

## UNDER SECRETARY OF DEFENSE 4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

The Honorable John McCain Chairman Committee on Armed Services United States Senate Washington, DC 20510

JUL 19 2016

Dear Mr. Chairman:

The enclosed report is in response to Senate Report 114-63, pages 205-206, which accompanied S. 1558, the Department of Defense (DoD) Appropriations Bill, 2016. The Senate requested that the Assistant Secretary of Defense (Health Affairs) provide the congressional defense committees a report on the status of the development and integration of system-wide policies and practices of complementary and alternative therapies for the management of pain.

The Department has designated the Defense and Veterans Center for Integrative Pain Management, under the auspices of the Uniformed Services University of the Health Sciences, as its proponent for world-class pain management services for military and Veterans Affairs beneficiaries, and for the development of consensus recommendations for Department-wide improvements in pain medicine policies, practice, education, and research. The enclosed report summarizes DoD strategies for expanded research and utilization of integrative medicine pain therapies in the Military Health System, and details certain challenges ahead.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter has been sent to the other congressional defense committees.

Sincerely,

Peter Levine

Acting

Enclosure: As stated

cc:

The Honorable Jack Reed Ranking Member



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The Honorable Rodney P. Frelinghuysen Chairman Subcommittee on Defense Committee on Appropriations U.S. House of Representatives Washington, DC 20515

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# Department of Defense Report to Congress Senate Report 114-63, Pages 205-206 to Accompany S. 1558, the Department of Defense Appropriations Bill, 2016

# **Improving Military Medicine's Management of Pain**

The estimated cost of this report for the Department of Defense is approximately \$ 4,800 for the 2016 Fiscal Year. This includes \$ 0 expenses and \$ 4,800 labor.

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# Senate Report 114-63, Pages 205-206, to Accompany S. 1558, the Department of Defense (DoD) Appropriations Bill, 2016

In February of 2016, the Assistant Secretary of Defense for Health Affairs, on recommendation from the Military Health System Centers of Excellence Oversight Board, designated the Defense and Veterans Center for Integrative Pain Management (DVCIPM) as the Department of Defense's (DoD) seventh medical Center of Excellence. DVCIPM, under the auspices of the Uniformed Services University, and in collaboration with the pain management program, clinical and research leads of the Uniformed Services and the Veterans Health Administration, continues to champion the implementation of system-wide policies and practices for expansion of integrative medicine practice and research, as recommended in numerous professional publications, including DoD Pain Management Task Force (PMTF) Report, Institute of Medicine (IOM) "Pain in America Report," National Center for Complementary and Integrative Health (NCCIH) Council Working Group Report, and the National Pain Strategy. The ongoing integration of these therapies includes necessary preparatory activities to change the way pain is assessed, implementation of a tiered structure of pain capabilities, improvements in current methodologies for measuring pain outcomes, and provisions for the education of Military Health System (MHS) providers and patients.

#### 1. INTRODUCTION

Senate Report 114-63, pages 205-206, which accompanied S. 1558, DoD Appropriations Bill, 2016, requested the Assistant Secretary of Defense for Health Affairs to provide a report to the congressional defense oversight committees on the status of the integration of complementary and alternative therapies for the management of pain in system-wide policies and practices.

Following release of the DoD PMTF Report (2010), DVCIPM, under the auspices of the Uniformed Services University of the Health Sciences, has served as the organization primarily responsible for coordinating implementation of the PMTF recommendations, including expanded integration of what were previously referred to as "CAM" therapies for pain management [note that these are now referred to as Complementary and Integrative Medicine (CIM) pain management therapies]. This report will summarize DoD strategies and activities to lay the foundation for expanded research and utilization of integrative medicine pain therapies in the MHS, and will detail some of the challenges faced in executing these lines of effort.

#### 2. BACKGROUND

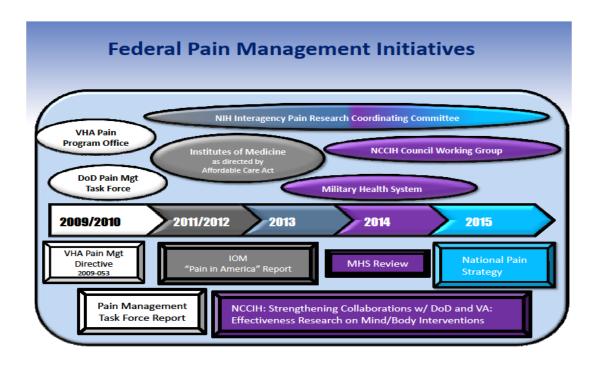


Figure 1. Federal Pain Management Initiatives

Over the last 20 years, pain medicine has undergone several evolutionary advances. Federal Medicine, particularly the DoD and Veterans' Health Administration (VHA), has been instrumental in many national initiatives related to pain medicine (Figure 1). In 2009, the DoD chartered the PMTF to assess current DoD pain management capabilities and to make recommendations for a pain management strategy. The PMTF Report contained more than 100 recommendations for a multidisciplinary, multimodal, scientific, evidence-based pain strategy, to optimize pain care for Service members, Veterans, and their families. The report urged that the MHS expand access and utilization of all evidence-based, effective pain management treatments, and in light of growing concerns with the overuse of prescription pain medications, increase research into, and utilization of, complementary integrative medicine therapies that have evidence of safety and effectiveness. This issue is not unique to the military, the 2011 IOM (now known as the National Academy of Medicine) "Pain in America" report referenced the PMTF Report and largely mirrored PMTF's assessment and recommendations for the nation.

The National Advisory Council on Complementary and Integrative Health (the national advisory council to the NCCIH of the National Institutes of Health (NIH)) convened a working group in 2014 to develop of a large-scale initiative to examine the effectiveness of mind and body practices in Military and Veterans' Health System care settings. With the assistance of the NCCIH (formerly the National Center for Complementary and Alternative Medicine, or NCCAM) the group chose to focus on chronic pain, given that chronic pain is a major societal problem, estimated to affect about 100 million U.S. adults on a daily basis, but disproportionately affecting those who are serving or have served in the military

As the country faced the Centers for Disease Control and Prevention (CDC)-designated "epidemic" of prescription opioid medication overuse, abuse, and diversion, DVCIPM and the Service pain management leaders continued to play instrumental roles in national efforts to develop and implement innovative solutions. DoD actively participated on the NIH's Interagency Pain Research Coordinating Committee when it was directed to develop a National Pain Strategy. The DoD's pain management strategy informed and is aligned with the newly released National Pain Strategy (March 2016) and highlights that "Primary care clinicians and specialists in relevant fields need to know more about the biopsychosocial characteristics and safe and appropriate management of pain, to include complementary and integrative medicine."

Synchronization of the DoD and VHA pain management efforts were strengthened with the DoD/ Department of Veterans Affairs (VA) Health Executive Committee's (HEC) charter of a HEC Pain Management Work Group (PMWG). Since 2011, the HEC PMWG has been coordinating major pain management efforts across the Military and Veterans' Health Systems care settings. Over the last two years, the HEC PMWG was involved in two Joint Incentive Fund (JIF) Projects (jointly funded by the MHS and VHA) aimed at achieving the culture change required to accelerate the move towards a biopsychosocial model of pain care in the DoD and

VHA. The first of the two JIF projects, the Joint Pain Education Program, developed a standardized curriculum for primary care pain management for use across the DoD and VHA. The second JIF project, Acupuncture Training Across Clinical Settings (ATACS), aimed to standardize teaching, credentialing, and documentation of acupuncture, and was followed by the dissemination of an introductory acupuncture technique (modified ear or auricular acupuncture also known as "Battlefield Acupuncture" or BFA) that is available to all levels of providers and can be utilized to decrease the demand or dosages of prescription pain medications.

# Pain Management Transformation in the DoD

The 2010 DoD PMTF recommendations for a MHS pain management strategy included a call for change in military pain management that would support expanded use of integrative medicine modalities. The PMTF recognized that conventional approaches for managing pain (medications, procedures, surgeries) were not necessarily effective in all categories of pain patients and in some cases were prematurely applied and counterproductive in meeting all the needs of the MHS community. The PMTF foresaw that the MHS lacked the necessary strategy, training, "tools," and orientation/culture to effectively manage the complex problems of acute and chronic pain. More specifically, while a growing number of patients and providers were reporting positive experiences with the use of several complementary integrative medicine approaches for pain management, there remained a paucity of available research to inform policy development and to justify investment in making these CIM modalities consistently available across the MHS.

The PMTF was clear in its recommendation that the MHS adopt a biopsychosocial model of pain care that would support expanded use of integrative medicine modalities for pain management. According to the prior, achieving this objective would require much more than adding these "tools" to the MHS pain management "toolbox." Full execution would require a shift in the culture and practice of how pain care is structured, discussed, assessed, managed/treated, and how the "success" of MHS pain management is ultimately measured by patients, providers and leaders.

#### **Shifting from Traditional Medical Model of Pain Management**

Traditionally, the predominant model of provider-based care begins with the expectations from both providers and patients that the provider's role is to "do something to the patient" that will resolve the patient's problem. The complex physical and emotional nature of the chronic pain disease problem renders this approach ineffective, and in many circumstances, dangerous. Patients present with a complaint of pain to a provider, and following an assessment and examination, are provided with a treatment plan that often includes prescription medication(s) and instructions on activity limitations. Rarely is the patient tasked to do anything other than take the medication and return for refills if the pain does not resolve. The patients are largely devoid of ownership of the condition and treatment plan and is largely a passive participant in his

or her own care. Around the time the PMTF provided its recommendations, the MHS launched the Patient Centered Medical Home (PCMH) initiative. The team-based PCMH approach to patient care, coupled with tiered "echelons" of referral care for more difficult cases, was an excellent delivery system for the PMTF recommendations, emphasizing that pain management implementation required coordinated efforts with primary care. The Army began implementing its Comprehensive Pain Management Campaign Plan in 2011 and the Navy followed with its Comprehensive Pain Management Program Statement in January 2015. The Air Force is aligning its pain management capabilities and efforts with MHS policies and closely coordinating their pain management efforts.

DVCIPM executes its programs, projects, and initiatives in collaboration with a complex array of Service, Defense Health Agency (DHA), and VA leaders and stakeholders. The Director, DVCIPM, serves as the DoD co-chair of the HEC PMWG and together with the VA co-chair, coordinates major pain strategies and actions with the HEC leadership and other HEC working groups. As with all important clinical initiatives, MHS governance requires many pain management initiatives to be socialized with, or approved by, the Service senior leader representatives on the Medical Operations Group. The Surgeons General of the Army, Navy, and Air Force have a designated clinical consultant for pain medicine and a pain program lead, who, with representatives from DVCIPM and DHA, are members of the DoD PMWG, with responsibility coordinating DoD-specific pain management actions. This ongoing communication and collaboration is necessary to maximize unity of effort, reduce duplicative actions, and ensure visibility of DoD-wide efforts of policy development, implementation, and integration of pain strategies.

#### **Stepped Care Model of Pain Management**

Expanded use of integrative medicine modalities requires consistent structure on which to deploy these new adjuncts, as well as acknowledgement that most pain can and should be managed appropriately in primary care with education and encouragement of patient self-care. It was therefore imperative that the MHS implement a model that provides fidelity on the structure and resources necessary for the continuum of pain management: from acute to chronic; from point of injury, to evacuation and rehabilitation; and final recovery, rehabilitation, and reintegration. Common elements need to be present across the enterprise to ensure that appropriate resources are available at each level of care, in terms of personnel, time, training, tools, and data.

The MHS Pain Strategy incorporates the Stepped Care Model of Pain Management developed by VHA (Figure 2). The Stepped Care Model is instituted as a strategy to provide a continuum of effective treatment to patients with acute and chronic pain. It covers acute pain caused by wounds, injuries, or diseases and longitudinal management of chronic pain diseases and disorders that may be expected to persist for more than 90 days and possibly throughout life. A general overview of the Stepped Care Model is outlined below:

- Step One, Primary: The Primary Care Manager (PCM) provides pain management of low complexity common conditions, such as back pain and peripheral neuropathy or nerve pain. The PCMs are additionally supported by the Primary Care Pain Champion (PCPC) and an Integrated Behavioral Health Coordinator.
- Step Two, Secondary, Co-Management: The PCM has access to regional Interdisciplinary Pain Management Center (IPMC) resources to co-manage patients not responding to primary care treatment. The IPMC primary care advisor provides tele-mentoring consultation, collaboration, and/or education to the PCMH via the PCPC.
- Step Three, Tertiary: Higher risk patients with complex or multiple co-morbidities are referred to specialty pain management. When possible, referrals are made to the regional IPMC and Service functional restoration programs.

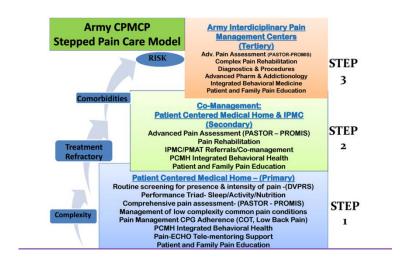


Figure 2. Example Stepped Care Model

#### **Assessing Pain**

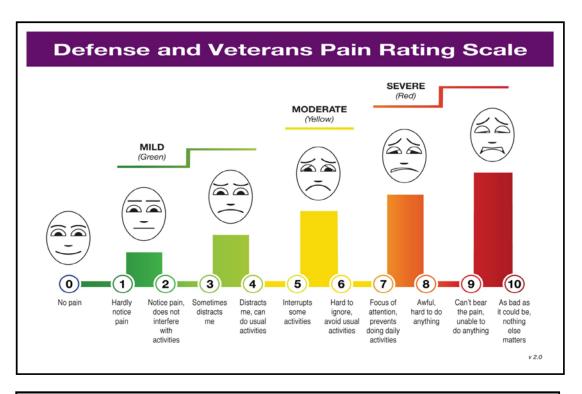
The current methods for assessing pain do not allow for a holistic approach to pain management, nor allow patients to accurately report the true impact that pain has on their lives. Currently, each time a patient has a medical appointment or hospital admission, they are queried about their pain intensity. On the surface, this appears to be a positive action following years of claims that pain management needs were not being addressed both in military and civilian settings. But, merely asking the patients about their pain intensity and providing standard treatments (e.g., surgical interventions or medications) might not be the optimal protocol. Furthermore, with pain intensity as the sole metric for defining pain care success, the current overreliance on opioid medications for pain is understandable, given that opioids represent an almost unrivaled standard for lowering pain intensity in the acute pain setting. Another major finding from the PMTF was the consistent negative feedback regarding the value of the

conventionally employed 11-point, 0-10 Visual Analog Scale (VAS - 0 = no pain, 10 = worst pain imagined) as a tool for discussing and managing pain. Clinicians at all levels noted the inconsistent administration of the VAS scale, subjective nature of the information obtained, lack of functional orientation to the question, and therefore, the generally low value that VAS assessments held in guiding pain therapy. The PMTF determined that a new Federal medicine pain assessment tool was needed that would be capable of providing consistent and actionable data across the continuum of care.

The PMTF utilized the best available pain scale research and experts to develop the Defense and Veterans Pain Rating Scale (DVPRS) with the ultimate objective of validating the tool within the MHS and eventually proposing the new scale as the Federal medicine standard. The DVPRS enhanced the conventional VAS-based rating system with visual cues and functional word descriptors to assist patients with a more objective method of selecting a number representing their pain, based on perceptual experiences and functional limitations imposed by the pain ("pain interference"). The DVPRS developers integrated multiple visual cues to include graduated intensity bars, green-yellow-red colors, and easily understood graphic "pain faces" that could be employed in a variety of situations where clinical inquiry into a patient's pain state was desirable, but communication was constrained (Figure 3).

Perhaps the single most important evolution on the DVPRS was the integration of functional language anchors to re-cast the experience of pain in terms of patient functional disturbance as it relates to increasing pain intensity. More importantly, the use of functional anchors to define the 0-10 pain levels in terms of function rather than intensity is essential to effect the cultural change required to stop pharmacologic-only (usually opioid) based efforts to reduce pain intensity to zero. While achieving zero pain seems intuitively desirable for patients and providers, it is often an unrealistic goal particularly with complex traumatic injuries and with the interplay of biopsychosocial factors, when other issues are considered. The DVPRS was designed to be the first and perhaps most fundamental step in changing the way both providers and patients discuss painful conditions, as well as how they measure what constitutes successful pain management.

Lastly, the PMTF also recognized that pain transcends simple measurement of one parameter (intensity) and actually impacts on all aspects of a patient's wellbeing. Therefore, the DVPRS also includes supplemental questions assessing the impact of pain on certain key areas of both physical and emotional function, to include general activity, sleep, mood, and stress (Figure 3). The supplemental questions provide additional essential indicators of the success or failure of pain therapeutic plans, far beyond reducing the pain intensity to zero. The reorientation of the MHS on how pain is assessed with the DVPRS will help improve biopsychosocial parameters and allow CIM modalities to be compared with traditional pain therapies.



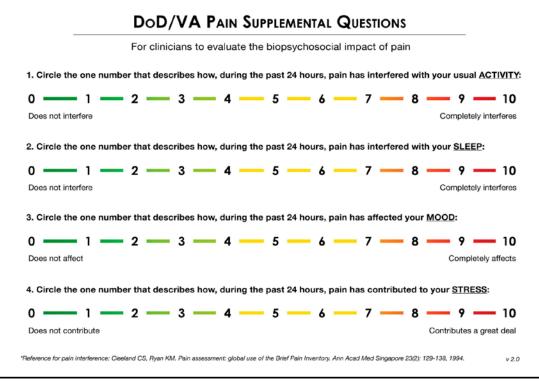


Figure 3. DVPRS Pain Rating Scale

#### **Measuring and Reporting Patient-Reported Outcomes for Pain**

In addition to recommending that the MHS develop a revised pain rating scale (DVPRS), the PMTF also identified a requirement for an MHS registry of data related to pain, pain treatment, and the impact of pain on a person's quality of life and function. This tool has been designated the Pain Assessment Tool and Outcomes Registry (PASTOR). During the early stages of PASTOR development, the PMTF began researching validated measures and tools that could be integrated into PASTOR. This inquiry revealed that the NIH had already invested over \$100M in developing a state-of-the-art and comprehensive system for measuring patient-reported outcomes and symptoms. The NIH system is called Patient Reported Outcome Measurement Information System or PROMIS. PROMIS integrated several innovative concepts that were recognized as extremely useful for PASTOR. For example, one of these unique aspects of the PROMIS measures is that they are domain, rather than disease-focused and thus can be applied across many other chronic conditions beyond pain. PROMIS developed more efficient patientreported outcomes tools through the use of computer adaptive testing that greatly reduces patient response burden to questions. This system allows for a consistent, highly validated method for obtaining detailed patient information concerning one's pain condition, far beyond just pain intensity. Key components of PROMIS were subsequently integrated into PASTOR through collaboration with the PROMIS development team at Northwestern University.

PASTOR integrates the DVPRS and also supports the clinical encounter by screening the patient for potentially life threatening conditions such as substance abuse or major depression and provides information on depression, anxiety, anger, physical function, social function, pain interference, sleep disturbance, and fatigue. Most patients are able to complete PASTOR in less than 20 minutes, while at home, through a web-enabled application, prior to their clinical appointment. This information provides a far richer context and background for patients and clinicians to have a meaningful discussion about pain, develop pain management strategies, and determine the success of those strategies. Additionally, standardization of the PASTOR throughout the DoD will provide a rich data resource of evidence to support best pain practices.

Like the clinician report, the data registry is patient-centered. Patients report their symptoms, their outcomes, and their progress toward personally relevant goals. The data are aggregated and used to evaluate the effectiveness of pain management strategies based on patient-reported, quality of life impact. And because of the large number of patients treated within the MHS, the PASTOR registry will be well powered for subgroup comparisons critical to understanding individual variations in responses to pain management approaches. This will provide significant insight on the comparative effectiveness of different combinations of pain management therapies that include both conventional and integrative medicine modalities.

#### Pain as a Priority Focus for Integrative Medicine Research

The symptom overlap among traumatic brain injury (TBI), Post-Traumatic Stress Disorder (PTSD), and chronic pain is almost universal and these three conditions, often coexisting in a recovering battle-trauma casualty, have been termed the "polytrauma triad." Although research and investment in TBI and PTSD have been commensurate with the magnitude of the challenge resulting from recent conflicts, this has not been the case with pain. Pain is the number one complaint of veterans seeking medical services and if the current crisis in opioid misuse and abuse is any indicator, the nation's approach to pain management is in need of additional study and improvement. Federal medicine has served and can continue to serve as a model for the nation in developing pain educational products, novel measuring tools, and clinical systems to improve pain care throughout all roles of care. For too long, pain has been thought of only as a symptom of some other disease or traumatic condition. Modern understanding recognizes pain as a disease condition of the nervous system itself and is worthy of medical attention and investment. Future pain research must recognize the full biopsychosocial impact of pain on the patient and leverage new pain assessment and patient-reported outcomes data tools that allow assessment of pain beyond just treating pain intensity. This effort necessarily should expand efforts to look critically at the role of non-pharmaceutical-based approaches to pain management that can be used as equal partners to traditional approaches, but tend to lack significant side effects that tend to plague current standards of practice. Given that pain is a component in all aspects of medical care, this research will enhance patient care in all fields of medical endeavor.

#### 3. PROGRESS

#### **Implementing Integrative Medicine in the MHS**

Over the past 12 months, the MHS integration of pain-related CIM policy and practice has steadily progressed.

- Following approval by the MHS Patient Care Integration Board in February, DVCIPM is conducting a pilot project on implementation of the DVPRS as the designated pain rating scale at three DoD medical treatment facilities. DVCIPM, in coordination with the DoD PMWG and PCMH representatives, will evaluate the most effective ways to educate and orient patients and providers on the use of this new pain rating scale. Lessons learned during this pilot will inform consideration of expansion of DVPRS across DoD and the recommendation to shift MHS pain management culture to focus more on function and quality of life when managing pain.
- PASTOR is an MHS registry of data related to pain, pain treatment, and the impact of pain on a person's quality of life and function. This system allows for a consistent,

highly validated method for obtaining detailed information concerning the patient's pain condition, far beyond just pain intensity. Patients report their symptoms, their outcomes and their progress toward personally relevant goals. The data are aggregated and used to evaluate the effectiveness of pain management strategies based on patient-reported, quality of life impact. Fully implemented, the PASTOR registry will provide significant insight on the comparative effectiveness of different combinations of pain management therapies that include both conventional and integrative medicine modalities. PASTOR pilot projects were successfully conducted in 2013-15 at Madigan Army Medical Center (MAMC), Joint Base Lewis McCord, and at Naval Medical Center San Diego. In collaboration with the Informatics Team at MAMC, the Tri-Service PASTOR Steering committee has developed a plan for the MHS-wide rollout of PASTOR that is funded to begin in 2017.

- Army Medicine has been integrating acupuncture (including licensed acupuncturists), movement/yoga therapy, massage therapy, biofeedback, and other CIM therapies into its Interdisciplinary Pain Management Centers since 2013. Navy Medicine has chartered a "CAM Tiger Team" to explore possible revisions in CIM policy and practice, and the Air Force redesignated the Air Force Acupuncture Center at Joint Base Andrews to the Air Force Acupuncture and Integrative Medicine Center.
- The HEC PMWG-led Joint Pain Education Project (JPEP) has completed the first version of its primary care pain management education modules. Over the next 6 months, the JPEP will begin integrating additional CIM content into the JPEP curriculum developed from the VHA's Integrative Health Coordinating Center's collaboration with University of Wisconsin. The JPEP content will be utilized in the Army, Navy, VHA, and Joint Extension for Community Healthcare Outcomes (ECHO) Pain tele-mentoring programs and will also be shared with the Indian Health Service and civilian ECHO tele-mentoring programs. The JPEP content will be part of the DoD and VHA responses to develop prescriber pain education content directed by the Presidential Memorandum Addressing Prescription Drug Abuse. The JPEP content also reinforces the recently released CDC Opioid Prescribing Guidelines.
- The ATACS project has trained over 2100 providers in BFA and approximately 100 BFA faculty for the sustainment training activities. ATACS will report on provider successes, barriers, and lessons learned while integrating this innovative and simple technique into clinical practice. Additionally, the ATACS project is in the process of developing a Joint DoD-VHA acupuncture document that will provide consensus guidance for acupuncture education, training, and credentialing/privileging, documentation, coding, and practice in the DoD and VHA. It is the goal of the

ATACS project to decrease variability of utilization and availability of acupuncture across DoD and VHA facilities.

DVCIPM and Service representatives are participating in the ongoing U.S. Army
Medical Research and Material Command's Clinical and Rehabilitative Medicine
Capabilities-Based Assessment process, ensuring pain management CIM is
recognized as a current capability gap and integrated into future research priorities.

#### 4. CONCLUSION

As recommended by the 2010 DoD PMTF, the MHS continues to integrate complementary integrative medicine approaches to pain management as part of its comprehensive, multi-disciplinary and multimodal pain management strategy for the MHS. The development and implementation of CIM-related clinical policy and practice guidelines are being conducted through coordinated lines of effort across Health Affairs, Uniformed Services, Uniformed Services University, VHA, other Federal Agencies, and civilian healthcare experts. Further success with CIM implementation, currently being piloted in three DoD medical treatment facilities, will be predicated on demonstrating MHS success in changing the culture and practice of how: pain is assessed (DVPRS); how pain is treated (Stepped Care Model of Pain Management); how pain outcomes are measured (PASTOR); and how the MHS trains and educates providers (JPEP).