Ambulatory Treatment of Pain and Opioids: New Challenges for Drug Safety

G. Caleb Alexander, MD, MS
December 17, 2012
Road Map

- Center for Drug Safety and Effectiveness
- Prescription Drug Abuse
  - Overview of the epidemic
  - Three research investigations
  - Discussion
Welcome

Prescription drugs help millions of people in the United States and around the world. However, they are not without risk. The Center for Drug Safety and Effectiveness seeks to improve the safe and effective use of medications by bringing together researchers at Johns Hopkins to accomplish a fourfold mission—training, research, patient care and public service—towards best medication practices.

Center Launch

The Center will launch on October 24, 2012, with an inaugural lecture by Mark McClellan, MD, PhD. A physician and economist, McClellan works to promote high quality, innovative and affordable health care. Formerly commissioner of the U.S. Food and Drug Administration and administrator of the Centers for Medicare and Medicaid Services, he now directs the Engelberg Center for Health Care Reform at the Brookings Institution.

McClellan’s comments, to be available here, will provide compelling motivation for the Center’s work in core problem areas such as the need for more information about the benefits and risks of widely used therapies.

Upcoming

Center for Drug Safety & Effectiveness
Noon Seminar Series

October 22, 2012
12:00-1:00 pm

Center for Drug Safety & Effectiveness
Inaugural Lecture & Launch

October 24, 2012
4:00-5:00 pm
Reception to Follow

Click here for our Center At A Glance
Vision

The Center will improve the safe and effective use of medicines in the United States and around the world through a four-part mission of training, research, clinical care and public service.
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Core Problem Areas

- Clinical Decision-Making
- Comparative Effectiveness
- Global Medicines
- Medication Safety
- Pharmaceutical Policy
- Prescription Drug Abuse
Core Problem Areas

• Clinical Decision-Making
• Comparative Effectiveness
• Global Medicines
• Medication Safety
• Pharmaceutical Policy
• Prescription Drug Abuse
Motor vehicle traffic, poisoning, and drug poisoning death rates of all intents, United States, 1980-2009.

Source: National Center for Health Statistics Data Brief, Dec 2011.
Overdose deaths of all intents by major drug type, United States, 1999-2009.

Source: National Center for Health Statistics Data Brief, Dec 2011.
Public Health Impact of Opioid Use

For every 1 overdose death in 2010 there are

- Past Year Nonmedical Users: 733
- People with abuse/dependence: 108
- ED visits for misuse or abuse: 26
- Abuse treatment admissions: 10

Treatment admissions are for primary use of opioids from Treatment Exposure Data set
Emergency department (ED) visits are from DAWN, Drug Abuse Warning Network, https://dawninfo.samhsa.gov/default.asp
Abuse/dependence and nonmedical use in the past month are from the National Survey on Drug Use and Health

Opioid Analgesics: Users in the Past Month

Nonmedical users
4.5 million

Medical users
9.0 million


Houston, we have a problem
Motor vehicle traffic, poisoning, and drug poisoning death rates of all intents, United States, 1980-2009.

Source: National Center for Health Statistics Data Brief, Dec 2011.
Complex problem

- Undertreatment Of Pain
- Externalities
- Diversion
- Stakeholders
Rates of Prescription Opioid Sales, Death and Substance Abuse Treatment Admissions, 1999-2010.


**Diversion Schematic: Lawful distribution; primary diversion; layers of redistribution, non medical uses; measurement of impacts**

- **PPSG, 2007**
  - * = Amounts reported by law on DEA Form 106
## The Blind Man and the Elephant?

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<th>Stakeholders</th>
<th>Key issues</th>
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<td>Health insurers</td>
<td>Coverage determinations; costs of care; quality</td>
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<td>Prescribers</td>
<td>Prescriber autonomy; tension between regulatory oversight and ability for professional self-discipline</td>
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<td>Pharmacies</td>
<td>Pharmacist autonomy; pressure to identify and intervene upon rogue prescribers or dispensaries</td>
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<td>Wholesalers</td>
<td>Important role in supply chain; subject to fines and other legal action for support of “pill-mills”</td>
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<td>Consumer groups</td>
<td>Access to therapies; historical under treatment of pain</td>
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<td>Manufacturers</td>
<td>Marketing and promotion of therapies; effort to identify safer therapies less prone to abuse or diversion</td>
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<td>Public health agencies</td>
<td>Availability of treatment services; costs for the safety net</td>
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<td>Monitoring and intervening at multiple steps of supply chain to reduce abuse</td>
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Three research investigations

- Progress in identification and treatment of pain
- Epidemiology of opioid abuse
- Impact of policies to reduce abuse and diversion
Three research investigations

• Progress in identification and treatment of pain

• Epidemiology of opioid abuse

• Impact of policies to reduce abuse and diversion
Three research investigations

• Progress in identification and treatment of pain
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• Impact of policies to reduce abuse and diversion
Status of State Prescription Drug Monitoring Programs (PDMPs)

- States with operational PDMPs
- States with enacted PDMP legislation, but program not yet operational
- States with pending legislation

© 2012 Research is current as of January 11, 2012. In order to ensure that the information contained herein is as current as possible, research is conducted using both nationwide legal database software and individual state legislative websites. Please contact Sarah Kelsey at 703-836-6100, ext. 119 or at skelsey@namsdl.org with any additional updates or information that may be relevant to this document. Headquarters Office: THE NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS (NAMSDL), 215 Lincoln Ave. Suite 201, Santa Fe, NM 87501
Amount of prescription painkillers sold by state per 10,000 people (2010)

Kilograms of prescription painkillers per 10,000 people
- 3.7 - 5.9
- 6.0 - 7.2
- 7.3 - 8.4
- 8.5 - 12.6

SOURCE: Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 2010
Heroin deaths rise as crackdown on prescription drug abuse succeeds

By Kevin Rector and Andrea K. Walker, The Baltimore Sun
9:34 p.m. EST, December 7, 2012

As efforts to crack down on the abuse of prescription drugs have worked, a new problem has emerged, with addicts who can no longer get their fix by popping pills turning to the old-fashioned street drug heroin, health and law enforcement officials say.

The trend shows up in local arrests, drug seizures and overdose deaths. Drug dealers are finding new markets in the suburbs, where teenagers once got their stash from local drugstores or their parents' medicine cabinets, some experts say.

"The kids who got addicted to prescription pills are flipping to heroin, and, as a result, these kids are dropping like flies," said Mike Gimbels, a longtime drug counselor in Baltimore County who now works at University of Maryland St. Joseph Medical Center.
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Protecting Health, Saving Lives—*Millions at a Time*

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