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United States Centers for Disease Control and Prevention, Veterans Administration, and Law Enforcement Versus The "Opioid Crisis" – Incompetence or Bad Faith?

Richard A. Lawhern, PhD [1]

[1] Volunteer, Speakers' Bureau of the US National Campaign to Protect People In Pain

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ABSTRACT

Introduction: This paper provides an overview of major scientific errors and mis-directions in published guidelines in the US, Canadian, and United Kingdom addressing prescription of opioid pain relievers to patients with chronic severe pain. Key papers in the clinical literature of pain and addiction are discussed and their significance assessed. Major fatal errors of public policy and practice are identified.

Methods: Critical review and analysis of key studies in the clinical literature.

Findings: Fundamental assumptions and assertions in prevailing public health policy restricting prescription of opioid analgesics are demonstrated to be fundamentally wrong on science, on facts, and on ethics. Consequences of these fatal errors are seen in the denial of safe and effective pain care to millions of patients in severe pain; deserted patients are committing suicide in significant numbers. Doctors are leaving medical practice or being persecuted or imprisoned by law enforcement on false grounds. The author calls for major changes in policy direction and implementation.

Introduction

The United States and much of the world are now involved in a profoundly contentious public health policy debate concerning the sources of and remedies for what has been termed "the Opioid Crisis." Opioid prescribing guidelines written and published by the United States Centers for Disease Control and Prevention (US CDC), the US Veterans Administration (VA) and similar organizations in Canada and the United Kingdom are a central focus of this debate. The impact of these guidelines has been to support the widespread criminalization of medicine, particularly on the part of the US Drug Enforcement Agency (DEA), Federal and State law enforcement, and some US State Boards of Medicine.

Fundamental assumptions of several guideline documents include:

1. That the origins of a worldwide opioid crisis have deep roots in over-prescribing of opioid analgesics by healthcare providers to their patients,
2. That any and all patients who are prescribed opioid analgesics are at immediate and significant risk of opioid addiction and/or overdose,
3. That restrictions on opioid prescribing and on doctors who prescribe are a necessary step in moderating the current "opioid epidemic" of addiction and overdose deaths.

This paper offers conclusive evidence that all three of these assumptions are not only false, but that writers and approving officials of the US CDC and VA prescribing guidelines were aware of their own fatal errors before publication; these officials chose to publish regardless of predictably horrific consequences for millions of patients who would be deserted in agony. By similarity to US policy, the public health practices of countries throughout the world have had similar terrible impacts on both patients in pain and their healthcare providers.

Methodology

Critical review of the clinical literature and analysis of key seminal papers.

Background

At age 80, I am a widely published healthcare writer and data analyst [1], having authored or coauthored over 300 papers, articles and interviews in peer reviewed journals and mass media during 28 years. My "beat" is public health policy for treatment of severe pain and addiction.

I am motivated. I interact every week with hundreds of US and Canadian patients and caregivers who can no longer find a doctor to treat their pain, or a pharmacy willing to dispense legitimate prescriptions for opioid analgesics. From extensive research, I am convinced that "everything the US government thinks it knows about the opioid crisis is wrong." [2] Patients and doctors are being harmed needlessly.

For more than a decade, the US public has been hearing that prescription opioid pain relievers are always and forever a "*BAD THING*." Doctors and Pharma companies are supposedly responsible for an epidemic of addiction and drug overdose deaths. However, patients are being denied pain care all across America. Doctors are being sent to prison [3] for imagined "offenses" that have harmed not one patient.

The US CDC, VA, and law enforcement (Drug Enforcement Administration - DEA) have chosen to "pile on" this catastrophe. They have assumed without supporting evidence that doctors are guilty of causing widespread addiction and overdose in patients who are treated with opioid pain relievers. The de facto institutional "solution" for this mess is to deny effective pain relief to people in agony and to persecute their healthcare providers based on unscientific innuendo and prosecutorial slight-of-hand, rather than science.

I believe CDC and VA knew they were lying before they published their restrictive prescribing guidelines. Despite widespread and predictable damage from their policies to millions of people denied safe and effective pain treatment, the Agencies continue defending themselves against public challenge by any means, fair or foul. [4]

Three Landmark Studies

Three major studies demonstrate beyond any doubt that US, UK, and Canadian healthcare agencies are guilty of gross incompetence, bad faith or both. [5]

GABRIEL BRAT ET AL

In 2018, Gabriel A Brat [6] and his colleagues reviewed records of 37 million commercially insured patients for six years, to identify a million "opioid naïve" patients who underwent eight types of surgery. These patients had been prescribed opioids for no more than seven days in the sixty days immediately preceding surgery.

Brat et al defined "opioid misuse" as any diagnosis of opioid "dependence", "abuse" or "overdose" during up to six years following surgery. Estimated rate of such "misuse" was 0.6% (six patients per thousand) within six years.

Unlike Brat et al, we now know that "dependence" is not a voluntary misuse of opioid pain relievers. It is a purely physiological response [7] to prolonged opioid use at doses strong enough to build tolerance. Doctors also know that dependence is much more frequent in patients under a doctor's care, than are either addiction or overdose.

According to the American Medical Association, [8] "an estimated 3% to 19% of people who take prescription pain medications develop an addiction to them." The work of Brat strongly contradicts that estimate and is confirmed by work of Dr. Nora Volkow, [9] Director of the US National Institute on Drug Abuse. Addiction is a very rare and unpredictable outcome of prescribing.

If opioid dependency occurs even as few as five times more often than opioid addiction among post-surgical patients, then the estimated number of post-surgical patients in Brat's large records review who may actually be in danger of addiction caused by clinical treatment is on the order of one patient in a thousand or *substantially* less. Some researchers would put the estimate at one in 100,000.

Someone should tell us: how does such a low risk factor justify under-treating the pain of 999 patients out of 1,000? And how might a clinician reliably predict which of a thousand patients in pain might be vulnerable to substance use disorder?

Brat et al also found that prolonged prescribing following surgery was much more frequent for some types of surgery than for others. Prolonged prescribing is in fact highest for procedures like Total Knee Replacement (TKR) or orthopedic back surgery, and lowest for gynecological procedures. Thus, it may reasonably be argued that lengthy prescribing of opioids is not caused by opioid prescribing. Extended prescribing may instead result from higher failure rates and more persistent pain following some classes of surgery.

ELIZABETH OLIVA ET AL

In 2017, Elizabeth M Oliva and colleagues at the US Veterans Administration set out to determine if patient medical history might allow identification of patients who were at higher risk for opioid overdose or suicide following exposure to prescription opioids. The result of their work was the highly accurate STORM predictive risk model.[10]

The STORM model was developed from two years of Veterans Administration electronic health records for over 1.1 million patients who had been treated with opioids for pain. 50 factors in patient records were documented and odds were estimated for the occurrence of overdose or suicide events in patients where those factors appeared.

Veterans have higher risks than civilians who have never served. Overdose or suicide attempts occurred in 2.5% of VA patients within a year. However, the strongest predictors for high risk were related not to opioid prescribing, but to a medical history of inpatient mental health visits, opioid overdose or suicide attempts, Emergency Room visits, or hospitalization for detox. Odds ratios for these predictors were four to 23 times higher than for opioid prescribing.

HOWRE JALAL ET AL

Another major false theme in public policy is also contradicted by published data of the US Centers for Disease Control and Prevention (CDC). This is the false claim that prescription drugs are responsible for some reliably large portion of all accidental drug overdose deaths. A 2018 study published in the prestigious journal *Science*,[11] conclusively refutes this notion.

Jalal and his colleagues downloaded reports from US CDC, for 600,000+ accidental drug overdose deaths that occurred from 1978 to 2016. As these authors observed:

"There is a developing drug epidemic in the United States... Although the overall mortality rate closely followed an exponential growth curve, the pattern itself is a composite of several underlying sub-epidemics of different drugs..."

However, prescription drugs have never appeared in more than 22% of all death reports in any year, and often appeared in combination with illegal opioids or stimulants. The same pattern [12] has continued since 2016, with even lower contributions (~12% in 2022) by prescription drugs. Thus, prescriptions have never been the major driver in drug overdose deaths. *EVER!* Such deaths are certainly tragedies when they occur, but contrary to the posturing of US, Canadian, and United Kingdom (UK) healthcare agencies, they are not an "epidemic" and doctors didn't cause them.

Denial of Patient Pain Care in United Kingdom and Canada

The same conditions observed in US pain medicine are also prevalent in Canada and the UK. Prescribing guidelines of the Royal College of Physicians published by National Institute for Health and Care Excellence [13] demonstrate the same fatal errors as appeared in the CDC guidelines of 2016 and 2022. A quotation from this document is highly telling:

"Based on their experience, the committee agreed that even short-term use of opioids could be harmful for a chronic condition. The evidence of long-term harm, along with lack of evidence on effectiveness of opioids, persuaded the committee to recommend against starting opioid treatment for people with chronic primary pain…"

Like the US CDC and VA guidelines, this document recommends against use of opioid analgesics solely on a basis of opinions unsupported by data or clinical references. Like the US guidelines, NICE is utterly silent on the implications of genetic polymorphism in liver enzymes that mediate most drug metabolism, including opioids. Strong, sweeping recommendations are made from very weak clinical evidence and opinion unsupported by data or trials.

The Canadian Guideline for Opioid Therapy and Chronic Noncancer Pain provides comprehensive recommendations to

"…assist healthcare providers in the safe prescription of opioids. It emphasizes the need to restrict opioid doses to less than 90 mg morphine equivalent per day (MED) to minimize risks associated with higher dosage."

Again, like its US equivalents, the Canadian guideline states:

"For patients with chronic noncancer pain who are beginning opioid therapy, we recommend restricting the prescribed dose to less than 90 mg morphine equivalents daily, rather than having no upper limit or a higher limit on dosing (strong recommendation) (www.magicapp.org/goto/guideline/8nyb0E/rec/jmJ0VL)." [14]

Canadian guidelines are silent with respect to genetically mediated opioid metabolism, and strongly centered upon Morphine Milligram Equivalent Daily Dose (MMEDD). MMEDD is widely understood by clinicians to be a mythology unsupported by any large scale trials data – not a metric. [4] [15] However, the Canadian guidelines are organized around this mythology:

"Recommendation 1: When considering therapy for patients with chronic noncancer pain, we recommend optimization of nonopioid pharmacotherapy and

nonpharmacologic therapy, rather than a trial of opioids (strong recommendation) (www.magicapp.org/goto/guideline/8nyb0E/rec/LqqP6L)."

Conclusions

It is now clear that the opioid crisis is not doctors' or pharmaceutical companies' fault. Reports summarized above should be required reading for every government bureaucrat who claims otherwise, in any country of the world. The same message should be read by lawyers and legislators worldwide. The message to healthcare Agency heads who have destroyed the lives of millions is plain. It is time for government agencies in multiple countries to publicly repudiate and withdraw their published opioid prescribing guidelines and end political interference in the practice of evidence-based medicine. [16]

About the Author

Richard A Lawhern PhD is a technically trained non-clinician data analyst and healthcare writer with 28 years' experience in the public health policy for regulation of prescription opioid analgesics and clinicians who employ them. He is a member of the Speakers' Bureau of the [US] National Campaign to Protect People in Pain. He declares no financial or professional conflicts of interest. Email point of contact: Lawhern@hotmail.com.

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