Opioids: Suffering Relieved, Suffering Created – What’s Next?

Douglas E. Brandoff, MD
Dr. Robert E. McKee Memorial Keynote Presentation
The Carol Dietrich Memorial Symposium
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Disclosures and Background

• I do not have any financial disclosures or conflicts of interest to report for myself or my spouse.

• My work includes:
  – Director, Opioid Safety and Compliance, DFCI
  – Member, Partners Health Care Opioid Task Force
  – Attending, Palliative Care Clinic, DFCI
Agenda

• “Suffering Created”
  – Brief historical review of opioids and addiction
  – Data and statistics
  – Policy and legislative responses

• “Suffering Relieved”
  – Prototype: role of opioids in oncology and palliative care

• “What’s next?”
  – Impact upon our patients, families, and clinical practice
  – What can we do? Should we do? Must we do?
The devastating effect of heroin police want you to see 03:30
~85% of patients with advanced cancer will experience pain
Competing Needs and “Crises”

Many patients have legitimate pain.
Undertreatment of pain = UNACCEPTABLE
Opioids must be available when appropriate.

Prescription opioid drug misuse is abundant.
Heroin and illicit fentanyl abuse has skyrocketed.
Addiction and related suffering have placed our society in a **public health crisis**.
Some of our prescribing practices have contributed to the problem.

Complacency is the enemy – “all hands on deck are urgently needed”
Brief History of Opioids

• **Morphine**
  – used to treat Civil War injuries
  – subsequent addiction amongst Civil War veterans

• **1898** – commercial production of heroin by Bayer Co.
  – Touted as “Wonder Drug” for pain and antitussive effects
  – IV injection to amplify effects discovered by addicts

• **1914** – Harrison Narcotics Tax Act
  – Taxes levied on opium when made, imported, or sold

http://www.cnn.com/2016/05/12/health/opioid-addiction-history/
• **1920s** – more physician reluctance to use opioids given addiction concerns
  – Heroin made illegal in 1924

• **WWII – 1960s:**
  – Devastating battlefield injuries; more opioids used
  – Development of nerve blocks

• **1970s:**
  – Federal crackdown on heroin, marijuana and cocaine
  – Marketing of oxycodone/acetaminophen and hydrocodone/acetaminophen

• **1980:** New England Journal editorial –
  – “development of addiction is rare in a patient without a previous history of addiction”

• **1980s** – paper touting opioids for chronic pain
  – "opioid maintenance therapy can be a safe, salutary and more humane alternative to surgery or to not treating a patient with chronic pain"

• **1990s** – pain = 5\textsuperscript{th} vital sign
  – OxyContin onto market, 1996
    • “They don’t have serious side effects; these drugs are our best, strongest pain medications; they should be used much more for patients in pain.”
  – 1999: 11 million more opioid prescriptions filled vs. 1998
• **2000s** –
  – **Joint Commission, 2001**: “Assess pain in all patients”
    • Continuing Education book for purchase by doctors
    • “There is no evidence that addiction is a significant issue when persons are given opioids for pain control.”
  – **Litigation, 2007, OxyContin**: $635M settlement due to “misbranding of drug and downplaying of addiction risk”
  – **Joint Commission, 2009** – standard removed
    • "The Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information."
• **2010** – abuse-deterrent formulation, OxyContin
  – Fewer people “getting high” from it, BUT….
  – Beginning of shift to heroin

• **2011** –
  – “I had tried to destigmatize opioids….if I had an inkling of what I know now, I wouldn’t have spoken in the way I did.”

• **March 2016** – CDC Guideline; editorial in NEJM
  – “We know of no other medication for a nonfatal condition that kills patients so frequently.”
  – One out of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after their first opioid prescription
How Opioids Have Been Viewed
Suffering Created

Data and Statistics
Drug deaths rising in all 50 states

Drug and opioid overdose deaths per 100,000 people (age-adjusted), 1999–2014

- 1.9–7.5
- 7.5–11.5
- 11.5–15.5
- 15.5–21.5
- 21.5–36.3
- Unavailable

Source: CDC
Drugs now kill more people than cars, guns

Number of deaths from drug poisonings vs. other causes, 1999–2014

Source: CDC
HEROIN'S DEADLY EFFECT

How heroin drives opioid overdose deaths

Number of opioid-related deaths involving heroin, 1999–2014

- Red: Heroin
- Pink: All opioids

Source: CDC
### Drug overdoses, by state

**Deaths per 100,000 people, 2014–2015**

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>West Virginia</td>
<td>↑12%</td>
<td></td>
<td></td>
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<tr>
<td>New Hampshire</td>
<td>↑24%</td>
<td></td>
<td></td>
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<tr>
<td>Kentucky</td>
<td>↑13%</td>
<td></td>
<td></td>
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<tr>
<td>Pennsylvania</td>
<td>↑28%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ohio*</td>
<td>↑11%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Mexico</td>
<td>↓9%</td>
<td></td>
<td></td>
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<tr>
<td>Massachusetts</td>
<td>↑28%</td>
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<tr>
<td>Nevada</td>
<td>↑4%</td>
<td></td>
<td></td>
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<tr>
<td>Maine</td>
<td>↑19%</td>
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<tr>
<td>Utah</td>
<td>↓9%</td>
<td></td>
<td></td>
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<tr>
<td>Oklahoma</td>
<td>↓8%</td>
<td></td>
<td></td>
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<tr>
<td>Missouri</td>
<td>↓2%</td>
<td></td>
<td></td>
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<tr>
<td>North Carolina</td>
<td>↑22%</td>
<td></td>
<td></td>
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<tr>
<td>South Carolina</td>
<td>↑14%</td>
<td></td>
<td></td>
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<tr>
<td>Alaska</td>
<td>↓3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorado</td>
<td>↓4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alabama</td>
<td>↑0.2%</td>
<td></td>
<td></td>
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<tr>
<td>Illinois</td>
<td>↑6%</td>
<td></td>
<td></td>
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<tr>
<td>Idaho</td>
<td>↑4%</td>
<td></td>
<td></td>
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<tr>
<td>Arkansas</td>
<td>↑7%</td>
<td></td>
<td></td>
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<tr>
<td>Montana</td>
<td>↓2%</td>
<td></td>
<td></td>
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<tr>
<td>Virginia</td>
<td>↑2%</td>
<td></td>
<td></td>
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<tr>
<td>Minnesota</td>
<td>↑10%</td>
<td></td>
<td></td>
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<tr>
<td>Iowa</td>
<td>↑12%</td>
<td></td>
<td></td>
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<tr>
<td>Nebraska</td>
<td>↑18%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Source: State health departments, Pennsylvania Coroners Association, CDC, U.S. Census Bureau*

*Does not include suicides*
Appalachia has struggled with a number of high-profile overdose cases recently.

West Virginia is home to six of the top 20 counties in the country with the largest concentrations of drug-related deaths. Kentucky has the most, with nine counties on that list. Ohio has also been hard-hit by the epidemic.
Elephant sedative

Carfentanil, a sedative for large animals, has led to several overdose deaths in the Cincinnati area as well, authorities said.

Carfentanil is the most potent opioid used commercially. It is 10,000 times stronger than morphine, and is a version of the painkiller fentanyl.

Carfentanil is a synthetic opioid and can slow breathing significantly. It's not approved for human use, but is used commercially to sedate large animals, such as elephants.

As little as 2 milligrams can knock out an African elephant weighing nearly 2,000-pounds.

Ohio has been one of the states hardest hit by the epidemic.

Dealers have been cutting heroin with fentanyl to give it a boost and stretch their supply, according to the Drug Enforcement Administration.

In 2014, the state had the second-largest number of deaths related to opioids nationwide.

Related Article: Heroin laced with elephant tranquilizers hits the streets
Based on the data available as of 06/30/2016, DPH estimates that there will be an additional 47 to 67 deaths in 2014 and 107 to 150 deaths in 2015, once these cases are finalized. For the first 6 months of 2016, the number of confirmed cases of unintentional opioid overdose deaths was 488, with an estimated additional 431 to 509 deaths. Current estimates for the first 6 months of 2016 are higher than the first 6 months of 2015.
Data Brief: Opioid-related Overdose Deaths Among Massachusetts Residents

Opioid-related Deaths, All Intents by Month
Massachusetts Residents: January 2015 - June 2016

Confirmed | Estimated
---|---
January 2015: 135 | 17
March 2015: 119 | 19
May 2015: 140 | 12
July 2015: 97 | 11
September 2015: 100 | 18
November 2015: 122 | 11
January 2016: 120 | 11
March 2016: 124 | 11
November 2016: 126 | 8
January 2017: 97 | 13
March 2017: 136 | 12
May 2017: 156 | 46
June 2017: 95 | 20
July 2017: 171 | 2
In 2015, the estimated rate of unintentional opioid-related overdose deaths was 24.6 deaths per 100,000 residents. The 2015 rate is the highest ever for unintentional opioid overdoses and represents a 23% increase from the rate of 20 deaths per 100,000 residents in 2014.

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1Unintentional poisoning/overdose deaths combine unintentional and undetermined intents to account for a change in death coding that occurred in 2005. Suicides are excluded from this analysis.

2Opioids include heroin, opioid-based prescription painkillers, and other unspecified opioids. This report tracks opioid-related overdoses due to difficulties in identifying heroin and prescription opioids separately.
**Toxicology Analysis: Fentanyl and Other Drugs**

Fentanyl is a synthetic opioid that has effects similar to heroin. It can be prescribed for severe pain. According to the U.S. Department of Justice, Drug Enforcement Administration’s 2015 Investigative Reporting, while pharmaceutical fentanyl (from transdermal patches or lozenges) is diverted for abuse in the United States at small levels, much of the fentanyl in Massachusetts is due to illicitly-produced fentanyl, not diverted pharmaceutical fentanyl.

The standard toxicology screen ordered by the Office of the Chief medical Examiner includes a test for the presence of fentanyl. In 2016, the number of fentanyl-related deaths continues to increase. Among the 439 individuals whose deaths were opioid-related in 2016 where a toxicology screen was also available, 289 of them (66%) had a positive screen result for fentanyl. In the first quarter of 2016, heroin or likely heroin was present in approximately 30% of opioid-related deaths that had a toxicology screen. Cocaine was present in approximately 30% of these deaths while benzodiazepines were present in approximately half. The rates of benzodiazepines and cocaine present in opioid deaths have been fairly steady since 2014, while the rates for heroin and prescription drugs have been decreasing at roughly the same rate that fentanyl has been increasing.

While screening tests can be used to note the rate at which certain drugs are detected in toxicology reports, they are insufficient to determine the final cause of death without additional information. The cause of death is a clinical judgement made within the Office of the Chief Medical Examiner.
Confirmed Unintentional/Undetermined\(^1\) Opioid-related Deaths by Gender: January 2016-June 2016

<table>
<thead>
<tr>
<th>Gender</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>365</td>
</tr>
<tr>
<td>Female</td>
<td>123</td>
</tr>
<tr>
<td>Total</td>
<td>488</td>
</tr>
</tbody>
</table>

Confirmed Unintentional/Undetermined\(^1\) Opioid-related Deaths Compared to All Deaths by Age: January 2016-June 2016

<table>
<thead>
<tr>
<th>Age Group</th>
<th>0-14</th>
<th>15-24</th>
<th>25-34</th>
<th>35-44</th>
<th>45-54</th>
<th>55-64</th>
<th>65+</th>
<th>Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Deaths</td>
<td>166</td>
<td>209</td>
<td>569</td>
<td>645</td>
<td>1,459</td>
<td>2,916</td>
<td>21,074</td>
<td>4</td>
<td>27,042</td>
</tr>
<tr>
<td>Confirmed Unintentional/Undetermined(^1) Opioid Deaths</td>
<td>0</td>
<td>41</td>
<td>165</td>
<td>126</td>
<td>103</td>
<td>50</td>
<td>3</td>
<td>0</td>
<td>488</td>
</tr>
</tbody>
</table>

Confirmed Unintentional/Undetermined\(^1\) Opioid-related Deaths Compared to All Deaths by Race: January 2016-June 2016

<table>
<thead>
<tr>
<th>Race/Other</th>
<th>White non-Hispanic</th>
<th>Black non-Hispanic</th>
<th>Asian non-Hispanic</th>
<th>Hispanic</th>
<th>Other/Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Deaths</td>
<td>24,163</td>
<td>1,156</td>
<td>483</td>
<td>961</td>
<td>279</td>
<td>27,042</td>
</tr>
<tr>
<td>Unintentional/Undetermined(^1) Opioid Deaths</td>
<td>391</td>
<td>19</td>
<td>4</td>
<td>67</td>
<td>7</td>
<td>488</td>
</tr>
</tbody>
</table>
### MA Prescription Monitoring Program County-Level Data Measures (2016 Quarter 2)

<table>
<thead>
<tr>
<th>County (County classifications are by patient zip code; patient state must also = MA)</th>
<th>Census Population</th>
<th>Total Schedule II Opioid Prescriptions</th>
<th>Total Number of Schedule II Opioid Solid Dosage Units</th>
<th>Individuals Receiving Schedule II Opioid Prescription</th>
<th>% of Individuals Receiving Schedule II Opioid Prescription (of total population)</th>
<th>Individuals with Activity of Concern</th>
<th>Rate of Individuals with Activity of Concern (per 1,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barnstable</td>
<td>214,914</td>
<td>28,637</td>
<td>1,621,530</td>
<td>13,045</td>
<td>6.1</td>
<td>23</td>
<td>1.8</td>
</tr>
<tr>
<td>Berkshire</td>
<td>128,715</td>
<td>15,646</td>
<td>869,800</td>
<td>6,936</td>
<td>5.4</td>
<td>6</td>
<td>0.9</td>
</tr>
<tr>
<td>Bristol</td>
<td>554,194</td>
<td>81,201</td>
<td>4,942,922</td>
<td>35,437</td>
<td>6.4</td>
<td>30</td>
<td>0.8</td>
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<tr>
<td>Dukes</td>
<td>17,356</td>
<td>2,056</td>
<td>121,526</td>
<td>966</td>
<td>5.6</td>
<td>&lt; $</td>
<td>NR</td>
</tr>
<tr>
<td>Essex</td>
<td>769,091</td>
<td>81,781</td>
<td>4,476,816</td>
<td>39,141</td>
<td>5.1</td>
<td>55</td>
<td>1.4</td>
</tr>
<tr>
<td>Franklin</td>
<td>70,862</td>
<td>10,462</td>
<td>623,240</td>
<td>4,429</td>
<td>6.3</td>
<td>&lt; $</td>
<td>NR</td>
</tr>
<tr>
<td>Hampden</td>
<td>468,161</td>
<td>67,418</td>
<td>3,981,200</td>
<td>29,818</td>
<td>6.4</td>
<td>34</td>
<td>1.1</td>
</tr>
<tr>
<td>Hampshire</td>
<td>160,939</td>
<td>18,873</td>
<td>1,185,383</td>
<td>7,933</td>
<td>4.9</td>
<td>6</td>
<td>0.8</td>
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<tr>
<td>Middlesex</td>
<td>1,570,315</td>
<td>117,920</td>
<td>6,367,104</td>
<td>60,209</td>
<td>3.8</td>
<td>68</td>
<td>1.1</td>
</tr>
<tr>
<td>Nantucket</td>
<td>10,856</td>
<td>1,142</td>
<td>51,001</td>
<td>548</td>
<td>5.0</td>
<td>&lt; $</td>
<td>NR</td>
</tr>
<tr>
<td>Norfolk</td>
<td>662,254</td>
<td>63,530</td>
<td>3,626,002</td>
<td>31,162</td>
<td>4.5</td>
<td>48</td>
<td>1.2</td>
</tr>
<tr>
<td>Plymouth</td>
<td>507,022</td>
<td>62,467</td>
<td>3,705,914</td>
<td>29,318</td>
<td>5.8</td>
<td>25</td>
<td>0.9</td>
</tr>
<tr>
<td>Suffolk</td>
<td>767,254</td>
<td>56,035</td>
<td>3,368,364</td>
<td>27,616</td>
<td>3.6</td>
<td>29</td>
<td>1.1</td>
</tr>
<tr>
<td>Worcester</td>
<td>813,475</td>
<td>94,167</td>
<td>8,037,675</td>
<td>43,149</td>
<td>5.3</td>
<td>50</td>
<td>1.2</td>
</tr>
<tr>
<td>MA</td>
<td>6,746,408</td>
<td>701,136</td>
<td>40,978,476</td>
<td>329,707</td>
<td>4.9</td>
<td>368</td>
<td>1.1</td>
</tr>
</tbody>
</table>

**Note 1:** Individuals with activity of concern "thresholds" for this report are based ONLY on a 3-month time period; see notes on previous pages CY16-Q2.

**Note 2:** Counts greater than 0 but less than or equal to 5 are not reported. Rates based on these small values also are not reported (NR).

**Note 3:** Rates of individuals with activity of concern are based on the population of individuals who have received one or more Schedule II opioid prescriptions during the specified time period from 4 different prescribers and filled at 4 different pharmacies.

**Note 4:** PMP data are preliminary and subject to updates. The MA PMP database is continuously updated to allow for prescription record correction data submitted by pharmacies. This data were extracted on 07/07/2016; Release Date: August 2016.

**Note 5:** National Center for Health Statistics. Postcensal estimates of the resident population of the United States for July 1, 2010-July 1, 2014, by year, counties, single-year of age (0, 1, 2, ..., 85 years and over), bridged race, Hispanic origin, and sex (Vintage 2014).
Suffering Created

Legislative and Policy-Based Responses
Broader Levels of Regulation for Opioids in Clinical Care

• Many ongoing efforts at institutional, state, and federal levels to regulate prescribing and dispensing, and to promote best practice
  – Institution-specific guidelines and practice points
  – Medical societies and their guidelines
  – State laws
  – Congress
  – CDC
  – FDA
  – DEA
  – White House
“Goal: Preserve access to medications for patients with legitimate need”

- PDMP structure and operations should encourage broad use
- PDMPs should maintain a health care focus
- PDMP objectives should be reinforced through other policies
Pennsylvania physicians who are licensed, registered, or otherwise lawfully authorized to prescribe controlled substances, other drugs or devices in the course of professional practice or research in this Commonwealth are required to register in the state’s new prescription drug monitoring program (PDMP).

Once you have registered, the system will be ready for query beginning Aug. 25, 2016, according to the Pennsylvania Department of Health (DOH). DOH’s PDMP webpage contains more information, including a link to register.

According to the law, once registered, prescribers shall query the system for each patient the first time the patient is prescribed a controlled substance by the prescriber for purposes of establishing a baseline and a thorough medical record. A prescriber shall also query the system if he or she believes or has reason to believe, using sound clinical judgment, that a patient may be abusing or diverting drugs.

**Querying the PDMP System - Additional Access for Prescribers**

A prescriber may query the system for:

- An existing patient; and
- Prescriptions written using the prescriber’s own Drug Enforcement Administration number

**Assigning Designees - Prescribers**

Prescribers may designate employees as designees for purposes of accessing the system according to standards established by the ABC-MAP Board. In assigning a designee, a prescriber shall give preference to a professional nurse licensed by the State Board of Nursing.
MA PMP as a Compliance Tool

- PMP Medical Review Group (MRG)
  - Reviews prescribing habits and trends amongst individuals and geographic areas

- Nov 2014 – Dec 2015: 26 cases reviewed
  - 10 referred to licensing boards
  - 15 found consistent with provider’s area of practice / acceptable within appropriate medical care
  - 1 referred to law enforcement
MA Drug Formulary Commission

• Evaluate “abuse deterrent” opioid formulations
  – Accessibility
  – Cost
  – Efficacy
  – Efficacy of abuse deterrent properties
• Determine “therapeutically equivalent” substitutes
  – Insurance must cover equally
• Produce a guidance document with “prescribing crosswalk”
• Voluntary for prescribers but strongly encouraged
• Very fluid market – many ADF in pipeline
• Limited post-marketing data for ADF opioids currently available – long-term benefits not proven
• Unique in scope
The “new opioid law” in MA – 3/14/2016

• H4056 – An Act Relative to Substance Abuse, Treatment, Education and Prevention
  – Improve substance use disorder prevention efforts
  – Enhance care and services available to patients throughout Massachusetts

• Some provisions took effect immediately
H4056 (MA) – Key Points

- 7-day opioid prescription limits
  - Exemptions for cancer-related pain, chronic pain, and/or palliative care
- Extended-release opioids and Medication Management Agreement
- Partial fill permissibility
- PMP review – check every time Rx written (10/15/16)
- Prescriber ranking within specialty/practice (volume and quantity of opioids prescribed) – 12/1/2016
- Voluntary non-opioid directive (12/1/2016)
FDA REMS for ER/LA Opioids

REMS = Risk Evaluation and Mitigation Strategy
ER/LA = Extended release, long-acting
REMS – Other Issues and Questions

• TIRF products (transmucosal immediate-release fentanyl)
  – Degree of restriction and regulation
  – How affecting prescribing patterns

• Will ER/LA opioid REMS follow suit from TIRF products?
  – Access for patients?
  – Impact upon workflow?
  – Do these regulations help?
FDA Opioid Action Plan

• Specific actions:
  – Expand use of advisory committees
  – Develop warnings and safety info for immediate-release opioid labeling
  – Strengthen post-market requirements
  – Update REMS program
  – Expand access to ADF opioids to discourage abuse
  – Support better treatment (e.g. naloxone accessibility, CDC Guideline)
  – Reassess the risk-benefit approval framework for opioid use

"Evidence-based, bipartisan efforts focus on prescribing practices and treatment to reduce prescription opioid and heroin use disorders”

- Providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions and address the over-prescribing of opioids.

- Increasing use of naloxone, as well as continuing to support the development and distribution of the life-saving drug, to help reduce the number of deaths associated with prescription opioid and heroin overdose.

- Expanding the use of Medication-Assisted Treatment (MAT), a comprehensive way to address the needs of individuals that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

National Pain Strategy

- Released March 18th, 2016 by the Office of the Assistant Secretary for Health at Department of Health and Human Services
- Seeks to reduce the burden and prevalence of pain and to improve the treatment of pain
- Outlines actions for improving pain care in America
  - Population research
  - Prevention and care
  - Disparities
  - Service delivery and payment
  - Professional education and training
  - Public education and communication

CDC Guideline for Prescribing Opioids for Chronic Pain

- Released March 15th, 2016
- **Intended for primary care clinicians prescribing opioids for chronic pain outside active cancer treatment, palliative care and end-of-life-care**
- Input obtained from experts, stakeholders, public, peer reviewers and a federal advisory committee
- Widely criticized amid concerns would lead to under-treatment of patients’ pain and medication coverage and legislative changes that would impact the care of the excluded patient populations

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65:1–49. DOI: [http://dx.doi.org/10.15585/mmwr.rr6501e1](http://dx.doi.org/10.15585/mmwr.rr6501e1)
CDC Guideline March 2016 – Key Categories

• When to initiate or continue opioids for chronic pain

• Opioid selection, dosage, duration, follow-up, and discontinuation

• Assessing risk and addressing harms of opioid use
Obama Administration July 2016

“Action from Congress urgently needed to provide resources for treatment”

- Called for $1.1B new funding for “treatment of opioid use disorder wherever Americans live”
- HHS/SAMHSA – increase from 100 → 275 number of patients to whom qualified physicians can Rx buprenorphine
- Indian Health Service and VA – prescribers must check PDMP
- Accelerate Research on Pain and Opioid Misuse / Overdose
- Expand Telemedicine in Rural America
- Safe Disposal of Unneeded Prescription Opioids
- Improve Housing Support for Americans in Recovery

July 2016 – Compact signed by 43 Governors

- **Reduce inappropriate opioid prescribing**
  - Develop evidence-based guidelines (start with CDC)
  - Limit to opioid quantities for certain situations
  - Prescribers and dispensers must check PDMP

- **Change nation’s understanding about opioids and addiction**
  - Social media campaigns
  - Partnership with clinicians, law enforcement, professional associations

- **Help ensure a pathway for recovery from addiction**
  - Reduce coverage barriers with Medicaid et al
  - Promote access to Medication Assisted Treatment
  - Good Samaritan laws to promote use of Naloxone
DEA reduces opioid production in US amid painkiller addiction epidemic

The federal government’s new quotas for 2017 will cut the manufacturing of prescription painkillers by 25% as overdose deaths increase.

The painkiller hydrocodone is among several addictive prescription drugs that the DEA has included in the new quotas. Photograph: Toby Talbot/AP

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**DEA production limits for select opioid drugs**

In kilograms of anhydrous acid or base

- Oxycodone
- Hydrocodone
- Morphine
- Codeine

Source: Drug Enforcement Administration | Graphic: Jan Diehm and Nacja Popovich/The Guardian
Suffering Relieved
Cancer patients and palliative care patients are not immune to the risks of misuse and addiction inherent to opioid therapy.

Opioid medications remain critically important and essential tools for relieving legitimate and often profound physical suffering from devastating illnesses.
Cancer Patient Pain Scenarios

- 34 y/o man with osteosarcoma, infiltrating his pelvic bones and sacral nerves
- 57 y/o woman with metastatic breast cancer to bone, liver, lung, and brain, with pathologic fracture of femur and humerus, and studding of diaphragm
- 62 y/o woman with ovarian cancer, malignant bowel obstruction, unrelenting abdominal pain

*Can these patients be managed without opioids?*
Heterogeneity of Pain Experienced by Cancer Patients

• Longer survival = more potential opioid exposure
• Multiple different types of pain possible
  – Acute or chronic, cancer- or treatment-related pain
  – Chemotherapy, radiation, and/or surgical
  – Acute or chronic non-malignant pain
• Duration of therapy similarly variable, may be:
  – During active treatment
  – Through survivorship with NED status
  – In end-of-life phase
Pain Syndromes in the Post-Cancer / Treatment Setting

- Chemotherapy-induced peripheral neuropathy
- Lymphedema
- Phantom limb pain
- Graft vs. Host disease, post stem cell transplant
- Post-radiation therapy pain syndromes

“Opioid therapy may be appropriate for a carefully selected subgroup, as long as benefits clearly outweigh risks over time and treatment can be monitored.”

2016 ASCO Policy Statement on Opioid Therapy
Undertreatment of Pain in Cancer Patients

• Prospective observational study of 3000 outpatients with breast, lung, colorectal, or prostate cancer

• Significant underprescribing of pain medications
  – 66% patients reported pain at first visit to oncologist
  – 33% received inadequate medication relative to degree of pain one month later
  – 43% with severe pain did not receive an opioid at first assessment or one month later; 20% had no analgesic

• Risks for undertreatment
  – Lack of advanced disease
  – Treatment center with predominance of minority patients
  – Minority patients treated at any center

Our conundrum in oncology

- Pain is very prevalent in cancer
  - 64% with advanced/metastatic disease
  - 53% patients at all stages
  - 33% after curative treatment

- 40% survivors live longer than 10 years

- Little is known about the prevalence of addiction or opioid misuse in oncology patient

van den Beuken-van Everdingen MH et al. Ann Oncol. 2007 18(9 1437-49.)
Cancer Patients: A Special Population

Cancer patients represent a special population that should be largely exempt from regulations intended to restrict access or limit doses, in recognition of the unique nature of the disease, its treatment, and potentially life-long sequelae. Cancer is very heterogeneous, with some diseases experiencing high rates of cure and others having an indolent biology extending over many years. Cure and prolonged remission represent trajectories that raise varying concerns and complexities, including the problem of chronic pain in survivors. Both solid tumors (with the exception of non-invasive skin cancers) and hematological neoplasms represent serious and potentially life-limiting illnesses, even if the course is relatively prolonged. This complexity in the presentation and course of cancer must be appreciated, as it has implications for practices and policies related to opioid therapy. From the clinical perspective, there is broad agreement that opioid therapy is generally the first-line approach for moderate to severe chronic pain associated with active cancer, whether or not the patient is receiving anti-neoplastic therapy; for this group of patients, access to opioids must be assured, and laws and regulations intended to address abuse and overdose should be crafted to avoid creating impediments to this treatment—particularly as there is no evidence that the treatment of cancer pain has in any way contributed to these problems.
Updated, Supportive Evidence and Advocacy

- National Comprehensive Cancer Network Guidelines (NCCN) on Acute Cancer Pain
- 2016 ASCO Policy Statement on Opioids
- American Academy of Hospice and Palliative Medicine – Policy Statements / Opioid Initiatives
- Abrahm, JL. A Physician’s Guide to Pain and Symptom Management in Cancer Patients (3rd Ed)
- Journal of Clinical Oncology – comprehensive series of papers in June 2014 on cancer pain
What’s Next?

Impact upon patients, families, and clinical practice
Broad Range of Impact

• Insurance coverage restrictions
  – Quantity limits
  – Prior authorizations

• DEA → decreased production of opioids

• Pharmacies
  – Partial fills due to lack of full supply on site
  – Declining to fill prescriptions

• Clinicians
  – “More hoops to jump through, not enough time already”
  – Phasing out opioid prescribing within scope of practice
Broad Range of Impact

• Legislative and Policy Initiatives
  – Greater scrutiny by licensing boards
  – Bills → laws, best practice guidelines
  – Voluntary non-opioid directives (e.g. in MA)
  – Expansion of REMS
  – Ranking by specialty (volume/quantity of opioids Rx’d)
  – Improved curricula in professional training schools
  – Law enforcement protocols

• Industry
  – Abuse-deterrent formulation opioids

• Patients, families, and clinician advocates for pain management
What’s Next?

What can we do?
What should we do?
What must we do?
Best Practice Recommendations

• Bring stakeholders together
• Use the PMP routinely
• Use Medication Management Agreements when prescribing opioids ("universal precautions").
• Have electronic health record visibly list MMA when activated for a patient.
• Assume prior authorizations will be needed for proposed opioid therapies – applies to our work both in inpatient and outpatient settings. Be preemptive.
Best Practices

• Routinely perform substance abuse screening.
• Risk stratify with and for our patients
• This isn’t to be punitive – it is to be educational, informational, and in compliance with regulatory expectations.
• When using “abuse-deterrent” opioid formulations, be aware of potential benefits and limitations.
• Ongoing patient assessment, monitoring, communication
• Learn Addiction Medicine at the “201” and “301” level
Best Practices with Documentation

- Pain Diagnosis
- Substance abuse screening performed
- Risk stratification assessment / pt education
- Counseling re: driving, lockbox use, disposal
- Anticipated duration of opioid treatment
- Use of abuse deterrent formulations (or not)
- PMP reviewed; irregularities or not
- Prior authorization activity
- Medication management agreement on file including designated opioid prescriber
- Urine toxicology results
- Plan for follow-up including interim prescriptions / coverage-based care
Pursue scholarly inquiry

- Addiction and substance misuse in oncology and palliative care populations
- Non-opioid pharmacologic and non-pharmacologic treatment modalities for pain
- Post-marketing studies for abuse-deterrent formulations

(And there are many, many more....)
Closing Thoughts – All Hands On Deck

• Opioids and illicit drugs (heroin, fentanyl) are part of a major public health crisis.

• We’ve an opportunity (no, MANDATE) to update and improve our practice, awareness, and education.

• How do we achieve balance with opioids
  – preserving access when medically appropriate
  – eliminating outdated, unsafe prescription habits
  – Providing the help that is needed (pain management, addiction management, or both)

• We need to work together to address these crises.