

Treating Pain and Preventing Abuse: The Societal Balancing Act



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- Know that insufficient pain management is a world-wide public health concern
- Gain an awareness of the growing problem of prescription drug abuse in the United States
- Understand the difficulty in balancing opioid availability with avoidance of abuse, diversion, and overdose deaths
- Appreciate the role of national and state policies in governing the prescribing, dispensing, and administering of controlled substances, while attempting to combat nonmedical use

Objectives

- "Unrelieved cancer pain is a cause of major worldwide suffering, not because we don't have the tools necessary to relieve pain, but because most patients don't have access to the essential pain-relieving medications," said Dr. Nathan Cherny, presenting a global survey on opioid use and pain.
- "Policies introduced to control and regulate opioid use are now forming a barrier to the legitimate use of morphine for pain relief," according to Dr. Cleary.
- In many countries, a big issue is the drug-control policies that restrict the prescribing of these opioid drugs by imposing limits on dose and/or duration of treatment.
- An estimated 80% of the world population has inadequately treated pain (WHO 2007).

October 10, 2012 Presentation at the European Society for Medical Oncology (ESMO) Congress-Vienna, Austria

- <http://youtu.be/vg5UofpSuj4>



Life Before Death

- **Fear of addiction**
- Lack of training of health care professionals
- **Laws or regulations that restrict the manufacturing, distribution, prescribing, or dispensing**
- Reluctance to prescribe or stock opioids for fear of legal consequences
- Overly burdensome administrative requirements
- Insufficient quantities imported or manufactured
- Fear of diversion
- Cost
- Inadequate health care resources
- Lack of national policy or guidelines

Barriers to Opioid Availability- 2007 INCB survey

- In 2006, there was NO oral morphine available in the country of 6 million.
- In 2008, the only hospice received its first shipment of morphine after 2 years of advocacy.
- Patients first received morphine in 2009.
- A database tracks consumption, and the government increased the amount of imported morphine (from 500 g to 1 kg*) because there was no evidence of diversion.

*in 2007, the U.S. consumed 700 mg morphine *per person*

Sierra Leone



- In 2009, only 4 of Columbia's 32 states had opioid analgesics available 24/7 in pharmacies.
- In Romania, there is a maximum dose of oral morphine allowed for patients with non-cancer pain: **60 mg.**
- **5 billion people** live in countries with low or no access to opiates.



Other countries

- More Americans suffer from uncontrolled pain than heart disease, diabetes, and cancer *combined*.
 - Meghani, Pain Medicine 2012; 13:5-28
- **How do we balance the provision of adequate access to opioids for the treatment of pain with the growing problem of prescription drug abuse?**

The Balancing Act

WHO 3-Step Analgesic Ladder
1986



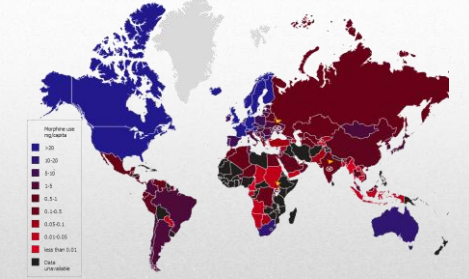
SUPPORT trial
1995

- Investigated the care of 9105 seriously ill and dying hospitalized adult patients
- Of 50% of conscious patients who died in the hospital, family members reported **moderate to severe** pain at least **half** the time



Veterans Administration
1999

Pain is the fifth vital sign



Despite the TRIPLING of global consumption of morphine since 1984, the prevalence of pain has not declined.



What was the prevalence of pain in metastatic, advanced, & terminal CA?

- 64%
- In patients on anticancer treatments? 59%
- In patients who had been cured? 33%



-Ann Oncol 2007; 18:1437-1449



Study of consecutive inpatients surveyed about pain 2008

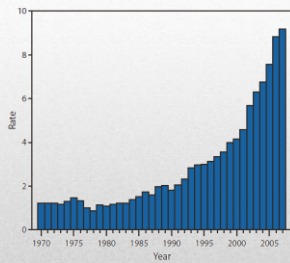
- 87% moderate to severe pain
- 71% of patients had solid tumors
- 41% had a hematologic malignancy
- 17% had no analgesic prescribed!

-Fairchild, Current Opinion in Supportive and Palliative Care 2010; 4:11-15

The ongoing problem...



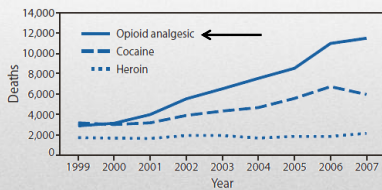
Rate* of unintentional drug overdose deaths — United States 1970–2007



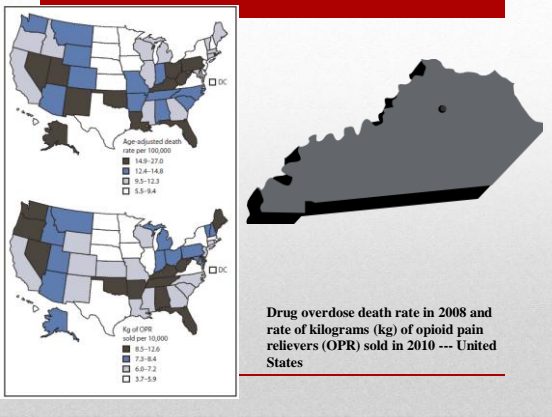
* Per 100,000 population. Source: National Vital Statistics System. Available at <http://www.cdc.gov/nchs/nvss.htm>

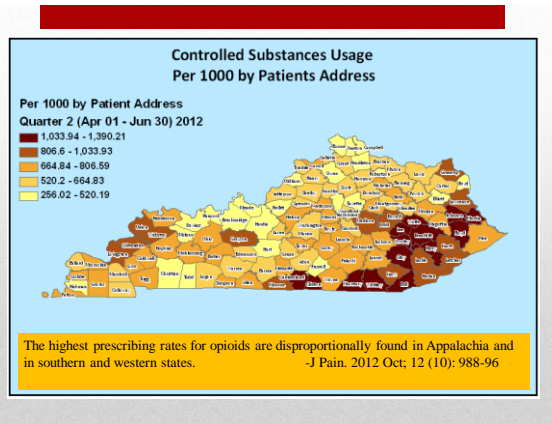
In 2007, approximately 27,000 unintentional drug overdose deaths occurred in the United States, one death every 19 minutes.

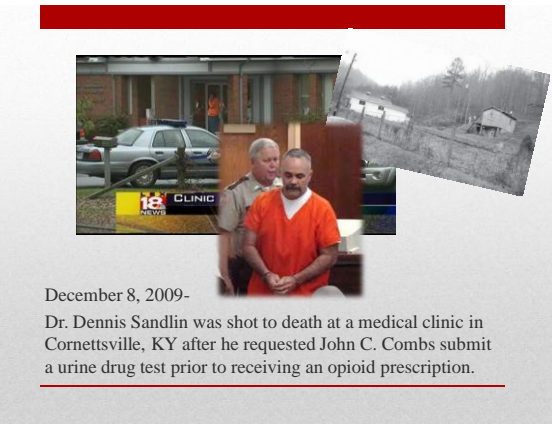
Number of unintentional drug overdose deaths involving opioid analgesics, cocaine, and heroin — United States, 1999–2007



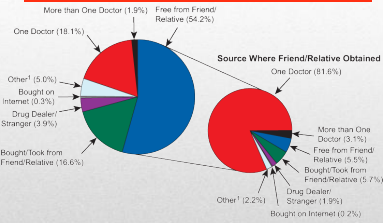
CDC Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic, January 13, 2012 / 61(01):10-13







Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2010-2011



Where do they obtain opioids?

Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings

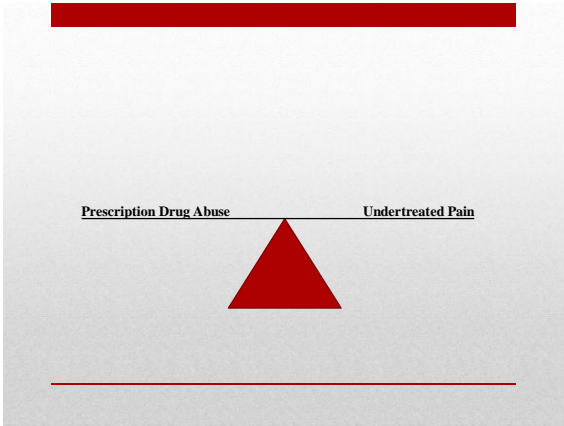
- Family history of prescription drug or alcohol abuse
- Personal history of substance abuse disorder
- History of legal problems or motor vehicle accidents

Risk Factors for Opioid Abuse

Pain Medicine, Vol. 10, No. S2, 2009

- A recent analysis showed that consistent exposure to opioid therapy in chronic pain patients leads to addiction in 3.27% of patients.
 - In patients who did not have a current or past history of use, abuse, or addiction, the rate of abuse was only 0.59%.
- Of 801 patients treated with prescription opioids in a primary care setting, only 3.8% met the criteria for opioid use disorders.
- Little is known about CA patients...one of few studies showed 0 (n=100) CA patients given opioids developed psychological dependence.

What about patients who are prescribed opioids?



1. Treatment and rehabilitation of prescription drug abusers
 2. Prescription Drug Monitoring Programs (PMPs) and insurance restrictions
 3. Improved legislation and enforcement of existing laws
 4. Optimize medical practice in prescribing opioids
- Strategies to Reduce the Burden of Prescription Drug Abuse**

- A recent study on pain education in U.S. and Canadian Medical schools showed that, of US medical schools, a median of **9 hours** (of 3000 curriculum hours=3%) were spent on education in pain.
 - A survey of FPs showed that 51% believed that prescribing long-acting opioids to patients with moderate to severe chronic pain would lead to addiction.
 - California mandates its physicians obtain 12 hours of CME in pain management and end-of-life care before license renewal: 90% of physicians reported their practices had changed 4 months after completing a seminar series on pain management
- Physician Education**

- An initiative sponsored by the FDA in response to the 2011 plan by the National Drug Control Policy to fight prescription drug abuse
- Goal to reduce irresponsible prescribing practices and the misuse of opioid analgesics while maintaining patient access to these medications
- Includes 1) educating prescribers, 2) risk stratification, 3) monitoring, and 4) patient education
- May result in unwillingness to prescribe opioids: a survey of PCPs showed only 50% would be willing to prescribe opioids controlled by the new REMS

Risk Evaluation and Mitigation Strategies (REMS)

- Started in the 1940s, with 40 states having current programs and 9 with legislation to set up PMPs
- KASPER (Kentucky All Schedule Prescription Drug Reporting) participation by physicians is now mandatory in Kentucky under House Bill 1
- A 2011 study **failed** to show the impact of PMPs on rates of drug overdose, opioid-overdose-related mortality, or rates of consumption of opioid drugs.

Prescription Drug Monitoring Programs (PMPs)

- “Anti-pill mill” legislation passed in the 2012 special session of the KY General Assembly
- Original version planned to put KASPER in the **Attorney General’s office**
- Requires pain management clinics to be owned by a licensed medical practitioner
- Mandates professional licensure boards to investigate prescribing complaints immediately
- Mandates continuing medical education
- Tasks the **Kentucky Board of Medical Licensure** with revising (and expanding) regulations. An “educational period” on the regulations was extended from October 1 to November 1, 2012.

House Bill 1

- More *recent* policies that have a greater amount of positive language (encouraging adequate pain relief and drug availability for legitimate use):
 - do not contain many provisions that could restrict such practice
 - are authored by state medical, pharmacy, and nursing boards
 - follow the Federation of State Medical Boards' *Model Guidelines*

University of Wisconsin Pain and Policy Studies Group (PPSG)

- When a patient with chronic non-cancer pain had a history of substance abuse, only one-fifth (21%) of respondents believed such prescribing opioids was legal.
- 11% of respondents indicated that federal, state, or local law enforcement agencies (e.g. DEA) are more likely than medical boards to investigate a physician's improper prescribing practices.
- 18% reported addiction=physical dependence or tolerance.

State Medical Board Members-2004 survey

"Let me be very clear. "We are al
 If you need a prescription, get your medi
 you p
 right i
 nothing
 -Governor
 September 9, 2012

What will be the impact of House Bill 1?



- The nonmedical use of prescription opioids continues to burden our society and triggers state policies that may impact the legitimate use of opioids for the treatment of pain.
- A *balanced* approach to this public health issue requires less emphasis on law enforcement and more funding toward education and research.
- We all have the potential to bring attention to the need for improved pain management by speaking up and contacting our state and federal legislators. Go to www.TreatThePain.com, the Hospice Action Network of the NHPKO, or <http://www.painpolicy.wisc.edu/> to find out more.

Conclusions

- "Legislation" refers to rules of conduct adopted by the legislature that have binding legal force; legislation also can be called "statutes". The most common legislation affecting the prescribing of controlled substances for pain management at the state level include Controlled Substances Acts, Medical Practice Acts, Pharmacy Practice Acts, and Intractable Pain Treatment Acts.
- "Regulations" refer to official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations have binding legal force and are intended to implement the administrative policies of an agency created by the legislature. For example, regulations from the state medical board establish what conduct is or is not acceptable for physicians licensed in the state. The most common regulations affecting the prescribing of controlled substances for pain management at the state level include Medical Board Regulations and Pharmacy Board Regulations.
- "Guidelines" refer to official policy issued by a government agency to express the agency's attitude about, or position on, a particular matter. Although guidelines do not have binding legal force, they can clarify acceptable practice for those regulated by an agency. Guidelines can also include an officially adopted "policy statement" that appears in a position paper, report, article, letter, or agency newsletter. A number of state medical boards have issued guidelines or policy statements regarding the medical use of controlled substances for treating pain, which define the conduct the board considers to be within the professional practice of medicine.

Definitions: Types of Policies

-Gilson, Health Policy 74 (2005) 192-204
