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Research Article

An Indictment of US Public Health Policy on Pain Management

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Abstract:

This paper reviews and assesses published clinical and demographic data that in the aggregate reveal that the entirety of present US public health policy on regulation of opioid pain relievers is fundamentally misdirected and wrong on both facts and ethics.

Methodology: critical review of clinical literature of addiction and pain management.

Keywords: Opioid Analgesics, Public Health, Policy, Regulation, Clinical Practice, US Centers for Disease Control and Prevention, Opioid Guidelines, Drug Enforcement Administration, Indictment

Background

For more than a decade, the US and international public has been hearing that prescription opioid pain relievers are always and forever a "*BAD THING"* -- and that doctors and Big Pharma companies are supposedly responsible for an epidemic of addiction and drug overdose related deaths. In effect, if not intentionally, the de facto public health policy of the United States with respect to regulation of opioid pain relievers and of clinicians who employ them in pain management has become one of intentionally restricting availability of opioid therapies to patients, and driving doctors who employ opioids out of practice or into prison – even when consistent with prescribing practices approved by the US Food and Drug Administration.

However, many Agency assertions underlying present policy are now known widely to be misrepresentations of fact. More fundamentally, the US Centers for Disease Control and Prevention, the US Veterans Administration and key law enforcement authorities are fully aware of this reality and have continued defending themselves against public scrutiny or challenge by any means, fair or foul. [1] [2]

It can also be argued compellingly – as the author has, in multiple published venues [3] [4] – that the recent "National Opioid Settlement" is bogus as a three-dollar bill. Its associated injunction published secretly with the collusion of 30+ State Attorney Generals is destroying patient lives and pharmacy businesses by creating entirely unjustified shortages of legitimately prescribed controlled substances (opioid analgesics and others). [5]

One of the prevailing memes that has distorted and misdirected public health policy on pain management is the outright silly idea that any patient who uses prescription opioids is at immediate risk of addiction or overdose. A second false meme is the idea that doctors prescribing to their patients have supposedly contributed in major ways to a rising death toll in drug overdose related mortality. [6]

Both of these memes are outright lies -- and in the view of the author, many of the people telling those lies are fully aware that they are doing so. This paper offers evidence of their incompetence and bad faith.

Gabriel Brat Et Al:

Let us address the first meme first. Multiple studies prove that immanent risk of opioid addiction is simply not a significant consequence of prescribing. Two very large published papers provide conclusive medical evidence of this reality. [7], [8]

In 2018, Gabriel A Brat and his colleagues published an analysis of 37,651,619 medical records of commercially insured patients, between 2008 and 2016 [7]. Each of these patients had undergone one of eight common surgical procedures:

- General Surgery
- Gynecology
- Neurology
- Orthopedics
- Plastics
- Thoracic
- Urology
- Vascular

Among this large cohort, 1,017,116 patients were identified who were assessed to have been "opioid naïve" prior to surgery. This term was defined to mean that the patient's opioid use prior to surgery was a maximum of seven days over the period of 60 days prior to surgery.

Three diagnostic codes were identified in electronic health records by the authors as evidence of "opioid misuse":

- Opioid dependence
- Opioid abuse
- Opioid overdose

In the data collected for this study, the median follow-up was 2.67 years; median time to "misuse" as the authors defined it was 1.74 years. (183.2 cases per 100,000 person-years). Median dose level in the post-surgical population was 50 morphine milligram equivalents per day. Rate of "misuse" as defined by Brat et al, was 0.6%.

In fairness to Brat et al, it should be acknowledged that they wrote from a significantly anti-opioid perspective. Only in detailed examination of their data do we come to understand that their interpretations of the data were incorrect even though sincere and far reaching for other reasons [references below are from the original paper].

"Overprescribing of opioids is thought to be a major contributor,7 where two thirds of opioid misuse can be attributed to opioids obtained through a single physician.2 Overprescribing enables opioid diversion and increases the potential for addiction.89 Surgical patients are nearly four times more likely to get post-discharge opioids than their non-surgical counterparts. Orthopedic surgeons alone were responsible for 7.7% of opioid prescriptions in 2009.10 11 Despite these numbers, surgeons have yet to find the right balance of opioid prescriptions: between 3% and 10% of opioid naive patients become chronic users, and emerging research suggests that as many as 80% of prescribed pills in the remaining group of patients are unused.12"

Since 2016, it has become known that "opioid dependence" does not comprise a voluntary "misuse," as the term is applied in clinical practice. Dependence is a purely physiological outcome characterized by emergence of withdrawal symptoms and/or breakthrough pain when opioid dose levels are tapered down too rapidly after days or weeks of sustained use. [9]

Confusion over the appropriate uses of this term was created by the overly-broad definition for "opioid use disorder" proposed in the Diagnostic and Statistical Manual (Version 5) of the American Psychiatric Association. On grounds of poor field research, this document was repudiated two weeks before publication by the National Institutes of Mental Health, as a framework for organizing mental health research [10].

It is observed in clinical practice, that incidence of "opioid dependence" among patients who are prescribed opioids is significantly greater than the incidence of substance use disorder seen in patients prescribed opioids [11]. Although the author has been unable to locate published estimates of the ratio, it seems reasonable to suggest that the ratio in clinical practice may be on the order of one case of iatrogenic addiction versus at least five of opioid dependence -- if not greater. If we accept this estimate as a rough order of magnitude postulation, then the incidence of opioid overdose or substance use disorder in the patient population addressed by Brat and his colleagues may be on the order of one patient per thousand who are treated with opioids for post-surgical pain.

How many clinicians today would feel confident basing their decisions on whether to prescribe opioids for pain on restriction of pain relieving medications to protect a potential cohort of one patient in one thousand? Surely such a low incidence is within the range of confounds on diagnosis itself, introduced by poor medical training [12] and very short encounter times in the clinical office, due to heavy patient loads and billing restrictions imposed by third-party medical insurers.

A second dimension of the findings of Brat et al is also of high importance. The findings confirm that incidence of protracted prescribing and diagnostic codes for opioid dependence, overdose, or substance use disorder following surgery are significantly higher for some categories of surgery than for others. Notably, incidence of prolonged prescribing is highest for procedures like Total Knee Replacement (TKR) or orthopedic back surgery, and lowest for gynecological procedures. Failure rates for TKR and disc fusion (for instance) are among the highest in surgical practice. Incidence of complications from gynecological surgeries is lower [13],[14]. Thus the findings of Brat et al should have been expected – albeit for reasons other than those they initially posited. By contrast to their conclusions, it is reasonably arguable that protracted prescribing of opioids is not a significant "function of" opioid dose or type. Long-term prescribing may instead be the consequence of higher failure rates and higher levels of persistent pain following some types of surgery.

Oliva et al

In 2017, Professor Elizabeth M Oliva and her colleagues at the US Veterans Administration set out to determine if factors in patient medical history might identify patients at highest risk for opioid overdose or suicide following exposure to clinically managed opioid analgesics. The result of their work was the highly accurate STORM predictive model. [8]

Oliva et al processed two years of Veterans Administration electronic health records - 2010 to 2011 - for 1.135 million patients under clinical management incorporating opioid analgesics for pain. They documented 50 factors in patient records and generated odds ratios for the occurrence of overdose or suicide events in patients where those factors were noted in medical records.

Overdose or suicide events occurred in 2.5% of all patients followed – a significantly higher risk level than estimated in commercial insurance records. This statistic was an expected outcome. For a variety of demographic and career-exposure reasons, veterans display significantly higher risks than civilians who have never served [8].

From Table 1 in Oliva et al, we learn several startling facts for four general categories of risk indicators.

1. The strongest predictors for higher risk in Veterans Administration patients (and by inference, also among civilians) are related not to opioid prescribing as such, but rather to any medical history of past inpatient mental health visits, opioid overdose or suicide attempts, Emergency Room visits, or hospitalization for detox.
2. Risk ratios for these predictors vary between four and 23, relative to opioid prescribing as such. Of the top eight predictors, only one (three or more sedating medications prescribed) is related to prescribing history as such A detailed extract of odds ratio data from Oliva et al is provided at Table 1 below.

Table 1: Factors in VA Medical Patient History [Oliva et al]

Variable in Patient History	Number of OD or Suicide Events	Odds Ratio
Overdose or suicide event	3,879	23.1
Detoxification	640	18.5

Inpatient Mental Health Treatment	6,769	16.6
Sedative Use Disorder	809	11.2
Opioid Use Disorder	2,779	8.0
Stimulant Use Disorder	4,613	8.1
3 Classes of Sedating Pain Meds	562	6.1
Bi-Polar Disorder	4,276	5.8
Other Mental Health Disorder	562	6.1

Howre Jalal et al

Yet a third major false meme in public policy is also contradicted by published demographic data accumulated by the US Centers for Disease Control and Prevention (CDC) and the National Bureau of Statistics. This is the false idea that prescription drugs are responsible for the majority (or even a reliably large portion) of all accidental drug overdose deaths. A major study of drug-related mortality published in the prestigious journal *Science* in 2018, conclusively refutes this notion.

Howry Jalal and Jeanne M Buchanich et al addressed the "Changing Dynamics of the Drug Overdose Epidemic in the United States from 1979 through 2016" [16] They downloaded and graphed drug overdose mortality reports from US CDC, in eight contributing categories.

- Heroin
- Prescription Opioids
- Methadone
- Synthetic Opioids Other than Methadone
- Cocaine
- Unspecified Narcotics
- Methamphetamine
- Unspecified Drugs

As these authors observed: [15]

"There is a developing drug epidemic in the United States. Jalal *et al.* analyzed nearly 600,000 unintentional drug overdoses over a 38-year period. Although the overall mortality rate closely followed an exponential growth curve, the pattern itself is a composite of several underlying subepidemics of different drugs. Geographic hotspots have developed over time, as well as drug-specific demographic differences."

Significant findings of this study included:

1. Overall aggregate US drug overdose mortality throughout the data collected historically closely follows an exponential curve, Magnitude of contributions from various components varies from year to year and region to region of the US. Arguably, the US "opioid crisis' comprises not one "epidemic" but thousands of mini-epidemics that vary in intensity from US county to county [16]. Several factors appear to play roles in these variations – notably, socio-economic determinants of health, drug cartel transportation networks, "pill mill" operators and the conditions under which people live daily [16], [17].
2. The number of morality reports listing prescription drugs as contributing causes has never been higher than 22% of total drug overdose mortality during this 37 year period. Thus patients clinically managed by a doctor cannot have been the major drivers in this complex crisis. This reality is further confirmed from additional and more recent sources [18].
3. There is also significant uncertainty in contributing causes of death in the reports of County Coroners or Medical Examiners. The sum of reports referencing unspecified narcotics or unspecified drugs was also about 22%.
4. From 2010 through 2016, deaths involving synthetic opioids other than Methadone or stimulants like Methamphetamine or Cocaine, or combinations among the three can be said to have "skyrocketed." US CDC has acknowledged the contribution of illegally manufactured and imported Fentanyl in counterfeit prescription pills sold in street markets as the major driver in this increased mortality [19]. These combinations are almost never seen in clinically managed pain patients.

Aubry and Carr -- and Others

Most technically or professionally trained readers have encountered the statement "correlation is not cause." But we may be less familiar with the associated corollary to this statement:

"Without correlation, there can be no cause-and-effect relationship."

In an exhaustive correlation analysis of US opioid prescribing volumes versus overdose-related hospitalizations [20] Larry Aubry and B Thomas Carr have demonstrated that there is no correlation between volume of opioids prescribed in the US from 2010 to 2019 versus either hospital admissions for opioid overdose treatment or mortalities involving prescription opioids. As opioid prescription volume was driven downward by US public health policy and the active advocacy of US CDC, overdose-related mortality continued to sharply increase.

The findings of Aubry and Carr have been confirmed independently [21].

Fundamental Errors in US Public Health Policy

Omissions of key studies from discussion and analysis are by no means the only serious – perhaps fatal – errors in US public health policy. There is ample published evidence of deliberate and unconscionable misdirection in such policy [2].

Specifically:

1. It has been well known for over 20 years that the metabolism of opioid pain relievers is moderated by individual genetics of the CYP-450 enzyme series in the human liver. There may be at least a 12-to-1 range in minimum effective dose for opioid analgesics – among many other common medications [9], [23].
2. Although genetic effects are mentioned in one footnote to a table in the revised and expanded 2022 CDC opioid prescribing guidelines, this mention was made only to note

that such effects are not addressed in computing Morphine Milligram Equivalent Dose for various opioid analgesics.

3. Members of the Opioid Workgroup of the National Centers for Injury Control and Prevention appointed to oversee draft findings of the authors of the 2022 CDC Guidelines, were also aware of genetic effects [2]. But nowhere in the CDC Guidelines are the effects of individual opioid metabolism even addressed, much less analyzed. This glaring omission in effect renders the CDC Guidelines scientifically invalid if not outright fraudulent.
4. The 2022 CDC opioid prescribing guidelines, like the 2016 predecessor document, recommend that "non-opioid" therapies are "preferred" to opioids for both acute and chronic pain. However, unmentioned in the references supporting this recommendation is the fact that there are no published trials directly comparing opioids with non-invasive, non-pharmacological therapies on an "either/or" basis. Likewise, the state of methodological rigor in the existing trials literature for non-invasive therapies is simply abysmal.
5. In a 2019 Systematic Outcomes Review by the Agency for Healthcare Research and Quality, just over 220 published trials of non-invasive therapies passed a rigorous quality review, from over 5,000 published trials; of these, over half were evaluated as "medical evidence weak"; improvement in pain levels was assessed at two points on a Visual Analog Scale of zero to ten. But none of these significant limitations were mentioned in the executive summary of the review [22]
6. The term "risk" is mentioned over 400 times in the 2022 US CDC opioid prescribing guidelines. The term "taper" appears 50 times. However, neither the guidelines nor any of the references incorporated in them offer a validated patient profiling instrument by which to accomplish risk versus benefits assessment as directed in the guidelines. Likewise, none of the references address the fact that tapering (whether voluntary or involuntary) is associated with elevated risks of patient mental health collapse and overdose [24].

   The message clearly communicated to clinicians "between the lines" in the CDC prescribing guidelines is that clinicians are themselves at risk of sanctions if they prescribe any opioid to any patient for any reason.
7. Finally, it is very telling that the trends and drug overdose data reported by Jalal et al have been known to the US Drug Enforcement Administration (DEA) since at least as far back as 2020. Graphics reported by Jalal were presented in detail to a February 2020 conference of clinicians renewing their DEA licenses to prescribe controlled substances [25]. However, this knowledge has apparently not impacted the ongoing DEA witch hunt against doctors who prescribe opioids to patients in pain. [26]

Conclusions: An Indictment of Us Public Health Policy on Pain Management

From data published by the US CDC itself – and in direct contradiction to its public declarations -- it is clear that doctors prescribing to their patients in pain are not now and have never been a significant cause of our US opioid crisis. That distinction belongs instead to illegal or diverted street drugs. Likewise, from the largest available studies of outcomes from opioid prescribing, it is clear that addiction in medical patients is so rare that it cannot be measured or predicted accurately in individuals.

On the very rare occasions when drug overdose or suicide does occur among medical patients treated for pain, previous mental health issues are the dominant risk factors -- not opioid prescribing.

It is likewise clear that both US public health and law enforcement authorities are completely aware that present policy on pain management is profoundly lacking in science, medical ethics and simple justice. In the vernacular, it might be said that it is time for both to "get out of Dodge" [27]

There is no reasonable prospect of "solving" our US opioid crisis by denying pain care to millions of US citizens, or persecuting hundreds more clinicians out of pain medicine or into prison. Present US public health policy on regulation of opioid analgesics and doctors who employ them is clearly fraudulent. That policy is in need of major revision and redirection. It is time for US public health and law enforcement authorities to start that process. Public repudiation and withdrawal of US CDC and Veterans Administration opioid prescribing guidelines may be a necessary first step.

About the Author:

Richard A Lawhern PhD is a technically trained data analyst and technology analyst. He is recognized as a subject matter expert on the intersections of US public health policy and the practices of pain medicine and addiction medicine. He has 28 years' experience in this field, having authored or co-authored over 250 papers, articles, and interviews in a mixture of peer-reviewed or editor-reviewed journals and mass media.

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Also pertinent: this paper has been edited and expanded from another paper accepted for publication by KevinMD [28] in November 2024. This venue is arguably the most widely read healthcare newsletter in the US. When published, the KevinMD manuscript will be copyrighted to that publisher.

The present paper is offered to *Nursing and Primary Care*, as a public service to clinical professionals and patients whose lives and livelihoods are being destroyed by misdirected public health policy. It will be publicized widely to press, lawyers and healthcare regulators. [29]

Conflicts of Interest:

Research reported in this paper has not been funded by any organization. The author declares no financial or professional conflicts of Interest.

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