



June 15, 2020

Department of Health and Human Services
Centers for Disease Control and Prevention
Docket Number CDC-2020-0029
Management of Acute and Chronic Pain: Request for Comment

The U.S. Pain Foundation is pleased to respond to the Centers for Disease Control and Prevention's (CDC) Request for Comment on pain management announced on April 17, 2020, in the Federal Register. The U.S. Pain Foundation is the largest 501(c)(3) organization for people who live with chronic pain from a myriad of diseases, conditions, and serious injuries. Our mission is to connect, support, educate, and advocate for those living with chronic pain, as well as their caregivers and healthcare providers.

The U.S. Pain Foundation strongly endorses the HHS Pain Management Best Practices Inter-Agency Task Force Report (PMTF Report) completed in 2019 at the request of Congress in the Comprehensive Addiction and Recovery Act (CARA) of 2016. Many of the questions the CDC has asked of stakeholders in this Request for Comment are answered in that excellent document that has been endorsed by more than 160 organizations, including the American Medical Association, the Association of American Physicians and Surgeons, the American College of Physicians, the American Academy of Pain Medicine, the Consumer Pain Advocacy Task Force (an alliance of 16 patient organizations representing Americans living with chronic pain), and Human Right Watch.

A central tenet of the PMTF Report is that current best practice in pain management is a ***multimodal, multidisciplinary, integrated model of care*** in which a knowledgeable, empathic healthcare provider, working with the patient, develops an individualized care plan that includes a combination of pharmacological and non-pharmacological treatments. These treatments should be selected from a broad range of evidence-based therapeutic options. Combining multiple treatments has a synergistic benefit that has been documented to reduce pain severity, improve overall quality of life, and increase function. The Task Force uses the following five classifications for the wide range of therapeutic options appropriate for treating pain: 1) Medications; 2) Restorative Therapies; 3) Interventional Procedures; 4) Behavioral Approaches; and, 5) Complementary and Integrative Health. (Categorizations in current literature are more or less equivalent.) Each of these categories is further broken down into commonly used therapies or classes of therapies. For example, the medications section of the report discusses seven commonly used classes of pain management medications: acetaminophen, NSAIDs, anticonvulsants, antidepressants, musculoskeletal agents, anxiolytics, and opioids. Please refer to this report for specific therapies within each of the five broad classifications.

Another cornerstone of the PMTF Report that must go hand-in-hand with the multidisciplinary, integrated model discussed above is ***individualization*** of every aspect of the care plan. Chronic pain is extremely complex and difficult to treat. What helps one person's pain may or may not help another's, even when the source of their pain may be the same (i.e. both have complex regional pain syndrome or both have fibromyalgia).



Successful management of chronic pain requires individualization of care in the selection of therapies tried, in the consideration of benefits and risks of therapies, in the duration of treatment, in the optimal dosing of medication, and so on. This is extremely important when it comes to the benefits and risks of each treatment. One person may be more willing to try a medication that carries the risk of long-term health problems when weighed against their near-term improved quality of life. The U.S. Pain Foundation believes these benefit-risk decisions regarding treatment should be made by each patient in consultation with their physician and other healthcare providers. Individualization is also necessary in terms of the patient as a person: each individual has different values, preferences, goals, histories, cultural views of pain, etc., that inform their treatment decisions and interactions with the healthcare system. Care must be patient-centered and focus on helping the patient improve their quality of life on their terms.

While the U.S. Pain Foundation and the Pain Management Task Force strongly support integrated, multidisciplinary, and multimodal care as best practice in pain management, it must be recognized that there are enormous barriers to this form of care. These barriers include inadequate insurance coverage for a full spectrum of pain management services, lack of education and training of physicians and other healthcare providers on core competencies in pain management, time constraints that deter physicians from comprehensively managing chronic illness, shortages of pain management specialists, and a lack of research or a solid evidence base on the efficacy of current treatment modalities, especially in terms of which modalities are best for which type of pain and in what combination.

The Task Force report has made many recommendations to overcome these barriers. If the CDC was to recommend this best practice approach to pain management in an updated Guideline, and the U.S. Pain Foundation hopes it will, considerable thought and effort must be put into removing these barriers for patients. It is extremely frustrating and demoralizing for people with pain to be told to try treatments that could help them, when many options are not covered by insurance or only partially covered or otherwise unaffordable. Treatments and therapies like physical therapy, massage, behavioral therapy, acupuncture, yoga, and gentle exercise in particular may be helpful, but few insurance plans cover these options fully, if at all. In addition, these types of interventions typically require numerous appointments over a long period, which quickly add up in terms of copays and out-of-pocket costs. This is prohibitively expensive, especially for a person with severe pain who is on disability or struggling to work part-time. In general, the more severe the pain, the more likely an individual is to need multimodal interventions--and the more likely they are to be unable to afford them. Furthermore, these options may not be readily available if an individual lives in a rural area, or has difficulty driving, which many people with pain do.

Increasingly, the consensus among patient groups, healthcare providers, and even policymakers is that multimodal approaches to pain are ideal, especially given the opioid crisis. But this view is not in line with or reflected by current insurance policies or practices. Until we address the immense obstacles to affording and accessing truly multidisciplinary care, patients will need to rely on a more narrow scope of traditional treatment options, like medications, injections, and so on. These treatment options are important, of course. However, truly effective pain care must incorporate all of the options for relief that are available. An untold



amount of quality of life, function, and productivity could be restored through better coverage of a diverse range of treatment options.

On the important issue of opioid medication, the CDC's Federal Register announcement indicated that public comment could help the CDC decide whether there is a need to update or expand the CDC's Guideline for Prescribing Opioids for Chronic Pain published in 2016. The PMTF Report recommended updating and expanding the Guideline, and the U.S. Pain Foundation agrees certain revisions would benefit people living with chronic pain.

We agree with the CDC that opioids should be used judiciously, and rarely as a front-line option. But the reality is that they are an important treatment, particularly for millions of Americans with severe pain, who have used them appropriately and legitimately to manage their long-term chronic pain. Beginning in April of 2016, soon after the CDC Guideline for Prescribing Opioids for Chronic Pain was published, the U.S. Pain Foundation and numerous other pain-related organizations began hearing from pain patients about their struggles to access their opioid medication that they had relied on, on stable doses, for many years, to help manage their pain and maintain quality of life.

These patients reported that their doctors had abruptly refused to prescribe opioids any longer and were reducing, force-tapering, discontinuing and even abandoning their chronic pain patients altogether, because the risks of regulatory scrutiny and challenges of treating them were too great. Many of the patients who wrote to our organization expressed suicidal ideation, hopelessness, and utter despair; they often directly cited the CDC Guideline as the reason their healthcare provider had reduced or ended their opioid therapy.

Frequently, and horrifically, patients indicated that providers offered little guidance or information in terms of alternative options for relief. Patients felt they were left to fend for themselves, and that no one cared enough to help them with their pain. (Even if these harms are eventually corrected, many now harbor a deep mistrust of the entire health care system, which undoubtedly will hamper their willingness to access and engage with their care in the future.) Indeed, by April of 2019, the situation got so bad that the FDA issued a safety warning to the nation's healthcare providers, saying that sudden discontinuation of opioid pain medications was causing serious harm to patients including withdrawal, uncontrolled pain, psychological distress, and suicide.¹

With funding from the federal government, the CDC's Guideline was promoted to state health departments and licensing boards. Soon thereafter, it was widely adopted as policy. A total of 28 states have enacted legislation aimed at limiting the prescribing of opioids for pain, based on the CDC Guideline.

As I personally stated in testimony to the U.S. Senate HELP Committee on February, 12, 2019, "Speaking from personal experience and from 18 years of helping hundreds of chronic pain sufferers manage their conditions, opioid prescription medications are not the enemy nor the savior when it comes to managing chronic pain."²

¹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes>

² <https://www.help.senate.gov/imo/media/doc/Steinberg.pdf>



The truth is that they lie somewhere between those extremes. The U.S. Pain Foundation urges the CDC to restore **balance** in revisions to the Guideline to opioid medications' use in providing relief to people with chronic pain. Like any medication, they have benefits and risks that must be considered on an individual basis, taking into consideration the patient's detailed history, results of risk screening tools, side effects, and previous treatment options tried, as well as the amount of possible pain relief they provide for that specific patient.

Guideline number 5, which discusses specific dosage limits, has perhaps caused the most consternation, controversy, and harm for people living with chronic pain. Broad, one-size-fits-all dosage limits are a direct contradiction to a central tenet of the PMTF Report that best practice for pain management is individualized care. Indeed, the CDC Guideline authors, writing in the *New England Journal of Medicine* in its June 13, 2019, edition, decried the "misapplication" and "inflexible application" of the 90MME dosage threshold. The authors admitted this guideline had resulted in policies with hard limits, causing abrupt tapering, sudden opioid discontinuation, or dismissal of patients from physicians' practices that, in combination with other "misapplications" were "likely to result in harm to patients".³

In its review of the CDC Guideline, the PMTF Report states that there is wide variation in patient and disease factors that determine the dose of opioids that is optimal for each patient, balancing effectiveness and safety. The PMTF Report further states that the balance of benefit and risk for doses above 90MME may be acceptable in some patients. The U.S. Pain Foundation strongly agrees with the PMTF Report recommendations that clinicians should individualize dose based on a carefully monitored medication trial and on progress toward patient goals for functionality, activities of daily living, and quality of life measures. In light of these recommendations, and the harms that have resulted from inclusion of specific MME thresholds, the U.S. Pain Foundation urges the CDC to remove the 50MME and the 90MME dosage thresholds from Guideline 5, and restate Guideline 5 without specific dosage numbers.

Further, the Guideline focuses almost exclusively on opioids as if they are the only treatment for chronic pain. This was a grave oversight. Effectively, the Guideline broadly condemned one treatment option with little discussion of alternatives, scant guidance to healthcare providers on what modalities could take its place, and no acknowledgement of the immense barriers patients face in accessing non-pharmacological treatment.

As discussed earlier in this comment, best practice in pain management is an **individualized, synergistic combination of multimodal treatment options**. There are a multitude of treatments that have been found to help some subset of the enormous population of Americans living with chronic pain. The PMTF report discusses most of these evidence-based treatments and the Guideline would benefit from inclusion and discussion of these treatments and treatment classes.

³ Dowell D, Haegerich, T, Chou R. No Shortcuts to Safer Opioid Prescribing. *New England Journal of Medicine*. 2019. <https://www.nejm.org/doi/full/10.1056/NEJMp1904190>



The CDC would also do well to take note that we believe the PMTF Report is as comprehensive, well-rounded, and widely endorsed as it is because it was written by widely respected pain management experts who sought and received extensive patient and public input in a transparent manner. We encourage the CDC to ensure that the patient voice and perspective, as well as that of nationally respected pain management physicians and advocates, is solicited and incorporated into any revisions of the Guideline. A more balanced Guideline, with a less harmful impact, would likely have resulted if patients, pain patient groups, and leading pain management physicians had been more involved initially in the 2016 edition. It is important to point out, too, that if the CDC's goal is to achieve and maintain a reasonable reduction in our national reliance on opioids, only reforms that are fair, balanced, and more fully address the problem of pain will be both sustainable and successful.

The U.S. Pain Foundation is pleased to respond to the CDC's request for comments concerning pain management and whether there is a need to update or expand the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain. The views expressed in this comment to the docket reflect the perspective of thousands of our constituents living with chronic pain. We hope the CDC will give these views serious consideration as it moves forward with this important work. Should we be able to provide additional information or assist the CDC's efforts in any way, please feel free to contact me at the information listed below.

Sincerely,

A handwritten signature in black ink that reads "Cindy Steinberg". The signature is fluid and cursive, with the first name "Cindy" being more prominent than the last name "Steinberg".

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