PRESCRIPTION DRUG OVERDOSES: AN AMERICAN EPIDEMIC

- Grant Baldwin, PhD, MPH  
  *Centers for Disease Control and Prevention*  
  Why Are Drug Overdoses a Public Health Problem?

- Len Paulozzi, MD, MPH  
  *Centers for Disease Control and Prevention*  
  Rationale for Prevention Strategies

- Gary Franklin, MD, MPH  
  *Washington State Agency Medical Directors Group*  
  Washington State Opioid Guidelines and Regulations

- R. Gil Kerlikowske  
  *Office of National Drug Control Policy*  
  Prescription Drug Abuse: Federal Policy Perspective
WHY ARE DRUG OVERDOSES A PUBLIC HEALTH PROBLEM?

Grant Baldwin, PhD, MPH
Director, Division of Unintentional Injury Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Prescription Drug Overdose
Definition

- Type of poisoning
- Prescription drugs used in amounts or in ways NOT recommended
- No harm intended by user
- Limited number of ingestions by young children or innocent mistakes by patients
Types of drugs
- Drugs that depress breathing
  - Opioid analgesics
  - Sedative/hypnotics
- Usually multiple drugs involved
- Frequently combined with illicit drugs

Reason for use
- Original use of drug might have been their intended purpose: relief of pain or anxiety
- Development of tolerance
- Escalated use for “high”
Drug-induced and Other Types of Injury Deaths
United States, 1999–2007

Unintentional Drug Overdose Deaths
United States, 1970–2007

27,658 unintentional drug overdose deaths:
1 death every 19 minutes

Unintentional and Undetermined Intent Drug Overdose Death Rates by State, 2007

Age-adjusted rate per 100,000 population

- MD: 12.5
- MA: 12.5
- NH: 11.7
- RI: 11.1
- CT: 11.1
- DE: 9.8
- DC: 8.8
- VT: 7.9
- NJ: 7.5

Unintentional Overdose Deaths Involving Opioid Analgesics, Cocaine, and Heroin United States, 1999–2007

Deaths

Year

Unintentional Overdose Deaths Involving Opioid Analgesics Parallel Opioid Sales United States, 1997–2007

- **Distribution by drug companies**
  - 96 mg/person in 1997
  - 698 mg/person in 2007
    - Enough for every American to take 5 mg Vicodin every 4 hrs for 3 weeks

- **Overdose deaths**
  - 2,901 in 1999
  - 11,499 in 2007

National Vital Statistics System, multiple cause of death data set and Drug Enforcement Administration ARCOS System

* 2007 opioid sales figure is preliminary
Public Health Impact of Opioid Analgesic Use

For every 1 overdose death there are

- Abuse treatment admissions: 9
- ED visits for misuse or abuse: 35
- People with abuse/dependence: 161
- Nonmedical users: 461

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
Mental impairment leads to other types of unintentional injuries
- Falls and fractures among elderly
- Motor vehicle crashes involving “drugged driving”

Substance abuse leads to intentional injuries
- Drug-related self harm and drug-crime-related interpersonal violence

Intravenous use of drugs leads to infections
- HIV transmission related to injection of dissolved tablets
- Hepatitis C: “Graduating” from oral OxyContin to injected heroin

Reproductive health effects
- Congenital defects associated with opioid exposure in utero
- Newborn withdrawal syndrome
- Infertility from chronic heavy use
RATIONALE FOR PREVENTION STRATEGIES

Len Paulozzi, MD, MPH
Medical Epidemiologist, Division of Unintentional Injury Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
High-risk Groups for Opioid Abuse and Overdose Deaths

- Men for overdose deaths
- Ages 20–64 for deaths and emergency department visits
- Whites
- Medicaid populations
- Rural populations
- Mentally ill, especially people with depression

Opioid Analgesics: Users in the Past Month

Medical users
9.0 million

Nonmedical users
5.3 million

Opioid Analgesics: Sources for Nonmedical Users
United States, 2009

- Prescribed to user: 76%
- Prescribed to someone else: 20%
- Other: 4%
# Nonmedical Users Among People Dying of Opioid Overdoses

<table>
<thead>
<tr>
<th>Study population of prescription opioid-related deaths</th>
<th>% without opioid prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>West Virginia, 2006</td>
<td>66</td>
</tr>
<tr>
<td>Utah, 2008–2009</td>
<td>37</td>
</tr>
<tr>
<td>Ohio, 2006–2008</td>
<td>25</td>
</tr>
</tbody>
</table>

Utah: Lanier W. 2010. CDC Epidemic Intelligence Service Conference
## History of Seeing Multiple Prescribers among People Dying of Opioid Overdoses

<table>
<thead>
<tr>
<th>Definition</th>
<th>% deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥5 prescribers per year</td>
<td>21</td>
</tr>
<tr>
<td>West Virginia, 2006</td>
<td></td>
</tr>
<tr>
<td>Average of 5 prescribers per year over 3 years</td>
<td>16</td>
</tr>
<tr>
<td>Ohio, 2006–2008</td>
<td></td>
</tr>
</tbody>
</table>

Risk of Overdose by Prescribed Opioid Dosage among Medical Users of Opioids

Distributions of Opioid Usage and Overdoses by Prescribed Opioid Dosage

Distribution of Patients and Overdoses by Risk Group

- Patients involved in drug diversion
- Patients seeing one doctor, high dose
- Patients seeing one doctor, low dose

- Patients
- Overdoses
High Impact Strategies

- Improve usage and effectiveness of prescription drug monitoring programs
- Use insurance mechanisms to
  - Prevent doctor shopping
  - Reduce inappropriate use of opioids
- Improve state legislation
Strategies Targeting High-risk Groups: Monitoring and Insurance

- Improve effectiveness of prescription drug monitoring programs
  - Track the rate of use of multiple providers and high dosage,
- Restrict selected patients to one provider and one pharmacy (by Medicaid and others insurers)
- Insurers can restrict payment for inappropriate use, e.g., use of long-acting opioids for short-term pain
Strategies Targeting High-risk Groups: Improving Legislation and Enforcement

- Improve legislation and enforcement of existing laws including:
  - Doctor shopping: Laws exist in 33 states
  - Reduce “pill mills” and other fraud through:
    - Licensure and inspection laws: 3 states
    - Requirements for physical exams before prescribing: 32 states
    - Stopping drug distribution to “pill mills”
  - Dispensing practice: ID requirement at dispensing: 11 states
Strategies Targeting High-risk Groups: Improving Physician Practice

- Develop physician guidelines
  - Especially in emergency departments
  - With accountability
- Improve physician competence for safe prescribing of methadone
- Use single copy, serialized, tamper-resistant paper prescription forms or E-prescribing

Strategies Targeting High-risk Groups: Secondary and Tertiary Prevention

- Expand use of overdose harm reduction programs
  - Including more widespread distribution of the opioid antidote, naloxone
- Expand use of buprenorphine for treatment of opioid dependence
Gary Franklin, MD, MPH
Medical Director, WA Dept of Labor and Industries
Chair, Washington State Agency Medical Directors Group
Research Professor, Occupational and Environmental Health, Neurology, and Health Services, University of Washington
“To write prescriptions is easy, but to come to an understanding with people is hard.”

– Franz Kafka, *A Country Doctor*
By the late 1990s, at least 20 states passed new laws, regulations, or policies moving from near prohibition of opioids to use without dosing guidance.

- WA law: “No disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed.” (WAC 246-919-830, 12/1999)

Laws were based on weak science and good experience with cancer pain.

Average Daily Dosage of Long-acting Opioids

MED, Morphine equivalent dose
Overall, the evidence for long-term analgesic efficacy is weak

Putative mechanisms for failed opioid analgesia may be related to rampant tolerance

The premise that tolerance can always be overcome by dose escalation is now questioned

100% of patients on opioids chronically develop dependence

Ballantyne J. Pain Physician 2007;10:479-91
Chronic Opioid Use among Workers with Back Injuries, Washington State, 2002–2005

- Prospective study of 1,843 injured workers with back pain
- 37.6% received an opioid early, most on first visit
- 6.0% received opioids for 1 year
  - Daily dose increased significantly from 1st – 4th quarters after injury
- Clinically significant improvement was limited to a fraction of patients
  - 26% patients improved in pain and 16% improved in function

Strategies in Washington State to Address Opioid Overdosing

- Provide Opioid Dosing Guidance for primary care providers
- Strengthen the legislation
- Improve physician access to pain management specialists
- Offer community-based treatment of chronic pain
Washington Agency Medical Directors’ Opioid Dosing Guidelines

- Developed with clinical pain experts in 2006
- Implemented April 1, 2007
- First guideline to emphasize dosing guidance
- Educational pilot, not new standard or rule
- National Guideline Clearinghouse

Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain:

An educational aid to improve care and safety with opioid therapy

2010 Update
Part I – If patient has not had clear improvement in pain AND function at 120 mg MED (morphine equivalent dose) “take a deep breath”

- If needed, get one-time pain management consultation (certified in pain, neurology, or psychiatry)

Part II – Guidance for patients already on very high doses >120 mg MED

The main emphasis was on preventing future cohorts of high-dose patients
Establish an opioid treatment agreement

Screen for
- Prior or current substance abuse
- Depression

Use random urine drug screening judiciously
- Shows patient is taking prescribed drugs
- Identifies non-prescribed drugs

Do not use concomitant sedative-hypnotics

Track pain and function to recognize tolerance

Seek help if dose reaches 120 mg MED, and pain and function have not substantially improved
Please check the statement that most accurately reflects your experience when prescribing opioids for chronic, non-cancer pain

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO concerns about development of psychological dependence, addiction, or diversion</td>
<td>2%</td>
</tr>
<tr>
<td>OCCASIONAL concerns about development of psychological dependence, addiction, or diversion</td>
<td>45%</td>
</tr>
<tr>
<td>FREQUENT concerns about development of psychological dependence, addiction, or diversion</td>
<td>54%</td>
</tr>
</tbody>
</table>

## Washington State Primary Care Survey 2009: Adherence to State Guidelines

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Never or almost never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always or almost always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use treatment agreement</td>
<td>10%</td>
<td>22%</td>
<td>20%</td>
<td>49%</td>
</tr>
<tr>
<td>Screen for substance abuse</td>
<td>&lt;1%</td>
<td>3%</td>
<td>15%</td>
<td>81%</td>
</tr>
<tr>
<td>Screen for mental illness</td>
<td>&lt;1%</td>
<td>12%</td>
<td>30%</td>
<td>58%</td>
</tr>
<tr>
<td>Use random urine screen</td>
<td>30%</td>
<td>32%</td>
<td>18%</td>
<td>20%</td>
</tr>
<tr>
<td>Use patient education</td>
<td>34%</td>
<td>38%</td>
<td>19%</td>
<td>9%</td>
</tr>
<tr>
<td>Track pain</td>
<td>40%</td>
<td>31%</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Track physical function</td>
<td>69%</td>
<td>20%</td>
<td>7%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Open-source Tools Added to June 2010 Update of Opioid Dosing Guidelines

- Opioid Risk Tool: Screen for past and current substance abuse
- CAGE-AID screen for alcohol or drug abuse
- Patient Health Questionnaire-9 screen for depression
- 2-question tool for tracking pain and function
- Advice on urine drug testing

<table>
<thead>
<tr>
<th>OPIOID DOSE CALCULATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid (oral or transdermal)</td>
</tr>
<tr>
<td>codeine</td>
</tr>
<tr>
<td>fentanyl transdermal (in mcg/hr)</td>
</tr>
<tr>
<td>hydrocodone</td>
</tr>
<tr>
<td>hydromorphone</td>
</tr>
<tr>
<td>methadone</td>
</tr>
<tr>
<td>up to 20mg per day</td>
</tr>
<tr>
<td>21 to 40mg per day</td>
</tr>
<tr>
<td>41 to 60mg per day</td>
</tr>
<tr>
<td>&gt;60mg per day</td>
</tr>
<tr>
<td>morphine</td>
</tr>
<tr>
<td>oxycodone</td>
</tr>
<tr>
<td>oxymorphone</td>
</tr>
<tr>
<td>TOTAL daily morphine equivalent dose (MED) = 520</td>
</tr>
</tbody>
</table>

CAGE, “cut down” “annoyed” “guilty” “eye-opener”

http://www.agencymeddirectors.wa.gov/opioiddosing.asp#DC
Average Daily Dosage for Opioids, Washington Workers’ Compensation, 1996–2010

MED (mg/day)

Quarter/Year

Long-acting opioids

Short-acting opioids
Unintentional Prescription Opioid Overdose Death and Hospitalization Rates

*Tramadol-only deaths included in 2009, but not in prior years.
Washington State Department of Health, Death Certificates and Comprehensive Abstract Reporting System (CHARS)
Washington State Legislation on Opioid Treatment in 2010

- Repeals current regulation; new expected by June 2011
- Provides specific dosing guidance and guidance on consultations, assessments, and tracking
- Signed into law by Governor Gregoire on March 25, 2010
Emphasize tracking patients for improved pain AND function

Emphasize widely agreed-upon best practices
- Screening for substance abuse and other comorbidities
- Prudent use of urine drug screens
- Opioid treatment agreement
- Single pharmacy and single prescriber

Encourage use of Prescription Monitoring Program and Emergency Department Information Exchange, when available
Improving Physician Access to Pain Specialists in Washington State

- **Issue**
  - Moderate capacity problem: not enough pain specialists
  - Interventional anesthesiologists generally will not see these patients to assist with opioid issues

- **Solution**
  - Advanced training for primary care to increase proficiency
  - Have successfully “beta tested” telemedicine consults and webinar trainings with pain specialists and primary care physicians
  - Telephonic or video consultation with experts
  - Public payers working on payment codes to incentivize these activities
Components Being Developed for Community-based Treatment of Chronic Pain

- Cognitive behavioral therapy
- Graded exercise
- Activity coaching
- Interdisciplinary care
- Care coordination
Lessons Learned from Washington State

- Opioid overdose is a public health crisis
- High doses and rampant tolerance are key factors
- A more comprehensive approach to effectively treating chronic pain must be developed
- Statewide change through collaboration is needed
- Prescriber education requires appropriate tools and dosing guidance
- Prescriber education alone is not adequate
- New state regulations are needed to ensure best practices and to prevent worst practices
PRESRIPTION DRUG ABUSE:
FEDERAL POLICY PERSPECTIVE

R. Gil Kerlikowske
Director
Office of National Drug Control Policy
Executive Office of the President

www.whitehousedrugpolicy.gov
Overview

- Authority and role of the White House Office of National Drug Control Policy (ONDCP)
- Federal policy perspective
- Federal, state, local, and tribal coordination
ONDCP’s Authority

- Established by the Anti-Drug Abuse Act of 1988
- Principal purpose: Establish policies, priorities, and objectives for the nation's drug control program
- Goals: Reduce illicit drug use, manufacturing, and trafficking, drug-related crime and violence, and drug-related health consequences

www.whitehousedrugpolicy.gov
ONDCP’s Role

- Responsible for developing the *National Drug Control Strategy*
- Advise the President regarding Federal Drug Control Agencies’ activities
- Coordinate/oversee international and domestic anti-drug efforts of executive branch agencies
- Establish a program, budget, and guidelines for cooperation among federal, state, and local entities

www.whitehousedrugpolicy.gov
2010 National Drug Control Strategy

- Science-based, public health approach to drug policy
- Coordinated federal effort on 106 action items
2010 National Drug Control Strategy
Signature Initiatives

- Three signature initiatives
  - Prescription drug abuse
  - Prevention
  - Drugged driving

www.whitehousedrugpolicy.gov
Federal Policy Perspective

- Policy must balance the desire to minimize abuse with the need to ensure legitimate access
- Multifaceted approach and collaboration among federal, state, local, and tribal groups is key
- Four focus areas
  1. Education
  2. Prescription drug monitoring programs
  3. Proper medication disposal
  4. Enforcement
1. Education

- **Education for parents and patients**
  - Increase awareness
  - Safe medication use, storage, and disposal

- **Education for health care providers**
  - Appropriate prescribing
  - Adverse events and drug interactions
  - Identifying those at risk for abuse
  - Counseling on proper storage and disposal
  - Screening, intervention, and referral for those misusing or abusing prescription drugs
Distribution of Narcotic Analgesics to Patients by Health Care Setting

- Emergency departments: 39%
- Surgical specialty offices: 10%
- Hospital outpatient departments: 8%
- Medical specialty offices: 13%
- Primary care offices: 30%

2. Prescription Drug Monitoring Programs (PDMPs)

- **Tool to identify**
  - Inappropriate prescribing, dispensing, and drug-seeking behavior
  - Drug interactions and therapeutic duplication

- **Goals**
  - All states have operational PDMPs
  - Mechanisms in place for communication between states
  - High utilization among health care providers
    - Regular part of office visit like checking insurance coverage

- **Positive data are starting to surface***
  - More data on effectiveness and outcomes is needed

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http://www.pmpexcellence.org/sites/all/pdfs/NFF_wyoming_whole.pdf*
3. Proper Medication Disposal

- National Take Back Day
  - September 2010: 121 tons of drugs were taken back at >4,000 sites across the country
  - April 30, 2011: Next Take Back Day

- Secure and Responsible Drug Disposal Act 2010
  - Object: Allow ultimate users to give back controlled substances to an authorized entity

- Drug Enforcement Administration rule-making underway

www.nationaltakebackday.com
3. Proper Medication Disposal

- **Goals**
  - To be easily accessible and an environmentally friendly method of drug disposal
  - To be cost-effective and not a burden on consumers
  - To reduce the amount of prescription drugs available for diversion and abuse
4. Enforcement

- Assist states in addressing “pill mills” and doctor shopping
  - Provide technical assistance to states on model regulations/laws for pain clinics
  - Encourage high-intensity drug trafficking areas to work on prescription drug abuse issues
  - Support prescription drug abuse-related training programs for law enforcement
Federal, State, Local, and Tribal Coordination
Drug Free Communities Program (DFC)

- Support community coalitions in their efforts to reduce local substance use
  - Reduce substance use among youth in the community
  - Increase collaboration in the community regarding substance use
- 1,600 grantees since 1997
- $85.6 million awarded to 746 DFCs in 2009
- Planning process based on SAMHSA’s Strategic Prevention Framework
  - Assessment, capacity, planning, implementation, and evaluation
- 56% of current grantees target prescription drug abuse in their communities

http://www.ondcp.gov/dfc
http://www.jointogether.org/resources/samhsas-strategic-prevention.html
SAMSHA, Substance Abuse and Mental Health Services Administration
Drug Free Communities

741 Drug Free Communities Program Grantees for Fiscal Year 2010

http://www.ondcp.gov/dfc
National Youth Anti-Drug Media Campaign

www.abovetheinfluence.com
National Youth Anti-Drug Media Campaign

- Combined national and local approach
  - Engaging Local Communities: Aimed at getting teens to share insights about positive and negative influences in their communities and their approach to “staying above it”
- Balances broad prevention messaging at the national level with targeted efforts at the local community level
- “Self-reported exposure to the ONDCP campaign predicted reduced marijuana use”

Conclusions

- Prescription drug abuse and its consequences are the fastest growing drug problem in America
- Comprehensive four pillar approach addresses each aspect of the prescription drug abuse epidemic
- Parents, peers, youth influencers, health care professionals, and policy-makers all have a role to play
- Success will come from coordination and collaboration at the federal, state, local, and tribal level