



American Society of
Anesthesiologists[®]

April 7, 2022

Rochelle Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia
30329

Re: ASA Comments on Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids;
Docket No. CDC-2022-0024

Dear Dr. Walensky:

The American Society of Anesthesiologists[®] (ASA), on behalf of our more than 55,000 members, appreciates the opportunity to comment on the above-captioned Proposed CDC Guideline. We commend the agency's efforts to reduce fatalities from the opioid crisis and provide guidance for treating pain. ASA is especially pleased the update and expansion of the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, promotes safe, effective, and informed pain treatment options with the goal of being a flexible tool for improving patient-clinician communication and supporting individualized, patient-centered care.

General Comments

ASA supports the added clarity for physicians and other health care professionals with the scope of the updated Guideline. Unfortunately, the 2016 Guideline was often misinterpreted by different entities including insurers, legislatures, and others to create rigid prescribing policies that led to negative consequences for patients, including the inability for some patients to access appropriate pain care. Following these unintended consequences, ASA is pleased to see the updated Guideline clearly stipulate that it is NOT: 1) a replacement for clinical judgment or individualized, person-centered care; 2) intended to be applied as inflexible standards of care across patients, and/or patient populations by health care professionals, health systems, pharmacies, third-party payers, or governmental jurisdictions or to lead to the rapid tapering or discontinuation of opioids for patients; or 3) a law, regulation, and/or policy that dictates clinical practice or a substitute for FDA-approved labeling.

ASA is supportive of the recommendations outlined in the updated Guideline and is pleased to see that dose thresholds or “one-size-fits-all” prescribing limits are not stipulated in the recommendations. Instead, opioid selection and dosage examples are listed within the broader discussion text to guide clinicians, and emphasis is placed on shared decision-making between clinicians and patients with individualized pain care in mind. Below, ASA outlines key areas of agreement and concerns related to a lack of emphasis on interventional procedures to treat pain and recommendations around opioid tapering.

Scope and Audience

The updated Guideline defines the audience as wide-encompassing—clinicians, meaning “physicians, nurse practitioners, physician assistants, and oral health practitioners.” It further mentions that the recommendations are meant for primary care and other clinicians in outpatient settings. As the medical specialty society representing the largest number of practicing physician anesthesiologists, ASA supports the wise decision to carve out patients who are receiving inpatient care or those presenting in an emergency department. For those patients, there are a sufficient number of guidelines and best practices that take into account individual patient needs and risk of opioid dependence. In addition, many physician

anesthesiologists specialize in pain medicine and are experts in treating and diagnosing chronic pain conditions. The updated Guideline acknowledges that many of the principles for managing pain are similar regardless of whether the treating clinician is a pain specialist. ASA agrees with this sentiment but appreciates that the CDC underscores that “use by pain management specialists is not the focus of this clinical practice guideline...they might see patients with clinical situations that are more complex, less prevalent, and not well-addressed by the available evidence; thus, the balance of benefits and risks to patients might differ when the treating clinician is a pain management specialist treating patients with complex pain conditions.” Chronic pain patients being treated by pain medicine specialists are a highly complex and unique subset, and it is important that they have access to physician-led comprehensive, multidisciplinary care that improves their mobility, function, and lives.

ASA recommends that the agency note in the updated Guideline that clinicians defer to professional medical society guidelines and standards of care for surgical procedures. Medical specialty societies, including ASA, are the experts in perioperative pain care, including postsurgical pain, and are best suited to develop clinical guidelines in this specific area. The CDC notes that the Guideline applies to “pain related to procedures (e.g., postoperative pain, pain from oral surgery)” and that “for postoperative pain related to major surgery, procedure-specific opioid prescribing recommendations are available with ranges for amounts of opioids needed.” In addition, the CDC notes the evidence around treatments for acute pain to be mixed—that “findings for postoperative pain were somewhat inconsistent” and “results were based on a small number of trials and pain related to a limited set of surgical procedures.” Thus, the agency lacked comprehensive information to formulate recommendations on the topic of perioperative acute pain. The agency fails to recognize the complexities around the many different types of surgery that require different forms of pain control, especially that some patient populations may need more pain relief and different therapies than others. This gap within the guideline presents an opportunity for the CDC, physicians, and others to simply recognize that other medical specialty guidelines and expertise should be used. In fact, ASA recently organized a novel collaboration with 14 other medical societies to develop best practices for [managing acute pain](#), as well as [how to manage complex patients](#), including those on opioids preoperatively, with chronic pain or a substance use disorder. The work products of this multi-society collaboration should serve to inform future CDC Guideline recommendations for pain management in the perioperative period.

Excluded Populations

The CDC notes that the updated Guideline is not applicable to the following types of pain treatment: sickle cell disease-related pain, cancer pain, palliative care, or end-of-life care. The medical community tends to place sickle cell disease in the same category as chronic pain or end-of-life care. However, ASA feels strongly that there is a need for multispecialty collaboration to devise guidelines on outpatient opioid-prescribing and inpatient management of sickle cell disease patients. It should also be noted that there is little evidence of efficacy or safety with opioids in this population and there may even be increased risks due to their underlying medical conditions. While the agency excludes this population in the updated Guideline, it is worth noting these points in the broader discussion about sickle cell disease patients.

Interventional Treatments—CDC Recommendation #2 on Nonopioid Therapies

Interventional pain modalities are only briefly mentioned (pages 89-90) in the updated Guideline. CDC states that “evidence is limited for many of these procedures, and additional research is needed to establish the clinical benefits of specific interventional procedures for specific pain conditions” but fails to acknowledge the evidence for intermediate to long term efficacy that does exist. Condition-specific level I evidence exists for complex regional pain syndrome/causalgia, lumbar stenosis, and vertebrogenic pain,

and the cadre of evidence for interventional therapies continues to grow.¹ These conditions alone account for millions of Americans who might be on opioids and have therapies that could ameliorate their quality of life. There are treatments that have demonstrated ability to minimize or eliminate the need for opioid analgesics.^{2 3 4 5 6} These modalities should be emphasized and supported, as the updated Guideline includes substantial discussion on pain treatment options. We would also recommend that the discussion on interventional therapies be given the same attention to detail as the pharmacologic options, with each modality discussed individually, rather than grouped together.

Opioid Selection and Dosage—CDC Recommendations #3 and #4

In the implementation considerations (page 91, line 2148), CDC discusses the benefits of immediate release opioids versus extended release/long-acting opioids. In the second bullet, ASA does not understand the reasoning for including examples of 60 mg daily of oral morphine and 30 mg daily of oral oxycodone (these really do not equate one another). We suggest changing the example to 60 mg daily of oral morphine or 40 mg oral oxycodone for equivalent dosing strategies. ASA supports the CDC recommendation of a starting dose for opioid naïve patients at 20-30 MME/day (page 96). The recommendations around initiating opioids should emphasize individualized prescribing and patient monitoring. The benefits and risks are discussed extensively but fail to highlight the importance of ongoing patient monitoring⁷ by clinicians prescribing opioids. While there is acknowledgement of some states requiring certain protocols with respect to prescribing certain doses of opioids, the updated Guideline fails to mention Opioid Patient Prescriber Agreements, sometimes referred to as opioid treatment agreements or opioid contracts. These are regularly used in practice to spell out what's expected of the patient taking opioids (e.g., no other substances, dose and duration, etc.) and what the patient can expect from the clinician regarding monitoring and screening practices. ASA recommends CDC acknowledge these types of agreements in its recommendations.

Tapering—CDC Recommendations #5 and #6

ASA agrees with the key themes highlighted in the Guideline that “clinicians should avoid abrupt discontinuation of opioids” and should “avoid dismissing patients from care” but believes further guidance should be provided on opioid tapering with reference to [best practices summarized by the National Academy of Medicine](#). The implementation considerations (page 101) are vague and include an array of

¹ See attachment.

² Cohen SP, Bhaskar A, Bhatia A, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. *Regional Anesthesia & Pain Medicine* 2020; 45:424-467.

³ Kreiner, D. S., Matz, P., Bono, C. M., Cho, C. H., Easa, J. E., Ghiselli, G., Ghogawala, Z., Reitman, C. A., Resnick, D. K., Watters, W. C., 3rd, Annaswamy, T. M., Baisden, J., Bartynski, W. S., Bess, S., Brewer, R. P., Cassidy, R. C., Cheng, D. S., Christie, S. D., Chutkan, N. B., Cohen, B. A., Yahiro, A. M. (2020). Guideline summary review: an evidence-based clinical guideline for the diagnosis and treatment of low back pain. *The spine journal: official journal of the North American Spine Society*, 20(7), 998–1024. <https://doi.org/10.1016/j.spinee.2020.04.006>.

⁴ Deer TR, Krames E, Mekhail N, et al; Neuromodulation Appropriateness Consensus Committee. The appropriate use of neurostimulation: new and evolving neurostimulation therapies and applicable treatment for chronic pain and selected disease states. *Neuromodulation Appropriateness Consensus Committee. Neuromodulation*. 2014 Aug;17(6):599-615.

⁵ Smith, C. C., McCormick, Z. L., Mattie, R., MacVicar, J., Duszynski, B., & Stojanovic, M. P. (2020). The Effectiveness of Lumbar Transforaminal Injection of Steroid for the Treatment of Radicular Pain: A Comprehensive Review of the Published Data. *Pain medicine (Malden, Mass.)*, 21(3), 472–487. <https://doi.org/10.1093/pm/pnz160>.

⁶ Schneider, B. J., Doan, L., Maes, M. K., Martinez, K. R., Gonzalez Cota, A., Bogduk, N., & Standards Division of the Spine Intervention Society (2020). Systematic Review of the Effectiveness of Lumbar Medial Branch Thermal Radiofrequency Neurotomy, Stratified for Diagnostic Methods and Procedural Technique. *Pain medicine (Malden, Mass.)*, 21(6), 1122–1141. <https://doi.org/10.1093/pm/pnz349>.

⁷ Levy, N., Quinlan, J., El-Boghdady, K., Fawcett, W. J., Agarwal, V., Bastable, R. B., Cox, F. J., de Boer, H. D., Dowdy, S. C., Hattigh, K., Knaggs, R. D., Mariano, E. R., Pelosi, P., Scott, M. J., Lobo, D. N., & Macintyre, P. E. (2021). An international multidisciplinary consensus statement on the prevention of opioid-related harm in adult surgical patients. *Anaesthesia*, 76(4), 520–536. <https://doi.org/10.1111/anae.15262>.

options for tapering. For example, it is stated that “a taper slow enough to minimize symptoms and signs of opioid withdrawal should be used” but it is also noted that “tapers of 10% per month or slower are likely to be better.” Another point that is unclear in the recommendations is who determines whether a taper should occur. ASA appreciates the message that the tapering process should be collaborative between the clinician and the patient but believes the recommendations should also emphasize that in certain situations, a more physician-led approach is necessary. In addition, the scenarios (p. 106) for when taper should be considered can be expanded upon. Another missing concept related to tapering is patient monitoring. If tapering is taking place, patients must be monitored closely and frequently, and the recommendations in the updated Guideline should stipulate this clearly.

Naloxone

Recommendation #8 states that naloxone should be offered for patients on opioid dosages exceeding 50 MME/day. ASA recommends that naloxone be offered to ALL patients and their household and/or family members, particularly considering the total amount of opioids that may be present and the potential for other medications to interact adversely with opioids. CDC notes one observational study (page 42) which found that naloxone provided to patients prescribed opioids in primary care clinics was associated with decreased likelihood of emergency department visits, but no difference in overdose risk. While evidence is limited on risk mitigation and this is just one study, getting naloxone into the hands of those who need it is one tool to help address number of opioid related fatalities plaguing the nation. Naloxone is also mentioned throughout the updated Guideline as recommended when a patient is determined as high-risk. Again, ASA suggests that these recommendations be broader and cover any individual with an opioid prescription.

ASA appreciates the opportunity to provide feedback on the Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids. We commend the agency for its efforts to further appropriate opioid prescribing and ensure patients get the pain treatments they deserve. For further information or questions, please contact Ashley Walton, ASA’s Associate Director of Congressional & Political Affairs at a.walton@ashq.org or (202) 289-2222.

Sincerely,

A handwritten signature in black ink that reads "Randall M. Clark". The signature is written in a cursive, flowing style.

Randall M. Clark, MD, FASA
President
American Society of Anesthesiologists

Condition-specific Level I Evidence

Basivertebral Nerve Radiofrequency Ablation is superior to conservative therapy and sham in the management of vertebrogenic pain. This also demonstrated reduction in opioid use.

SMART 2yr

Fischgrund JS, Rhyne A, Franke J, Sasso R, Kitchel S, Bae H, Yeung C, Truumees E, Schaufele M, Yuan P, Vajkoczy P, Depalma M, Anderson DG, Thibodeau L, Meyer B. Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain: 2-Year Results From a Prospective Randomized Double-Blind Sham-Controlled Multicenter Study. *Int J Spine Surg*. 2019 Apr 30;13(2):110-119.

SMART 5yr

Fischgrund JS, Rhyne A, Macadaeg K, Moore G, Kamrava E, Yeung C, et al. Long - term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain : 5 - year treatment arm results from a prospective randomized double - blind sham - controlled multi - center study. *Eur Spine J*. 2020.

INTRACEPT-Crossover

Khalil JG, Smuck M, Koreckij T, Keel J, Beall D, Goodman B, Kalapos P, Nguyen D, Garfin S; INTRACEPT Trial Investigators. A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. *Spine J*. 2019 Oct;19(10):1620-1632.

INTRACEPT-2yr

Koreckij T, Kreiner S, Khalil JG, Smuck M, Markman J, Garfin S; INTRACEPT Trial Investigators. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-Month treatment arm results. *N Am Spine Soc J*. 2021 Oct 26;8:100089.

Indirect Lumbar Decompression (Superion) is non-inferior to placement of surgical interspinous device (X-stop) in the management of lumbar stenosis with neurogenic intermittent claudication. This also demonstrated reduction in opioid use.

IDE-2yr

Patel VV, Whang PG, Haley TR, Bradley WD, Nunley PD, Davis RP, Miller LE, Block JE, Geisler FH. Superion interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial. *Spine (Phila Pa 1976)*. 2015 Mar 1;40(5):275-82.

IDE-5yr

Nunley PD, Patel VV, Orndorff DG, Lavelle WF, Block JE, Geisler FH. Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. *Clin Interv Aging*. 2017 Sep 6;12:1409-1417.

Opioid Reduction

Nunley PD, Deer TR, Benyamin RM, Staats PS, Block JE. Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis. J Pain Res. 2018 Nov 20;11:2943-2948.

Dorsal Root Ganglion Stimulation is Superior to Dorsal Column Stimulation in the Management of CRPS 1 and 2.

ACCURATE

Deer TR, Levy RM, Kramer J, Poree L, Amirdelfan K, Grigsby E, Staats P, Burton AW, Burgher AH, Obray J, Scowcroft J, Golovac S, Kapural L, Paicius R, Kim C, Pope J, Yearwood T, Samuel S, McRoberts WP, Cassim H, Netherton M, Miller N, Schaufele M, Tavel E, Davis T, Davis K, Johnson L, Mekhail N. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain. 2017 Apr;158(4):669-681.