

Comments on Updated CDC Guideline for Prescribing Opioids

Introduction

My name is Mike McAulay. I'm 48 years old, a professional programmer, a father of an 8-year-old, and a husband these last 22 years.

I am a chronic pain patient with significant nerve damage going down both my legs. While I have experienced a degree of pain from it most of my life, things got bad about 15 years ago. So a little over twelve years ago, I began taking opioids as a part of my pain treatment. Funnily enough, the treatment was initiated in Denmark.

Approximately four years ago, I was force tapered and had a third of my pain medications removed. What followed was three and a half years of hell. The pain has been torturous. I lost nearly everything, and it would have been a complete loss but for the grace of God and the kindness of my immediate managers at work. This circumstance can be drawn directly back to the issuance of the CDC's Opioid Prescribing Guidelines from 2016. My life had been transformed into a nightmare. I had striven to live on the absolute minimum dosage I could and still work a job. So, when a third of my regimen was removed, I found myself unable to go to the office at all. Working from home, only part of the day. In the afternoon, I would go from my desk in my room to my bed and collapse. I'd wake about 9 PM to take some medications and go back to sleep. Then do the same the next day. Even at that level, I had to sleep all weekend to recover. The entire time I lived in torturous pain. I had nothing I could do for my wife or my son. I lost out on his life between 5-8 years old.

Towards the end of last year, my previous doctor was beginning to force another round of tapering. It severed the last thin thread to my ability to function. Virtually no doctors were taking new pain patients in my area, and certainly not ones who were looking to continue taking opioids. I can not express the agony I endured as I prayed and looked for some doctor to step in. Finally, I found one, and it has been miraculous. But, unfortunately, those three and half years left me in a horrible hole, with a body almost devoid of strength and more damaged due to my inability to manage tricky surfaces like the shower floor.

No matter how great the public concern may be about the *risk* of opioid addiction, no reasonable person would dare suggest this was an acceptable price for a person to bear. Yet here we are. Chronic pain can not be put in context if you are not living with it. There are millions of chronic pain patients, many suffering as badly as me or worse.

Whether you've been sheltered by disbelief, lack of contact, or some other reason, this is the reality created by the guidelines. Pain matters. Chronic pain patient's suffering isn't temporary. Anyone who has not lived with constant horrific pain should be asking us how they can get back on course. That's a question of expertise through experience, not a self-absorbed perspective. I am now advocating for chronic pain patients. While I'm grateful for what my new doctor has done, we are still trying to dial in

my meds so I can function properly. I also have a very weak and broken body to deal with due to the tapering. The CDC must own the fact their actions directly destroyed lives, much of which cannot be regained. The new recommendations still carry some of those most pernicious attitudes that created this crisis. You have the chance to end it now. You need to step up and do the right thing. Make it so that no pain patient ever needs fear for losing the medications that have made life bearable.

General Comments:

The need for reliable science and research

One of the more critical comments I have relates to the state of the science of pain and how it impacts patients' lives in extreme ways. We simply don't understand enough to make the kind of recommendation outlined in the updated guidelines. The consequences & scale are too great to leave to weak findings. The cost to patients has been repeatedly underplayed by the media, the government, and researchers.

Pain is a completely subjective experience. Attempting to boil it down to numbers and inferences has already led to major misunderstandings and suffering. Many things are regarded as "facts" by the general public and even doctors that simply are not true. A great deal of the common understanding completely contravenes what patients are saying. If your findings are at complete odds with what patients are consistently telling you, it's time to go back to the drawing board. To enshrine the assumption that the patients will not be truthful in the foundations of these studies is beyond the pale. Opioids are not a magic potion that renders every person a liar. Yet, I have heard doctors repeatedly espouse things that sound more like superstition and wishful thinking regarding opioids.

Pain is incredibly complex, but it is most often rooted in a physical condition, and so the many methods taken from psychological studies are inappropriate. Furthermore, pain is not about addiction or psychology. I understand that the issue being addressed is addiction, but it appears that much of the effort has been focused on repainting pain as a primarily psychological condition. This perspective has led to patients being completely ignored or having things they've said misinterpreted to fit the researchers' goals.

While the CDC does not have control over what research is done and how it's performed, it's absolutely critical that any studies included in policy decisions have a much stronger foundation than what has gone before. In addition, these guidelines must live up to the heavy responsibility it takes up when making assertions about the nature of pain and how it is to be treated or not treated with prescription opioids.

The balancing act of public health and an individual treatment

In order to speak to such a critical and impactful question, one must be exhaustive in understanding the realities of both sides of the equation.

This has been an utter disaster.

Not only has the cost to pain patients been extremely underrepresented and understood, but the risks, as portrayed, of prescription opioid addiction have been well overplayed. You may wonder at that last, but it is not hard to look at the actual numbers and see that there is a significant misalignment in the public message and the reality. Even the director of NIDA (Dr. Nora D. Volkow) states, "Addiction occurs

in only a small percentage of persons who are exposed to opioids — even among those with pre-existing vulnerabilities"

[<https://www.nejm.org/doi/full/10.1056/NEJMra1507771?fbclid=IwAR29gpWLB5gBEC87gsC8dW0b8Lc4IC9tb-GguXBPLHyQn-YDs2kRNi4xds4>]. We can also refer to the CDC's own data to see that the majority of the problem lies in illicit drugs like illegal fentanyl and its analogs. Yet, we are bombarded with the sentiment that every pain patient must be hanging on by a thread against the overpowering draw of addiction. This idea is so far from the truth I'd laugh if the consequences were not so severe. It is not that I believe it does not occur, but that for long-haul pain patients, the idea that we are constantly at war with ourselves over addiction doesn't fit the facts. We don't want to escape. We want to engage in the world and live. Addiction can happen, but as noted by Dr. Volkow, the numbers are small.

Flipping to the other side, I've read documents on opioid prescription practices that state that it is not helpful and should not be used to reduce the "discomfort" of pain patients. As someone who has lived with horrific chronic pain for about 15 years, this is one of the most insulting, demeaning things I've ever seen. I was forcefully tapered, and it led to three and a half years of torture level pain. That's not an exaggeration or "catastrophizing." So please don't tune out. This is the very real experience of countless Americans, and yet we've largely been ignored. Allowing personal fears of addiction to outweigh the actual numbers we can see was a great evil when measure by the consequences.

There are also numerous reasons to be suspect of what OD numbers have been reported as associated with "prescription opioids" when the CDC's records make clear, some drugs like illicit fentanyl and methadone were swept up in the definition of "prescription opioids for pain." When considering things like people holding an active prescription for what was found in their system, the numbers plummet to something like 300 a year! I do not say this to indicate the other lives do not matter. It is that the actions taken to solve this issue must be applied where the actual problem resides. It's like you've tried to stop pollution by damming up the river versus dealing with the people dumping illegal poisons into the veins of America. You've sampled the water and decided it was better to cut off everybody than allow the poison to flow downstream. The problem is, of course, is the poison comes whether the river is dammed or not. It is also disingenuous to suggest that we have not steadily marched towards a total ban on opioids. As each year has passed, no matter the reassurances we received, the noose has tightened, and the supply continually reduced.

An entire report could be dedicated to this subject, but I'll leave it at this.

Dosages

Including **any** numbers regarding dosages will be counterproductive. If you talk to the doctors on the front lines, you will find that some patients were on dosages over a 1000 mme and yet showed no more severe side effects than those on lower dosages. This fact alone should shut down the idea that any single dosage can be set as a standard for all patients. A patient-centric treatment necessarily means taking that person's tolerances etc., into consideration. Given how we've seen the last numbers used in the Guidelines, it should be clear that the risk of misuse by anyone involved is much too high. The elephant in the room is that these numbers were used by policymakers at various government levels, hospitals, and the health insurance industry to deny the much-needed care that should have remained available.

The CDC's responsibility for what has gone before and in the future

I believe it will take several years to truly understand the damage done by the wave of activities set in motion by the release of the 2016 Opioid Prescribing Guidelines. When the CDC assumed an authoritative voice on the matter, they helped unleash a nightmare for pain patients like me. Even now, any sort of pain is treated as suspect (chronic pain has come to mean "drug seeker" in far too many places). Then when they do decide to treat us, it's with medications that are simply not up to the task of providing adequate pain relief. One should not have to fear going to the hospital because you know they will provide virtually useless pain relief. Yet, I know personally, I will not enter a hospital willingly as even lying in a hospital bed increases my pain dramatically. How can I believe I'll ever get the treatment that would be necessary for me to stay in a hospital? The idea that temporary pain is ok for the good of the patient has been stretched to ludicrous proportions to suggest (permanent) pain for patients is an acceptable trade-off to tackle a largely unrelated public health issue. The numbers are now clear, pain patients are not perpetuating this. Even the AMA has stated that we are no longer in a crisis fueled by prescription opioids and never were in one where it was the only contributor.

I believe the CDC must take this opportunity to help set the record straight on the importance of treating pain. There is enough research to show it aids healing, among other things. It is also important to recognize that the state of pain treatment is still in its infancy. Many of the "alternatives" recommended simply do not help or fall so short of effective pain relief as to be useless. Chronic pain patients live a life of exhaustion. Living with constant pain wears you down in ways that are hard to imagine for most people.

Accepting that we, as pain patients, have an extremely limited energy budget which means we likely won't be jumping at every new thing someone claims that works. You may think we should be willing to try anything and be grateful, but that attitude completely ignores the reality we have to live with. Yes, we are open to new things, but something has worked well for us, has not caused us to become addicted (speaking of the many current chronic pain patients), and requires minimal from our energy budget. This has to stop being about a moral crusade with ideas like "lazy patients." We fight every day as few people understand. And it's not the pain (this is a common misconception.) we fight. We fight to retain the focus and strength it takes to take the next step, then the next, etc. The stigma and judgment need to end. Our pain matters. And it's destroying us at present because we are not getting the care we desperately need.

Misreading pain patients fears as addiction

One of the biggest barriers to treatment at present is the fact that patients' legitimate fears for the consequences of tapering for their future are being read as a sign of addiction. Based on the idea, we are "catastrophizing" whether to get the meds we "want" or are simply in a panic over losing a vice.

The truth for pain patients is quite simple. We know from our own experience and others that the loss or reduction of pain medication usually has a devastating effect on one's life. Not just in terms of pain experienced but also the ability to have a career, be a functioning member of a family, and even society beyond that. Forgot for a moment this has anything to do with opioids and put yourself in our shoes. Imagine that you are currently forced to see a doctor once a month. That each time you go may result in a complete or partial debilitation and the end of your life as you know it. Virtually every pain patient at present faces this PTSD-inducing experience every month. These medications are a lifeline for us. These guidelines need to lead in the opposite direction now, based on what we've observed these last five

years. Careers, families, and even lives have been lost due to the intransigence of medical professionals who have been primed to see addiction wherever pain is involved. Just read the testimonies coming in. You can see many examples on Twitter by looking at the #SavingUsToDeath hashtag. Unfortunately, the updated set of recommendations does not seem to be aware at all of the devastation wrought by the set released in 2016. If you want to serve the public good, then at least try to restore patients who have been cast out of practices or put on such reduced treatments as to prevent them from having a life. The fact that this reality doesn't even seem to be acknowledged in the new set of recommendations is incredibly troubling. As addressed elsewhere, the studies that led to the conclusions that produced the 2016 guidelines were fundamentally flawed. Often suffered from one form of bias or another, but most of all seemed content to ignore what patients were saying completely. The studies and statistics on illegal opioids have been conflated with medications that have served a critical purpose throughout human history. There are plenty of situations where doctors know best. This isn't one of them, given the completely subjective nature of the ailment.

Understanding that pain is different

There seems to be a persistent lack of understanding by most people about pain. Doctors are used to blood tests, biopsies, CT scans, and x-rays to tell them the "truth" of a medical situation, and that is reasonable.

However, pain is completely subjective. There is currently no reliable method for measuring pain or even if it's present. When it comes to the phenomena of chronic pain, the medical field is currently out of its depth. So much of what I've read and heard from doctors and researchers regarding chronic pain simply doesn't hold with the experiences of chronic pain patients. We are the only witnesses. There is no reliable forensic evidence to rely upon.

The CDC needs to take chronic pain patients into account, spend months with chronic pain patients, listening to their experiences. Pain is unlike any other study. I think that's partially why it's been shoe-horned into a sort of psychological malady because the doctors can't measure it physically. The problem with that, of course, is it puts you into the mind that it is actually a psychological disease versus a predominately physical one. Consider the long-term psychological damage of having every doctor you see tell you it's all in your head, when in fact, it's not. But here's an important point in that. If the person is experiencing it, it is real. These policies are so aggressive it seems like better 1000 legitimate patients suffer in agony than one person becomes addicted. If you honestly believe this, please remove yourself from the care of patients or the teaching of new practitioners.

It would have also benefited the CDC actually to go to where these patients live. See what the lack of proper treatment has produced. To see what we mean by, "I had enough energy to make breakfast this morning, and that was a triumph."

Pain Matters

Very simply stated, pain matters. Currently, pain seems to be treated as virtually immaterial. No matter what is said to assuage fears, what is delivered falls well short of providing humane care to others. There are exceptions, of course, but they are just that, exceptions. In these last five years, I have been shocked to discover how callous the medical field has become to the suffering of individuals. The overplayed fears of addiction have caused a kind of hysteria that virtually any pain is worth enduring to avoid any *risk* of addiction. The kicker, of course, is the people making those decisions are not the ones

who will have to endure that pain. I would consider it a violation of human rights to allow individuals to experience pain that they consider unbearable knowingly. Given the poor track record of making compassionate decisions on behalf of patients, especially in these last five years, we need the standard of care to be made explicit and guarantee a level of care that does not leave patients in agony. We are adults. We can choose to make the trade-offs in terms of risk and benefits. The reality is, we are talking about the risk of addiction versus the certainty of pain. Given that, we need to lean towards dealing with the pain rather than succumb to the fear, particularly if it's fear on behalf of someone else.

Recommendation Comments

Recommendation #1

I have two key points about this recommendation. First, it perpetuates the idea that patients are incapable of evaluating their own pain and its severity. Most people will know if Tylenol will cut it or not. What's currently happening in surgery wards and ER's shows this viewpoint ends with patients suffering unnecessarily. This recommendation needs to hinge more on the patient's judgment because it's their pain and subjective experience. Secondly, the risk and benefits are very poorly understood by clinicians. The reason being one side of the equation is the experience of the person under care. And once again, the evidence regarding addiction in patients is far from well understood. Until a more reasonable grasp is held by the medical community, it is appropriate to bend to the patient's current experience. One can still carefully manage its administration. We need and deserve proper care. Leaving a patient in agony is 100% unacceptable. We will no longer accept the mantle of "collateral damage."

Put simply, we must stop acting like the doctor can best determine the patient's subjective experience. This attitude has resulted in unbelievable suffering.

Recommendation #2

Once again, this belies a fundamental distrust of a patient's judgment. While that may seem appropriate to many, the result of this perspective has been disastrous. Moreover, baking these presumptions into the guidelines themselves guarantees a form of care that is adversarial and detrimental to the patient.

If non-opioid treatments are not providing enough relief to render the patient capable of having a modest life, then the doctor needs to listen carefully to the patient and find solutions that provide real help. Something else that is not well understood is pain scales for chronic pain patients are vastly different than those for typical patients. Pain scales, in general, are far from helpful as it gives a false sense of security to practitioners about patient's state over time. To a chronic pain patient, we know it will be compared to previous numbers, so we do attempt to identify whether the pain is worse or better. The problem is we've literally had thousands of minute changes in our pain since the last we saw the doctor. I myself have found it incredibly difficult to provide a number that would represent the truth. But looking beyond that, what if we say "4." The cost of living with a "4" can be utterly devastating

when you haven't felt better than that for five years. Doctors need to stop viewing chronic pain through the same lens they evaluate acute pain. They are very different animals.

The only recommendation I think is appropriate for treating chronic pain patients is to make it completely patient-centric. The cost of not treating chronic pain can not be measured against the public's concerns over opioid addiction. The gap is simply too large.

Recommendation #3

Leave chronic pain out of this recommendation.

Recommendation #4

Doctors' attempts at assessing pain have proven particularly bad. I've been surprised at how few seem to acknowledge pain treatment as a human right. I've also noticed a tendency to try to play it down to the patient constantly. This is incredibly disrespectful and can leave patients with PTSD. Too many doctors erroneously believe that there are no long-term effects from pain. This is an outdated view that is not supported by science. I've sadly known too many doctors who consider patients' pain as of little importance. These are not the people who should have the final say in the relief of pain. Too much power has been left in the hands of people whose empathy has been worn down by their practice.

Recommendation #5

Scrap it. Seriously. No more tinkering with high dosage patients.

Recommendation #6

One needs to tread incredibly carefully here. I've never had surgical pain last less than a week. I've never known anyone who didn't need more than three days for any surgery, let alone particularly painful ones. Allowing those people's bodies and minds to truly rest is an important part of recovery. The recent trend in post-operative pain relief seems to completely ignore the long-term psychological effect on people's fear of medical procedures and hospital visits in general. It is a terrible feeling to be in major pain post-op while trying to rest, but the pain won't allow it. The important thing here is personal care. Trying to find these, more or less, hard and fast rules (please face they will be used as such) is counterproductive and once again leads to an adversarial relationship with the patient. The hard part is, doctors need to have the time to commit to actually helping manage a patient's pain instead of either denying it or writing such an excessive prescription that can cause problems. Setting a 3-day limit will not prevent any doctors who still routinely prescribe 60 days post-op. I would be shocked if even one of those still exists. There seems to be a massive disconnect between what is assumed to be the current landscape and what patients are actually encountering. Maybe it's regional, but then that should be addressed at that level.

Recommendation #7

Remove chronic pain from your recommendation. The fact that subacute and chronic pain are lumped together does not bode well. It shows a lack of understanding of the costs to chronic pain patients. So many of these recommendations rest on the assumption that clinicians possess a strong enough grasp of the actual risks versus the actual costs to discern what's fair to the patient. Without it, this simply becomes the backdoor to offload patients seen as a liability. I've seen so many people abandoned now. It's hard to believe it's not regularly in the news. One does not need to invoke conspiracy theories to see that there is a particular narrative regarding addiction and prescription opioids. Most seem unwilling to

challenge that for fear of seeming "pro-drugs." The patient needs to be in the driver's seat until both sides of this equation are better understood by practicing doctors. I've been horrified recently at hearing recent graduates preaching an anti-opioid gospel. There is a hard truth to swallow that doctors are not the trustworthy party when it comes to the treatment of pain. Based on my own experiences, it's been shocking to realize how few pain specialists have actually read and understood the studies they are touting as proof of one thing or another. I have read many of these reports and studies, and the takeaways presented to patients do not match the actual conclusions of the papers! This isn't just my personal opinion, but I've noted several professionals in the field decrying the very same thing.

Recommendation #8

Once again, the idea that the current state of understanding allows a reasonable calculation of risks versus rewards, particularly by third parties, establishes the near certainty of under treatment or even denial of treatment. This idea that pain patients are constantly on the verge of addiction has to stop. Unless some very serious life changes occur, the likelihood of a long-haul pain patient suddenly becoming addicted seems incredibly small. It is time to fix the issue that erring on the side of assuming addiction has created. And if you don't believe that's occurring, you haven't been sitting in the chair across from pain doctors the last five years. It is also inappropriate to put "higher doses" in the category for more likely addiction. Long-term pain patients experience relief. Our pain is severe enough that if there is any euphoria, it's being masked. Unfortunately, the only people who truly know this are those who are living with it. It's why some kind of patient advisory committee must be formed to potentially outright reject some recommendations. That may sound ludicrous to you, but we have been blasted by these policies for the last five years. Allowing a strong patient involvement is likely the only way any sense of balance would be restored.

Recommendation #9

While this would seem to make sense, PDMP's appear to have become a clearinghouse for some outrageous opinions. The issue at present is it takes the opinions of doctors, including those attending ER's, and takes their rapid-fire judgments, and lends an air of certainty and reliability to them that is unwarranted. We have just had five years of doctors acting in a near-hysterical manner in interpreting patient's behavior. PDMP's need to be re-assessed as a whole to ensure fair representation is occurring. It's especially important considering human nature will lend more credibility to something committed to a computer system. Given the usually short time frames of ER visits and doctors primed to see signs of addictions everywhere, it's inadvisable to take the results of these systems into account until a proper balance can be restored. Without this, a perpetuation of denial of care will continue. The guidelines need to represent the perspective that denial of care to a legitimate patient is not an acceptable outcome. There is simply too much at stake for the individual to make them constantly justify themselves. The more exposure they have to a system with flaws, the more likely they are to be impacted by those flaws. Pain matters. Our perspective matters. The current state of affairs is untenable and needs to be addressed as soon as possible, even if that means employing extraordinary means. The CDC must take steps to end the crisis of suffering and death set in motion by the release of the first set of guidelines.

Recommendation #10

Chronic pain is unique enough that it should be omitted from the CDC's guidelines unless to explicitly state that none of these recommendations apply to the care of chronic pain patients. Perhaps even

making it explicit that due to the complex issues of each case, general guidelines or regulations should not be attempted and left to the sole discretion of the doctor and the patient. There are simply too many sources of chronic pain to make generalizations. Even one like this, which I'm suspecting, feels "light" to the writers of the guidelines. Just because it isn't recommended doesn't mean a doctor won't do it when warranted. The CDC needs to start thinking in terms of the protection of the patients, given the way their recommendations have been used thus far (and still are).

Recommendation #11

The evidence for this is still not strong enough to force patients to choose between the two. Responsible doctors and patients should not be subject to scrutiny for providing the best possible care on all fronts. Suggesting otherwise has already produced grievous harm. Scrap it.

Recommendation #12

While this would certainly seem sensible, putting it into this format must be assumed to be applied the way the previous guidelines have been. As such, this would result in an excessive diagnosis of UD. This would be safer left out of these recommendations. Scrap it.

Conclusion

There are several fundamental assumptions in these recommendations that would certainly continue the harm we see today. First, the CDC must own the fact that by releasing the Guidelines in 2016, it assumed an authority to speak on something that was outside of its area of expertise. The result has been incredible suffering, maltreatment, and deaths of pain patients. There are no grounds to continue such an egregious policy. While there is a public issue related to illicit drugs or illegally obtained prescription drugs, the guidelines outlined in 2016 put genuine patients in the crosshairs of multiple parties. The barriers to proper treatment are more or less total. Attempting to receive treatment for pain in America is now seen as the act of drug addicts by many practitioners. Those who have not spent the time analyzing the underlying studies to see that liberties have been taken with a number of assertions by the CDC's original guidelines. Various institutions used the guidelines as a fig leaf to take on an issue that has a great deal more to do with predispositions and socio-economic conditions than exposure to opioids through medical care. The time has come to put these types of assumptions to rest and write a set of recommendations, if you must, that truly represents the patients whose lives are most directly affected.

The fact that such a large-scale change to a massive group of people's medical care was set in motion while making no attempt to track patient outcomes casts a dark shadow over the intentions of the writers of the 2016 guidelines. Do not follow in their footsteps. Acknowledge the damage done, flee from the policies that cause it, and write new recommendations that are patient-centric with a view to making sure every pain patient receives care that allows them to live, perhaps even thrive. Imagine that a policy that would enable millions of Americans to thrive. This shouldn't be a difficult choice.