PHYSICIAN RESOURCES FOR MANAGING PATIENTS ON LONG-TERM OPIOID MEDICATIONS

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Epidemiology of Pain

- 80% of all MD visits include the complaint of pain
  - Turk & Gatchel 1996
- Over 1/3 of Primary Care visits are for the primary complaint of pain

  Upshur et al. 2006
- Up to 50% of US adults have pain at any time
  - Gatchel et al. 2007; Elliott et al 1999; Walker 2000
- Psychosocial factors strongly contribute to pain onset, severity, chronicity and disability

  Van Dorsten 2010, Van Dorsten & Weisberg (2011), Van Dorsten 2006

Epidemiology of Pain

Johannes et al. (2010) conducted an internet-based survey of 27,035 US adults

- 30.7% point prevalence of chronic pain
- 34.3% for females, 26.7% for males
- 50% reported daily pain (16% of total cohort)
- 32% (10% of total) rated pain as severe (≥ 7 on a 0-10 scale)

Moulin et al. (2002) Large survey of Canadian adults: 29% reporting chronic pain in the past year

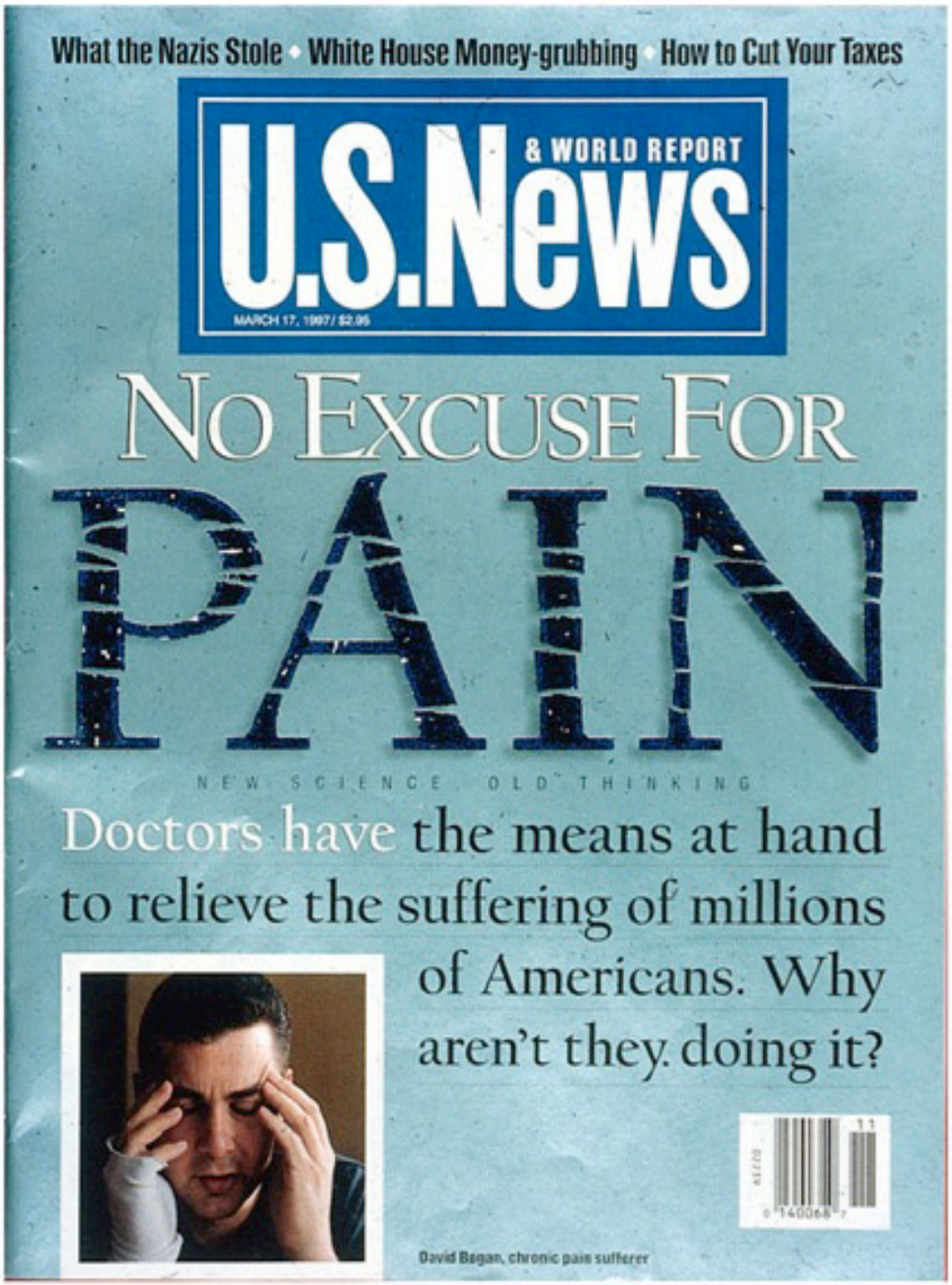
Comparable Prevalence of Chronic Disease States in US Adults?

- 41.9 Obesity CDC (2023)
- 45.4% Hypertension CDC (2020)
- 9% Type II Diabetes Mellitus CDC (2022)

History of Opioid Controversy

Late 20th Century – (1990's to early 2000's)

- Public and Media backlash against under-prescribing
- Promoted a culture of "responsibility to use the tools available to us to end unnecessary suffering…"
  - JCAHO: Pain as 5th Vital Sign (2001)
  - Multiple Opioid Guidelines for the Management of Chronic Non-Cancer Pain
  - Multiple organizations supporting increased opioid use for pain
  - Aggressive marketing of Oxycontin for pain relief



US News and World Report 2006

History of Opioid Controversy

- Recent past (2000-2015)
  - Evidence that JCAHO standard did not improved pain care
  - Little evidence that evidence-based guidelines were widely used by providers in prescribing Iorio et al. 2000
  - Enormous proliferation of prescription medication misuse, fatal overdoes, and increased vigilance of physician practices for "over-prescribing"

Illegal Opioid Prescription Trade USA Today, February 24, 2011

Florida practitioners prescribed 41.2 million Oxycodone pills in 2009

Entire remainder of US: 4.8 million pills in 2009

Broward county, FL practitioners prescribed 16 million doses (1.8 million people in county)

Of top 25 prescribers in US; 18 in Broward county

ER visits from misuse of opioids more than doubled from 144,644 in 2004 to 343,628 in 2009

Drug Abuse Warning Network

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Prescription-drug toll soars

Deaths, pharmacy thefts rise in frenzies to find painkillers

By Felisa Cardona *The Denver Post*

The number of people who abuse painkillers in Colorado is on the rise and the problem is manifesting itself in a string of recent pharmacy robberies, according to the U.S. Drug Enforcement Administration.

"The Hooded Pain-Med Bandit," a young dark-haired man with a gun tucked in his waistband, has hit three Walgreens pharmacies in Wheat Ridge and Arvada since December, police say.

The latest occurred Feb. 12 in Arvada when he lifted his shirt, flashed the gun and ordered the pharmacist to hand over painkillers.

In Wheat Ridge, he specifically demanded Oxycontin and Vicodin.

"Obviously, this is concerning because an addict, or someone desperate, who is trying to steal narcotics is also armed," said Arvada police Cmdr. Aaron Jacks.

The numbers of people who died from prescription-drug abuse rose 95 percent in Colorado in almost a decade, according to the DEA.

In 2000, there were 228 deaths in the state linked to prescription drugs. By 2009, 445 people died from abusing painkillers in Colorado.

In Denver, 70 percent of the drug-related deaths are attributable to painkillers, said Kevin Merrill, acting special agent in charge of the DEA's Denver division.

"For some reason, the society today has an appetite for pain-killing drugs," Merrill said. "These painkillers are very, very potent and much more potent than your normal morphine. A lot of these painkillers were made for people who have terminal cancer or major invasive surgery. They are not made for long-term relief."

The drugs are also attractive to thieves and unscrupulous doctors because they are worth a lot of money.

Oxycontin costs $1 per milligram on the street and comes in a range of doses from 15 to 80 milligrams.

If a dealer sells 1,000 tablets that are 80 milligrams each, that seller can make $80,000, Merrill said.

"Some pharmacies across the country have frankly decided not to be involved in some narcotic drugs, and I've even seen pictures of (pharmacies) that put signs in their window: 'We do not carry Oxycontin. Don't break our door down. We don't have them.' "

And while the drugs are available on the street, Merrill says most users are getting drugs out of their parents' or other relatives' medicine cabinets.

On April 30, the DEA is planning its second national Prescription Drug Take Back Day allowing anyone to turn unused pharmaceuticals over to local police or sheriff's deputies — with no questions asked.

"It is a matter of getting these pills off the street," Merrill said. "There is no way for people to really properly dispose of these pills and flushing them down the toilet is not the best method of destruction."

Last year, 9,000 pounds of pharmaceuticals were turned in across Colorado during the one-day program.

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95 percent

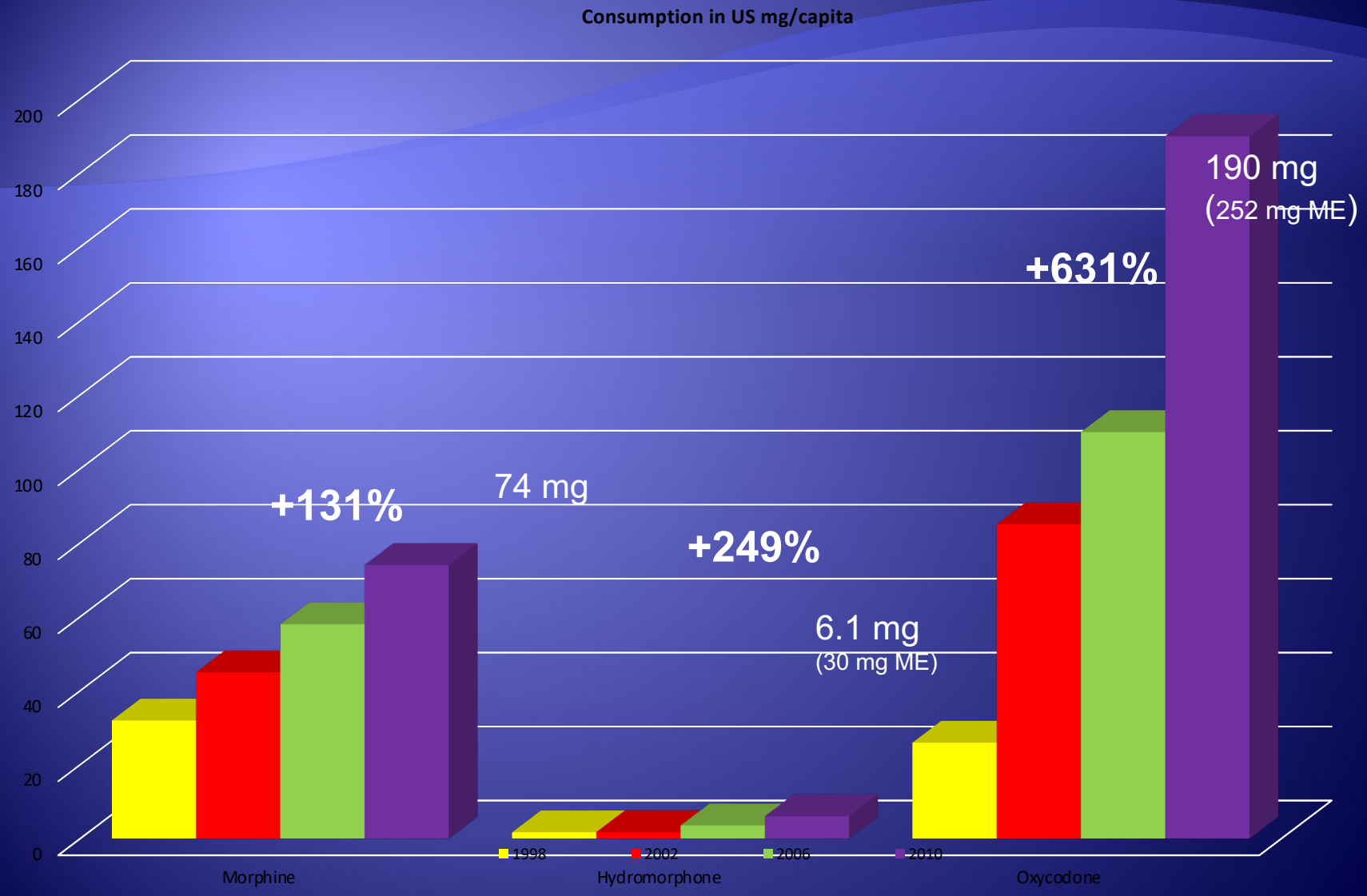
increase in almost a decade the number of Colorado deaths from prescription-dru abuse, according to the DE

445

deaths from painkiller abus in Colorado in 2009, compared with 228 deaths linked to prescription drugs 2000, according to the DEA

95% increase in CO deaths from prescribed opioid drugs from 2000-2009
Denver Post, February 28, 2011

Per Capita Consumption



Pain & Policy Studies Group, University of Wisconsin-Madison
http://www.painpolicy.wisc.edu/country/profile/united-states-america

Forbes.com

U.S. EUROPE ASIA

Pharmaceuticals

America's Most Popular Drugs

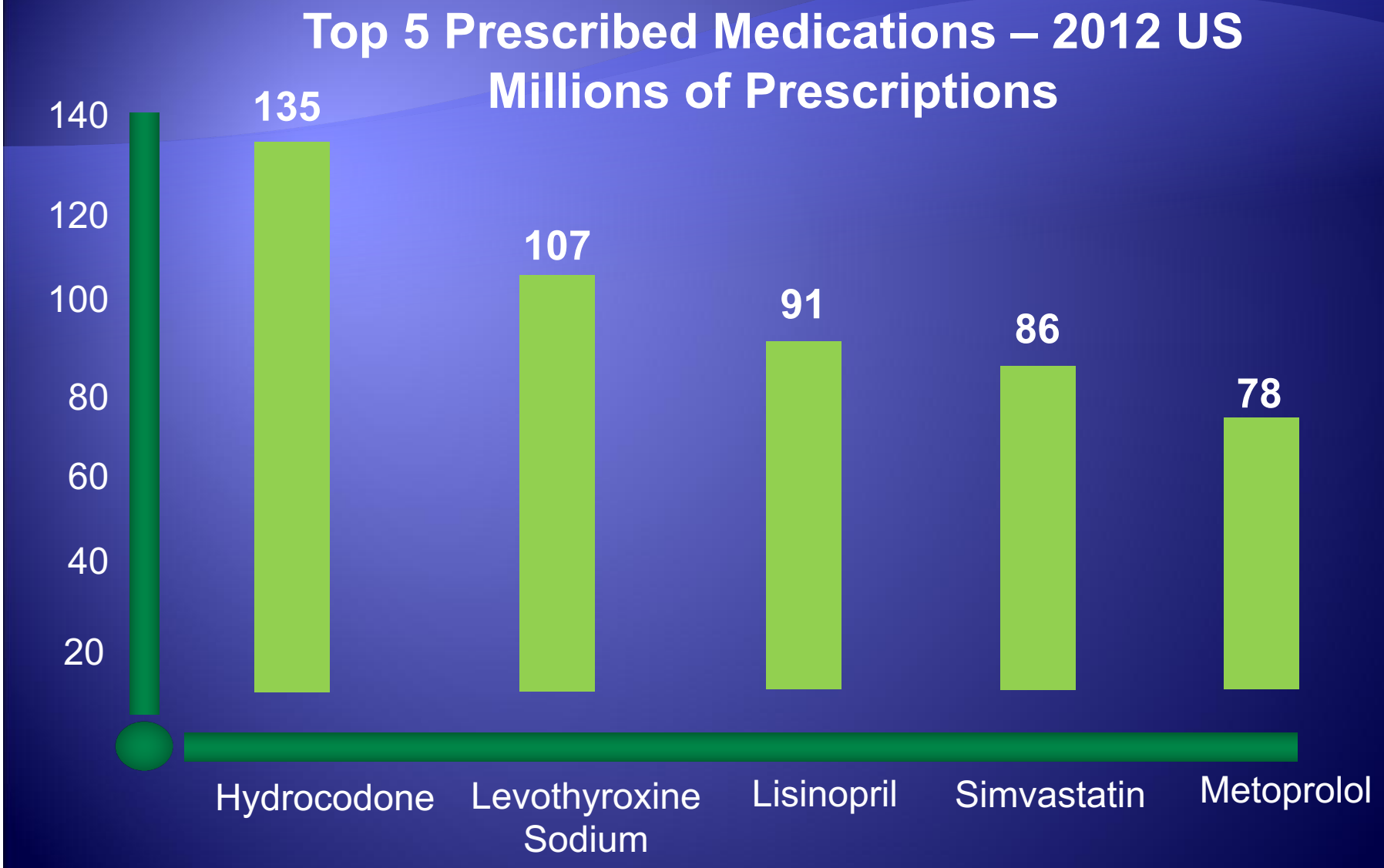
Matthew Herper, 05.11.10, 04:00 PM EDT

A narcotic painkiller tops Forbes' list of the most prescribed medicines.

In Pictures: America's Most Popular Drugs

Forbes.com
May 11, 2010

Top Medicines by Prescription in the United States



Report by the IMS Institute for Healthcare Informatics

Change? Fast-Forward to 2022
20 Most Prescribed Medications in US 2022

1. Vitamin D
2. Amoxicillin
3. Levothyroxin
4. Lisinopril
5. Ibuprofen
6. Adderal
7. Norvasc
8. Albuterol
9. Prednisone
10. Gabapentin
11. Benzonate
12. Xanax
13. Cyclobenzaprine
14. Zithromax Z-Pak
15. Lipitor
16. Zyrtec
17. Cozaar
18. Augmentin
19. Keflex
20. Metformin

2022 Ten Most Prescribed Pain Medications

1.	Hydrocodone-Acetaminophen	23.9%
2.	Ibuprofen	13.1%
3.	Tramadol HCL	12.3%
4.	Oxycodone-Acetaminophen	9.6%
5.	Oxycodone-HCL	7.7%
6.	Aspirin	6.1%
7.	Acetaminophen-Codeine	3.8%
8.	Morphine Sulphate	2.0%
9.	Butalbital-Acetaminophen-Caffe	2.0%
10.	Acetaminophen	2.0%

Prescription Medication Abuse Overuse or Illicit Drug Use

- Drug Abuse: 18-41% of CPP receiving opioids
- Illicit Drug Use in CPP: 14-16% in those without controlled substance prescriptions; 34% in those with controlled substance prescriptions
- Estimated Prevalence of ANY Drug Overuse, Abuse, or Divergence > 40% in CPP

Christo et al. 2011; Havens et al. 2007; Hoffman et al. 1995; Manchikanti et al. 2003; 2004; 2005; 2006; National Institute on Drug Abuse 2004; Pesce et al. 2010; SAHMSA 2009;

Prescription Opioid Overdose and Drug-Related Auto Deaths

- 2008 Prescription Drug Overdose Deaths 20,044
  - Prescription opioids involved 14,800 (73.8%)
  - This rate TRIPLED in the 10 years from 1999-2008
- 2009 21,798 MVA fatalities, 13,846 drug tested
  - 3,952 positive for any drug (33%)
  - Opioids (21%) ; Cannabinoids (25%), alcohol (34%)
  - 50% of fatally injured drivers tested positive for BOTH
- 1 in 8 weekend drivers positive for illicit drug

CDC Morbidity and Mortality Weekly Report, Dec 2011; Office of National Drug Control Policy 2011

Deaths from Drugs, Firearms and Traffic Accidents

- 2009 First time in recorded history (1979) that drug-induced deaths outnumber traffic deaths
  - Traffic deaths: 36,284; down 20.3% since 1979
  - Firearm deaths: 31,228; down 6.6% since 1979
  - Drug-induced deaths: 37,485; up 72.6% since 1979
    - 1 drug-related death every 14 minutes
    - $6,120 per second costs to public

CDC 2009 Preliminary Data Report

Opioid Type and Dose and Risk of Overdose Death

- Compared 300 NM overdose death CPP's with 5,993 CPP's with matching 6-month opioid exposure periods
- Increased overdose risk was associated with:
  - Male (odds ration 2.4)
  - Use of one or more sedative/hypnotic prescriptions (OR 3.0)
  - Number of prescriptions (OR 1.1 for each additional prescription)
  - Prescription for Buprenorphine (OR 9.5)
    - " Methadone (OR 4.9)
    - " Fentanyl (OR 3.5)
    - " Hydromorphone (OR 3.3)
    - " Oxycodone (OR 1.9)
  - Overall opioid dose ≥ 40 mg morphine equivalent (OR 12.2)

Paulozzi et al. (2012). A history of being prescribed controlled substances and risk of drug overdose death. Pain Medicine, 13, 87-95..

National Center on Addiction and Substance Abuse 2009

Which is easiest for someone your age to buy: cigarettes, beer, marijuana or prescription drugs such as OxyContin, Percocet, Vicoden or Ritalin without a prescription?

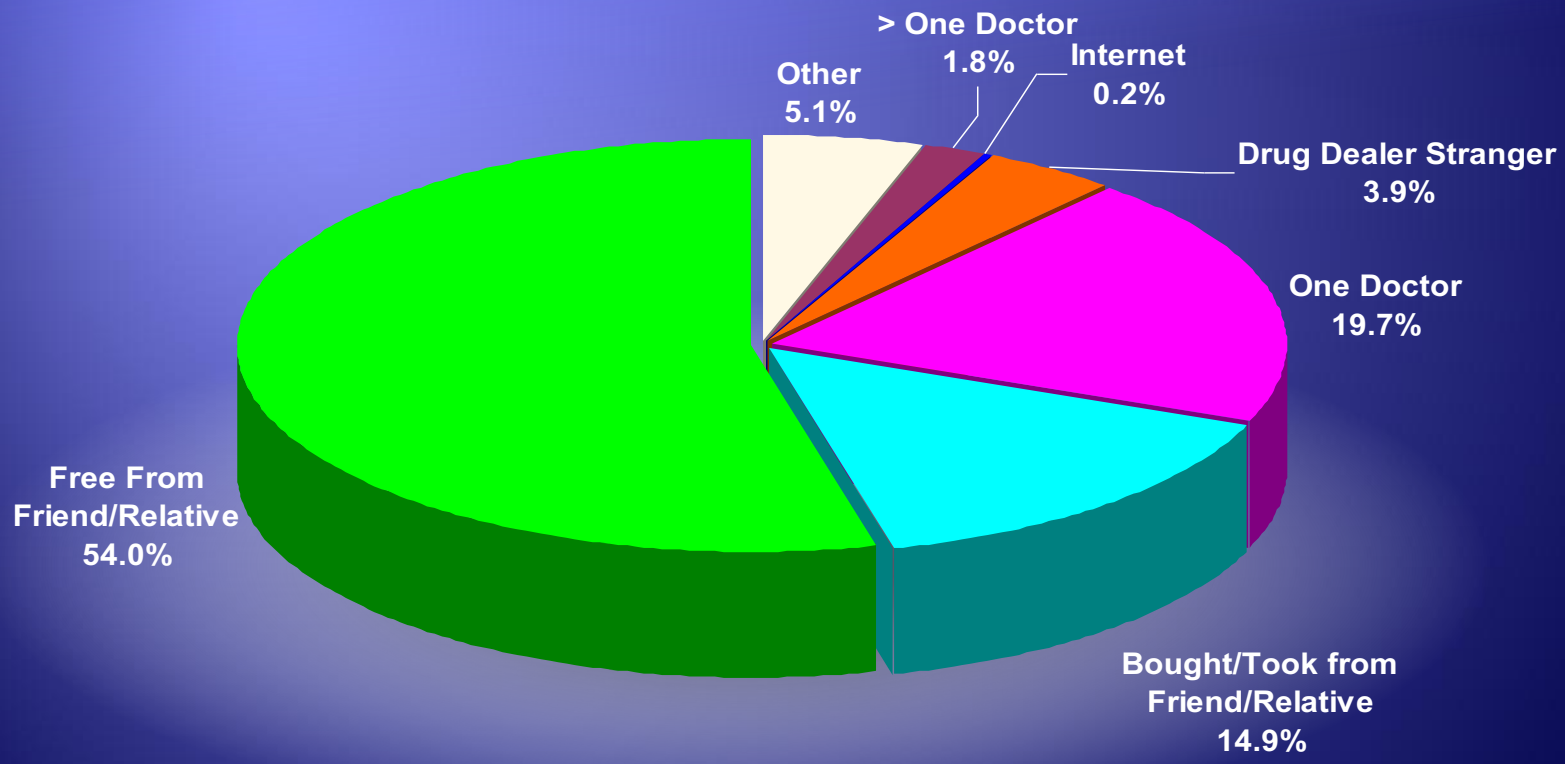
For the first time in history, teens (age 12-17) perceive prescription drugs to be easier to obtain than beer!!!

- Cigarettes: 26% (26% in 2007)
- Marijuana: 26% (19% in 2007)
- Prescription Drugs: 16% (13% in 2007)
- Beer: 14% (17% in 2007)

National Center on Addiction and Substance Abuse (August 2009). National Survey of American Attitudes on Substance Abuse XIV: Teens and Parents.

2011 – 2012 National Survey

How nonmedical users of prescription pain relievers obtained the drugs



http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.pdf

Change in US? Fast-Forward to 2022

- > 96,700 people die from drug overdoses per year
- 72% Opioids involved in 7 of 10 overdose deaths
- 1 Million dead from drug overdoses since 1999
- March 2020-March 2021
  - 96,799 overdose deaths (20,044 in 2008)
  - 4X as many overdose deaths as firearm deaths
  - Drug overdose deaths rose 29.6% in one year
  - Overdose deaths exceeded firearm deaths by 306.7%

National Center for Drug Abuse Statistics 2022

Change in CO? Fast-Forward to 2022

- > 1079 drug overdoses 2021
  - 445 "Painkiller" deaths in Colorado 2009
  - 228 Prescription drug overdose deaths in CO in 2000

- OD deaths increased 2.85% per year past 3 years
- 2.8% of all deaths are from drug overdose
- 13.04% below national average
- 1.58% of all US overdoses occur in CO

National Center for Drug Abuse Statistics 2022

What We Know

- Opioid analgesics, stimulants, and tranquilizers among most frequently abused prescription medications
- More Americans abuse prescription drugs than use cocaine, heroine, inhalants, and hallucinogens *combined*
- Most physicians prescribing pain medications readily admit to little to no training in addiction

Substance Abuse and Mental Health Services 2005

Risk of Disciplinary Action by State Medical Boards for Opioid Prescription Issues

- One reason for under-treatment of pain with opioids is MD concern of disciplinary action
- Reviewed all disciplinary actions of NY medical board for 3 years and all other US state boards for 9 months to determine risk of Board discipline for (over)prescription of opioids

Richard J & Reidenberg MM. The Risk of Disciplinary Action by State Medical Boards Against Physicians Prescribing Opioids. J Pain Symptom Manage 2005;29;206-212.

Risk of Disciplinary Action by State Medical Boards for Opioid Prescription Issues

- NY (7.8% of all US MDs) – 10 disciplines annually
- US total – 120 MD's disciplined annually for over-prescribing opioid medications (2.45%)
- Most MDs disciplined had ***multiple*** violations
  - 43% Prescribing for themselves or non-patients
  - 42% None/Inadequate record documentation
  - 19% No medical indication for opioid
  - 13% Ruled incompetent to practice medicine
  - 12% Did nothing to account for patient addiction*
  - 8% Having sexual relations with patients

Risk of Disciplinary Action by State Medical Boards for Opioid Prescription Issues

Summary/Conclusions:

"Not a single physician for whom any data is available was disciplined solely for overprescribing opioid medications."

"The actual risk of a US physician being disciplined… for treating a real patient with opioids for a painful medical condition is virtually non-existent."

DEA/State Medical Board Investigative Leads Sources

- Referrals from state and local law enforcement and regulatory agencies
- Complaints from the public (patients, relatives, other medical professionals, **pharmacists**)
- "Cooperating" individuals
- Excess purchase reports

"Benign" Opioid Complaint Resolutions

- Medical Board contacts for complaint details
- MD provides all details, records, and "strategies" used to ensure safe and appropriate patient care (e.g., meet standard of practice)
- Medical board reviews and resolves complaint
- Most common resolution impact on provider:
  - Listing of complaint
  - Few thousand dollars for attorney letters/guidance
  - Considerable # of personal hours to address complaint

Opinion formed via practice of Brent Van Dorsten, Ph.D.

"Complex" Complaint Resolution

- Medical board contacts for details regarding complaint
- MD provides all details, records, and "strategies" used to ensure safe and appropriate patient care (e.g., meet standard of practice)
- Legal representation required
- May take several months/thousands of $$$ to resolve
- Potential resolution impact on provider:
  - Listing of complaint
  - Administrative Hearing
  - Arrest
  - Revocation of registration
  - Letter of Admonition
  - Loss of License

Opinion formed via practice of Brent Van Dorsten, Ph.D.

How Can a Provider Win With Regard to Opioids for Pain Management?

- Calls for improved patient care and increased physician training in pain IOM 2004; JCAHO 2001
- MD's facing threat of tort liability to accelerate implementation of pain management standards Furrow 2001; White 2001
- Legal cases (NC, CA) holding providers and institutions liable for failure to relieve pain Rich 2007
- Many "famous" media cases of MD arrests for over-prescription of opioid medications

NO DOCUMENTED "CORRECT" AMOUNT

Resources to Assist Physicians in Providing Safe and Objective Opioid Treatment

What resources/tools are available to assist physicians in maintaining an "evidence based" practice approach?

- Urine Drug Screening (best available gold standard)
- Prescription Monitoring Program (objective measure)
- Aberrant Behavior Documentation (most available)
- Opioid Treatment Contracts (recommend)
- Paper and Pencil Screens (recommended)
- Thorough Documentation of Issues/Strategies
- FDA: Risk Evaluation and Mitigation Strategy (REMS)

Urine Drug Testing

- Neither clinician opinion nor patient self-report reliably detects substance misuse in opioid-treated patients
- Nearly all published clinical guidelines, pain and addiction experts recommend routine use of opioid monitoring tools (e.g. UDT) to:
  - Mitigate risks and adverse affects of prescription opioid misuse, abuse and addiction
  - Screen for presence of illicit, non-prescribed medications

Bair & Krebs 2010; Christo et al. 2011; Chou et al. 2009; 2010; Pergolizzi et al. 2010; Webster & Dove 2007

Urine Drug Testing

- Potential Advantages of Urine Drug Testing
  - Inexpensive (??) and Highly Accurate in Detection
  - Differing Testing Strategies Available
  - Ease of Sample Collection
  - Rapidly Available Results
  - Ability to Test for Multiple Substances Simultaneously

Christo et al. 2011; Chou et al. 2009, 2010; Heit & Gourlay 2004; Manchikanti et al. 2010; Nichols et al. 2007; Pergolizzi et al. 2010; VA/DOD 2010

Potential Urine Screening Schedules or Strategies

- All new patients
  - UDT at first 2 visits
  - Baseline SOAPP-R or ORT
  - Incorporate results of PDMP
- Two consecutive visits after behavioral concerns
  - Document behavioral issues and follow-up plan
- Twice per year random if no issues
  - 2 consecutive visits after a positive/negative test

Alliance of States With PDMP's

- According to the Alliance of States with Prescription Monitoring Programs, all 50 US states have operational PDMPs that have the capacity to receive and distribute controlled substance prescription information to authorized users.
- Now with the capacity to assess opioid prescriptions from regional providers

Aberrant Drug-Related Behaviors

- More Predictive of Addiction/Diversion
  - Selling prescription drugs
  - Lost/Stolen scripts
  - Prescription forgery
  - Stealing/borrowing drugs from others
  - Obtaining prescription drugs for non-medical sources
  - Concurrent abuse of illicit drugs
  - Multiple unsanctioned dose escalations

Passik and Portenoy 1998

Treatment "Agreements"

- Not a "*contract*" but a partnership *agreement* defined as an "explicit bilateral commitment to a well-defined course of action"

  Quill 1983
- Specify responsibilities to improve patient commitment and monitor adherence. These agreements should specify the course of action if violations occur

  Donovan et al. 1999
- Devise *at treatment onset* and *record consent* to randomly conduct urine drug screening, document existence in initial evaluation record, scan/keep with patient file, modify as necessary, explicitly state course of action for violations

Paper and Pencil "Screens"

Many exist with little identification of "best."

Passik et al. 2008 for comprehensive review of 24 tools

- Opioid Reporting Tool — Webster 2005
  - 5 Items scored to criterion number
  - Considers family/personal history of substance abuse, age, history of sexual abuse, psychological disease
- Screener & Opioid Assessment for Patients in Pain (SOAPP-R)

  Butler et al. 2008
  - 24 Items, Scored 0-4, Criterion score of 18
  - Self-report questionnaire designed to predict aberrant medication-related behaviors among patients being considered for long-term opioid therapy.

Potential Documentation Topics

- Initial evaluation notes/baseline
  - Baseline PDMP, paper and pencil inventory result
  - Opioid agreement, consent for urine testing
  - "Relative risk" based upon current information
  - Conditions under which termination WILL occur
- Pain diagnosis, opioid use history, treatment plan
  - Current opioid, medication use; etoh, marijuana use
  - History of non-prescription drug use, substance abuse
  - Serial documentation of pain and function improvements
  - Adverse side effects with opioids

Accepting "Inconvenience"

- Providers *must* accept some short-term "*inconvenience*" to make reasonable changes. Doing nothing is *convenient*…and dedication to improved practice *accepts* some inconvenience.
  - Necessary changes of *inconvenience* in our lives:

    Seat Belts — Sun Screen

    Life Jackets — Bike/Ski Helmets

  - Necessary changes of *inconvenience* in our practices:

    Electronic Records — Urine Drug Testing

    Insurance Pre-Authorization — PDMP

    Malpractice Insurance — REMS (07/12)

Summary

- Vastly increasing numbers of patients with pain
- Vastly increasing problem of high volume prescription, opioid misuse, addiction, overdose
- Knowledge/Insight into problem has proven to be a necessary but insufficient factor in change
- Clinical treatment guidelines and opioid risk reduction strategies remain greatly under-utilized in clinical practice

Bair & Krebs 2010; Starrels et al. 2011

Summary

- Aberrant behaviors very common in most patient populations (chronic pain, cancer, AIDS) and insufficient to identify potential misuse
- Providers must utilize combination of available tools to increase confidence in patient veracity
- Thorough documentation, urine screening, PDMP review and behavioral monitoring should be used with paper-and-pencil screens where desired