What's Going on in the U.S. to Improve Pain Treatment and Deter Prescription Drug Abuse?

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Conflict of Interest Disclosure

• Authors Conflicts of Interest:
  – C. Carlson, No Conflict of Interest
  – A. Gilson, No Conflict of Interest

True Disclosure:

➢ WE ARE ONLY RESPONSIBLE FOR WHAT WE SAY........
➢ NOT WHAT THE GOVERNMENT DOES!!!
The Problem....

➢ Deaths involving prescription opioid analgesics now outnumber deaths from heroin and cocaine combined

Overdose Deaths Involving Opioid Analgesics, Cocaine and Heroin: United States, 1999–2010

2010: Statistics on Death in the U.S.

<table>
<thead>
<tr>
<th>Drug Overdose</th>
<th>Numbers of Deaths</th>
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<tbody>
<tr>
<td>Drug Overdose</td>
<td>36,121</td>
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<tr>
<td>Pharmaceutical Drug Overdoses</td>
<td>22,134</td>
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<tr>
<td>Prescription Opioid Pain Reliever Overdoses</td>
<td>16,651</td>
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<td>Car Crashes</td>
<td>35,498</td>
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<td>Firearms</td>
<td>33,672</td>
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Past Month Nonmedical Use of Psychotherapeutic Drugs

Aged 12 or Older, 2002-2012

2010: Statistics on Death in the U.S.

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<th>Pain Relievers</th>
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Non-Medical Use of Rx Opioids

What is “non-medical use” of prescription opioids?

The Problem...
- Nonmedical users of pain relievers most often get the drug from family and friends

Considering the Spectrum of Non-Medical Use of Rx Opioids

- Misuse (intentional)
  - recreational use for psychic effects
  - decide to increase dose for pain control
  - suicidal gesture or attempt

- Misuse (unintentional)
  - sharing with others
  - unknowingly taking larger amounts than directed
  - inadvertent poisoning

- Use involving aberrant behaviors
  - forgoing/altering prescriptions
  - going to multiple doctors
  - stealing drugs

- Concurrent use of illicit drugs or undisclosed Rx medication use

- Opioid Dependence ("Addiction")

- Substance Use Disorder
"Diversion" is the transfer of a drug from a licit to an illicit channel of distribution or use.

Manufacturers and Distributors

• Pharmacists
• Hospitals/Clincs
• Internet w/Rx
• Practitioners
• Dispensers
• Nursing homes
• Hospitals

(Elapsed Medication)

Patients (Lawful medical use)

• Theft from manufacturers and distributors
• Theft in transit
• Theft from hospitals
• Pharmacies/pharmacy
• Employee/customer
• Pilferage
• Theft of Rx/forgery
• Script-doc/pill mills
• Inappropriate prescribing
• Doctor shopping
• Patient sells or gives
• Theft from home
• Theft from patient
• Improper disposal

• International smuggling
Controlled Substances Act (CSA)

- First enacted in 1970 to regulate the manufacture, importation, possession, use, and distribution of certain substances
- DEA is responsible for interpreting and enforcing the CSA, although DHHS has a number of supporting responsibilities

Principle of Policy Change
Balance

- Opioids can be effective, are indispensable
  - Must be available to relieve pain and suffering
- Opioids have a potential for abuse
  - Must be controlled
- “Controlled substance” label does not change medical value of medications
- Efforts to prevent abuse must not interfere with medical practice and patient care

Law Enforcement on the Principle of Balance

“...the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care...”

U.S. Drug Enforcement Administration
2001 Joint Policy Statement

PPSG. Achieving balance in federal and state pain policy: A guide to evaluation (CY 2013-2014.)
Still Awake???

Update: What is Happening at the Federal Level....

1. Legislative and Regulatory Mandates
2. Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) Requests/Rulings
3. Office of National Drug Control Policy (ONDCP) - White House Initiatives

Disposal of Controlled Substances

New Federal Law

Changes to Current Authorizations (effective 10/9/14)
- Permits certain registrants to become “collectors” *
  - “Collection means to receive a controlled substance for the purpose of destruction...”
  - Manufacturers, distributors, reverse distributors, OTPs, hospitals/clinics with onsite pharmacies, retail pharmacies
  - LTCFs where registered hospitals/clinics or retail pharmacies maintain drop boxes
- Authorizes collection by law enforcement
  - Take-back events
  - Mail-back programs*
  - Drop boxes*
- Methods of destruction (“rendered non-retrievable”)

21 CFR §1300.01
21 CFR Part 1317
Disposal of Controlled Substances

Currently Allowable Methods

Registrants

➢ Request assistance from the local Special Agent in Charge of the DEA
  ▪ List the CS that (s)he desires to dispose of on DEA Form 41, and submit 3 copies of that Form to the Agent

➢ Agent authorizes and instructs disposal in one of the following ways:
  ▪ Transfer to reverse distributors
  ▪ Delivery to DEA agent/nearest DEA office
  ▪ Destruction in presence of DEA agent/authorized person
  ▪ Other such means as determined by Agent

➢ Does not change procedures defined in state law

21 CFR 81307.21

Hydrocodone Rescheduling:
Yesterday’s Solutions for Today’s Problem

- Hydrocodone combination products were officially rescheduled, 8.22.2014
  - Effective 10.6.2014

State Pain Policy Advocacy Network

- Concerned about the effects that this change will have on people living with chronic pain
- Concerned about the potential negative effects that these restrictions will have on healthcare professionals who are diligent in their efforts to alleviate patients’ pain and suffering
New Rule Effect

- Beginning 10.6.2014
  - Pharmacies will not be able to refill prescriptions for hydrocodone containing products
  - Need a new written prescription for each 30 day supply
  - May write up to 90 day supply (multiple prescriptions – with instructions indicating earliest date when pharmacy may fill each)
  - May fax prescription, but patient must have written prescription to obtain Rx from pharmacy
  - May call in for an emergency
    - Only for amount needed to cover emergency
    - Need written prescription within 7 days

Beware of Unintended Consequences

“supply reduction ... in the absence of demand reduction and harm reduction could paradoxically increase overdoses.”

Albert et al., 2011, Project Lazarus: Community-based overdose prevention in rural North Carolina: Pain Medicine, 12, p. S83
FDA Requests/Rulings

- Hydrocodone bitartrate extended-release capsules (Zohydro ER) approved 10.25.2013
- Combination products with greater than 325 mg of acetaminophen per unit were voluntarily withdrawn by the manufacturers at FDA’s request
  - Effective 01.01.2014
- Naloxone hydrochloride auto-injection (Evozio) approved 04.03.2014
- Request for comments for the use of innovative packaging, storage, and/or disposal systems to address the misuse and abuse of opioid analgesics.
  - Comments were due 06.09.2014
- Oxycodone hydrochloride and naloxone hydrochloride extended-release tablets (Targiniq ER) approved 07.23.2013

Office of National Drug Control Policy (ONDCP)

National Drug Control Strategy 2014

1. Emphasizing prevention over incarceration
2. Training health care professionals to intervene early before addiction develops
3. Expanding access to treatment
4. Taking a “smart on crime” approach to drug enforcement
5. Giving a voice to Americans in recovery
Office of National Drug Control Policy (ONDCP)

_Epidemic: Responding to America’s Prescription Drug Abuse Crisis 2011_

1. Education – parents, youth, patients, & HCP
2. Tracking & Monitoring
3. Proper medication disposal
4. Enforcement

Enhancing Access to Prescription Drug Monitoring Programs

A national effort to reduce prescription drug abuse and overdose through technology and policy

- **Goals**
  1. Connect PDMPs to Health IT with existing technologies
  2. Improve timely access to PDMP data
  3. Establish standards for facilitating information exchange

Prescription Drug Monitoring Programs (PDMPs)

- **Where**
  All states but 4 (3 of the 4 have legislation)
- **When**
  Most states established PDMPs to address the prescription drug abuse problem beginning in 2005
- **Why**
  To reduce prescription drug abuse and diversion
- **What**
  Statewide electronic databases
  - Collect, monitor, and report electronically transmitted dispensing data on controlled substances
- **Who**
  Authorized healthcare professionals
  - Physicians (known as prescribers)
  - Pharmacists (known as dispensers)
  - Other authorized HCPs
PDMP Value

- PDMPs contain useful information
  - Identify patients who are potentially abusing or diverting prescription drugs
  - Inform clinical decisions regarding controlled substances
- The issue is how to make this information more available to three key groups of clinical decision-makers:
  - HCP practices
  - Emergency departments
  - Pharmacies

PDMP Usage

- PDMPs are not used as much as desired because of issues with awareness and system registration
- Members of the care team supporting prescribers and dispensers often are not permitted access to PDMP systems
- The use of standalone Web portals and unsolicited reports do not adequately support clinical practices and workflows
- There is a lack of system-level access and standards among PDMPs, EHRs, and pharmacy systems.
- The business and health IT landscape increasingly contains third-party intermediaries which currently lack optimized business agreements to adequately protect information

National All Schedules Prescription Electronic Reporting Reauthorization Act

- S. 2529 – 2014
  - Assigned to a congressional committee on 6.25.2014
    - 2% chance of getting past committee.
    - 0% chance of being enacted.
- H.R. 3528 – 2013
  - Referred to Committee on 11.18.2013
    - 13% chance of getting past committee.
    - 4% chance of being enacted
We Cannot Bury Our Heads in the Sand and Not Act

What We Can Do to Engage Federally

Ad hoc legislative mechanism
- Carefully study many barriers to treat pain
  - Policy, legal, financial, systemic, etc.
- Multidisciplinary (both governmental and nongovernmental stakeholders)
  - Staff
  - Anticipate other policy implications
- Establish relationships with and possibly enhance awareness of policy-makers

Let's Change from Federal to State
Why State Policies are Important

- **Authorize** healthcare practice, medical use of drugs
- **Define** unprofessional conduct, and **prohibit** unauthorized distribution of controlled substances
- **Restrict** prescriptive practices

Policies can also...

- **Recognize** value of controlled substances and pain management
- **Encourage** pain management
- **Address** barriers (e.g., concern about regulatory scrutiny)

Recognizing Types of State Policy

<table>
<thead>
<tr>
<th>Legislation (Statutes)</th>
<th>Regulatory Policy (Regulations or Guidelines/Policy Statements)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Substances Act</td>
<td>Nursing Practice Acts</td>
</tr>
<tr>
<td>Legislature (members of legislative committees)</td>
<td>Nursing Regulations</td>
</tr>
<tr>
<td>Past sponsors of related bills</td>
<td>Entity Governing Controlled Substances</td>
</tr>
<tr>
<td>Executive Director (with Nursing, focus on license-specific division)</td>
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Policy Change/Adoption

- **Add** language that promotes safe and effective pain relief and palliative care
- **Repeal** or avoid potential barriers
  - Severe restrictions
  - Archaic terminology
  - Ambiguous requirements
- **Content and clarity of policy is essential**
  - Unintended consequences

(+) Criteria: Policy Language
Enhance Pain Management

1. Controlled substances necessary for public health
2. Pain management is general healthcare practice
3. Medical use of opioids is legitimate professional practice
4. Pain management is encouraged
5. Addresses practitioners’ concerns about regulatory scrutiny
6. Prescription amount is insufficient to determine legitimacy
7. Addiction not confused with physical dependence/tolerance
8. Other positive language

Category A: Issues related to healthcare professionals
Category B: Issues related to patients
Category C: Regulatory or policy issues

(-) Criteria: Policy Language
Impede Pain Management

9. Opioids are relegated as last resort
10. Opioids are outside legitimate practice
11. Addiction is confused with physical dependence/tolerance
12. Medical decisions are unduly restricted
13. Prescription validity is restricted
14. Additional undue prescription requirements
15. Other restrictive language
16. Ambiguous language

Category A: Arbitrary standards for legitimate prescribing
Category B: Unclear intent contributing to misinterpretation
Category C: Conflicting or inconsistent policies or provisions
Why a Progress Report Card?
- Simplifies complex evaluation
- Single index of quality to compare states
- Positive context for critical evaluation
- Simplifies measurement of progress
- Supports goal-setting
- Increases visibility of the need to improve pain policy

Distribution of Grades 2006, 2012, & 2013

National Council of State Boards of Nursing


Pain Management Policies (n=49)
Nursing Regulatory Pain Policy (n=27)

APN Prescribing Authority 2010, 2012-2014

Independent Prescribing Authority (23 states)
- Alaska
- Arizona
- Colorado
- Connecticut
- DC
- Hawaii
- Idaho
- Iowa
- Maine
- Maryland
- Minnesota
- Mississippi
- Montana
- Nevada
- New Hampshire
- New Mexico
- North Dakota
- Oregon
- Rhode Island
- Vermont
- Virginia
- Washington
- Wyoming
### Prescribing Requires Formal Physician Involvement (12 states)
- California
- Delaware
- Indiana
- Kansas
- Massachusetts
- Nebraska
- New Jersey
- New York
- Tennessee
- Texas
- Utah
- Wisconsin

### Prescribing Requires Formal Physician Involvement/Other Limits (8 states)
- Illinois
- Kentucky
- Louisiana
- Michigan
- North Carolina
- Ohio
- Pennsylvania
- South Dakota

### No Prescribing Authority (8 states)
- Alabama
- Arkansas*
- Florida
- Georgia*
- Missouri*
- Oklahoma*
- South Carolina*
- West Virginia*

*No prescribing authority for Schedule II medications only
Potential Policy Barriers to Nursing Pain Practice

- Prescribing authority is prohibited
- Formal physician involvement (??)
- Additional requirements/limitations
  - Supply limits (e.g., 24 hours, 72 hours, 7 days, 30 days)
  - Not for chronic pain (including cancer pain)
- Ambiguous language
- Recent, not widespread, regulatory guidance

Improving Clinical Practice and Patient Care Relating to Pain Management

- Non-policy actions or resources
- Mitigating abuse/diversion extends beyond prescribing practices
- Policies outside methodology
- Unadopted policies (i.e., Bills)
- Policy content ≠ stated intent
- Perceptions ≠ policy content
- Policy change ≠ final step

P.S. MUELLER
**States with Prominent “Pill Mill” Activity**

*(n=40)*

*Assessed via Internet search, July 23, 2014*

**Engage with existing initiative**

- Established network with policy-makers
- Supportive of pain management issues
- Sponsors
- “Cue-givers” (Matthews & Stimson, 1975)
- Multidisciplinary
- Anticipate other policy implications
- Relevant initiatives becoming more prevalent

What We Can Do to Engage at the State Level

- **State Pain Policy Advocacy Network (SPPAN)**
  - State Legislation and Regulations Tracking
    - [http://sppan.aapainmanage.org](http://sppan.aapainmanage.org)

- **ACS Cancer Action Network**
  - Quality of Life/Access to Care Initiatives
    - [http://www.acscan.org](http://www.acscan.org)

- **U.S. Pain Foundation**
  - Pain Advocacy Efforts (e.g., PDMPs, Federal)
    - [http://uspainfoundation.org/uspain-advocacy-efforts.html](http://uspainfoundation.org/uspain-advocacy-efforts.html)

Questions???

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 Osteopathic Academy of Addiction Medicine (AOAAM), 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)

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