

Disclosure Statement

 James Rick, Priya Noor and Michael Ascari have no conflicts of interest or relevant financial/nonfinancial relationships to declare.

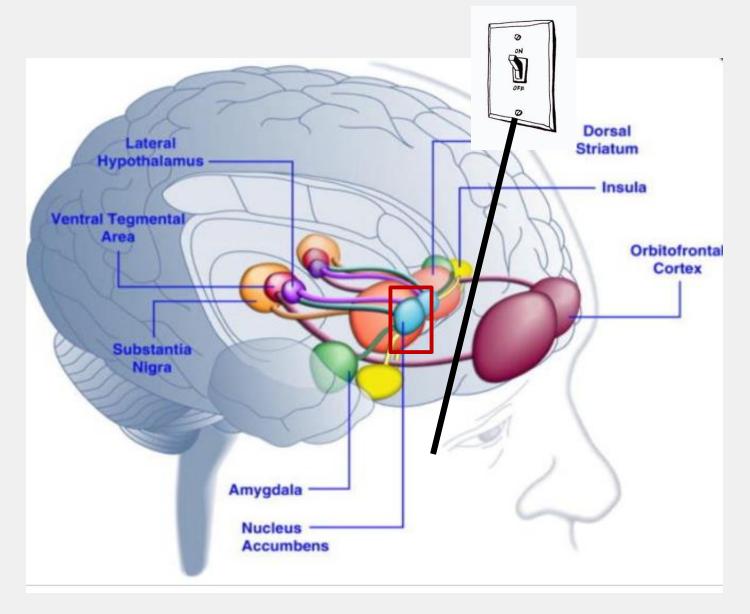
The Way We Were

- Safe for routine use
- Not addicting < 1%
- Good for all types of pain
- No dosage ceiling
- No Long Term Side Effects
- Prescribed as first line monotherapy
- Not prescribing viewed as reckless and negligent

How We Got There

- Patients prescribed high dose opioids without evidence of benefit
- Documentation of functional goals, risk, or safety lacking
- Prescribing pressure from governing bodies, press, journals, peers, patients
- Follow up often inadequate
- Pain assessment inadequate and infrequent

Dopamine: Neuroanatomy of Desire



CORRESPONDENCE

Addiction Rare in Patients Treated with Narcotics

N Engl J Med 1980; 302:123 <u>January 10, 1980</u>

To the Editor:

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only **four cases** of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. **We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.**

Jane Porter Hershel Jick, M.D.

Boston Collaborative Drug Surveillance Program Boston University Medical Center, Waltham, MA 02154

Provider Basis for Prescribing Medications a la Commercial Detailer

Personal experience

Colleague

Visit from Drug Rep

Academic detailing

Guidelines

Expert opinion

Ads direct to consumer

Journal ads

Peer or patient pressure

Formulary

Up-to-date

Ghost writers

Swag

Insurance

Branded vs. Generic

Pharmacy Benefits Manager

Non inferiority studies

Subset analysis

needed to treat or harm

Community standards

Journal article

Cost

Ethics

PCRCT

The Perfect Storm



The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy

Art Van Zee, Am J Public Health. 2009 February; 99(2): 221–227.

Q12 duration

Sophisticated Prescriber Data Base

15,000 videos : "I Got My Life Back"

Speaker training symposia all expenses paid by Purdue

Starter Coupons

Swag



Sales rep message: addiction < 1%

Journal Articles

The Joint Commission

Studies (Porter and Jick)

Increased Drug Reps 318 -> 671

Lucrative Sales Incentive Bonuses

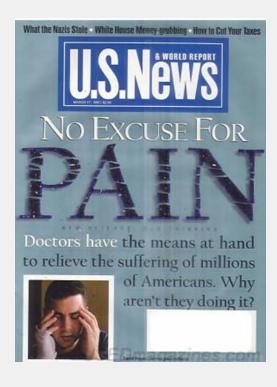
Purdue's "Partners Against Pain" Web site: low addiction risk

The Times They Are A - Changin

3/1997

9/2014

6/2015







Every Day a Little Death

Opioids killed more than 28,000 people in 2014, more than any year on record. At least half of all opioid overdose deaths involve a prescription opioid.

28,000 deaths / 365 days = 77 deaths/day =

3 deaths per hour

PERSPECTIVE

Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline Thomas R. Frieden, M.D., M.P.H., and Debra Houry, M.D., M.P.H. N Engl J Med 2016; 374:1501-1504 April 21, 2016



Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription; the proportion was as high as 1 in 32 among patients receiving doses of 200 MME or higher. We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.

Opioid Safety Initiative (OSI) 2014

- Opioid Dashboard Standard data base and MED
- Functional Goals: National Informed Consent
- Step 2 Pain Clinic
- Patient Education: "Taking Opioids Responsibly"
- Provider Education: national, regional and local
- Document efficacy and safety assessment (risk tools)
- High dose opioids: Review & reduce
- Reduce methadone, OxyContin, hydromorphone
- State Prescription Drug Monitoring (PDMP)
- Random Urine Drug Testing: annually at minimum
- Reduce opioids + sedative hypnotics
- Offer Complementary Alternative Modalities (CAM)

Opioid Safety Initiative: Local Actions

LEADERSHIP BUY-IN and SUPPORT

- Medical Center Director
- Chief of Staff
- Chief of Primary Care / Service Chiefs
- Chief of Pharmacy
- Hiring Pain Specialist
- Patient Advocate/ Consumer Affairs
- Congressional Representatives

New Rules

- PDMP query annually (minimum) and all new patients prescribed opioids
- One pharmacy, one prescriber of opioids
- UDS annually (minimum)
- ED prescribing limited to 3 days
- No early fills of opioids
- No change in providers because of opioids
- Face to face visits minimum every 6 months
- National Consent + Patient Educational material
- Gradual reduction in allowable quantities of opioids

Stepped Pain Care

Step 1 – Primary Care

Opioids for CNMP restricted to Primary Care

Step 2 Pain Clinic

- All patients prescribed methadone
- Patients prescribed > 200 MED
- Interdisciplinary support
- Patients aggressively challenging reduction

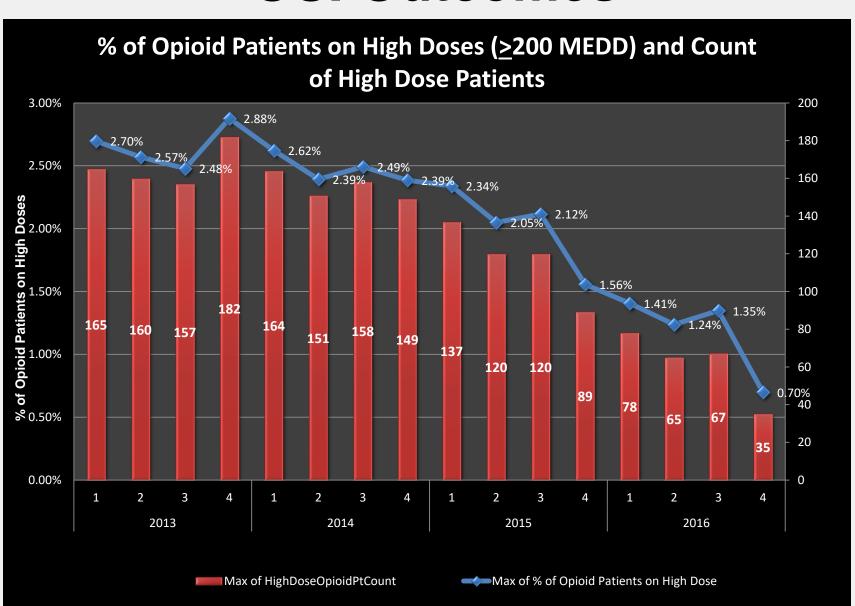
Academic Detailing

- Access to data and provider
- Provider specific education based upon outlier prescribing data
- Assistance in gradual dose reduction strategies
- Promotion of Naloxone kits
- Follow up visits to individual providers

Enhanced Availability of Complementary Alternative Medicine

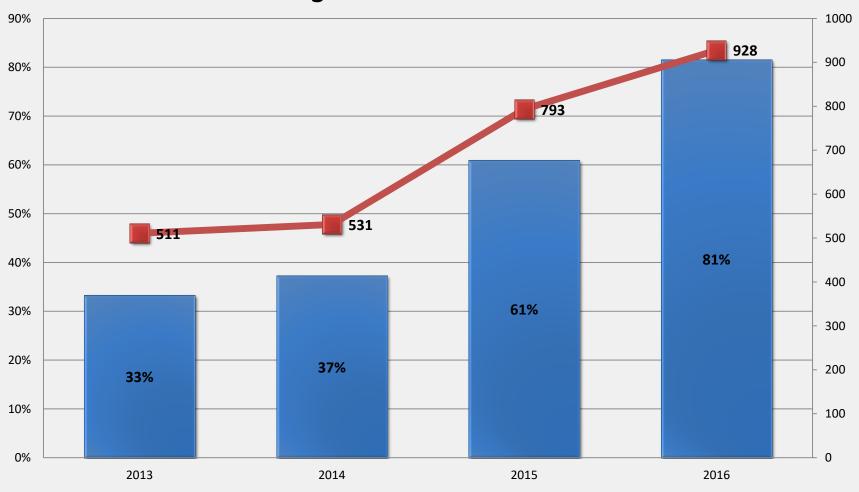
- Acupuncture
- Mindfulness
- Sleep Hygiene Techniques
- Spinal Manipulation
- Physical and kinesiotherapy
- Yoga
- Tai Chi

OSI Outcomes

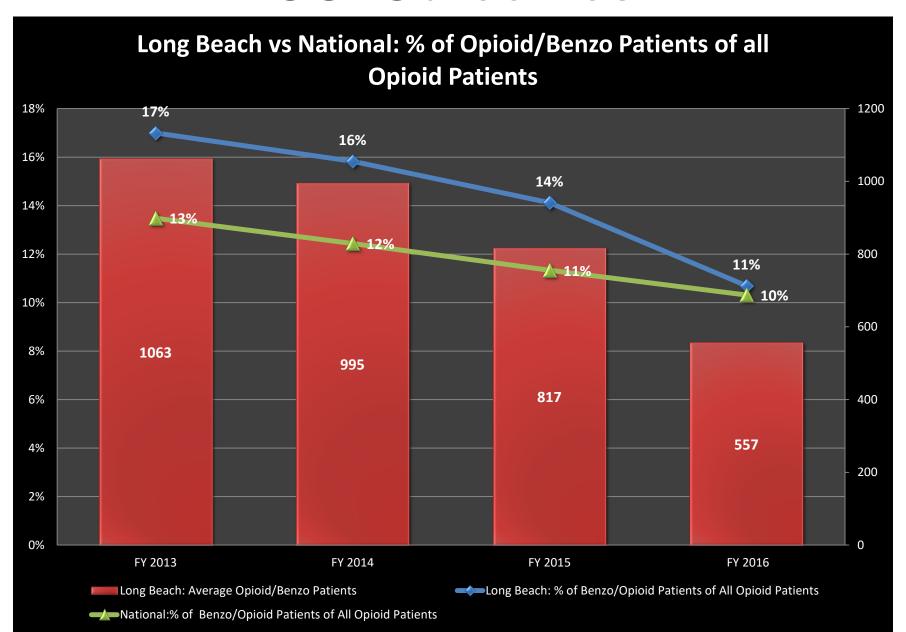


OSI Outcomes

Percentage of CNMP Patients with UDS



OSI Outcomes



OSI Challenges

- New patients presenting with opioid dependence
- Concomitant use of opioids with marijuana, sedative hypnotics and or muscle relaxants
- Resistance from prescribers
- Comorbid mental illness
- Abuse, Dependence, Diversion
- Education & Culture shift: Function & Quality of life
- Patient demands and complaints
- Focus on function and quality of life rather than pain
- Time and effort required to reverse habituated patients

Tempis Fugit

One minute to write an opioid prescription versus 45 minutes of aggravating polemics to explain why you're not prescribing it!

Where are we Going?

Legislation

H.R.5046 Comprehensive Opioid Abuse Reduction Act of 2016

Regulation

FDA top officials call for sweeping review of agency opioids policies

Accreditation

The Joint Commission changes standards standard

Guidelines

CDC Guidelines for Prescribing Opioids for Chronic Pain

VHA/DOD Guidelines for Prescribing Opioids for Chronic

Litigation - 1-800 BAD DRUG

Education

Function, Safety, Quality of life, non opioid alternatives and the apie

Academic Detailing

Opioid Stewardship

Direct-To-Consumer (DTC) Messaging

What is DTC advertising?

 Message sent directly to patients via some medium (ie. mail)

Goal:

- To elicit a reaction from the recipient of the message
 - Ie. Address the patient's benzodiazepine prescription with his/her prescriber at the next visit



Message



Reaction

Original Investigation

Reduction of Inappropriate Benzodiazepine Prescriptions Among Older Adults Through Direct Patient Education The EMPOWER Cluster Randomized Trial

Cara Tannenbaum, MD, MSc; Philippe Martin, BSc; Robyn Tamblyn, PhD; Andrea Benedetti, PhD; Sara Ahmed, PhD

- Direct to Consumer Contact and shared decision making
- Patient decision aids
- Provider decision aids

EMPOWER Patient Decision Aid





Unintended Consequences of OSI



Bob Dylan, 1963

Come gather 'round people
Wherever you roam
And admit that the waters
Around you have grown
And accept it that soon
You'll be drenched to the bone
If your time to you is worth savin'
Then you better start swimmin' or
you'll sink like a stone
For the times they are a-changin'

Come senators, congressmen
Please heed the call
Don't stand in the doorway
Don't block up the hall
For he that gets hurt
Will be he who has stalled
There's a battle outside and it is ragin'
It'll soon shake your windows and
rattle your walls
For the times they are a-changin'

