

Appendix 1: Comment on HHS Docket No. CDC-2020-0029

Management of Acute and Chronic Pain

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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 Task Force Report,³ the ACP,⁴ and as part of comprehensive pain care¹ by the AHRQ,⁵ NIH,⁶ 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 Guidelines²** 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

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.¹ Over 4 million American adults receive acupuncture annually.¹² Acupuncture is generally considered safe when performed by licensed, well-trained practitioners using single-use pre-sterilized needles,¹³⁻²⁰ with infrequent minor side effects such as feeling relaxed, elated, tired or having sensation or itching at point of insertion.¹⁷ Rare serious complications such as infection or pneumothorax are directly related to insufficient training.^{18,19,21} 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.²²⁻²⁴ Acupuncture is feasible and highly acceptable for adult and pediatric inpatients^{25,26} for acute pain in the emergency department setting^{27,28} and for chronic pain conditions.^{29,30} 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 osteoarthritis¹¹ 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.³¹

Biological mechanisms of acupuncture:³² 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^{33,34} 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:³⁵ verum acupuncture elicits more and distinct modulation effects on neurological components than sham acupuncture.³⁶ 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.³⁵ Long term increases in opioid receptors following acupuncture were associated with greater reduction in pain.³⁵ Translational research using functional magnetic resonance imaging (fMRI) in carpal tunnel patients found verum acupuncture modulates the somatosensory cortex area of the brain, providing a correction for maladaptive change present in carpal tunnel syndrome patients.^{37,38} Acupuncture also deactivates limbic brain areas, important for emotion and internal homeostasis, processes that are important in chronic pain.³⁹⁻⁴¹ In addition to systemic effects of endorphins and brain modulation, acupuncture needling can modulate local tissue producing an anti-inflammatory effect.^{42,43} 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,⁴⁴⁻⁴⁶ an emerging field relevant to acupuncture's role in treating pain and improving function in CLBP.^{64,47} Acupuncture research has also provided unanticipated insights in biomedicine generally.⁴⁸

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.²

Chronic pain has bio-psycho-social aspects and comprehensive care is necessary.⁴⁹ Unimodal treatment with opioids is problematic for the course of pain and for patient function.⁵⁰⁻⁵³ 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.⁵⁴ 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

1. Tick H, Nielsen A, Pelletier KR, et al. Evidence-based Nonpharmacologic Strategies for Comprehensive Pain Care: The Consortium Pain Task Force White Paper. *Explore (NY)*. 2018;14(3):177-211.
2. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain--United States, 2016. *JAMA*. 2016;315(15):1624-1645.
3. Office of the Army Surgeon General. Pain Management Task Force Final Report May 2010. 2010; <http://www.dvcipm.org/site/assets/files/1070/pain-task-force-final-report-may-2010.pdf>. Accessed June 9, 2020.
4. Qaseem A, Wilt TJ, McLean RM, Forcica MA. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2017;166(7):514-530.
5. Skelly AC, Chou R, Dettori JR, et al. Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update. Comparative Effectiveness Review No. 227. AHRQ Publication No. 20-EHC009. 2020; <https://effectivehealthcare.ahrq.gov/products/noninvasive-nonpharm-pain-update/research> Accessed April 17, 2020.
6. Nahin RL, Boineau R, Khalsa PS, Stussman BJ, Weber WJ. Evidence-based evaluation of complementary health approaches for pain management in the United States. *Mayo Clin Proc*. 2016;91(9):1292-1306.
7. U.S. Food and Drug Administration. FDA education blueprint for health care providers involved in the management or support of patients with pain (May 2017). 2017; <https://www.fda.gov/downloads/Drugs/NewsEvents/UCM557071.pdf>. Accessed May 22, 2019.
8. National Academies of Sciences Engineering and Medicine. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use (2017)*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/24781>; 2017.
9. Pain Management - Leadership Responsibilities for Providing Nonpharmacologic Modalities for Managing Pain - LD.04.03.13 EP 2 2019; <https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/leadership-ld/000002158/>. Accessed July 26, 2019, 2019.
10. The Joint Commission. Clarification of the pain management standard. 2015; https://www.jointcommission.org/assets/1/18/Clarification_of_the_Pain_Management_Standard.pdf. Accessed May 22, 2019.
11. Vickers AJ, Vertosick EA, Lewith G, et al. Acupuncture for chronic pain: update of an individual patient data meta-analysis. *J Pain*. 2018;19(5):455-474.
12. Fan AY, Stumpf SH, Faggert Alemi S, Matecki A. Distribution of licensed acupuncturists and educational institutions in the United States at the start of 2018. *Complement Ther Med*. 2018;41:295-301.
13. Adams D, Cheng F, Jou H, Aung S, Yasui Y, Vohra S. The safety of pediatric acupuncture: a systematic review. *Pediatrics*. 2011;128(6):e1575-1587.
14. Bergqvist D. Vascular injuries caused by acupuncture. A systematic review. *Int Angiol*. 2013;32(1):1-8.
15. Ernst E, White AR. Prospective studies of the safety of acupuncture: a systematic review. *Am J Med*. 2001;110(6):481-485.
16. MacPherson H, Thomas K, Walters S, Fitter M. A prospective survey of adverse events and treatment reactions following 34,000 consultations with professional acupuncturists. *Acupunct Med*. 2001;19(2):93-102.
17. MacPherson H, Thomas K. Short term reactions to acupuncture--a cross-sectional survey of patient reports. *Acupunct Med*. 2005;23(3):112-120.
18. White A. A cumulative review of the range and incidence of significant adverse events associated with acupuncture. *Acupunct Med*. 2004;22(3):122-133.

19. Yamashita H, Tsukayama H, White AR, Tanno Y, Sugishita C, Ernst E. Systematic review of adverse events following acupuncture: the Japanese literature. *Complement Ther Med*. 2001;9(2):98-104.
20. Zhao XF, Du Y, Liu PG, Wang S. Acupuncture for stroke: evidence of effectiveness, safety, and cost from systematic reviews. *Top Stroke Rehabil*. 2012;19(3):226-233.
21. Yamashita H, Tsukayama H. Safety of acupuncture practice in Japan: patient reactions, therapist negligence and error reduction strategies. *Evid Based Complement Alternat Med*. 2007;5(4):391-398.
22. Liu XL, Tan JY, Molassiotis A, Suen LK, Shi Y. Acupuncture-point stimulation for postoperative pain control: a systematic review and meta-analysis of randomized controlled trials. *Evid Based Complement Alternat Med*. 2015;2015:1-28.
23. Wu MS, Chen KH, Chen IF, et al. The efficacy of acupuncture in post-operative pain management: a systematic review and meta-analysis. *PLoS One*. 2016;11(3):e0150367.
24. Sun Y, Gan TJ, Dubose JW, Habib AS. Acupuncture and related techniques for postoperative pain: a systematic review of randomized controlled trials. *Br J Anaesth*. 2008;101(2):151-160.
25. Painovich J, Herman PM. Acupuncture in the inpatient acute care setting: a pragmatic, randomized control trial. *Evid Based Complement Alternat Med*. 2012;2012:309762.
26. Wu S, Sapru A, Stewart MA, et al. Using acupuncture for acute pain in hospitalized children. *Pediatr Crit Care Med*. 2009;10(3):291-296.
27. Arnold AA, Ross BE, Silka PA. Efficacy and feasibility of acupuncture for patients in the ED with acute, nonpenetrating musculoskeletal injury of the extremities. *Am J Emerg Med*. 2009;27(3):280-284.
28. Cohen MM, Parker SJ, Xue CC, et al. Acupuncture for analgesia in the emergency department: a multicentre, randomised, equivalence and non-inferiority trial. *Med J Aust Medical Journal of Australia*. 2017;206(11):494-499.
29. Zhang Y, Bao F, Wang Y, Wu Z. Influence of acupuncture in treatment of knee osteoarthritis and cartilage repairing. *Am J Transl Res*. 2016;8(9):3995-4002.
30. Liu L, Skinner MA, McDonough SM, Baxter GD. Acupuncture for chronic low back pain: a randomized controlled feasibility trial comparing treatment session numbers. *Clin Rehabil*. 2017;31(12):1592-1603.
31. Witt CM, Vertosick EA, Foster NE, et al. The Effect of Patient Characteristics on Acupuncture Treatment Outcomes: An Individual Patient Data Meta-Analysis of 20,827 Chronic Pain Patients in Randomized Controlled Trials. *Clin J Pain*. 2019;35(5):428-434.
32. Nielsen A, Tick H, Mao JJ, Hecht F. Academic Consortium for Integrative Medicine & Health Commentary to CMS; RE: National Coverage Analysis (NCA) Tracking Sheet for Acupuncture for Chronic Low Back Pain (CAG-00452N). *Glob Adv Health Med*. 2019;8:2164956119857648.
33. Pomeranz B, Chiu D. Naloxone blockade of acupuncture analgesia: endorphin implicated. *Life Sci*. 1976;19(11):1757-1762.
34. Han JS. Acupuncture and endorphins. *Neurosci Lett*. 2004;361(1-3):258-261.
35. Harris RE, Zubieta JK, Scott DJ, Napadow V, Gracely RH, Clauw DJ. Traditional Chinese acupuncture and placebo (sham) acupuncture are differentiated by their effects on mu-opioid receptors (MORs). *Neuroimage*. 2009;47(3):1077-1085.
36. Scheffold BE, Hsieh CL, Litscher G. Neuroimaging and Neuromonitoring Effects of Electro and Manual Acupuncture on the Central Nervous System: A Literature Review and Analysis. *Evid Based Complement Alternat Med*. 2015;2015:641742.
37. Napadow V, Liu J, Li M, et al. Somatosensory cortical plasticity in carpal tunnel syndrome treated by acupuncture. *Hum Brain Mapp*. 2007;28(3):159-171.
38. Maeda Y, Kim H, Kettner N, et al. Rewiring the primary somatosensory cortex in carpal tunnel syndrome with acupuncture. *Brain*. 2017;140(4):914-927.
39. Hui KK, Liu J, Makris N, et al. Acupuncture modulates the limbic system and subcortical gray structures of the human brain: evidence from fMRI studies in normal subjects. *Hum Brain Mapp*. 2000;9(1):13-25.
40. Hui KK, Napadow V, Liu J, et al. Monitoring acupuncture effects on human brain by FMRI. *J Vis Exp*. 2010(38).
41. Yin N, Yang H, Yao W, Xia Y, Ding G. Mast Cells and Nerve Signal Conduction in Acupuncture. *Evid Based Complement Alternat Med*. 2018;2018:3524279.
42. Huang M, Wang X, Xing B, et al. Critical roles of TRPV2 channels, histamine H1 and adenosine A1 receptors in the initiation of acupoint signals for acupuncture analgesia. *Sci Rep*. 2018;8(1):6523.
43. Zijlstra FJ, van den Berg-de Lange I, Huygen FJPM, Klein J. Anti-inflammatory actions of acupuncture. *Mediators Inflamm*. 2003;12(2):59-69.
44. Langevin HM, Churchill DL, Fox JR, Badger GJ, Garra BS, Krag MH. Biomechanical response to acupuncture needling in humans. *J Appl Physiol (1985)*. 2001;91(6):2471-2478.

45. Langevin HM, Churchill DL, Cipolla MJ. Mechanical signaling through connective tissue: a mechanism for the therapeutic effect of acupuncture. *FASEB J.* 2001;15(12):2275-2282.
46. Langevin HM, Churchill DL, Wu J, et al. Evidence of connective tissue involvement in acupuncture. *FASEB J.* 2002;16(8):872-874.
47. Lim TK, Ma Y, Berger F, Litscher G. Acupuncture and Neural Mechanism in the Management of Low Back Pain-An Update. *Medicines (Basel).* 2018;5(3):63.
48. MacPherson H, Hammerschlag R, Coeytaux RR, et al. Unanticipated Insights into Biomedicine from the Study of Acupuncture. *J Altern Complement Med.* 2016;22(2):101-107.
49. hhs.gov. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. 2019; <https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html>. Accessed June 9, 2020.
50. Scherrer JF, Salas J, Sullivan MD, et al. The influence of prescription opioid use duration and dose on development of treatment resistant depression. *Prev Med.* 2016;91:110-116.
51. Mai J, Franklin G, Tauben D. Guideline for prescribing opioids to treat pain in injured workers. *Phys Med Rehabil Clin N Am.* 2015;26(3):453-465.
52. Sullivan MD, Ballantyne JC. What are we treating with long-term opioid therapy? *Arch Intern Med.* 2012;172(5):433-434.
53. Ballantyne JC. Opioids for the Treatment of Chronic Pain: Mistakes Made, Lessons Learned, and Future Directions. *Anesth Analg.* 2017;125(5):1769-1778.
54. Bokhour BB, Hyde JK, Zeliadt S, Mohr DC. Whole Health System of Care Evaluation- A Progress Report on Outcomes of the WHS Pilot at 18 Flagship Sites. 2020; Veterans Health Administration, Center for Evaluating Patient-Centered Care in VA (EPCC-VA); <https://www.va.gov/WHOLEHEALTH/professional-resources/clinician-tools/Evidence-BasedResearch.asp> Accessed June 12, 2020.