American Society of Anesthesiologists™

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Robert R. Redfield, M.D.
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30329-4027

Deborah Dowell, M.D.,
Chief Medical Officer
Centers for Disease Control and Prevention
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Dear Dr. Redfield and Dr. Dowell:

On behalf of the 53,000 members of the American Society of Anesthesiologists®(ASA), I am writing to express concerns regarding the misapplication of the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain ("Guideline") by state medical and disciplinary boards, public and private payers, pharmacies and others. **ASA recommends that the CDC Guideline be reviewed and revised to both clarify the intent of the Guideline and include the most up-to-date scientific evidence available.**

We believe the CDC Guideline has been misapplied in a number of venues. The Guideline was meant as guidance for primary care providers, not for its recommendations to be applied to all patients in all circumstances. With a membership of experts in pain medicine, ASA is especially concerned about the negative impact such sweeping policy and misapplication of the Guideline is having on patient care. The across-the-board application of the Guideline is not undertaken for any other medical disease where guidelines have been developed. While we acutely recognize and greatly appreciate the concerns with overprescribing of opioids, we worry that the pendulum has swung too far in the direction of not treating chronic pain in accordance with evidence-based methodology. Chronic pain is a disease— with systematic effects, impacting a range of organs, including the brain— which must be diagnosed, evaluated and properly treated.

In November 2018, the American Medical Association (AMA) issued a directive, *Inappropriate Use of CDC Guideline for Prescribing Opioids*. This directive advocates against the misapplication of the CDC Guideline and opposes "communications that include a blanket proscription against filling prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care." ASA strongly supports this directive and the stipulation that "no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical

privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline."

Clarifying Intent of the Guideline
Though the Society is pleased with two recent developments regarding the Guideline, **ASA believes the CDC should take a more direct approach to ensure the Guideline is clearly understood and used appropriately**. First, on April 9, *Medpage Today* reported that the CDC clarified in a letter dated February 28, to three national cancer organizations, "The Guideline was developed to provide recommendations for primary care clinicians…the guideline is not intended to deny any patients who suffer from chronic pain opioid therapy as an option for pain management." ASA is pleased that CDC has made this clarification, but we believe it is necessary for the agency to make a more prominent statement that is widely distributed and not just meant for a limited audience. Second, we are pleased the authors of the CDC Guideline published an article in the *New England Journal of Medicine,* acknowledging that the Guideline has been used to develop policies beyond those meant for primary care providers treating chronic pain patients. Again, ASA urges that CDC go one-step further and ensure this is widely distributed and endorsed as an official statement of the agency. It is important for CDC to send official communications to medical boards, payers, pharmacies and state government entities to ensure there is wide-spread knowledge about the intent of the Guideline.

Chronic Pain and Individualized Patient Care
In September 2018, the CDC released a report in the Morbidity and Mortality Weekly Report (MMWR), Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016, which provided new insight into how pain affects the nation. The report estimates that chronic pain affects approximately 50 million U.S. adults, and high-impact chronic pain (i.e., interfering with work or life most days or every day) affects approximately 20 million U.S. adults. Population-based estimates of chronic pain among U.S. adults range from 11-40 percent, with considerable population subgroup variation. This report's newer, more precise estimates indicating the prevalence of chronic pain and high-impact chronic pain, demonstrate the great need to ensure patients have all necessary treatment options, including opioids where appropriate.

Individualized patient care and safety should be the utmost priority when treating chronic pain. The treatment plan and modality should be the decision of the treating physician and the patient after jointly discussing options, weighing benefits and risks, as well as expectations. Physician anesthesiologists treat both acute and chronic pain. Some physician anesthesiologists specialize in pain medicine, a separate board certification involving extra training and education, treating patients with complex chronic pain conditions. Pain medicine physicians have the expertise to manage this unique and complicated subset of patients and in some cases, the best treatment for the patient does not fall within the purview of the CDC Guideline. **Thus, ASA is urging CDC to clarify the intent of the CDC Guideline as a mechanism to ensure patients continue to receive compassionate pain care.**

Value of CDC Guideline
ASA recognizes the importance of the CDC Guideline during this time when the nation is facing an opioid crisis. The Guideline was created to improve patient care, comprehensively promoting best practices in patient selection and monitoring, as well as in treatment planning with the end goal of improving the safety of opioid prescribing. It was also developed with intense scrutiny by clinical stakeholders from dozens of professional societies and medical specialties. However, it was intended to be a clinical tool for patients in the primary care setting, not under the care of pain specialists.

Examples of Inappropriate Interpretation and Enforcement
Many state medical boards have used the Guideline to discipline physicians prescribing outside of the recommendations in the CDC Guideline. The Federation of State Medical Boards (FSMB) have attempted to apply the dosing thresholds of the Guideline to all patients regardless and to physicians beyond primary care. Additionally, many payers— such as Medicare, Cigna, Aetna, and Oregon Medicaid— to name a few have used the Guideline to implement strict prescribing policies. Last, some of the retail pharmacy chains, such as CVS and Walmart— have required soft and hard limits to opioid prescribing and used the CDC Guideline as justification.

Unintended Consequences
With the misapplication of the Guideline, patients have suffered the consequences. A patient on a chronic stable regimen of opioids that has a successful level of function and quality of life, can be cut-off based on daily dosing thresholds based upon the CDC Guideline. This is especially problematic because the CDC Guideline is being applied retroactively. For some patients, the rapid decrease in their medications has been unmanageable— resulting in depression, illegal substance use and even suicide. Consequently, the FDA recently announced the harm caused from sudden discontinuation of opioid pain medicines and required label changes to guide prescribers on gradual, individualized tapering.

Other unintended consequences have been both a reduction in physicians willing to treat chronic pain patients and an overwhelming flood of patients to physicians still willing to provide care to these patients and prescribe opioids. This can also have negative impacts on physician wellbeing, due to the high volume of transfers in care and may ultimately lead to burn out— in turn, this affects patients.
Finally, **an underlying problem that is exacerbated by misapplication of the Guideline is a lack of comprehensive pain care options available to patients.** Barriers to access to many pain care treatments, including insurance coverage and payment for different pain modalities, often results in opioids as a first line of therapy when another treatment might be more appropriate. Therefore, **it is important to address these barriers by improving insurance coverage and reimbursement for evidence-based medical, behavior and complementary pain services.** This is particularly necessary for non-pharmacological treatments such as interventional procedures and behavior health care.

Revise and Update of Guideline Supported by HHS Pain Task Force
The CDC Guideline is primarily consensus-based and is lacking scientific evidence. For example, there is an absence of high-quality data on the duration of opioid effectiveness for chronic pain. However, this has been interpreted as a lack of benefit. ASA believes these shortcomings can be addressed and the **HHS Pain Management Best Practices Inter-Agency Task Force has developed recommendations to support building the applicable evidence necessary for the Guideline**. In fact, the Task Force released a report recognizing the misinterpretation of the Guideline and the consequences of unintended adverse outcomes, especially the recommendation regarding the 90 MME dose. The Task Force recommends 1) updating the scientific evidence and 2) emphasizing or expanding on content already in the Guideline. ASA fully supports these recommendations.

The Task Force recommends studies to determine the long-term efficacy of opioids in the treatment of chronic pain and clinical trials on specific disease entities, with a focus on patient variability and response to tissue injury and on the effectiveness of opioid analgesics. Additionally, the Task Force recommends specific pathways for expanding on the CDC Guideline. Developing recommendations that take into consideration patient variables that may affect dose as well as additional risk factors for opioid use disorder are two such examples. In addition, recommendations to address opioid tapering and escalation need to be addressed.

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ASA supports the recommendations of the Task Force to build the applicable evidence for revising and updating the Guideline and the considerations that should be accounted for to expand the Guideline. Other priorities to include in an updated Guideline should be how patients and clinicians should discuss pain, recommendations on where to find resources on best practices, as well as key information on safe storage and disposal. **The Society encourages the CDC to revise and update the Guideline through collaborating with others.** All stakeholders should be engaged—including medical specialties, patients, insurance companies, retail pharmacies and state licensure boards.

Conclusion

The CDC Guideline for Prescribing Opioids for Chronic Pain has negatively impacted patients with chronic pain. While ASA commends the agency for taking steps to rectify negative outcomes and clarify the intent of the Guideline, there is more to be done. The Society urges the CDC to do more and welcomes the opportunity to work together to ensure a revised and updated Guideline is not only best for patient care but also appropriate for physician practice.

Thank you for your time. ASA appreciates the opportunity to provide this input and hopes the CDC will take this information into careful consideration.

Sincerely,

Linda Mason, M.D., FASA
President
American Society of Anesthesiologists