

May 20, 2015

Linda Porter, Ph.D.
NINDS/NIH
31 Center Drive
Room 8A31
Bethesda, MD 20892

Re: National Pain Strategy: A Comprehensive Population Health-Level Strategy for Pain

Dear Dr. Porter:

The American Osteopathic Association (AOA), which represents 110,000 osteopathic physicians and osteopathic medical students nationwide, commends the Department of Health and Human Services (HHS) for its comprehensive approach to addressing the challenges related to chronic pain and its treatment. We appreciate the opportunity to comment on the draft National Pain Strategy and offer the AOA's unique insight based on the principles of osteopathic medicine – we commend HHS for having representatives of the osteopathic profession involved in the development of this strategic plan through the expert working groups.

The AOA is pleased to be joined in our comments by the American Association of Colleges of Osteopathic Medicine (AACOM), which represents the 31 accredited colleges of osteopathic medicine in the United States. These colleges are accredited to deliver instruction at 44 teaching locations in 29 states. In the 2014 - 2015 academic year, these colleges are educating over 24,600 future physicians – more than 25 percent of new U.S. medical students.

The osteopathic medicine philosophy encompasses patient-centeredness, prevention, wellness, touch, empathy, and the mind/body/spirit approach to address disease states as well as the full spectrum of patient care (e.g., primary, secondary and tertiary). As such, osteopathic physicians empower their patients to make choices that result in better health outcomes. This engagement requires trust and strong communication, both of which are deeply engrained in the osteopathic physician's relationship with his/her patients.

Additionally, osteopathic physicians (DOs) receive extra training in the musculoskeletal system—the body's interconnected system of nerves, muscles and bones that makes up two-thirds of the body mass. This training provides osteopathic physicians with a better understanding of how an illness or injury in one part of the body can affect other parts and can impact or cause pain. The osteopathic approach to medicine and the use of osteopathic manipulative treatment (OMT) effectively address several of the issues and objectives outlined in the National Strategy.

To begin, we agree that primary care physicians bare much of the responsibility for front-line pain care and greater collaboration is needed between pain specialists and primary care clinicians. We believe Patient-Centered Medical Homes (PCMH) play an important role in patient-centered care coordination and collaboration and should be applied on a broader level to enable this collaboration nationwide.

We also believe that collaboration and education between all stakeholders within health care must continue in an effort to address appropriate pain treatment. This includes creating a better understanding of the challenges faced by prescribers and dispensers when dealing with controlled substances, and the unintended consequences, like misuse and diversion, that have led to our nation's current prescription drug epidemic.

Our comments focus on the plan's objectives as they relate to the core principles of osteopathic medicine, and we make the following key observations and recommendations:

1. The National Strategy should consider Osteopathic Manipulative Treatment as part of the multimodal recommended therapies.
2. Reimbursements and payment incentives should recognize and allow for the counseling of patients on the full range of biological, psychological, and social effects of pain on the individual.
3. Opioids can be safely and effectively used to manage pain, but strategies to prevent overuse of opioids by patients should be implemented.
4. A longitudinal curriculum in pain management, which includes addressing psychological, social and behavioral issues, should run parallel with the utilization, application, and risk mitigation training in the use of opiates and other highly addictive pain management medications.
5. Additional resources are needed to support the convening of the various groups indicated for assessing curricula and developing recommendations, and for faculty development and curriculum change support.
6. AACOM, as well as the AOA Commission on Osteopathic College Accreditation (COCA) should be included in the list of stakeholders and collaborators for addressing professional education and training.
7. Racial and ethnic disparities may be alleviated through improvements in the cultural competency skills of physicians and through effective recruitment of underrepresented minorities into health professional schools.
8. HHS should consider pulling together the most effective patient educational material and outreach messages from physician associations and disseminate that information nationally.

PREVENTION AND CARE

The AOA and AACOM agree with the Institute of Medicine's position that "the treatment of pain is a moral imperative" of physicians, and supports the importance of multimodal treatment of pain in order to avoid the overuse of opioids. We support the strategy's aim to advance evidence-based, culturally sensitive and individualized prevention and care of pain, using the biopsychosocial model and providing value determined by accepted, validated, and systematically collected outcomes.

The AOA and AACOM also concur that when chronic pain develops, treatment should begin with a comprehensive assessment, followed by creation of a care plan that can evolve over time to address the full range of biological, psychological, and social effects of pain on the individual. This model supports osteopathic physicians' approach to medicine.

With regard to the use of pain medications, physicians have a shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose. The AOA, in collaboration with several other medical and pharmacist care stakeholder organizations, developed a

[consensus document](#) highlighting the warning signs for health care practitioners to detect diversion, misuse, and abuse of controlled substance medications.

Objective 1: Characterize the benefits and costs of current prevention and treatment approaches.

The Pain Strategy calls for a thorough benefit-to-cost analysis of current prevention and treatment approaches to identify and create incentives for use of interventions having high benefit-to-cost ratios. According to the strategy, such an analysis may help guide the choice between therapies that are equally efficacious but whose cost differs.

We believe the guiding principle for such research should be to enhance the ability of physicians to provide the highest quality care to patients utilizing the best proven and widely accepted evidence-based medical information at the time of treatment. Research results should be advisory and not be used to control medical decision-making authority. Physicians in practice should be involved in discussions and decisions regarding such research. The physician/patient relationship must be protected and the needs of the patients should be paramount.

There are numerous approaches to treating pain. As pain varies by the clinical and sociological situation of the patient, the provider's approach should be tailored to the patient's medical needs and circumstances. Addressing symptoms may involve activities other than clinical intervention such as addressing socio-structural issues that exacerbate pain and offering strategies to mitigate these issues. In order to learn more about these critical factors, providers need to spend time with patients to inquire about key symptoms and build trust with patients in order to engage them in the best treatments to address these symptoms.

Other pain management strategies may require clinical intervention. We offer commentary on two types of clinical intervention for pain: OMT and opioids. **The counseling described above underpins both of these treatment strategies, as well as any other pain treatment strategy, and should be incentivized with appropriate reimbursement.**

Osteopathic Manipulative Treatment

Osteopathic Manipulative Treatment (OMT) is a viable treatment plan which has been shown to alleviate pain and likely to reduce costs, according to [OMT studies](#). With OMT, osteopathic physicians use their hands to examine the back and other parts of the body such as joints, tendons, ligaments, and muscles, for pain and restriction during motion that could signal an injury or impaired function. The hands-on approach of osteopathic medicine builds a closer relation between the physician and patient which enables the patient to discuss the psychosocial elements of their pain. The goal of osteopathic treatment is to enhance the patient's ability to function independently with minimal or no pain, while maintaining this independence through appropriate home exercises, nutrition, and lifestyle.¹

OMT can be helpful in relieving back pain as well as relieving discomfort and musculoskeletal abnormalities associated with a number of disorders including asthma, carpal tunnel syndrome, menstrual pain, sinus disorders, and migraines. When appropriate, OMT can complement, and even replace, drugs or surgery. In this way, OMT brings an important dimension to standard medical

1 <http://www.spine-health.com/treatment/spine-specialists/treatment-osteopathic-physician>

care. **HHS should include Osteopathic Manipulative Treatment as part of the multimodal recommended therapies.**

A [study](#) conducted at UNT Health Science Center in Fort Worth (UNTHSC) reported that patients receiving OMT for low back pain required significantly less medication and less physical therapy than those who did not receive the treatment. OMT and ultrasound therapy were used to treat chronic low back pain in 455 adults. Patients in the study who received ultrasound therapy did not see any improvement, but the patients who received six treatments of OMT did see significant improvement in pain, used less prescription medication and were more satisfied with their care over the 12 weeks of the study than those patients who did not receive OMT.² Nearly two-thirds of the patients who received OMT had a 30 percent reduction in their pain level, and half had a 50 percent reduction in their pain level.

According to the author of the study, John Licciardone, D.O., “Not only does OMT work to reduce pain, it seems to work even better in people who experience higher pain levels. These are the very people who are often treated with potentially addictive drugs such as OxyContin and Vicodin, epidural steroid injections or surgery. If we can reduce the use of these drugs and invasive procedures by helping people to feel better with a hands-on treatment that has few side effects...it makes a significant contribution to the management of chronic pain.”³

Opioids

Opioids have been an increasing focus of discussions in recent months due to the potentially addictive nature of these medications, the active management needed by providers for patients on this medication, and the subsequent growth of self-directed use of this medication outside the recommendations of the prescribing physician.

Opioids can be safely and effectively used to manage pain, but strategies to prevent overuse of opioids by patients should be implemented. Opioids have tremendous value to some patients in the management of their pain. In particular, hospice patients and late-stage cancer patients have a favorable risk-benefit ratio for the use of this medication. However, for other patient populations, more judicious prescribing is required. In order to mitigate concerns with overuse of opioids by patients, we support prescription drug monitoring programs (PDMPs) at the state level which can track each patient’s prescriptions for opioids. As prescribing physicians can use PDMPs to check on a patient’s history of opioid prescriptions in advance of prescribing opioid-based medication, PDMPs empower physicians to coordinate and ensure the patient is not over-prescribed with opioids. In order to maximize PDMPs’ value, we support:

- a. Interoperability between PDMPs that enables regional data sharing;
- b. User-friendly, intuitive design seamlessly integrated with the EHR system, and that minimizes the physician’s time and effort to successfully look up and input information into the PDMP; and
- c. Use of PDMPs not inhibiting physicians’ ability to practice medicine.

Patient misuse of opioids also has resulted in increased rates of unintentional overdose. As the rates of death due to opioid toxicity have risen in recent years, we believe availability of naloxone, a medication which can prevent death once a patient is suspected of overdose, should be increased. Laws should protect first-responders, physicians, and others from liability in administering naloxone.

² [ScienceDaily](#), “Hands-on Treatment Improves Chronic Low Back Pain”, March 18, 2013

³ ScienceDaily

Objective 2: Develop nationwide pain self-management programs

The osteopathic profession supports patient education on the nature of pain, how to prevent it, and how patients can utilize non-pharmaceutical self-treatment. Osteopathic physicians work in partnership with their patients and believe the body is capable of self-regulation, self-healing, and health maintenance. Therefore shared decision-making in a patient's care plan requires patients to be well-educated about their conditions and health care options, including self-management of their conditions. The more patients understand their treatment options and how to maintain good health, the more likely it is they will comply with treatment and achieve better outcomes.

We agree that self-management programs should be integrated into the health care system to bolster their use and prevalence and to guide patients through the several levels of pain, and we believe the patient-centered medical home (PCMH) can assist with them. The PCMH's team-based approach to care can give patients access to resources and tools to support them in their effort to maintain good health and well-being. **HHS should consider pulling together the most effective patient educational material and outreach messages from physician associations and disseminate that information nationally.**

Objective 3: Develop standardized, consistent, and comprehensive pain assessments and outcome measures across the continuum of pain.

We agree that in the development of additional quality metrics around pain measurement, it is important to clearly define the diagnosis for each clinical condition and the pain assessment tools or scales that are acceptable for documentation. We also support the inclusion of physician specialty societies in development of these metrics to model real-world treatments.

PROFESSIONAL EDUCATION AND TRAINING

According to the National Strategy, most health profession's education programs have yet to give pain adequate attention. Improvements are needed in discipline-specific core competencies, including basic knowledge, assessment, effective team-based care, empathy, and cultural competency. The AOA and AACOM support pain education at pre-and post-graduate levels for all practitioners whose patient populations face pain-related conditions, and osteopathic medical education has a special focus on non-pharmaceutical treatment of acute and chronic pain. We refer to the Journal of the American Osteopathic Association's articles of [November 2004](#) and [November 2007](#) for additional information.

Objective 1: Develop, review, promulgate, and regularly update core competencies for pain care education and licensure and certification at the undergraduate and graduate levels.

The AOA appreciates being included in the list of stakeholders and collaborators for this objective. The AOA and AACOM support a further look at pain-related issues in the curricula as they develop over the continuum of physician education, from medical school, through residency, to maintenance of licensure and certification, particularly in regard to risk evaluation and mitigation of narcotics prescribing and application.

Since 2010, the AOA has also been working with ten multidisciplinary professional associations to develop educational resources to address the misuse and abuse of extended release/long acting (ER/LA) opioids, resulting in the formation of the Collaborative for REMS Education ([CO*RE](#)) in 2013. CO*RE partners have developed a curriculum that is fully compliant with the Food and Drug Administration's REMS educational requirements. The AOA delivers ER/LA Opioid REMS

curriculum at osteopathic Continuing Medical Education (CME) conferences, and as of 2014 has educated more than 7,000 health professionals using the CO*RE curriculum.

We agree a longitudinal curriculum in pain management should run parallel with training on the use, application, and risk mitigation training in the use of opiates and other highly addictive pain management medications. Psychological, social, and behavioral health issues also need to be a major part of the approach on these issues.

Additionally, addressing the issue of pain management throughout the continuum of the patient population from pediatric through geriatric subsets needs to be addressed in any curriculum due to alterations in pain perception, application of treatment modalities, response to treatment, and considerations for drug addiction and abuse risk that is varied among them.

Resources are needed to support the convening of the various groups indicated in the Plan for assessing curriculum and developing recommendations, and for faculty development and curriculum change support. In addition to what is described in the Strategy, resources should include:

- Webinars and teaching modules;
- Development of an inclusive working consortium;
- Examples of tailored educational program objectives;
- Pain and educational assessment tools;
- Access to prescription monitoring programs and data;
- Pain-related listings of publications and online references;
- Listing of organizations related to pain education, clinical practice/treatment, and research;
- Listing of organizations that are directed at pain management literacy for patients;
- Example framework policies and guidelines on informed consent, patient agreements, institutional pain management resource manuals, etc.; and
- Educational research funding as grants and fellowships.

The AOA, AACOM, and the Accreditation Council on Graduate Medical Education have agreed to a single accreditation system for graduate medical education programs in the United States, with AOA-accredited training programs transitioning to ACGME accreditation between July 1, 2015 and June 30, 2020. For the present time, we recommend that the Strategy concerning professional education and training include Osteopathic Graduate Medical Education (OGME). **AACOM also should be included among the organizations necessary to address these areas, as should the AOA Commission on Osteopathic College Accreditation (COCA).**

With regard to certification programs, the AOA [Conjoint Pain Medicine Examination Committee](#) is the group of certifying boards responsible for the evaluation and recommendation of the Certificate of Added Qualifications in Pain Medicine. In doing so, it enhances the public's access to pain care by identifying board-certified osteopathic physicians who have advanced knowledge, skills and abilities in pain medicine. Osteopathic Pain Practice is a multi-disciplinary subspecialty of osteopathy concerned with the assessment, diagnosis and treatment of the entire scope of pain, painful diseases and disorders, and sequelae which emphasizes the use of osteopathic principles, practices, and manipulative treatment.

DISPARITIES

The AOA and AACOM commend HHS for recognizing that pain is more prevalent in a diverse set of population groups typically of interest to public health programs, including people with limited access to health care services, racial and ethnic minorities, people with low income or education, and those at increased risk because of where they live or work. We agree with the objectives to eliminate disparities and promote equity in pain assessment and treatment.

Osteopathic medicine has long emphasized the importance of practicing in rural and underserved areas, with more than 20 percent of osteopathic physicians practicing in a designated medically underserved area. While DOs make up 8 percent of all U.S. physicians, they comprise 40 percent of all physicians who practice in medically underserved areas, where a disproportionate number of Medicaid eligible patients reside.

Objective 1: Reduce bias (implicit, conscious, and unconscious) and its impact on pain treatment by improving understanding of its effects and supporting strategies to overcome it.

The AOA and AACOM believe cultural competency – a set of academic and personal skills – allows one to understand and appreciate cultural differences among groups. The better a health care professional understands a patient’s behavior, values and other personal factors, the more likely that patient will receive effective, high quality care.

Objective 2: Improve access to high-quality pain services for vulnerable population groups.

In addition to improving in the cultural competency skills of physicians, health care disparities may also be alleviated through effective recruitment of underrepresented minorities into health professional schools and the development of approaches to encourage all physicians to provide care to underserved minority populations.

The AOA and AACOM support early intervention and treatment programs for minorities suffering from breast cancer, hypertension, diabetes, prostate cancer, alcoholism, and other diseases that disproportionately affect minority populations. Many of these conditions can involve acute pain that can turn into chronic pain if not correctly treated. We also support increased funding for programs, including those targeted at minority populations, which decrease mortality rates and increase immunization and access to other preventive health care services.

The Strategic Plan should consider the development of an app in addition to the proposed interactive web-based gateway to information and resources for patients and families. Mobile phones are plentiful in various communities, and individuals may have these devices more easily available than a computer for a web-based program that only runs smoothly on a computer screen.

Objective 3: Facilitate communication among patients and health professionals.

The AOA and AACOM support the identification of new methods to involve physician members in the communities in which they serve. In addition, we recommend focus groups of patients to obtain their perspective on the best way to facilitate communication. The AOA and AACOM also support reimbursement and incentives for direct translation services and interpreters.

Objective 4: Improve the quality and quantity of data available to assess the impact of pain on higher risk population groups, including data on group members’ access to high-quality pain care and the costs of disparities in pain care.

The AOA and AACOM support efforts to expand outreach to culturally diverse populations, including enhancing research efforts and improving healthcare options in communities where incidents of certain healthcare conditions are more prevalent than in the community as a whole. The AOA and AACOM also support the evaluation and analysis of medical information which would permit the targeting of populations who are at greatest risk.

SERVICE DELIVERY AND REIMBURSEMENT

The AOA and AACOM strongly support delivery models that enhance and promote the role of primary care physicians as the foundation for the health care system and emphasize the provision of coordinated care across the health care spectrum. The AOA and AACOM concur with the Pain Strategy's endorsement of a population-based, disease management approach to pain care that is delivered by integrated, interdisciplinary, patient-centered teams and is consistent with real world experience.

Objective 1: Define and evaluate integrated, multimodal, and interdisciplinary care for people with acute and chronic pain, and end of life pain.

As we described earlier, the osteopathic philosophy addresses the challenges and issues cited in the National Strategy. Given the comprehensive approach already used in osteopathic medicine, the AOA and AACOM believe the PCMH and other coordinated care models such as Accountable Care Organizations (ACOs) (aka medical neighborhood), which are comprised of physician-led integrated health care teams, are well-equipped to address pain management on a broader level.

The PCMH is a necessary component of integrated care and provides the foundation and infrastructure of the ACO's medical neighborhood. We believe greater participation of small and mid-sized practices should be incentivized to establish a fully integrated health care delivery system. PCMHs and ACOs already use many tools to coordinate and integrate treatment plan activities into medical care. Studies show that the comprehensive care in PCMHs leads to improvements in categories such as costs, utilization, access to care, prevention and population health.

Depending on the coordinated care model, the physician-led health care team can include primary care physicians, nurse practitioners, physician assistants, mental health practitioners, social workers, care coordinators, pharmacists and community health services; a robust electronic health records (EHR) system supports the health care team and the patients they serve.

An EHR system documents a patient's treatment and can apply clinical decision support and analytics to tailor a patient's treatment plan, including pain care and management. As we noted earlier, the latest advances in health IT should be applied to enhance interoperability and integration of EHR systems with state monitoring programs to allow physicians timely access to their patients' total prescription drug history at the point of care.

Objective 2: Enhance the evidence base for pain care and integrate it into clinical practice through defined incentives and reimbursement strategies, to ensure that the delivery of treatments is based on the highest level of evidence, is population-based, and represents real-world experience.

The AOA and AACOM agree more studies are needed to enhance the evidence base for pain care. We support the development of research projects grounded in osteopathic medicine that have the most promising potential to impact both individual patient outcomes and evidence-based medicine as well as facilitate collaboration within and outside the osteopathic community.

Among the AOA's focus areas for research is exploring osteopathic approaches to chronic pain management that improve patient outcomes, enrich quality of life, and demonstrate cost effectiveness as well as provide a better understanding of the effect of an integrative holistic approach in pain management (including, but not limited to, Osteopathic Manipulative Medicine and Treatment). Areas of exploration include, but are not limited to low back pain, pain in obstetrics, and chronic pain experienced by at-risk or special populations.

In addition, the AOA's Clinical Assessment Program (CAP), a Web-based performance measurement program, analyzes data abstracted from patient medical records in order to evaluate clinical practices against evidence-based guidelines. The overarching purpose of CAP is to improve patient outcomes and ultimately increase quality of patient care.

The AOA CAP addresses pain in relation to Back Pain through its Back Pain CAP module. This module uses a combination of PQRS measures and questions developed by the AOA related to osteopathic treatment of back pain. The osteopathic questions focus on whether a complete structural examination was done, whether there is a diagnosis of somatic dysfunction, and whether osteopathic manipulative treatment (OMT) was done and which techniques used. Pain assessment before and after OMT is also addressed, and the acceptable pain assessment tools or scales that meet the criteria of the back pain module are specifically identified.

The AOA and AACOM stand ready to collaborate with HHS in the effort to collect meaningful evidence that will enhance the treatment and management of pain-related conditions.

Objective 3: Tailor reimbursement to promote and incentivize high-quality, coordinated pain care through an integrated bio-psychosocial approach that is cost-effective, comprehensive, and improves outcomes for people with pain.

The AOA and AACOM agree that the care model must shift from the current fragmented fee for service approach to one based on better incentives for prevention and for collaborative care along the continuum of the pain experience. As noted in the National Strategy, payers tend to provide incentives for mono-therapy and interventional procedures instead of services that conform to the biopsychosocial model of care and incorporate patient and family education, coordinated team-based medication management, counseling, etc.

One significant barrier that prevents more DOs and other physicians from applying OMT and other such non-pharmaceutical treatments is poor reimbursement and time constraints. Although Medicare provides payment for OMT, its payment regulations create obstacles under the current fee-for-service payment model. **Reimbursements and payment incentives should recognize the elements highlighted in the National Strategy, particularly the time for counseling of patients on the full range of biological, psychological, and social effects of pain on the individual.**

The AOA and AACOM also agree that payment models should be value-based. Overall, payment rates must foster investments needed to provide efficient high quality care which is based on value and not volume, as well as maintain the level of resources and services needed for an integrated health care delivery system that will provide comprehensive patient-centered care.

CONCLUSION

We concur with the Strategic Plan that the key to a cultural transformation in pain care is a greater understanding—among members of the public and people with pain alike—of important aspects of chronic pain. Chronic pain is an illness unto itself and not a symptom.

We agree that improvements are needed in pain assessment techniques and practices to assure they are high-quality and comprehensive. The osteopathic approach to medicine provides the pathway to better pain treatment and self-management. The AOA and AACOM look forward to working with HHS on implementation of the National Pain Strategy.

Sincerely,



Robert S. Juhasz, DO
AOA President



Stephen C. Shannon, DO, MPH
AACOM President and CEO

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