

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

**NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY
AND INTEGRATIVE HEALTH
MINUTES OF THE SIXTY-SIXTH MEETING
June 1, 2018**

NACCIH Members Present

Dr. Belinda Anderson, New York, NY
Dr. Martin Blaser, New York, NY
Dr. Alice Clark, University, MS
Dr. Lynn DeBar, Seattle, WA
Dr. Tracy Gaudet, Washington, DC²
Dr. Steven George, Durham, NC
Dr. Christine Goertz, Davenport, IA
Dr. Joel Greenspan, Baltimore, MD
Dr. Bin He, Pittsburg, PA
Dr. Patricia Herman, Santa Monica, CA
Dr. Susmita Kashikar-Zuck, Cincinnati, OH
Dr. Jean King, Worcester, MA¹
Dr. Helene Langevin, Boston, MA
Dr. John MacMillan, Santa Cruz, CA
Dr. Cynthia Price, Seattle, WA
Dr. Eric Schoomaker, Bethesda, MD²
Dr. Gloria Yeh, Boston, MD

¹Telephone

²Not Attending

Speakers

Dr. Christina Bethell, Baltimore, MD
Dr. Erica Sibinga, Baltimore, MD
Dr. Catherine Spong, Bethesda, MD

Federal Staff Present

Barbara Sorkin, ODS, NIH

Members of the Public:

Danita Byrd-Clark
Beth Clay
Mary Paine

I. Closed Session

The first portion of the sixty-sixth meeting of the National Advisory Council for Complementary and Integrative Health (NACCIH) 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 164 applications were assigned to NCCIH. 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 83 applications, requesting \$29,238,532 in total costs.

II. Open Session—Call to Order

The open session convened at 10:25 a.m. Dr. Partap Khalsa, NACCIH Executive Secretary, called the meeting to order. The minutes of the February 2018 Council meeting were approved unanimously.

III. NCCIH Director's Report

NCCIH Acting Director Dr. David Shurtleff welcomed the three new Council members, Drs. Belinda Anderson, John MacMillan, and Gloria Yeh. Dr. Magdalena Naylor has joined NCCIH as the new Clinical Director in the Division of Intramural Research. Other new staff include Dr. Pamela Jeter, scientific review officer in the Division of Extramural Activities, and Dr. Inna Belfer, program director in the Division of Extramural Research (DER). The DER is currently recruiting for a program director in behavioral science.

The FY 2018 budget included substantial increases for both the National Institutes of Health (NIH) as a whole and for NCCIH, which received a \$7.3 million increase over FY 2017. The Federal response to the opioid crisis continues to be a major discussion topic in Congress, with many committee hearings in both houses. Congress hopes to finalize the legislative package by August 2018.

In launching the HEAL (Helping to End Addiction Long-term) initiative, which will focus on research on both pain management and treatment of opioid use disorder, NIH specifically referenced NCCIH's work on nondrug therapies as a program to build upon. Specifics about the initiative and the allocation of the \$500 million Congress provided for this research should be announced in the next month.

Highlights of recent NCCIH-funded research include:

- An animal study from the intramural program showing that chronic pain downregulates opioid receptors, possibly explaining the poor efficacy of opioids in relieving chronic pain. The study also showed a correlation between the reduction in opioid receptors and anhedonia, which may help explain the comorbidity of chronic pain and depression.
- An innovative proof-of-concept study on the use of genetically engineered yeast to synthesize natural products.
- A report on the prevalence and drug treatment of plantar fasciitis, which may drive research on the development of nonpharmacologic treatments.
- A study from the intramural program demonstrating that pain is more than nociception, a concept that may help in understanding the potential role of mind and body approaches in pain management.

- A study demonstrating that tai chi is at least as effective as aerobic exercise in managing fibromyalgia symptoms.
- An intramural study of patients with sickle cell disease, some of whom continued to experience pain and remained on opioid therapy after haematopoietic stem cell transplant. Some factors that correlate with continued pain in this special population were identified.
- A report from the NIH workshop on music and the brain, in which NCCIH played a leading role. Dr. Shurtleff thanked Dr. Emmeline Edwards for her efforts on this project.

Secretary of Health and Human Services Alex Azar toured the NCCIH intramural facility during his visit to NIH on March 20. A roundtable on emotional well-being—an area that fills a gap for NCCIH—was held April 3–4. On April 26, NCCIH partnered with the National Institute on Alcohol Abuse and Alcoholism for a well-received Twitter chat on addiction. NCCIH sponsored multiple symposia at the International Congress on Integrative Medicine and Health (ICIMH) meeting on May 9–11. NCCIH continues to play a leadership role in the NIH Health Care Systems Research Collaboratory, which held a steering committee meeting and workshop on May 14–16. The Centers for Advancing Research on Botanicals and Other Natural Products (CARBON) program held its annual meeting on May 21–22.

Upcoming NCCIH events include the final lecture in the Integrative Medicine Research Lecture Series for spring 2018, the launch of the HerbList™ app, and an NCCIH-sponsored satellite symposium on complementary approaches for chronic pain at the World Congress on Pain.

IV. Emotional Well-Being: New Direction for NCCIH Prevention Research Portfolio

Dr. Emmeline Edwards, Director of the Division of Extramural Research (DER), explained that the current strategic plans for both NIH and NCCIH highlight a new research direction—fostering health promotion and disease prevention. Research on emotional well-being fits well into this context.

NCCIH has been taking preliminary steps in this area by participating in meetings and workshops, and NCCIH sponsored its own workshop in August 2016 on mind and body approaches to improve children’s health. The role of complementary and integrative approaches in fostering healthy mental, emotional, and behavioral development will be one of the topics addressed in a National Academy of Sciences consensus report to be released next year. NCCIH has funded or cofunded prevention-related research on (1) spinal manipulation for preventing the transition from acute to chronic back pain, (2) engaging veterans seeking service connection payments in pain treatment, and (3) parent-focused prevention in pediatric primary care.

On April 3–4, 2018, NCCIH and the Office of Behavioral and Social Sciences Research, along with other NIH agencies, held a roundtable meeting, “Emotional Well-Being: Emerging Insights and Questions for Further Research,” chaired by Dr. Richard Davidson of the University of Wisconsin–Madison and Dr. Bruce McEwen of Rockefeller University. The discussion was framed around ongoing experiments that can serve as models of success, including those in which (1) a component of emotional well-being was explicitly identified as the intervention target, (2) a change in emotional well-being mediated a change in health, or (3) improvement of some aspect of emotional well-being itself was the desired outcome. Examples of strategies used to promote emotional well-being in these experiments included mindfulness practices, enhanced psychosocial supports, spiritual interventions, and meditative exercise.

Discussions at the workshop highlighted the many gaps in the current understanding of emotional well-being, its relationship to health outcomes, the optimal timing of interventions, and the populations most likely to benefit. Key recommendations from the workshop included (1) focusing on mediators of

emotional well-being, (2) remembering the importance of culture and context when developing interventions to promote emotional well-being, (3) possibly deconstructing some of the components of emotional well-being to enable better understanding of mechanisms (although not all workshop participants agreed with this approach), and (4) developing better definitions and measures of interpersonal and social processes (e.g., social bonding, connectedness) and concepts such as purpose and meaning. A full summary of the workshop is being prepared. The next steps will involve establishing a research network, and Council members' input is welcomed.

Discussion: Dr. Shurtleff said that involving other NIH institutes and centers (ICs) will be important. Dr. Christina Bethell of the Johns Hopkins Bloomberg School of Public Health, one of the speakers for the afternoon symposium on pediatrics, asked to what extent the dialogue related to the development of attachment. Dr. Edwards replied that one of the models of success was an intervention involving pregnant women, in which the impact on the child was assessed. In response to a question from Dr. Bethell about using behavior change to help adults, Dr. Edwards said that the challenge is to appropriately narrow the focus and set priorities for future research.

V. Concept Clearances

Career Development for Clinician-Scientists With Complementary and Integrative Health Clinical Degrees

Program Director Dr. Lanay Mudd presented this concept, which was developed in response to the 2015 report of the Council working group on Clinician-Scientist Workforce Development. The proposed initiative would leverage existing NIH-supported institutional career development programs to support additional research training opportunities, within an interdisciplinary environment, for clinicians with complementary and integrative health degrees. Trainees would conduct mentored research and could pursue a formal research degree program. They would have access to the resources associated with the existing career development program and opportunities to foster research partnerships.

Discussion: Dr. Shurtleff commented that this initiative is an important piece of the puzzle of getting more clinicians into the research pipeline. Dr. Anderson explained that the shrinking funding going to complementary and integrative health institutions is reducing their research culture. She said that developing a relationship between these institutions and recipients of funding awards would be helpful. In response to a question from Dr. Langevin, NCCIH Acting Deputy Director Dr. Wendy Weber explained that new slots would be added to existing programs. Dr. Shurtleff added that the initiative would capitalize on existing, well-established programs at research-intensive institutions and that outreach to appropriate clinical trainees will be needed to make them aware of this opportunity. Dr. Goertz expressed support for the initiative but cautioned that if not managed carefully, it could result in a brain drain from complementary health institutions.

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

Center of Excellence for Natural Product Drug Interaction Research

Dr. Craig Hopp, Deputy Director of the DER, presented the concept for renewal of this Center of Excellence program. He noted that continued work on natural product drug interactions is needed because much of the information currently available is based on preclinical models, case studies, or purely hypothetical arguments. Even when statistically significant interactions are shown in humans, they may not be clinically relevant.

The current Center of Excellence, funded in 2015, has produced numerous publications about important factors to consider in studying pharmacokinetic interactions involving complex plant products and has created a comprehensive data repository other scientists can access directly. However, many unanswered questions remain. NCCIH proposes to continue the existing approach, with systematic *in vitro* and *in vivo* characterization of potential interactions and continued development of the data repository. The cooperative agreement mechanism would continue to be used to allow for close coordination between the Center of Excellence and NCCIH.

Discussion: Dr. Shurtleff explained that this is a research area NCCIH is building. In response to a question from Dr. MacMillan about working with the U.S. Food and Drug Administration (FDA), Dr. Hopp said that the FDA has clear guidance on drug–drug interactions, but natural product–drug interactions are more complex. Dr. Clark said that this is an area that has been an issue for a long time, and this Center of Excellence is a great start but only a start; better methods and tools are needed. She urged Council to support the concept. Dr. Blaser said that some interactions may be mediated by the microbiome, and this is an important area to consider. NCCIH may not necessarily want to require including the microbiome in the Center’s research but may want to encourage it. High-throughput approaches are being developed, but the involvement of the microbiome would ultimately need to be studied *in vivo*. Dr. MacMillan suggested having pilot grants to develop high-throughput approaches for evaluating interactions involving the microbiome.

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

The Science of Music Interventions—A Sound Health Initiative

Dr. Wen Chen, Acting Chief of the DER’s Basic and Mechanistic Research Branch, presented a proposal to support highly innovative two-phase basic and mechanistic studies on music interventions to address some of the recommendations resulting from the NIH workshop on music and the brain. Although the brain’s auditory cortex is the key region for processing many of the unique sound features of music, preliminary evidence suggests that brain regions involved in emotional regulation, reward, cognitive and motor function, other sensory functions such as pain, and regulation of internal bodily functions may also be activated during music listening or performance. These findings provide a theoretical premise to investigate the potential value of music interventions for various health conditions. Because of limited preexisting data in this area, projects funded under this initiative are likely to have a high-risk first phase, but the risk would be mitigated by the go/no-go criteria or milestones required for the transition to the second phase. The award would require partnerships and promote collaboration among basic, technological development, and clinical researchers and music therapists.

Discussion: In response to a question from Dr. He about whether the projects would use imaging tools, Dr. Chen said that the initiative would be open to many kinds of studies but that neuroimaging tools would likely be important to probe effects in the brain. Dr. Yeh expressed support for the initiative and explained that music interventions are already being used in clinical contexts for patients with injuries or illnesses affecting the brain. The science in this area is ripe for development, she said. Dr. Shurtleff commented that this is a very exciting area that allows the arts and science to come together. Dr. Price noted that music therapists were not pleased that they were excluded from a previous collaboration, so it’s a plus that they would be included in this initiative.

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

VI. Pediatric Complementary and Integrative Health

Introduction

Dr. Shurtleff introduced the panel on pediatrics, noting that the topics to be discussed fit in well with NCCIH's Strategic Plan and its emphasis on prevention. Congress has asked NIH to conduct and support research on children's health, and the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD) will lead a trans-NIH consortium to coordinate pediatric research across all of NIH. Dr. Weber will serve as NCCIH's representative to this group. In addition, pediatric pain was discussed during the development of the National Pain Strategy and Federal Pain Research Strategy, and a trans-NIH workshop on gaps and opportunities related to pediatric pain is being planned. Dr. Catherine Spong, one of the speakers here, is heading a task force on the effects of natural products in pregnant and nursing women. There is much activity in pediatric research at NIH, which makes it important for NCCIH to coordinate with other agencies and set priorities. Dr. Shurtleff asked for Council's input on priority setting. He then introduced NCCIH Lead Epidemiologist Dr. Richard Nahin, chair of the panel, who introduced the speakers.

NCCIH Pediatric Portfolio

Dr. Wendy Weber, Acting Deputy Director and Clinical Research Branch Chief at NCCIH, explained that across NIH, pediatric projects account for about 10 percent of the total budget. At NCCIH, they have accounted for 3 to 6 percent, and there is room to expand the pediatric portfolio. Much of NCCIH's past pediatric research has focused on probiotics and other natural products. More recently, however, an increasing amount of pediatric mind and body research has been funded, and this fits in well with the Strategic Plan's focus on health promotion and disease prevention.

Challenges in pediatric mind and body research include the need to adapt interventions developed for adults to make them appropriate for children or adolescents, poor understanding of the impact of mind and body interventions on the developing brain, a lack of knowledge about dose response for these interventions in children, and a lack of pediatric-trained providers to deliver interventions in research and clinical care settings. Challenges in pediatric research on natural products include special ethical considerations and regulatory requirements because children are a vulnerable population, possible differences in pharmacokinetics and safety between children and adults, a lack of knowledge about dose response, and the need to modify formulations to make them tolerable for young children (e.g., children may not be able to swallow pills, liquid formulations may have an unacceptable taste).

Challenges in conducting school-based trials include difficulties with consent, burdensome data collection, and sample size issues due to cluster randomization. Challenges with traditional clinic-based trials include difficulty scheduling visits with busy families and the need for child care for the participant and siblings while parents complete study visit requirements.

Despite these challenges, pediatric research is valuable because it provides the opportunity to intervene early before symptoms such as pain become chronic. It also may provide opportunities to prevent long-term conditions that often begin in adolescence, such as depression, anxiety, and substance use disorders.

NCCIH's future plans for pediatric research include (1) outreach to promote pediatric prevention research using existing NCCIH clinical trial funding opportunity announcements, (2) working with other

ICs to plan a trans-NIH pediatric pain workshop, and (3) participating in the new trans-NIH pediatrics research consortium.

Pediatric Research at NIH, and NICHD Research on Complementary and Alternative Therapies

NICHD Deputy Director Dr. Catherine Spong explained that only 18 percent of NIH pediatric research is funded by NICHD. Most of the ICs have some involvement with pediatrics, and the agencies need to work together. NIH pediatric research is highly collaborative, with many formal interagency collaborations on specific pediatric topics. An overall trans-NIH pediatric research consortium is being started. Its goals are to harmonize efforts in child health research across the ICs, identify gaps and opportunities for cooperation, enhance NIH's communication with advocacy groups and Congress, encourage senior pediatric researchers to serve on review panels, and support training to grow the pediatric research workforce.

NICHD's mission involves studying human development beginning at conception. The NICHD research portfolio includes studies of complementary and integrative health approaches as well as research on other types of nonpharmacologic, nonsurgical interventions such as human-animal interaction, exercise interventions, lifestyle changes, physical and occupational therapy, and psychological and behavioral therapies. Research topics have included the role of dietary supplements in preventing birth defects; dietary supplements, probiotics, or mind and body practices for various conditions in children; and the use of complementary and integrative approaches in reproductive health, rehabilitation, and pregnancy and lactation.

A task force on research specific to pregnant women and lactating women was established by Congress in December 2016 as part of the 21st Century Cures Act. The task force decided to focus on therapeutic products—including dietary supplements—used by these women. The task force will recommend that women who are pregnant or lactating be included in studies of the safety, effectiveness, and dosing of these products rather than being excluded, as has often been the case in past research. In general, research on many aspects of pregnancy and lactation is limited. For example, remarkably little research has been done on therapies for nausea and vomiting in pregnancy or low milk supply.

A new NIH project called PregSource is using crowdsourcing to define typical pregnancy. Pregnant women can provide information about their experiences in real time by completing questionnaires, and the data will be used to build a more complete picture of normal pregnancy and develop ways to improve health care for pregnant women. Additional questionnaires on postpartum experiences and infant health up to 36 months are planned.

Complementary and Alternative Medicine Use Among U.S. Children and Youth: Prevalence and Key Associations With Health Status and Conventional Care and Opportunities To Improve Population Health

Dr. Christina Bethell, Director of the Child and Adolescent Health Measurement Initiative (CAHMI) at the Johns Hopkins Bloomberg School of Public Health, explained that CAHMI has been working with NCCIH to assess the use and impact of complementary medicine and conventional care among U.S. children. Its mission includes working with stakeholders to specify child and adolescent complementary/integrative health services research priorities; producing peer-reviewed publications from survey data; and developing a series of epidemiologic profiles of complementary health use among specific groups of U.S. children (e.g., children with emotional, mental, or behavioral conditions; children with pain-related conditions).

Five population-based surveys, most recently the 2016 National Survey of Children's Health (NSCH), provide data on children's use of complementary health care. Approximately 4.7 million children (6.4 percent) use such approaches, with the proportion varying substantially among states, from 2.1 percent in Louisiana to 15.1 percent in North Dakota. Most children who use complementary approaches have a chronic condition. The 2016 NSCH showed that the prevalence of use in children with special health care needs (CSHCN) varied with the complexity of their needs; 12.6 percent of those with more complex needs used complementary approaches, as compared to 6.5 percent of those with less complex needs. Only 5.4 percent of those without CSHCN used complementary approaches. Other data show that children with a greater number of chronic conditions are more likely to use complementary approaches, especially biologically based therapies and mind and body therapies.

Notable patterns in the data on children's use of complementary approaches include (1) lower use of mind and body approaches by boys than girls; (2) lower use of mind and body approaches in the South compared to other regions; and (3) greater use of complementary approaches by children with a larger number of conventional health care visits per year, those who lack a medical home, and those with delays in obtaining conventional care. About 46 percent of parents of children with chronic conditions who use complementary approaches did not tell the child's conventional health care providers about their use.

Dr. Bethell said that there is a need and opportunity to leverage integrative methods to improve population health, for example to address toxic stress in children and improve resilience. Therapies that could help children overcome emotional and behavior problems, including mind and body approaches, are currently underutilized.

Behavioral Therapies for Management of Chronic Pediatric Pain Disorders

Council member Dr. Susmita Kashikar-Zuck, who leads the pediatric chronic pain research program at Cincinnati Children's Hospital Medical Center, explained that pediatric pain disorders—most commonly headache, functional abdominal pain, or localized or widespread musculoskeletal pain—affect about 20 percent of school-age children, many of whom will continue to have symptoms in adulthood. Early treatment of chronic pain in childhood may prevent long-term pain and disability. Among nonpharmacologic approaches for pediatric pain conditions, behavioral approaches and cognitive-behavioral therapy (CBT) have been the best studied, and the evidence for their value is strong. CBT for pediatric pain focuses on coping skills training and involves the parents as well as the child. There is evidence that psychological therapies are effective in reducing pain in pediatric headache and other pediatric pain conditions.

In a CBT trial in juvenile fibromyalgia led by Dr. Kashikar-Zuck, both specific and nonspecific effects of treatment were observed, and disability tended to improve before pain. Children who received CBT continued to improve over time—a pattern also observed in other CBT research, such as a trial in chronic pediatric migraine. Recent studies on CBT for chronic pain conditions in children have started to assess the addition of other techniques, such as mindfulness-based stress reduction and biofeedback-assisted relaxation, to the CBT treatment program. In Dr. Kashikar-Zuck's research on adolescents with fibromyalgia, neuromuscular exercise training and CBT are being integrated into an overall program, which is being evaluated in comparison with CBT alone and graded aerobic exercise alone.

Research has shown that acupuncture is safe and well-accepted in children and that yoga is generally beneficial in children with pain. Little research has been done on chiropractic care and massage therapy for pediatric pain. In general, the quality of trials of complementary approaches for pediatric pain has been low, so further study is needed. Research is also needed to clarify which children are at risk for

pediatric pain and for poorer long-term outcomes; current evidence indicates that emotional distress, social isolation, and family factors may be important predictors. Mechanistic neurobiologic studies are also an important research priority because they may show whether pain pathways in the developing nervous system can be rewired to reverse the course of chronic pain and disability.

Discussion of Opportunities and Gaps

Dr. Erica Sibinga, associate professor of pediatrics at Johns Hopkins University School of Medicine, moderated the discussion. She highlighted key points from the presentations, including the importance of ensuring that research is appropriate for children's developmental stages and the opportunity to educate young people to engage in their own health care, including pain management. She said that opportunities for research include finding ways to mitigate the negative effects of toxic stress and adverse childhood experiences on children's development; improving the rigor of research on conditions for which complementary approaches are frequently used and medical treatment is inadequate, such as autism; and developing a better understanding of the mechanisms of action of complementary approaches and how they relate to a child's development. She pointed out the importance of recognizing that some populations may not have access to integrative therapies, and she noted that interventions in childhood can have a positive impact for the rest of an individual's life.

Dr. Blaser asked whether comparisons have been made between direct breastfeeding and the feeding of pumped breast milk. Dr. Spong said that NICHD is not currently studying this topic, but that there is a trans-NIH task force on nutrition that focuses on understanding breast milk and breastfeeding. Dr. Blaser asked whether NIH supports its own employees who breastfeed, and Dr. Spong replied that the extent of support has increased over time. NIH now has lactation support on campus, and many buildings have designated rooms for breastfeeding or pumping.

Dr. Goertz asked about the extent of NIH's involvement in dissemination science. Dr. Spong said that this differs across ICs. Some have public health campaigns, such as NICHD's focus on safe sleep environments for infants.

Dr. Langevin suggested that research on nonpharmacologic pain management could take advantage of experience gained in managing childbirth without drugs. Dr. Spong said that one current area of concern is the impact of opioid medication given after childbirth; for example, opioids are often prescribed for women who have given birth by caesarean section.

Dr. Shurtleff noted that research in children and in pregnant or lactating women poses special challenges and asked whether there is a role for observational studies. Dr. Spong said that observational studies can be useful, but clinical trials are also possible. Dr. Bethell added that there are large gaps in knowledge where observational studies, including those using citizen science methodologies, can be valuable and can provide preliminary data that could eventually lead to a randomized trial. Dr. Sibinga cautioned that one challenge in observational studies is distinguishing a child's actual experience from the interests of parents or teachers who may report on the child's experience.

Dr. Nahin asked about the most appropriate outcome measure in pediatric pain studies. Dr. Kashikar-Zuck explained that self-report is still the gold standard, and it can be used with verbal children at ages as young as 4 years. She also noted that pediatric clinical trials are expensive because it is usually necessary to conduct them at multiple sites. Even for relatively common conditions, it is hard to recruit enough study participants at a single location.

Dr. DeBar asked whether the National Institute on Drug Abuse (NIDA) is involved in research on nonpharmacologic approaches because of concerns about opioids. Dr. Shurtleff explained that this is an overlap area for NCCIH and NIDA but that generally, NIDA is more interested in pharmacologic approaches. Nevertheless, there are opportunities for NCCIH and NIDA to work together, especially in the context of the HEAL initiative. Dr. DeBar also commented that when she did trials that included yoga, she found that there was cultural variation in its acceptability to families. Dr. Sibinga said that it is important to emphasize the secular nature of mind and body interventions when working with families and to be aware of community concerns in this area. Dr. Bethell added that some people think of mind and body approaches as being for white people only, but if there is good science behind an approach, other population groups will accept it. Dr. Kashikar-Zuck said that in her research on mind and body interventions including CBT, an open-ended, participatory, patient- and family-centered approach has proven useful in enhancing acceptance of the interventions. Dr. Weber said that developing language to explain interventions to potential study participants and evaluating the acceptability of interventions should be part of the pilot and feasibility phase of research before a large-scale clinical trial is attempted.

Dr. Goertz said that for some types of interventions in children, such as chiropractic and massage, current knowledge is so inadequate that it isn't even possible to decide what to study. Creating a registry of data on what's happening in clinical practice and then using the registry data to develop research questions could be a good way to start work on such topics. She recommended that NCCIH consider developing funding opportunities of this type. Dr. Shurtleff agreed that this could be one way to move forward on some topics. Dr. Bethell added that observing practitioners and patients in their normal clinical settings can provide valuable information.

In response to a question from Dr. Kashikar-Zuck about whether complementary health practitioners have training in working with children, Dr. Goertz explained that all chiropractors learn some basic pediatric approaches and some have advanced training in pediatrics. Dr. Anderson said that acupuncturists generally receive only a little training in working with children, but some practitioners obtain extensive continuing education in this area.

Dr. Spong said that a literature search on the use of dietary supplements and nonprescribed therapies by pregnant or lactating women showed huge gaps in knowledge. Dr. Shurtleff said that the prevalence of use could be one area to emphasize. Dr. Spong explained that PregSource will provide some data, perhaps up to age 36 months for the child, and Dr. Shurtleff suggested that NCCIH might be able to work with NICHD to capture appropriate data from PregSource. Dr. Price said that with the current focus on prevention and on emotional well-being, studies of the long-term impact of postpartum depression on child development are important. Dr. Spong said that this is an area of interest to multiple ICs, but it is understudied.

Dr. Shurtleff thanked the panel and explained that pediatric issues would be brought back to Council for further consideration after discussion among NCCIH staff.

VII. Public Comment and Adjournment

Ms. Beth Clay, Director of Government Relations for the International Chiropractors Association (ICA), commented that there is a need for more research focused on the opioid epidemic, including research on chiropractic. She said that it is important to think about chiropractic care as a whole system of healing, not just a technique for pain management, and that there is a great need to focus on how chiropractic care can be used across the lifespan to improve well-being. Ms. Clay urged that chiropractic and other manual therapies be emphasized in the pediatric research portfolio, particularly for children with

developmental disabilities, autism, and other chronic conditions, and she explained that families of these children would be happy to participate in conversations about research. She said that the ICA is supportive of research to help these children.

The meeting was adjourned at 3:20 p.m.

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

Partap Khalsa, D.C., Ph.D., D.A.B.C.O.
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Complementary and Integrative
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