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Contents

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Commentary

Chronification of Pain and the Science of Pain Management

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Pain hurts. Without good care, pain removes the joy and love of life that our Veterans deserve. Even in the most resilient Veterans with strong family and community support, inadequately managed pain can lead to depression, substance misuse, and suicide. The biospsychosocial epiphenomena of chronic pain, such as disability, obesity, social distress, and isolation further exacerbate pain's burden on Veterans, their families, and their communities. The importance of pain research in VHA has never been higher.

The 2011 Institute of Medicine study of pain's public health impact, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,* made a compelling argument for major changes in education and health policy.[1] The increasing rate of drug overdose deaths, often involving opioid analgesics prescribed for pain is a second, related, public health challenge and a consequence of the 'pain disability epidemic.' Together, these challenges raise the stakes for our pain management enterprise nationally, compelling us to improve access to cost-effective, evidence-based treatment approaches.

Such approaches are urgently needed across VHA. The exposure of Middle East troops to repetitive physical and psychological stress of combat in multiple deployments explains the higher rates of painful musculoskeletal (>60 percent) and mental health (>50 percent) diagnoses in Veterans than in the general population. Older Veteran cohorts, many retired from employment and turning to VA for care, face painful disease and illness as consequences of earlier service-related physical and psychological injuries, as well as from those associated with aging, such as arthritis or cancer.

Ironically, the well-meaning effort to control pain with opioids and their subsequent over-use helped galvanize societal attention on the need for more pain research and better pain care: lives shortened by pain-related deaths from suicide or unintended drug overdose as well as the consequences of chronic exposure to living with pain, such as disability, obesity, depression, social distress, and substance abuse. Defining pain as a public health problem invites an understanding of its phenomenology and an examination of opportunities for HSR&D research.[2]

Pain as a Public Health Problem

As medicine and society consider the vast domain of human pain and its burden, how do we find our focus for producing meaningful research, particularly for our Veterans? I find it helpful to consider this question through the lens of an illness construct—pain chronification—describing the progression from acute pain to persistent pain to "complex chronic pain" with its sociomedical consequences.[3] We

Tackling the Opioid Crisis

At a recent HSR&D meeting to discuss non-opioid alternatives for treating chronic pain, Bob Kerns, a longtime VA pain clinician and researcher, observed that he could "remember when opioids were bad, before they were good, before they were bad again." These oscillations in clinical attitudes and policy reflect the challenge of adequately treating chronic pain while avoiding the problems caused by inappropriate or indiscriminate use of opioids. After a period when the focus was on addressing under-treatment of pain, most agree that the pendulum in the United States has swung too far towards overuse of opioid pain medication—last year a study tied declining life expectancy in middle-age whites to problems related to substance abuse, including opioids. This problem is particularly important for VA, given the high prevalence of musculoskeletal pain in Veterans returning from conflicts in Iraq and Afghanistan.

While the effectiveness of opioids for chronic pain remains debated, the side effects of prescription opioids are well known, including dependence, potential overdose, and death. Their toll has received increasing attention at state and national levels, and last Fall the White House convened a Summit on the Opioid Epidemic. A key to addressing this problem is to equip clinicians with better options for addressing pain in their patients, as outlined in the articles in this issue. Stepped care therapy, cognitive behavioral therapy, structured exercise programs, and certain integrative approaches can all be effective in certain patients. The challenge for VA, and for other health systems, is to build an effective program that integrates pain management into primary care, providing an array of alternative strategies so that the busy primary care clinician doesn't feel compelled to reach for their prescription pad.

There is no easy fix for our current crisis, just as there often is no easy fix for our patients with chronic pain. But by being clear about our goals and honest about the challenges, and by incorporating careful research into our attempts to improve clinical care and policy, we can chart a path forward for improving care for our Veterans as well as improving practice and policy as a nation.

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know co-morbidities, such as catastrophizing, depression, PTSD, and substance use disorder are key indicators of risk for chronification and poor outcomes—no matter the initiating cause of pain. How does the VA healthcare system, at Veterans' first encounter for pain in primary care or hospital, incorporate practical methods for ensuring screening and immediate clinical attention for them?

HSR&D researchers have a complex array of pressing questions to consider. Does VHA implement interventions to identify and manage co-morbidities, to prevent chronification? Can we do more than just screen for pain intensity at hospital admission or during recovery by identifying risk factors that portend higher suffering and costs (e.g., catastrophizing, depression, obesity)? Are VHA behavioral health and pain consultation teams able to respond with evidence-based interventions to prevent chronification? Can we measure the cost-effectiveness of such clinical process improvements, and then implement these widely? Can we measure the impact of process improvement across our health system?

Role of VHA's Research Enterprise

VHA's research enterprise is poised to provide national leadership to these research challenges. Our electronic medical record (EMR) already informs VHA about risky opioid prescribing, and by providing feedback and education, lowers these risks in our Veterans. Two clinical support tools, the Opioid Therapy Risk Report (OTRR) and the Stratification Tool for Opioid Risk Management (STORM), use EMR-derived reports to help front-line clinicians identify overall overdose risk level for individual Veterans and specific risks that become targets of intervention. Are these data improving Veterans' quality of life by helping them join the work force, maintain stable family relationships, or achieve other markers of successful return to a healthy and fulfilling life? Are rates of suicide positively impacted when we coalesce our skills and attention to pain? When and how can we develop models of combining medical and non-medical treatments to interrupt the cascade to chronification?

Our VHA pain research enterprise is poised to take advantage of new developments in pain research. Our "Million Veteran" project will collect a database of sufficient size to understand more about the "pain genome" in well-defined phenotypes, helped by data registries such as CHOIR and PASTOR PROMIS, which will propel pain management toward evidence-based, personalized medicine. For example, what are the clinical and genetic factors contributing to catastrophizing or depression in response to persistent pain conditions, thereby increasing chronification risk? Who is susceptible to opioid over-use and misuse when treated for acute pain or a chronic pain condition? What factors shift the trajectory towards recovery of function and quality of life?

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Response to Commentary

Meeting the Challenge of Chronic Pain as a Public Health Problem

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In his commentary, Dr. Gallagher emphasizes the public health importance of chronic pain. We could not agree more. Back pain is the leading cause of disability in the United States and worldwide—a fact worth restating—and the other top five conditions are closely related: neck pain, other musculoskeletal disorders, depression, and anxiety. Given its immense public health burden, our approach to chronic pain must extend beyond interventions focused solely on symptom alleviation. At both population and individual levels, prevention of chronic pain disability is a critical target for interventions. For patients already affected by disability, promotion of recovery should be a primary goal.

A key recommendation of the recently published National Pain Strategy is to "define and evaluate integrated, multimodal, and interdisciplinary care" for pain.[1] Similarly, acknowledging that improved management of pain is key to prevention of opioid-related injuries, the first recommendation in the new CDC guideline for opioid prescribing focuses on non-opioid pain management: "non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain."[2] We see numerous opportunities for health services research to reduce the burden of chronic pain and disability among Veterans.

VA Research Progress

Consistent with these recommendations, VA's investment in research related to pain and pain management is substantial and continues to grow.[3] This growth is particularly true in some of the key scientific knowledge gaps and challenges highlighted by Dr. Gallagher in his commentary. As he suggests, growing evidence points to the role of mental health comorbidities in the perpetuation, if not development, of chronic pain, or the process of "chronification." A variety of research methods are relevant to this central issue, including use of existing databases to identify key factors that may moderate or mediate the development of chronic pain. HSR&D-funded projects, including the Musculoskeletal Diagnosis Cohort and Women Veterans Cohort Study by Drs. Cynthia Brandt, Joe Goulet, Sally Haskell, Robert Kerns, and colleagues have already contributed important findings in this domain.

Randomized effectiveness trials of innovative collaborative interventions targeting chronic pain and important mental health comorbidities, particularly depression, have led to identification of a growing number of effective pain care delivery approaches. Trials by Drs. Matthew Bair, Steve Dobscha, and Kurt Kroenke on primary care-based collaborative care and telecare management are particularly noteworthy in this regard. Other projects are specifically relevant to the dual public health crises of pain and prescription opioid harms. For example, Dr. Erin Krebs and colleagues are in the final year of the HSR&D-funded Strategies for Prescribing Analgesics Comparative Effectiveness trial, which is comparing opioids vs. non-opioid medications over 12 months for back and osteoarthritis pain.

Dr. Gallagher also highlights a widely acknowledged challenge to the field of pain management that's far from unique to this field—dissemination and implementation of empirically supported interventions across VA facilities. It is exciting that the Quality Enhancement Research Initiative (QUERI) continues to make investments in pain, most recently by funding Drs. William Becker, Alicia Heapy, and Amanda Midboe's Improving Pain Related Outcomes for Veterans (IMPROVE) QUERI program. A related challenge from Dr. Gallagher is to conduct high fidelity evaluations of important VA initiatives. In this regard, a QUERI study led by Dr. Mark Ilgen is assessing effects of the Opioid Safety Initiative (OSI) on opioid prescribing practices and an HSR&D study led by Dr. Krebs is assessing OSI effects on patient-reported outcomes.

One area not specifically highlighted by Dr. Gallagher that is garnering considerable attention is the study of complementary and integrative health (CIH). HSR&D recently commissioned an Evidence Synthesis Program review of selected CIH approaches for pain. Also, in 2014, HSR&D partnered with the National Center for Complementary and Integrative Health in an initiative that funded several ongoing studies of CIH for pain among Veterans.

Future Directions

We see numerous opportunities for HSR&D researchers to continue to lead the way with patient-centered comparative effectiveness, implementation, and partnered health services research. First, we should continue to address critical gaps in pain management evidence, such as those identified in the CIH review, as well as those related to therapies with established efficacy. For example, although multiple exercise programs have demonstrated effectiveness in chronic pain, uncertainties about key components, dosing, and maintenance strategies are barriers to their broader implementation. Second, we should target implementation research to advance the spread of pain care delivery strategies, such as telephone-based pain care management, that have demonstrated effectiveness in VA settings. Finally, to meet the public health challenges of chronic pain, we should be thinking about population- and organizational-level methods to realign services toward Veteran-empowered pain self-management.

References

1. U.S. Department of Health and Human Services. National Pain Strategy. Available at: www.iprcc.nih.gov/docs/HHSNational_Pain_Strategy.pdf.
2. Dowell D., Haegerich T.M., and Chou R. "CDC Guideline for Prescribing Opioids for Chronic Pain," *Morbidity and Mortality Weekly Report*, Recommendations and Reports 2016; 65:1–49.
3. Kusiak A.N. "Department of Veterans Affairs Office of Research and Development's Pain Portfolio," J*ournal of Rehabilitation Research and Development* 2016; 53(1):xi-xiv.

Research Highlight

Opioids and Dual Healthcare System Use

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The United States is in the grip of an unprecedented epidemic of prescription opioid and heroin overdose. Drug overdose is now the leading cause of death due to injury and the leading cause of death overall in adults aged 24 to 44 years. Prescription opioid medications have played a major role in the development of this epidemic; over the past 20 years, annual prescriptions for opioids more than doubled, now with enough prescriptions for every adult in America to have a bottle of pills. The death rate from opioid analgesics more than tripled between 1999 and 2012.[1]

Understanding Non-VA Use of Opioids

VA is not immune to these national trends. The number of Veterans receiving opioids from VA providers nearly doubled between 2001 and 2013, from 651,000 to 1,101,346. In 2013, almost one in four VA pharmacy users received an opioid medication. The number of overdoses due to prescription opioids among Veterans has increased as well.[2] While VA has adopted several strategies to mitigate the risks of opioid medications, these efforts focus almost entirely on monitoring prescriptions dispensed within VA. Many patients are receiving opioid medications—and other medications that interact with opioids—outside VA. Without understanding this non-VA use, VA will be unable to develop fully successful interventions to address opioid safety.

While much is known about how Veterans receive healthcare from both VA and non-VA health systems, very little is known about opioid prescribing across multiple systems. The theoretical concerns about 'dual use,' namely care fragmentation and duplication, are magnified for opioid medications given the added risks from high dosages and concomitant benzodiazepine use. A large majority of Veterans have some form of non-VA health insurance in addition to their VA benefits, but rates of prescription coverage vary—roughly one out of four VA enrollees have private drug coverage, and one in three VA/Medicare dual enrollees have Part D drug coverage.[3] The issue of dual use of opioids is increasingly relevant not only because of the overdose epidemic, but also because of the expansion in insurance options through Medicaid and insurance exchanges under the Affordable Care Act (ACA), and the Veterans Choice Program. Each additional opportunity for Veterans to receive care in multiple health systems—from multiple providers who have limited or no communication with each other—represents an additional opportunity for care fragmentation. Most would agree that fragmented healthcare is not beneficial when it comes to managing pain and opioids.

Research Illustrates Challenges of Fragmented Care

We are currently investigating these very concerns about dual use of opioids through an HSR&D funded project. We are examining linked VA and non-VA data at a national level and talking to VA primary care doctors about their experiences managing dual health system use of opioids. Our analyses are in the early stages, but already it is quite clear that dual use of opioid medications is a problem. Concurrent dual use of opioids and benzodiazepines is also occurring—non-VA providers prescribing opioids while VA providers prescribe benzodiazepines, each potentially not knowing what the other is doing. This fragmentation presents real challenges for the safe use of opioid medications.

What to do about this dual use of opioids? There are programs in place that try to address such use. For example, state prescription drug monitoring programs (PDMPs) allow VA providers in some states to look for non-VA opioids and other scheduled drugs before prescribing through VA. These programs are generally voluntary, do not interface directly with decision support systems within VA, and are state-based and thus difficult to aggregate at the national level. Systems could certainly be developed to incorporate real time queries of the PDMPs into CPRS decision support, but those systems would take time (i.e., years) to develop. In Pennsylvania, for example, the state with the eighth highest drug overdose rate, PDMPs are not yet available for query by providers, and for those providers in the western part of the state, they would have to search not only the Pennsylvania PDMP, but also Ohio and West Virginia, given the close borders. The Veterans Lifetime Electronic Record (VLER) health exchange has potential for allowing real-time notification to providers when opioids are prescribed in multiple systems, but only if the medication lists on both sides are properly updated and the electronic ordering systems query both systems when searching for interacting medications.

Systemic solutions to the problem of dual use of opioid medications are still years away from materializing. The short term solution is increased vigilance by VA providers about their opioid prescribing, and constant reminders that they are not the only ones providing medications to their patients. As in other aspects of dual health care system use, VA HSR&D investigators have an important role to play in identifying these problems and developing, testing, and implementing solutions.

References

1. Warner M., Hedegaard H., and Chen L. *Trends in Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012.* CDC. Available at www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning_deaths_1999-2012.pdf.

2. Bohnert A.S., et al. "Trends and Regional Variation in Opioid Overdose Mortality Among Veterans Health Administration Patients, Fiscal Year 2001-2009," *Clinical Journal of Pain* 2014; 30(7):605-12.

3. Gasper J., Liu H., Kim S., and May L. 2015 Survey of Veteran Enrollees' Health and Use of Health Care. Available at http://vaww.va.gov/VHAOPP/SOE/2015/Survey_of_Veteran_Descriptive_Report.pdf.

Research Highlight

Opioid Safety and Challenges Related to Expanded Access

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Chronic pain is highly prevalent in Veterans and one of the most common reasons for outpatient healthcare utilization across the VA health system.[1] Increasingly, Schedule II and III opioids are a main treatment modality for chronic pain, with duration of therapy lasting potentially for years. Yet, despite high rates of opioid prescribing, evidence supporting the use of opioids for chronic pain is modest, and furthermore, serious safety and addiction issues appear to be increasing.[2] Among those issues are unsafe medication combinations. For example, benzodiazepines potentiate the sedative properties of opioids and were listed as co-ingestions in 30 percent of opioid overdose deaths in 2010. Given these potential harms, experts have called for restraint in opioid use, targeting de-implementation of high-dose therapy, avoidance of opioid-benzodiazepine co-prescribing, and promotion of non-pharmacological treatment.

VHA has implemented a multi-pronged approach to address this burgeoning public health crisis. This approach includes publication of safety-oriented prescriber guidelines, development of the Opioid Safety Initiative, which requires signed informed consent for the use of long-term opioid therapy, and requiring VHA facilities to contribute VHA controlled substance prescribing data to state prescription drug monitoring programs (PDMPs). PDMPs are provider-searchable databases that contain prescription data—listed by patient—of all controlled substance prescriptions filled in the state. While the degree to which Veterans access out-of-system controlled substance prescriptions is unknown, one seminal study found that 40 percent of overdose decedents had no VHA controlled substance prescriptions in the 90 days prior to death, strongly suggesting out-of-system access is a serious issue.[3]

Impact of VACAA and Expanded Access to Care in the Community on Opioid Safety

The Veterans Access, Choice and Accountability Act of 2014 (VACAA) covers Veterans' visits to private pain management providers and any resulting prescriptions. Given the relatively large proportion of non-VHA reimbursed care that is pain-related (around 25 percent) and the likelihood that private pain management will include opioid prescriptions, we hypothesize that VACAA will increase participants' risk of unsafe opioid therapy, including rapid-dose escalation, crossing into risky dose ranges and co-receipt of benzodiazepine therapy.

We have assembled a multi-disciplinary team of clinical researchers and operations partners to improve methods of measuring outside-of-VHA controlled substance receipt. This team is supported by several Centers—VHA's Pharmacy Benefits Management, Brandeis University's PDMP Center of Excellence, and the Pain Research, Informatics, Multi-morbidities & Education Center of Innovation—that each bring important perspectives and expertise to the work.

Pilot Findings Suggest Need for Improved Safety Measures

Using data supplied by the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system, we identified all individuals with VA source of payment for controlled substance prescriptions in Kentucky during fiscal year 2014. We divided the sample into two categories: those for whom the only source of payment was VA ("sole source") and those for whom sources of payment were VA plus at least one other source, whether Medicare, Medicaid, private insurance, and/or cash ("multiple source"). We then compared differences between groups on proportion of two measures of risky opioid therapy: combination opioid/benzodiazepine therapy and high-dose opioid therapy. We performed two multivariable models to examine the association between multiple sources of payment and: 1) percentage of opioid prescription days with overlapping benzodiazepine prescriptions; and 2) logistic and high-dose opioid therapy.

Of nearly 17,000 individuals included in the analyses, approximately 11,000 were sole source participants and 6,000 multiple source. Sole source participants' rates of combination opioid/benzodiazepine therapy were well below those for multiple source participants. In terms of high-dose opioid therapy, the rates among sole source participants were just over half the rates among multiple source participants. On multivariable analyses controlling for age and gender, having multiple sources of payment was independently associated with percentage of opioid prescription days with overlapping benzodiazepine prescriptions and odds of high-dose opioid therapy. This pilot work suggests that expanded access through programs such as VACAA may indeed lead to riskier pain treatment for Veterans unless there are new measures in place to improve safety.

We are undertaking a more granular analysis using the methods piloted above in a targeted evaluation of VACAA in both Kentucky and Arizona, states with high rates of opioid use (KY) and VACAA-eligible Veterans (AZ), respectively. Ultimately, we seek to develop interventions that will help to improve the safety and quality of pain care for Veterans. For example, if our work reveals hot spots where Veterans are receiving low-quality pain care from non-VHA providers, we can target those providers for academic detailing and other provider education models developed and shown to be effective in VHA.

References

1. Hing E., Cherry D.K., Woodwell D.A. National Ambulatory Medical Care Survey: 2004 Summary. In: U.S. Department of Health and Human Services, ed.: Centers for Disease Control and Prevention, National Center for Health Statistics; 2006.

2. Chou R., Turner J.A., Devine E.B., et al. "The Effectiveness and Risks of Long-term Opioid Therapy for Chronic Pain: a Systematic Review for a National Institutes of Health Pathways to Prevention Workshop," *Annals of Internal Medicine* 2015;162:276-86.

3. Bohnert A.S.B., Valenstein M., Bair M.J., et al. "Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths," *JAMA: The Journal of the American Medical Association* 2011; 305:1315-21.

Research Highlight

A VA Priority: Complementary and Integrative Health Approaches to Addressing Pain

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Almost half of Veterans experience chronic pain, making it the most common condition for Veterans seeking care within VA. Additionally, 15 percent use opioids after combat.[1] These rates are much higher than those seen in the general population, which is experiencing an opioid "epidemic," as underscored by a continued rise in opioid-related deaths.

In response to these concerns, VA Secretary McDonald committed VA and HSR&D to the White House to lead the examination of non-opioid alternatives to pain management. To fulfill this commitment, HSR&D sponsored a small, one-day expert meeting in April 2016 to plan for a November 2016 State of the Art (SOTA) meeting. To prepare for the expert meeting, the VA Evidence Synthesis Program (ESP) conducted a rapid review of the literature evaluating the effects of complementary and integrative health (CIH) therapies on opioid use, while a second group of CIH and pain researchers reviewed the literature on the effects of CIH on pain. The November 2016 SOTA will evaluate evidence about the effectiveness of non-opioid therapies (including but not limited to CIH) for pain, and identify promising practices, operational barriers, and a research agenda on non-opioid therapies for pain.

CIH (formerly "CAM," or complementary and alternative medicine) includes yoga, meditation and acupuncture—all of which are emerging non-pharmacologic options that might effectively address pain with fewer of the risks or side effects associated with traditional medical therapies.

The Institute of Medicine and others report patients often use CIH therapies because they prefer non-pharmacological self-management options or experience unwanted side effects or lack of response with pharmacologic and other commonly offered approaches. CIH therapies appear acceptable not only to Veterans, but also to active duty troops, with 29 percent of military treatment facilities offering CIH approaches through 275 programs in total. CIH therapies were also recommended in the Office of The Army Surgeon General's 2010 *Standardized DoD and VHA Vision and Approach to Pain Management*.

The Effectiveness of CIH Approaches on Pain

Over 2,000 randomized controlled trials on CIH have been reported in the English-language scientific literature.[2] In 2014, VA's ESP conducted four reviews of systematic reviews and found yoga, tai chi, mindfulness, and acupuncture have "strong" or "promising" effects on pain.[3] For example, the VA ESP found evidence of a positive or a potentially positive effect of acupuncture on chronic pain, headaches, pain in general, and osteoarthritis pain. They found yoga had been studied most extensively for low back pain and showed consistent short-term benefits for that pain.

Clearly, the effectiveness of CIH therapies on pain might not translate to its deterrence or reduction of opioid use, but that can be better understood through an examination of the literature and relevant intervention studies. Patients can easily become addicted to opioids, and that addiction is not likely to be broken through meditation, acupuncture, or yoga. However, busy clinicians are often overwhelmed by patients with pain, and prescribing drugs can be a quick solution when non-pharmacologic options are poorly provisioned. Appropriately resourced CIH might contribute to patient-centered self-management and offer busy clinicians a feasible alternative to opiates for patients' pain.

Are CIH therapies cost-effective approaches to addressing pain? We should have an initial answer in late 2017 from our cost-effectiveness analysis of several types of CIH therapies on musculoskeletal pain. However, a breathing meditation program was shown by Stahl and colleagues (2015) to result in an average 43 percent reduction in billable encounters.

Examining and Providing Complementary and Integrated Health is a VA Priority

Given the potential for CIH to improve Veterans' health and the patient-centeredness of care, the recently-passed 2015 U.S. Omnibus budget called for the expansion of research and education on, and delivery of, CIH to Veterans. CIH figures prominently in several recent VA initiatives, including VA's Blueprint for Excellence (as the focus of needed research under strategy 7j), the 2015 MyVA Integrated Plan, and a VA Office of Patient Care Services' *PACT Pain Roadmap*.

CIH therapies are offered throughout VA. In fact, a recent survey conducted by the VA Healthcare Analytics & Information Group found 82 percent of facilities offered some type of mindfulness or meditation, 73 percent offered yoga, 60 percent offered acupuncture, 49 percent offered Tai Chi/QI Gong, and 37 percent offered chiropractic care.

CIH holds promise as a Veteran-centered approach to improving pain. VA has an opportunity to strengthen the evidence base for CIH as a pain intervention, and understand how CIH impacts pain, the patient-centeredness of the care experience, and provider experiences and approaches including opioid use.

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Research Highlight

Treatments for Veterans with Chronic Low Back Pain: The CAMEO Trial

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Musculoskeletal pain is common, accounting for two-thirds of all primary care visits for pain, and chronic low back pain (CLBP) is the most prevalent, disabling, and costly of all musculoskeletal pain conditions.[1] As highlighted in practice guidelines, many options are available to treat CLBP, yet management is difficult because of the lack of consensus to guide clinician decisions. Analgesics, or painkillers, remain the first line of treatment, but clinicians often do not use the entire array of analgesics that have been shown in clinical trials to be efficacious for CLBP.

Until recently, use of opioid analgesics has increased both outside and within VA for many pain conditions, including CLBP. While some pain experts viewed this trend as evidence of improved pain treatment, others have equated this practice to "flying blind," given the paucity of trials evaluating the effectiveness and safety of opioids.[2] Many patients continue to experience severe, disabling pain despite opioid treatment; others report intolerable side effects from opioids. Primary care providers often struggle with opioid treatment decisions and worry about fostering prescription drug abuse, misuse, and opioid use disorder. These struggles have increased as the rate of prescription opioid overdose deaths in the United States has risen four-fold between 1999 and 2009, reflecting an epidemic of prescription opioid overdoses.[3]

For non-pharmacological treatments, the strongest trial evidence is for those that use cognitive or behavioral approaches. Despite this evidence, primary care settings have not routinely implemented non-pharmacological treatments for CLBP because of time constraints, lack of provider knowledge in non-pharmacological and self-management strategies, and limited availability of specialists to deliver non-pharmacological treatments. However, the integration of psychologists into VA primary care settings increases the feasibility of delivering non-pharmacological interventions. While multidisciplinary pain clinics produce the best outcomes using both pharmacological and non-pharmacological treatments, the availability of such clinics is limited. Even if more referral services were available, the enormous burden of CLBP among Veterans requires that most management still needs to occur in the primary care setting.

Given the heightened safety concerns surrounding analgesic use, especially opioids, and data revealing that analgesics provide clinically significant relief for only a minority of patients, research to compare pharmacological and non-pharmacological treatments to improve the management of CLBP is needed. To meet this need and address some barriers to effective pain management that can be practically applied in VA primary care settings, our research team designed the **CA**re **M**anagement for the **E**ffective use of **O**pioids **(CAMEO)** Trial. CAMEO is an HSR&D-funded, two-armed randomized clinical trial to compare the effectiveness of pharmacological versus non-pharmacological approaches for primary care patients with CLBP. The pharmacological arm involves algorithm-based co-analgesic treatment coupled with guideline-concordant opioid management. Patients in the non-pharmacological arm (BEH) receive pain self-management and pain coping skills training. The primary study aim is to compare the interventions' effects on pain intensity and function at 6 and 12 months.

The CAMEO interventions last for six months. This duration is predicated on the likelihood that prospective adjustment of medications will be required to optimize pharmacological treatment. In addition, pain self-management and coping skills will require time for the patient to learn, apply, and optimize non-pharmacological treatment for CLBP. The length of the follow up and schedule of outcome assessments are to detect three types of treatment effects: 1) "early" (3 months) intervention benefit; 2) immediate post-intervention benefits at 6 months; and 3) sustained benefits at 9 and 12 months post-randomization.

Analgesics are the most common mode of treatment for chronic low back pain in primary care. However, monitoring of treatment response with appropriate adjustments and assessing adherence, side effects, and signs of misuse are often suboptimal in clinical practice. Many patients continue to have inadequate pain relief and poor functioning despite analgesics, including long-term opioids. Primary care providers (PCPs) need other treatment options if their patients' CLBP does not respond to analgesics or if intolerable side effects emerge.

Effective pain management should encompass more than pharmacological management directed at pain scores; it should address a variety of contributing psychological, social, and behavioral factors. Nurse care managers or clinical psychologists, working in concert with PCPs, may be in an ideal position to identify these factors and deliver interventions that relieve Veterans' pain. Nurse care management for optimized pharmacological management and psychologist-delivered optimized non-pharmacological treatment are central to CAMEO, and study findings will elucidate the comparative effectiveness of these two approaches.

References

1. Schappert S.M. "Ambulatory Care Visits to Physician Offices, Hospital Outpatient Departments, and Emergency Departments: United States, 1997," *Vital & Health Statistics* 13 1999; 14:1-39.

2. Von Korff M. and Deyo R.A. "Potent Opioids for Chronic Musculoskeletal Pain: Flying Blind?" *Pain* 2004; 109:207-9.

3. Calcaterra S., Glanz J., and Binswanger I.A. "National Trends in Pharmaceutical Opioid Related Overdose Deaths Compared to other Substance Related Overdose Deaths: 1999-2009," *Drug Alcohol Dependence* 2013; 131(3):263-70.

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How do we change the vital equations involving the sequential and simultaneous neurobehavioral processing of persistent somatic pain signals in the context of an individual's lived environment and experience? A well-funded pain research portfolio has great potential for affecting this trajectory so that Veterans hurt less and have a better quality of life and that VHA and its clinicians feel rewarded for their dedication to good pain care.

References

1. The National Academies Press. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (2011). Available at www.nap.edu/read/13172/chapter/2.
2. Carr D.B. "'Pain is a public health problem'—what does that mean and why should we care?" *Pain Medicine* 2016; 17(4):626-27.
3. Gallagher R.M. "Chronification to maldynia: Biopsychosocial failure of pain homeostatis," *Pain Medicine* 2011; 12(7):993-5

Continued from page 6

References

1. Toblin R.L., Quartana P.J., Riviere L.A., Walper K.C., Hoge C.W. "Chronic Pain and Opioid Use in US Soldiers after Combat Deployment," *JAMA Internal Medicine* 2014;174(8):1400-1.

2. Elwy A.R., Johnston J.M., Bormann J.E., Hull A., Taylor S.L. "A Systematic Scoping Review of Complementary and Alternative Medicine Mind and Body Practices to Improve the Health of Veterans and Military Personnel," *Medical Care* 2014; 52(12 Suppl 5):S70-82.

3. Available at: www.hsrd.research.va.gov/publications/esp/cam_mindfulness.cfm
www.hsrd.research.va.gov/publications/esp/acupuncture.cfm
www.hsrd.research.va.gov/publications/esp/taichi.cfm
www.hsrd.research.va.gov/publications/esp/yoga.cfm