies take a different approach to the evaluation of treatments, comparing them under everyday clinical conditions, using a broad range of settings and participants. Pragmatic

approaches are being used within the HCS Research Collaboratory, a NIH Common Fund program co-chaired by NCCAM and NIMH. Treatments are typically compared with real-world alternatives rather than placebos. The goal is not to replace RCTs but to complement them by producing results that translate more rapidly and are more relevant to stakeholders. Pragmatic trials promote learning health care systems in which research influences practice and practice influences research.

Dr. Glasgow showed examples of the use of the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS), a tool that summarizes the extent to which a trial is pragmatic or explanatory on multiple dimensions. The use of this tool can help maximize transparency about the nature of a study.

Discussion. In response to questions, Dr. Glasgow explained that the rapid movement to electronic health records (EHR) is speeding recruitment for pragmatic trials and may eventually help with dissemination of study findings. Both RCTs and pragmatic trials have a significant place in clinical research, but it is important to maintain a broad perspective and use real-world data when available. Within NIH, views on pragmatic trials differ. One potential disadvantage of pragmatic trials is that they do not develop the large body of ancillary data and samples that come out of other large NIH trials.

Dr. Briggs noted that one of the goals of NIH's Health Care Systems Research Collaboratory, which she co-chairs, is to examine methodology for pragmatic trials, including how to obtain outcome data from EHR.

VIII. Update on Low-Back Pain Workshop

NCCAM Program Officer Dr. Partap Khalsa updated Council on the activities of the Research Task Force on Research Standards for Chronic Low Back Pain, which is sponsored by the NIH Pain Consortium and administratively led by NCCAM. The task force has held three face-to-face meetings and has developed a recommendation for a draft set of research standards, including:

- A definition of chronic low-back pain (cLBP)
- A subclassification of cLBP by impact and prognosis
- A minimum dataset that should be reported in all cLBP trials, including:
 - Data on demographics and history
 - A small number of physical examination findings
 - Answers to a 24-item questionnaire covering the behavioral, psychological, and psychosocial domains.

The task force is currently drafting a manuscript for publication in one or more pain journals. Feedback will be obtained from key Federal agencies before publication, and the new standards will be presented at meetings of scientific and professional societies. The task force hopes to obtain journal editors' agreement to require use of the standards in studies accepted for publication, as well as NIH's agreement to require their use in grant applications.

Discussion. In response to questions, Dr. Khalsa explained that the task force discussed patient phenotypes in detail but decided that the data were insufficient to include phenotyping in the minimal dataset at this time. The task force's work was limited to low-back pain, rather than including thoracic and neck pain, for practical reasons. Including the other areas would have made the establishment of standards more complex and difficult.

Dr. Cherkin commented that research cannot wait for clarification of phenotypes. Psychosocial factors are known to be the strongest predictors of outcome. Despite gaps in knowledge in some areas, including phenotyping, the research community needs to move forward and implement current knowledge about the relative effectiveness of treatments.

Dr. Briggs explained that the task force's recommendations are a work in progress. NIH moves gently when promoting standardization, but the proposed recommendations are a well-thought-out first step.

IX. Strategies for Improving Pain Measurements in the NCCAM Research Portfolio

Dr. Emmeline Edwards, Director of NCCAM's Division of Extramural Research, chaired a minisymposium on strategies for improving pain measurements. She explained that in the majority of NCCAM-funded studies related to pain, investigators use subjective measures and patient-recorded outcomes. Although these measures are valuable, NCCAM wants to encourage the use of objective measures as well. The speakers are investigators whose research involves the measurement of pain or correlates of pain using a variety of approaches.

Overview of Current Pain Scales

Dr. Khalsa presented an overview of current methods of assessing pain. He explained that pain is a complex perception, not a primary sensation like taste or smell. The International Association for the Study of Pain defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Both a sensory pathway and an emotional (affective) pathway are integral to pain perception. Regions of the brain consistently activated by pain include those involved in the affective components of all parts of life.

Assessment and management of pain often rely on a biopsychosocial model, in which the biological component includes the intensity and nature of pain; the psychological component includes distress and health beliefs; and the social component refers to the effect of pain on daily functioning. Different scales for measuring pain assess different aspects of the pain experience.

Classic patient-reported outcome scales assess pain intensity using verbal ratings, numeric pain ratings, or visual analogues. Scales for measuring the impact of pain on a person's ability to function are also available. However, the results obtained with the classic scales may differ from one scale to another, and some are disease- or condition-specific.

NIH's Patient Reported Outcomes Measurement Information System (PROMIS) was designed to overcome the limitations of previous patient-reported outcome scales. PROMIS is in the public

domain, and its scales can be used at no cost. PROMIS has item banks for many domains related to physical, mental, and social health, each of which includes questions that have been validated and normed to the U.S. population. PROMIS uses item response theory, which enables the use of small numbers of questions, and its items can be applied to any pain condition. PROMIS represents a major step forward in the assessment of pain.

Quantitative Sensory Testing

Dr. Joel Greenspan, Professor and Chair, Department of Neural and Pain Sciences, University of Maryland Dental School, described research on quantitative sensory testing (QST). QST involves the quantitative study of the relationship between stimuli and the perceptions they evoke. In QST, an objective phenomenon is measured as a surrogate for subjective experience. The surrogate may be a behavioral measure, a physiological measure, or in human studies, a verbal report. A key feature of QST is its quantitative aspect, which facilitates many types of research.

A variety of stimulation modalities can be used in QST studies of pain, including electrical, heat, cold, mechanical, chemical, and ischemic stimulation. Fundamental aspects of pain that can be assessed include pain thresholds, pain tolerance, and ratings of pain intensity.

QST can be used to quantitatively characterize the relationship between stimulus level and perceptual intensity. It can demonstrate alterations in pain in response to injury, such as allodynia (pain evoked by a stimulus that is not normally painful) and hyperalgesia (increased intensity of pain in response to a pain stimulus). The affective component of pain (i.e., its unpleasantness) can be assessed separately from pain intensity; studies that included both types of measures have shown that the unpleasantness/intensity relationship differs for different types of stimuli.

The German Neuropathic Pain Network has developed a set of standardized QST protocols specifically designed to identify sensory abnormalities associated with neuropathic pain. This set of protocols has been used around the world and allows for comparison of data sets from different studies.

Studies using QST have shown that pain intensity increases with repetitive stimulation, and that this effect may be stronger in women as compared with men and in people with chronic pain as compared with healthy individuals. Studies using QST have also demonstrated an effect called conditioned pain modulation, in which pain in one part of the body can inhibit pain in another area. Conditioned pain modulation appears to be reduced in people with various clinical pain conditions, perhaps reflecting a compromised endogenous pain system. As these examples illustrate, studies using QST have produced intriguing findings that may be relevant to clinical pain issues.

Brain Activity Correlates of Pain

Dr. Randy Gollub, Associate Professor in Psychiatry at Harvard Medical School, explained that imaging is producing tremendous advances in the study of pain. However, no single brain signature of pain has been identified.

Different neuroimaging modalities permit the detection of changes in the brain at many scales over time and space. The ability to image people multiple times during the course of a disease enables the assessment of alterations over time. Dr. Gollub's research emphasizes the use of functional magnetic resonance imaging (fMRI), but much work is also being done with other forms of imaging, including positron emission tomography, optical imaging, and electroencephalography.

fMRI does not examine neural activity directly. Instead, it detects changes in cerebral blood flow that are coupled to changes in neural activity. Aspects of the pain experience that can be studied with fMRI include ascending sensory input, cognitive evaluation, affective response, and modulation by treatment.

The patterns of change in brain activity detected by imaging are complex. Some regions of the brain become active during exposure to pain stimuli, while others simultaneously show decreased activity.

Imaging has been used to investigate a variety of aspects of pain; for example:

- Different regions of the brain show unique patterns of response to pain stimuli. Some show consistent increases or decreases in activity when the intensity of a pain stimulus increases, whereas others respond to the onset and end of a pain stimulus rather than the intensity of pain.
- Some of the responses in the brain produced when a person experiences pain also occur if the individual re-imagines previously experienced pain or observes someone else experiencing pain.
- Two different types of placebos—a placebo cream and sham acupuncture—produced different patterns of activity in the brain, indicating that the brain can modulate its experience of pain in multiple ways.
- Expectancy can influence both pain intensity ratings and the patterns seen on brain imaging.
- Some brain responses to experimental pain differ between people with chronic pain and healthy people.

Much current research uses structural MRI to try to identify structural correlates of functional changes in the brain produced by pain. This research is in an early stage of development. Results to date have been variable, and many brain regions seem to be involved.

In summary, neuroimaging has made and continues to make valuable contributions to understanding the neurobiology of pain. It is also contributing to the understanding of chronic pain disorders.

Behavioral Measures of Pain

Dr. Francis Keefe, Professor in Psychiatry and Behavioral Sciences at Duke University, defined pain behaviors as those behaviors that communicate to others the fact that pain is being experienced.

Researchers need to be aware that:

- Pain behavior can be measured in a reliable and valid fashion
- Instruments are available for use in both research and clinical settings
- Pain behavior assessments may be especially useful in populations where other measures of pain are hard to obtain
- Understanding how pain behavior links to controlling factors (e.g., emotions, coping, responses of significant others) can help elucidate the variability in adjustment to pain
- Assessments of pain behavior can be used to aid in treatment selection.

Dr. Keefe described four strategies for measuring pain behavior: direct observation, facial coding, observer ratings, and self-reports.

- **Direct observation.** Studies involving direct observation have identified five behaviors associated with pain—guarding, rubbing, bracing, grimacing, and sighing. Standardized observation of these behaviors can yield a quantitative measure of pain behavior, which correlates with the individual’s self-report of pain and is sensitive to changes in pain produced by treatment. Pain behavior assessed by direct observation has been found to predict disability; in particular, guarding predicts disability outcomes.
- **Facial coding.** Key facial features observed during pain include brow lowering, tightening of the orbital muscles around the eye, nose wrinkling/upper-lip raising, and eye closure. Coding of facial expressions can enable evaluation of pain in people with communication limitations (newborns, people with intellectual disabilities, older adults with dementia, and critically ill people who cannot communicate).
- **Observer ratings.** Observer rating scales are designed for use in clinical practice, especially in children and nonverbal adults, in whom pain is often underrecognized and undertreated. The patient performs a task likely to induce pain, and an observer (who may only have minimal training) rates observed behaviors on a rating scale. Rating scales can be adapted for parents to use to rate their child’s pain.
- **Self-reports.** Self-reports of pain behavior include checklists in which the patient rates the frequency of various behaviors such as changes in walking, distress, and seeking help. The NIH PROMIS pain behavior item bank may also be used. Self-reports of pain behavior are used extensively in psychosocial research studies and correlate with pain self-report measures and pain behavior observations.

Important directions for future research on pain behavior include longitudinal research to uncover how maladaptive pain behaviors develop and are maintained; further studies of how emotion and cognition affect pain behavior; studies to capture the dynamic interplay between pain behavior and the social environment; and research to rigorously test the effects of pain treatments on pain behavior.

Novel Technologies for Functional Assessments Associated With Pain

Dr. Julia Finkel, Chief of the Division of Pain Medicine at Children’s National Medical Center, described a system, used at her hospital, for objective pain diagnosis and rehabilitation monitoring through game play.

Unlike most current methods of assessing pain, which are subjective, intrusive, and inconsistent, the system at Children’s Hospital relies on patient motion and facial expression data, as well as thermography, to assess pain while children participate in video games that involve movement. Children are very willing to participate in the novel and interesting activities that are part of the system. For therapeutic use, games can be designed that implement physical therapy paradigms, forcing motions that enhance compliance. The system also has applications for occupational therapy; for example, games can be designed to enhance executive functioning. A biofeedback device, in the form of a heated waterbed with lights that change color in response to physiological changes, is also part of the system.

Clinical trials using this system are currently in progress. Algorithms are being developed to analyze the large amount of data collected. Comparative effectiveness trials, which compare therapy performed using the game system with standard therapy, are also under way. Current research also includes translation to a Web portal that can be used for physical therapy at home.

X. Public Comments and Adjournment

No public comments were offered.

The meeting adjourned at 4:00 p.m.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Martin Goldrosen, Ph.D.
Executive Secretary
National Advisory Council for
Complementary and Alternative
Medicine

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Chairperson
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