An Agenda for Development of Pain Management Best Practices

Presentation to HHS Inter Agency Task Force on Best Practices in Pain Management

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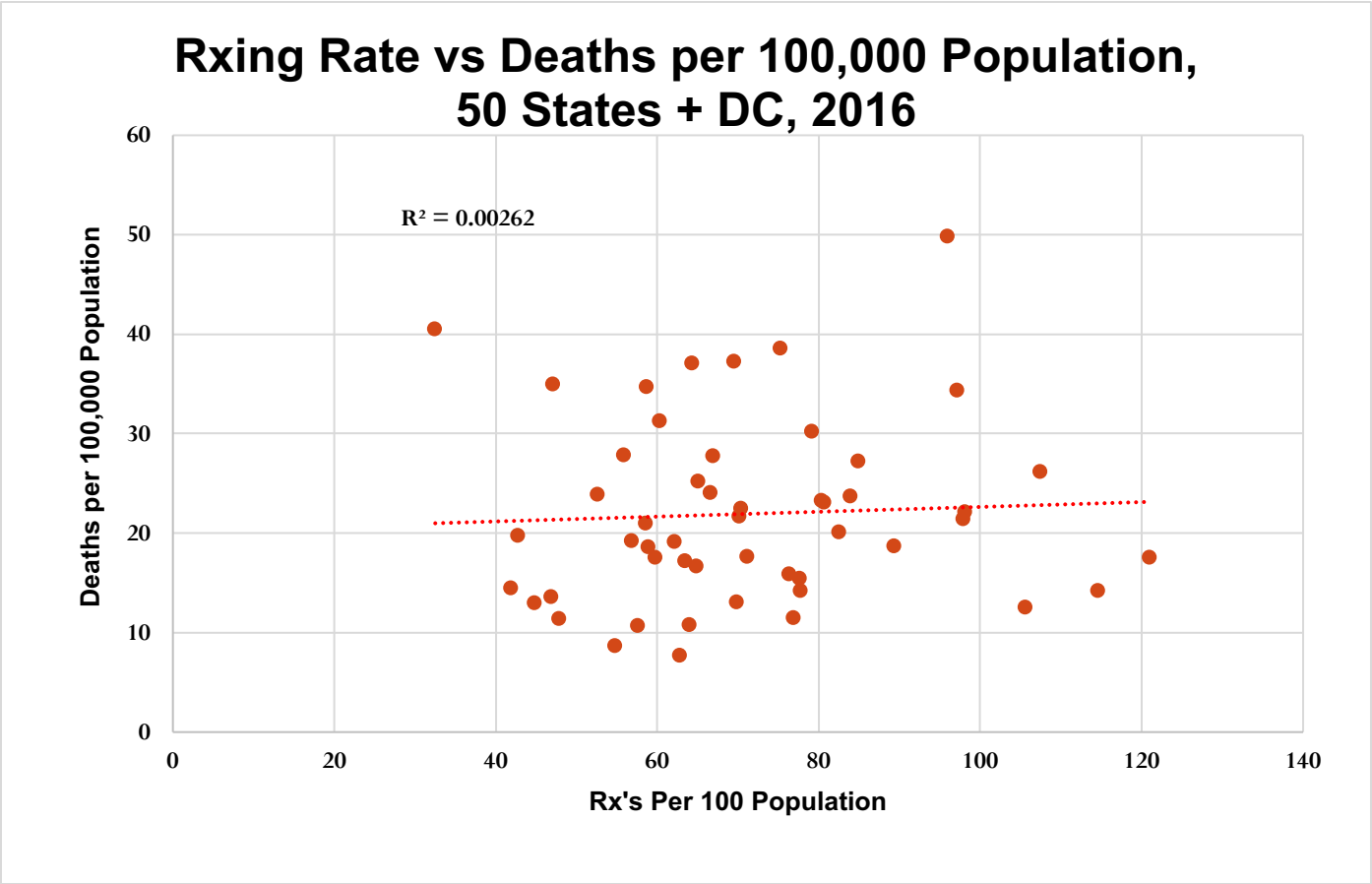
Your Task 1: Rewrite 2016 CDC Opioid Prescription Guidelines

- There is no relationship between State by State rates of opioid prescribing and rates of overdose deaths or ER visits.*



* Data Source: US CDC Wonder Database, 2018

ATIP
The Alliance for the Treatment of Intractable Pain

Realities of Pain Management Practice

- Opioid analgesics are not the first therapy of choice.
  - Many pts do not tolerate opioids well.
  - Other analgesics may be effective for some pts and disorders
    - NSAIDs also have mortality risks.
- In many patients, opioid analgesics are effective and safe for acute or chronic pain
  - Risk of opioid-related death similar to blood thinners (~.025% -.05%/yr).
  - Optimum therapeutic dose from 50 to 1000 MMED due to genetic polymorphism affecting mu-receptors or individual metabolism. (1)
  - Tolerance may develop; but no medical evidence for "opioid induced hyperalgesia" in other than animal models.
  - Dependency may develop with long term use and is an expected, accepted and manageable outcome for people otherwise in agony. (2)
  - Opioid abuse (opioid "use" disorder) is rare in medically managed pts. (3)

(1) Clinical experience of Stephen E Nadeau MD, author of >100 peer reviewed articles in medical literature. Likewise note: ~1.6 million seniors now maintained on >90 MMED (source: HHS/CMS and CDC Surveillance Reports)

(2) "Dependence" characterized by withdrawal symptoms if tapering is too fast. Different from "addiction".

(3) Defined by a spectrum of obsessive drug seeking behaviors. Volkow and McLellan "Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies" . *NEMJ* 2016; 374:1253-1263

Realities of Pain Management Practice (2)

- Incidence of opioid abuse diagnosis or chronic prescribing is less than 0.6% in post-surgical patients treated with opioids (1, 2)
  - Fewer than 1% of post-surgical pts continue prescriptions beyond 13 weeks
  - Incidence of abuse only weakly sensitive to doses 20-120 MMED
  - Many OUD diagnoses made by poorly trained doctors who fail to recognize emergence of chronic pain due to failed surgeries.
- No controlled trials have shown that alternative therapies can substitute for opioid therapy in severe pain.
  - Medical trials literature is very weak
  - We do not know if alternative therapies are more effective than placebo (3)
  - If used, non-analgesic therapies should be viewed as adjuncts, not replacements

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

(2) Gabriel A Brat, Denis Agniel, Andrew Beam, Brian Yorkgitis, et al, "Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study", *BMJ* 2018;360:j5790

(3) Agency for Healthcare Research Quality "Noninvasive, Nonpharmacological Treatment for Chronic Pain: A Systematic Review" circulated in draft, December 2017. Conclusion of R.A.L., after deep review of report details.

Realities of Pain Management Practice (3)

- There is no validated body of medical evidence to support a single "one size fits all" threshold of risk for bad outcomes from opioid therapy versus dose.
  - Variability between patient metabolism and medical conditions treated
  - No body of trials data taken under representative conditions of pain management practice

- There are alternatives to the 2016 opioid prescription guidelines
  - Federation of State Medical Boards "Guidelines for Chronic Use of Opioid Analgesics", April 2017
  - "European Pain Foundation Position Paper on Appropriate Opioid Use in Chronic Pain Management," *European Journal of Pain,* Eur J Pain 21 (2017) 3-19
  - Other Guidelines from Medical Specialties, Associations and Academies
  - Whatever guidelines the Task Force proposes must be patient-centered and evidence-based. Stakeholder input should be embraced and integrated by the Task Force.