

Treating Pain in an Established Patient: Sifting Through the Guidelines

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ABSTRACT

The CDC Guideline for Prescribing Opioids for Chronic Pain, published last March, provided major steps toward bringing the medical community together to address the opioid epidemic in the U.S. However, the Guideline focuses primarily on treatment of new inductions into opioid therapy for pain. Physicians may have difficulty figuring out how to apply the CDC's recommendations to patients who are already receiving opioid maintenance therapy for chronic pain. Patients already maintained on opioids for chronic pain should not be subjected to abrupt cessation or rapid tapers, and the CDC's Guideline confirms this. Physicians should not balk from treating opioid-dependent patients with chronic pain, and the CDC's recommendations do contain helpful information if one reads through them carefully. This article attempts to distill the major points from the Guideline for the treatment of chronic-pain patients already on long-term opioid therapy.

KEYWORDS: Centers for Disease Control and Prevention (U.S.), chronic pain, analgesics, opioid, practice guidelines as topic

INTRODUCTION

The CDC Guideline for Prescribing Opioids for Chronic Pain,¹ published March 2016, provided major steps toward bringing the medical community together to address the opioid analgesic abuse, addiction, and overdose epidemic that has gotten exponentially worse in the last 15 years. There was reason to focus on prescribing practices, and there is reason to believe that these new guidelines will be broadly implemented with a positive effect. However, readers may note that the guidelines focus primarily on treatment of *new* inductions into opioid therapy for acute pain. There may be cause for concern that patients already receiving opioid maintenance therapy (i.e., "established patients") may not gain optimal benefit from the CDC guideline.²

This is not to say that the CDC did not include optimal practice suggestions for patients already taking opioids. At earliest opportunity, the provider is urged to outline treatment goals with opioid-maintained established patients,

emphasizing functional improvement; this is similar to standard practice in initial encounters with opioid-naïve patients.^{1, p.19} The visit should culminate in an agreement on objective outcomes that will govern opioid therapy being continued, changed, or terminated.^{1, p.19} Established patients taking in excess of 90 MME per day should be seen at an encounter separate from a regular prescribing visit to offer opportunity to reconsider treatment.^{1, p.23} Guidelines suggest that all relevant decisions should be made with the patient's active involvement. Should tapering be sought by the patient, the clinician may cautiously implement a taper, as suggested.^{1, p.24} This unique taper is the longest of those utilized in standard practice and may include repeated pauses.^{1, p.24} The optimal target dose may or may not be complete opioid discontinuation, as decided by the patient who has been educated by the treatment provider.^{1, p.24} These are reasonable medical suggestions that, if broadly implemented, would likely provide substantial benefit.

PROBLEMS WITH THE GUIDELINE

Unfortunately, the CDC's recommendations for established patients appear within a lengthy, cumbersome document in incongruent patches. Pertinent passages for these patients appear near the middle of the recommendations, and there are no shortcuts, hints, or hyperlinks in the document that would afford efficient reference. If one skims headlines and summaries to find specific information, the document seems to imply that treatment of established patients is similar and auxiliary to the treatment of patients who have not been on opioid medication. In fact, however, treating established patients differs strongly from therapies afforded to opioid-naïve patients but is equally important. Not one of the several clinical tools created to ease guideline implementation outlines unique details of treating established patients. Any reasonable physician might invest several hours studying the guideline and still lack clarity regarding standards of practice.

Significant numbers of patients are *already* taking over 90 MMEs a day by prescription, and the CDC's guideline says little about how the physician is expected to treat such patients.³ Abruptly switching a patient to a significantly lower dose or rapidly tapering a patient who is already dependent on opioids would arguably represent a deviation

from the standard of care, not to mention a violation of medical ethics (“*first, do no harm*”). A potential contributor to the current opioid epidemic is the unwillingness of some prescribers to help patients who have a substance abuse history or who are having difficulty tapering down from long-term opioid prescriptions.⁴ Abandoning such patients can precipitate crises and increase psychosocial risk factors that contribute to worse outcomes.

There is a possible unintended consequence of the guideline as currently available. A new prescribing pattern may arise as providers – motivated by their misreading or their institution’s misreading of the guideline, or by payer restrictions on reimbursement – discontinue or alter medical treatment in a manner contrary to the new practice standards and contrary to the humane treatment of patients experiencing chronic pain.² As the AMA notes:

“[T]he recommendations on dosage and duration limits conflict with the approved product labeling for opioids and with the U.S. Food and Drug Administration’s own conclusions about the wisdom of establishing a maximum dose based on daily morphine milligram equivalents. We [the AMA] are concerned that insurers and other payers will use the recommendations to deny or impose new hurdles to coverage of any dose that exceeds the CDC’s recommended thresholds. We are concerned that pharmacies will be under pressure to deny prescriptions that exceed those thresholds, and that patients who require more than 50 morphine milligram equivalents per day could face additional prejudice and stigma.”⁵

It is likely to benefit the entire medical community if the CDC were to update its recent guideline and clinical tools, such that tailored recommendations for treating opioid-established patients could be obvious and easy to obtain.

Several commentators have criticized the CDC’s reliance on very limited empirical evidence, including low-quality study data, in its development of the recommendations in the 2016 guideline.^{5,6} Busse, Juurlink, and Guyatt, for example, object to the “excessive use of strong recommendations in the face of low-quality evidence; and vagueness in some recommendations.”^{3, p.1210} This vagueness bears special mention, as the guideline’s recommendations can easily be misinterpreted by well-meaning, overworked physicians.

APPLYING THE GUIDELINE TO ESTABLISHED PATIENTS

The CDC’s guideline presents 12 recommendations, most of which are worded in such a way as to apply primarily to novel opioid induction patients. **Table 1** (*next page*) presents suggested applications of these recommendations to treating *established* patients who are already on long-term opioid medication for chronic pain.

SUGGESTIONS FOR CHANGE

Just as the opioid epidemic has resulted from a complex interaction of factors, its resolution will need to come from multiple sources, not just the issuance of additional clinical practice guidelines and restrictive policies that further discourage physicians from helping patients with chronic pain and/or a history of substance abuse.⁷

Research

The FDA⁷ and other scholars⁴ have called attention to the dearth of high-quality scientific research evidence on the treatment of chronic pain, underscoring the importance of funding for programs and studies to find safe, effective treatments for chronic pain. Long-term follow-up data are particularly lacking, which contributes to the poor quality of studies.³ High-quality research, however, is expensive, and improving the empirical data available to help inform treatment decisions for patients with chronic non-cancer pain will likely require increased funding to support longitudinal studies.

Education

Education will also play an important role in reversing the opioid epidemic. There is evidence that continuing education through the use of clinical vignettes can help to improve prescribing behaviors in primary care physicians,⁸ for whom the new CDC guideline is intended. The hectic pace of modern medicine places extreme demands on the physician’s time;⁹ it is unrealistic and unreasonable to expect most physicians to weed through a lengthy set of cumbersome guidelines repeatedly whenever decisions must be made about treating patients with chronic pain. For clinical education to be effective, priority should be given to materials that simplify the application of guidelines like the CDC’s.

Additionally, there is room for improvement in the education that patients receive about treatments for chronic pain.^{9,10} For example, many patients have never heard of opioid-induced hyperalgesia. Similarly, more patients and members of the public are familiar with opioid analgesics than with non-opioid treatments like Duloxetine or Pregabalin.⁹ The CDC’s guideline places a high emphasis on improving communication between the physician and the patient and allowing the patient to take a more active role in treatment decisions regarding the use of opioids.¹⁰ Physician assistants and other medical practice staff (e.g., nurses, secretaries) may be able to assist in locating useful patient- and family-education resources.

Policy Changes

Individual physicians should be expected to make a very important contribution reversing the opioid epidemic, however effective strategy will require, a systematic approach that includes public education, policy changes and access to care. As Kay and Bernstein argue, “[i]nterventions beyond

Table 1. Applying the CDC's Guideline to Opioid-Established Patients

Recommendation	Application to Established Patients
1. "Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate."	Discuss with the patient various nonpharmacological treatments and nonopioid medications that may help to lessen risk. Patients may not be aware of existing non-opioid treatments.
2. "Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety."	Re-evaluate with the patient the goals of treatment, and consider renewing or reformulating the treatment plan as the patient's goals may change. Provide the patient with educational materials to help inform their treatment-planning decisions.
3. "Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy."	Periodically reevaluate the treatment plan, and reaffirm the responsibilities of the clinician and the patient in the treatment process.
4. "When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids."	If the patient is currently taking ER/LA opioids, consider transitioning to an opioid with a shorter half-life.
5. "When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day."	If dose escalation presents, consider the likelihood of tolerance or opioid-induced hyperalgesia, and discuss with the patient the pros and cons of different treatment options, such as transitioning to a different opioid or trying a slight decrease in dose if hyperalgesia is suspected. For patients already taking ≥ 90 MME/day, re-assess treatment goals with the patient, and discuss the risks and benefits of different treatment options. Monitor for factors that may increase risk, such as concurrent use of other medications such as tricyclic antidepressants.
6. "Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed."	In the event of new-onset acute pain in an established patient, consider the likelihood of tolerance or opioid-induced hyperalgesia, and discuss with the patient the risks and benefits of different treatment options, including the risk that dose escalation may result in long-term pain escalation.
7. "Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids."	Schedule treatment-planning appointments every three months with established patients.
8. "Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present."	During the treatment-planning appointment, discuss existing risk factors and steps the patient can take to reduce these risks.
9. "Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months."	Shortly before each treatment-planning appointment, check the PDMP to monitor any new prescriptions of controlled substances for the patient.
10. "When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs."	In established patients, consider adding a urine tox screen as a component of the annual physical exam.
11. "Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible."	Shortly before each treatment-planning appointment, review the patient's current medications. If benzodiazepines or other medications that may increase risk (e.g., tricyclic antidepressants) are present, plan to devote some of the treatment-plan discussion time to educating the patient about these risks and strategies for harm prevention.
12. "Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder."	Keep contact information for methadone clinics, pain specialists, and buprenorphine waiver clinicians handy, and review the common warning signs of opioid misuse. In the event of suspected misuse, consider screening for opioid use disorder, and consider consultation and/or referral for specialist care if warning signs of opioid misuse are present and do not resolve. Do not abruptly dismiss patients with opioid use disorder from your practice.

* Quotations from the CDC Guideline's Box 1.^{1, p.16}

the provider level, such as policy change and increasing access to care, are likely necessary to adequately address the opioid situation.¹⁹ The AMA has noted that the current situation in the U.S. with payment models and insurance coverage may result in undesirable uses of the CDC's guideline by insurers and other payers to deny coverage to patients with legitimate treatment needs.⁵ Although radical change in payment models for medical care in the U.S. is unlikely to happen overnight, some existing problems might be addressed through advocacy on the part of patient groups and professional organizations such as the AMA, AAAP, ASAM and others. Target legislative changes, for example, might include requiring insurance reimbursement for medication-assisted treatment for opioid use disorder. Patients and their families will likely have an important role to play in driving policy changes.

CONCLUDING THOUGHTS

The CDC has noted that improved physician-patient communication about opioids is one of the key objectives of the guideline.¹¹ The guideline's individual recommendations, at first glance, may intimidate prescribers whose patients are already taking over 90 MMEs per day, but physicians should not discharge these patients from care or initiate rapid tapers. The guideline itself recommends against rapid tapers. Instead, patients should be given an active role in treatment planning.⁶ The physician's practice as a whole, including other staff, may be able to assist in providing educational materials to patients and their families to facilitate this process.

There are numerous resources freely available from the CDC and other agencies, including decision checklists, informational handouts and posters for patients, and training materials.^{10,11,12} Lembke, Humphreys, and Newmark provide excellent risk-management suggestions, including a set of easy-reference tables, one for each stage of treatment (before beginning opioids, during opioid treatment, and during a taper to discontinue).¹⁰ These materials may be helpful starting points for discussions with patients about realistic expectations and treatment goals.

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