

The unique origins of the opioid crisis, and the special role of academic detailing in addressing it

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Disclosures

- Neither I nor anyone at DoPE accepts any consulting funds from any pharmaceutical company.
- Most of the support for our Division comes from federal sources such as NIH, AHRQ, FDA, and PCORI.
- We also accept unrestricted research contracts from pharmaceutical companies to study specific adverse drug effects and related topics, as long as we can maintain control over the study design and publish whatever we find.
- Alosa health is a non-profit organization and I receive no payment for any of my academic detailing work.

The issues that academic detailing usually confronts

- ***Inadequate training*** in medical school on a given topic
- Limited or distorted ***evidence base***, inadequate comparative effectiveness research studies
- Vigorous ***promotion*** of products by manufacturers
- Dealing with the ***culture*** surrounding a given condition or drug class
- Problematic ***CME*** courses
- ***Patient demand*** considerations
- ***Legal issues*** re prescribing (rare)
- ***Consequences*** of sub-optimal use

Special properties of opioids

- Inadequate training in medical school on a given topic
 - Until recently, management of pain was taught minimally if at all.
 - Education about substance abuse has been either very thin or absent.
- Limited or distorted evidence base, inadequate comparative effectiveness research studies
 - FDA requirement for approval of a pain med usually requires only brief studies.... yet much use is for chronic pain
 - Manufacturers played this laxity like a violin
 - No decent RCT of opioids for chronic pain was published until 2018 ! (Krebs, JAMA)

Special properties of opioids, cont'd

- Vigorous promotion of products by manufacturers
 - Notorious and well-documented distortions/deceptions by Purdue Pharma in its promotion of OxyContin:
 - Minimized the risk of addiction when used as directed
 - Lied about its actual duration of action
 - Ignored its addictive potential
 - Exaggerated its appropriate indications
 - Had to pay >\$600 million to settle charges with federal authorities
 - Top execs had to pay an additional \$34 million out of their own pockets
 - → the well of clinical 'knowledge' was thus poisoned

FOR MODERATE TO SEVERE MALIGNANT OR POST-OPERATIVE PAIN

going on holiday
the family

along the garden
walking the dog
sundays
fish and chips

Let them focus on the things
that matter

OxyContin ▼

oxycodone hydrochloride tablets

Indications and Usage

OxyContin is indicated for the management of moderate to severe pain in patients who are opioid-tolerant. OxyContin is not indicated for the management of mild to moderate pain. OxyContin is not indicated for the management of acute pain. OxyContin is not indicated for the management of pain in patients who are not opioid-tolerant. OxyContin is not indicated for the management of pain in patients who are not opioid-tolerant.

Contraindications

OxyContin is contraindicated in patients with known hypersensitivity to oxycodone or any of the other ingredients. OxyContin is contraindicated in patients with acute or chronic respiratory depression, severe asthma, or severe chronic obstructive pulmonary disease. OxyContin is contraindicated in patients with severe hepatic impairment.

Warnings

OxyContin is a Schedule II controlled substance. OxyContin has a high potential for abuse. OxyContin may cause respiratory depression, sedation, and coma. OxyContin may cause constipation. OxyContin may cause dizziness. OxyContin may cause headache. OxyContin may cause nausea and vomiting. OxyContin may cause dry mouth. OxyContin may cause blurred vision. OxyContin may cause difficulty swallowing. OxyContin may cause urinary retention. OxyContin may cause hypotension. OxyContin may cause tachycardia. OxyContin may cause bradycardia. OxyContin may cause hypothermia. OxyContin may cause hyperthermia. OxyContin may cause hypokalemia. OxyContin may cause hyperkalemia. OxyContin may cause hyponatremia. OxyContin may cause hypernatremia. OxyContin may cause hypocalcemia. OxyContin may cause hypercalcemia. OxyContin may cause hypomagnesemia. OxyContin may cause hypermagnesemia. OxyContin may cause hypophosphatemia. OxyContin may cause hyperphosphatemia. OxyContin may cause hypoproteinemia. OxyContin may cause hyperproteinemia. OxyContin may cause hypoglycemia. OxyContin may cause hyperglycemia. OxyContin may cause hypotension. OxyContin may cause hypertension. OxyContin may cause tachycardia. OxyContin may cause bradycardia. OxyContin may cause hypothermia. OxyContin may cause hyperthermia. OxyContin may cause hypokalemia. OxyContin may cause hyperkalemia. OxyContin may cause hyponatremia. OxyContin may cause hypernatremia. OxyContin may cause hypocalcemia. OxyContin may cause hypercalcemia. OxyContin may cause hypomagnesemia. OxyContin may cause hypermagnesemia. OxyContin may cause hypophosphatemia. OxyContin may cause hyperphosphatemia. OxyContin may cause hypoproteinemia. OxyContin may cause hyperproteinemia. OxyContin may cause hypoglycemia. OxyContin may cause hyperglycemia.



Oxycontin video

- <https://www.youtube.com/watch?v=Er78Dj5hyel>

FREEDOM FROM PAIN!

Extra strength pain relief
free of extra prescribing
restrictions.

- Telephone prescribing in most states
- Up to five refills in 6 months
- No triplicate Rx required

Excellent patient acceptance.

In 12 years of clinical experience, nausea, sedation and constipation have rarely been reported.¹

COMPARATIVE PHARMACOLOGY OF TWO ANALGESICS				
	Constipation	Respiratory Depression	Sedation	Physical Dependence
HYDROCODONE		X		X
OXYCODONE	XX	XX	XX	XX

Blank space indicates that no such activity has been reported. Table adapted from Facts and Comparisons 1991 and Catalano FB. The medical approach to management of pain caused by cancer. *Semin Oncol* 1975; 2: 379-92 and Fleiter JH, et al. The chronic pain syndrome: misconceptions and management. *Ann Intern Med* 1980; 92:96.

The heritage of VICODIN[®] over a billion doses prescribed.²

- VICODIN ES provides greater central and peripheral action than other hydrocodone/acetaminophen combinations.
- Four to six hours of extra strength pain relief from a single dose
- The 14th most frequently prescribed medication in America²

vicodin ES [®]

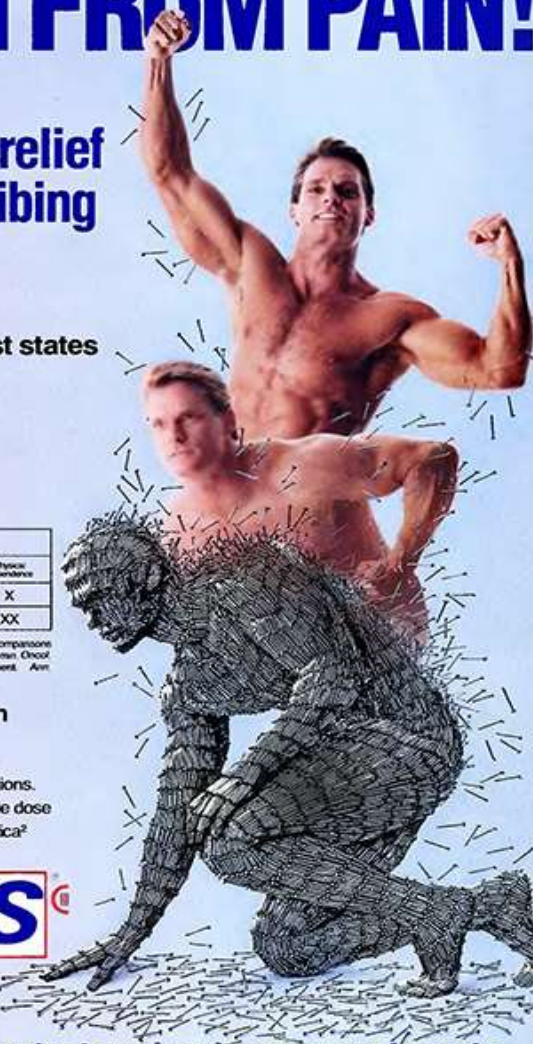
(hydrocodone bitartrate 7.5mg (Warning: May be habit forming) and acetaminophen 750mg)

Tablet for tablet, the most potent analgesic you can phone in.

¹ (hydrocodone bitartrate 5 mg [Warning: May be habit forming] and acetaminophen 500mg)

² Data on file, Knoll Pharmaceuticals
³ Standard industry new prescription audit

Please see brief summary of prescribing information on adjacent page.



The problem has ancient roots

(ad from early 1900s)

BAYER
PHARMACEUTICAL
PRODUCTS.

Send for samples
and Literature to

ASPIRIN
The substitute for the salicylates

ARISTOL
The analgesic and cerebral

CREOSOTE CARB
The specific for tracheitis

PROTARGOL
The antirheumatic

QUINALGEN
The antirheumatic

PIPERAZINE
The antispasmodic

GUAIACOL CARB
The specific for tracheitis

EUROPHEN
The cerebral sedative

HEROIN-HYDROCAL
The sedative for cough

HEROIN
The sedative for coughs

LYCETOL
The uric acid solvent

SOMATOSE
The most powerful solvent

SYCOSE
The soluble sugar

SULFONAL
The soluble iodine

IODOTHYRINE
The active principle of the thyroid gland

PHENACETIN
The relief to tracheitis

TRIONAL
The solvent for tracheitis

SALOPHEN
The antirheumatic and antineuralgic

FARBENFABRIKEN OF ELBERFELD CO.

40 STONE STREET, NEW YORK.

Special properties of opioids, cont'd

- Dealing with the *culture* surrounding a given condition or drug class
 - Creation of a new 'culture of pain' to argue that pain undertreatment is a major problem
 - 'Pain as the fifth vital sign'
 - Background work with hospitals, JCAHO, patient advocacy groups to change standards
 - Coincided with rise of patient satisfaction movement

Smiley and sad faces

The pain scale



Special properties of opioids, cont'd

- Problematic CME courses
 - Education on ER/LA opioids often sponsored by manufacturers of those drugs
 - The distortion of meaning: “abuse-deterrent” formulations
- Patient demand considerations
 - These drugs are **addictive**, obviously!
 - Dramatically greater problem than usual prescribing issues:
 - ‘I really want an antibiotic’
 - ‘That pill doesn’t look like my usual one’
 - ‘I don’t believe in generics’
 - etc.
 - Only a few medication groups have similar attributes, on a far smaller scale:
 - Habituation to benzodiazepines
 - Rebound hyper-acidity if PPIs are stopped abruptly

Special properties of opioids, cont'd

- Legal aspects of prescribing
 - Odd mix of clinical and criminal issues
 - Improper prescribing can lead to use of illegal drugs, and death
 - Some bad prescribing *is* driven by criminal activity
 - Sometimes-draconian legislation on how to prescribe
 - You can go to jail for mis-prescribing these drugs
- Consequences of sub-optimal use
 - Addiction, ER visits, ICU stays, death
 - Nationwide emergency of the opioid mis-use epidemic

Physician motivations and how to address them

- Unique issues of physician attitudes and motivations toward the drugs, their users, and pain
 - vitally important, differ widely.
- It's imperative to understand these in order to influence practice
 - That's why *interactive conversation* is key
 - ...not just "Sit still, I have a 15 minute lecture to do at you."
 - Interesting cross-national differences in opioid use, attitudes
 - Northern vs. southern Europe
 - UK practice patterns
 - 'Stiff upper lip' vs. 'There, there, dear.'
 - Fighting back against the 'culture of pain relief'
 - Clinicians' blame vs. compassion concerning substance use disorders
 - Some question disease model altogether, prefer 'will power'

Prescriber in the middle

“If I prescribe too much opioid, I get identified as an over-user and dinged for that. If I prescribe too little, my patients hate it, it takes forever to explain why, I feel bad that I’m not relieving their pain, and then I get low satisfaction scores and get dinged for that.”

- Therefore it’s vital to understand the clinician’s plight and offer practical rules for dealing with these stresses.
- ...not just telling them to read the CDC Guidelines.

Special issues related to medication-assisted treatment (MAT)

- Most effective care, vs. ‘catering to the addict’?
- Unusual need for special training, testing, certification to use an effective therapy.
- System-based concerns about “being the doctor that all the addicts are sent to”
- Paying doctors to get certified....
 -sometimes results in more certified doctors who don’t prescribe
- This is a ***systems-oriented*** prescribing problem more than most others
 -that therefore requires systems-oriented solutions

Different responsibilities, jurisdictions

- Opioids are among the only prescription drug classes in which medical practice and the law intersect
 - ...and therefore the only drug classes in which poor prescribing can actually be against the law
- → required topic-specific CME requirements and regulatory punishments for poor medication choices
 - These can motivate interest in academic detailing to address such CME requirements and avoid sanctions.
 - Good cop, bad cop principle
- Academic detailing programs view the prescriber as a colleague who seeks education, rather than a potential criminal or scofflaw.

Some practical aspects

..that we integrate into Alosa academic detailing materials

- Clinical guidance:
 - appropriate role of NSAIDs
 - drugs for neuropathic pain
 - non-pharmacological approaches that work
- Morphine mg-equivalent conversion tables
- Patient brochure about pain management
- Tear-off sheets for patients
 - Why it's better for you not to get an opioid Rx
 - Inspired by our earlier antibiotic work
 - Importance of tapering, what to expect, and how to do it.
- www.AlosaHealth.org

Good news: New funders on the scene

- Governmental programs to educate physicians have previously been rare, tiny, and short-lived
 - except for the very effective VA Academic Detailing Service, which is a model of federally supported AD, esp. re opioids
 - Has already published some results, incl. uptake of naloxone
 - But until recently, little support for non-VA prescribers
- Now, many more entities are lining up to help educate clinicians about the opioid crisis:
 - CDC
 - SAHMSA
 - Health insurers
 - Others
- Many of these programs have begun to support academic detailing.

In conclusion

- The opioid crisis differs markedly from other prescribing problems, in many ways:
 - Origins
 - Legal status
 - National scope at epidemic-level scale
 - Potentially lethal results of poor prescribing
 - Clinical decisionmaking processes
 - Physician attitudes, biases
 - Effective approaches
 - Potential to save lives
 - Funding opportunities
- It may provide one of the most fruitful and life-saving opportunities for academic detailing programs to improve care and patient outcomes.