Appendix 1: Comment on HHS Docket No. CDC-2020-0029
Management of Acute and Chronic Pain
Arya Nielsen, PhD; Heather Tick, MD, Co-chairs Academic Consortium Pain Task Force

The Academic Consortium for Integrative Medicine & Health (Academic Consortium) agrees with the 2016 CDC Guideline that nonpharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain and supports multimodal comprehensive pain care that includes all evidence-based nonpharmacologic strategies. We recommend the following:

1. **Legal definitions for regulated professions**: use of definitions for nonpharmacologic disciplines that are consistent with legal definitions for regulated professions, and the use of professional organization definitions for nonregulated approaches. (*Appendix 2* contains current definitions.)

2. **Evidence-based standard**: adoption of a consistent standard that uses evidence to determine benefits and harms for the inclusion of medical/health practices into protocols and guidelines. 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.1 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.

3. **Safety profiles**: effective nonpharmacologic therapies are low risk and are a preferred/first line of pain care per current recommendations by the CDC,2 the Army Surgeon General General Task Force Report,3 the ACP,4 and as part of comprehensive pain care1 by the AHRQ,5 NIH,5 FDA,7 NAM,8 and the Joint Commission (TJC).9,10 Safer nonpharmacologic options are being effectively used in the community11 and the VA to improve pain care and reduce opioid use and risk. (ref).1

4. **Update of the literature (page 1632) of the 2016 CDC Guidelines**2 The literature on which the 2016 Guideline is based is dated. We recommend updating the literature to include the following evidence-based nonpharmacologic therapies:1

   - 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
   - Self-care/self-efficacy strategies

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1 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; NAM National Academy of Medicine (formerly the Institute of Medicine (IOM); TJC The Joint Commission; VA Veterans Health Administration
Using Acupuncture therapy as an example: Acupuncture therapy is effective in acute and chronic pain care. Acupuncture is generally considered safe when performed by licensed, well-trained practitioners using single-use pre-sterilized needles, with infrequent minor side effects such as feeling relaxed, elated, tired or having sensation or itching at point of insertion. Rare serious complications such as infection or pneumothorax are directly related to insufficient training. In multiple systematic reviews with meta-analyses, acupuncture was effective in reducing post-surgical pain compared to sham acupuncture, controls and usual care with reduction in opioid need with lowered incidence of opioid-related side effects such as nausea, dizziness, sedation, pruritus and urinary retention. Acupuncture is feasible and highly acceptable for adult and pediatric inpatients for acute pain in the emergency department setting and for chronic pain conditions. An individual patient meta-analysis evaluating 39 trials (20,827 patients) of acupuncture for chronic nonspecific back pain, neck pain, shoulder pain, chronic headache or osteoarthritis 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 one year after randomization. Only severity of pain was found to be a positive predictor of response; gender, duration of chronic pain, age and psychological status did not impact response. Biological mechanisms of acupuncture: Research over 40 years provides a robust and complex physiological basis for acupuncture’s therapeutic effects. Early research showed acupuncture stimulates endogenous opioid release in the brain and into the cerebral spinal fluid, contributing to a systemic analgesic effect able to be blocked by naloxone. This endorphin response can be activated with sham acupuncture as well, contributing to the confusion in early randomized acupuncture trials that used penetrating needles as controls, assuming them to be inert. More recently, neuroimaging has established central neurobiological mechanisms of acupuncture in the treatment of pain, and as distinct from placebo interventions: verum acupuncture elicits more and distinct modulation effects on neurological components than sham acupuncture. In humans, brain imaging using positron emission tomography (PET) found that acupuncture treatment increases short and long term opioid receptor binding potential in multiple pain and sensory processing regions of the brain in patients with fibromyalgia. Long term increases in opioid receptors following acupuncture were associated with greater reduction in pain. Translational research using functional magnetic resonance imaging (fMRI) in carpel tunnel patients found verum acupuncture modulates the somatosensory cortex area of the brain, providing a correction for maladaptive change present in carpel tunnel syndrome patients. Acupuncture also deactivates limbic brain areas, important for emotion and internal homeostasis, processes that are important in chronic pain. In addition to systemic effects of endorphins and brain modulation, acupuncture needling can modulate local tissue producing an anti-inflammatory effect. Research in both animals and humans have shown acupuncture needling can modulate proteins and fibroblast cells in connective tissue that, in turn, produce mechanotransductive signals able to restore tissue integrity, an emerging field relevant to acupuncture’s role in treating pain and improving function in chronic pain. Acupuncture research has also provided unanticipated insights in biomedicine generally.

We attach the Academic Consortium’s White Paper on Evidence-based Nonpharmacologic Strategies for Comprehensive Pain Care (Appendix 3) as a resource for acute and chronic pain care options as well as safety profiles of evidence-based nonpharmacologic therapies. As with all medical treatments, updating analysis of benefit/harms, clinical indications, frequency, dosage and timing of care is recommended.

5. 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. Chronic pain has bio-psycho-social aspects and comprehensive care is necessary. Unimodal treatment with opioids is problematic for the course of pain and for patient function. Chronic pain patients and those who care for them need resources for understanding comprehensive care options and how to access them.
6. Real world models of care. A progress report on outcomes for veterans with chronic pain from the Veterans Administration Whole Health System of Care indicates that the benefits of this comprehensive approach are reduced opioid doses, increased well-being and reduced stress. There are indications that the most stressed populations benefit the most. This program provides social support and behavioral health services in addition to access to evidence-based nonpharmacologic therapies including but not limited to acupuncture therapy, manual therapies such as massage and chiropractic, yoga, group visits, self-care/self-efficacy strategies.

References