

The Integrative Health Policy Consortium (IHPC)

Response to the Draft 2016-2021 NCCIH Strategic Plan

The following comments respond in order to the primary objectives set forth by NCCIH in its Strategic Plan Draft. (<https://nccih.nih.gov/about/strategic-plans/2016>)

Objective 1: Advance Fundamental Science and Methods Development

Your reference to mechanistic research in the discussion of objective 1 misses the spirit of integrative health and medicine. Rather than focus on the molecular action of a particular intervention, we recommend you focus on real-world health outcomes. Comparative effectiveness research is a much more appropriate investigational method to evaluate complementary and integrative health approaches, with the results influencing health policy and clinical guidelines. With that said, we understand the value of investigating the mechanisms of a particular intervention – if completely understood, we can then combine it with other interventions synergizing the therapeutic impact. For example, if acupuncture increases the ability of the brain to bind to endogenous opioids, then using acupuncture in conjunction with exogenous opioids may provide more effective pain therapy, perhaps allowing for lower drug doses.

We appreciate your interest in furthering research in the gut microbiota, and use of pre- and probiotics, but do not believe that studying compounds isolated from natural products to be research dollars well-spent unless the natural products are in short supply or very expensive to harvest/process and transport. In that case, isolating the active therapeutic agents to be synthesized in the future could be of great value.

Objective 2: Improve Care for Hard-to-Manage Symptoms

This objective laudably targets conditions that have a large public health impact, and for which the majority of patients seek complementary and integrative health approaches. Furthermore, the decision to conduct pragmatic studies demonstrates a willingness to grapple with the complexities of how patients seek out and integrate their own care at the point of actual delivery. Under “Imaging and Neurotechnologies” you mention that they may “provide an improved means of measuring and understanding the neurologic circuits that underlie symptoms.” We recognize the all too common mistake of focusing on treating the symptoms alone rather than evaluating and eliminating the root causes. Managing symptoms may be necessary at times to alleviate immediate suffering, but

does not ultimately promote health and well-being. We recommend far less emphasis on symptom management and more emphasis on understanding the underlying factors inhibiting wellness, to include environmental factors, stress and diet.

We support NCCIH's strategy of continuing to fund preliminary studies to refine treatment interventions and research methods to conduct definitive clinical trials. In this regard we urge NCCIH to support multidisciplinary teams of investigators, including scientists and clinicians from complementary and integrative health and medicine disciplines to help best describe and apply the clinical practice nuances that arise in their actual clinical practices; which contribute to significant treatment outcomes. As we have previously commented, there is a strong need to fund clinical research that studies real-world clinical practice. We appreciate the increased emphasis on real-world CIH use as stated under Objective 2 in the context of pain, anxiety, and depression. IHPC's perspective comes from representing patients and practitioners using complementary health approaches in the real world. Most of the complementary and integrative health delivered in the United States and received by Americans takes place in the small practices of CIH-trained clinicians who have little, if any, interface with academic research institutions. While this is not convenient to your researcher teams, it doesn't diminish the importance of these clinics as the real-world laboratory in which health and healing occur daily. Support of practice-based research networks, community-based participatory research, IT-supported pragmatic trials, and observational studies would all be appropriate ways to study these real-world settings.

Another resource that may be valuable in meeting the goal of real-world research are teaching clinics found in schools of the non-pharmacologic specialties such as acupuncture, chiropractic and naturopathic medicine. There are, for example, over 60 accredited acupuncture/Chinese medicine schools in the U.S. and they virtually all have teaching clinics that could provide a rich resource for these types of studies.

We hope this positive shift in methodology extends beyond CIH for symptoms and also invites investigation into CIH for conditions of public health significance such as cardiovascular disease, diabetes, and cancer. However, in order for these methods to be successfully reviewed, culture change and training are required within NCCIH to increase the understanding and valuation of the benefit public health can reap from CIH approaches.

IHPC wholeheartedly supports NCCIH's plans to conduct both efficacy and pragmatic effectiveness studies that will provide practical answers. Embedding scientific data collection methods in health delivery organizations is becoming more feasible, and innovative efforts like the NIH Health Care Systems Research Collaboratory has excellent potential. (We note that Dr. Briggs is a co-leader of this program, and hope that her role

will be fruitful to NCCIH's goals.) Deploying such resources similar to those being developed by PCORI (eg, PCORnet), and plumbing condition-specific patient registries being developed by many disciplines could prove to be very cost-effective from a research investment perspective.

NCCIH should not, however, ignore the inconvenient fact that many complementary and integrative approaches are not yet available in the great majority of mainstream health delivery systems. For example, Doctors of Chiropractic are only minimally represented in the VHA and DoD systems, and have virtually no visible presence in patient-centered medical homes and accountable care organizations. The same is true for other so-called complementary licensed disciplines. Consequently, additional challenges will need to be surmounted to provide fair evaluations of how these approaches can appropriately benefit "real world" patients in "real world" settings. In order to meet this strategic goal, NCCIH will need to become immersed in policy matters that have traditionally kept these non-medical disciplines generally limited to small individual practices. Providing incentives to health delivery organizations to include complementary and integrative approaches will be necessary.

Nonpharmacological Management of Pain

This is an outstanding scientific priority, but the omission of biomechanical and physical medicine interventions such as massage and spinal manipulation, is conspicuous. These should be explicitly listed as a bullet as promising for their impact on pain. IHPC is working closely with the State Pain Policy Advocacy Network as well as the American Academy of Pain Management in an effort to promote nonpharmacological approaches to acute and long-term pain. NCCIH can provide valuable information related to best practices in pain management.

Objective 3: Foster Health Promotion and Disease Prevention

IHPC strongly supports the inclusion of Objective 3 as part of your strategic plan. While the language identifies complementary health approaches, we hope it also examines the role of complementary health **practitioners** as agents of change. We also recognize the importance of health and well-being within the hands of the individual. Research into this area will support access to information by the individual to make informed decisions about their lifestyle choices, health behaviors, and self-care. Research and surveys indicate that individuals who made positive lifestyle choices have subjectively experienced improved health. The focus of NCCIH in this area shows respect for the capability of people to recognize the effectiveness of complementary health approaches

and to take control and personal responsibility for their wellness, as well as disease prevention.

While resiliency is the chosen outcome for NCCIH research, we suggest that a systems approach be included as well. This is substantiated by the NCCIH observation in the Strategic Plan that complementary health approaches are used more often for wellness goals than for treating a specific illness. Wellness is the result of complex, interactional processes and needs to be approached from a “whole person” view. Most CIH practices reflect this view and require non-traditional research methodologies that preserve the integrity of the discipline.

Exploring the demographics and behaviors of CIH users is an important goal. However, using this information to target and influence adherence to conventional practices, such as standardized immunizations and medical screenings, is not appropriate. Scientific inquiry should objectively address comparative outcomes for all interventions and determine whether conventional practices actually contribute to improved health or just temporary symptom management. Individuals should be well-informed to make their own decisions about treatments and practices that enhance their health. The Strategic Plan states that this group of users is healthier, with healthier behaviors. If research into complementary and integrative practices shows improved resilience to infection and disease, then an investigation into the need for standardized mass immunizations and screening procedures may be necessary. Research may identify a more individualized and targeted use for these public health efforts.

We are very excited that NCCIH has included health and wellness strategies that focus on reaching diverse and traditionally underserved and vulnerable populations. A paradigm shift away from disease management towards wellness and health promotion in non-clinical settings is critical for reaching these populations. Programs emphasizing complementary health approaches to health and wellness are perfect for delivery in non-clinical settings as well as clinical settings. It is important to bring health and wellness messages and affordable programs to people where they spend their time; at work, in faith communities, at cultural center activities, etc. We support enhancing programs to reach people where they are, both physically and philosophically. The majority of people do not have the time and/or resources to travel to a specific place for a program that may or may not meet their needs. It is also important to ensure that health and wellness programs are culturally sensitive and tailored to reach and effectively communicate to a wide range of diverse populations. Data gathered from methodologies used in non-clinical, “real world” settings will enhance the ability to compare program reach and effectiveness across a variety of environments and to identify promising and best practices.

A valuable research area would be to investigate 5,000+ healthy octogenarians and collate what they have in common: Jogging, close relationships with their family, active social lives, religion/spirituality, intellectual pursuits such as reading or playing chess, yoga, diet, vitamin and mineral supplementation, etc.

Objective 4: Enhance the Complementary and Integrative Health Research Workforce

We applaud the return of a strategic priority addressing the importance of developing research capacity and investment in our future investigators. We appreciate the specific consideration of clinician-scientists with CIH degrees in the Workforce Development Working Group Report. We hope this prioritization will be paralleled with a higher proportion of clinician-scientists on review panels so that the efforts to enhance this domain of the workforce isn't thwarted by review emphasizing PhD basic science.

One potential way to effectively collect data from small practice environments would be to provide research literacy training to interested practitioners in conjunction with a cloud-based collection tool to study specific conditions or general health outcomes.

Objective 5: Disseminate Objective Evidence-based Information on Complementary and Integrative Health Interventions

We wholeheartedly support this objective in theory. However, NCCIH produced a total of thirty-five press releases between 2012 and 2016; none of which covered the effectiveness of acupuncture, massage therapy, naturopathic medicine, homeopathy, midwifery, or chiropractic care. We strongly advocate you include this information in future press releases. Hopefully your education strategy will begin with a review of the information (and mis-information) on NCCIH's website. We hope that the "presentation of evidence-base and safety and effectiveness information on complementary health interventions" is balanced with common sense context such that consumers are not discouraged from experimenting with things that are inherently safe and beneficial. For example, the risks and harms of mindfulness and the use of natural products are so small and the growing evidence base is so substantial that the majority of Americans should be encouraged to adopt mind-body techniques and use natural products rather than wait for further evidence.

When considering "evidence-based information" regarding CIH, a vital component that is conspicuously absent are studies investigating the cost of treating the side-effects of conventional care, especially drug therapy. Any analysis attempting to calculate the

cost-effectiveness of much safer therapies that comprise the bulk of CIH can only truly be found by calculating the costs of adverse events of the therapies being compared. Since drug companies historically do not fund such studies, it is imperative funding comes from special-interest free sources.

Special Comments

The IHPC respectfully requests for our records an estimate of NCCIH funding to CAM institutions over the past four years, both in total dollars and as a percentage of the total research budget.

Please note that IHPC's Partners for Health program is made up of non-profit educational and advocacy organizations across the CAM / conventional spectrum and includes such academic institutions as Bastyr University and Palmer College of Chiropractic, both of whom house research institutes dedicated to the continued advancement of natural health practices through research.

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