Pain Care and Prescription Drug Abuse: Current Topics, Legislation, and Policy

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Disclosure

CLAAD’s funders include pharmaceutical companies, treatment centers, and laboratories, and are disclosed on its website, www.claad.org.

CLAAD is managed by DCBA Law & Policy, which provides professional services to health care companies and professionals. To avoid conflicts of interest, DCBA adheres to the District of Columbia Rules of Professional Conduct §§ 1.7-1.9.

Preview

• Introduction
• Prevalence of Pain
• Prescription Drug Abuse & Heroin Use
• Abuse-Related Trends
• Federal Activity
• State Activity
• Unintended Consequences
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Introduction to CLAAD

- Access: High-quality treatment for pain, anxiety, ADHD, addiction, hepatitis C, HIV, and other conditions
- Abuse deterrence: Reducing fraud, diversion, misuse, and abuse

Prevalence of Pain & SUD

- 100 million Americans have persistent pain (IOM study, 2011)
- Pain costs society at least $560-$635 billion annually (IOM study, 2011)
  - $261-$300 billion in health care costs
  - $297-$336 billion in lost productivity
- In 2013, 1.9 million people had a substance use disorder (SAMHSA, 2014)

Rx Opioid Abuse

- Over 16,000 died of an opioid-related overdose (SAMHSA, 2014)
- 4.3 million nonmedical users of Rx opioids age 12 or older (SAMHSA, 2014)
- 4.67,000 adolescents were current nonmedical users of Rx opioids, with 168,000 having an addiction to them (SAMHSA, 2014)
Abuse of Other Controlled Rx Medications

- Stimulants
  - 17% of college students abuse Rx ADHD medications
  - 20% of middle & high school students who use Rx are asked by friends for medications; 50% give medications to friends
- Benzodiazepines
  - Overdose deaths quadrupled between 2001 and 2013
  - PA: Present in 50% of drug-related overdose deaths (40% involved alprazolam)
  - GA: Misuse of alprazolam leading cause of drug-related death (35%, 231 out of 644)
- Sedatives
  - Violence
  - "Ambien defense" in murder
  - Sedative drug medications as most commonly used rape drug (DEA)
  - Impaired driving ("sleep-driving")

Partial Progress

- Decrease in prescription drug abuse-related deaths
  - CDC: 3% nationwide in 2012
  - SAMHSA: 14% among adults ages 18 to 25 nationwide in 2011
- Decrease in prescription opioid-related deaths
  - CDC: 5% nationwide in 2012 (1st time in over a decade)
  - 27% in FL between 2010 and 2012
  - 29% in Staten Island between 2011 to 2013

Heroin Use

- 517,000 had a heroin use disorder, compared with 189,000 in 2002 (SAMHSA, 2014)
- Between 2002 and 2013, the rate of heroin-related overdose deaths nearly quadrupled. Over 8,200 died in 2013 (CDC)
NIDA Report

- People who abuse Rx opioids rarely use heroin, and the transition to heroin use appears to occur at a low rate (NIDA 2016).
- Researchers suggest that the major drivers of the recent heroin use increases and related deaths are:
  - Increased accessibility
  - Lower market price
  - High purity

Heroin Supply

- Heroin Pills
  - Counterfeit oxycodone containing heroin in KY & OH
  - Undetectable from legitimate pills, identified through lab tests
- Heroin laced with fentanyl
  - 60 times stronger than pure heroin
  - 700 heroin + fentanyl-related deaths from late 2013 through 2014
  - 70 people overdosed in 3 days in Chicago
- "China White" – heroin laced with acetyl fentanyl (analog)
  - 40 times as strong as pure heroin
  - 700 heroin + fentanyl-related deaths from late 2013 through 2014
  - 74 people overdosed in 3 days in Chicago
- Profiting
  - Opioid analgesic pill mills
  - Fraud and abuse in urine drug testing
  - Buprenorphine pill mills
- Demands for action and knee-jerk responses

Abuse-Related Trends

- Hepatitis C and HIV transmissions
  - Outbreak in southeastern Indiana community of 4,200: 170 with HIV and 122 with hepatitis C (06/2015)
  - Miami-Dade and Broward County are the top two counties in the U.S. for new HIV cases; transmissions presumed to be associated w/ opioid abuse/heroin use (09/2015)
- Profiting
  - Opioid analgesic pill mills
  - Fraud and abuse in urine drug testing
  - Buprenorphine pill mills
- Demands for action and knee-jerk responses
Opioid-Focused Policy Responses

- Supply reduction efforts limited to Rx opioid analgesics (vs. all controlled Rx medications)
- Tremendous advances in opioid overdose rescue
- Inadequate demand reduction (interventions and treatment)

Federal Activity

- CDC guidelines
  - Could be adopted by legislatures and licensing boards
  - Likely to be adopted by insurers
  - Congressional investigation into process and potential conflicts of interest

Federal Activity

- HHS regulations
  - Increase use of buprenorphine for opioid dependence
  - Increase number of prescribers?
  - Increase patient limit?
  - Expected to be finalized before new presidential administration
Federal Activity

- National Pain Strategy
  - Population Research
  - Prevention and Care
  - Disparities
  - Service Delivery and Reimbursement
  - Professional Education and Training
  - Public Education and Communication

- ER/LA opioid REMS (under review)
- Abuse-deterrent guidance, approvals, and labeling
- Opioid labels ("severe enough")
- DEA enforcement (distributors, pharmacies)
- Hydrocodone rescheduling
- Secure and Responsible Drug Disposal Act (rule effective 10/9/14)

Federal Legislation

- Ensuring Patient Access and Effective Drug Enforcement Act (Raid/Regulate) – S.483, H.R. 471 (Passed)
- Stop Tampering of Prescription Pills Act – H.R. 2335
- The Recovery Enhancement for Addiction Treatment Act (TREAT) – H.R. 2536, S.1455: would permit qualified advanced practitioners to prescribe buprenorphine for opioid dependence
Federal Legislation

- Jason Simcakoski Memorial Opioid Safety Act – S.1641: VA/DOD guidelines for opioid therapy for chronic pain
- Opioid Overdose Reduction Act of 2015 – S.707: Good Samaritan

State Activity

- Safer prescribing standards (push to adopt CDC guidelines)
  - Opioids for pain
  - Buprenorphine for opioid dependence
  - Limits to FDA‐approved indication
- Prescriber education requirements
- Mandatory PMP data checks
- Pain clinic registration and regulation
- Good Samaritan, naloxone laws
- Step therapy
Unintended Consequences

- Access to care
  - Ability to find qualified and willing providers
  - Proliferation of and decisions of pharmacies
- Core systems and values
  - Consistency in federal judiciary (DHS, CDC)
  - Federal supremacy (states’ attempted medication bans)
  - State plenary police powers (states regulate the professions - not the federal govt)
  - Compassion
  - People with pain, addiction, hepatitis C
  - Women and newborns
  - Privacy of patients and providers
  - Law enforcement access
  - Prescription monitoring programs

Resources

- Active Verification and Vigilance: A Method To Avoid Civil and Criminal Liability When Prescribing Controlled Substances, 15 Ind. Flat Tax, Health Care L. 93 (2015)

Conclusion

- Thanks to PCSS-D
- Thank You
- Questions and Discussion
- Contacts:
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PCSS-O Colleague Support Program and Listserv

- **PCSS-O Colleague Support Program** is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- **PCSS-O Mentors** comprise a national network of trained providers with expertise in addiction medicine/psychiatry and pain management.
- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit: [www.pcss-o.org/colleague-support](http://www.pcss-o.org/colleague-support)

**Listserv:** A resource that provides an “Expert of the Month” who will answer questions about educational content that has been presented through PCSS-O project. To join email: pcss-o@aaap.org.

PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (INNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: [www.pcss-o.org](http://www.pcss-o.org)
For questions email: pcss-o@aaap.org

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