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**The Gang That Couldn't Shoot Straight: Revisiting the CDC Guideline**

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## Disclosure

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Nothing to disclose

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## Learning Objectives

- Cite the multifactorial issues contributing to the opioid crisis
- Describe how the politicians, state and federal laws have conspired to help destroy the lives of chronic noncancer pain patients and increase patient deaths from overdose and suicide
- Identify further issues that complicate and make the "opioid crisis" more of a political and legal issue than a medical problem

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## What Will Be Covered

- The Opioid Crisis
- OUD and Addiction
- Effects on Chronic Pain Patients
- Legal and Political Weaponization of the Opioid Crisis

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## The Opioid Crisis: Historical Highlights

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## The "Opioid Crisis"- Historical Highlights #1

- The Current Opioid Crisis began in the late 1980s and early 1990s
  - The Insurance Industry collectively refused to pay for adjunctive pain medicine care
    - No More Physical Therapy, Psychotherapy, Biofeedback Therapy, acupuncture, etc
  - They had no problem paying for the only thing they would pay for- opioid pain medication
- 1995- Purdue Pharma received approval for oxycontin
  - People played recreationally with the medication via crushing, snorting or injecting
- 1997- Purdue paid a $634 M fine for lying about Oxycontin
  - They claimed it was less addictive than other opioids
- 1991-2011- Opioid prescriptions tripled
  - Some doctors overprescribed the drugs- giving more than might have been necessary for acute pain, so opioids flooded the market and they feel into the wrong hands

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## The "Opioid Crisis"- Historical Highlights #2

- In response, the government decided to crack down on opioid prescriptions
- HOWEVER:
  - It was felt by some that pain was being undertreated
  - Pain was announced as the 5th Vital Sign to improve pain management by the Veterans Health Administration and the "Pain as the 5th Vital Sign" initiative in was launched in1999, requiring a pain intensity rating (0 to 10) at all clinical encounters
  - Hospitals were expected to have "pain groups" to deal with pain that was "high"
  - OPIOID PAIN MEDICATIONS were the main tool in the toolbox throughout this time

- Two surveys, one done in 1998 and one in 2004, indicated that at least 30 percent of those with moderate pain and more than half of people with severe pain, don't get adequate relief.
  - Research showed, too, that 50 percent to 75 percent of cancer patients who die do so in moderate to severe pain, despite the availability of treatments to alleviate most of their discomfort.
    - https://www.painresource.com/addiction/why-is-pain-undertreated/

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## The "Opioid Crisis"- Historical Highlights #3

- The Insurance Industry still wasn't covering adjunctive pain care (PT, OT, PSYCH)
- Chronic Pain being Bio-psycho-social was irrelevant to them

- 2010- Purdue released an abuse-resistant formulation of Oxycontin
  - The Days of crushing, snorting, injecting Oxycontin were over
    - More people started abusing Heroin
  - Simultaneously, physicians became reluctant to give opioid prescriptions
- When Purdue did something good and well, it started the real problem:
  - Despite the good intensions of the ADF, addicts and other recreational users, who could not use Oxycontin to obtain their "highs", and who no longer easily obtain Vicodin, Oxycontin and other Opioids- turned to Heroin
  - Opioid-related deaths continued to increase

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## The "Opioid Crisis"- Historical Highlights #4

- Deaths from prescription opioids alone were and are rare
  - The reason so many people- typically recreational drug users, overdose, was because they were mixing opioids with other drugs including alcohol or benzodiazepines
  - Heroin is often laced with illegal fentanyl, (a drug that is 50-100X more potent than morphine)- and lethal dosages were not uncommon
- The CDC Guidelines were Published, 2016, and unabashedly taken as gospel, by states' Medical Boards, legislatures, insurance companies and pharmacies, the VA and CMS
  - This led to 3 years of patients being forcibly taken off their pain medications, totally, or, if they were lucky, to 90 MED, either way, making them non-functional (GWJ, DAM, 2018); a very significant increase in CPP suicides associated with opioids (and OUD)-40% to 60% (Oquendo MA, Volkow ND. NEJM, 2018; 378:1567-1569)
  - Debra Dowell, MD, from the CDC, noted in April 2019 that the CDC Guidelines had been taken and used zealously, and not as intended. No apology re: the severe issues of CPPs suffering from these guidelines was given- within several days of this statement, the FDA stated that there was no medical/scientific reason to withdraw people from opioid medications simply because they were taking them (but no comment was made re: the real fear and loathing of physicians who in the interest of self-care- not wanting to go to jail, took CPPs off medications or stopped treating Chronic Pain Patients- and still do

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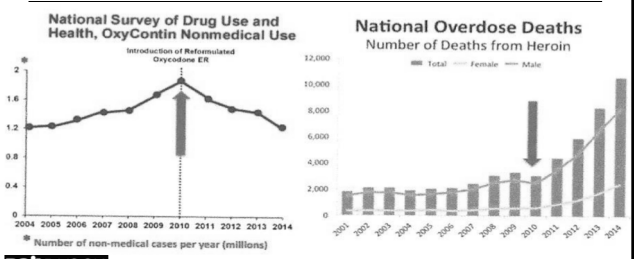
**When Oxycodone was reformulated- 2010[2]**

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**In Case You Missed It:**

***"The reformulation [of OxyContin] did not generate a reduction in combined heroin and opioid mortality—<u>each prevented opioid death was replaced with a heroin death</u>."***

***Walter N. Evans, et. al.,*** *"How the Reformulation of OxyContin Ignited the Heroin Epidemic" February 2018*

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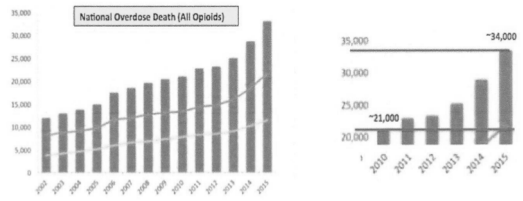


*Figure 3. Deaths from all opioids by year (2010-2015). The graph on the right is a magnification of the key data from the full graph on the left. Source: Adapted from NIH (https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates)*

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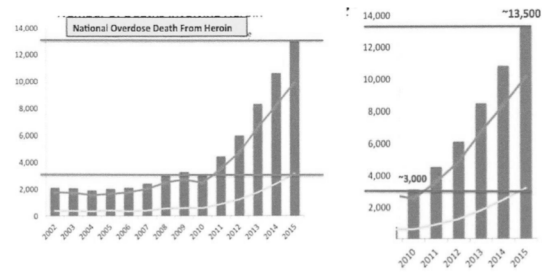


*Figure 4. Deaths from heroin by year (2010-2015) Source: Adapted from NIH*

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## The Bottom Line- 2

- The CDC guidelines resulted in severe restriction on the availability of opioid pain medications (As I described last year)
  - The "Guidelines" were turned into laws, and essentially mandated forced tapering, the closing of pain clinics, physicians leaving pain management en masse and increasing persecution of the physicians who continued to appropriately treat CPPs
  - These added to the burden of CPPs who use, NOT ABUSE, these medications, increasing difficulty to get the medications
  - These CPPs are terrified, with good reason, and some are committing suicide rather than face untreated pain
  - Some go to the street to obtain heroin to hopefully control their pain and increase their functioning
  - There are now fentanyl test kits so undertreated pain patients and recreational users who have been forced to turn to heroin, can tell if there is fentanyl in the heroin
  - THE NUMBER OF PAIN PERSCRIPTIONS CONTINUES TO DROP, BUT THE TOTAL OPIOID OVERDOSE DEATHS KEEP RISING (https://dancesafe.org/product/fentanyl-test-strips-pack -of-10/)

Bloom, American Council On Science and Health, April 2018

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## Trouble!

*The progression from pharmaceuticals like OxyContin to heroin is called substitution. Conceptually and economically it is no different than raising the taxes on soda and being surprised that people are now drinking more juice. Worse still, illicit drugs are by their nature untrustworthy. Can you expect your drug dealer to use the same quality controls as pharmaceutical companies? Of course not. So it is no surprise that in the absence of trust, people who need but cannot obtain pain relief are forced to test what they buy on the black market. This is an abomination.*

*Dr. Chuck Dinerstein, Medical Fellow, American Council on Science and Health*

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## So, Where Are We?

- Thanks to the CDC Guidelines being used inappropriately
  - Thanks to the AOZ from PROP
  - Thanks to the DEA
- We have more CPPs and addicts dying AND Pain Patients suffering unnecessarily




http://www.pharmaciststeve.com



## Opioid Use Disorder (OUD)- Common?

- The National Institute on Drug Abuse (NIDA) reports that 8-12% of patients on long-term opioid therapy develop an OUD
  - Per Dr. Volkow, NIDA Director, "the best and most recent estimate of the percentage of patients who will develop an addiction after being prescribed an opioid analgesic for long-term management of their chronic pain stands at around 8%,:
- Cochrane found in a major review of studies of long-term opioid therapy for non-cancer pain that only 0.27% of patients were at risk of opioid addiction, abuse or other serious side effects.
- In another large study in the BMJ, only about 3% of previously opioid naïve patients continued to use them more than 90 days after major elective surgery

Chrisa, R. Pain News Network, Aug 6, 2018; Volkow, N et al, 2016, NEJM

## Opioid Use Disorder (OUD)- Common?-2

- Large scale analysis of medical insurance records demonstrates that incidence of chronic opioid prescribing in populations of non-surgical patients is on the order of 0.136%.
  - "Chronic" in this context is taken to mean 10 or more opioid prescriptions in a year or continuous prescribing for 120 days or more.
  - When records of surgical patients were analyzed after 11 common surgical procedures, it was found in four of these procedures that incidence of chronic prescribing remained unchanged after surgery. In the remaining seven procedures, chronic prescribing was observed in a maximum of 0.7% of post surgical patients. This maximum was associated with total knee replacement, a procedure known to be associated with development of treatment-resistant chronic pain.

Eric C. Sun, Beth D. Darnall, Laurence C. Baker, Sean Mackey, "Incidence of and Risk Factors for Chronic Opioid Use Among Opioid-Naive Patients in the Postoperative Period", JAMA Internal Medicine 2016;176(9):1286-1293.

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## Opioid Use Disorder (OUD)- Common?-3

- Recent large-scale analysis of insurance records of post-surgical patients confirms that incidence of later diagnosis of opioid abuse disorder among patients who are prescribed opioids after surgery is less than 0.6%. Given the current hostile regulatory environment, it is plausible that actual risk of patient opioid abuse from managed medical exposure may be significantly lower than 0.6%. Some doctors mistake the emergence of post-surgical chronic pain for evidence of increasing risks of opioid abuse. Others may be rendering the diagnosis out of personal discomfort and concern for being sanctioned by State authorities or the US Drug Enforcement Agency.

Gabriel A Brat, Denis Agniel, Andrew Beam, Brian Yorkgitis, Mark Bicket, Mark Homer, Kathe P Fox, Daniel B Knecht, Cheryl N McMahill-Walraven, Nathan Palmer, Isaac Kohane, "Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study", BMJ 2018;360:j5790 http://www.bmj.com/content/360/bmj.j5790.long

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## So, What Exactly is OUD?

- Two disorders – In 2013 "Opioid Dependence" and "Opioid Abuse" -- were combined into one to give us "Opioid Use Disorder."
  - This had a major impact on chronic pain patients, as well as inflated the number of Americans needed SUD treatment
- Opioid Use Disorder can be applied to anyone who uses opioid drugs (legal or illegal) and has at least two of the following symptoms in a 12-month period:
  - Taking more opioids than intended
  - Wanting or trying to control opioid use without success
  - Spending a lot of time obtaining, taking or recovering from the effects of opioids
  - Craving opioids
  - Failing to carry out important roles at home, work or school because of opioid use
  - Continuing to use opioids despite relationship or social problems
  - Giving up or reducing other activities because of opioid use
  - Using opioids even when it is unsafe
  - Knowing that opioids are causing a physical or psychological problem, but using them anyway
  - Tolerance for opioids
  - Withdrawal symptoms when opioids are not taken
- The last two criteria will apply to almost every chronic pain patient on a prescription opioid regimen. So might some of the others. Typically all of us develop a tolerance for opioids, and if they are stopped or greatly reduced, we will experience withdrawal symptoms.

Odell, R, Pain News Network, Oct. 18,2017

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## OUD and Drug Misuse

- 2016- about 2.1 M Americans over the age of 11 had an "addiction to opioids such as the prescription pain medications oxycodone and hydrocodone/acetaminophen or the illegal drug heroin.
- At the same time, 11.8 M (6 times as many Americans) reported misusing opioids, primarily prescription medications
- The OUD is complex, affecting both the brain and body- characterized by the compulsive use of one or more drugs, such as opioids, despite serous health and social consequences; typically develops during adolescence and may affect him/her for an extended period
- Drug misuse- a problematic pattern of drug use-including the use of Sched II pain medications: 1)Without a prescription (e.g. someone else's medications);2) For a reason other than the condition for which they were prescribed; or 3) at higher doses, more often, or for a longer period than prescribed
- Misused opioids most frequently obtained from a friend or family member, not a physician

Freedman H, The Buzz, 2018

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## Addiction-1

- A brain disorder characterized by compulsive drug use despite adverse consequences; a component of substance use disorder
  - An overexpression of the gene transcription factor ΔFosB in the nucleus accumbens places an important role in the development of an addiction to opioids and other drugs by sensitizing the drug reward system and amplifying compulsive drug-seeking behavior.
  - Overuse of opioids leads to increased ΔFosB expression in the nucleus accumbens.
  - Opioids affect dopamine neurotransmission in the nucleus accumbens via the disinhibition of the dopaminergic pathways secondary to inhibiting the GABA-based projections to the ventral tegmental area (VTA) from the rostromedial tegmental nucleus (RMTg) which negatively modulates dopaminergic neurotransmission
  - Opioids inhibit the projections from the RMTg to the VTA, which in turn disinhibits the dopaminergic pathways that project from the VTA to the nucleus accumbens and elsewhere in the brain
  - Chronic intake of opioids may induce long-term effects in the orbitofrontal area (OFC), essential for regulating reward related behaviors, emotional responses and anxiety
  - Neuroimaging and neuropsychological studies show dysregulation of circuits associated with emotion, stress and high impulsivity
  - See next slide for references

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## Addiction-References


- Nestler EJ, 2013; Dialogues in Clinical Neuroscience. 15 (4): 431–43.
- Robison AJ, Nestler EJ, 2011; Nature Reviews. Neuroscience. 12 (11): 623–37
- Blum K, Werner T, et. al. 2012; Journal of Psychoactive Drugs. 44 (1): 38–55
- Olsen CM 2011; Neuropharmacology. 61 (7): 1109–22
- Ruffle JK, 2014; The American Journal of Drug and Alcohol Abuse. 40 (6): 428–37
- http://www.genome.jp.keg-bin/show-pathway?hsa05032
- Leong HF, Yuan Z, 2017; Frontiers in Human Neuroscience. 11: 169
- Bourdy R, Barrot m, 2012; Trends in Neurosciences. 35 (11): 681–90
- Goldstein RZ, Volkow ND, 2011; Nature Reviews, Neuroscience 12 (11): 652-69


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## ΔFosB-1

- ΔFosB is induced in the nucleus accumbens (NAc) by chronic exposure to several drugs of abuse and transgenic expression of ΔFosB in the striatum enhances the rewarding property of morphine and cocaine
- Studies show that the opioid and cannabinoid receptor signaling are differentially modulated by expression of ΔFosB and indicate that ΔFosB expression may produce some of its effects via enhanced mu and kappa opioid receptor signaling in the NAc
- ΔFosB is induced in the brains reward regions by chronic exposure to virtually all drugs of abuse and mediates sensitized responses to drug exposure
- ΔFosB contributes to addiction by regulating the expression of specific target genes in brain reward pathways
- ΔFosB plays a role in tramadol dependence with increased MOR levels during tramadol treatments, possibly secondary to receptor desensitization

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## ΔFosB- References


- Sim-Selley LJ, Cassidy MP, et5 al. Neuropharmacolgy 2011; 61(8):1470-1476
- Matthes HWD, Maldonado R, et al. Nature. 1996; 383:819-823
- Bozarth MA, Wise RA. Science 1984; 224:516-517
- Zangan A, Solinas M, et al. 2006; 4901-4907
- Nestler EJ. Philos Trans R Soc Lond B Biol Sci. 2008; 363(1507): 3245-3255.
- Nestler EJ, Barrot M, et al. Proc. Natl Acad Sci USA. 2001; 98: 11042-11046
- McClung CA, Ulery PG, et al. 2004; Mol Brain Res. 132: 146-154
- Shirazi MS, Babhadiashar N, et al. Amer J Drug Alcohol Abuse, Jan. 2019; ResearchGate


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## A Study Looking at Prolonged Opioid Use After Major Surgery

- In Acute Care hospitals in Ontario, Canada
- 39,140 opioid naïve patients aged 66 or older who had major elective surgery, including cardiac, intrathoracic, intra-abdominal and pelvic procedures
- Approximately 3% of previously opioid naïve patients continued to use opioid for more than 90 days after major elective surgery
  - Specific patient and surgical characteristics were associated with the development of prolonged postoperative use of opioids

Clarke H, Soneji N, Et al. BMJ 2014; 348:1251

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## Another View: Thomas Kline-1

- There are 2 types of addiction
  - Type 1 addiction group: cocaine, marijuana, amphetamines and most overuse of alcohol (Substance use negatively affecting daily life)- if daily life is not effected, then no addiction disease.
    - Responds to talk therapy and traditional rehabilitation
  - Type 2 addiction- the opiate or heroin addiction which is multiple genetic errors in gene A118G which controls the mu receptor in the brain, the peripheral nerves and in inflammatory tissue- also associated with Intense Seeking of substances without regard to consequences
    - Addition of opiate Type 2 addiction in patients with strong family history's and abnormal genes is immediate on first exposure (major question: "Have you every had an opiate?" If not, they may be carrying the gene)
    - Does not respond to residential treatment and leads to overdose deaths due to forced abstinence and the changed tolerance to opioids- these patients need Medication Assisted Treatment (MAT)
  - Major Issue here- in patients with genomic changes, just 1 pain pill will induce the addiction.

Kline T. Medium:Opioid Addiction, is it rare? Is it caused by Substance Exposure?. IATH Educational Consortium, April 2019

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## Addiction Studies-1

- Study of 125 Burn Treatment centers with 20,000 burn patients found after prolonged parenteral injections for pain control, opiate addiction was found in only 22 people. (1%) (Perry s, Heidrich G. Pain. 1982; 13:267-80)
- In 2010, the Cochrane Collaboration reviewed 26 long term opioid use studies and concluded "serious adverse events, including iatrogenic opioid addiction were rare" Noble M, Treatwell JR, et al. Cochrane Database of Systematic Reviews 2010, Issue 1, Art. No: CD006605)
- More recently, a study at Loyola found only one person addicted out of 1100 patients given postoperative opiates Shah AS et al. J of Urology, 2017; 198(5):1130-1136)

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## Addiction Studies-2

- 700 soldiers returning from Vietnam on a high dose of pure, IV heroin- Most had withdrawal symptoms, but only 2% were found to be addicted (Robins LN. Problems of Drug Dependence 2010; 19:203-211 (reprinted from 1997 Proceedings of the 39th Scientific Meeting of the Committee on Problems of Drug Dependence)
- A smaller cohort of Vietnam heroin users were studied in 1979 and replicated Robins findings
- Volkow noted in 2016: "Unlike tolerance and physical dependence, addiction (opiate type) is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids- even among those with preexisting vulnerabilities." (Volkow, N, McLellan A. NEJM, 2016; 374: 1253-1263)

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## Addiction Studies-3

- Kline notes more evidence of low addiction rates:
  - Population statistics supported the rarity of addiction: the rate of addiction in 1915 When the Harrison Act was passed was 3/1000; the NIH figures currently show a similar rate of addiction today of 4/1000, unchanged in over 100 years
  - Neuroscience research at the NIH, Montreal, Bonn and Sydney (just a few) show consistent evidence that true addiction is a genetic mu opioid receptor polymorphism found in families showing a genetic predisposition
  - Studies as well as epidemiological data show that less than 1% of people will become addicted after exposure to high dose IV Heroin (as noted previously)
  - Based on experience along with the experience of pain management physicians, once exposed to an opiate without addiction (with intense seeking and more) further exposures do not lead to addiction type 2.
  - Looking at the confirmed government figure of 2 million people with substance abuse disorder (SAD) divided by the U.S. population of 320 M, the figure is 0.6% or one half of one percent, confirming the incidence of addiction of less than 1%

Kline, Medium, 2019

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## Addiction Information

- Informal studies show about 50% of physicians have stopped seeing chronic pain patients
  - Various surveys have indicated that 6-7 M CPPs have been made non-functional by the forced tapering to CDC Guideline levels of opioids or have been taken off of their medication

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## Addiction Information- (Some Q&As)-1

- Addiction rates in the US in 1920, 1950, 1970, 2016 and currently in Canada and the UK and Portugal all equal a rare rate of opiate addiction of 0.5%
  - Supporting a genetic variation responsible for opiate addiction- 99.5% of the population does not have the gene (Kline, Medium, 2018)
- Is the increasing number of prescriptions responsible for overdose deaths? (The US is the only country with “Drug Police”)- by law, we physicians must write a new prescription for each month, unlike Canada, where one prescriptions with three refills can be written) so yes, we are writing more prescriptions secondary to the law, but giving the same amount of medicine as seen in Canada, for example (Jay, 2019)

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## Addiction Information- (Some Q&As)-2

- Opioid medication given for more then 90 days doesn't work! Not true, as I've personally treated hundreds of patients who did well for many years, with no evidence of misuse, abuse or addiction, but whom attained and maintained function (Jay, 2019)
- The CDC recommended limiting pain medication dosages to 90 MMEs to prevent addictions and overdose deaths! Yes, but when I threw my dart at the board it landed on 105 MMEs. The number is totally artificial (arbitrary) without any EBM to back it up (Jay, 2019)
- What is high impact pain- Nearly 10 percent of Americans over age 50 suffer from high-impact, long-standing pain that has a substantial negative effect on work, social or other everyday activities. Compared to people with chronic pain without activity limitations, those with High Impact Chronic Pain had higher levels of anxiety, depression, fatigue, and cognitive difficulty. They also tended to report more severe pain, worse health, and higher health care use.

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## High Impact Pain

- 4.8 percent of the U.S. adult population (10.6 million people) had High Impact Chronic Pain and another 13.6 percent (29.9 million) had chronic pain without limitations in major life activities.
- Activity limitations were more common in the chronic pain population than in groups with other chronic health conditions, such as stroke, kidney failure, cancer, diabetes, or heart disease.
- About 83 percent of people with High Impact Chronic Pain were unable to work for a living, and one-third had difficulty with self-care activities such as washing themselves and getting dressed.

NIH, Aug. 2018

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## The Real Problem(s)

- Of the 100 M Chronic Pain Patients in the US
  - 10-11 M take daily opiates
  - It has been estimated that 6-7 M of these patients have had their opiates reduced "Per the CDC Guidelines" or totally stopped
    - This leaves essentially functionless CPPs
    - This does increase the number of CPP Suicides
- There are a lot of questions about opioid use and appropriateness, but look at the FDA Science Review (2012-P-0818) which was the rejoinder to the AOZ PROP – and their excellent re-evaluation of "PROP Mandates"
- Big four "Suicide Diseases: Complex Regional Pain Syndrome, Trigeminal Neuralgia, Adhesive Arachnoiditis and Interstitial Cystitis plus about 25 more pain disorders- in about 10 M CPPs with rare/significant painful disorders- None will become addicts, but 2/3 have been forced off their pain medicines ( Kline, Medium, is Addiction Genetic, 2019)
- Pain medication has been relegated to "trash" as people inappropriately worry about "addiction"-
  - Pain Programs have stopped using opioids-
  - Some market that they are purely interventional and don't use opioids

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## Polymorphism of A118G

- Just to note the fact that functional polymorphism (A118G) of the mu-opioid receptor gene (OPRM1) is thought to have clinical significance with substance dependence.
  - Bart G, Heilig M, LaForge KS, Pollak L, Leal SM, Ott J, et al. Substantial attributable risk related to a functional mu-opioid receptor gene polymorphism in association with heroin addiction in central Sweden. Mol Psychiatry. 2004;9(6):547–9
  - Bond C, LaForge KS, Tian M, Melia D, Zhang S, Borg L, et al. Single-nucleotide polymorphism in the human mu opioid receptor gene alters beta-endorphin binding and activity: Possible implications for opiate addiction. Proc Natl Acad Sci U S A. 1998;95(16):9608–13
  - Kreek MJ. Role of a functional human gene polymorphism in stress responsivity and addictions. Clin Pharmacol Ther. 2008;83(4):615–8
  - Haerian BS, Haerian MS. Oprm1 rs1799971 polymorphism and opioid dependence: Evidence from a meta-analysis. Pharmacogenomics. 2013;14(7):813–24
  - Manini AF, Jacobs MM, Vlahov D, Hurd YL. Opioid receptor polymorphism A118g associated with clinical severity in a drug overdose population. J Med Toxicol: Off J Am Coll Med Toxicol. 2013. doi: 10.1007/s13181-012-0286-3.

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## Lest We Forget…

- The CDC Guidelines using a decided lack of EBM enhanced background (Recommendations 1-11 weak or very weak EBM background) stated that there would be 25% of pain patients in a primary care physicians office who would be addicted to pain medications.
- As documented: WRONG!

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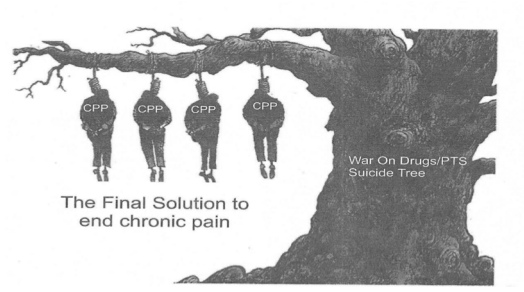


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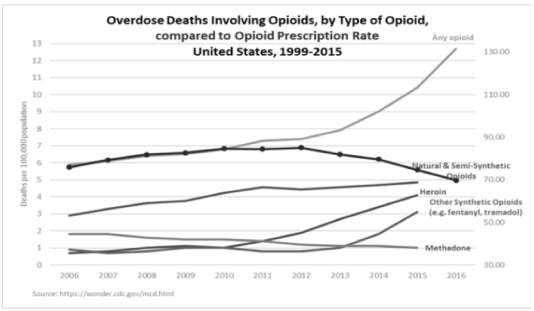
http://www.pharmaciatieve.com/

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## Chronic Pain Patients (CPPs)-1

- The CDC Guideline- recommendations for primary care physicians totally overshot that mark, becoming mandatory, if not "law" per the legal/political weaponization of this set of "recommendations" by Medical Boards, State legislatures, The CMS, the VA and multiple other groups, all at the detriment of both CPPs and their physicians who typically did what they could for the CPPs until they realized that their livelihood and their freedom became issues

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## Chronic Pain Patients (CPPs)-2

- The purported purpose of the CDC Guideline was to help fight the "opioid crisis"
  - It is clear that the overdose deaths were the result of polypharmacy and illicit fentanyl other illicit or illegally obtained drugs
  - We have been told the "opioid crisis" was secondary to a "prescription opioid crisis" and an "addiction crisis" but these statements have never been backed up with evidence
    - Co-occurring addiction in CPPs is very low- "less than 1% of chronic pain patients without a history of substance abuse problems become addicted to opioids during treatment" (https://www.cochrane.org/CD006605/SYMPT_opioids-long-term-treatment-noncancer-pain)

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## Chronic Pain Patients (CPPs)-3

- Common sense also tells us that CPPs with severe debilitating pain are not going to divert their legally obtained opioid medication because they need them to be functional.
- As this author noted last year, the ability to determine opioid Overdose deaths was poor at best. This hasn't changed.
- It would appear that the CDC counts overdose deaths repeatedly based on the number of substances found in decedents at autopsy via toxicology reports-
  - Deaths involving more than one drug were counted in all relevant drug categories – someone with 4 drugs in their blood would be counted 4 times
  - The CDC states "Drug overdose deaths may involve multiple drugs; therefore, a single death might be included in more than one category when describing the number of drug overdose deaths involving specific drugs"

https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_09-508.pdf https://www.cdc.gov/nchs/livers/vsrr/drug-overdose-data.htm

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## Chronic Pain Patients (CPPs)-4

- I spoke last year about Seth et al's editorial stating that the overdose statistics were significantly inflated.
- I also stated that the CDC Guideline was inappropriately used
  - The CDC in April 2019 claimed the guideline was "misapplied" – 3 years after the fact, without even an apology, as if it should have taken that long to figure it out
  - Since the Guideline was released, many patients have died, many more suffer for the lack of pain medication; more CPPs will continue to suffer and die and physicians will continue to force taper patients because they are concerned about "self-preservation", as the DEA may come calling, esp. if they don't strictly follow the arbitrary pain medication caps promulgated by the CDC Guideline

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## So, Has Anything Changed for the Better?-1

- Several years ago I spoke about the number of patients who needed pain management after surviving cancer- a group in the UK numbered over 200,000 CPPs
- This remains a problem- new research shows that 1 in 3 cancer survivors (34.6%) have chronic pain- almost 5.4 M Americans who have survived CA
  - 1 in 6 survivors (16%) represent almost 2.5 M people in the US- reported high impact chronic pain which limited QOL, work on most days or every day in the last 6 months, and restricts daily functioning
  - This is double the rate in the general populations
  - Not infrequently, after successful CA treatment, the oncologist will release the patient who has significant treatment induced pain, and has a very difficult time finding a pain management physician, esp. now, post CDC Guideline

Jiang, et al, JAMA Oncol, 2019; 1439

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## Suicide: Painless?-1

- Last year I quoted Dr. Oquendo
- This year: a new paper: "Suicide: A silent contributor to opioid-overdose deaths" (NEJM 2018: 378: 1567-1569)
  - They estimate that between 40% to 60% of Opioid overdose deaths may be secondary to suicide
  - Looking at the VA patient population, nearly 5 M veterans found that diagnoses of OUD increased the suicide risk: 86/1000, 6 times the general US population rate of 14/1000
  - Older data, 2006-2011 data from the Nationwide Emergency Department Sample, looking at > 250,000 ED visits by adults for opiate OD: 54% of the ODs were classified as "unintentional": 26.5% were intentional and 20.0% were "undetermined"- a 20%-30% number at that time

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## Suicide: Painless?-2

- Kline published a paper giving stories of 41 CPPs who committed suicide secondary to inability to obtain pain medication for Chronic Pain, some High Impact, but of long duration
- When the CDC Guidelines mentions the word "taper" 44 times but then the CDC denies they recommend tapering.
- He notes that Kolodny and the rest of his organization PROP believe strongly that tapering will solve the problem of addiction. Kolodny stated in a Tweet that "High doses (of opiates) should be reduced even if the patient refuses"

Kline, Medium, Suicides with forced tapering of Opiate pain medication. March 2019

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## Suicide: Painless?-3

- To note, and not forget:
  - A Pleasant Grove, Utah man suffering from chronic neuropathic pain was force-tapered off his medications too quickly- died by suicide in January 2019 (ABC News)
  - A Montana woman, a deputy sheriff, committed suicide in May, 2018; she had a physician in Montana, who treated her until his license was suspended, she saw another pain specialist in CA, who himself became a target of the DEA (with no legal reason)- she felt helpless and alone, and committed suicide (National Pain Report, May, 7, 2018)
  - A 76 YO veteran, former policeman, disabled in car accident, committed suicide in VA parking lot after pain care denied (PharmacistSteve.com, July 5, 2019)
  - And many more

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## Medicine as Sadism

- A patient in S.CA with a daily pain level of 5-6 before the step down- is bedridden, doesn't leave home except for a physicians appt. went out for lunch once, increased his pain to a 9/10 for 3 days.
- March 2019, Kaiser Permanente gave him a choice, they would further taper him, or he would go cold turkey. His pain is an 8/10. "Sooner or later at a pain level of 9/10- I will euthanize myself. I have started grieving my own death and prioritizing my books-to-be-read and movies-to-watch. Now I'm waiting. I will get to go until my next medication refill and then… then…then I endure the painful horror as long as I can and finally will love myself enough to let go via self euthanasia."

PharmacistSteve.com, March 21, 2019: http://pharmaciststeve.co /?p=29386

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http://pharmaciststeve.co /?p=29386

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## Old Problems Persist

- But in Alaska, it's been a painful transition for those who rely on controlled pain medication. Pharmacies have been turning them away, to the point where the patients have reached out to the State Pharmacy Board for relief.
- In response to these complaints, a letter went out to Alaska's pharmacists from the Pharmacy Board, telling them to follow the law, which is to fill legitimate prescriptions.
- The trend toward "refusal to fill" prompted the board to issue specific guidelines and reminders to pharmacists
- After the federal legislation to crack down on the opioid epidemic, wholesalers have begun cutting off the supply to pharmacists.
- In Alaska and elsewhere, that has meant that if a wholesaler notices an increase in orders, they can refuse to send them. Alaska pharmacies are finding it increasingly difficult to even get the drugs being prescribed by doctors.

Must Read Alaska, Downing, S. January 27, 2019

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## Last Year We Talked About CVS and Walgreens

- Walmart!
- Walmart grades patients using NarxCare
- It wants to know ALL drugs a patient takes and how much
- Walmart calls 40 MME of Opioid an "unsafe condition" and is recommending tapering or discontinuing other drugs such as diazepam.
- If your score is >/= 10, it may be hard to get a legal prescription filled
- But, its not just the medications: Other things effect your score with this pharmacy:
  - See your doctor too often within a certain time period.
  - See more than five different doctors in one year. It doesn't matter if they are dermatologists or cardiologists.
  - Use more than four pharmacies in a three-month period.
  - Take an average of more than 40 morphine equivalents (less than three 10 mg acetaminophen/oxycodone) in one day
  - Take a total of 100 morphine equivalents (total) in a day. There are plenty of pain patients who need more than this just to get by.
- Like CVS:
  - "Within the next 60 days, Walmart and Sam's Club will restrict initial acute opioid prescriptions to no more than a seven-day supply, with up to a 50-morphine milligram equivalent maximum per day. This policy is in alignment with the Centers for Disease Control and Prevention's (CDC) guidelines for opioid use."
  - Walmart press release (2017).

Bloom J. American Council on Science and Health, May 11, 2018

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## As Predicted

- Interventional Pain Management physicians are pushing non-FDA approved injections, radiofrequency ablations, pain pumps and spinal cord stimulators, and demonizing opioid pain medication
- Pain Centers are opening and advertising that they only do interventional procedures, and don't use opioids.
- This patient was on opioids, they were tapered off and he was given an interventional procedure- nothing else to do- and was devastated by it. Crippled by it, took away his ability to work and even some self-care

Emelio, Pain News Network, June 14, 2019

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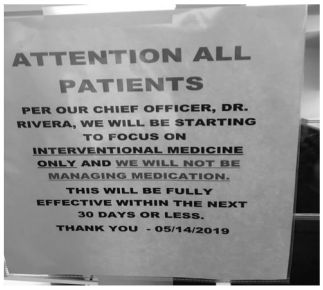


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## An Idea That May Hold Merit!

- Canadian Physicians Prescribe opioids to keep patients off street drugs
  - This "Safer Supply" program is only intended for patients who have failed at addiction treatment programs where methadone or buprenorphine are prescribed

Anson P, Pain News Network, July 2, 2019

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## Dateline: Michigan

- Access to primary care may be reduced for patients taking prescription opioids
- A Study was published in JAMA Network and indicated that unintended consequences such as conversion to illicit substances or reduced management of other medical comorbidities could occur
- Patients who can't find treatment, called, "opioid refugees", the authors state that the restrictions by primary care providers… "may leave patients without options for slow opioid tapers; non opioid treatment options"
- 194 of 219 eligible clinics were interviewed. 40.7% said outright the providers were not willing to provide care for new patients taking opioids. 41.8% were willing to schedule an initial appointment and 17% wanted more information

Coughlan, National Pain Report, July 14, 2019

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## So It Continues-1

- A patient with arthritis, degenerative disc disease, bone spurs in his shoulders and fractures in his back and spine; he was able to receive pain medications
- The Drug Enforcement Administration raided his pain doctor's offices in January, seized medical records and prohibited any more opioid prescribing, but the patient only lived 34 more days.
- The Odessa, Texas man died of a heart attack, after a month-long withdrawal that left him in bed shaking or in the bathroom vomiting and with diarrhea, his daughter said.
- Even though the Centers for Disease Control and Prevention officials acknowledge the agency's influential 2016 chronic pain guideline has been used incorrectly to justify harmful practices such as rapidly reducing pain pills or doctors abandoning patients
  - No one appears to believe real change in these policies have occurred- fear of the DEA and state boards enforcing the CDC Guidelines continues

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## So It Continues-2

- The patient couldn't get copies of his medical records from the DEA, so no new doctor would take him on as a patient- he was taking 60 mgs of hydrocodone to be functional
- A U of Michigan study published in JAMA found 41% of 194 primary clinics surveyed refused to take new pain patients
- The FDA wants to put new opioid medications in blister packs and there are concerns that it would make it more difficult for patients with painful conditions to open their pill packs

Alltucker K, O'Donnell J, USA Today, July 12, 2019

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## And the Millennials?

- Young adults were more likely than any other age group to die from drugs, alcohol and suicide over the past decade, underscoring the despair Millennials face and the pressure on the health care system to respond to a crisis that shows little sign of abating
- Drug-related deaths among people 18 to 34 soared 108% between 2007 and 2017, while alcohol deaths were up 69% and suicides increased 35%, according to an analysis of the latest federal data by the non-profit Trust for America's Health and Well Being Trust
- The analysis of Centers for Disease Control and Prevention data found the increases for these three "deaths of despair" combined were higher than for Baby Boomers and senior citizens

O'Donnell, J USA Today, "Deaths of Despair", June 13, 2019

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## The Other Opioid Crisis

- While everyone is watching the drama in the USA, 80% of the world's population goes without appropriate pain relief
- Dr. Rajagopal, "The father of palliative care in India" states "only a tiny, tiny minority of people in India have access to pain relief."
  - "We have people travel as far as 300 KM to get their refill of morphine prescriptions. There are many states where it is totally unavailable.
  - According to Human Rights Watch, 96% of needy patients in India can't access opioids.
  - Now, Rajagopal worries that the dependency crisis in the US will harm the slow progress being made in India
  - Americans use 80% of the global opioid supply
  - Total opioid consumption in India (and other low-income countries) accounts for less than 1% of the global amount"
  - The World Health Organization (WHO) has estimated that "roughly 80% of the word population has either no, or insufficient, access to treatment for moderate to severe pain"

Seth-Smith N, New Humanist, December 10, 2018

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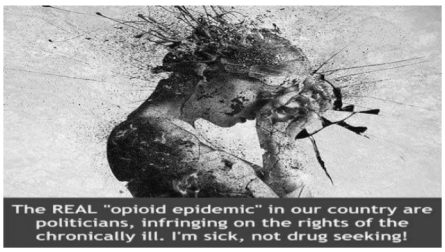


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https://painweek.com/

## February 5, 2019: Wisconsin

- Matthew D. Krueger, US Attorney or Eastern District of Wisconsin and Scott C. Blader, US Attorney for the Western District of Wisconsin sent letters to over 180 physicians, physician assistants and nurse practitioners advising that a review of their prescribing practices "showed that they were prescribing opioids at relatively high levels compared to other prescribers."
- These letters warned that "these prescribing practices may be contributing to the flow of prescription opioids into illegal markets and fueling dangerous addictions.
  - The letters did acknowledge that the prescriptions may be medically appropriate, the letters remind the practitioners that prescribing opioids without a legitimate purpose could subject them to enforcement action including criminal prosecutions.
- No charges of any type were made against any of the letter's recipients

The United States Attorney's Office Western District of Wisconsin, Feb. 5, 2019

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## March 14, 2019: Oregon

- Oregon's plan to force Medicaid patients off of opioid pain medication was placed on hold- because of a medical expert's potential conflict of interest, they were getting "independent reviews of recommendations"
- May 17, 2019- The Oregon health panel tabled a controversial plan to have forced tens of thousands of Medicaid patients with neck and back pain to stop taking opioid medication.
  - The Health Evidence Review Commission (HERC) voted unanimously to wait for additional studies to be completed this year which effectively delays any change in medical coverage under the Oregon Health Plan until 2022.
    - Patient advocates state some physicians have already implemented HERCs forced tapering proposal without waiting for it to be finalized

Anson, P. Pain News Networks, May 17, 2019

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## April 9, 2019: FDA

- Reacting to the unintended harm to chronic pain patients:
- The FDA made a safety announcement noting "serious harm" including "withdrawal symptoms, uncontrolled pain, psychological distress and suicide" as a result of sudden discontinuation or rapid dose decreases in opioid pain medication (https://.fda/gov/news-events/pres=announcements/statement-douglas-throckmorton-md-deputy-center-director-regulatory-programs-fdas-center-drug-0)
- The FDA noted, as is clinically known, "there is no standard opioid tapering schedule; rather, a schedule must be tailored to each patient's unique situation considering a variety of factors, including the type of pain the patient has."

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## April 9, 2019: CDC

- The CDC Responded the same day stating the "People with severe pain from cancer or sickle cell anemia should not be denied coverage for opioid painkillers"(HealthDay News, April 9, 2019)
- In the CDC letter, it also indicates that the guidelines weren't designed to "deny any patients who suffer with chronic pain" the option of opioid medications
- They also indicated that the CDC Guidelines were not intended for patients undergoing cancer treatments
- The letter also indicated that while patients with chronic pain should have the option of opioid medications, insurance companies should not refuse to pay for IV opioids for patients hospitalized with severe pain episodes in, for example, Sickle Cell Crises", but the Insurance Companies use the CDC Guidelines as the reason for non-approval

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## April 25, 2019: Study

- A study with 15,000 patients published April 2019 (JAMA Netw Open 2019 APR 5; 2(4):e192613 DOI: 10:1001/jamanetworkopen.2019.2613) showed that variability in opioid dose could be a risk factor for opioid overdose, suggesting that practitioners should seek to minimize dose variability when managing long-term opioid therapy.
  - It would be the stability of dosage, not the actual dosage itself that is important to maintain prescription opioid safety
- Not surprisingly, a group called PharmedOut, a partner of Physicians for Responsible Opioid Prescribing (PROP) pushed back, and was circulating a petition in support of the CDC opioid Guidelines

National Pain Report, April 25, 2019

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## May 28, 2019: Florida

- Florida implemented a law on July 1, 2018 to reduce the supply of circulating opioids.
- The law limits opioid prescriptions for acute pain to a three-day supply
  - It can be extended up to seven days if medically necessary
  - It does not apply to traumatic injuries with an Injury Severity Score of 9 or more for chronic pain
- A study of more than 1000 outpatient surgical encounters at Jackson memorial Hospital showed that fewer patients received opioid prescriptions, and less milligram morphine equivalents (MMEs) of opioids were prescribed following implementation of the law (House Bill 21).
  - There was an increase in MMEs prescribed per day- ? Unintended consequence of restricting the duration but not the amount of dosage of opioid prescriptions

Anesthesiology News PRN; May 28, 2019

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## June 13, 2019:CDC-1

- 3 of the Authors of the CDC Guideline published a response in the NEJM to the FDA action, a letter from more than 300 health care practitioners and increasing news of harms to people with pain from the CDC Guidelines (NEJM 2019; 380:2285-87)
  - They noted that the Guideline had been misapplied and applied inflexibly in some instances. However, they also vigorously defended the Guideline, stating that the "medical and health policy communities have largely embraced its recommendations" it has sparked "accelerated decreases in prescribing" and it was rated "high quality by the ECRI Guidelines Trust Scorecard."
  - They further note: " The authors stated, 'patients may find tapering challenging', 'could face risks related to withdrawal', and 'if dosages are abruptly tapered, may seek other sources of opioids or have adverse psychological and physical outcomes'. They go on to say that 'some clinicians may find it easier to refer or dismiss patients from care' and 'Clinicians might universally stop prescribing opioids, even in situations in which the benefits outweigh the risks.'" [Emphasis underlined] (U.S. Pain Foundation, May 1, 2019)

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## Is the Change an Actual Change? -1

- Almost 2 months after the FDA and CDC statements, pain patients and pain physicians are still not sure if any change occurred, so things continue as before: patients having great difficulty in finding/obtaining pain medications or, in many cases, finding a physician to give them a pain medication
- CPPs are becoming more vocal and trying to influence the "system"
- However, the CDC Guidelines, while the CDC stated that the guidelines were used inappropriately, which may effect the medical aspects of health, should be used as intended (but that's doubtful as the DEA, the state regulators, health insurers and even disability administrators have cited the CDC Guidelines to justify policies to limit pain pill prescriptions)

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## Is the Change an Actual Change? -2

- USA Today published a story noting a patient had his long-term pain medication dosage reduced by a decision by a Physician who never examined him, just appeared to arbitrarily state that his dosage was too high ("Unsafe levels of opioids") citing the CDC guidelines data and the New York State's non-acute medical treatment guidelines.
- He used the CDC Guideline, said that "medical evidence does not support long-term opioid use for chronic pain patients."
  - While no RCTs have ever been done showing that patients safety take opioids for a year, those of us who have treated chronic pain patients for decades have seen this without problems

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## Is the Change an Actual Change? -4

- If it is, is hasn't happened yet!

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## Interlude

- The Federal Advisory Inter-Agency Task Force- pain management report which had >5000 comments during its draft period was finalized, May 23, 2019
- This report, by the HHS, recommended that pain management be balanced, multimodal and focused on individualized patient care
  - Stating that opioid medication should be prescribed cautiously, of at all
  - The report noted the CDC Guidelines had many negative unintended consequences, including forced opioid tapering
  - The task force noted that the CDC Guidelines were not meant to be mandatory or to be used as a state model, suggesting a more "even-handed approach"
  - It failed to recommend withdrawal of the CDC Guidelines
  - The Report states that "duration of opioid treatment for acute pain, included trauma and surgery, is best determined by providers without the need for guidelines to inform appropriate decision making"

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PAIN MANAGEMENT

BEST PRACTICES


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## The Task Force-1

- Vanila Singh, MD, the Task Force Chair and CMO of the HHS Office of the Assistant Secretary for Health noted: "There is no one-size-fits-all approach when treating and managing patients with painful conditions." Furthermore, "Individuals who live with pain are suffering and need compassionate, individualized and effective approaches to improving pain and clinical outcomes. This report is a roadmap that is desperately needed to treat our nation's pain crisis."
- The Task Force took an approach focusing on the needs of pain patients, improving their quality of life, and establishing a "therapeutic alliance" between patient and clinician"

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## The Task Force-2

- The Task Force noted several sensible points:
  - The task force did not call for a repeal of the CDC's controversial opioid prescribing guideline but said the guideline should be clarified and updated with better evidence to supports its recommendations.
  - The task force called for a more "even-handed approach" to opioid prescriptions that allows doctors to use their own clinical judgement on how to treat patients.
  - "Various health insurance plans, retail pharmacies, and local and state governments are implementing the CDC Guideline as policy, limiting the number of days a patient can receive prescription opioids even when the seriousness of the injury or surgery may require opioids for adequate pain management for a longer period. A more even-handed approach would balance addressing opioid overuse with the need to protect the patient-provider relationship by preserving access to medically necessary drug regimens and reducing the potential for unintended consequences," the task force said.

Anson, Pain News Network, June 01, 2019

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## 39 Attorneys' General Practice Medicine Without a License!

- In reaction to the Task Force's draft: The Attorneys' General (39 of them) wrote that "as a matter of public safety, there is simply no justification to move away from the CDC Guidelines to encourage more liberal use of an ineffective treatment that causes nearly 50,000 deaths a year" and
- "it is incomprehensible that officials would consider moving away from key components of the CDC Guidance"
- Regardless, "The Draft Report states that duration of opioid treatment for acute pain including trauma and surgery is best determined by providers without the need for guidelines to inform appropriate decision making."
- The AGs have a political and monetary reason to say these things: demonizing opioid medications is important- there are over 1,900 law suits filed by states, cities and others against pharmaceutical companies, opioid manufacturers and distributors and physicians (April 2, 2019): Currently (July 2019) the OK trials are in progress

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## The 39th AG

- Attorney General T.J. Donovan (Vermont) has joined 38 state attorneys general to send a letter to the U.S. Department of Health and Human Services (HHS) criticizing the Pain Management Best Practices Inter-Agency Task Force Draft Report. The letter was addressed to Dr. Vanila Singh, chief medical officer for the Office of the Assistant Secretary for Health.
- "As attorneys general, we have witnessed the devastating effect of unfettered opioid manufacturing, distribution and prescribing on our public health, social services and criminal justice systems. The well-established risks associated with higher doses of opioids, prescriptions of longer duration, and concurrent prescriptions of opioids and benzodiazepines demand continued constraints," reads the NAAG letter signed by 39 state and territory attorneys general.
- The letter includes several other concerns, including that HHS does not provide a reason for departing from "evidence-based" CDC guidelines and does not explicitly state that there is no completely safe opioid dosage.

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## Greatest Concern

- "Moving away from the CDC Guideline at this critical time would undermine ongoing legislative initiatives, as well as refinements to standards of medical care," the letter continued. "As a matter of public safety, there is simply no justification to move away from the CDC Guideline to encourage more liberal use of an ineffective treatment that causes nearly 50,000 deaths annually."

Office of the Vermont Attorney General TJ Donovan, Vermont Attorney General, April 1, 2019

- Per AG Ferguson (Washington State) in harnessing the AG Letter:
  - "In addition to eliminating prescribing guidelines, the draft report pushes the same discredited claims that opioid manufacturers made for years prior to the epidemic, including the baseless assertion that opioids only have addictive properties in certain at-risk populations."
  - In fact, many studies demonstrate that anyone who takes an opioid is at risk for misuse and addiction, especially if they are exposed to longer duration prescriptions. For example, a study of a million surgical patients who had not previously taken opioids found that each additional week of opioid treatment increased the risk for opioid misuse by 20 percent. A refill increased their risk by 44 percent. (Office of Attorney General Bob Ferguson April 1, 2019)

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## Not to Forget

- The CDC Guideline has minimal if any real Evidence Based medical evidence on 11 of 12 "recommendations"
  - 1-11 were deemed to have weak or very weak medical evidence (Types 3 and 4, below)
  - Only number 12, using MAT to treat OUD was rated at strong EBM
- EBM:
  - Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.
  - Type 4 evidence: Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations

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## June 13, 2019: OK Opioid Trials

- The major consultant for the state, Andrew Kolodny, who called J&J a "drug kingpin" was asked about his fees-
  - Apparently, he will make about $500,000 for his work in this, the first state law suites re: opioids
  - Purdue settled before trial for $270 M and Teva Pharmaceuticals settled for $85 M
  - J&J Remains on trial as this is written

Law360, Portfolio Media, June 13, 2019

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## June 2019: Pennsylvania

- Senate Bill 112- "which seeks to prevent addiction stemming from opioid prescriptions by limiting the prescription for controlled substance containing an opioid to seven days unless there is a medical emergency that puts the patients' health or safety at risk.
  - This bill would make it a crime for doctors to write a prescriptions of more than seven days for an opioid painkiller such as oxycodone or acetaminophen and hydrocodone (with exceptions for adults for cancer, terminal illness or patients who have had major surgery
  - Purpose- to cut into long term use that can lead to dependence and addiction or result in unfinished supplies that can fall in to the hands of young people or others who might abuse the pills and become addicted
  - The CDC has stressed to doctors that opioids are intended for severe short-term pain and long-term use can result in dependence and increased tolerance and risk of overdose, respiratory failure and death- the CDC has further advised doctors to prefer other forms of treatment such as non-opioid painkillers and physical therapy for long-term pain
- The main sponsor of the bill that would ban doctors from prescribing more than 7 days worth of opioids says it also time to consider stiffer penalties for doctors who overprescribe the highly addictive painkillers.
- So, to make things easier on a physician:
  - Pa. might devise punishments for physicians who give more than a week of opioid painkillers

Pennsylvania Real time News, January 26, 2019

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## June 29, 2019: APS

- The American Pain Society (APS) filed for bankruptcy after an overwhelming vote by its members to dissolve the financially troubled medical organization
- The APS was targeted as a defendant by Simmons Hanly Conroy and several other law firms seeking to recover billions of dollars in damages in opioid litigation cases
- It was felt that it was "pointless to continue operations just to defend against superfluous lawsuits."

Anson, Pain News Network, June 29th, 2019; MedPage Today, Business Wire

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## July 8, 2019: The US Surgeon General

- US Surgeon General Jerome Adams, MD- notes that post-op, Tylenol should be sufficient for post-op pain
- He then tweets about a 2015 study showing, supposedly, that 1 gram of IV Tylenol was found equivalent to IV Morphine (based on body weight, but in some cases greater than 6 mg)
  - This study was done in Iran in 2015 (www.ncbi.nlm.nih.gov/pmc/articles/PMC4608332/)
  - However, evaluation of the study data reveals significant problems
    - i.e. "presentation of side effects was similar in both groups" (IV acetaminophen vs. IV morphine)

J. Bloom, American Council on Science and Health, July 8, 2019

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## July 13, 2019: USA

- A bill introduced by West Virginia Democratic and Republican senators , which they call the "FDA Opioid labeling Accuracy Act would "Prohibit the FDA from allowing opioids to be labeled for intended use of "around-the-clock", long-term opioid treatment" until a study can be completed on the long-term use of opioids.
  - Per Jeffrey Singer of the Libertarian Cato Institute: Senator Joe Manchin (D-WV) and Mike Braun (R-IN) are still trying to address the fentanyl and heroin overdose crisis- soon to be joined by a methamphetamine and cocaine overdose crisis- by denying chronic pain patients access to pain relief."
  - Per Dr. Manchin, (oops!) "the FDA Opioid Labeling Accuracy Act would prohibit opioids from being labeled for intended use to treat long-term chronic pain, except for cancer pain, end-of-life care or when a prescriber has determined that all non-opioid treatments are inadequate or inappropriate."
    - I think there will be strings attached if this should pass!

Coughlan E, National Pain Report, July 13, 2019

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## Caveats

- Not noted: Exceptions to state opioid prescription rules secondary to:
  - Pharmacy decisions (Walgreens, CVS, Walmart, etc)
  - Insurance Company decisions
  - CMS decisions
  - VA decisions
  - Forced tapering
  - Mandatory use of CDC Guideline MMEs

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## August 14, 2019: Preventing OUD by Ignoring Patients' Pain-1

- For years prior to the CDC Guidelines, pain patients were treated purely by protocol, with little interest in treating the individual patient
- The CDC Guidelines set "new standards of care" using opioids
- The draconian issues that ensued caused the CDC to issue a clarification of its own guidelines (April 2019)
- Things deteriorated to the point that 300 medical experts, including three former White House drug czars wrote a letter to the CDC in response to these guidelines, stating the guidelines were harming patients
  - The letter noted "Payer-imposed payment barriers…high stakes metrics imposed by quality agencies and legal or professional risks for physicians often based on invocation of the CDC Guideline"

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## August 14, 2019: Preventing OUD by ignoring Patients' Pain-2

- Per the author, Subhash Jain, MD:
  - Insurers refused to cover pain medication for a chronic back pain patient, but they'd pay for surgeries (his patient)
  - A cancer patient was denied medication based on the number of pills prescribed (his patient)
  - It appears that we may be returning to the time when pain was not cared for- when "patients with genuine need are denied access to the care that they need"
  - While the "medical profession was complicit in the epidemic of opioid abuse in the United States," medical professionals are also key to the solution

Jain S, Harvard Business Review, August 14, 2019

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## August 21, 2019: No Correlation between Medication Abuse or Addiction Rates-1

- "The dramatic increase in deaths involving prescription analgesics since 2000 cannot be explained by a dramatic increase in misuse or addiction rates, because there was no such increase"
- Prior National Survey on Drug Use and Health (NSDUH) data showed the rate of "prescription pain reliever misuse" fell in 2016 and 2017, while deaths involving those drugs continued to rise.
  - The rate fell again in 2018
- Per the NSDUH, rates of "past-month nonmedical use" and "past year Pain reliever use disorder" barely changed from 2002 (when the survey in its current form began) through 2014, even as deaths involving these drugs rose by 175%

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## August 21, 2019: No Correlation between Medication Abuse or Addiction Rates-2

- In 2017, only 30% of "opioid-related deaths" involved prescription analgesic and the records compiled by the CDC indicated that 68% of these cases also involved heroin, fentanyl, cocaine, barbiturates, benzodiazepines or alcohol
- The role of drug mixtures is considered larger than the records suggest
  - In NYC, with one of the country's most thorough systems for reporting drug-related deaths, 97% of them involved more than one substance
- The "opioid crisis" which appears to be "a part of a long-term upward trend in drug related deaths that began in 1979, might more accurately be described as a problem of increasingly reckless polydrug use, a problem that cannot be solved, and may be worsened- by demanding wholesale reduction in pain pill prescriptions."

https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf assessed August 24, 2019; Sullum J, REASON, 8/21/2019

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## QUESTIONS?

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