Opioids in Primary Care: Reducing Harm and Restoring Sanity

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Disclosures

- None
Objectives

• Recognize the scope of opioid abuse in our community, and how we got here
• Review CDC Guidelines for Prescribing Opioids for Chronic Pain
• Review PA legislation targeting Provider prescribing behaviors
• Demonstrate naloxone prescribing as a harm reduction strategy in a primary care environment
Scope of the Problem

- 2.6 million individuals with opioid use disorders
- 4-fold increase in opioid prescriptions for pain in the last 10 years
- 276% increase in deaths from prescription opioids from 2000 to 2016
- 20% increase in overdose deaths in PA from 2014-2015

CDC MMWR November 4, 2011 / 60(43):1487-1492
How did we get here?

“All patients should be routinely screened for pain, and when it is present, pain intensity should be recorded in highly visible ways that facilitate regular review by health care providers.”
Revising the APS Guidelines

Table 1. Comparison of 1995 APS QI Guidelines and 2005 Recommendations

<table>
<thead>
<tr>
<th>1995 APS QI Guidelines</th>
<th>2005 Updated and Expanded Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognize and treat pain promptly</td>
<td>Recognize and treat pain promptly</td>
</tr>
<tr>
<td>(emphasis on routine assessment and</td>
<td>(emphasis on comprehensive assessment and importance of preventive</td>
</tr>
<tr>
<td>documentation of pain intensity)</td>
<td>and prompt treatment based on evidence for neuroplasticity)</td>
</tr>
<tr>
<td>Make information about analgesics readily available</td>
<td>Involve patients and families in pain management plan</td>
</tr>
<tr>
<td></td>
<td>(emphasis on customization of care and participation of patient in treatment plan)</td>
</tr>
<tr>
<td>Promise patients attentive analgesic care</td>
<td>Improve treatment patterns (eliminate inappropriate practices,</td>
</tr>
<tr>
<td>(emphasis on urging patients to report pain)</td>
<td>provide multimodal therapy)</td>
</tr>
<tr>
<td>Define explicit policies for use of analgesic technologies</td>
<td>Reassess and adjust pain management plan as needed</td>
</tr>
<tr>
<td></td>
<td>(respond not only to pain intensity but to functional status and side effects)</td>
</tr>
<tr>
<td>Examine the process and outcomes of pain management</td>
<td>Monitor processes and outcomes of pain management</td>
</tr>
<tr>
<td>with the goal of continuous improvement</td>
<td>(new standardized QI indicators and comments about forthcoming</td>
</tr>
<tr>
<td></td>
<td>national performance indicators)</td>
</tr>
</tbody>
</table>

Abbreviations: APS, American Pain Society; QI, quality improvement.
The belief that chronic, non-malignant pain relief can be achieved with opioids has caused broad iatrogenic harm.

- **Clinical iatrogenesis** – overdose, abuse and adverse affects in patients
- **Social iatrogenesis** – escalating opioid diversion, abuse, and overdose in adolescents and poor rural middle-aged adults.
- **Cultural iatrogenesis** – erosion of our ability to manage pain in non-medical ways, and unrealistic expectations of relief.

Use of opioids for >90 days => 60% more likely to still be on chronic opioids in 5 years

Why are we in pain?
ACE Matters

Research Article

Relationship of Childhood Abuse and Household Dysfunction to Many of the Leading Causes of Death in Adults

The Adverse Childhood Experiences (ACE) Study

Vincent J. Felitti, MD, FACP, Robert F. Anda, MD, MS, Dale Nordenberg, MD, David F. Williamson, MS, PhD, Alison M. Spitz, MS, MPH, Valerie Edwards, BA, Mary P. Koss, PhD, James S. Marks, MD, MPH
Why are we in pain?

The ACE (Adverse Childhood Experience) Study
Conducted by the US Center for Disease Control & Kaiser Permanente

17,000 PARTICIPANTS SURVEYED

Female Participants:
13% emotional abuse
27% physical abuse
24.7% sexual abuse

Male Participants:
7.6% emotional abuse
29.9% physical abuse
16% sexual abuse

The ACE Study Findings suggest that certain experiences are major risk factors for the leading causes of illness and death as well as poor quality of life in the United States.

It is critical to understand how some of the worst health and social problems in our nation can arise as a consequence of adverse childhood experiences.

Realizing these connections is likely to improve efforts towards prevention and recovery.
## Probability of Outcomes Per 100 American Adults

<table>
<thead>
<tr>
<th></th>
<th>No ACE’s</th>
<th>1-3 ACE’s</th>
<th>4-8 ACE’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 in 9 smokes</td>
<td>1 in 6 smokes</td>
<td>1 in 6 smokes</td>
<td></td>
</tr>
<tr>
<td>1 in 9 alcoholic</td>
<td>1 in 6 alcoholic</td>
<td>1 in 6 alcoholic</td>
<td></td>
</tr>
<tr>
<td>1 in 3 IVDU</td>
<td>1 in 43 IVDU</td>
<td>1 in 30 IVDU</td>
<td></td>
</tr>
<tr>
<td>1 in 14 heart disease</td>
<td>1 in 7 heart disease</td>
<td>1 in 6 heart disease</td>
<td></td>
</tr>
<tr>
<td>1 in 96 attempts suicide</td>
<td>1 in 10 attempts suicide</td>
<td>1 in 5 attempts suicide</td>
<td></td>
</tr>
</tbody>
</table>
• Personal History of Substance Abuse
  Alcohol
  Illegal Drugs
  Prescription Drugs
• Age 16-45
• History of Preadolescence Sexual Abuse
• Psychological Disease:
  Attention Deficit Disorder, Bipolar, Schizophrenia, Obsessive Compulsive Disorder
  Depression


Opioid Risk Tool
Rising morbidity and mortality in midlife among white non-Hispanic Americans in the 21st century

Anne Case\(^{1}\) and Angus Deaton\(^{1}\)

Woodrow Wilson School of Public and International Affairs and Department of Economics, Princeton University, Princeton, NJ 08544

Contributed by Angus Deaton, September 17, 2015 (sent for review August 22, 2015; reviewed by David Cutler, Jon Skinner, and David Weir)

Significance

Midlife increases in suicides and drug poisonings have been previously noted. However, that these upward trends were persistent and large enough to drive up all-cause midlife mortality has, to our knowledge, been overlooked. If the white mortality rate for ages 45–54 had held at their 1998 value, 96,000 deaths would have been avoided from 1999–2013, 7,000 in 2013 alone. If it had continued to decline at its previous (1979–1998) rate, half a million deaths would have been avoided in the period 1999–2013, comparable to lives lost in the US AIDS epidemic through mid-2015. Concurrent declines in self-reported health, mental health, and ability to work, increased reports of pain, and deteriorating measures of liver function all point to increasing midlife distress.
All-cause mortality, ages 45–54 for US White non-Hispanics (USW), US Hispanics (USH), and six comparison countries: France (FRA), Germany (GER), the United Kingdom (UK), Canada (CAN), Australia (AUS), and Sweden (SWE).

Anne Case and Angus Deaton
2015 November 2, 2015, doi:10.1073/pnas.1518393112
Mortality by cause, white non-Hispanics ages 45–54.
AIDS and the Opioid Overdose Epidemic

- Parallels:
  - Stigma
  - Fear
  - Intentional neglect

- What Can we Do?
  - Follow
  - Lead
Responsible opioid prescribing in chronic pain management
What is the purpose of the new CDC guideline?

- Helps providers make informed decisions about pain treatment for patients 18 and older in primary care settings.
- Focuses on the use of opioids in treating chronic pain—pain lasting longer than three months or past the time of normal tissue healing.
- Reminds us that Opioids pose a risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing.
Pain Management Continuum

Appropriate Pain Treatment

...relieves symptoms
...assist patients in achieving a higher quality of life.
...leads to a higher level of provider satisfaction.

Narcotic Misuse

...leads to individual drug-related problems.
...causes damage to communities.
...causes provider dissatisfaction.
Overdose risk approximately doubles at doses between 20 and 49 mg/day MED, and increases nine-fold at doses of 100mg/day MED or more.

Triple Aim – Improving Population Health

If prescribing practices change, will fatalities decrease?

- State of Washington instituted new opioid dosing guidelines in 2007. After implementation,
  - Morphine equivalent dose (MED) per day declined 27%,
  - 35% decline in the proportion of workers on high doses of MED.
  - Number of deaths was reduced by 50% from 2009 to 2010.

Satisfaction is not achieved by keeping pain levels low and/or reducing pain, but rather by:

- Full explanation of the patient’s condition
- Perceived merits of treatment recommendations
- The better patients thought the pain problem was explained to them, the more they agreed with the treatment recommendations.

Appropriate treatment of chronic, non-malignant pain:

- involves a caring patient-provider relationship,
- communication of realistic treatment goals, and
- patients having trust and confidence in their providers.

Institute for Healthcare Improvement (IHI) Key Strategies

- **The Opioid Naïve Patient** – Avoid starting, thus preventing opportunities for opioid use and abuse
- **High-Dose Chronic Use** – compassionately taper opioids and move to alternative pain management
- **Opioid Dependent, Seeking Within Health Care** – Address opioid-seeking behavior without moving patients to illegal means of obtaining opioids.
- **Opioid Dependent, Seeking Outside of Health Care** – Address addiction behaviors and outcomes of opioid-seeking individuals.

Use non-opioid therapies first

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, then opioid therapy as last resort
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients
Start low and go slow

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations – even low doses (20-50 MME) increase risk; avoid >90 MME
- Duration of treatment – 3-7 days or less if possible
- Considerations for follow-up and discontinuation of opioid therapy – see pts frequently and have plans for taper and discontinuation
Predictive factors for transition from acute to chronic pain

- Demographic Factors - level of education, female sex, older age, poor health status
- Acute Pain Characteristics - acute pain intensity, duration, cumulative trauma exposure (Low back pain), severe pain intensity
- Psychological Factors - high baseline fear, anxiety, negative beliefs on chronic pain severity, depression
- Contextual Details - early use of prescription opioids (acute low back pain), injured at work, disability, litigation

### Perspectives on Acute to Chronic Pain

<table>
<thead>
<tr>
<th>Disease</th>
<th>Dimensional</th>
<th>Behavioral</th>
<th>Life Story</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distinction</td>
<td>What the patient has</td>
<td>Who the patient is</td>
<td>What the patient does</td>
</tr>
<tr>
<td>Logic</td>
<td>Categorical</td>
<td>Quantitative</td>
<td>Goal and Purpose</td>
</tr>
<tr>
<td>Treatable Risk Factors for Chronic Pain</td>
<td>Neuropathic Pain Inflammation /MDD Brain Circuitry Epigenetics</td>
<td>Shape Shifting Somatosensory Amplification Multiple Somatic Symptoms</td>
<td>Fear and Avoidance Substance Abuse</td>
</tr>
<tr>
<td>Treatments</td>
<td>Antidepressants Anticonvulsants</td>
<td>Relaxation Training CBT</td>
<td>Physical Therapy Substance Abuse Counseling</td>
</tr>
</tbody>
</table>

Opiate Induced Hyperkatifeia

Over time...

Increasing sensitivity to pain despite increasing opioid doses and duration of rx

Follow-up

- The guideline provides more specific recommendations compared to previous guidelines on monitoring and discontinuing opioids when risks and harms outweigh benefits.
- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk (e.g. naloxone)
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder (MAT)
Patient satisfaction is not related to reduced pain scores but rather to a caring provider/patient relationship and excellent communication.

Always consider how to prevent chronic, non-malignant pain when seeing someone with a pre-chronic (acute) pain episode.

Consider chronic pain as similar to other chronic diseases which require a complex, multidimensional treatment strategy such as chronic disease management.

If opioids are used for pre-chronic or chronic pain monitor the patient for clinically meaningful improvement and discontinue the opioid if this does not occur.
New legislation in PA

- Acts 124 and 191 - PDMP
  - FLA – showed 50% decrease in overdoses; NY/TN – 35 to 75% decrease in pts seeking opioids from multiple providers
New legislation in PA

- **Act 122** – opioid prescribing limits in ER and urgent care settings – max. 7 days supply, no refills; incentivize follow-up with PCP within 7 days
New legislation in PA

- Acts 124 and 126 – mandate opioid prescribing education for trainees and medical providers: 4 hrs first year, 2 hrs subsequent years
- In CA, 90% of providers changed their opioid prescribing practices 4 months after that initial 4 hr module.
Opioid Abuse in the US and HHS Actions to Address Opioid-Related Overdoses and Deaths – (3/26/15)

- Initiative targeted three priority areas to combat opioid abuse:
  1. **Opioid Prescribing Practices** to reduce opioid use disorders and overdose
  2. Expanded use and distribution of **Naloxone**
  3. Expansion of **Medication-assisted Treatment (MAT)** to reduce opioid use disorders and overdose

Primary Directive: Prevent Overdose Deaths!!

- Legislation and education aimed at providers and prescribing habits
- Public health initiatives emphasized naloxone distribution

How do we use our time most effectively?
Community Medicine*

https://www.youtube.com/watch?v=nPF-Juks2N0
Harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use. Harm Reduction is also a movement for social justice built on a belief in, and respect for, the rights of people who use drugs.

Pragmatism – Are we going to eliminate drug use?
Humanistic Values – Not approval but not moral judgment
Focus on Harms – Not the use itself
Balancing Costs and Benefits - Evaluation
Priority of Immediate Goals
State Naloxone and Good Samaritan Legislation
as of November, 2014

(Please check the individual statute as the language is nuanced and varies from state to state.)
FIGURE 2. Number* and location of local drug overdose prevention programs providing naloxone to laypersons, as of June 2014, and age-adjusted rates† of drug overdose deaths§ in 2013.

CDC, National Center for Health Statistics - the number and location, by state, of local drug overdose prevention programs providing naloxone to laypersons, as of June 2014, as well as the age-adjusted rates of drug overdose deaths in 2013.
Naloxone – Mechanism of action

Competitive antagonist
Precipitates withdrawal

Efficacy of IM = Intranasal
Onset: 2 to 13 min
Half life = 60-90 min

Typical dosage: 0.4 to 2 mg,
Repeat in 2-3 min
Costs:
IM $20/dose,
intranasal + adapter $75/dose
Evzio $580 two doses
Naloxone is extraordinarily effective

- 152,283 naloxone kits dispensed, with 26,463 reversals
- 164 naloxone scripts = one prevented death, at a cost of $420/quality adjusted life year gained
- Recent studies suggest closer to 36 scripts = one prevented death

- Prostate cancer screening – more than 1000 men to prevent one death
- Aspirin primary prevention for MI in elderly men – 511
- Statin prevention in men with 5 yr risk of 7.5%: stroke 606, MI 186

Coffin, Annals of Internal Med, 2013
High Risk Criteria

- Recent emergency medical care involving opioid poisoning/intoxication
- Suspected history of illicit or nonmedical opioid use
- High-dose opioid prescription ( > 50 mg of morphine equivalence/day)
- Methadone prescription to opioid naïve patient
- Any opioid prescription AND:
  - Smoking/COPD/Emphysema/Asthma or other respiratory illness
  - Renal dysfunction, hepatic disease
  - Known or suspected concurrent alcohol use
  - Concurrent benzo prescription
  - Concurrent SSRI or TCA anti-depressant prescription
  - Release from opioid detox or mandatory abstinence program
  - Voluntary request from patient
  - Patients in methadone or buprenorphine detox/maintenance
  - Patient with difficulty accessing emergency medical services
  - Recent release from incarceration

Project Lazarus, with permission
Barriers to Naloxone Distribution

- Cost/Insurance Coverage
- Naloxone availability
- Stigma/Misperceptions
- Availability of substance abuse treatment
Original Investigation

Reduction of Inappropriate Benzodiazepine Prescriptions Among Older Adults Through Direct Patient Education The EMPOWER Cluster Randomized Trial

Cara Tannenbaum, MD, MSc; Philippe Martin, BSc; Robyn Tamblyn, PhD; Andrea Benedetti, PhD; Sara Ahmed, PhD

**IMPORTANCE** The American Board of Internal Medicine Foundation Choosing Wisely Campaign recommends against the use of benzodiazepine drugs for adults 65 years and older. The effect of direct patient education to catalyze collaborative care for reducing inappropriate prescriptions remains unknown.

**OBJECTIVE** To compare the effect of a direct-to-consumer educational intervention against...
Naloxone Letter Project

- Educates patients about dangers of opioid overdose
  - Motivates patients to accept naloxone prescriptions
  - Encourages patients to ask for help to wean down opioid use, if appropriate

- Helps providers counsel new patients who request opioid refills at 1st visit
  - Decreases contentious tenor of those visits
  - Improves provider satisfaction/feelings of empowerment
February 2014 through February 2015

Letters sent* = 71
Naloxone dispensed* = 97

Dear Patient,

You are receiving this letter because your doctor at the Family Health Center knows that you have been prescribed opioid medications to treat pain or other problems.

Opioid medications include hydrocodone, oxycodone, codeine, Percocet, OxyContin, Vicodin and other common pain medications. While these medications can be very helpful to reduce disconcerting pain and help you maintain an active, healthy lifestyle, they can also have dangerous, even fatal effects. In order to keep you safe and healthy we are sharing information below that could save your life.

Opioids can be habit forming, so it is important to take them in combination with other types of medication or alcohol. Some important factors that can increase the risk of overdose include:

- If you are taking an opioid on a daily basis, your body adapts to the medication and you may take more medication to get pain relief. Your body will also use less of the higher dose. However, if you suddenly increase the dose or stop taking the medication, your body may experience symptoms of withdrawal, which can cause severe pain.

- If you take certain anti-nausea medications, such as Zanex, Ativan, Lioresal, Xanax and alcohol or other substances that may depress the central nervous system, this can dramatically increase your risk of overmedication, poisoning and overdose death.

Here is some good news from the Family Health Center:

1. Prescribe naloxone (Narcan) or naloxone-like medications that can save you or a loved one by calling any of our preferred pharmacies, which are also available in a hospital or other medical facility, and save yourself.

2. Have your Family Health Center/Emergency staff coach you to use the drug yourself, if you are a healthcare provider with information on how to use the drug, and save yourself in case of accidental overdose.

3. Take a look at naloxone (Narcan).

4. Review with your doctor medications that you might be prescribed from other doctors to determine if they are safe to take with your pain medication.

5. Here are some websites that can give you more information about using naloxone (Narcan) that can save your life:
   a. Project Learn: http://www.projectlearn.org/
   b. Opioid Overdose Project: http://opioidoverdoseproject.org

Prescription opioid pain medicine should always be stored out of reach of children and pets in your home. Any unnecessary, unused or expired opioid pain medicine should be properly disposed of in a nearby community drop box.

One of our healthcare goals is to keep you safe and healthy. We will do our best to provide a safe and healthy environment for you. Please call us if you have any questions.

Thank you.

Sincerely,

Provider, MD.
Naloxone Project – improves patient/provider satisfaction

**Level of comfort talking to PCP about opioid use (n=16 patients)**

- Low: 5%
- Neutral: 15%
- High: 80%

**Face-to-face naloxone counseling improves my satisfaction caring for new patients seeking refills of chronic opioids (n=22 FMR)**

- Disagree: 0%
- Neutral: 20%
- Agree: 80%
Naloxone Project – saves lives!

<table>
<thead>
<tr>
<th>Dates</th>
<th>Letters</th>
<th>Kits</th>
</tr>
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<tbody>
<tr>
<td>2/1/14 – 5/31/15</td>
<td>71</td>
<td>97</td>
</tr>
</tbody>
</table>

5 Reversals Reported
Among chronic opioid patients receiving naloxone:

- ER visits for opioid-related injuries decreased
- No association with level of opioid use among naloxone recipients
Thank you

- John Boll, DO; Williamsport Family Medicine Residency Program, UPMC Susquehanna
- Nil Das, MD
- Marianne Koenig, PharmD
- Lucas Hill, PharmD
- Brittany Sphar, MD
- Ron O’Neill, PharmD
- Mary Popovich RN and FHC Staff
- Alice Bell, LCSW Prevention Point PGH
- Beth Nolan, PhD, Pitt School of Public Health
- Gerald Cochran, PhD, Pitt School of SW