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# CDC Revised Opioid Prescribing Guideline Falls Short of What People in Pain Need

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*Author's note: I submitted the following response to the revised opioid prescribing guideline of the CDC to be posted in the public comment section. Unfortunately, it was labeled restricted for containing "personally identifiable information." Inquiries for how I might edit the comments so they could be read by the public went unanswered. I referenced one person who is a public figure.*

*I believe the public should see my comments, so here they are, for those who are interested in the topic.*

The draft update[1] to the "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016"[2] is a substantial improvement over its predecessor. However, harm from the 2016 guideline will not be easily erased and will require more specific wording than is currently present.

The guideline was never intended to set a standard of care in the treatment of pain, much less was it intended to serve as a means to criminally prosecute clinicians. There was never consensus regarding the guideline's recommendations, illustrated by the call for major revisions from the American Medical Association (AMA), among other professional societies. Eventually, the CDC's own authors issued cautions not to misapply the guideline recommendations to require specific dose or quantity restrictions.[3] Nevertheless, the guideline and policies created to comport with it were weaponized to investigate, sanction and sometimes imprison clinicians for practicing non-concordant guideline medicine. These are gross errors that require immediate remedy.

The update commendably clarifies that it is not to be applied as an inflexible standard of care across patients or patient populations by health systems, pharmacies, third-party payors, "governmental jurisdictions" or—in another location in the text—"government entities."[1] However, the terms, "governmental jurisdictions" and "government entities" are not specific enough. Now, guideline drafters should go further and mention governmental entities who have misused guideline-concordant care, such as:

- the Drug Enforcement Administration (DEA);
- the Department of Justice (DOJ);
- federal prosecutors;
- government expert witnesses;
- judges who gave jury instructions; and
- legislators, including Senate Finance Committee Ranking Member Sen. Ron Wyden (D-Ore.).

The CDC must take an active societal role in reversing unapproved usage of the guideline. Poor medical practice should be regulated by the states by way of state medical boards. Criminal charges involving controlled substances require evidence of intent to breach the bounds of legitimate medicine. The guideline update should expressly state that law enforcement and policymakers should not use it to set a standard of care or to prosecute clinicians.

**Prosecutorial Misuse of 2016 Guideline**

Prosecutors and government expert witnesses have used guideline recommendations—including those of the CDC—around

opioid dose, toxicology screening, prescription drug monitoring programs (PDMPs), failure or perceived failure to use nonopioid treatments, and more to impugn prescribing practices, portraying them as outside the bounds of legitimate medicine. These effects were predictable—if not intended—and were, in fact, predicted.[4]

A list of resources detailing these results include the following:

- "Jailing Hippocrates: Criminalizing Deviations from the Opiate Prescribing Standard of Care and Its Chilling Effect on Health Care"[5]
- "Doctors Prescribing Opioids in Good Faith Should Not Be Prosecuted"[6]
- "Doctors Who Prescribe Pain Medicine in a Bind With CDC Guidelines, Data-Driven DOJ/DEA Investigations"[7]
- "A More Sensible Surge: Ending DOJ's Indiscriminate Raids of Healthcare Provider"[8]

As shown in court transcripts and described in *Scientific American*[6]:

> Prosecutors have based their cases in part on guidelines published by the CDC in 2016, and they have argued successfully that dosing outside the amounts mentioned in the guidelines is not a legitimate medical purpose.
>
> "We saw prosecutors using the CDC guidelines as evidence for their expert witnesses," said Ronald Chapman, an attorney who specializes in defending physicians accused of improperly prescribing drugs.
>
> "The government would target physicians for prosecution based on the amount of medication they were prescribing—not on patient outcomes or sort of general factors of dangerousness to the patient population," Chapman added, explaining that by searching through prescription drug monitoring databases, law enforcement can simply designate the doctor who prescribed the most opioids to patients in a particular city or state as a criminal. "The doctors who ended up with the largest target on their back were the pain management professionals who were taking the most problematic patients," he said.

It is noteworthy that government expert witnesses sometimes have professional backgrounds and, therefore, an inferred interest in the interventional treatments that they testify are preferable. These treatments are not risk-free, and, as the CDC states, "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."[1]

A nonopioid treatment might be beneficial for a given patient, but choosing opioid therapy ahead of any specific therapy is not necessarily failure to meet standard of care or evidence of criminality. The CDC update now agrees by stating that patients should not be required to fail therapies sequentially. Furthermore, "when needed, medications should ideally [emphasis added] be combined with nonpharmacologic therapy to provide greater benefits to patients in improving pain and function. Multimodal therapies are not always available or reimbursed by insurance and can be time-consuming and costly for patients, and disparities for being able to access multimodal care exist."[1]

Moreover, the DOJ and federal enforcers have targeted not only prescribers of opioids for pain but prescribers of medications for treatment of opioid use disorder (OUD).[8] This, even though the strongest evidence contained in the guideline update says clinicians should offer or arrange this very treatment. Commendably, the update states, "Recommendations on opioids used specifically as medications for opioid use disorder are not the focus of this clinical practice guideline."[1] Whether the damage done can be reversed remains to be seen.

**Misuse of the Threshold Dose**

The threshold dose of 90 morphine milligram equivalents (MME) contained in the 2016 guideline has been a most misunderstood and misused recommendation in courts and in public policymaking. Conflating difference of medical opinion with a criminal standard for prosecution under the Controlled Substances Act (CSA), the DOJ has used MME-threshold doses as a benchmark to label certain clinicians "high prescribers" without feature in complicated cases of pain. From the CDC update: "Pain management specialists often have extensive training and expertise in pain management modalities that other clinicians do not, and 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."[1] These nuances are not often appreciated by investigators who judge by MME alone.

Most importantly, evidence shows that the MME threshold is not an optimal benchmark for judging patient care or a precise predictor of opioid overdose.[9] As early as Oct. 1, 2015, in a letter written to the former director of the CDC, the AMA correctly observed that the MME threshold was not supported by scientific evidence, that patients vary in responsiveness to opioids, and that morphine equivalent calculators are uncertain. The AMA even cited data that enforcement of an MME-threshold dose in Ohio had lowered prescription quantities and doses but also coincided with a rise in opioid death rates. This scenario has played out nationally in recent years as prescriptions written for opioids have dropped in every state; yet opioid deaths continued to rise.[10]

Regardless, the MME metric was misused by policymakers, enforcers and officials in various contexts. In his capacity as a ranking member of the Senate Finance Committee, Wyden probed the American Academy of Pain Medicine (AAPM) for purported conflicts of interest by asking why AAPM had not adopted the 2016 CDC guideline, particularly the threshold MME dose for a "high dose."[11] The senator all but demanded AAPM to adopt the dosing guideline, although the scientific basis of the MME has never been established and was, even at that time, directly challenged by the AMA.

**Action Needed to Safeguard Patient Care**

Numerous changes in the update are noted improvements to the 2016 version. Among them:

- the explicit MME dose limit at the upper threshold was removed;
- days of opioid supply for acute pain are no longer specific; and
- dosage recommendations are separated by patients starting opioids versus patients already receiving opioids at higher doses.

It is now an accepted truth that the 2016 guideline was used to make policy beyond its intended purpose. Non-collaborative tapers and other patient harms resulted when clinicians tried to force patients into one clinical context.[3,12-16] Algorithms generated through PDMP usage have been similarly used to label clinicians "overprescribers" and resulted in forced tapers, discontinued prescriptions and patient abandonment.[17] The CDC cites these results and describes these effects in the guideline update.

The CDC further accedes that complicated prescribing is sometimes a dosing box. The CDC now states, "These actions are not consistent with the 2016 CDC Guideline and have contributed to patient harm, including untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose, and suicidal ideation and behavior."[1]

The CDC acknowledges it is a concern to prevent misapplying the updated clinical practice guideline "beyond its intended use or implementing policies purportedly derived from it that might lead to unintended consequences for patients."[1] Therefore, the CDC must take a stand in rolling back these particular policies and misapplications. The importance of these steps cannot be overemphasized because there has been a deleterious effect on patient care.

It is noted that the CDC agreed to place a callout box at the beginning of the update to highlight that the guideline is not:[18]

- a replacement for clinical judgment or individualized, patient-centered care;
- a law, regulation or policy that dictates clinical practice or a substitute for FDA-approved labeling; or
- intended to be applied as an inflexible standard of care among patients and/or across patient populations by healthcare professionals, health systems, pharmacies, third-party payors or governmental jurisdictions, or lead to the rapid tapering or discontinuation of opioids for patients.

These changes are good insofar as they go. However, the damage is done. The 2016 guideline led to many patients losing access to medications and medical care, many pain care providers leaving the field and those providers who remain continuing to fear investigation and sanctions—up to and including loss of liberty—for prescribing legal opioids to patients, even when indicated. The guideline update drafters even cite "a shortage of pain management specialists" as a factor in insufficient patient access to therapeutic options for pain. Because of this circumstance, patients have suffered. Unless the CDC is specific about "misapplications" in the legal and policymaking reams, patients will continue to suffer.

**What Guideline Drafters Should Do Now**

*Clarify Regulatory and Legal Intent of Guideline*

A specific statement should be added to the guideline: 1) acknowledging that specific entities have misused guideline-concordant care; 2) acknowledging that harm has resulted to clinicians and to patient care; 3) emphasizing that use by law enforcement or policymakers to set a standard of care or to prosecute criminally under the CSA is not intended and is a misapplication of the guideline; and 4) reiterating that the regulation of medical practice resides with state medical boards, who have the expertise necessary to evaluate the practices of an individual clinician and the power to exact appropriate penalties.

Experts and community members who gave feedback on an early guideline draft agreed that statements should be more explicit regarding its misuse in the legal and regulatory realms. The Opioid Workgroup (OWG) report states[18]:

> "Many workgroup members felt there should be an explicit statement that the Guideline is a clinical Guideline, and not payer or governmental policies."

In further support, the Overview of Community Engagement and Public Comment Opportunities document, which represents lived experiences and perspectives of patients, caregivers, clinicians and the public, included the following input[19]:

> "Many comments, particularly those from patients and clinicians, described instances in which the 2016 Guideline was used by outside industries (e.g., pharmacies, insurance companies, policymakers) in ways that limited the patient-clinician relationship. … In some instances, this misapplication even arose in policies, whether legislative, regulatory or institutional, that intended to shape clinicians' scope of practice and enforce punitive action against clinicians who failed to adhere to those policies."

*Pledge to Roll Back State and Payor Policies*

The CDC update lists examples of laws, regulations and policies created in the mistaken belief that they comported with a CDC-established standard of care but that, instead, resulted in harms, including[1]:

- extending the guideline to apply to cancer and palliative care patients;
- opioid tapers and abrupt discontinuation of opioids without patient collaboration;
- rigid application of opioid dosage thresholds;
- extending the recommendation to medications used to treat OUD;
- patient dismissal from care and abandonment; and
- prescription duration limits set by insurers and pharmacies.

The CDC pledged in the updated Guideline version to work with public and private payers to improve coverage and access for its recommended nonpharmacologic treatment options. This is a welcome development. Now the CDC should go further and pledge similarly to work with states and localities to roll back policies that were created and implemented with the goal of seeking concordance with the more restrictive recommendations contained in the 2016 version. Some state laws that changed restrict prescription duration and quantity in apparent obeisance to the 2016 Guideline version may be viewed online.[20]

*Roll Back Harm to Clinicians*

The CDC pledged to evaluate consequences of the 2016 guideline on patients and clinicians.[3] The current draft update does not adequately cover the effect on clinicians. Several organizations, experts and individuals named as defendants accused of acting to advance marketing messages in the ongoing opioid lawsuits have long proposed many recommendations now arrived at by the CDC workgroup. For instance, the collaborative clinical practice guidelines published in 2009 by AAPM and the American Pain Society (APS)—which was forced to dissolve—are now notable, not for its industry entanglements but for its striking concordance with the current CDC recommendations. A systematic review evaluating 13 guidelines gave a high grade to this joint publication, along with one other by the Canadian National Opioid Use Guideline Group.[21] Roger Chou, MD, an author heavily featured in the CDC update, once said of the APS/AAPM guidelines (for which he was lead author)[22]:

> "I think the fact that the guidelines say that opioids aren't always appropriate and provide the concept of a 'trial of therapy—that the decision to continue opioids should always be a deliberate and conscious one—have been helpful to people.
>
> "I think the guidelines were one of the first real efforts to really critically look at the evidence on using opioids for chronic

noncancer pain.

"The guidelines are very clear about the need to perform risk assessment, that opioids aren't always appropriate, and that there are circumstances in which opioids should be discontinued."

This is not to say that the science has not progressed in the 13 years since the APS/AAPM guidelines appeared; it is merely to point out the zealotry with which these organizations and others were unjustly pursued by lawmakers, prosecutors, the media and others without a basic understanding of where they actually stood on patient care. Their proposals were not that different from what the CDC proposes now. For instance, patient abandonment has been feared by patient advocates and those who have treated them for years. Additional examples include calling for special cautions and practitioner expertise with methadone for pain;[23-26] avoiding prescribing benzodiazepines and opioids together;[24,25,27] understanding how mental health disorders complicate pain treatment;[27] obtaining appropriate diagnostic tests and considering whether nonopioids would be more appropriate treatment;[28] calling for evidence-based alternatives to opioids to be covered by insurance payors;[29] and considering opioid treatment for chronic pain when potential benefits are likely to outweigh risks and there is no alternative therapy that is likely to pose as favorable a balance of benefits to harms.[28]

It is not merely a matter of professional pride to correct these misunderstandings. Certain groups and individuals—including this author—have been targeted for espousing views that have been targeted for espousing views that, at most, qualify as reasoned scientific debate or science as it was then understood. Surely these examples demonstrate clearly how imperative it is for the final CDC draft to roll back use of the guideline in policymaking and legal proceedings.

*Address Misinterpretations Regarding Monitoring Tools*

Because legal misuse has occurred, all tools, including risk assessment, toxicology screening and PDMP checks must be interpreted in the context of the clinical situation and should not be used by government investigators, prosecutors or government experts at trial to impugn clinicians. The CDC update must strongly repudiate this type of misuse.

The OWG report showed that its participants were keenly aware of the dangers of this approach[18]:

"Interpretation of urine drug tests results can be complicated, and many providers lack this knowledge, which can lead to inappropriate negative consequences. In addition, because most urine drug tests are screening tests, false positive or false negative tests are not uncommon."

In addition, several workgroup members discussed not taking a "punitive approach." Yet, the CDC response to the OWG's concerns does not adequately address the punitive way results have been used against healthcare providers. It should say specifically that toxicology screening tests are not intended for "policing patient behavior," given their limitations, sometimes burdensome costs, the variation among state laws for requiring the tests and the expectation that it will be explained to patients that the testing is for their safety (the inference being not for law enforcement purposes). For each tool used to assist clinicians in making prescribing safer for patients and which has been misused in legal or regulatory proceedings (opioid treatment agreements, PDMP, toxicology screening), the CDC should state that it was not intended as a tool for law enforcement. Medical boards are in place to make sure patients are not harmed by unprofessional or suboptimal care.

**Additional Issues and Areas for Improvement**

*Correct Messaging Regarding the Opioid Overdose Fight*

The OWG apparently had a good discussion regarding benefits to society versus providers' obligation to treat individual patients, and concluded that the 2016 guideline was not sufficiently patient centered. From the OWG report: "Similarly, the tension between risks and benefits for individual patients versus the public health should be explicitly addressed. A patient-centered approach should be strongly encouraged."[18] This is a beneficial development, as fighting the opioid crisis through a pure public health perspective has targeted the wrong parameters and allowed public health to worsen as well as patient suffering to increase.

Unfortunately, the current document continues to argue that there was a fourfold increase in prescribing between 1999 and 2010 that paralleled a nearly fourfold increase in overdose deaths associated with prescription opioids, thus suggesting cause and effect. However, it discounts the precipitous drop in opioid prescribing that has been associated with a skyrocketing rise in drug overdoses deaths, principally fueled by illicit opioids. This is a contradiction and one that threatens to pull resources for containing the opioid crisis astray. From the Garrison Project[30]:

> "The overdose crisis is indeed worse than ever—there were nearly 100,000 drug-involved overdose deaths in the US in 2020—but, since 2016, the leading cause of overdose deaths has been illicitly manufactured synthetic opioids, not pharmaceutically manufactured prescription opioids.[31] After peaking in 2011, opioid prescribing is at its lowest level since 1993."

It has become apparent that the CDC estimates of overdoses due to prescription opioids have been incorrect. According to recent analyses[32]:

- In a 2018 report, four senior CDC analysts, including the head of the Epidemiology and Surveillance Branch, acknowledged for the first time that the number of prescription opioid overdose deaths reported by the CDC in 2016 was erroneous.
- The error was caused by miscoding deaths involving illicitly manufactured fentanyl as deaths involving prescribed fentanyl.
- In 2019, more than seven times more methadone was administered or dispensed for OUD treatment than prescribed for pain, yet all methadone-involved deaths are coded by the CDC as involving the prescribed form of the drug.

The authors noted that the CDC has been called on to modernize its drug overdose–reporting system, but this has not been done. Accurate statistics are vital to fighting the opioid crisis, and these failures have had significant adverse effects on public and individual patient safety.

*Update Understanding Regarding MME and Conversion Tables*

It is not a stretch to predict déjà vu in further misapplications if the nonscientific MME threshold of 50 MME currently contained in the draft update is left intact and subsequently misinterpreted by media members and policymakers as a hard dose limit. The OWG called the threshold of at least 50 MME per day "arbitrary."[18] It is agreed that this benchmark dose is every bit as arbitrary as the 90-MME threshold that the update drafters commendably removed. However, the wish for a specific "benchmark" dose at which clinicians should reevaluate treatment was apparently too strong.

The CDC concedes that experts expressed concern that dosage thresholds have the potential to be interpreted as authoritative and result in non-collaborative tapers or other harmful consequences. It also acknowledges that there is no standard formula for calculating MME.[33]

The same can be said of conversion tables for equianalgesic opioid doses. From Dasgupta et al[33]:

> "Conceptually, an equianalgesic dose is that at which two opioids provide the same pain relief. Contrary to conventional wisdom, conversion values are not based on pharmacologic properties. Instead, they arose 60 years ago from small single-dose clinical studies in postoperative or cancer populations with pain score outcomes; toxicologic effects (e.g., respiratory depression) were not evaluated."

Bioavailability, metabolism and elimination all affect what dose is best for the individual patient. Data suggest at least a 13-fold dosage variability, and further suggest a genetic contribution.[34] Possible reasons for high variability needed for pain control in chronic pain include[34]:

- pain severity;
- genetic differences in hepatic metabolism (can account for threefold or greater variability);
- genetic differences in the receptor interactions of different opioids; and
- genetic differences in neural transmission.

There is danger that any reference to conversion tables and MME will be interpreted as codifying them with predictable adverse effects. At least, the lack of a scientific basis for their use in overdose prevention and a warning that they could be dangerous in some cases should be added. The precautions advised by the CDC at 50 MME, including more frequent follow-up and offering naloxone and overdose prevention education to the patient and household members, should be done at any dose when risks grow more apparent versus benefits in an individualized manner. To recommend otherwise could instill overconfidence that a benchmark dose is "safe" for any given patient.

**Concluding Thoughts**

The updated guideline contains beneficial changes. Among them, certain prescription duration limits and the upper MME dosage threshold have been removed. There is some acknowledgment that pain treatment is indeed important. Yet, the inappropriate usage of the 2016 guideline and policies created in its image to harass, prosecute and even jail clinicians must be specifically and adequately addressed. The MME threshold now in the revised version is no more scientifically sound than the ones in the previous version, and it has already been shown that dosage levels are too easily interpreted with rigidity by policymakers and payors. Until these issues are resolved, the fallout has the potential to harm patient care into the future.

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