

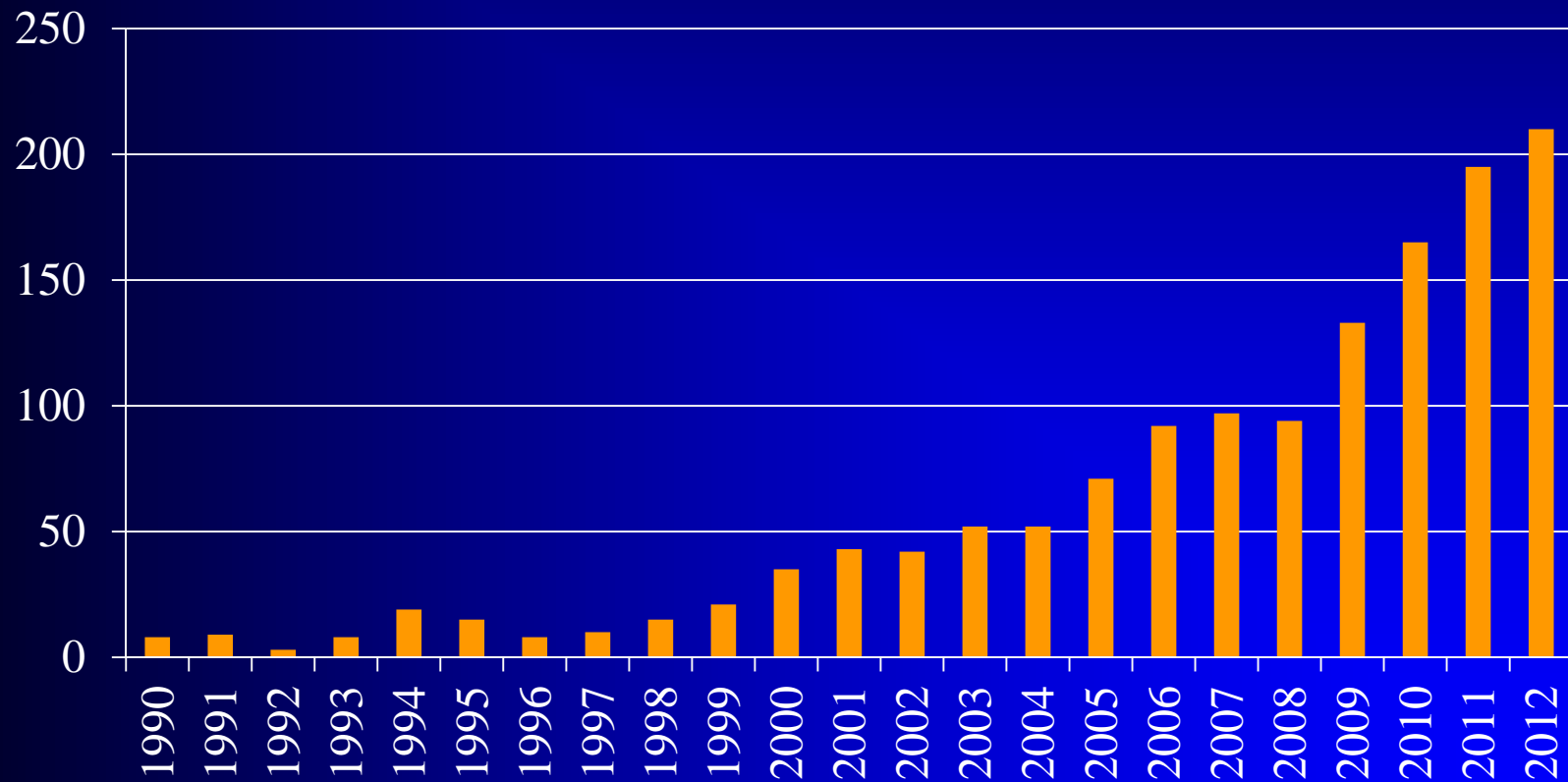
**Overview of the prescription
drug abuse epidemic
Oral vs. alternative routes of
administration**

Nathaniel Katz, MD, MS
Analgesic Solutions
Tufts University School of Medicine

**Abuse Deterrent Formulation Science Meeting
Bethesda, MD Sept. 30-Oct. 1, 2013**

Prescription Opioid Abuse Publications

Publications



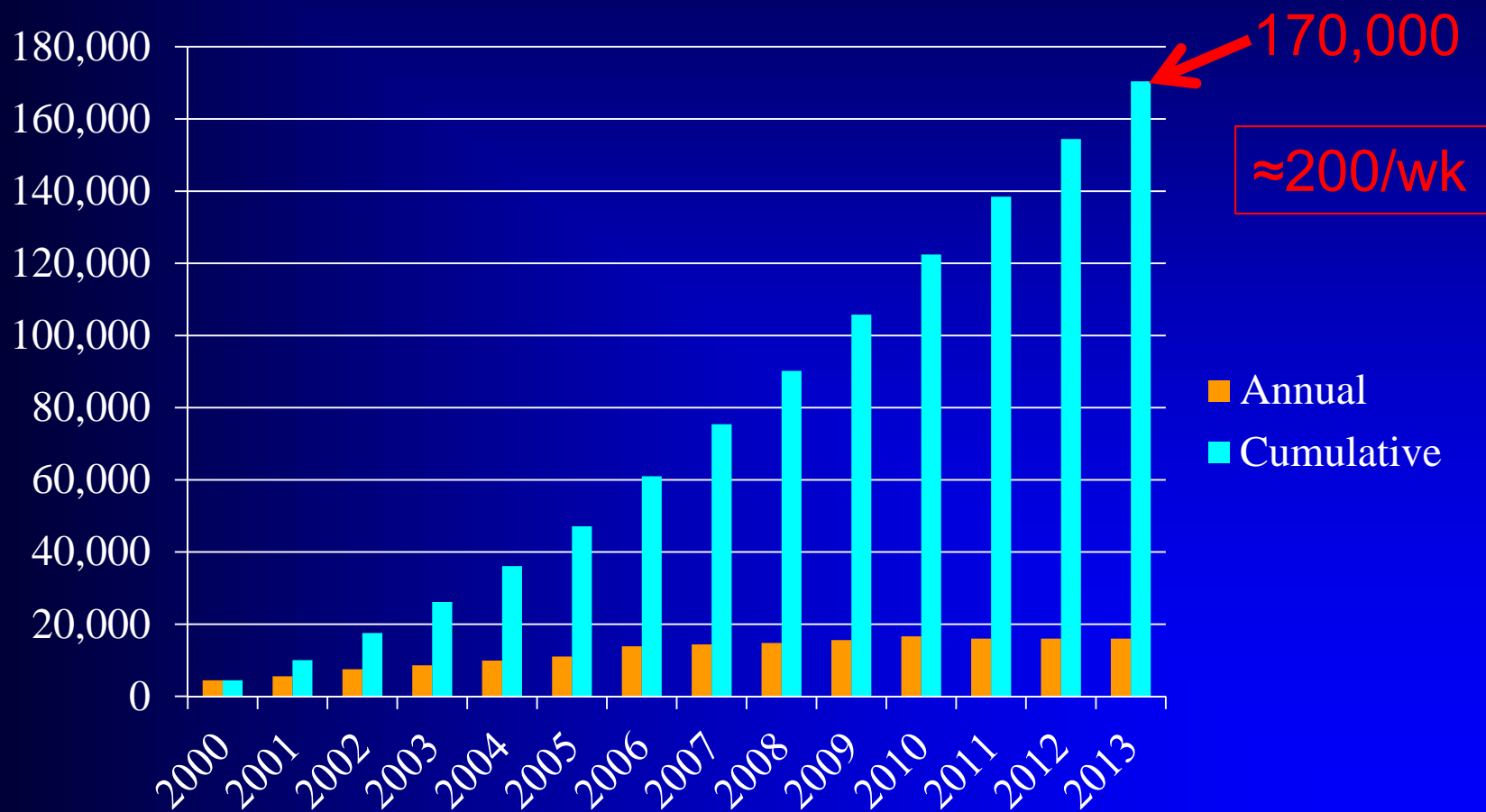
Pubmed, accessed Sept. 29, 2013

Questions Informed by Epidemiology

- How big is the problem
- Who is affected
- Pathways
- Consequences
- Costs
- Effectiveness of interventions

HOW BIG IS THE PROBLEM?

U.S. Prescription Opioid Overdose Fatalities, 2000-2013*



Source: CD Wonder Online Database, Accessed Sept. 29, 2013. 2012 and 2013 estimated.

In 2008, there were **14,800** prescription painkiller deaths.⁴

For every **1** death there are...



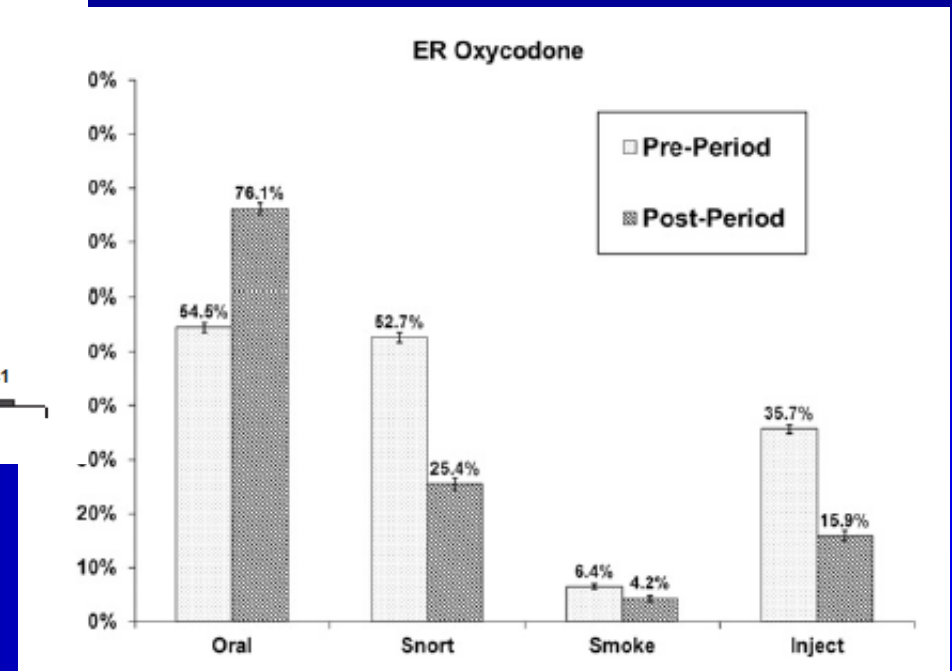
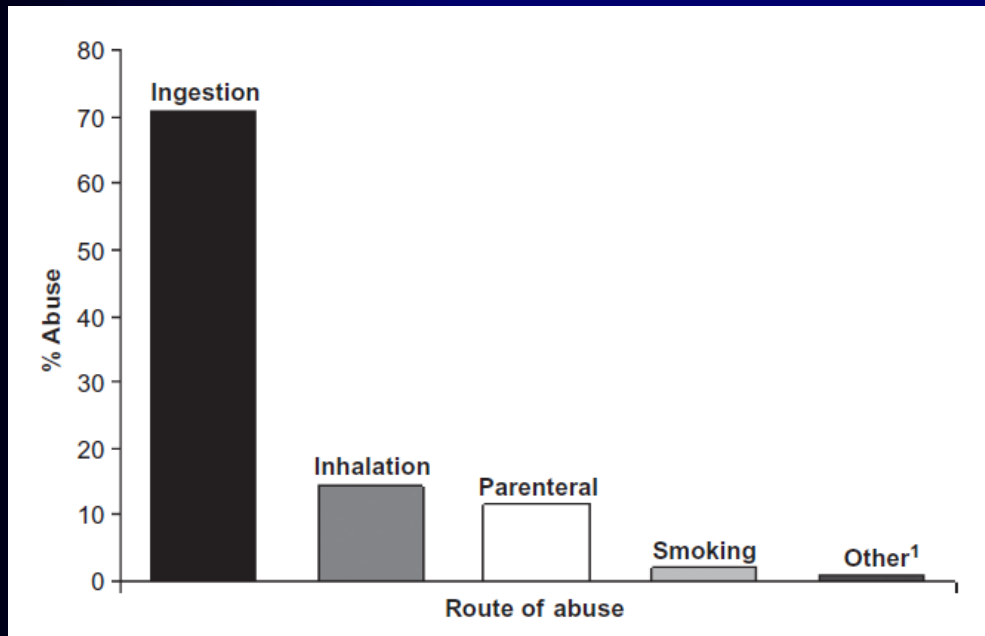
10 treatment admissions for abuse⁹

32 emergency dept visits for misuse or abuse⁶

130 people who abuse or are dependent⁷

825 nonmedical users⁷

Prevalence by Route of Administration



Sources: Katz N et al, Am J Drug Alc Dep, 2011 (Treatment Episode Data Set 2006); Butler S et al, J Pain, 2012 (ASI-MV-Connect)

WHO IS AFFECTED?

Risk Factors

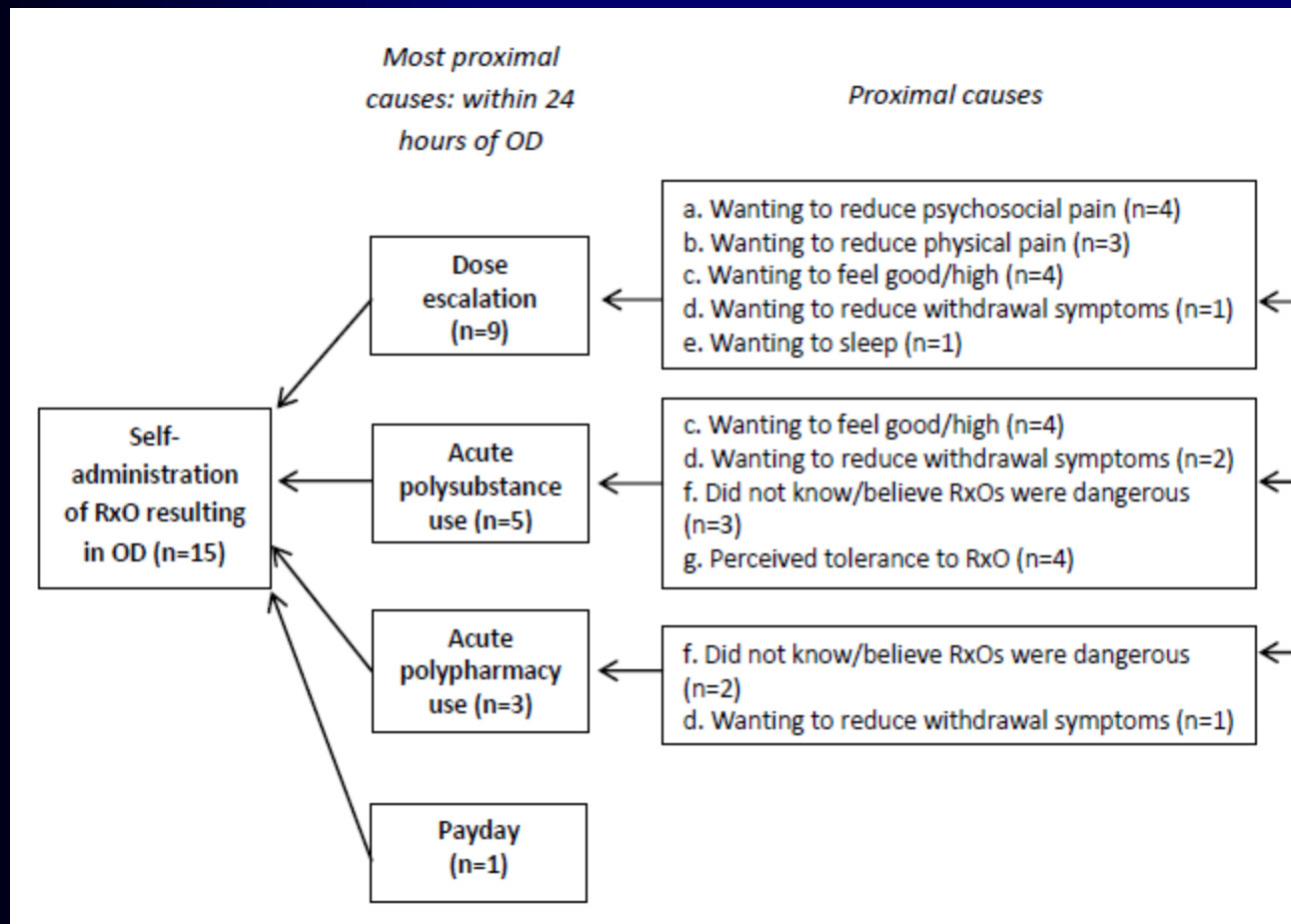
- History of substance abuse
- Mental illness
- Family history of same
- Poor, rural
- Pain, opioid prescriptions, high doses
- Doctor shoppers

Models to Predict Prescription Opioid Abuse with Claims Data

- Database: over 800,000 in Maine 2005-6
- Model included:
 - Age, gender, no. pharmacies, early refills, dose escalation, substance abuse, depression, PTSD, cancer, mental health visits, hospital visits
- Area under ROC curve for prediction of dx of prescription opioid abuse: 0.93
- Who is using this algorithm: nobody

PATHWAYS

Root Cause Analysis of Prescription Opioid Overdose

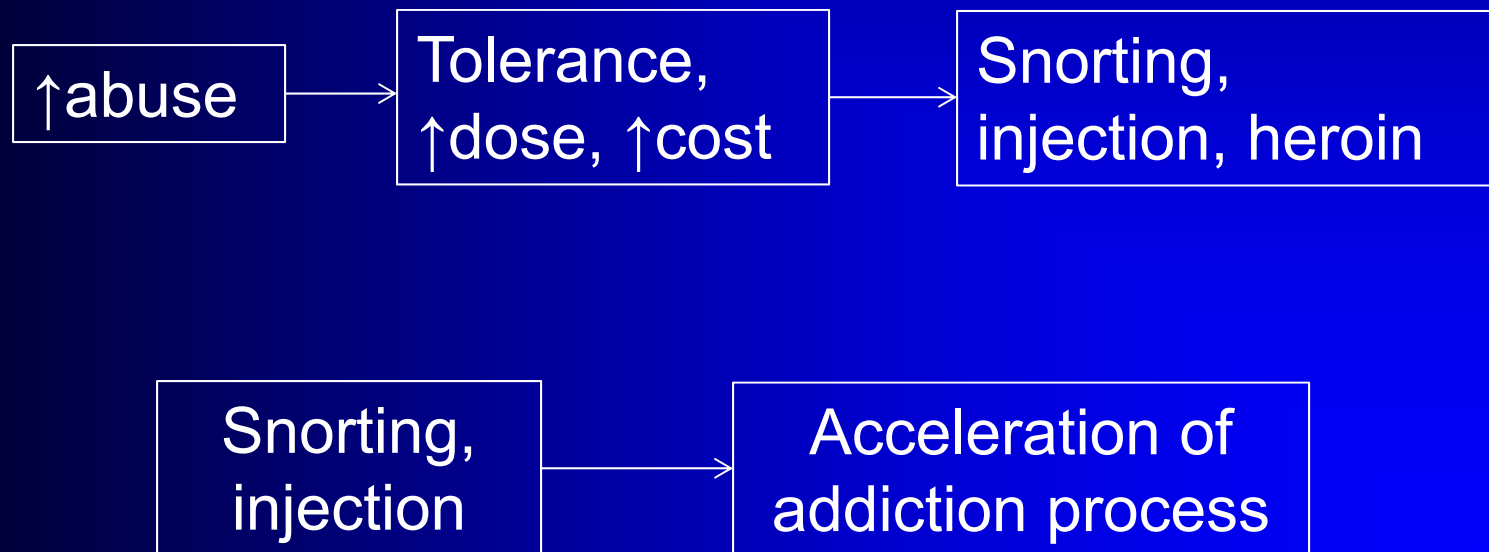


- Poor coping
- Misinformation
- Physical & psychological pain
- Chronic mental illness
- Substance abuse

**OVERDOSES
RESEMBLE
SUICIDE
ATTEMPTS**

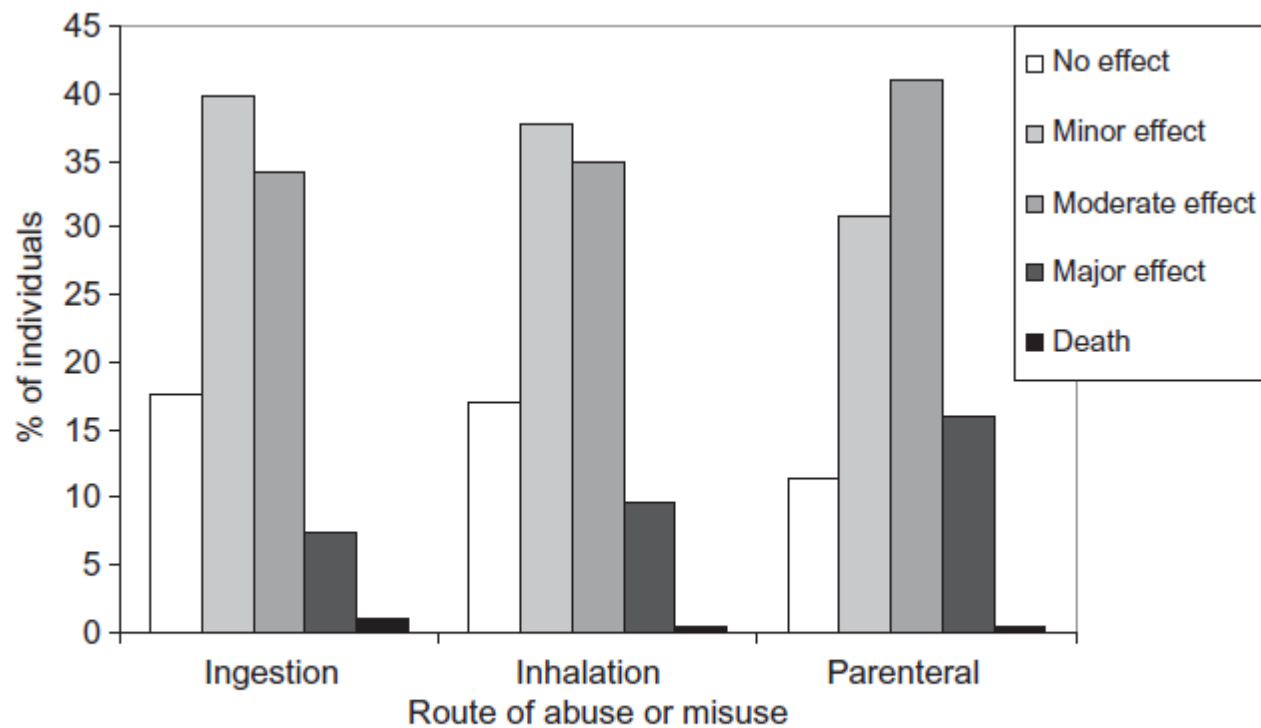
Pathways to Tampering: Pilot Study

- Relationship between tampering and prescription opioid addiction appears bidirectional



CONSEQUENCES

Consequences of Tampering



Notes: Data courtesy of Richard Dart and Elise Bailey; RADARS[®] System Poison Center Data, 2007-2008; Rocky Mountain Poison & Drug Center, Denver Health, Denver, Colorado.

Katz N et al, Am J Drug Alc Dep, 2011

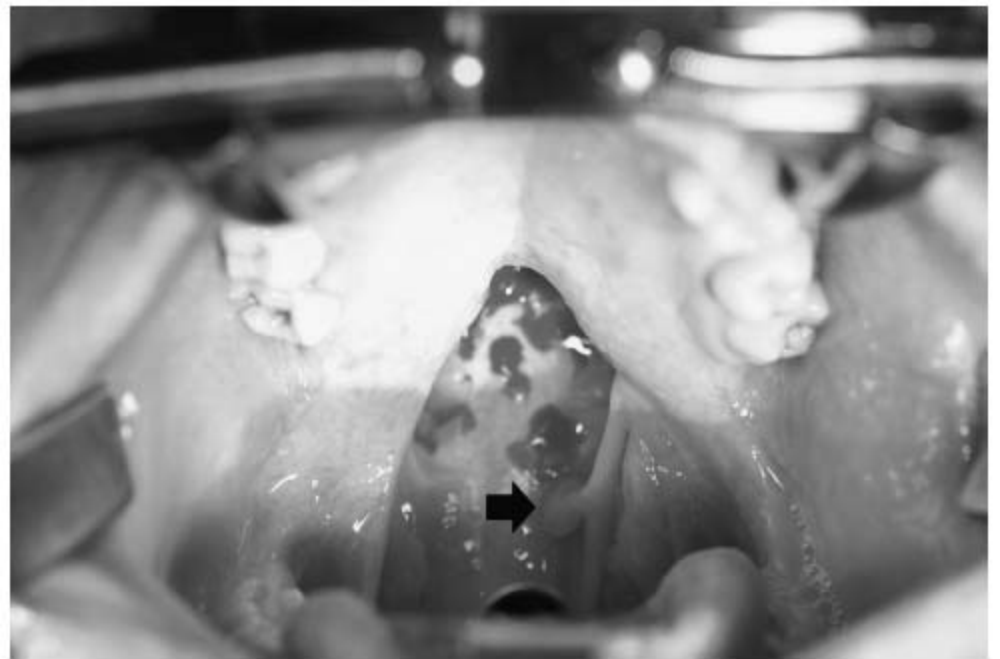
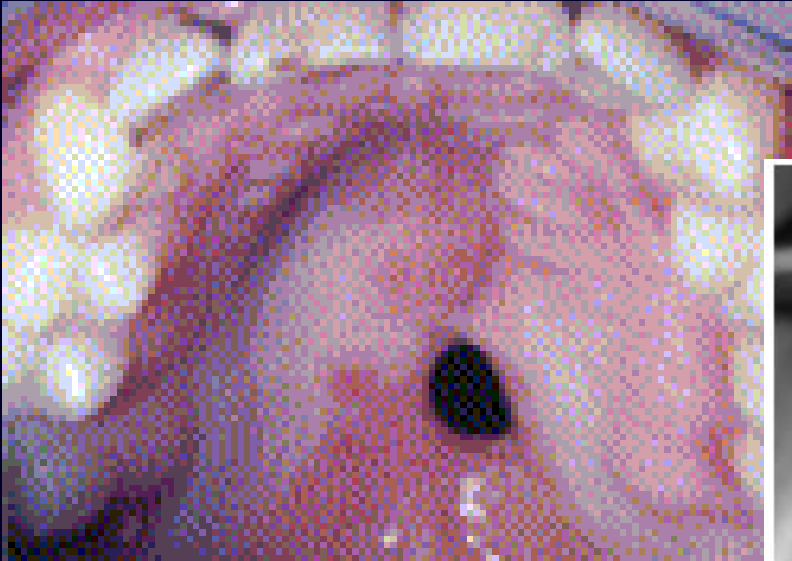


Fig 1 Preoperative oropharynx and palate. Intraoperative image showing soft palate defect. Arrow marks remnant uvula adherent to left posterior oropharynx. Punctate bleeding from local anesthesia injection is noted along posterior pharynx. Note entire soft palate defect with a normal hard palate and intact lateral oropharynx.

Jewers WM, Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 2005;
Birchenough SA, J Craniofacial Surg, 2007

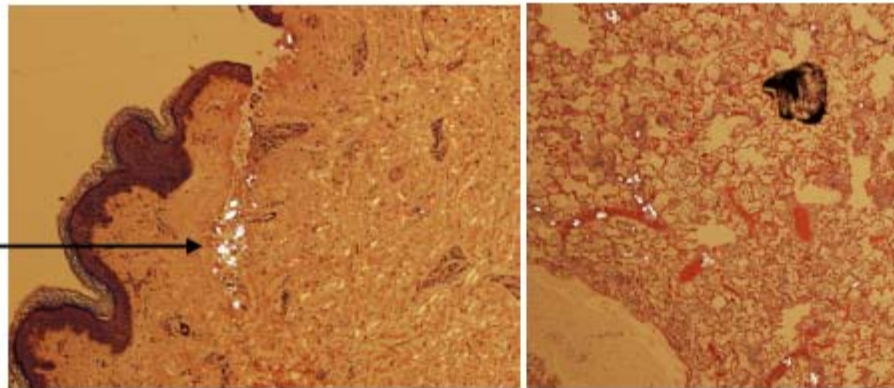


Figure 1. Pathology specimen of lung tissue from the patient showing polarizable fibrin arterioles (arrows). There were acute inflammatory cells, necrotic debris, and fibrin congestion consistent with an acute event.



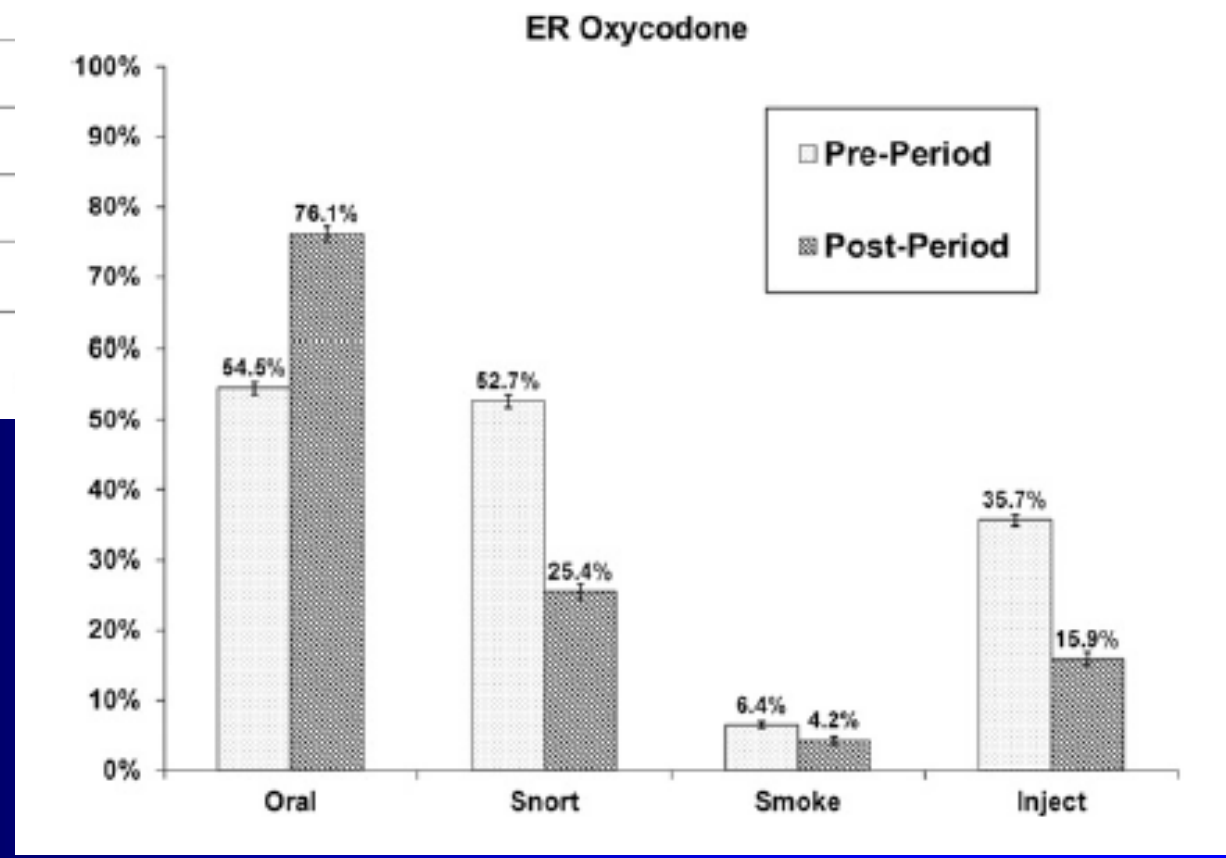
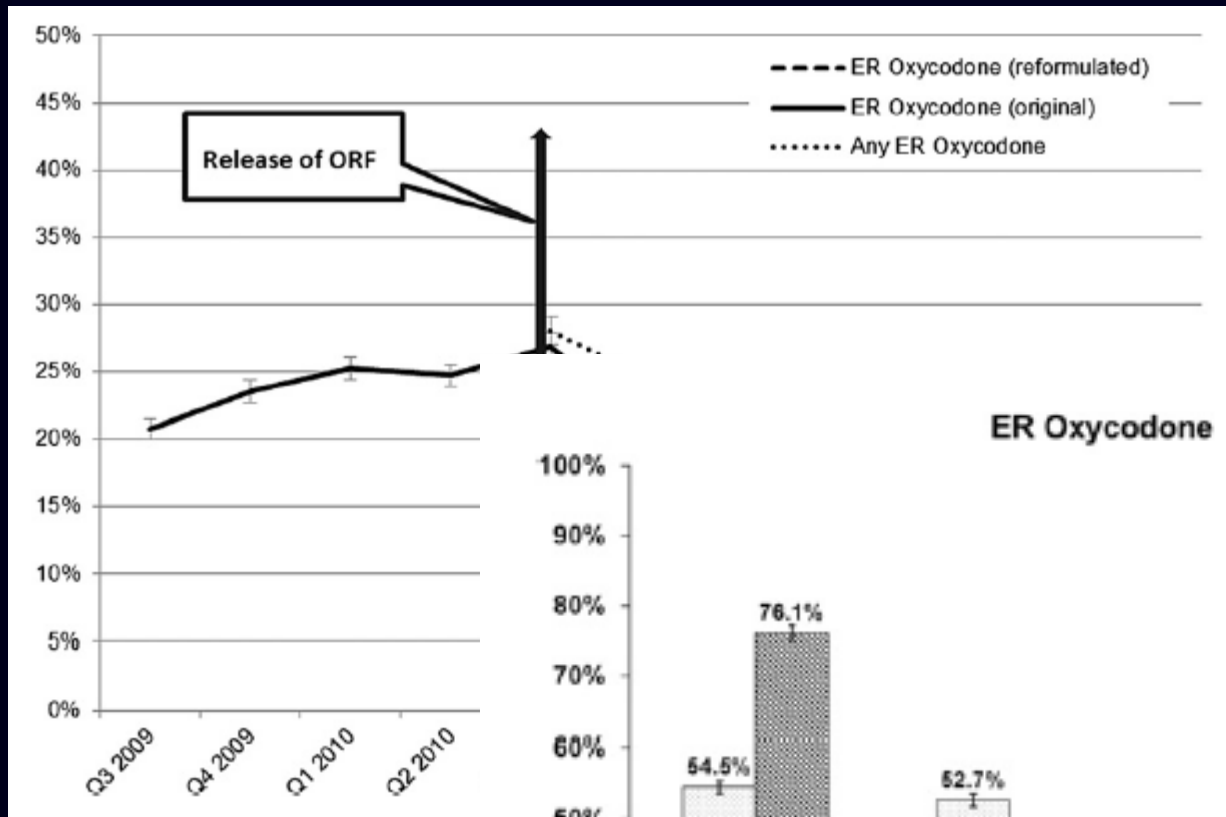
FIGURE 1
 A, Chest CT in October 2004. Centrilobular, clustered micronodular opacities are present bilaterally. Other findings include mosaic attenuation, moderate cylindrical bronchiectasis with peribronchovascular thickening, and mucoid impaction. B, Chest CT 2 months later. Increased prominence of centrilobular, clustered micronodular opacities can be seen. Multiple areas of large patchy opacities are present.

Smith KJ, Pediatrics, 2006;
 Galante JM, J Emerg Med, 2012

EFFECTIVENESS OF INTERVENTIONS

Interventions

- Federal
 - ER/LA REMS
- State
 - PDMPs
 - Tamper-proof scripts
 - Naloxone
 - Multifaceted programs
- Local
 - Integrated community-based programs
- Payer
 - Medicaid lock-in programs
- Manufacturer
 - ADFs



Butler S et al, J Pain, 2012

Conclusions

- Prescription opioid abuse remains a huge public health problem, with a floor estimate of 170,000 deaths since the start of the epidemic
- Tampering and altering routes of administration is a common and particularly dangerous form of abuse
- What little has been done on a national level has been ineffective
- Diverse forms of data suggest that some interventions, including ADFs, can address the parts of the problem they are designed to address