Understanding and Combating the Heroin Epidemic

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Department of Psychiatry and Behavioral Sciences
Talk Outline

- What is causing the heroin epidemic?
- How does that impact opioid overdose?
- What can be done?
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• What is causing the heroin epidemic?
• How does that impact opioid overdose?
• What can be done?
Treatment of Pain is a Billion Dollar Industry

Over one-third of spending is concentrated in the top 5 therapies

Spending in leading therapy areas

<table>
<thead>
<tr>
<th>Therapy Area</th>
<th>$Bn</th>
<th>% Growth</th>
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<tbody>
<tr>
<td>Oncology</td>
<td>27.9</td>
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<tr>
<td>Antidiabetes</td>
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<td>Mental health</td>
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<td>Respiratory</td>
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<td>Pain</td>
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<td>Autoimmune</td>
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<td>Vaccines</td>
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<tr>
<td>Hormonal Contraceptives</td>
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<td>2.1%</td>
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Source: IMS Health, National Sales Perspectives, Jan 2014
Narcotics are Among the Top 5 Prescribed Medications

On-therapy patients - 2013

Treated patients in selected therapies, millions

- Hypertension: 45.7
- Cholesterol: 24.4
- Antidepressants: 22.3
- Ant-Ulcerants: 15.3
- Narcotics: 14.9
- Antidiabetes: 14.0
- Thyroid: 13.6
- Anti-Epileptics: 11.4
- Contraceptives: 9.1
- Respiratory: 8.9
- Anticoagulants: 6.0
- ADHD: 5.7
- Insomnia: 5.3
- Benign Prostate Hyperplasia: 4.5
- Antipsychotics: 3.5
- Osteoporosis: 2.1
- Overactive Bladder: 1.7
- Parkinson's: 1.6
- Migraine: 1.3
- Alzheimer's: 1.2

Source: IMS Health, NPA Market Dynamics, Jan 2014
Top Generic Prescriptions (2010)

1. **Hydrocodone + acetaminophen [Vicodin] (n=122,806,850)**
18. Oxycodone + acetaminophen [Percocet] (n=28,705,243)
46. Propoxyphene + acetaminophen [Darvon] (n=14,274,354)
51. **Oxycodone [OxyContin] (n=12,652,375)**
114. Fentanyl patch (n=4,914,785)
121. Methadone (n=4,558,532)
170. Morphine (n=2,740,358)
192. Hydromorphone [Dilaudid] (n=2,272,481)

- Top 200 generic drugs by units in 2010. SDI’s Vector One® National
Opioid Prescriptions Dispensed

Source: IMS Vector One® National (VONA)
Drug Availability Corresponds to Drug Use

Figure 7.9 Received Most Recent Treatment in the Past Year for the Use of Pain Relievers among Persons Aged 12 or Older: 2002-2013

* Difference between this estimate and the 2013 estimate is statistically significant at the .05 level.
FDA Response to Opioid Abuse and Diversion

Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids

On July 9, 2012, FDA approved a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioid medications.

ER/LA opioids are highly potent drugs that are approved to treat moderate to severe persistent pain for serious and chronic conditions (list of ER/LA opioid products). The misuse and abuse of these drugs have resulted in a serious public health crisis of addiction, overdose, and death.

The REMS is part of a multi-agency Federal effort to address the growing problem of prescription drug abuse and misuse. The REMS introduces new safety measures to reduce risks and improve safe use of ER/LA opioids while continuing to provide access to these medications for patients in pain.

Efforts to reduce prescription opioid abuse are working.
Drug Availability Corresponds to Drug Use

Figure 8.5 Past Year Nonmedical Pain Reliever Use among Youths in NSDUH and MTF: 2002-2013

MTF = Monitoring the Future; NSDUH = National Survey on Drug Use and Health.
* Difference between this estimate and the 2013 estimate is statistically significant at the .05 level.
Note: Data for MTF are for "narcotics other than heroin."
So Why is Heroin Use Increasing?

![Graph showing the increase in heroin use from 2002 to 2012. The graph compares the number of people who used heroin in the past month (red line) and in the past year (blue line). The numbers in thousands are: 2002 - 166, 2003 - 119, 2004 - 166, 2005 - 136, 2006 - 560, 2007 - 373, 2008 - 455, 2009 - 582, 2010 - 620, 2011 - 620, 2012 - 669.]}
Percentage of NDTs Respondents Reporting High Heroin Availability in Their Jurisdictions
2007-2011, 2013


Note: The National Drug Threat Survey was not administered in 2012.

US Department of Justice, Drug Enforcement Agency National Drug Threat Assessment Summary (2013)
In correspondence dated August 10, 2010, Purdue notified FDA that it had ceased shipment of original OxyContin, and FDA subsequently moved original OxyContin to the “Discontinued Drug Product List” section of the Orange Book. In a letter to FDA dated March 19, 2013,
How Does Route of Drug Administration Play A Role?

- Change in OxyContin formulation means that pill was being used orally instead of IV/IN
  - May require much larger quantities of oral OxyContin to meet demands for physiological tolerance in IV drug users
  - There are very few (if any?) prescription opioid substitutes for OxyContin IV use because most others are compounded with NSAIDs (acetaminophen, aspirin)
Decline in OxyContin Use Corresponds to INCREASE in Heroin Use
Decline in OxyContin Use Corresponds to *INCREASE* in Heroin Use

Cicero & Ellis, 2015 JAMA Psychiatry (online only)
Decline in OxyContin Use Corresponds to *INCREASE* in Heroin Use

Figure 2. Effect of Abuse-Deterrent Formulation (ADF) of OxyContin in Subsamples of Respondents

A) Did the formulation change of OxyContin have any impact on the drugs you chose to get high with?
- Yes, I stopped using all drugs to get high
- No, I did not use OxyContin enough for my choice of drugs to change
- No, I continued to use OxyContin after the formulation change
- Yes, I replaced OxyContin with other drugs

B) Which of the following ways apply to your use of both new and old formulations of OxyContin to get high/alter your mood?
- I primarily swallowed the old version of OxyContin and continued to swallow the new one
- I continued to inject/snort the new OxyContin like I did with the previous version
- I switched from primarily injecting/snorting the old version of OxyContin to primarily swallowing the new OxyContin

Cicero & Ellis, 2015 JAMA Psychiatry (online only)
Decline in OxyContin Use Corresponds to *INCREASE* in Heroin Use

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Reminder that opioid use disorder is a chronic, relapsing disease
Opioid Users Require Extensive Treatment Experience Before Abstaining

- Opioid users enter treatment an average of 8 times before staying abstinent.

Current Long-term Prognosis is not Very Promising

Hser et al., 2015, Harv Rev Psychiatry, Vol. 23 (2), pp 76-89.
Opioid Users Require Extensive Treatment Experience Before Abstaining

Talk Outline

- What is causing the heroin epidemic?
- How does that impact opioid overdose?
- What is being done nationally and in research to reduce the epidemic?
Opioid-related Overdose is Increasing

- Opioid OD has increased in all segments of society:
  - Drug users
  - Chronic pain patients
  - Elderly
  - Children
  - Women
  - Adolescents
  - Homeless Individuals

- Significantly more likely to occur following change in tolerance
  - Detoxification
  - Leaving jail or prison
  - Induction onto methadone treatment

Baggett et al., 2013; Bailey et al., 2009; Bohnert et al., 2011; Cobaugh et al., 2006; Coben et al., 2010; Dunn et al., 2010; Palmiere et al., 2010; Paulozzi et al., 2006; Rosca et al., 2012
# 10 Leading Causes of Injury Deaths by Age Group Highlighting Unintentional Injury Deaths, United States – 2011

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<th>Rank</th>
<th>Age Group</th>
<th>Cause</th>
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<td>1</td>
<td>&lt;1</td>
<td>Unintentional Suffocation</td>
<td>896</td>
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<tr>
<td>2</td>
<td>&lt;1</td>
<td>Unintentional Drowning</td>
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<td>Homicide Unspecified</td>
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<tr>
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<td>65+</td>
<td>Unintentional MV Traffic</td>
<td>5,569</td>
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<td>Unintentional Poisoning</td>
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<td>Suicide Firearm</td>
<td>4,325</td>
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<td>102</td>
<td>65+</td>
<td>Suicide Firearm</td>
<td>27,493</td>
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</table>

* Two Tied*
Opioid OD Rates Increase as a Function of Drug Availability

Rates of PO related deaths, treatment admissions, and kilograms of PO’s sold

OPR Sales (2008)

OPR Deaths (2008)

MMWR, 2011. Vol. 60 (43)
Talk Outline

• What is causing the heroin epidemic?
• How does that impact opioid overdose?
• What can be done?
What can be done?

1. Increase patient and public education
   - Prescription opioid use is perceived as safer and less risky than other drugs
   - Utah Prescription Safety Program is a good model

Johnson et al., 2011, Pain Medicine Vol. 12, pp S66-S72
2. Increase Access to Treatment (Reduce Barriers):

Figure 7.11 Reasons for Not Receiving Substance Use Treatment among Persons Aged 12 or Older Who Needed and Made an Effort to Get Treatment But Did Not Receive Treatment and Felt They Needed Treatment: 2010-2013 Combined

- No Health Coverage and Could Not Afford Cost: 37.3%
- Not Ready to Stop Using: 24.5%
- Did Not Know Where to Go for Treatment: 9.0%
- Had Health Coverage But Did Not Cover Treatment or Did Not Cover Cost: 8.2%
- No Transportation/Inconvenient: 8.0%
- Might Have Negative Effect on Job: 6.6%
- Could Handle the Problem without Treatment: 6.6%
- Did Not Feel Need for Treatment at the Time: 5.0%

Percent Reporting Reason
What treatment(s) should be provided?

• Agonist replacement (Maintenance)
  – Methadone
    • Schedule II, prescribed from regulated clinic
  – Buprenorphine (Suboxone)
    • Schedule III, can be prescribed from primary care setting

• Antagonist treatment
  – Naltrexone (oral, extended release Vivitrol)

• Detoxification
  – Outpatient vs. Residential
What treatment(s) should be provided?

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• Antagonist treatment
  – Naltrexone (oral, extended release Vivitrol)

• Detoxification
  – Outpatient vs. Residential
Increase Access to Treatment (Make Treatment More Available):

- 3. Increase number of providers who CAN prescribe buprenorphine

http://buprenorphine.samhsa.gov/waiver_qualifications.html
Increase Access to Treatment (Make Treatment More Available):

4. Increase number of waived physicians who WILL prescribe, and/or the number of people to whom they will prescribe:

- In a survey of 152 national providers, adoption rates were 17% (buprenorphine), 7.2% (methadone), 9.3% (naltrexone), reaching only 9.2% of patients with opioid use disorder (Knudsen & Roman, 2012).

- Lack of access to a prescribing physician cited as barrier in 38% (public sector treatments) and 23% (private sector) of cases (Roman et al., 2011).

4.a. Develop supportive resources for prescribers

- Telehealth, computer-based counseling services for prescribers
Increase Access to Treatment (Make Treatment More Available):
Increase Access to Treatment (Make Treatment More Available):

- Treatment options are even more scare in rural areas
  - Study conducted in VT reported:
    - Wait list of 964 people for methadone clinic (a 1.9 year delay in treatment access)
    - Majority of patients travel more than 60 min/day to attend treatment
    - 22% reported that travel directly interfered with their ability to be employed

5. Reduce Stigma Associated with Treatment

- Stigma stems from
  - Lack of understanding that opioid use disorder is a chronic, relapsing medical illness
  - Treating opioid use disorder treatment separate from the rest of health care
    - Other needs are frequently not met
  - Language regarding methadone conveys negative associations (both community and patients)

6. Inform Providers About the Wide Range of Empirically-Supported Treatment Options Available
No Difference in Methadone vs. Buprenorphine Maintenance

- Meta-analysis of 31 randomized, controlled trials (5430 participants) reported equal:
  - Retention in treatment
  - Reduction in opioid-positive urine samples
  - Reduction in comorbid drug use

** Provided buprenorphine dose was ≥7mg

Mattick et al., 2014 Cochrane Reviews, 2: CD002207
Maintenance is more effective than detoxification

Detox may still be preferable in some subgroups:

- Younger individuals
- People with less severe dependencies
- Prescription opioid vs. heroin users
- Rural areas that are lacking maintenance options
- Hospital-based settings
Residential Detoxification vs. Outpatient Detoxification

- Residential is more successful than outpatient detoxification but is more costly and has similar relapse rates.

<table>
<thead>
<tr>
<th></th>
<th>Completion</th>
<th>Taking naltrexone 1 month later</th>
<th>Opioid-free at 1 month</th>
<th>Opioid-free at 6 months</th>
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</thead>
<tbody>
<tr>
<td>Residential</td>
<td>51.4%</td>
<td>14%</td>
<td>22.9%</td>
<td>22.9%</td>
</tr>
<tr>
<td>Outpatient</td>
<td>36.4%</td>
<td>18%</td>
<td>15.1%</td>
<td>9.1%</td>
</tr>
</tbody>
</table>

Day & Strang, 2011 JSAT Vol 40, pp 56-66
Regarding Outpatient: Longer Detoxifications are More Effective Than Shorter Detoxifications

- 4-week taper produced greater reductions in opioid-positive UA’s and higher likelihood of beginning naltrexone treatment

Majority of Patients Relapse Following Detox

- Up to 89.9% fail to complete detoxification, and 70% of completers relapse within 30 days of completing a detoxification.

- *Naltrexone can delay relapse prevention but many providers do not know about and/or prescribe naltrexone*  
  - 7. Increase prescriber knowledge of naltrexone

Bailey et al., 2013; Dunn et al., 2011; Fiellin et al., 2014
Oral Naltrexone is Effective At Preventing Relapse

- 30-days of oral naltrexone substantially improves long-term outcomes
- However, patients do not take it
  - Meta-analysis of 13 studies (1158 patients) concluded there is no benefit of ORAL naltrexone except following release from jail/prison
    - May be ideal following incarceration because they have been detoxed already
  - Supportive programs can increase ORAL naltrexone adherence
    - 8. Develop supportive programs to increase naltrexone compliance

Greenstein et al., 1983; DAD Vol 12, pp 173-180e; Minozzi et al., 2011, Cochrane’s Database of Systematic Reviews, CD001333
Extended Release Naltrexone (Vivitrol) is More Effective than Oral Naltrexone

Kruptisky et al., 2012, Arch Gen Psychiatry Vol. 69 (9), pp 973-981.
Talk Outline

• What is causing the heroin epidemic?
• How does that impact opioid overdose?
• What is being done nationally to reduce the epidemic?
  – Treatment of opioid use disorder
    • Barriers
    • What do we know?
  – Overdose prevention
9. Make naloxone (Narcan) widely available

- An *antidote* to opioid OD
- Reverses opioid-ODs
  - Not addictive
  - No other side effects
- Available in IV/IM and IN formulations
  - All formulations reverse OD ~8 min following administration
  - IN version is not yet FDA-approved
LIVE! Using Injectable Naloxone to Reverse Opiate Overdose

HIT’EM IN ARM, THIGH, OR ASS

http://www.anypositivechange.org/menu.html
There are Substantial and Impressive Nationwide Efforts to Train and Distribute Naloxone to Bystanders for OD Intervention
10. Develop brief OD education interventions
   – 5-10 min session is effective

11. Standing pharmacy orders for Narcan?
   – Other states are developing standing pharmacy orders to enable Narcan without personal prescription

Overdose Reversal

• 12. Increase public and law enforcement acceptance of Narcan
  – Support Good Samaritan Laws for bystander intervention
    • Civil immunity for person calling 911 and for the person overdosing
    • Civil/Criminal immunity for administration of naloxone
  – Educate people that there is NO EVIDENCE that Narcan increases drug use
Welcome to the Naloxone (Overdose Response Program - ORP) Site

The Department of Health and Mental Hygiene (DHMH) launched Maryland’s Overdose Response Program (ORP) in March 2014 to train and certify qualified individuals—e.g. family members, friends and associates of opioid users; treatment program and transitional housing staff; and law enforcement officers—most able to assist someone at risk of dying from an opioid overdose when emergency medical services are not immediately available. Successfully trained individuals will receive a certificate allowing them to obtain and have filled a prescription for naloxone (Narcan®), a life-saving medication that can quickly restore the breathing of a person who has overdosed on heroin or prescription opioid pain medication like oxycodone, hydrocodone, morphine, fentanyl or methadone.

DHMH authorizes private or public entities to conduct educational training programs using a core curriculum that includes information about prescription and non-pharmaceutical opioids and training on how to recognize and respond to an opioid overdose, proper rescue breathing technique, and how to properly administer naloxone and care for the individual until emergency medical help arrives. The training also stresses the importance of calling 911 for the person in distress and reporting the naloxone administration event to the Maryland Poison Center.

Overdose Response Program
Training & Dispensing Statistics*
As of February 28, 2015

- 5,081 individuals trained, including 2,321 law enforcement officers
- Approximately 4,771 doses of naloxone dispensed
- 64 naloxone administrations reported**

* Training and dispensing statistics are maintained by authorized training entities and reported to DHMH on a monthly basis.

** Naloxone administration information is voluntarily reported by certificate holders to the Maryland Poison Center or to an authorized training entity and subsequently provided to DHMH on a monthly basis.
New Naloxone Products in Pipeline

FDA approves new hand-held auto-injector to reverse opioid overdose

First naloxone treatment specifically designed to be given by family members or caregivers

The U.S. Food and Drug Administration today approved a prescription treatment that can be used by family members or caregivers to treat a person known or suspected to have had an opioid overdose, Evzio (naloxone hydrochloride injection), rapidly delivers a single dose of the drug naloxone via a hand-held auto-injector that can be carried in a pocket or stored in a medicine cabinet.

It is intended for the emergency treatment of known or suspected opioid overdose, characterized by decreased breathing or heart rates, or loss of consciousness.

FDA Fast-Tracks Naloxone Nasal Spray

Ryan Marotta, Assistant Editor
Published Online: Wednesday, February 18, 2015

Lightlake Therapeutics recently announced that the FDA has granted Fast Track designation to Adapt Pharma’s intranasal naloxone, an opioid overdose reversal agent.
Opioid Overdose Prevention Toolkit - Updated 2014

Average Rating: 5 out of 59 ratings.

Price: FREE (shipping charges may apply)

Equips communities and local governments with material to develop policies and practices to help prevent opioid-related overdoses and deaths. Addresses issues for first responders, treatment providers, and those recovering from opioid overdose. Updated in 2014.

Pub Id: SMA14-4742
Publication Date: 8/2014
Popularity: 405
Format: Kit
Audience: Community Coalitions, Law Enforcement, People In Recovery as Audience, Family & Advocates, Professional Care Providers, Prevention Professionals

Download Digital Version
- Opioid Overdose Prevention Toolkit - Full Document (PDF, 1 MB)
- I. Facts for Community Members (PDF, 952 KB)
- II. Essentials for First Responders (PDF, 562 KB)
- III. Safety Advice for Patients (PDF, 317 KB)
Conclusion

- Increased opioid use corresponds to increased number of analgesic prescriptions
  - Heroin epidemic developed from prescription opioid use epidemic
- Once acquired, majority of patients need treatment to abstain
  - May need several courses of treatment
- Good treatment options are available, but need to increase provider acceptance, availability to patients, and reduce stigma regarding treatment
- Overdose can be prevented by addressing risk factors and reversed by prescribing Narcan
What Can You Do?

1. Increase patient and public education
2. Increase Access to Treatment (Reduce Barriers)
3. Increase number of providers who CAN prescribe buprenorphine
4. Increase number of waivered physicians who WILL prescribe, and/or the number of people to whom they will prescribe
   a. Develop supportive resources for prescribers
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9. Make naloxone (Narcan) widely available
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11. Standing pharmacy orders for Narcan?
12. Increase public and law enforcement acceptance of Narcan
Thank you!

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