

CDC Issues Final Guidelines For Opioid Prescribing

The recommendations are for non-cancer chronic pain patients, and are aimed at reducing the opioid epidemic of misuse, abuse, and overdose.

n 2013, nearly 2 million Americans aged 12 years or older either abused or were dependent on opioid drugs, according to the Centers for Disease Control and Prevention (CDC). In that same year, more than 16,000 Americans died from overdoses related to prescription opioid drugs—the height of opioid prescribing.

In response to this epidemic of death from overdoses of opioids, the CDC has issued recommendations about opioid prescribing for primary care clinicians treating adult patients with chronic pain who do not have cancer or who are not in palliative care. The official-and voluntary-recommendations, known as the "Guidelines for Opioids for Chronic Pain" were released on March 15, 2016.1

The initial draft guidelines were met with sharp criticism from a number of medical organizations, including the American Academy

of Pain Medicine (AAPM), American Medical Association (AMA), and the American Academy of Pain Management.2 In addition, the Food and Drug Administration has released its own action plan to address the opioid epidemic.3

To measure the pulse of pain physicians, Practical Pain Management solicited responses from our editorial board members. What follows are the reactions from **Jennifer Schneider**, MD, a pain and addiction specialist; Gary W. Jay, MD, FAAPM, FACFEI, a pain practitioner; **Leonard** Goldstein, DDS, PhD, a licensed dentist and acupuncturist; and Elmer Pinzon, MD, MPH, an interventional pain specialist.

Their views offer insight to and interpretation of the 12 recommendations contained in the document, which the CDC hopes to modify as more research becomes available (Table 1). To view the official guidelines, visit www.CDC.gov.

Table 1. 12 Recommendations From the Centers for Disease Control and Prevention For Prescribing Opioids for Chronic Pain

Determining When to Initiate or Continue Opioids for Chronic Pain

- 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.
- 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.
- 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.

Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation

- 4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
- 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) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to titrate dosage to 90 MME or more per day.
- 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 7 days will rarely be needed.

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 therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

- 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/d), or concurrent benzodiazepine use are present.
- 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.
- 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.
- 11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
- 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.

Source: 1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *JAMA*. March 15, 2016. [Epub ahead of print].

CDC Recommendations Fall Short—Ignore Important Aspects of Pain Management

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"There is nothing new about the recently published CDC guidelines. (They) are a mixture of guidelines that have been in existence for many years, along with some useless or irrelevant recommendations as well as statements that are not evidence based and that will be a disservice for many patients if they are followed."



For several years I have been teaching a remedial (or proactive) course, "Opioids, Pain Management, and Addiction" in several locations across the U.S.⁴ The course was developed for all prescribers as well as other

physicians, physician assistants, and nurse practitioners who are dealing with administrative or disciplinary licensing board issues related to their prescribing of controlled substances.

As a result, I am familiar with what can go wrong when treating chronic pain, as well as how to do it right. I have learned that too many well-intentioned prescribers are solely focused on relieving chronic pain without understanding the need for risk assessment and without recognizing that a major goal of treating chronic pain is to improve the patient's functioning. This involves incorporating modalities such as physical therapy (PT), exercise, and attention to behavioral health issues, which all too often have a significant impact on the patient's pain.

At the other extreme are clinicians who believe there is no, or a minimal, role for opioids in the treatment of chronic pain. Neither of these approaches is in the patient's best interest.

Why The Recommendations Fall Short

When I heard that new guidelines were in the works, I was hopeful that they would indeed include

discussion of these critical elements. Unfortunately, I was disappointed.

There is nothing new about the recently published CDC guidelines. The 12 recommendations are a mixture of guidelines that have been in existence for many years, along with some useless or irrelevant recommendations as well as statements that are not evidence based and that will be a disservice for many patients if they are followed.

Here is my review of each recommendation:

#1. Agree. "Non-drug therapy and nonopioid therapy should be considered first"; pain and function should both be evaluated, and that opioids, when used, should be combined with non-opioid medications and other modalities.

#2. Disagree. PT is important but is not stressed in the guidelines. I agree that "Goals need to be established on the first visit and subsequent visits should assess improvements in both pain and function." But I don't agree that assessment of improvement in pain and function "that outweighs the risks to patient safety" is the main reason to continue opioids. The main reason is the improvement in the patient's pain and function. Obviously, avoiding side effects is part of that picture, but not the main goal.

In my opinion, function should be stressed more. Patients should be asked—at every visit—to describe specific activities that they can do at home, and to explain the length and intensity of those activities. Unfortunately what often happens is that the prescriber does little more than rate the patient's

"function" on a scale of 1-10 or checks a box on the template indicating "improved function."

PT should be a key recommendation, and should include a plan for home exercises and activities based on the individual patient's symptoms and needs. When a patient reports that "PT didn't work," rather than recording in the chart that PT failed, a conversation should be started so the patient understands the goals of PT and the important role of activity in minimizing the progression of muscle weakness and disability.

#3. Reality check. With regards to "periodic discussions with patients [about] known risks and realistic benefits of opioid therapy".... I have reviewed templates of electronic medical records and found that when there's a box to check on each visit confirming that the matter was discussed the reality is that the box usually gets checked, but the provider doesn't actually take the time to discuss the matter. This is unfortunate.

#4. Unacceptable omission. "When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release." I agree. When opioid-naïve patients start an opioid, the dose is typically low, in order to assess side-effects such as sedation and nausea/vomiting, and later titrated upwards to efficacy. If a side effect occurs, it certainly makes sense to have a short-acting formulation rather than allowing patients to be miserable all day. But there is no mention in this guideline of what to do when the opioid is continued!!!! This is an unacceptable oversight.

It is generally accepted that once an effective dose is reached, the patient should be converted as early as possible to an extended release/long acting (ER/LA) formulation. Although there are no studies that show that an identical dose of a given opioid has a better analgesic effect when it's in an ER formulation than immediate release (IR), there are other good reasons for using the ER formulation, including:

- Less-frequent dosing means less clock-watching and longer pain relief, which can enable the patient to sleep through the night without having to wake up to take the next dose.
- Less-frequent dosing results in smoother blood levels and therefore more constant pain relief.
- Smoother blood levels result in fewer CNS effects such as euphoria. (As we know, the reason drug

- abusers prefer to inject or inhale a crushed opioid pill is that the resulting rapid increase in blood levels in the brain causes a euphoric feeling.)
- Value on the street. These days most ER/LA formulations have abuse-deterrent features, which have diminished their street value substantially.
 On the other hand, IR hydrocodone and oxycodone have a high street value and thus greater abuse potential.
- · Delay makes switching difficult. The longer you wait to switch a patient from an IR to ER formulation, the harder it becomes to make the switch. Most of us have had patients who insist that the IR formulation works better than the identical dose of ER drug we switched them to. They aren't necessarily drug abusers. Rather, the IR formulation is more likely than the ER (see above) to cause a "feel good" response that the patientunderstandably—attributes to pain relief. When switched to the ER formulation, the CNS effect is less noticeable, which the patient interprets as lower efficacy. A patient accustomed to taking oxycodone IR 15 mg qid for a year, for example, is likely to resist the switch, which may leave the practitioner wondering if they are selling some of the high-street-value oxycodone IR.

The bottom line is, when you have a patient with chronic pain on a stable opioid dose, don't leave him or her on a round-the-clock IR formulation; transfer as soon as possible to the ER.

#5. Numbers are arbitrary. "When opioids are started, clinicians should prescribe the lowest effective dosage. . . and carefully reassess evidence of individual benefits and risks when increasing dosage to 50 morphine milligram equivalents (MME) per day." This is true, and you should assess the benefit of whichever dose you are prescribing, not just if it is ≥50 MME/day; there is no evidence that a dose higher than 50 mg morphine has specific features. The same is true of the next statement that clinicians "should avoid increasing dosage to ≥90 MME/day or carefully justify a decision" to prescribe this dose. These are arbitrary numbers. Is it okay then to not carefully justify a decision to prescribe 70 or 80 MME/day? These decisions should be based on the patient's function as well as pain relief no matter what the dose, along with the patient's willingness to be engaged in other recommended activities such as physical therapy, exercise, and counseling if there are behavioral health problems.

The result of this unhelpful recommendation is that many prescribers will want the patient to see a pain specialist for confirmation that he/she is indeed benefiting from this dose. Sadly, there just aren't enough pain specialists to take on such a task, so the alternative will be to simply decline to prescribe a dose higher than some arbitrary quantity, regardless of the patient's response.

#6. Not detailed enough to be helpful. "Long-term opioid use often begins with treatment of acute pain." This is true, but these guidelines specifically state they are for chronic pain, not acute. There is no reason to throw in recommendations for acute pain, especially when they are absurd. I take issue with the following statement: "Prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids." Where is the guidance?

The fact is, there are many different types of acute pain, and it is often difficult to assess the expected duration. The guideline goes on to say: "Three days or less will often be sufficient; more than 7 days will rarely be needed." How can they recommend this without having any idea of the specific injury, surgery, or event? And if the patient is prescribed 2 days of medication and then needs a few more, will you have time in your schedule to see him on the third day? What if the patient doesn't feel well enough to make another trip to your office? Remember that hydrocodone, along with oxycodone and most other opioids, are now Schedule II, meaning you can't phone in a prescription. This language should not be included in these guidelines.

#7. Nonopioid therapies should be addressed. This guideline suggests "seeing a patient at 1 - 4 weeks after starting opioid therapy for chronic pain, and following up at least every 3 months or more often"... Absolutely. It then advises "if the benefits do not outweigh the 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." The problem with this is the implication that if the benefits do outweigh the risks then there is no need to optimize other therapies.

This is precisely what's wrong with this entire document—it doesn't clearly make the point that "other therapies" such as nonopioid medications for

neuropathic pain, PT, osteopathic manipulation, injections, behavioral health treatment, etc.—are not just for those who've failed opioids, but rather should be considered for everyone as a part of an integrated approach right from the start.

Risk Assessment Recommendations

A necessary aspect of prescribing opioids concerns risk assessment, but the next 5 recommendations tackle the topic without giving practical advice or emphasizing what's important.

#8. Definition of risk is confused. "Strategies to mitigate risk should include considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages than ≥50 MME/day, or concurrent benzodiazepine use, are present." What's wrong with this? They have lumped together situations that do not present any significant risk with those that should mandate not prescribing opioids by anyone other than an addiction specialist/pain specialist.

Let's start with the recommendation of a naloxone pen for someone who's on ≥ 50 MME/day. The patient package inserts for several opioids state that doses of ≥ 60 mg of morphine per day are likely to result in withdrawal symptoms when suddenly stopped. In other words, a dose of ≤ 60 mg/day of MME is unlikely to cause significant withdrawal symptoms, much less death.

There is no reason for a patient on such a low dose to need to have naloxone on hand. On the other hand, a patient who has a known history of opioid overdose or opioid addiction should not be prescribed opioids for chronic pain unless the patient has been assessed by an addiction specialist, is involved in addiction recovery if they have been addicted, etc. In complicated scenarios such as this, a primary care prescriber should not undertake the task on his own.

#9. Lacks interpretation. The guideline states, "Clinicians should review patient's history of controlled substance prescriptions using the state's 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." However, looking for dangerous combinations is not the main reason for checking the PDMP: The main reasons are

to see if the patient has been getting opioids from more than one source; whether or not and when he/ she has been filling the prescriptions; and—if this is the person's first visit with you—when, at what dose, and from whom he/she received the last controlled substance prescription.

Lets say, for example, that on the first visit the patient tells you he's been getting 60 mg/day of oxycodone from the previous doctor. You don't want to send him home with a prescription for the same dose of the same drug before confirming that he recently filled a prescription for that drug, and before you've done a urine drug screen to confirm that he indeed has been taking it. Otherwise, you risk giving him an unsafe dose.

#10. Patients should never expect to be tested urine drug testing (UDT) should be done randomly. "Use UDT before starting opioid therapy and consider testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs." Yes, but this recommendation is not specific enough to be useful for the following reasons:

- Too many prescribers make UDT a routine part of every visit. This takes away a key element of what makes these tests useful—the element of surprise. If a drug-abusing patient expects the test, he has time to prepare. He can avoid snorting cocaine or ingesting an illicitly obtained opioid in advance of the visit, or he can take the opioid that he's been diverting so that it appears in the urine. It is more effective, and a lot less expensive, to require a urine specimen a few times a year at random as well as if you are suspicious for some reason.
- It is also important for the patient to provide the time and date when he last took each of the drugs that you prescribed and are testing for, and for you to document this. Most IR opioids have a short half-life, approximately 4 hours, and will not appear in the urine if more than 24 hours or so have elapsed since the dose was taken.
- If the drug does not appear in the urine, you need to know in advance if the reason could have been legitimate (that it was taken too many hours ago rather than that it was diverted). This is an especially important consideration with drugs prescribed as needed rather than on a schedule; the patients are supposed to take the medication

only for breakthrough pain and may not have needed it.

Today many prescribers believe they are supposed to order UDT, but don't realize that that is only the first step. They are also supposed to review the results and take action if the findings are unexpected. The problem is that many opioids are metabolized to other opioids that also appear in the urine. If your patient has been prescribed oxycodone (Percocet), what does it mean when you also find oxymorphone (eg, Opana) in the urine? If you don't know, it's your responsibility to find out. If the UDT report doesn't clarify this, call the lab's toxicologist to find out. (Yes, oxymorphone is an expected metabolite of oxycodone). And if the urine contained an unexpected drug, it is also the responsibility of the prescriber to take action-discuss with the patient, decide whether to continue prescribing, etc.

#11 Ideal versus reality. Pain specialists agree that it's best to avoid concurrent opioid and benzodiazepine use. But because benzos are effective for treating anxiety, muscle spasm, and insomnia, which are common in patients with chronic pain, the combination is often used. The important caveat to keep in mind for providers is that we are trying to avoid the "unholy trinity": the combination of a short-acting opiate, muscle relaxant, and benzodiazepine-as this combination worsens outcomes.5

However, a benzodiazepine may be needed in some patients for appropriate treatment. An example might be a patient treated for PTSD who has long-standing back pain with improved function on long-acting opiates. Clonazepam TID is an acceptable adjunct therapy for PTSD in this patient along with an SSRI, and could be used concurrently with the long-acting opiate. What you want to avoid is patients using a short-acting opiate and benzodiazepine, such as alprazolam, to treat anxiety instead of pain. In this situation, the combination can be exceptionally dangerous.5

#12. Patients with substance use disorder need special treatment. "Clinicians should offer or arrange treatment [usually medication-assisted treatment with buprenorphine/naloxone or methadone in combination with behavioral therapies] for patients with opioid use disorder." Diagnosis and treatment of drug addiction (called "opioid use disorder" in the language of the Diagnostic and Statistical

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Manual of Mental Disorder, 5th Edition) is a specialty onto itself. Again, this is not something that should be undertaken by the PCP. To prescribe methadone or buprenorphine/naloxone (Suboxone) for addiction treatment requires a special permit (an "X waiver") from the Drug Enforcement Agency.

Regarding the approach to patients with an addiction disorder, I would have substituted a sentence that appears later (on page 28 of the complete CDC Guidelines): "Because pain management in patients with substance use disorder can be complex, clinicians should consider consulting substance use disorder specialists and pain specialists regarding pain management for persons with active or recent past history of substance abuse."

Summary

Few clinicians will take the time to read the entire 52-page report, with its 222 references, lengthy tables, and erudite discussion of the quality of various studies. Most of them will at most read the one-page listing of the 12 recommendations, or even more likely, the digested versions that have appeared recently in most newspapers and online. Thus, they will see only the wording that I have dissected in this commentary.

Of the 12 recommendations for prescribing opioids, the majority deal with risks, harms, and limiting maximum doses, and those that actually address prescribing tend not to be specific enough and to ignore important aspects of treating the patient and making decisions. The recommendations could have been a great deal more useful.

We Got Where We Were Going—Someone Please Right the Ship!

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"I saw over 36,000 patients in my interdisciplinary pain center over 25 years—and never had a death, overdose, or concurrent use with a benzodiazepine...Now, physicians aren't supposed to trust their patients, because it's the physicians fault that they prescribed opioids, and the patients fault that they 'did bad things with them,' purposely or not."

For some perspective, I'd like to reflect on where we've been and how we got here. We all are aware that chronic pain is a bio-psycho-social problem, and while I'm speaking to the choir, it's important to



remember that many of the hymns were written by reputable physicians about the positive, evidence-based medicine (including Cochrane Reviews) that focused on interdisciplinary pain centers (Level A).⁷⁻²⁴

Then, the insurance

companies said: "No More" and stopped (or cut) reimbursement for physical therapy (PT), psychological services, occupational therapy (OT), and other modalities that benefited patients by increasing their functionality, much more than did pharmacotherapy.

Where did that leave us pain specialists? With little to offer but medication and/or invasive interventions.

Most of us who understand pain mechanisms and neurochemistry would initiate selected anticonvulsant medications, or when we realized selective serotonin reuptake inhibitors (SSRIs) weren't helping the physical pathology of pain, we tried the norepinephrine-selective reuptake inhibitors (NSRIs). In some patients, if their pain was reduced by 20% to 40%,

an opioid might have been prescribed. Some clinicians of course, just used opioids.

The bottom line: good pain medicine was being practiced but when we were forced to stop using the interdisciplinary approaches that had been so successful, we were left with medication management. The insurers, in their magnificent conceit, determined that PT, psychotherapy, and OT would not be reimbursed in an interdisciplinary pain center. (Recall that the International Association for the Study of Pain had 4 levels of pain centers-I am referring to the third and fourth levels.)25 This made it almost impossible to provide appropriate therapy for a patient treated in an interdisciplinary Pain/Headache Neurorehabilitation Clinic to then find similar care from several different providers at different locations.

How Insurance Companies Changed The Rules and the CDC Let Them

You may remember "back in the day" when insurers allowed 4 to 6 PT visits but most patients needed 8 to 12 sessions for it to be most helpful. Getting approval for additional PT typically took weeks, so by the time more visits were permitted, restarting PT was often too late to be helpful.

So what were we "docs" left with? Medications! Of course, we could continue with PT, OT, and psychosocial interventions in our clinics, but only if we didn't expect to get reimbursed for it.

Unfortunately, the CDC never informed the insurance industry that evidence-based medicine demonstrated that interdisciplinary pain centers saved money and helped patients. Nope! They said nothing about this then, or in the CDC Guidelines now.

Physicians, including some pain specialists, have used opioids judiciously, attempting to provide some additional benefits to their patients. The vast majority of patients took their medications as prescribed. But human nature remained human nature and some misuse took place. Some patients shared opioids or became so depressed by the persistent pain that they took additional medication. Either way, the one tool physicians thought they had control of-prescribing opioids—they are now being "guideline-pressured" not to use.

What's Wrong with This Picture?

The CDC Opioid Guidelines do encourage non-opioid therapies for chronic pain outside of active cancer, palliative care, and end-of-life care. But they fail to indicate what documentation is required for a trial of therapies. Let's not even go into the enormous amounts of money called "escalating deductibles" that may need to be spent to obtain such care—office visits and even medication—so that a patient can feel less pain and become more productive.

Physicians don't have a problem with initiating the lowest possible effective opioid dose for a patient followed by titration. That's common sense. But, it does not appear that the CDC understood that the absence of long-term written "opioid efficacy" was worth the possible risks (opioid-related misuse, abuse, addiction, overdose, and death) that would allow for their use in many chronic non-cancer pain patients. Oh yes, and what about the thousands of patients on chronic pain medications at higher dosages for years???

There are a number of pain specialists who have successfully used opioids to treat their patients without incident. I saw more than 36,000 patients in my interdisciplinary pain center over 25 years—and never had a death, overdose, or concurrent use with a benzodiazepine. When I started in 1981, I required my patients to fill out paperwork (this was before it was "necessary"). The simple terms of my "contract" were: "Play straight with me and I'll do everything I can to help you."

Now, physicians aren't supposed to trust their patients because it's the physician's fault that they prescribed opioids, and the patient's fault that they "did bad things with them," purposely or not.

This situation makes me angry for a few reasons:

- The "Guidelines" provide an excuse for some physicians not to treat pain at all because their personal risk is too high.
- · Some physicians will think it's perfectly fine to prescribe some opioid in lower dosages (under 50 mg morphine equivalents), as suggested in the "Guidelines." After all, how could that be bad? Let me count the ways....
- · What about all the patients on higher doses of opioids—for years???
- Physicians may become intimidated by the "Guidelines" and attempt to provide pain relief using only nonopioids and analgesics, and then direct patients to a "pain specialist" who may be scarce or unavailable.

For these reasons, I fear many patients will not receive adequate and needed pain relief.

New Reason to Just Say "No"

Debra Houry, MD, MPH, Director of the CDCs National Center for Injury Prevention and Control said, "Doctors want to help patients in pain, and are worried about opioid misuse and addiction. [These Guidelines] will help equip them with the knowledge and guidance needed to talk with their patients about how to manage pain in the safest, most effective manner."

As noted above, I believe the CDC response offers a "Big Chill" to physicians looking for a reason to stop seeing pain patients—a new, federal "guidance" reason. I won't even comment on those who were responsible for the guidelines, and what their political alliances were.

And for those of us who know other mechanisms to assist patients, exactly who is going to provide reimbursement for those services when the deductible is already excessive and growing, and the patient doesn't have the finances to afford an interdisciplinary attempt at care? What's left? Medications! Antidepressants and anticonvulsants for example, which may have iatrogenic effects even with clinical monitoring, and to which the patients often respond initially, "I'm not depressed, I won't take an antidepressant" or "I don't have seizures." We've all tried to explain that these medications can also help diminish pain. But resistance—even when education is provided—may lead to non-compliance.

Patients know the words narcotic/opioids. And a small group of pain patients are so fearful of "getting addicted" that they object to using an opioid even once. There seems to be a total lack of recall about the long and successful record of treating both chronic non-cancer and cancer patients who took their pain medications with reasonable outcomes and without "a problem."

It appears foolish to look only at the lack of Evidence-Based Medicine studies of long-term opioid use, when the vast majority of pain specialists have had no problem working with them and giving patients what they needed to return to being healthy, functioning individuals.

Examine the Literature

Today, more women are surviving breast cancer. But the chemotherapy required to halt the cancer often induces a painful peripheral neuropathy. Although the cancer is gone, they are left with pain. There are over 180,000 women in the UK and even more in the US who have great difficulty obtaining pain medications for their peripheral neuropathy because their lives are no longer at risk from cancer. Their oncologist is finished and has provided a fine outcome. They are alive but in pain. Will their PCPs be comfortable prescribing "pain meds" for that?

I am saddened to see more excuses for physicians to "just say no" to opioids. Some patients may need opioids in larger doses than the "Guidelines" say since the "Guidelines" can't prevent the development of receptor site tolerance (which does NOT mean addiction to those who chatter on about it). Nor do the Guidelines accommodate a patient taking opioids for years and who may—perioperatively and post-operatively (as outpatients)—need more opioid medication than the "Guidelines" may, uh, suggest. Also, consider the patient with a premorbid pain history using polymodal/multimodal opioid pain treatment and who presents for a related or unrelated surgical procedure requiring analgesics.

I left the full-time practice of pain medicine to provide insight, knowledge, and a modicum of wisdom to pharma over a decade ago, although I still practice and consult. Lots of docs, even a neurologist/pain specialist like me, even those I considered friends, were livid with me, saying I had "gone to the dark side."

The CDC Guidelines were published on line two days before I wrote this. Care to guess how many of the physicians who chided me have contacted me in the last 48 hours for advice about joining pharma?? At last count, the number was in the double digits.

Ultimately, it is the patients who are victimized and may rightly be horrified. Upon further reflection, the "Guidelines" may undergo some modification. In the meantime, prescribers of opioids may be interested in a complete opioid reference/review articles and information on opioids and other nonopioid analgesic medications. ^{6,26}

We've been here before—in the name of "medical" and possibly "political" correctness—trying to fix the real problem of opioid over-dosage and death by causing more problems.

My Opinion: Information Somewhat **Biased and Incomplete**

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"I believe that all of us in the field of 'Pain Management' will agree that opioids are over-prescribed in many instances. However, there can be no denial of the efficacy in the use of opioid analgesics, when used properly, and monitored, even for chronic non-cancer pain."



While there must be some consensus with the statements in the CDC Guidelines, I believe that the information was somewhat biased and incomplete. All of us in the field of "Pain Management" agree that opioids are

over-prescribed in many instances. However, there can be no denial of the efficacy in the use of opioid analgesics, when used properly, and monitored, even for chronic non-cancer pain.

I can also agree with some of the points in the JAMA Editorial made by Yngvild Olsen, MD, MPH, suggesting that "... Education about substance use disorders and chronic pain management should start in medical school (and dental school, etc.) and continue through residency training in all patient-care specialties..."27

However, I believe that the CDC recommendations failed to include the integrative and complementary methods available for the treatment of most chronic pain conditions, including, but not limited to:

- Osteopathic Manipulative Treatment (OMT)
- Physical therapy and therapy modalities
- Acupuncture
- TENS, ultrasound, electro-Galvanic stimulation,
- · Transcranial electrical stimulation
- · Progressive relaxation and biofeedback training (including meditation and yoga)
- Behavioral modification and psychosocial interventions

In many cases, these therapies will result in similar outcomes to the use of opioid medication, with greater patient acceptance and lower costs.²⁸⁻³⁰

I hope that as we move forward, we will understand the benefits of the judicious use of prescription opioids for "acute" pain, using the best dosage for the needed time period; but also look to other methods either alone or in conjunction with low dose opioids for chronic, non-cancer pain (outside of palliative care or end-of-life treatments).























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"The prescription overdose epidemic is doctor-driven. It can be reversed in part by doctors' actions."

—Tom Frieden, MD, MPH, CDC Director



Due to the recent CDC Guidelines on opioid pain management, the pain management community has begun adapting to these non-binding guidelines.

For those of us who have always looked to other sources of pro-

viding pain-relief (eg, complementary alternative medicine, physical therapy, non-opioid management, exercise, etc.), the CDC Guidelines are welcome news and seem to encourage the pursuit of nonopioid treatment options. Here, a look at the CDC's position and reaction from notable medical groups.

The summary of the CDC comments included the agency's Director Tom Frieden, MD, MPH, who said in a recent news teleconference: "The science of opioids for chronic pain is clear. For the vast majority of patients, the known, serious and all too often fatal risks far outweigh the unproven and transient benefits, and there are safer alternatives."

Accordingly, the first of the agency's 12 recommendations states that opioids should not be the first-line therapy for chronic pain, and that clinicians should consider nonopioid pain relievers or non-pharmacological options like exercise and cognitive behavioral therapy before opioids.

Other recommendations include:

- Conducting a urine test before opioid therapy
- Starting at the lowest dose possible and avoiding doses of 90 morphine milligram equivalents (MME) or more
- Prescribing immediate-release as opposed to longer-acting opioids
- Limiting treatment for acute pain to usually no

more than 7 days

These non-binding guidelines do not apply to patients who are receiving palliative care or end-of-life care, or treatment for active cancer. The CDC tailored the recommendations for primary care clinicians (PCP), who account for roughly half of opioid prescriptions.

In Dr. Frieden's view, clinicians play a key part in reducing the rate of addiction and death associated with these drugs. "The prescription overdose epidemic is doctor-driven. It can be reversed in part by doctors' actions."

Research Not Robust

In spite of strong objections to the initial document from several major medical societies, the final recommendations were not substantially changed. The CDC pointed to a dearth of strong evidence supporting individual recommendations, such as the adequacy of nonopioid and nonpharmacological therapies to counter chronic pain.

On that point, the American Medical Association (AMA) and the American Pain Society noted that the widespread lack of reimbursement for non-pharmacological therapies deters clinicians from ordering them.

Dr. Frieden said that the agency based its guidance on the best available research on chronic pain, which he admitted, is "not as robust as we'd like." As more evidence emerges, the CDC will refine its recommendations, but in the meantime, he said, "we must act now."

With regards to little or no insurance coverage for nonpharmacological treatments, the director said the issue was discussed with physicians and patient groups. "I'm encouraged by the progress we've seen in a variety of insurance programs." he added.

Dr. Frieden's colleague, Debra Houry, MD, MPH,

Director of the CDC's National Center for Injury Prevention and Control, said that the new guidelines "can inform a lot of future changes."

Some medical societies took issue for initially setting numerical thresholds. For example, avoiding dosages of 90 MME per day, or suggesting that most non-traumatic pain unrelated to major surgery usually doesn't warrant more than 3 days of treatment.

In a January letter to the CDC, the American Academy of Pain Medicine, said that the dosage recommendation should not refer to any "arbitrary dose" and asked that the standard duration be extended to 2 weeks.

In the final guidelines, tweaks were added but the numbers largely remained unchanged. Clinicians are now advised to "carefully justify a decision" when prescribing a large dose. Some wording was added concerning duration and currently reads: "Three days or less will often be sufficient, more than 7 days will rarely be needed."

Dr. Houry said there was a lack of consensus in this area—some clinicians urged the CDC to leave out the numbers; others wanted them, and even advocated for lower dosages and durations. But as she pointed out, "these are guidelines, not regulations".

Response from Medical Groups Mixed

Initial response to the final CDC recommendations was mixed. The American College of Physicians came out in support of them with Thomas Tape, MD, Chairelect of its Board of Regents, describing the guidelines "an important document."

In contrast, the AMA was "largely supportive." Patrice Harris, MD, Chair-elect of the AMA's Board of Directors, cited qualms with the "evidence base for some recommendations"; insurance coverage limitations for nonpharmacological treatment; "and the potential effects of strict dosage and duration limits on patient care," among other things.

"If these guidelines help reduce the number of deaths resulting from opioids, they will prove to be valuable," she said in a news release. "If they produce unintended consequences, we need to mitigate them. They are not the final word."

Gregory Terman, MD, PhD, the President of the American Pain Society, told Medscape Medical News that the CDC improved the final recommendations by giving physicians more flexibility to operate around "specific numbers." (Dr. Terman was one of 10 experts convened by the agency in January to review the initial guidelines.)

"Primary care doctors wanted and needed some advice on this problem area," said Dr. Terman, who is also a professor and Director of Pain Medicine Research at the University of Washington in Seattle. "The CDC has done a good job in trying to make a good faith effort to produce guidelines that help (physicians) avoid overprescribing, but not restrict (patients) who really benefit from opioids on an individual basis."

We'd like to hear from you, too. Contact Nikki Kean, editor at: nikki.kean@verticalhealth.com

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