NCCIH Council Working Group

Strengthening Collaborations with the U.S. Department of Defense and U.S. Department of Veterans Affairs:

Effectiveness Research on Mind and Body Interventions

A National Advisory Council on Complementary and Integrative Health (NACCIH) Working Group Report

February 2015

DUKE UNIVERSITY MEDICAL CENTER
Department of Community and Family Medicine
Office of the Chairman

January 27, 2015

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Director
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Dear Dr. Briggs:

On behalf of the NACCIH Working Group, I am pleased to submit to you the report on the 2014 "Strengthening Collaborations with the U.S. Department of Defense and U.S. Department of Veterans Affairs: Effectiveness Research on Mind and Body Interventions". The report is the creation of the Working Group which was created at your request by the National Advisory Council on Complementary and Alternative Medicine in February, 2014. The report and recommendations reflect the unanimous view of the Working Group members and we take full responsibility for the contents. We remain available to meet with you and/or members of your staff to discuss our conclusions and recommendations.

The Working Group commends the Center's efforts to encourage research on complementary and integrative approaches for pain and symptom management in military personnel and veterans, and to collaborate with other NIH Institutes and federal agencies. Building on this base, the Working Group recommends that NCCIH now assess the feasibility of undertaking one or more large-scale studies in cooperation with the VA and the DoD/DHA to answer core policy and patient care questions about the use of integrative approaches in pain management.

Finally, on behalf of our entire Work Group, I would like to thank you for supporting the time and effort that NCCIH staff expended in order to prepare and organize information for our deliberation. Staff from throughout NCCIH were available and responsive. Special appreciation, however, goes to Kristen Huntley, PhD for her extraordinary effort in supporting this project.

Sincerely,

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Report of the Working Group on Strengthening Collaborations With the U.S. Department of Defense and U.S. Department of Veterans Affairs: Effectiveness Research on Mind and Body Interventions

National Center for Complementary and Integrative Health

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Executive Summary

The National Advisory Council on Complementary and Integrative Health (NACCIH) convened a working group to advise the full Council on the potential for development of a large-scale initiative to examine the effectiveness of mind and body practices in military and Veterans' health care settings. The working group was also asked to provide advice on strategies for collaboration with the Department of Defense (DoD) and Department of Veterans Affairs (VA) health systems and on implementation of any proposed initiatives.

The National Center for Complementary and Integrative Health (NCCIH), formerly the National Center for Complementary and Alternative Medicine (NCCAM), has used a phased approach over the past several years to promote research on complementary and integrative practices for pain and symptom management in military and Veteran populations. In cooperation with other agencies, NCCIH published several funding opportunity announcements in 2012–2014 for collaborative activities and relatively small-scale projects. The working group was convened to discuss potential future initiatives to build on these efforts.

The working group chose to focus on chronic pain. Chronic pain is a major societal problem, estimated to affect about 100 million U.S. adults, but it may disproportionately affect those who are serving or have served in the military. Data on the high prevalences of chronic pain and opioid use in the military and Veteran populations are alarming to policymakers. The current interest in the use of integrative approaches serves as an impetus to plan studies now so that widespread implementation of new interventions will benefit from concurrent research on outcomes. Pain research is a priority for NCCIH. About 30 percent of NCCIH's research budget is devoted to pain research, and the role of the brain in perceiving, modifying, and managing pain is the main emphasis of NCCIH's intramural research program.

The working group held five meetings that featured presentations from experts on pain research, study design, complementary and integrative approaches, and DoD and VA initiatives, practices, and priorities. Speakers also included a representative of a Veterans advocacy group and an Army Veteran who struggled with chronic pain after being injured during his service.

Presentations and discussions emphasized the strong commitment of the DoD and VA to pain research and improved management of pain and comorbid conditions, the ongoing shift toward an aspirational approach to health and healing, the role of innovative study designs in addition to individually randomized controlled trials, the value of pragmatic studies in real world settings where care is usually delivered, DoD and VA resources that could be leveraged for research, and the special considerations involved in working within a military environment.

Speakers agreed that, in general, pain is poorly managed, and better strategies are needed. Much emphasis was placed on concerns about opioids, which are widely used for chronic pain but lack compelling evidence for their effectiveness for chronic vs. acute pain and have risks

and side effects that may exceed benefits when opioids are used chronically. Working group members noted that the evidence of efficacy for complementary approaches for chronic pain is incomplete, and many studies suggest effects are modest; nonetheless, conventional techniques for managing chronic pain, including opioids and surgical and epidural interventions, also have limited efficacy. The balance of risk and benefit suggests that integrative approaches that utilize complementary techniques are promising and deserve more study.

Several speakers, including the patient and advocate, emphasized the importance of promptly translating research findings into clinical practice. However, implementing new approaches in a health care system is challenging. The VA and DoD settings, each of which has unique attributes, are settings in which innovative changes can be rigorously assessed. The development of a learning health care system, in which research is embedded into the delivery of care, is an important goal of many health policy leaders. It may help to overcome the translational challenges, but creating this type of system is not easy. Research and patient care were traditionally considered separate activities, and scientists who are now trying to bring them together have encountered a variety of challenges.

At the group's final meeting, the potential benefits of working cooperatively with the Defense Health Agency (DHA) to facilitate research were discussed. The DHA, now in its second year, is responsible for increasing the integration of health care provided by the individual armed services and may be interested in leveraging its resources for pain research. The DHA oversees shared services in enhanced multi-service markets (eMSMs), which include some of the largest military health care facilities, and has direct responsibility over military health care facilities in the National Capital Region. The involvement of the DHA in the proposed research initiative would be invaluable, but input from the health care leadership of all three armed services and the VA would also be needed for potential projects to be designed and implemented successfully.

Based on all these considerations, the working group recommends that NCCIH further assess the feasibility of undertaking one or more large-scale studies in cooperation with the VA and the DoD/DHA to answer important policy and patient care questions about the use of integrative approaches in pain management. The working group agreed that:

- The primary outcome measures should assess the impact of pain on patient function and quality of life, with changes in the use of opioids and other drugs as a secondary outcome.
- Instead of focusing on a single complementary modality, the research could focus on:
  - An integrated package of nonpharmacologic modalities that could be individualized;
  - An integrative model of care that could include complementary health approaches; and/or
  - A holistic or personalized approach to health care.
- Patients who are in the early stages of chronic pain may be the most appropriate population to study.

- Natural experiments and existing resources should be leveraged whenever possible.
- Studies should be pragmatic and research should be embedded in the delivery of care.

The proposed initiative could help the DoD and the VA achieve the goals presented in the DoD/VA *Pain Management Task Force Final Report* and recently outlined in the VA's *Blueprint for Excellence*. New knowledge gained through collaborative larger-scale studies may improve pain management in the general public as well as in military and Veteran populations.

Working Group Charge and Study Process

The Charge

The charge to the working group was to advise the National Advisory Council on Complementary and Integrative Health (NACCIH) on the potential for development of a large-scale initiative to examine the effectiveness of complementary health approaches, particularly mind and body practices, in military and Veterans' health care settings. The working group was also asked to provide advice on strategies for collaboration among the National Center for Complementary and Integrative Health (NCCIH), formerly the National Center for Complementary and Alternative Medicine (NCCAM),[*] and the Department of Defense (DoD) and Department of Veterans Affairs (VA) health systems and on implementation of any initiative that the group proposed.

The working group was asked to consider the following questions:

1. What are the current uses of mind and body practices in the DoD and VA, especially related to pain and symptom management?
2. What is the current evidence base for these practices?
3. What additional evidence would be useful in guiding decisionmaking for these practices by the DoD and VA?
4. What methods and resources, particularly information technology resources, would be needed for such studies?
5. Is there an opportunity for a large-scale initiative between NCCIH and the DoD and/or the VA to gather the needed evidence?
6. If so, how might we proceed?

The Process

During initial planning, the working group decided to focus on chronic pain. Chronic pain is a common health problem among U.S. Veterans. Recent research indicates that it is prevalent among active-duty military personnel as well—far more prevalent than in the general population. Research on nonpharmacologic approaches for pain management is a top priority for NCCIH. NCCIH is currently supporting a number of projects on the management of pain and comorbid conditions in military and Veteran populations, but these projects are relatively small.

The working group held five in-person meetings that featured presentations from experts on pain research, study design, complementary and integrative approaches, and DoD and VA initiatives, practices, and priorities.

[*] Congress recently changed the name of the National Center for Complementary and Alternative Medicine (NCCAM) to the National Center for Complementary and Integrative Health (NCCIH).

The purpose of the first meeting, held on June 5, 2014, was to describe the goals of the meetings and the charge to the group and to hear presentations on models of health care provision. Presentations and discussion focused on:

- The aspirational approach to health and healing, with an emphasis on the work of the Federal Health Futures Group, a cadre of aspirational and strategic thinkers from Federal agencies and the private sector who are working to develop ways to optimize U.S. health over a 20- to 30-year timeframe
- The concept of patient-centered medical homes and its applicability in the military and Veterans' health care settings
- Barriers and facilitators affecting research on integrative approaches in the DoD and VA systems
- Study design alternatives to randomized controlled trials.

Presentations and discussion at the second meeting, held on July 31, 2014, focused on:

- A current NCCIH-funded research project on improving opioid safety and pain management in Veterans by using collaborative care and decision support
- The objectives, emphases, and structure of the VA's research and development program
- The pain research portfolio of the Clinical and Rehabilitative Medicine Research Program in the U.S. Army Medical Research and Materiel Command.

Topics for the third meeting, held on August 28, 2014, were

- The Pain Assessment Screening Tool and Outcomes Registry (PASTOR), currently being tested at several DoD facilities, which incorporates elements of the National Institutes of Health (NIH)-developed Patient-Reported Outcomes Measurement Information System (PROMIS), as well as the Defense and Veterans Pain Rating Scale (DVPRS)
- Research on mindfulness training to promote resilience and cognitive enhancement, including studies in predeployment military personnel
- The continuum of pain care in the military and Veterans' health systems
- Priorities in VA pain research, including innovations in service delivery for complementary and integrative care.

Presentations at the fourth meeting, held on October 9, 2014, covered the following topics:

- Research questions important to military personnel and Veterans (with presentations by a representative of a Veterans' organization and a Veteran with chronic pain from service-related injuries)
- The power of big data for health system–based intervention and observational studies
- Military health system electronic health record and data usage
- Complementary and integrative approaches in the VA.

The remainder of the fourth meeting was devoted to synthesizing the working group's recommendations.

At the fifth meeting, held on December 22, 2014, NCCIH Program Director Dr. Kristen Huntley, the Designated Federal Official for the working group, reviewed the topics discussed by the group and preliminary recommendations the group had discussed so far. The group then heard presentations on:

- The activities of the Defense and Veterans Center for Integrative Pain Management (DVCIPM)
- The activities of the Defense Health Agency (DHA) Healthcare Operations Directorate.

General Introduction

The Problem of Pain in Military and Veteran Populations

Pain management is a significant public health issue for military and Veteran populations and more broadly throughout larger society.

About 100 million U.S. adults have chronic pain—more than the number affected by heart disease, diabetes, and cancer combined (IOM, 2011). Chronic pain is particularly common among active-duty military personnel and Veterans. A survey of postdeployment soldiers who were not seeking treatment found a 44-percent prevalence of chronic pain in this group, as compared to 26 percent in the general civilian population (Toblin et al., 2014). The use of opioids, which is of great concern because of the potential for abuse and overdose, was also higher in the military group than in the civilians: 15 percent versus 4 percent (Toblin et al., 2014).

Approximately half of aging Veterans report chronic pain. Pain is also common among younger Veterans who served in recent conflicts. Chronic pain in military personnel and Veterans often coexists with other health problems such as posttraumatic stress disorder (PTSD), substance use disorder, depression, anxiety, sleep disturbances, and persistent postconcussive symptoms. Among U.S. Veterans of Iraq and Afghanistan, mental health diagnoses, especially PTSD, are associated with an increased risk of receiving opioids for pain, high-risk opioid use (higher doses, early refills, or use along with sedative hypnotic drugs), and adverse clinical outcomes (such as opioid-linked accidents or overdoses) (Seal et al., 2012).

In a society with growing rates of chronic pain and opioid overuse, the disproportionate burden of chronic pain and comorbid conditions among military personnel and Veterans makes a compelling case for pragmatic studies and action now.

Mind and Body Practices and Pain Management

Although there is much interest in the potential role of complementary and integrative approaches in managing pain and comorbid conditions, the evidence for their efficacy is limited.

A 2014 Samueli Institute review of self-care complementary modalities (i.e., those not requiring the active involvement of a practitioner) noted a "disturbing paucity of high-quality studies that adhered to good study design and reported important features of a credible investigation such as the use of controls, attention to potentially biasing the outcome of the trial, and a focus on safety" (Schoomaker and Buckenmaier, 2014). The review gave weak recommendations in favor of using yoga, tai chi, and music for chronic pain but was unable to make recommendations on mindfulness/meditation, relaxation, qi gong, autogenic training, guided imagery, and several other modalities because of inadequate evidence (Jonas, 2014).

Experts have also reviewed the evidence on whether certain individual complementary modalities are helpful for chronic pain. One review found moderate evidence that mindfulness meditation programs could improve pain but no evidence that mantra-type meditation was helpful or that meditation was more effective than other techniques for managing pain (Goyal et al., 2014). A large meta-analysis found that acupuncture was more effective in reducing chronic pain than no-acupuncture controls and showed statistically significant, but small, differences between acupuncture and sham acupuncture (Vickers et al., 2012). The clinical relevance of these reported differences has been debated, and questions remain about whether the difference between acupuncture and sham acupuncture is clinically meaningful (Avins, 2012).

Clinical practice guidelines for treating pain conditions have noted the limitations of the evidence for complementary approaches. For example, the low-back pain guidelines from the American College of Physicians and the American Pain Society state that clinicians should consider nonpharmacologic therapy options, including complementary approaches such as spinal manipulation, acupuncture, massage therapy, yoga, or progressive relaxation, for patients who do not improve with self-care. However, this is a weak recommendation based on only moderate-quality evidence (Chou et al., 2007). Similarly, the American College of Rheumatology mentions tai chi and acupuncture in its nonpharmacologic recommendations for the management of knee osteoarthritis but gives both practices only a "conditional" recommendation (Hochberg et al., 2012).

Although better efficacy evidence on complementary approaches for chronic pain and comorbid conditions is needed, it is important to remember that the evidence supporting some conventional treatments, such as opioids, operative and surgical approaches, and epidural approaches, is not impressive, either. For example, opioids have not been shown to be superior to nonopioid pain relievers for treating chronic pain, and the risks of opioid use for treating chronic pain may exceed the benefits. In general, conventional care is doing a poor job of managing pain, and there is a need for other approaches.

Changing Perspectives on Health and Health Care

The challenge of improving the management of chronic pain in military and Veteran populations comes at a time when views of health, wellness, and health care are rapidly evolving. One important trend is a shift toward an aspirational approach to health and healing, in which patients' individual motivations become drivers for behaviors that improve health. Health involves the whole person, not just the patient role, and a clinical encounter that starts with the patient's chief aspiration rather than chief complaint can be game changing. The VA is currently working to develop clinical models that shift the conversation between health care providers and patients in this direction, and the Federal Health Futures Group has created an Aspirational Model that is designed to help groups develop strategies for this transition.

Another important current development is the increasing adoption of the concept of comprehensive health homes—a team-based health care delivery model that provides comprehensive care with the goal of achieving the best possible health outcomes.[†] The DoD has been working toward adopting the health home concept, and the VA has also been making shifts from a provider-driven model of health care delivery to a team-based model. The implementation of health homes involves major and sometimes difficult cultural changes, but some studies have suggested that when health homes are successfully put into place, they can outperform conventional health care delivery systems in terms of a variety of outcome measures. Also, interdisciplinary pain management programs, in which a patient receives coordinated care at the same facility from several health care providers (such as a physician, a psychologist, a physical therapist, and an occupational therapist), have been studied. These programs can be difficult to put into place but have shown favorable results (Eisenberg et al, 2012; Gatchel et al., 2014). Coordinated, patient-centered care programs for pain and comorbid conditions can include complementary approaches. These programs may be appropriate for patients who have multiple morbidities linked to suicide risk, such as pain, depression, PTSD, sleep disturbances, and/or substance use disorders (University of Wisconsin–Madison Integrative Medicine, 2014).

New perspectives are a key feature of the VA's September 21, 2014 *Blueprint for Excellence*, which calls for "a shift from sick care to health care in the broadest sense of the word" (Veterans Health Administration, 2014). Strategy Six of the *Blueprint* is to advance health care that is "personalized, proactive, and patient-driven, and engages and inspires Veterans to their highest possible level of health and well-being." The *Blueprint* acknowledges that this objective involves a paradigm shift. To reach its goals, the VA must be willing to "rethink the fundamental construct of health care and advance this new approach to health care for our Veterans, and for the country."

Research on Pain Management and Integrative Medicine at NCCIH, the DoD, and the VA

NCCIH

Pain is a major emphasis of NCCIH's extramural and intramural research programs. About 30 percent of NCCIH's research budget is devoted to pain research, and the role of the brain in perceiving, modifying, and managing pain is the main emphasis of NCCIH's intramural research.

[†] The concept of health homes (or patient-centered medical homes) does not refer to care provided in the patient's home. Instead, it is a team-based model of care in which care is provided primarily in a clinic or hospital-based setting.

At its June 2012 meeting, NCCIH's Advisory Council approved a concept on initiatives to stimulate research on the use of complementary and integrative approaches to pain and symptom management in military and Veteran populations. This concept was implemented in several phases. In FY 2012, NCCIH funded seven 1-year administrative supplements to existing grants to stimulate collaborations for future research in DoD or VA populations. In FY 2013, NCCIH published a funding opportunity announcement soliciting competitive revision applications to allow recipients of NCCIH research project (R01) grants to extend their research or analyses to DoD or VA settings or populations. Also in FY 2013, NCCIH participated in a National Institute on Drug Abuse (NIDA)-led initiative with the National Institute on Alcohol Abuse and Alcoholism and the DoD and funded two pilot research projects studying interventions to improve pain management and reduce substance use and abuse.

In September 2014, NCCIH, NIDA, and the VA announced that they were funding 13 research projects to explore nondrug approaches to managing pain and related health conditions among military personnel and Veterans. NCCIH is funding 11 of these projects, either alone or with the VA. Approaches to be investigated include mindfulness meditation, self-hypnosis, and bright light, as well as integrated or stepped-care programs that involve multiple modalities. Although the projects are varied and innovative, the scope of the research is relatively small; total funding for the 13 projects is approximately $21.7 million over 5 years.

The DoD

In August 2009, the DoD established a Pain Management Task Force to make recommendations for a comprehensive pain management strategy that is "holistic, multidisciplinary, and multimodal in its approach, utilizes state of the art/science modalities and technologies, and provides optimal quality of life for Soldiers and other patients with acute and chronic pain" (Pain Management Task Force, 2010). The Task Force's final report, issued in May 2010, called for incorporating integrative modalities into a patient-centered plan of care as part of an effort to build a spectrum of best practices, based on a foundation of the best available evidence (Pain Management Task Force, 2010).

The Task Force report has prompted new DoD projects to address its recommendations, including the development of a patient outcomes registry, which would be very useful in monitoring opioid use, and two complementary health studies: a tiered acupuncture training program and a clinical trial using yoga for musculoskeletal pain.

The DoD takes a pragmatic approach to complementary and integrative medicine and is interested in finding out what works. The Department has a broad pain portfolio and has a large investment in pain research.

The VA

Developing better ways to assess, manage, and treat chronic pain is a high priority for the VA research program. The VA accounts for 5.8 percent of the Interagency Pain Research Coordinating Committee Federal pain research portfolio.

Like the DoD, the VA is willing to support research on integrative approaches, as long as the scientific rigor of the studies is comparable to that of other types of research. The VA's complementary medicine portfolio includes research to determine efficacy and to understand the biological basis of action of complementary therapies. The VA is also interested in studying innovations in service delivery for complementary and integrative care. This involves capturing information about integrative care from electronic health records (EHRs), identifying effective incentives, and using health economics data to inform decision-making.

Research on complementary and integrative approaches, including both VA projects and those co-funded with NCCIH, is a component of the transformational actions called for in Strategy Seven of the VA's *Blueprint for Excellence.* The VA recognizes that complementary and integrative approaches can help empower Veterans to improve their own well-being, and this is one of the driving strategies behind VA research on these approaches.

The Veterans Health Administration (VHA) National Leadership Council has recognized the need to develop an infrastructure and operations to support a proactive, integrative approach to health and healing. In April 2014, the VHA Office of Patient Centered Care and Cultural Transformation was asked to create the VHA Integrative Health Coordinating Center (IHCC) to fill this need. In addition, the IHCC is partnering with VA Health Services Research and Development to expand related research, beginning with facilitators and barriers to the provision of integrative health in the VA. The IHCC has also prioritized implementation of integrative approaches to pain management.

Key Issues To Consider

Challenges to Research in Military and Veterans' Settings

Although the DoD and VA strongly support research, performing studies in military and Veterans' settings can be challenging. Research competes with the military operational mission, and health care providers may not have time to participate in studies; patient needs and clinic schedules are priorities. Like other large health care systems, the DoD and VA emphasize the provision of clinical care. Because the focus is on patients receiving treatment, there may be objections to study designs that involve randomly assigning patients to sham (placebo) groups.

Another challenge to research in the DoD setting is that personnel are highly mobile; by the time a research project is up and running, the health care providers and potential study participants who were present during the planning stages may have been transferred or

deployed. In the VA setting, mobility is less of a problem, but geographic variation may pose challenges; practice patterns in VA facilities are similar to those in surrounding communities and differ from one VA site to another. This variation may impact pain management and opioid use.

The lack of enthusiasm on the part of some military and Veterans' health care providers for nonpharmacologic approaches can be a barrier to both research and implementation. Providers' resistance to referring patients for complementary health approaches can pose challenges. The VA is taking steps to overcome these barriers by educating health care providers, support staff, and leadership about integrative approaches and how they can be incorporated into patient care. Such education can change the mindset of clinical staff so that they become more receptive to integrative approaches and can optimally use modalities with promising evidence of efficacy or effectiveness.

Implementing new approaches in any health care system can be a challenge. Even when sound evidence indicates a need for changes in patterns of care, such changes may be difficult to achieve in practice. However, as illustrated by the rapid adoption of the health home concept in the DoD and the VA, when a command decision is made, resistance to change may be less of a problem in military and Veterans' health care settings than in civilian health care systems.

Pain Research Questions That Are Important to Military Personnel and Veterans

At one of the working group meetings, a representative of a Veterans' organization and an Army Veteran who had struggled with chronic pain and opioid dependence addressed the group. They noted their impression that the findings from VA research on pain are often not translated to practice and that there have been breakdowns in the implementation of VA policies and guidelines for pain management. The military and Veteran populations want guidelines to be implemented and effectiveness of care to be assessed. In particular, they want to see efforts to control pain more effectively and to reduce risk of opioid dependence—which can have devastating effects on their quality of life. The patient representative expressed his opinion that Veterans do not want to be taking opioids for prolonged periods; they want to recover and move on with their lives.

The speakers told the working group that they think chronic pain patients would be better able to avoid drug dependence if they could access a pain specialist early and learn about other treatment options. It was also noted that these patients should have their drug use monitored proactively, with referrals to appropriate services if their pattern of use suggests a risk of dependence. Patient representatives also emphasized the importance of tracking patients' quality of life, which is affected by both pain and opioid use, as they go through treatment. Veterans also want to know whether they can obtain the same types of treatment at different geographic locations, whether they can continue to have contact with a pain specialist after

their first appointment, and whether they will actually be able to obtain the care that they and the specialist have agreed upon.

Examples of Current Research Projects

Current DoD or VA research projects on chronic pain and/or integrative approaches include the following:

- The DoD and VA are funding a 2-year project called Acupuncture Training Across Clinical Settings (ATACS). The mission of ATACS is to develop, pilot, evaluate, and implement a uniform, tiered acupuncture education and training program for DoD and VA providers to provide initial access to the auricular (ear) battlefield acupuncture technique and to expand its use across military and Veterans' treatment facilities.
- The Defense and Veterans Center for Integrative Pain Management (DVCIPM) and Northwestern University have developed PASTOR, a clinical decisionmaking tool that uses a 20-minute online survey to produce a report about a patient's chronic pain for clinical and research use. PASTOR incorporates the DVPRS, a screening tool for pain that assesses its impact on patient function, sleep, activity, mood, and stress, as well as the NIH-developed PROMIS outcomes measurement system. The PASTOR/PROMIS tool is now being evaluated at several military medical centers and has the potential to become a standard tool at all DoD facilities.
- Mindfulness training is being evaluated in predeployment soldiers as a method of protecting them against stress-related problems. Research has shown that long-form training (24 hours) protects against stress-induced degradation in working memory and mood, but only in those who practice mindfulness exercises outside of class. Current studies are evaluating shorter forms of training and train-the-trainer programs.
- The VA has conducted nine demonstration projects on meditation for PTSD and recently contracted with experts at the University of Rochester to review them. The evaluation showed that most of the meditation programs were well attended and had good rates of completion; that participants were generally satisfied with the programs; and that in general, participants showed clinically significant declines in PTSD symptoms from before to immediately after participation (Heffner et al., 2014).
- An NCCIH-funded study in a VA facility is focusing on improving opioid safety and pain management in Veterans by using collaborative care and decision support. The researchers are testing the acceptability, feasibility, and preliminary efficacy of a collaborative care intervention in which a care manager uses telephone motivational coaching to reinforce a pain care plan to improve pain management in primary care.

Complementary and Integrative Approaches in the VA and DoD

Strategy Seven in the VA's *Blueprint for Excellence*, which calls for the VHA to lead the Nation in research on and treatment of military service–related conditions, includes enhancing VA care with research on complementary and alternative medicine. Projects mentioned in the

Blueprint include newly funded VA studies on mindfulness-based therapies, as well as the studies on pain currently being conducted in partnership with NIH.

Various VA treatment programs for PTSD already incorporate a variety of complementary approaches. These include mindfulness, yoga, tai chi, qi gong, art or music therapy, hypnotherapy, biofeedback, or acupuncture, as well as other approaches (Libby et al., 2012).

In a 2014 report to Congress, the DoD reported that many military health care facilities are using complementary approaches, most commonly chiropractic or acupuncture. Some of the approaches used do not have formal evidence of safety and effectiveness; however, many of the sites offering the services evaluate them through patient assessment/feedback, qualitative assessment by the provider, pre- and post-appointment questionnaires, patient satisfaction questionnaires, and measurement of physical improvement (Department of Defense, 2014).

Can Research Be Embedded Into the Delivery of Care?

Many research organizations, including NIH and the Institute of Medicine (IOM), support the concept of a learning health care system, in which research is embedded into the delivery of care. In this type of system, data are collected every time a patient receives care; the system learns whether and how well the care worked; and whenever something is learned, it is applied.

Putting new knowledge into practice promptly is one of the transformational actions emphasized in Strategy Seven of the VA's *Blueprint for Excellence*. The *Blueprint* calls for rapidly translating research findings and evidence-based treatments into clinical practice, with the VA's Centers of Innovation facilitating collaboration among multidisciplinary research groups as well as engagement with clinical and operations partners.

Putting the concept of a learning health care system into practice is challenging. The EHRs currently in use are not uniform, and they were designed to meet business needs and facilitate patient care, not to support research. Many of the data collected in these records are not standardized and cannot be resolved into computable data with currently available techniques. The concept that research and patient care are separate activities that take place in different locations has led to the development of methods of research oversight that are poorly suited for research integrated into the clinical setting. Also, changes in usual patterns of care and institutional policies may not necessarily stop during a research project. For these and other reasons, research that is fully embedded into a health care system is challenging. Nevertheless, currently available data, such as diagnosis and procedure codes from EHRs and DoD billing records for prescription medications, could be incorporated into a research project. Future improvements in EHRs, such as inclusion of data on patient-reported outcomes, as recommended in the VA's *Blueprint for Excellence*, could further enhance the value of these records for research.

The VA has multiple freestanding databases, which are easy to use but do not necessarily have matched fields. The DoD has a central data repository for health records, but the repository

itself cannot be used for sophisticated analysis of data. Therefore, data that are to be queried for research purposes are copied into a data warehouse, where they are aggregated and de-identified, and where data extracts can be created to be shared with other agencies.

In its *Blueprint for Excellence,* Strategy Three, the VA emphasizes the potential benefits of increased interoperability between the VA and the DoD EHR systems. Bringing together data from the two systems could provide insight into the relationship between exposures during military service and later health outcomes and care needs. Efforts are already being made to combine DoD and VA EHRs, particularly at joint VA/DoD facilities such as the Captain James A. Lovell Federal Health Care Center in Chicago. The ultimate goal is a virtual lifetime electronic record that will seamlessly provide comprehensive information about a patient to all the health care providers that the patient sees, whether in the DoD, the VA, or the private sector.

Although linking the DoD and VA systems will not be easy, the advantages of doing so are clear. Linking DoD and VA data will allow military and Veterans health care providers to better understand the challenges faced by troops returning to civilian life and provide them with the highest quality of care.

Resources for Research

An important resource in the DoD is the Defense Health Agency (DHA), which was established in October 2013 and is responsible for driving greater integration of clinical and business processes in military health care. The DHA is working to bring together aspects of health care that were previously managed separately by the individual armed services. The main impetus for its creation was the cost of health care in the military. The DHA is mandated to find out how the military health system can be more efficient and effective without compromising the quality and safety of care or access to care.

The DHA oversees shared services and business plans in the military health care system's enhanced multi-service markets (eMSMs), which include some of the largest military health care facilities. The agency also has direct responsibility over military health care facilities in the National Capital Region. The DoD and the VA work closely together at some of the eMSM locations.

The DHA reportedly would like to leverage the eMSMs as pilot sites for new initiatives to help identify best practices that could be used across the military health system. The agency may be interested in fielding joint projects designed to improve ways of addressing chronic pain and comorbid conditions such as traumatic brain injury and PTSD.

Another valuable DoD resource is the DVCIPM, which is nested under the Uniformed Services University of the Health Sciences. This center spans all the armed services and works cooperatively with the VA. The DVCIPM's projects include PASTOR/PROMIS and joint DoD/VA efforts to develop a standardized pain management training curriculum and a

standardized acupuncture procedure. Another DVCIPM project, the Army's Interdisciplinary Pain Management Centers, might provide suitable settings for research.

A special resource for research in the VA system is the Million Veteran Program, an opt-in consented data repository and biorepository that seeks to support genomic and epidemiologic research. The repository has been enrolling for about 3 years; to date, almost 300,000 Veterans have completed baseline and lifestyle questionnaires and provided blood specimens, access to their records, and permission for analyses. This repository is already supporting studies of medical problems associated with deployment in the 1990–1991 Gulf War conflict and should prove very valuable for other studies as well.

As the capability for "big data" and predictive technologies improves, the need for a proactive approach to health care becomes ever more imperative. This information can create the opportunity for increased patient engagement, but the system must move beyond a predominantly reactive, disease-based model. The aspirational approach and the inclusion of more proactive therapies, such as many that are classified as complementary, can play a critical role for improving pain and symptom management as these technologies advance.

Study Design Considerations

During the working group's meetings, members and invited speakers emphasized the importance of finding out what natural experiments are in progress and what study designs could be used to take advantage of them. For example, a research component could be incorporated into a situation where a new intervention is being implemented on a staggered schedule at different locations, or geographic and facility-level variations in care at different facilities could be incorporated into a study design. Study designs other than individually randomized controlled trials, such as group-randomized trials, quasi-experimental designs, dynamic wait-list or stepped-wedge designs, and regression discontinuity designs, should be considered because they do not involve assigning individuals to placebo groups. Different types of study designs are appropriate at different stages of research. Quasi-experimental designs require only a few study sites and can provide preliminary evidence to plan efficacy studies. Group-randomized trials or regression discontinuity designs are appropriate for efficacy or effectiveness trials (Murray et al., 2010; Rhoda et al., 2011).

The choice of which patients to study is important. Given the current state of knowledge about integrative approaches, it may be unwise to focus on the most severe and intractable pain cases. Studies of patients with less severe and less prolonged chronic pain may be more appropriate. Working with this type of population would also enable researchers to avoid complexities in outcome assessment in patients with long-term opioid dependency. Studies of acute pain might also be worthwhile; improved approaches to the treatment of acute pain may decrease the likelihood that patients will develop chronic pain later.

The working group agreed that a potential initiative should not focus on a single complementary modality. Instead, they envisioned an intervention that would include a package of modalities and a specific method of service delivery. For example, an intervention might involve a personalized approach tailored to the patient's aspirations, in which various nonpharmacologic interventions, including some complementary practices, would be offered in a structured way, such as a stepped-care approach. In a stepped-care approach, self-care complementary modalities, such as yoga and meditation, could be offered along with conventional treatment in the early steps, with approaches that involve a practitioner, such as acupuncture or spinal manipulation, being used only if self-care modalities turn out to be inadequate. One of the small-scale studies currently being funded by the VA and NCCIH is collecting data from Veterans' EHRs to facilitate the assessment of stepped care for chronic pain.

Studies that involve both the DoD and the VA could be of particular value because the two agencies deal with the same people at different stages of their careers and lives. It might even be worthwhile to start with healthy military personnel and then track them through the DoD and VA health care systems. The data generated by tracking large numbers of people in this way could be used for multiple purposes.

Recommendations for Study Design and Project Structure

Study designs need to take into account the realities of the focus on provision of clinical care within DoD and VA settings, the high rate of migration of both patients and staff in the DoD, and the need to study sets of interventions, rather than single interventions alone. Design elements such as stepped-wedge and cluster randomization would be appropriate, as would alternatives to traditional randomized clinical trials, such as discontinuity analysis (Murray et al., 2010; Rhoda et al., 2011). Standardized recording and scoring systems for patient-reported symptoms and functional outcomes will be necessary. Such systems have already been developed and tested in civilian settings but have not been uniformly adopted in either the DoD or the VA.

A variety of structures for organizing and funding the new research initiative could be considered. One possibility is that NCCIH could fund a data coordinating center and collaborate with the DoD and/or VA on the design of the actual project(s).

For this research to be successful, the DoD, the VA, and NCCIH need to collaborate in offering integrative models of care and complementary therapies to military personnel and Veterans with chronic pain and evaluating the effectiveness of these models compared to current care. It may also be possible to collaborate with other NIH Institutes and Centers. For example, NIDA may wish to participate in aspects of potential research studies. Research opportunities should be offered to agencies and facilities in ways that are sensitive to their needs and priorities. For

example, rather than mandating site participation, it may be better to offer facilities the opportunity to take part in research on a concept that may become a requirement in the future.

The priorities outlined in the VA's *Blueprint for Excellence* in health care indicate that the VA would welcome opportunities to partner with NCCIH and other agencies on pain research projects. The initiative proposed here is consistent with the VA's objectives and should produce results that will help the VA achieve its goals.

A variety of possible projects could be considered. Two preliminary ideas were suggested by members of the working group: comparing integrative approaches to standard pharmacotherapy and evaluating the impact of changes in both the process and content of care. In addition, discussions at the final working group meeting included exploration of how NCCIH and the DHA might facilitate a joint NIH/DoD project with VA involvement. These three concepts are summarized in the next sections.

1. Comparing Integrative Approaches to Standard Pharmacotherapy

Can the DoD, the VA, and NCCIH collaborate on offering complementary therapies to military personnel and Veterans with chronic pain and evaluate the effectiveness of these therapies compared to traditional pharmacotherapy?

- For example, a study could be designed to assess whether providing a standard set of integrative medicine practices to primary care providers in DoD and VA settings, for patients requesting refills or escalating use of narcotics for chronic pain, leads to improved functional status for the patients, improved job satisfaction for the clinicians, and decreased opioid use/overuse compared to standard care.

    - The study population would be primary care providers in selected DoD and VA facilities located in the same community who manage significant numbers of chronic pain patients and have access to integrative medicine practitioners in the community.
    - The study could have a cluster randomization or stepped-wedge design, with an intervention that includes the following components: patient education in integrative medicine for chronic pain; provider training in alternatives to narcotics; and use of available integrative practices.
    - In the model of care to be studied, patients' aspirational goals could be used to develop a patient-centered pain care plan.
    - Outcome variables could include patient-reported functional status and pain levels; use of integrative approaches in each practice; total daily use of opioids; emergency room visits for opioid overdose; and, if feasible, rates of depression, suicidal ideation, and suicide.

- As a variant of the design described above, intervention sites with the highest and lowest opioid prescription rates could be selected, with the former receiving the intervention and

the latter serving as controls. This would provide a pragmatic test of whether the model will work in the most adverse setting.

2. Evaluating Process and Content Changes

There is interest in changing both the content and process of health care to more inclusive, patient-oriented models, particularly within the VA system. "Content" refers to the types of care offered, including integrative practices. "Process" refers to the context in which care is offered, which may involve a shift toward an individualized focus on what matters most to the patient.

To determine whether each of these changes contributes to improved outcomes, a study could be conducted using a 2 × 2 factorial design in which some groups of patients would receive two types of interventions (i.e., changes in both process and content), some would receive process innovations only, some would receive content innovations only, and some would receive usual care. The results would help health care providers and policymakers determine the extent to which each of the two types of change contributes to improved health care.

3. Working With the DHA To Facilitate Collaborative Larger-Scale Research Studies

At the working group's final meeting, the possibility of NIH working with the DHA to facilitate a joint project was discussed. Because the DHA spans all the armed services and coordinates with the VA, its leaders could bring together the people and resources needed to carry out a project in which integrative approaches to pain management would be evaluated in settings in which military personnel and Veterans normally receive care.

Because DoD health care facilities in the National Capital Region are under direct DHA control, they could be an appropriate location for a pilot project to determine whether the integrative interventions chosen for study are feasible on a large scale. If the pilot is successful, evaluation of the effectiveness of the interventions could then expand to additional military health care facilities, particularly the eMSMs, with comparison data being collected at other facilities that offer standard care. Because some of the eMSMs are in locations where the DoD and VA provide services cooperatively, both active duty personnel and Veterans could be included in research at these locations. At other locations, where DoD and VA facilities are administratively and geographically more separate, parallel studies of military personnel and Veterans may be more practical. The potential involvement of the DHA in the proposed research initiative is invaluable, but input from the health care leadership of all three armed services and the VA would also be needed for potential projects to be designed and implemented successfully.

Conclusions

The working group recommends that NCCIH further assess the feasibility of undertaking one or more large-scale studies in cooperation with the VA and the DoD DHA to answer important policy and patient care questions about the use of integrative approaches in pain management. With conflicts in Iraq and Afghanistan winding down and increasing numbers of military personnel and Veterans suffering from chronic pain, developing effective treatment approaches is a high priority. The alarming evidence about the high rates of chronic pain and opioid use in active-duty military personnel and Veterans provides a strong impetus for action.

The working group agreed that:

- The primary outcome measures should assess the impact of pain on patient function and quality of life, with changes in the use of opioids and other drugs as a secondary outcome.
- Instead of focusing on a single complementary modality, the research could focus on:
  - An integrated package of nonpharmacologic modalities that could be individualized;
  - An integrative model of care that could include complementary health approaches; and/or
  - A holistic or personalized approach to health care.
- Patients who are in the early stages of chronic pain may be the most appropriate population to study.
- Natural experiments and existing resources should be leveraged whenever possible.
- Studies should be pragmatic and research should be embedded in the delivery of care.

The proposed initiative could help the DoD and the VA achieve the goals presented in the DoD/VA *Pain Management Task Force Final Report* and recently outlined in the VA's *Blueprint for Excellence*, including the goal to evolve from a "sick care" model to a "health care" model by advancing health care that is personalized, proactive, and patient driven.

NCCIH is interested in innovative models of research that are embedded in care in the real world. The Center works to identify settings and partners for projects in which NIH funds some of the scientific expertise for research conducted in patient care settings. In military/Veteran settings, cooperative research of this type could be facilitated by the DHA and the VA, taking advantage of agency resources, extensive networking, and interest in addressing research questions about chronic pain.

As mentioned in the introduction to this report, chronic pain and related conditions are a major societal problem, affecting large numbers of Americans. Although they may disproportionately affect those who are serving or have served in the military, they are widespread in the civilian population as well. Many people are at risk for developing chronic pain, and therefore many could benefit from building the body of knowledge about how to manage pain more effectively. Future initiatives encouraging larger scale studies may provide evidence that could improve quality of life and increase options for safe, effective pain management not only for military

personnel and Veterans, but also for the millions of other Americans who struggle daily with chronic pain.

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Appendix A: Working Group Members, Staff, and Speakers

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Appendix B: Agendas for the Working Group Meetings

June 5, 2014

1:00–1:15 pm	**Welcome** *Josephine Briggs, M.D.* **Charge to the Group** *Kristen Huntley, Ph.D.* **Opening Remarks** *Lloyd Michener, M.D.*
1:15–2:00 pm	**Health Futures Group** *Col. Brian J. Masterson, M.D.*
2:00–2:45 pm	**Comprehensive Health Homes** *Ahmed Calvo, M.D., M.P.H.*
2:45–3:00 pm	**Break**
3:00–3:30 pm	**Joint Incentive Fund Acupuncture Project and NATO Activities** *Richard Niemtzow, M.D., Ph.D., M.P.H. and Joan Walter, J.D., P.A.*
3:30–4:15 pm	**Study Design Alternatives to RCTs** *David Murray, Ph.D.*
4:15–5:00 pm	**Discussion**

July 31, 2014

3:00–3:10 pm	**Welcome** *Lloyd Michener, M.D. and Kristen Huntley, Ph.D.*
3:10–3:35 pm	**Opioids and Chronic Pain in Veterans** *Karen Seal, M.D.*
3:35–4:00 pm	**VA Office of Research and Development** *Timothy O'Leary, M.D., Ph.D.*
4:00–4:25 pm	**DoD Pain Research Portfolio** *Tony Gover, Ph.D.*
4:25–5:00 pm	**Discussion**

August 28, 2014

2:00–2:10 pm	**Welcome** *Lloyd Michener, M.D. and Kristen Huntley, Ph.D.*
2:10–2:25 pm	**Current DoD Project: PROMIS/PASTOR** *Col. Chester "Trip" Buckenmaier, M.D.*
2:25–2:40 pm	**Meditative Training To Promote Resilience and Cognitive Enhancement** *Amishi Jha, Ph.D.*
2:40–2:55 pm	**VA Pain Management Program** *Rollin "Mac" Gallagher, M.D.*
2:55–3:10 pm	**VA Pain Research Priorities** *Robert Kerns, Ph.D.*
3:10–4:00 pm	**Discussion**

October 9, 2014

1:00–1:10 pm	**Welcome** *Josephine Briggs, M.D., Lloyd Michener, M.D., and Kristen Huntley, Ph.D.*
1:10–1:35 pm	**Research Questions That Are Important to Military Personnel and Veterans** *Jackie Maffucci, Ph.D. and Justin Minyard*
1:35–2:00 pm	**The Power of Big Data—Health System-based Intervention and Observational Studies** *Richard Platt, M.D., M.S.*
2:00–2:25 pm	**Military Health System Electronic Health Record and Data Usage** *Col. John S. Scott, M.D. for Warren Lockette, M.D.*
2:25–2:45 pm	**Discussion**
2:45–3:00 pm	**Break**
3:00–3:10 pm	**Complementary and Integrative Health Approaches in the VA** *Tracy Gaudet, M.D.*
3:10–5:00 pm	**Formulating an Action Plan**

December 22, 2014

2:00–2:05 pm	**Welcome** *Josephine Briggs, M.D., Kristen Huntley, Ph.D., and Eric Schoomaker, M.D., Ph.D.*
2:05–2:15 pm	**Defense and Veterans Center for Integrative Pain Management (DVCIPM) Activities** *Kevin Galloway, B.S.N, M.H.A. and Eric Schoomaker, M.D., Ph.D.*
2:15–2:35 pm	**Defense Health Agency Healthcare Operations Directorate** *Major General Richard W. (Tom) Thomas, M.D., D.D.S.*
2:35–2:50 pm	**Discussion**