PAINWEEK

Year of the Locusts: The CDC Guidelines Impact on Practitioners and Patients

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Disclosures

- 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 clinical alternatives to treat these patients without dealing with more opioids and overdose deaths

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Topic Agenda

- The current situation
- How the guidelines were developed
- Who they were developed for
- Opioid analgesic overdoses
- Opioid tapering
- The real opioid crisis: heroin and fentanyl

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The Facts

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AAPM Facts and Figures on Pain

- Pain affects more Americans than diabetes (25.8M), heart disease (16.3M), CVA (7.0 M) and cancer (11.9M) combined[2,3,4]
- There are 100M Americans with chronic pain[2]
- Total annual cost of health care due to pain ranges from $560 billion to $635 billion (in 2010 dollars)[2]
- Although therapies are present to alleviate most pain for those dying of cancer, research shows that 50%-75% of patients die in moderate to severe pain[5]

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Fact References

1. Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011. http://books.nap.edu/openbook.php?record_id=13172&page=1.
2. American Diabetes Association. http://www.diabetes.org/diabetes-basics/diabetes-statistics/
3. Heart Disease and Stroke Statistics—2011 Update: A Report From the American Heart Association. Circulation 2011, 123:e18-e209, page 20. http://circ.ahajournals.org/content/123/4/e18.full.pdf
4. American Cancer Society, Prevalence of Cancer: http://www.cancer.org/docroot/CRI/content/CRI_2_6x_Cancer_Prevalence_How_Many_People_Have_Cancer.asp
5. A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients. http://jama.ama-assn.org/cgi/content/abstract/274/20/1591

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The CDC Guidelines

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CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016

- From 1999 to 2014 greater than 165,000 deaths from opioid overdose from opioid pain meds (alone or in combination) in the US
- In 2014, 14,000 people died from prescription opioids (prescribed and not prescribed)
- Most commonly implicated: methadone, oxycodone, and hydrocodone (CII in 2014)
- Opioid naïve: no consistent daily opioids for at least 1 week (same doses, same intervals, same opioid)
- Opioid tolerant: opioid use ≥7d (morphine 60 mg/d, oxymorphone 20 mg/d, oxycodone 30 mg/d, hydromorphone 8 mg/d, (hydrocodone 40 mg/d, tapentadol 300 mg/d, fentanyl transdermal 25 mcg)
- If no legal pain medication obtainable, heroin is easy to find
- CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 Recommendations and Reports / March 18, 2016 / 65(1);1-49

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Intent of CDC Guideline

- Chronic persistent pain variously defined as persistent pain >3 months or past the time of normal tissue healing
- Few studies rigorously assess the long term benefits of opioids for chronic pain with outcomes examined at least 1 year later
- Guideline intent to improve communication between clinicians and patients
- RE: risks vs benefits of opioids for chronic pain, improve safety/effectiveness of pain treatment, reduce risks associated with long term opioid therapy

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Intent of CDC Guideline (cont'd)

- CDC guidelines provide "recommendations" for the prescribing of opioid pain medication by primary care clinicians for chronic pain (>3 months or past the time of normal tissues healing) in outpatient settings exclusive of active cancer treatment, palliative care, and end of life care

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There is abundant evidence for use of opioid analgesics for chronic pain

- Gilron I, Tu D, Holden RR, et al. Combination of morphine with nortriptyline for neuropathic pain Pain. 2015 Mar 5
- Backonja, MM. The role of opioid therapy in the treatment of neuropathic pain. Continuum Lifelong Learning Neurol 2009;15(5):84–100.
- Hanna M, O'Brien C, Wilson MC. Prolonged-release oxycodone enhances the effects of existing gabapentin therapy in painful diabetic neuropathy patients. Eur J Pain. 2008 Aug;12(6):804-13.
- Gilron I, Bailey JM, Tu D, et al. Morphine, gabapentin, or their combination for neuropathic pain. N Engl J Med. 2005 Mar 31;352(13):1324-34
- Gimbel JS, Richards P, Portenoy RK. Controlled-release oxycodone for pain in diabetic neuropathy: a randomized controlled trial. Neurology. 2003 Mar 25;60(6):927-34

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12 Recommendations for Consideration (Annotated) from the CDC

Grouped into 3 areas for consideration

1. Determine when to initiate or continue opioids for chronic pain
2. Opioid selection: process, dosage, follow up, and discontinuation
3. Risk assessment and addressing harms of opioid use

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EBM

- Type 1 evidence: Randomized clinical trials/overwhelming evidence from observational studies.
- Type 2 evidence: Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.
- 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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Results:

- Recommendations 1-11
  - All 3 (Weak Evidence) or 4 (Very Weak Evidence)
- Only Recommendation 12
  - 2 (Strong Evidence)

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What are Morphine Milligram Equivalents (MME) or MED, OME?

- Definition and purpose of MME
- MME, also called morphine equivalent dosing (MED) or oral morphine equivalent (OME), provides a means of comparing doses of analgesics with different potencies and mechanisms of action (MOA)[1]
- Equianalgesic doses of different opioids provide comparable analgesic efficacy
- Because MME is based on equianalgesia, it can be applied to non-opioids
- Morphine milligram equivalents (MME)/day; the amount of morphine an opioid dose is equal to when prescribed, often used as a gauge of the abuse and overdose potential of the amount of opioid that is being given at a particular time[2]

1.Nielson S et al. Pharmacoepidemiol Drug Safety. 2016; 26: 733-737.2.Guideline for Prescribing Opioids for Chronic Pain. https://www.cdc.gov/drugoverdose/pdf/guidelines_at_a_glance-a.pdf. Accessed May 13th, 2017

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MEDD—Ethics

- "As the intent of publishing these conversion factors is to offer a transparent method to calculate (oral morphine equivalents) for research purposes, these calculations do not reflect these individual factors that may be important in clinical practice."

Neilson S, et al, Pharmacoepidemiol Drug Saf. 2016; 23: 733-737

- Or, to put it another way, is your 50 MEDD (morphine equivalent daily dosage) for your 150 lb patient the same as mine for my 300 lb patient???
- Do such issues deal with the type of injury (bio), the concerns (psycho), and experience (social) of the patients?

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The CDC Guideline: MME Doses for Commonly Prescribed Opioids

Equianalgesic dose conversions are only estimates and cannot account for individual variability in genetics and pharmacokinetics

Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol	0.4

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Coda

- Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. MMEs are based on mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose dependent manner as observed with medications that are solely mu receptor agonists.
  - Dowell D, Haegerich TM, Chou R, CDC Guidelines for Prescribing Opioid for Chronic Pain- United States, 2015
  - MMWR Recomm Rep 2016; 65(No. RR-1)-1-49

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CDC Guideline MME Equivalence

What is the 90 MME/Day for tapentadol?

The MME/day is calculated by taking the morphine amount (90 mg) and dividing it by the MME of tapentadol (0.4) stated in the CDC guideline. For example, 90 mg of morphine per day/0.4 = 225 mg Tapentadol per day.

Calculations of MME for tapentadol

How much would 50 mg of morphine translate to for tapentadol using the CDC 0.4 MME? Divide the total daily dose of morphine by 0.4 to get the total daily dose of tapentadol. Example: 50 mg/day morphine ÷0.4 = 125 mg/day of tapentadol

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CDC Guideline MME Equivalence (cont'd)

Calculations to remember using the CDC 0.4 MME for tapentadol:

90 mg of morphine = 225 mg/day tapentadol
100 mg of morphine = 250 mg/day tapentadol
120 mg of morphine = 300 mg/day tapentadol

- Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. MMEs are based on mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists.
- The FDA approved maximum daily dosage limit for NUCYNTA ER is 500 mg/day (250 mg/q12h)
- The FDA approved maximum daily dosage limit for NUCYNTA is 600 mg/day (700 mg on Day 1)

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, MMWR Recomm Rep 2016; 65 (No. RR-1): 1-49.
2. NUCYNTA ER [package insert]. Newark, CA: Depomed, Inc.: 2016.
3. NUCYNTA [package insert]. Newark, CA: Depomed, Inc.: 2016.

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Really?

- 2012, 259 million prescriptions for opioid pain medications written
- In 2014, almost 2 million people abused and/or were dependent on prescription medications
- 1 in 4 (25%) individuals receiving prescribed opioids for noncancer pain in a primary care setting may present with addiction issues
- Daily, 1000 ER encounters for misusing prescription opioids (independently or co-ingestion with other substances)
- PCPs prescribe 52% of opioids to chronic pain patient (2007/2008)

- CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 Recommendations and Reports / March 18, 2016 / 65(1);1–49

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"Equianalgesic" Opioid Dosing*

Drug	Equianalgesic Doses (mg) Parenteral	Oral
Morphine	10	30 (chronic) 60 (acute)
Buprenorphine	0.3	0.4 SL buccal film
Codeine	No longer available, SC Avoid Use	200
Fentanyl	0.1 (12.5 to 25 mcg transdermal)	NA
Hydrocodone	NA	20-30
Hydromorphone	1.3 to 1.5	7.5
Meperidine	75	300
Oxycodone	10 (Not yet available in USA)	20-30
Oxymorphone	1	10
Tramadol	Not Determined, Not Yet Available	Not Determined
Tapentadol	Not Available	>100-150

Note: Caution is advised in utilizing such tables and the tables are for initial use only

* Vellejo, R, Barkin, R et al. Pharmacology of Opioids in Treatment of Chronic Pain Syndrome. Pain Physician 2011, 14: E347 E360

Caution!

- Ask Dr. Google: opioid equianalgesic charts differ widely (just look at them and compare… they can be very different)
- They are a major cause of overdose and death! (and the patients don't use them)

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What's Missing from the CDC Guidelines?

- The guideline is clearly oriented toward "new" patients, rather than giving guidance to clinicians as to what to do with patients who were placed on opioids prior to our awareness of these risks
- What do you do with the "inherited pain patient" who is already on doses well in excess of the 90 MME/day dose recommendations and who is functioning well, meeting all goals and expectations?

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How NOT to Develop Guidelines

- Have a total lack of iterative evaluation
  - Don't track to see what consequences, intended and unintended, are found and fix (change) the guidelines
- Make guidelines, which are recommendations, into law, freezing them to where they couldn't be changed without significant legal activity
- Refuse to notice the problems the guidelines/recommendations are causing and still refuse to amend them
  - Significant issues with lack of function from increased pain secondary to marked decreases in opioids (agreed upon or forced)
  - Increased suicide following opioid discontinuation or marked decrement
  - "Recommendations", yet unproven, which are made into law
  - WHO Handbook for Guideline Development. March, 2010, p. 56-57. www.who.int/hiv/topics/mtct/grc_handbook_mar2010_1.pdf

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Using Opiates

- Healthcare providers through their training and experience as well as their oath to relieve suffering must be able to:
  - Learn how to select patients for opioid therapy, when indicated
  - Manage patients on opioid therapy as safely and effectively as possible

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Opioid Analgesic Overdoses

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Opioid Analgesic Overdoses = Public Health Epidemic

- Opioid analgesics are among the most commonly misused or abused pharmaceuticals
  - Not counted here is the result of using the CDC guidelines, as well as physicians "dropping out of the system"
  - When chronic pain patients can't legally obtain their *previously" prescribed opioid medications (being cut per the CDC guidelines, their physicians stopping prescribing opioids) some do turn to heroin—it's cheap and available
- Overdose deaths from prescription painkillers have increased –16,651 in 2010; >4x # in 1999 but it has decreased after that, after increasing 13% annually from 1999-2009, the death rate increase from prescription opioids has remained steady at 3% per year since 2009

- Jones CM. Arch Intern Med. 2012 Jun 25:1-2; Prescription Painkiller Overdoses in the US. www.cdc.gov/VitalSigns/pdf/2011-11-vitalsigns.pdf; Opioids drive continued increase in drug overdose deaths. Accessed May 1, 2013; www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.htm. Accessed May 1, 2013; . https://www.catd.org/blog/stop-calling-it-opioid-crisis-its-heroin-fentanyl-crisis

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High Risks Include:

- Sleep apnea (OSA)/sleep disordered breathing
- Renal or hepatic insufficiency
- Older adults
- Pregnant women
- Depression and/or other DSM-V diagnoses
- Alcohol and/or other substance use disorders

- Volkow ND, et al, NEJM, 2016; 374:1253-1263

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Hot of the Presses-1

- Seth et al (2018) and 3 other members of the CDCs Division of Unintentional Injury stated (Am J Pub Health):
  - Many overdoses involving illicit fentanyl and other illicit opioids have been counted as prescription related drug deaths
  - "Availability of illicitly manufactured synthetic opioids (e.g. fentanyl) that traditionally were prescription medications has increased. This has blurred the lines between prescription and illicit opioid-involved deaths."

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Hot off the Presses-2

- "Traditionally, the CDC and others have included synthetic opioid deaths in estimates of "rescrption opioid deaths. However, with IMF (illicitly manufactured fentanyl and derivatives) likely being involved more recently estimating prescription opioid-involved deaths with the inclusion of synthetic opioid-involved deaths could significantly inflate estimates."

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Hot of the Presses-3

- How much overestimation?
- Using the CDC's "Traditional Definition" for prescription opioids, the CDC estimated 32,445 American died from overdoses of pain medication in 2016.
- They then pronounced, using a new "conservative definition"- one that excluded the "high proportion of deaths involving synthetic opioids like fentanyl-like compounds- the death toll associated with prescription opioids was cut nearly in half to 17,087 overdoses

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Hot off the Presses-4

- The decreased number may also be incorrect secondary to other issues, per these researchers:
- The number of deaths involving diverted prescriptions or counterfit drugs is unknown: toxicology tests cannot distinguish between pharmaceutical fentanyl and illicit fentanyl;
- Drugs are not specifically identified on death certificates in 20% of overdose deaths
- Multiple drugs are involved in almost half of drug overdose deaths

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Hot off the Presses and in your face!

- If we can't get real, factual information about the problem, how can we fix the problem???

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Factors That May Skew Estimates of Overdose Deaths Attributed to Specific Drugs, Specifically Opioids

1. At autopsy, the substances tested for and circumstances under which tests are performed to determine which drugs are present might vary by jurisdiction and over time
2. The % of deaths with specific drugs identified on the death certificate varies by jurisdiction and over time
    1. Nationally, 19% (in 2014) and 17% (in 2015) of drug overdose death certificates did not include the specific types of drugs involved
    2. In addition, the % of drug overdose deaths with specific drugs identified on the death certificate varies widely by state, ranging from 47.4% to 99%.
    3. Variations in reporting across states prevent comparison of rates between states

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Factors that may Skew Estimates of Overdose Deaths Attributed to Specific Drugs, Specifically Opioids-2

1. Improvements in testing and reporting of specific drugs might have contributed to some observed increases in opioid-involved death rates
2. Because heroin and morphine are metabolized similarly, some heroin deaths might have been misclassified as morphine deaths, resulting in underreporting of heroin deaths
3. The state-specific analyses of opioid deaths are restricted to 28 states, limiting generalizability

Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep 2016;65:1445–1452. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1

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Then what Happened? An Orgy of Breast Beating

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???

- Since the CDC Guidelines became "Next to law"
  - The docs who have used opioids for years have "reconsidered"
  - All of a sudden, opioids are not appropriate and it's perfectly reasonable to halve or decrease even further the opioids of stable, functional, chronic pain patients who need more than the CDC prescribed MMEs
  - Hyperalgesia, seen in animals, has been a "good reason" to not use opioids in humans-without EBM
  - Many docs using the CDC Guidelines as an excuse stopped prescribing opioids- and more will
  - Docs who used opioids for decades suddenly decided that opioids were "the Devil"

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How to avoid the opioid prescriber dragnet

- Curated by: Jan Greene for Univadis
- March 02, 2018
- Takeaway

- Physicians who prescribe opioids need to avoid certain red flags that could draw the attention of prosecutors and state medical board officials cracking down on doctors they believe are feeding the opioid overdose crisis.

- Pittsburgh attorney Efrem M. Grail, a former prosecutor who now defends medical providers, offers tips in a Physicians Practice article:

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Avoiding the Prescriber Dragnet-1

- Keep records documenting diagnosis, treatment, and overall care of patients receiving opioid prescriptions.
- Ensure the chart demonstrates an in-depth examination has taken place.
- Be aware of whether the practice's appointment list appears to reflect an unreasonably large number of patients in a single day who couldn't all be seen properly.
- Always write prescriptions with the patient in front of you, and don't sign them for staff to fill out later.
- Avoid manually dispensing narcotics from the office if possible.
- Don't prescribe controlled substances for yourself, immediate family, friends, or neighbors.
- Don't write a prescription for a controlled substance without examining a new patient first, in person.

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Again, So What?

- NC Board adopts CDC opioid guidelines
- At its January 2017 meeting, the Board voted to adopt the CDC Guideline for Prescribing Opioids for Chronic Pain. This document, which was developed in 2016 by the U.S. Centers for Disease Control and Prevention, replaces the Board's previous opioid position statement, effective immediately.

https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain

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DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017 and 2018

- It hasn't helped that the DEA has restricted 2017 opiate production to 75% of the production in 2016, and has decreased it again by 20% in 2018.
  - OCT 04 (WASHINGTON) - The United States Drug Enforcement Administration (DEA) has reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in 2017 by 25 percent or more, according to a Final Order being published in the Federal Register tomorrow and available for public inspection today. A handful of medicines were reduced by more, such as hydrocodone, which will be 66 percent of last year's level.

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Survey on the impact of the CDC's opioid prescribing guidelines.

- The online survey of 3,108 pain patients, 43 doctors and 235 other healthcare providers was conducted between February 15 and March 11, 2017 BY *Pain News Network* and the International Pain Foundation (iPain)
- Questions Q3 through Q10 were answered by pain patients only, while Q11 through Q19 were answered by doctors and healthcare providers

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Pain News Network Survey! Survey Says:

- Survey findings:
  - The Guideline harmed pain patients, reduced access to pain care and failed to reduce drug abuse and overdoses
  - Over 70% of pain patients say that they are no longer prescribed opioid medication or are getting a lower dose
  - 8 out of 10 patients say their pain and quality of life are worse
  - 84.23 % of patients- "I have more pain and my quality of life is worse"
  - 42.08%- "I have considered suicide because my pain is poorly treated"

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The Goal:

- We must prescribe and create a patient-specific, patient-focused, patient-centered personalized treatment plan for all pain/headache patients

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Unintended Consequences:

- Individuals with pain had a 29% increased risk of dying, while those who reported "quite a bit" or "extreme" pain had a 38% and 88% increased risk of dying respectively. The study showed it was not the pain itself that increases the risk of death, but the amount of disruption of everyday living linked to having long-term pain.
- Persistent pain was associated with faster memory decline and increased probability of dementia.
- Osteoarthritis and related joint pain were strongly associated with memory loss.

Smith et al, Arthritis Care and Research, 2017; Whitlock et al, JAMA Internal Med, 2017; Innes et al, Pain Med, 2017

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Opioid Tapering

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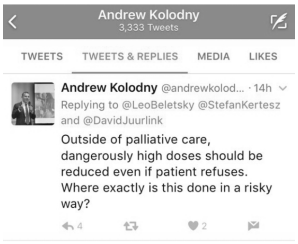
Prop Founder Calls for Forced Opioid Tapering-1



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Forced Opioid Tapering-2

- About 10 million Americans (of about 100M chronic pain patients) take opioid medication daily for chronic pain, and many are being weaned or tapered to lower doses -- some willingly, some not -- because of fears that high doses can lead to addiction and overdose.
  - The question is really, Whose Fears???
  - Yes, there is an Overdose "Crisis" but it appears to be driven by both political and societal forces, not medical issues

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Forced Opioid Tapering-3

- Kolodny's Twitter posts were triggered by recent research published in the Annals of Internal Medicine- 67 clinical studies on the safety and effectiveness of opioid tapering were evaluated. Most of those studies were considered very poor quality.
- "Although confidence is limited by the very low quality of evidence overall, findings from this systematic review suggest that pain, function, and quality of life may improve during and after opioid dose reduction," wrote co-author Erin Krebs, MD, of the Minneapolis Veterans Affairs Health Care System.
- Krebs was an original member of the "Core Expert Group" – an advisory panel that secretly helped draft the CDC opioid prescribing guidelines with a good deal of input from PROP. She also appeared in a lecture series on opioid prescribing that was funded by the Steve Rummler Hope Foundation, which coincidentally is the fiscal sponsor of PROP.

Anson P, PainNewsNetwork, July 20, 2017

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Forced Opioid Tapering-4

- Curiously, while Krebs and her colleagues were willing to accept poor quality evidence about the benefits of tapering, they were not as eager to accept poor evidence of the risks associated with tapering.
  - Not to forget- the very poor level of EBM found in the CDC Guidelines
- "This review found insufficient evidence on adverse events related to opioid tapering, such as accidental overdose if patients resume use of high-dose opioids or switch to illicit opioid sources or onset of suicidality or other mental health systems," wrote Krebs.
- But the risk of suicide is not be taken lightly

Anson P, PainNewsNetwork, July 20, 2017

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Forced Opioid Tapering-5

- And what about Kolodny's contention that high opioid doses should be reduced even if a patient refuses? Not a good idea, according to a top CDC official, who says patient "buy-in" and collaboration is important if tapering is to be successful.
- "Neither (Kreb's) review nor CDC's guideline provides support for involuntary or precipitous tapering. Such practice could be associated with withdrawal symptoms, damage to the clinician–patient relationship, and patients obtaining opioids from other sources," wrote Deborah Dowell, MD, a CDC Senior Medical Advisor, in an editorial in the Annals of Internal Medicine. "Clinicians have a responsibility to carefully manage opioid therapy and not abandon patients in chronic pain. Obtaining patient buy-in before tapering is a critical and not insurmountable task."

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Forced Opioid Tapering-5 (cont'd)

- The CDC guideline also stresses that tapering should be done slowly and with patient input.
- "For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan," the guideline states. "Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages."
- Yet, patients are being detoxed against their wishes, and physicians are fleeing the field, refusing to provide pain medication for these patients

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Forced Opioid Tapering-6

- The CDC recommends a "go slow" approach and individualized treatment when patients are tapered. A "reasonable starting point" would be 10% of the original dose per week, according to the CDC, and patients who have been on opioids for a long time should have even slower tapers of 10% a month.
- The Department of Veterans Affairs takes a more aggressive approach to tapering, recommending tapers of 5% to 20% every four weeks, although in some high dose cases the VA says an initial rapid taper of 20% to 50% a day is needed. If a veteran resists tapering, VA doctors are advised to request mental health support and consider the possibility that the patient has an opioid use disorder.

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Forced Opioid Tapering-7

- It is eye-opening, especially for nonphysicians and nonpain patients to read the responses to this article
- To get a real feel for this, go to: https://www.painnewsnetwork.org/stories/2017/7/20/prop-founder-calls-for-forced-opioid-tapering?rq=andrew kolodny

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A Recent Example- A "Leading Pain Physician"

- Started a mandatory opioid taper of 100 patients as he was going to retire
- He noted "Reaction from patients has been less enthusiastic than I had hoped. Many have refused to comply with even starting a tapering program."
  - Possibly secondary to a combination of fear and reluctance on the part of patients who had used opioids for a long time
- Of interest, the physician noted that he was surprised that the insurance companies were not cooperating with reducing patients' opioid doses (This was prior to the CVS decision)

http://nationalpainreport.com/leading-pain-physician-starts-mandatory-opioid-tapering-program-8827407.html accessed 10/15/17

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40,000 deaths in USA caused by aspirin and painkillers every year!

- Conservative calculations estimate that approximately 107,000 patients are hospitalized annually for nonsteroidal anti-inflammatory drug (NSAID)-related gastrointestinal (GI) complications and at least 16,500 NSAID-related deaths occur each year among arthritis patients alone." (Singh Gurkirpal, MD, "Recent Considerations in Nonsteroidal Anti-Inflammatory Drug Gastropathy", The American Journal of Medicine, July 27, 1998, p. 31S)
- "It has been estimated conservatively that 16,500 NSAID-related deaths occur among patients with rheumatoid arthritis or osteoarthritis every year in the United States. This figure is similar to the number of deaths from the acquired immunodeficiency syndrome and considerably greater than the number of deaths from multiple myeloma, asthma, cervical cancer, or Hodgkin's disease. If deaths from gastrointestinal toxic effects from NSAIDs were tabulated separately in the National Vital Statistics reports, these effects would constitute the 15th most common cause of death in the United States. Yet these toxic effects remain mainly a "silent epidemic," with many physicians and most patients unaware of the magnitude of the problem. Furthermore the mortality statistics do not include deaths ascribed to the use of over-the-counter NSAIDS." (Wolfe M. MD, Lichtenstein D. MD, and Singh Gurkirpal, MD, "Gastrointestinal Toxicity of Nonsteroidal Anti-inflammatory Drugs", The New England Journal of Medicine, June 17, 1999, Vol. 340, No. 24, pp. 1888-1889.)

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The Real Opioid Crisis: Heroin and Fentanyl

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PAIN NEWS NETWORK

https://www.painnewsnetwork.org/stories/2017/3/26/cdc-painkillers-no-longer-driving-opioid-epidemic

CDC: Painkillers No Longer Driving Opioid Epidemic

March 26, 2017

CATO AT LIBERTY

JANUARY 9, 2018 7:00AM

Stop Calling it an Opioid Crisis—It's a Heroin and Fentanyl Crisis

By JEFFREY A. SINGER SHARE

Heroin and Fentanyl Crisis-1

- National Center for Health Statistics (NCHS):
  - –63,600 overdose deaths in 2016
    - 20,000 secondary to fentanyl
    - >15,000 secondary to heroin
    - About 14,500 secondary to prescription opiates
      - –But known for years- in MOST cases of prescription opioid deaths, the victims had multiple other potentiating drugs onboard- alcohol, benzodiazepines, barbiturates etc.
    - The rest of the deaths were secondary to methamphetamines, cocaine, benzodiazepines and methadone

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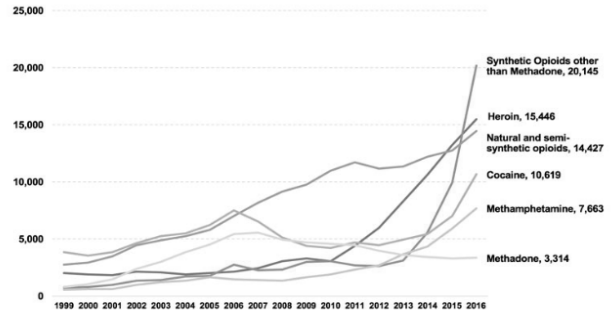

Heroin and Fentanyl Crisis-2

- Among more than 64,000 deaths in 2016, sharpest increase occurred among deaths related to fentanyl analogs (synthetic opioids) with over 20,000 OD deaths
- NCHS Noted deaths from fentanyl increased at a steady annual rate of 18%/year from 1999-2013; then up 88% from 2013-2016
- Evidence shows that the fentanyl is being smuggled in to the country from factories in China and elsewhere, where it is used to fill counterfeit prescription opioid Capsules or to lace heroin
  - Fentanyl in the US is typically prescribed in a transdermal patch

CDC Wonder

PAINWEEK

Heroin and Fentanyl Crisis-3

- NCHS found death rate steady, from heroin, from 1999-2014, and it has increased by 19%/year since 2014
- After increasing 13%/year from 1999-2009, the death rate increase from prescription opioids has remained steady at 3%/year since 2009

PAINWEEK

Heroin and Fentanyl Crisis-4

- The DEA has ordered decreases in prescription opioid production:
  - A 25% reduction in 2017 and a 20% further reduction in 2018
    - This appears to follow the false narrative that opioid overdose crisis was secondary to careless doctors and greedy pharmaceutical companies getting patients hooked on prescription opioids and making them into drug addicts
- Since 2010- more if not most states have set up drug monitoring programs that, among other things, allowed physician monitoring and surveillance of doctors and patients
  - This led to a significant reduction in opioid prescribing
  - "high dose" opioid prescribing fell 41% since 2010
  - 2010- brought the second generation of ADF form of oxycodone from Purdue

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Heroin and Fentanyl Crisis-5

- This cutback in opioid prescription has been a major cause for patient to endure needless suffering from chronic pain
- Some of these patients, desperate, and no longer functional, turn to the illicit market to get relief- via heroin, heroin laced with fentanyl and fentanyl, all cheaper and easier to find and obtain than doing so legally from a physician
  - Some commit suicide

PainWeek

Heroin and Fentanyl Crisis-6

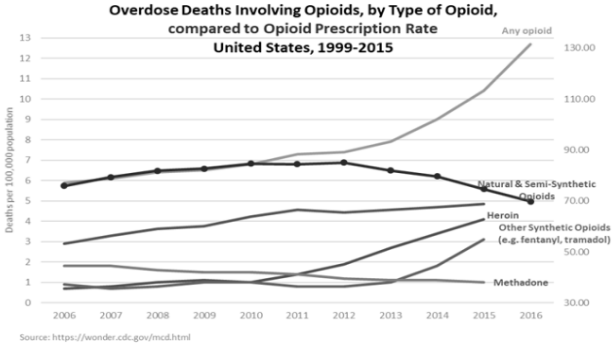
- In an unfettered plan to decrease opioid use, groups such as the DEA and State Medical Boards focused on physicians treating pain
  - This intrusion on patient-doctor relationship causes physician judgement to become secondary to physician self-help- they don't want to go to jail for using their best judgement to treat chronic noncancer pain patients
  - Another unintended consequence- by reducing the amount of prescription opioids, and scaring more physicians out of pain management- particularly the GPs, IMs, FPs, etc.- pain patients had no place to legally go
  - There was a reduction of the amount of prescription opioids that could be diverted to the illicit market- deriving nonmedical users (and them too) to heroin and fentanyl- both cheaper and easier to obtain on the street than prescription opioids- and extremely dangerous

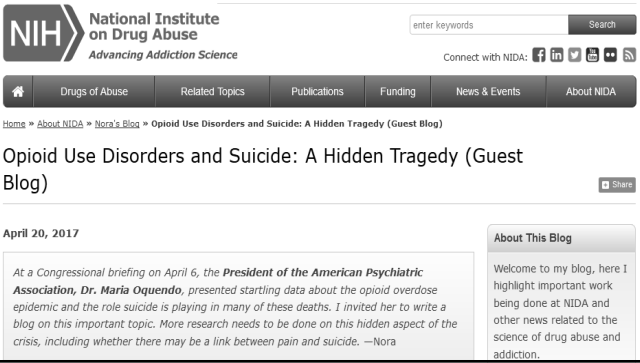
PainWeek

Heroin and Fentanyl Crisis-7

- Data from the Centers for Disease Control and Prevention show that from 2006 to 2010 the opioid prescription rate tracked closely with the opioid overdose rate, about 1 overdose per 13,000 prescriptions
- After 2010, when the prescription rate dropped and it became more difficult to divert opioids for nonmedical use, the overdose rate began to climb as nonmedical users switched to heroin and fentanyl
- There is a negative correlation between prescription rate to overdose rate of -0.99 since 2010
- The overdose rate is NOT A PRODUCT OF DOCTORS AND PATIENTS ABUSING PRESCRIPTION OPIOIDS- IT IS A PRODUCT OF NONMEDICAL USERS ACCESSING THE ILLICIT MARKET

PainWeek





Thus Sayeth the Doctor:

- "In 2015, over 33,000 Americans died from opioids- either prescription drugs or heroin or, in many cases, more powerful synthetic opioids like fentanyl. Hidden behind the terrible epidemic of opioid overdose deaths looms the fact that many of these deaths are far from accidental. They are suicides."- Dr. Maria, Oquendo, President of the American Psychiatric Association

PainWeek

Suicides Increasing…

- CDC states 42,000 Americans died of an opioid overdose in 2016
- An estimated 20%-30% (8,400-12,600) were likely suicides—could be as high as 40% (16,800)

Oquendo MA, Volkow ND, NEJM, 2018; 378(17): 1567-69

PainWeek

Excellent interview with Dr Dan Laird, a physician and attorney, and George Knapp of CBS affiliate in Las Vegas. Exposing the conflation of data in overdose for political purposes at the expense of people in pain and those suffering from OUD.

PainWeek

Again: The Insurance Cartel, uh, Companies

- The Naughty 1990s

PainWeek

A Multidimensional Problem- and a Solution?

- While more groups are currently looking to create "better molecules", enhancing the unidimensional treatment approach…
- The 1980s and early 1990s- with some pleasant exceptions
- A study performed in 1995 found that only 6% of all patients treated by "pain specialists" (6%=176,850 patients) were treated at an interdisciplinary pain center. These patients were sent to these facilities almost as a "last resort," as they had already had a mean 7-year history of pain and pain treatments, with $13,284/patient/year being spent on nonsurgical pain-related health care costs. These patients also had an average of 1.7 surgeries performed at an average cost (1994–1995 dollars) of $15,000/surgery.
- The cost of health care for these patients (only 6% of the pain patients seen in that year) was greater than $20 billion.

Marketdata Enterprises,1995

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A Multidimensional Problem- and a Solution?-2

- The cost of treatment at the interdisciplinary centers was greater than $1.4 billion (1995 average cost of $8100 × 176,850). The medical cost savings after one year (posttreatment at the interdisciplinary centers) was greater than $1.87 billion, an 86% reduction in health care costs
- The fact that the interdisciplinary pain centers are clinically effective, cost effective and provide clinical relief that lasts during the first year post treatment has been well documented.
- In one systematic review, it was concluded that patients could be returned to work with nonsurgical, interdisciplinary pain center treatment (37 controlled and noncontrolled studies were evaluated). In another systematic review, 65 controlled and noncontrolled studies were evaluated. The review supported the effectiveness of interdisciplinary treatment but noted methodological problems existed in some of these studies.

Turk, Loeser, et al, 2002; Cutler et al, 1994; Flor et al, 1992

PainWeek

A Multidimensional Problem- and a Solution?-3

- Another study found that treatment at an interdisciplinary center was more clinically effective and more cost effective than the traditional treatment methods, including medication; surgery; interventional procedures (nerve blocks); noninvasive treatment modalities such as physical therapy (alone); and implantable devices such as spinal cord stimulators and medication pumps. It was also found that the cost to return one injured worker after treatment at an interdisciplinary pain center was $11,913, while the cost to return one patient to work after back surgery was $75,000. The cost to return patients to work indicates that treatment at an interdisciplinary pain center is 6.3 times more cost effective than surgery
- When utilizing commonly accepted criteria, a systematic review (from the Cochrane Database) entitled "Multidisciplinary Bio-psychosocial rehabilitation for chronic low back pain" concluded that evidence showed intensive (>100 hours of therapy) interdisciplinary bio-psycho-social pain rehabilitation programs with a functional restoration approach engendered greater improvements in pain and function for patients with "disabling chronic low back pain," then did nonmultidisciplinary rehabilitation or "usual care."

Marketdata Enterprises, 1995; Guzman et al, 2002

PainWeek

A Multidimensional Problem- and a Solution?-4

- Turk and Burwinkle note an "epidemic of 'Mural Dyslexia'," the "inability to read the handwriting on the wall."
- There is a large cohort of published information indicating that the interdisciplinary pain centers are clinically effective, cost effective and via their treatment paradigm, able to provide significant savings in health care and disability payments.

Turk D, Burwinkle, 2004; Robbins et al, 2003

PainWeek

A Multidimensional Problem- and a Solution?-5

- Robbins et al. noted that patients in their interdisciplinary pain management programs who were forced by insurance company "carve outs" to have physical therapy elsewhere experienced negative treatment outcomes at one year, in comparison to those patients who were able to participate in the full, intact program.

Robbins et al, 2003

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A Multidimensional Problem- and a Solution?-6

- The restoration of function must be a primary goal of all interdisciplinary treatment programs. Rehabilitation, while it focuses on function and not specifically pain, is associated with decreased pain and improvements in psychological status as function improves, with fewer and less opioid usage
- Finally, dual diagnosis multidisciplinary pain programs which deal with chronic noncancer pain and substance abusing patients are also found to work well.

Schofferman et al, 2006; Mahoney et al, 1999

PainWeek

A Multidimensional Problem- and a Solution?-7

- It must, unfortunately, go without saying: as the Insurance Companies refused to fund interdisciplinary care, with few exceptions; there is a paucity of recent data, and a paucity of outstanding patient outcomes from interdisciplinary programs. There is a huge paucity of interdisciplinary pain programs.
- One way to "fix" the "opioid crisis" is to enable EBM proven interdisciplinary proven care.
- It has even been shown to be cost effective, and use fewer/less opioids- which should matter

Jay, 2010

PainWeek

In Summary

- What it appears that "they" are saying:
- So therefore we must give minimal dosages of opioids to patients who need more, and there must be fewer medications available (Thank the DEA) and fewer physicians who prescribe any opioid; that, and the unintended consequence of pushing chronic pain patients to have to obtain illicit medications to remain functional (especially when they can't find a physician to prescribe pain meds at all, even after their dosage has been forcibly cut); when the PROP written CDC guidelines force marked opioid reduction (secondary to "legalization" of recommendations) or discontinuation, and if the Heroin they buy is laced with fentanyl and they die? Well, they shouldn't have been drug addicts anyway!
- Or are they purposely "Thinning the herd?"

PainWeek

Email: August 27, 2018

- The people I see at the pain clinic don't want to treat my pain. I used Butrans for years, and now because people are paranoid and stupid, everyone who hurts gets to suffer, I guess. If you have any ideas I am happy to hear them. I am just starting to give up on walking or moving without pain for the rest of my life. Thank you for your help.

PainWeek