Pain, Law, Drug Abuse and Responsible Prescribing

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Disclosure

• I am not a lawyer and do not offer legal advice
• Information presented here is from the perspective of a concerned physician
• No Direct Financial Relationships with Drug Companies
  • Engage in official CME speaking
  • No Pharma / industry speakers or consultation programs
  • Past President and Chair, American Pain Foundation

The Problem of Undertreated Pain

• World Health Organization has said that undertreated pain is the number one health problem in America

• # of patients with chronic pain in the U.S. exceeds diabetes, heart disease and cancer combined


IOM

Relieving Pain in America 2011

• At the request of Congress and HHS
  • IOM assessed the state of the science regarding pain research, care, and education

• Chronic Pain
  • Affects an estimated 116 million American adults
  • Costs the nation up to $635 billion each year in medical treatment and lost productivity
IOM
Relieving Pain in America 2011

Recommendations
- HHS develop population-level strategies to increase awareness about pain and its treatments
- Offers a blueprint for action in transforming prevention, care, education, and research, with the goal of providing relief for people with pain in America

Generalized View of Opioid Therapy for Chronic Pain
- Opioids are not for everyone
  - Opioids seem to work for some
  - Opioids seem to be ineffective for some
  - Opioids seem to be problematic for some
- Although it may be difficult to know who is in which group
  - Opioids can be used chronically with efficacy and safety
    - Particularly when there is little else to offer
    - High-dose Tx is questionable

"Prescriptions for opiates (hydrocodone and oxycodone products) have escalated from around 40 million in 1991 to nearly 180 million in 2007, with the U.S. their biggest consumer. The U.S. is supplied 99 percent of the world total for hydrocodone (e.g., Vicodin) and 71 percent of oxycodone (e.g., OxyContin)."

Statement of Nora D. Volkow, M.D., Director, NIDA/NIH:
To US Senate Committee on Judiciary March 12, 2008
http://judiciary.senate.gov/hearings/testimony.cfm?renderforprint=1&did=3199&wit_id=7038:

"Opioid overdose is now the second leading cause of accidental death in the United States"
Thomas McLellan, MD: Director of the Center for Substance Abuse Solutions at the University of Pennsylvania School of Medicine & Former Deputy Director: ONDCP

CDC: National Centre for Injury Prevention and Control
MVA's are #1
Leading cause of accidental death in the U.S. for 45-54 age group

"Cracking down on prescription drug abuse"
April 07, 2003
Prescription drug abuse has grabbed recent headlines with the high profile deaths of celebrities like Cory Haim, Heath Ledger, Anna Nicole Smith, and Michael Jackson. But the epidemic of prescription drug abuse is not limited to Hollywood.

Prescription drugs are the number one cause of accidental death in the U.S.

"The OxyContin Express: South Florida: the Columbia of prescription drugs"

"The Boston Globe"
**DEA Facts on Prescription Drug Abuse**

- Nearly 7 million Americans are abusing prescription drugs
- More than the number who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined
- 80 percent increase in just 6 years

**Prescription pain relievers are new drug users’ drug of choice, vs. marijuana or cocaine**

- In 2009, 6,027 persons/day abused prescription pain relievers for the first time
- Every day 2,500 teens use prescription drugs to get high for 1st time
- 1 in 7 teens admit to abusing prescription drugs to get high in the past year
- 60% of teens who abused prescription pain relievers did so before the age of 15
- 56% of teens believe that prescription drugs are easier to get than illicit drugs

**CDC: Poisoning Deaths Involving Unintentional Opioids in US 1999-2006**

**CDC: Poisoning Deaths in US 1971-2007**

- Poisoning deaths
  - Rates have increased ~ 5X since 1990
  - “The increase in drug overdose death rates is largely because of prescription opioid painkillers”….CDC
  - Cases involving methadone increased ~7X
- In 2007, opioids were involved in more overdose deaths than heroin and cocaine combined
  - ~ 2X the number involving cocaine
  - > 5 X the number involving heroin

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Hall et al. Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities. JAMA, 2008; 300(22):2613-2620

- OD deaths in year 2006
  - Evidence of doctor shopping in 21% (1 in 5)
    - Prescriptions for CS from ≥5 clinicians in the year prior to death
      - Largely Female: F ≥M (~2:1, 31% to 17%)
      - Largely Older: 71% age > 35
    - Negative association between drug diversion + doctor shopping
      - Only 8% met criteria for both

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- OD deaths in year 2006
  - Methadone
    - Most attributed opioid in single-drug deaths
    - Involved in more deaths than any other drug (40% all deaths)
  - 95% w/ indicators of substance abuse
  - 79% of all cases associated with multiple contributory substances
  - 93% of all cases involved opioid analgesics
  - **66% did not have a prescription**
  - 34% had prescription

WA State Data on Opioid Poisoning

- 9940 people w/3 or more opioid prescriptions within 90 days for chronic non-cancer pain between 1997 and 2005 (8 yrs)
- Measures
  - Avg daily opioid dose over the previous 90 days from automated pharmacy data
  - Nonfatal and fatal overdoses identified through diagnostic codes from inpatient and outpatient care and death certificates (confirmed by medical record review)
  - 51/9940 opioid-related overdoses and 6 deaths
  - Patients receiving ≥ 100 mg/d = ~9X increase in OD risk compared with Patients receiving 1-20 mg/d
  - Patients receiving 50-99 mg/d had a ~4X increase in OD risk
- Compared w/controls, Opioid dependent individuals displayed
  - Decreased functional connectivity in seed regions that included the anterior insula, nucleus accumbens and amygdala subdivisions.
  - Longer duration of prescription opioid exposure associated with greater changes in functional connectivity

Paradigm Shift in Opioid Prescribing

- Competing Public Health Crises
  - Under Treated Pain
  - Prescription Drug Abuse
- Increasing Need for Safe & Effective Pain Management
  - Decreased barriers to appropriate opioid use
  - Increased safety in opioid use
Complcating Global Market

Internet Pharmacies

- anyone of any age can obtain dangerous and addictive prescription drugs with the click of a mouse
- Joseph Califano, Director of the National Center on Addiction and Substance Abuse at Columbia University & Former Secretary HHS
- 85% of all internet prescription sales involved controlled drugs (per DEA)
- Only 11 percent for regular pharmacies
Internet Pharmacies

- **Columbia University Study**
- Search of pharmacies advertising on Internet
  - Using popular search engines
    - Google, Yahoo and MSN
  - Found 206 sites selling controlled drugs
  - 159 sites directly sold controlled drugs
    - 135 (85%) did not require a prescription or provided them on the basis of online questionnaires

Ryan Haight Online Pharmacy Consumer Protection Act

- Named for Ryan Haight
- Died in 2001 at 18 after prescription narcotic OD purchased online
- Responds to concerns about rising availability of controlled prescription drugs on the Internet
- Took effect in April 2009 -- Amended CSA of 1970
  - Prohibited delivery, distribution, and dispensing of controlled prescription drugs over the Internet without a prescription from a physician who interviewed and examined the patient in person

Opioids & Driving


“...potential instructions to stop driving to a patient utilizing opioids essentially dooms the patient to a life of disability”

“...the answer to this controversy has widespread implications both for the patient and the medical practitioner”

Doctors, Drugs, and Driving

Tort Liability for Patient-Caused Accidents

George J. Annas, J.D., M.P.H.
NEJM vol 359(5) July 31, 2008

Do physicians have any duty to patients who are taking drugs the physician has prescribed when those drugs are likely to have an adverse effect on the patient’s ability to drive safely?
Reprinted from Time Magazine

California Marijuana Legalization Initiative
November 2, 2010 Ballot

Los Angeles Times | NATION
Marijuana bill officially introduced to Congress by Ron Paul, Barney Frank

Los Angeles Times | LOCAL
Marijuana legalization initiative headed for 2010 ballot, organizers say

San Francisco
Obama’s War On Weed: White House Launches Crackdown On Medical Marijuana

Huff Post San Francisco
Obama’s War On Weed: White House Launches Crackdown On Medical Marijuana
Many court rulings on MJ
• 2 supreme court rulings
• Restrict physicians and patients
• Many States legalize medical MJ
• Federal vs. State
• Supreme Court verdict on PAS

Criminal Charges For Overtreatment of Pain
• Numerous High Cases
  • Few cases
  • Relative to the # of MD
  • Amount of pain severe
• Good clinicians
  • Practicing at extremes of the normal curve
• Well intentioned clinicians
  • Practicing below standard of care
• Clinicians practicing outside of medicine
• Illegal activities

Elder Abuse Cases in Courts

Criminal Activity vs. Medical Incompetence
• Disturbing Trend
• Unclear line between incompetent medical practice and criminal activity
• Egregious/Illegal physician behavior
• Unclear why not deterred by Administrative processes
• Once criminal charges are made
• Law enforcement goes wild
• Fisher Case: Unabomber Scenario
• Shaygan Case
Dr. Ali Shaygan
- 36 yo Miami Physician
- Accused & acquitted
  - 141-count indictment
  - Writing illegal prescriptions
    - Reportedly met with patients at Starbucks
    - Prescribed to undercover DEA agents
  - One case involved patient’s death from a methadone overdose
- Faced minimum 20 years prison because patient death

The Quest to Understand Addiction

Addiction, Abuse, & Aberrant Behavior in Pain Patients

Terms Associated with Opioid Use
- Addiction
  - Psychological component
  - Drug-seeking behavior
  - Nonmedical use of drug despite potential harm
- Pseudo-addiction
  - Transient problem - misdiagnose analgesia
- Tolerance
  - Not relevant to efficacy if agents and dosage are adjusted
- Physical Dependence
  - Natural process, weaning from drug is a simple medical process

Dependence vs. Addiction vs. Abuse
- Clonidine
- Cocaine, Gambling, Food, Sex
- Entrepreneurs

Addiction vs. Analgesia
- Patients with addiction take increasing amounts of abusable drugs
  - Function does not improve
    - Usually worsens
- Patients usually find a stable dose
  - Pain doesn’t completely abate
    - Balance of least pain/most function
  - Function improves
    - Does NOT DECREASE
    - If decrease → does NOT = Addiction
Risk Management with Opioids

- Requires understanding of functional outcomes
  - Side effect management
    - Improved function $\rightarrow$ Efficacy
    - Static or decreased function $\rightarrow$ Toxicity
- Universal Precautions
  - Standardized programs that apply to all
    - Consistent risk management practices
    - Persistent vigilance
    - Minimized bias

FSMB Model Policy

Basic Tenants

- Pain management is important and integral to the practice of medicine
- Use of opioids may be necessary for pain relief
- Use of opioids for other than a legitimate medical purpose poses a threat to the individual and society

Goals of Treatment

- Improved level of independent function
- Decreased Pain
ADHERENCE

- History, Presentation, Side Effects
  - YELLOW & RED LIGHTS
- Diaries
- Questionnaire based screens
- Drug Screening
  - Urine, Serum, Hair, Markers (e.g. Phenobarbital, Digitalis)
- Opioid Agreements / Contracts
- PMPs

THE NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING ACT OF 2005 (NASPER H.R.3015)

National Prescription Monitoring Program

- Promise of improving pain care
- Greater oversight of abusable drugs
- Clinical utility at point of care
- Risks associated with chilling effects on pain control
- Clear message to prescribers
- Confidentiality concerns
- Variable PMP plans

OPIOID ANALGESICS

- The Gold Standard
  - Severe Pain
  - Unremitting Pain
Endogenous Opioids

- The body’s internal morphine
  - Endorphins
  - Enkephalins
  - Dynorphins

Categories of Opioid Drugs

- Short-acting opioids
  - Morphine sulfate (e.g., Roxanol™, MSIR®)
  - Codeine
  - Hydrocodone (e.g., Vicodin®, Lortab®, Vicoprofen®)
  - Oxycodone (e.g., Roxicodone™, Oxy IR®, Percocet®, Tylox®, Percodan®)
    - Newly FDA Approved Abuse Resistant Oxycodone Formulation Oxecta (from Acura/Pfizer)
    - Hydromorphone (Dilaudid®)
    - Oxymorphone (Numorphan®)
    - Fentanyl (Actiq®)

Categories of Opioid Drugs (cont)

- Long-acting opioids
  - Sustained-release morphine (e.g., MS Contin®, Avinza™; Kadian®, Oramorph® Embeda®)
  - SR oxycodone (Oxycontin®)
    - New formulation of Oxycontin®
    - Awaiting approval of Remoxy
  - SR Oxymorphone (Opana®)
  - SR Hydromorphone (Exalgo®)
  - Transdermal fentanyl (Duragesic®)
  - Methadone
  - Buprenorphine (Suboxone SL / Butrans TD)

Methadone

- Different Analgesic vs Plasma half lives
  - Equianalgesic Dosing
    - Opioid Naive
    - Opioid Tolerant
  - Unstable Biometabolism
  - Arrhythmia Potential

Methadone and Abuse

Is methadone less abusable?

- Maybe
- Compared with some
- Still is abusable
- Alarming statistics on methadone abuse and deaths in US

Abuse Resistant Formulations

Agonist/Antagonist

- Sequestered antagonist
- Bioavailable antagonist
- Antagonists are released only when agent is crushed for extraction
  - Opioid formulation sequestered antagonist becomes bioavailable only when sequestering technology is disrupted, targeted to prevent intravenous abuse
King Pharmaceuticals + Pain Therapeutics

**Remoxy**
- SR oxycodone formula in a viscous gel base
  - Deters dose dumping
    - Accessing entire 12-h dose of CR medication at 1 time
  - Difficult to crush, break, freeze, heat, dissolve
    - The viscous gel-cap base of PTI-821 cannot be injected
    - Resists crushing and dissolution in alcohol or water

Remaining Questions About Abuse Resistant Compounds
- How much does the barrier approach deter the determined
- How much do Agonist/Antagonist compounds retain efficacy
- How much do Agonist/Antagonist compounds pose serious adversity
- How to deter over use without manipulation

Buprenorphine
An Abuse-Resistant Opioid?
- Antagonist of Kappa opioid receptor
- Agonist of Mu opioid receptor
  - Tightly binds to mu receptor with less respiratory depression and withdrawal

Butrans
Buprenorphine TD Formulation
- Sublingual/Transdermal delivery bypasses first pass hepatic metabolism
- Oxidation via P450 isoenzyme 3A4
- Recent FDA approval of transdermal compound June 2010
  - Q-T prolongation at 40mcg/hr dose
  - Low dose formulation

Regulatory Agencies and Pain
“Final” Policy Statement
September 6, 2006

As a condition of being a DEA registrant
• A physician prescribing controlled substances has an obligation to take reasonable measures to prevent diversion
• Interim Report described physicians responsibility to minimize abuse and diversion
• Why the change from MINIMIZE to PREVENT?

Multiple Prescriptions for Schedule II Controlled Substances
Fed Register: November 19, 2007

• Issuance of Multiple Prescriptions for Schedule II Controlled Substances
  • Effective December 19, 2007
  • Final Rule amends DEA’s regulations
  • Allows practitioners to provide individual patients with multiple prescriptions for a specific schedule II controlled substance
    • Written on the same date
    • To be filled sequentially
  • Combined effect sequential multiple prescriptions allows a patient to receive over time up to a 90-day supply of that controlled substance
  • CSA does not permit refilling Schedule II controlled substances, requiring that a new prescription be issued for each quantity of the substance

FDA: REMS

Food and Drug Administration Amendments Act of 2007
FDAAA

• Signed into law September 27, 2007
  • Primary goal to enhance medical product safety
  • Represents many significant additions to FDA authority -- 200 specific provisions
• Risk Evaluation and Mitigation Strategies (REMS)
  • FDAAA authorizes FDA to require a “REMS” for new drug applications and drugs already approved if the Agency determines it’s necessary to ensure that the benefits of the drug outweigh the risks
“Final” Policy Statement
September 6, 2006

- Dispensing Controlled Substances for the Treatment of Pain
- Registrant responsibility TO PREVENT diversion and abuse
- Citing Gonzales v. Oregon
- Properly determine a legitimate medical purpose for the prescription of a controlled substance
- Act in the usual course of professional practice

6 Elements of REMS
March 7, 2008

1. Health care providers who prescribe the drug have particular training, experience, certification
2. Pharmacies, practitioners or health care providers that dispense the drug are specially certified
3. Drug dispensed to patients only in certain health care settings
4. The drug is dispensed with documentation of safe use conditions, such as lab results
5. Each patient taking the drug subject to monitoring
6. Each patient using the drug enrolled in a registry
Pain & legislation

- State Legislation
  - Most states are active
  - Most focused on prescription Rx Abuse
  - Washington State Guidelines and ESHB 2876

Pain & legislation

- National Legislation
  - VA Pain Care Act 2008
    - S 2162, HR 6122 (changed to HR 6445)
  - Military Pain Care Act 2008
    - Incorporated into The National Defense Authorization Act, H.R. 5658

Pain & legislation

- National Legislation: Health Reform
  - National Pain Care Policy Act of 2009
    - S 660 (Hatch Dodd), HR 756 (Capps/Rogers)
    - As passed in Health Reform Bill of 2010
      - Patient Protection and Affordable Care Act 3/23/10
  - IOM Conference/Report on Pain
    - Required report to Congress
  - HHS grant program for Education and Training in Pain Care
    - Authorized training grants
    - Increased focus and investment on pain research at NIH

Conclusions

- Responsible opioid prescribing requires Risk Management
- Legal & Regulatory Forces
  - Pushing this outcome
  - Uncertain components

Pharmaco-Vigilant Prescribing
Risk Stratification and Management

- Screen for Risk Before Prescribing
  - Multifactorial aspects including physical, psychological & social domains
- Prepare for Risks after Tx Prior to Prescribing
- Prepare Clear Objective Tx Outcomes / End Points
  - Follow-up goals
- Obtain Real Informed Consent Based on Risks & Benefits
  - Include available evidence
  - Adjust Risk:Benefit determination relative to above considerations

Conclusions

- Responsible opioid prescribing requires Risk Management
  - Uncertain components
    - What it is
    - Who needs what parts
    - If universal approaches work
      - Equitable
      - Stigmatizing
    - Does it improve outcomes
      - For patients
      - For regulators
      - Why should these be different?
Pharmaco-Vigilance with Opioids

- Risk Management
  - Risk stratification and monitoring
  - Functional outcomes
    - Improved function
    - $\rightarrow$ Efficacy
    - Static or decreased function
    - $\rightarrow$ ! Efficacy !Toxicity

- Uniform Application
  - Universal Precautions/Standardized programs
    - Consistent risk management processes
    - Persistent vigilance
    - Minimized bias

Fishman’s Basics of Chronic Opioid Prescribing

- Single prescriber - Single pharmacy
- Opioid agreement
- Lowest possible effective dose
- Caution using opioids with conditions potentiating AE’s
  - COPD, CHF, sleep apnea, substance abuse, elderly, or renal or hepatic dysfunction, Mental Illness
- Caution in combining opioids with sedative-hypnotics, benzodiazepines or barbiturates
- Screen universally for substance abuse & mental illness
- Use functional outcomes
- Monitor for medication misuse and check random urine drug testing and PMP data

CONCLUSIONS

- Prescribers are largely Untrained
- Education solutions must begin at the beginning
  - Medical, dental, NP, PA students
  - Postgraduate residency training
- Principles of safe opioid prescribing consistent with safe use of all controlled substances

Conclusions

- Advice
  - Err on the side of compassionate employment of best medical judgment
    - Bounds of medicine defined by intent
  - Get Trained
  - Follow FSMB policy suggestions
  - Manage Risk
    - Transparent Documentation

THANK YOU : smfishman@ucdavis.edu