PaiNweek

Measure for Measure: Prescribing Guidelines, Rules & Regulations

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Disclosures

- Stephen J. Ziegler, PhD, JD
  - Nothing to disclose

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Learning Objectives

- Discuss the diffusion and variation in prescribing guidelines and rules across the United States regarding chronic, noncancer pain
- Describe the history of Washington state's prescribing rules and the CDC's prescribing guidelines
- Discuss the potential impact that prescribing guidelines could have on medical practice, the treatment of pain, and reduction of overdose

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Increases in Overdose

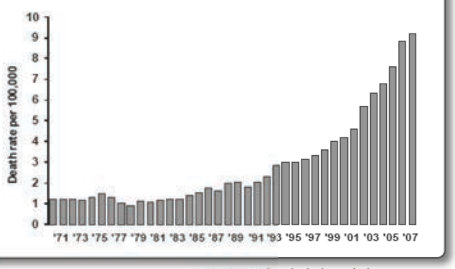
Drug overdose death rates in the United States have never been higher

- Drug overdose death rates have risen steadily in the United States since 1970. (See Figure 1)
- In 2007, 27,658 unintentional drug overdose deaths occurred in the United States.
- Drug overdose deaths were second only to motor vehicle crash deaths among leading causes of unintentional injury death in 2007 in the United States.

Rates have increased roughly five-fold since 1990.

- Age-adjusted rates of drug overdose death for whites have exceeded those among African Americans since 2003.

Figure 1: Rate of unintentional drug overdose death in the United States, 1970-2007



Source: National Vital Statistics System

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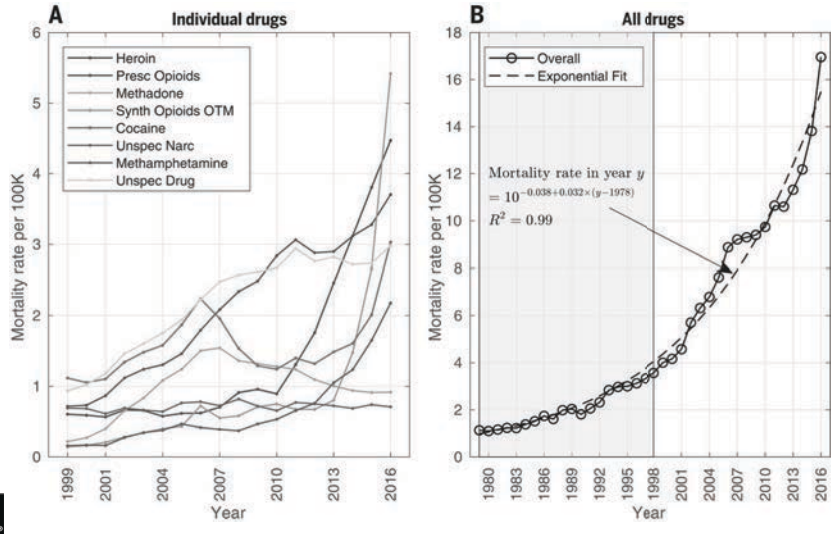
But is the increase drug specific? Jalal et al., *Science* 361, eaau1184 (2018)



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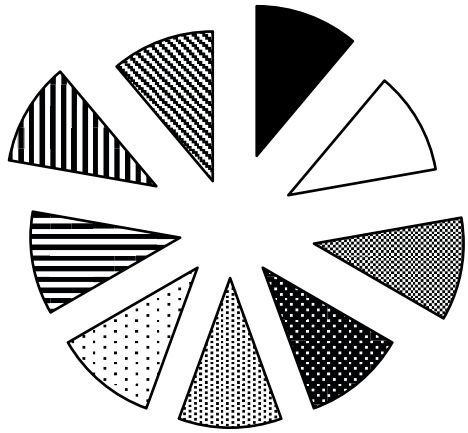
Some Variables Associated With Overdose Risk

OD Variables Not Equally Distributed



- Illicit opioids
- Poly-pharm (Benzo)
- Poly-substance
- Unauthorized >
- Drug interactions
- Genotype
- Methadone
- Depression
- Dosage levels (linear?)

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Bounded rationality and Hydraulic Pressure to do Something

- Great cases, like hard cases, make bad law. For great cases are called great not by reason of their real importance in shaping the law of the future, but because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment.
- These immediate interests exercise a kind of hydraulic pressure which makes what was previously clear seem doubtful, and by which even well settled principles of law will bend.
- [emphasis added] Justice Holmes (dissenting in Northern Securities Co. v. United States, 193 U.S. 197 (1904))
- Korematsu v. United States, 323 U.S. 214 (1944)

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Do Something =

- Hysteria
- Bounded rationality, hypotheses vs empirical evidence, bumper sticker solutions, sacred cows
- Result: Rx guidelines, rules, and regulations
- Do the terms get mixed up?
  - Voluntary guideline vs mandatory rule
  - Language matters: shall vs should
- Original purpose of guidelines: support clinical decision making
- But expanding … (regulators, insurance, ***standards***?)

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Definitions: Guidelines vs Rules

- Washington State DOH
- **Guidelines**
- A set of recommended practices designed by the Medical Commission to assist practitioners about appropriate health care for specific circumstances
- A guideline does not have the force of law, but may be considered by the Medical Commission to be the standard of care in our state. [Emphasis not in original]

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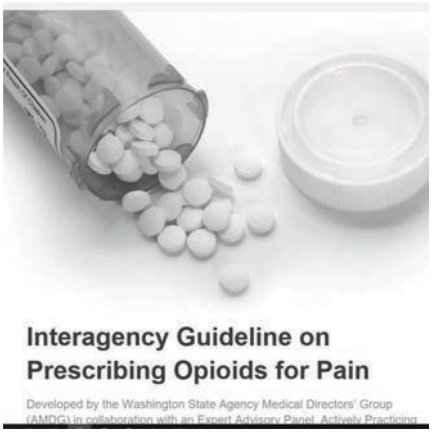
Guideline or Rule?



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Federation of State Medical Boards

- Guidelines for the Chronic Use of Opioid Analgesics
- "specific limitation and restriction that these Guidelines do not operate to create any specific standard of care, which standard must depend upon fact-specific totality of circumstances surrounding specific quality of care events."
- The Guidelines recognize that there is not just one appropriate strategy to accomplish the goals of these Guidelines. Effective means of achieving the goals of these Guidelines vary widely depending on the type and causes of the patient's pain, the preferences of the clinician and the patient, the resources available at the time of care, and other concurrent issues beyond the scope of these Guidelines.
- These Guidelines that follow do not encourage the prescribing of opioids over other pharmacological and nonpharmacological means of treatment but rather the Guidelines recognize the responsibility of clinicians to view pain management as essential to quality of medical practice and to the quality of life for patients who suffer from pain."

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But "Rules and Regulations" are different from Guidelines

- Carry force and effect of law
- Created by
- Admin/exec agencies who provide the clothing
- Open comment period
- Testimony (written, oral)
- Opportunity to speak!

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Regulations are assigned a number

- Published and codified = assigned administrative law chapter and section number (WAC)
- Many states have such regulations (that can be referred to as rules)

PAIN MANAGEMENT

246-919-850	Pain management—Intent.
246-919-851	Exclusions.
246-919-852	Definitions.
246-919-853	Patient evaluation.
246-919-854	Treatment plan.
246-919-855	Informed consent.
246-919-856	Written agreement for treatment.
246-919-857	Periodic review.
246-919-858	Long-acting opioids, including methadone.
246-919-859	Episodic care.
246-919-860	Consultation—Recommendations and requirements.
246-919-861	Consultation—Exemptions for exigent and special circumstances.
246-919-862	Consultation—Exemptions for the physician.
246-919-863	Pain management specialist.

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Common in Guidelines and Rules

- Patient eval, tx agreements, follow-up, check PMDP . . .
- But dosage thresholds (leading to trigger or ceiling) – expanding across US
  - Tied to MED—the myth of MED and its dangers (Fudin et al, 2016)

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Indiana
(your state med Assn more helpful)

- 844 IAC 5-6-3 Triggers for imposition of requirements; exemptions
- Sec. 3. (a) This section and sections 4 through 10 of this rule establish requirements concerning the use of opioids for chronic pain management for patients.
- (b) . . . this section . . . shall not apply to the use of opioids for chronic pain management for the following:
- (1) Patients with a terminal condition.
- (2) Residents of a health facility licensed under IC 16-28.
- (3) Patients enrolled in a hospice program licensed under IC 16-25.
- (4) Patients enrolled in an inpatient or outpatient palliative care program of a hospital licensed under IC 16-21 or a hospice licensed under IC 16-25.

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Indiana Triggers

- (c) The requirements in the sections identified in subsection (a) only apply if a patient has been prescribed [for more than 3 consecutive months]:
- (1) more than sixty (60) opioid-containing pills a month;
- (2) a morphine equivalent dose of more than fifteen (15) milligrams per day;
- (3) a transdermal opioid patch;
- (4) at any time it is classified as a controlled substance under Indiana law, tramadol, but only if the patient's tramadol dose reaches a morphine equivalent dose of more than sixty (60) milligrams per day
- or
- (5) an extended release opioid medication that is not in an abuse deterrent form for which an FDA-approved abuse deterrent formulation, if such a formulation exists for the opioid product the physician is prescribing to the patient. Nothing in this subdivision shall be construed to require a physician to prescribe an opioid in an abuse deterrent formulation.

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Origin of Dosage Thresholds

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Washington State's History

- Educational pilot
- MED 120
- Guideline (not a mandatory rule)
- CME?
- Rule

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Where did 120 come from?

- "there does not seem to be an evidence-based threshold for what constitutes a dangerously high dose. Although some clinical guidelines suggest an MED of 200 milligrams per day as a watchful dose, studies in our sample showed overdose and mortality increases at doses ranging from 40 to 200 milligrams per day MED." (King, et al, 2014) [systematic review of studies 1990-2013]
- "Ecologic studies suggest a near-linear association between the total amount of opioids dispensed and overdose morbidity and mortality . . . but there is new evidence that the shape of the curve is not linear. (Dasgupta et al, 2016)
- Higher doses of opioid analgesics were associated with increased overdose risk, however, there were smaller incremental increases in risk above 200 mg average daily MME. Much of the risk at higher doses appears to be associated with co-prescribed benzodiazepines" (Dasgupta et al, 2016)

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Dose alone not problem

- "Although risk for overdose was highest in those receiving higher doses, most overdoses occurred in patients receiving low- to moderate-dose regimens" (Dunn et. al, 2010 at 90). [emphasis added]
- "However, there does not seem to be an evidence based threshold for what constitutes a dangerously high dose. Although some clinical guidelines suggest an MED of 200 milligrams per day as a "watchful dose," studies in our sample showed overdose and mortality increases at doses ranging from 40 to 200 milligrams per day MED." (King et. al, 2014 at e35).

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So guidelines may not be the panacea?

- "Many poisonings and adverse effects occurred in patients without high dose or long-term opioid therapy,
- suggesting that opioid dosing and duration guidelines may not be sufficient to reduce morbidity related to prescription opioid use.
  Fulton-Kehoe et.al, 2013, at 1452)." [emphasis added]

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Diffusion, Implementation, & Complication across the US

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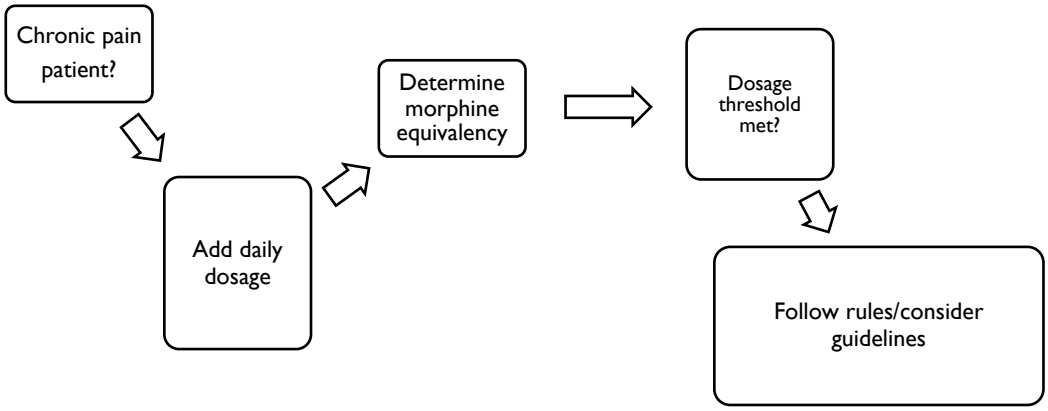
Chronic Pain & Rx: Simple Process?



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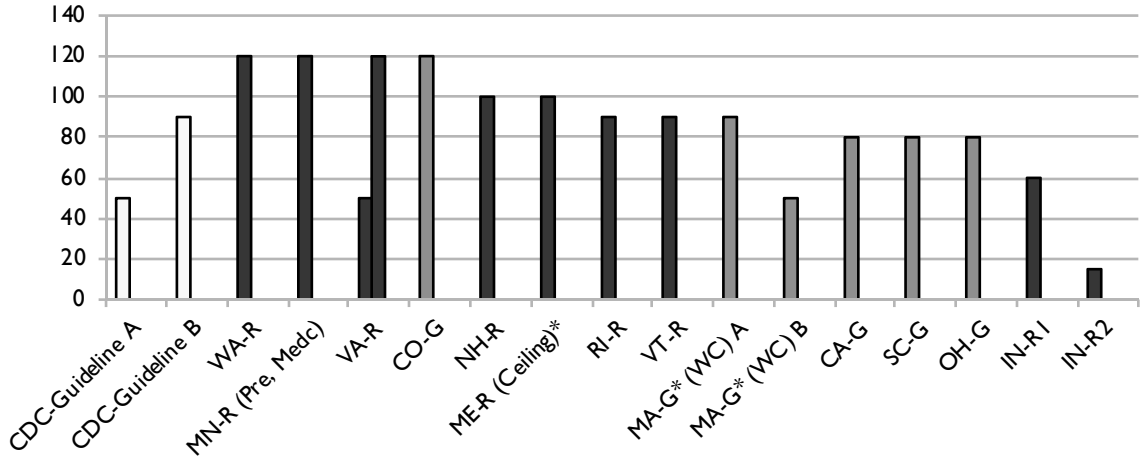
Variation on a theme: MED Levels (Red=Rules)



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Laboratories of the State?

- Different MED by state? Medicaid vs non?
- Calculation & conversion: something lost in translation.
- Washington state: **CAUTION: This calculator should NOT be used to determine doses when converting a patient from one opioid to another**. This is especially important for fentanyl and methadone conversions. Equianalgesic dose ratios are only approximations and do not account for genetic factors, incomplete cross-tolerance, and pharmacokinetics. [Recall earlier diagram about variables associated with OD?]

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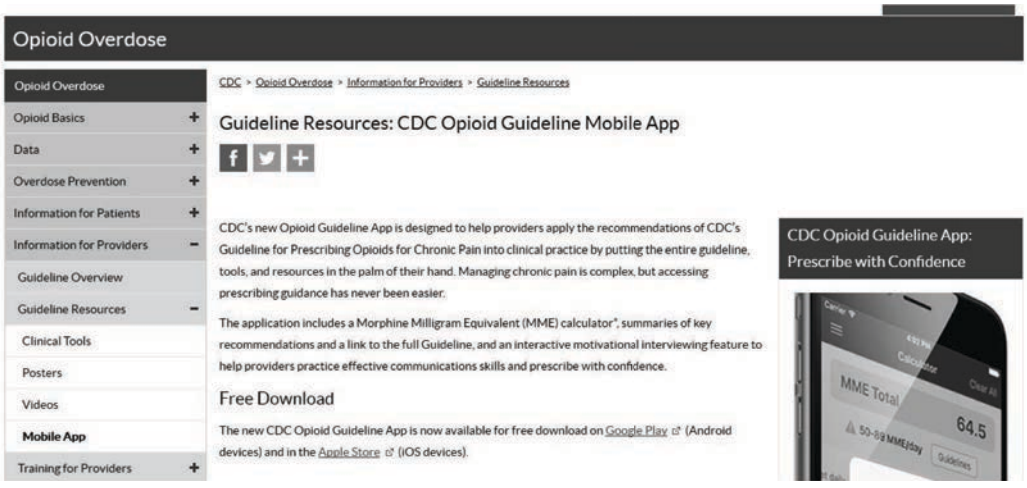
MED, CDC, Rx w/ CONFIDENCE!



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BEWARE OF THE SMALL PRINT

- What a difference an * makes
- The calculator does not account for incomplete cross-tolerance between opioids and should not be used to guide opioid rotation or conversion between different opioids.
- This is especially important for fentanyl and methadone conversions.
- Equianalgesic dose ratios are approximations and do not account for interactions between opioids and other drugs, patient weight, hepatic or renal insufficiency, genetic factors, and other factors affecting pharmacokinetics.
- https://www.cdc.gov/drugoverdose/prescribing/app.html

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Problems with primary fixation on daily MED

- Dosage is important
- But multiple contributors to OD
- Association not = causation
- Conversion tables = under and overdosing
  - "An increasing body of literature suggests that widely used opioid rotation practices, including the use of dose conversion ratios found in equianalgesic tables, may be an important contributor to the increasing incidence of opioid-related fatalities." Webster & Fine (2012).
- Race to bottom in thresholds by states?
- Methadone & Seattle Times (Berens & Armstrong, 2011)

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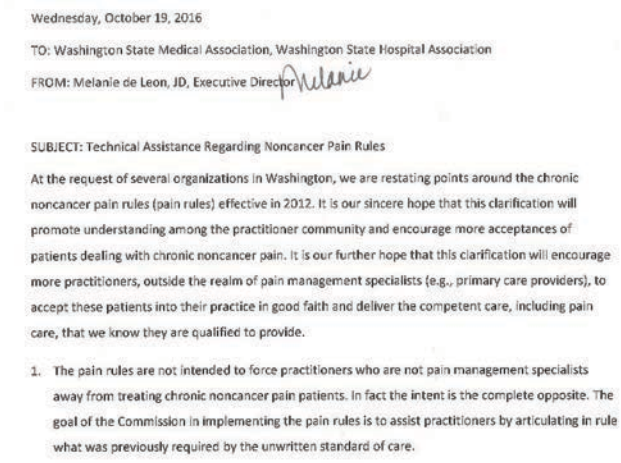
Impact on Patients and Prescribers: Opting Out in Washington state



Wednesday, October 19, 2016

TO: Washington State Medical Association, Washington State Hospital Association

FROM: Melanie de Leon, JD, Executive Director

SUBJECT: Technical Assistance Regarding Noncancer Pain Rules

At the request of several organizations in Washington, we are restating points around the chronic noncancer pain rules (pain rules) effective in 2012. It is our sincere hope that this clarification will promote understanding among the practitioner community and encourage more acceptances of patients dealing with chronic noncancer pain. It is our further hope that this clarification will encourage more practitioners, outside the realm of pain management specialists (e.g., primary care providers), to accept these patients into their practice in good faith and deliver the competent care, including pain care, that we know they are qualified to provide.

1. The pain rules are not intended to force practitioners who are not pain management specialists away from treating chronic noncancer pain patients. In fact the intent is the complete opposite. The goal of the Commission in implementing the pain rules is to assist practitioners by articulating in rule what was previously required by the unwritten standard of care.

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Opioid Refugees?

- Many patients have functioned well for years
- Involuntary tapers & “detox”
- Maine: 100. Without consent. Last minute save undermines the rule.
- LTD alternatives effective & reimbursable
- Self-medication
- Only 12% med boards have action plan to respond to loss of CS prescriber (Sera et al, 2017)

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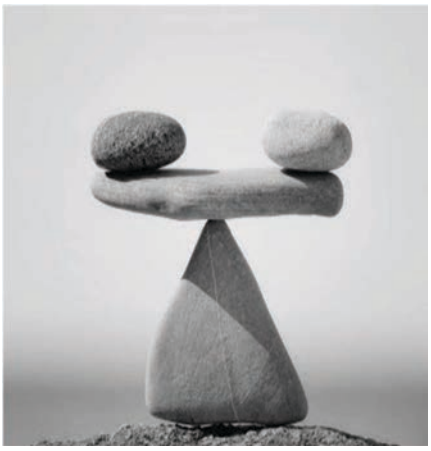
The Future?

- Thresholds because they are so easy? Race to bottom
- Pendulum swing & Other Side of Opioids series
- Alternatives: New Mexico CME, Project Lazarus
- Become part of solution
  - Advocate for balanced policies (guidelines, laws, and REGULATIONS—testify + language)
  - > Reimbursement>
  - Common ground and Gladwell



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Contact Information

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- Rhode Island. Rules and Regulations for Pain Management. http://bit.ly/2n441aV
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- The Other Side of Opioids. http://www.lasvegasnow.com/news/ourpain-the-other-side-of-opioids/852432872

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