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Academic Consortium for Integrative Medicine & Health Commentary to Health and Human Services (HHS) on Inter-agency Task Force Pain Management Best Practices Draft Report

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To the Inter-agency Pain Task Force at HHS:

The Academic Consortium for Integrative Medicine & Health (the Consortium) is the organizational home for the major academic health centers and health systems in North America that have programs in integrative medicine and health. Integrative medicine and health reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic and lifestyle approaches, health-care professionals, and disciplines to achieve optimal health and healing. The Consortium was founded in 1999 by 8 academic health centers including Duke University, Harvard University, Stanford University, University of California, San Francisco, University of Arizona, University of Maryland, University of Massachusetts, and the University of Minnesota. Now with over 75 institutional members, the Consortium continues to grow and represents thousands of scientists, educators, clinicians, and other health professionals who share an interest in the field of Integrative Medicine and Health. The Consortium's mission is to advance evidence-based integrative medicine and health in research, curricula, and sustainable models of clinical care.

We commend the committee's inclusion of conventional and nonpharmacologic therapies to achieve optimal comprehensive pain care.

The Consortium would like to thank the Inter-agency Pain Task Force authors for contributing their expertise and time in creating the 'Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations'[1] and providing thoughtful recommendations. The Consortium commends HHS for its decision to evaluate the evidence for acute and chronic pain care including nonpharmacologic options. The Consortium provides leadership and has extensive experience in incorporating evidence-based approaches such as acupuncture therapy, massage therapy, meditative movement, and mind–body therapies for comprehensive, integrative pain care. In response to the HHS call to comment, we respectfully submit this material supported by the current literature.

Consortium Comments to HHS

CDC	Centers for Disease Control and Prevention
ACP	American College of Physicians
AHRQ	Agency for Healthcare Research and Quality (US)
NIH	National Institutes of Health National Center for Complementary and Integrative Health
FDA	US Food and Drug Administration
TJC	The Joint Commission
HHS	Health and Human Services

1. Use definitions for nonpharmacologic disciplines that are consistent with legal definitions for regulated professions, and use professional organization definitions for nonregulated approaches (see definitions below).

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2. Adopt a consistent standard that uses evidence-based benefits and harms for inclusion of medical/health practices into protocols and insurance coverage. Evidence-based standards can be applied to procedures, surgeries, drugs, and nonpharmacologic practices including acupuncture therapy, massage therapy, osteopathic and chiropractic manipulation, physical therapy, meditative movement therapies Tai chi and yoga, mind–body behavioral interventions, music and relaxation therapies, dietary components, and self-care/self-efficacy strategies.
3. Present nonpharmacologic approaches as a first line of pain care per current recommendations by the CDC,[2] the Army Surgeon General Task Force Report,[3] the ACP,[4] and as part of comprehensive pain care the Academic Consortium[5] by the AHRQ,[6] NIH,[7] FDA,[8] and the Joint Commission (TJC).[9,10] Currently, conventional medical practices are situated as normative and nonpharmacologic options are categorized as "complementary or non-mainstream," relegated to a second tier of consideration. To encourage decisions based on evidence, we support the use of impartial terminology taking into account benefits and harms of procedural, surgical, pharmacologic and nonpharmacologic options.

Update Recommendations to Specific Sections of the HHS Report

Update to included literature for Section 2.6

Acupuncture therapy. Over 4 million American adults receive acupuncture annually.[11] Acupuncture is generally considered safe when performed by a licensed, well-trained practitioner using single-use presterilized needles,[12–19] with infrequent minor side effects such as feeling relaxed, elated, tired, or having sensation or itching at point of insertion.[16] Rare serious complications such as infection or pneumothorax are directly related to insufficient training.[17,18,20] In multiple systematic reviews with meta-analyses, acupuncture was effective in reducing postsurgical pain compared to sham acupuncture, controls, and usual care with reduction in opioid need and lowered incidence of opioid-related side effects such as nausea, dizziness, sedation, pruritus, and urinary retention.[21–23] Acupuncture is feasible and highly acceptable for adult and pediatric inpatients[24,25] for acute pain in the emergency department setting[26,27] and for chronic pain conditions.[28,29] An individual patient data meta-analysis evaluating 39 trials (20,827 patients) of acupuncture for chronic nonspecific back pain, neck pain, shoulder pain, chronic headache, or osteoarthritis[30] found acupuncture was superior to both sham and no acupuncture controls for each pain condition. The benefits of acupuncture were found to persist over time with only a small decrease, approximately 15%, in treatment effect at 1 year after randomization. Acupuncture biomechanisms involve complex interrelationships among local tissue mechanoreceptors, propagation of mechanical signals in the connective tissue and neurochemical brain signaling. As with all medical treatments, updating analysis of benefit/harms, clinical indications, frequency, dosage, and timing of care is recommended.

Gaps and Recommendations for Section 2.6

We recommend rewording of 'gaps and recommendations' to respect equitably applied standards of the evidence-base.

Gap 1: There are evidence-based modalities and health approaches "that remain unknown to the broader medical community" (p. 33) and are often overlooked in the management of pain.

- **Recommendation 1a:** Consider evidence-based modalities and health approaches, including acupuncture therapy, mindfulness meditation, movement therapy, art therapy, massage therapy, manipulative therapy, spirituality, yoga, and tai chi, in the treatment of acute and chronic pain, when indicated.
- **Recommendation 1b:** Develop up-to-date Clinical Practice Guidelines for the application of evidence-based nonpharmacologic options and health approaches for specific indications.

Gap 2: There is a gap in dissemination of research on biomechanism, efficacy, effectiveness, and cost effectiveness of nonpharmacologic modalities for acute and chronic pain. Generalization of existing research to special populations and strategies to incorporate evidence-based nonpharmacologic modalities into care models will benefit from further research.[5] Clinicians need clarification and guidance regarding dosage, frequency, and timing of comprehensive strategies that include nonpharmacologic options.

- **Recommendation 2a:** Support ongoing research of nonpharmacologic approaches and combinations with pharmacologic means to further clarify therapeutic value, benefits and harms, mechanisms of action, and contribution to the economics of pain care in distinct clinical settings including perioperative surgical pain and in chronic pain conditions and syndromes. Specific research is recommended regarding dosage, timing, and frequency of evidence-based interventions and combinations.
- **Recommendation 2b:** Include evidence-based modalities and health approaches as an integrative approach to the treatment of chronic pain.
- **Recommendation 2c:** Conduct further research on supplements such as alpha lipoic acid, L-carnitine

transferase, turmeric, and vitamin C and their effect on acute and chronic pain management.

Special populations Section 2.7

For all populations, promote the widespread collection of meaningful outcomes data on all interventions (including nonpharmacologic strategies, behavioral health, medications, procedures, and surgeries), to assess effectiveness for relief of suffering and improvement in function. Special populations should include multimorbidity in general and multimorbidity within specific populations.

Comments on CDC Guidelines Section 4

Opioid prescribing has become more complicated for many reasons. The CDC Guidelines recommend tapering opioid doses to safer levels and incorporating other pharmacologic and nonpharmacologic therapies.[2] It is important to ease the burden on overextended pain medicine prescribers so they can:

a. spend adequate time to assess the complexity of their patient's problems (as the HHS report recommends);
b. receive assistance for the many additional recording and instrumental tasks required to prescribe opioids;
c. provide adequate social supports and behavioral health services for their patients;
d. provide vocational counseling for their patients and access to evidence-based group programs that have been shown to optimize productive and meaningful lives for people in pain;
e. provide all these services in the primary language of the patient.

Additional Recommendations to Definitions Sections 2.5 and 2.6

Definitions of therapies need to reflect the legal status of regulated professions in the United States, modern research, as well as the historical roots of a therapeutic intervention. For example, acupuncture therapy is not based in China alone or as Chinese medicine only but as traditional East Asian medicine. Accurate definitions are essential to inform pragmatic clinical trials (PCTs) that are part of the NIH's vision for bridging the gap between research and care.[31,32] PCTs are performed in real-world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost/time needed to conduct a traditional clinical trial.[31,33] PCTs are also supported through initiatives at the Centers for Medicare & Medicaid (CMS), the Agency for Healthcare Research and Quality (AHRQ), the Patient Centered Outcomes Research Institute (PCORI), Practice-Based Research Networks (PBRNs), and community-based participatory research initiatives across the Federal government.[34] Studies of nonpharmacologic interventions cannot mirror drug studies because they are not practiced as single mechanical operations, and rather represent a clinically contextualized approach. Hence, if a nonpharmacologic intervention is to be studied in a pragmatic trial, its legal definition and real-world clinical practice will best inform stakeholders relying on this HHS report and recommendations.

Suggested

Acupuncture therapy in the United States is a state-regulated practice in which practitioners stimulate specific areas or points on the body by application of heat, pressure, electrical stimulation, or insertion and manipulation of thin (presterilized, single-use, filiform) needles for the purpose of achieving a therapeutic or prophylactic effect.[35] Type, location, dosage, and combinations of stimulation are based on physiological interrelationships of body organs and tissue with associated points or combination of points, informed by historical medical texts and modern research. Acupuncture therapy may be used to alleviate pain as a stand-alone therapy or as part of comprehensive pain care, as well as to treat other physical, mental, and emotional conditions.

Massage therapy is a state-regulated practice that involves manipulation of soft tissue structures of the body to prevent or alleviate pain, spasm, tension, or stress and to promote health and well-being.

Osteopathic and chiropractic manipulation are state-regulated practices. Spinal manipulative therapy (SMT) involves treatment of the spine and pelvic-related joints; manipulative therapy (MT) refers to the treatment of other joints in the body including upper and lower extremities. SMT and MT are often associated with high-velocity, low-amplitude (HVLA) thrust techniques, as well as low-velocity, low-amplitude (LVLA) or joint mobilization techniques. SMT, MT, HVLA, and LVLA are techniques commonly used to improve pain and function, primarily by osteopathic physicians and chiropractors.

Physical therapy is a state-regulated practice utilizing therapeutic exercise, physical modalities, assistive devices, and patient education and training for the preservation, enhancement, or restoration of movement and physical function impaired or threatened by disease, injury, disability, or pain.

Tai chi and Yoga are meditative movement therapies. Tai chi is a low-impact, mind–body exercise originating in China that has become increasingly popular in the West as an effective exercise for rehabilitation related to multiple medical conditions. Tai chi consists of slow prescribed movements with attention to breathing and meditative concentration.

Yoga originated in ancient India and has been adapted in the West. Yoga practice combines attention and meditation (dhyana), breathing (pranayama), and physical postures (asanas) and stretching to promote health and well-being and to help people with health problems manage their health conditions and reduce their symptoms.

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