

## Ethical Challenges and the Opioid Crisis

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### Disclosures

- No relevant conflicts of interest to disclose
- Off-label Rx may be discussed
- Some slides adopted and adapted from colleagues
- "...knowledge belongs to humanity..." Louis Pasteur

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### Pain Data USA

- 30% of U.S. adults (100+ million) have chronic pain
- 50 million American adults suffer from chronic pain daily or almost daily
- 19.6 million American adults have high-impact chronic pain
- 20% of all outpatient visits and 10% of all drug sales are pain related
- 80% of patients undergoing surgery have post-operative pain; < 50% report adequate pain relief.
- 60% of those visiting emergency department with acute pain receive analgesics (median = 1½ hr.); 74% are discharged in moderate to severe pain.
- 62% of U.S. nursing home residents report pain
- 60% of women report severe pain with first child birth
- 1 trillion dollars annual costs to developed countries

Institute of Medicine, 2011; Max, National Rev Drug Discov 2008

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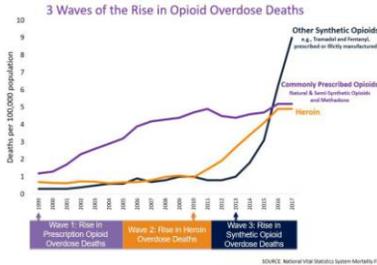
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The DEA is now talking about a 4<sup>th</sup> Wave – Amphetamines and Methamphetamines – “Breaking Bad” redux

In 2017, there were 70,237 overdose deaths (9.6% higher than 2016)

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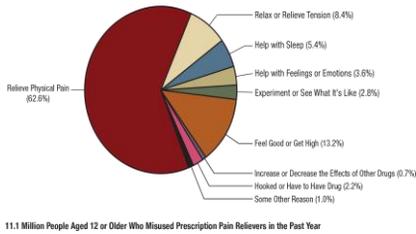
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**Main Reasons for the Most Recent Prescription Pain Reliever Misuse among People Aged 12 or Older Who Misused Prescription Pain Relievers in the Past Year: Percentages, 2017**




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**Management of Chronic Pain in the Aftermath of the Opioid Backlash**

Kroenke K, Cheville AC. JAMA 2017 (May 11)

1. Consensus guidelines in the past 5 years still included opioids as a later step in the analgesic ladder.
2. NIH and CDC guidelines recognize opioids as a viable “last resort” option in selected patients.
3. Is there collateral damage to patients with acute pain conditions or to 7 million Americans on chronic opioids?
4. Is there an “opioid epidemic”?
5. Clinical trials show modest analgesic effect of opioids
6. Long-term efficacy not shown for most pain treatments
7. Given small analgesic effect of any individual pain treatment, eliminating any evidence-based therapy from the current menu is undesirable.

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### Aims of CDC Guidelines for Prescribing Opioids for Chronic Pain

- Improve provider-patient communication about risks/benefits of opioid therapy for chronic pain
- Improve the safety/effectiveness of pain treatment
- Reduce risks associated with long-term opioid therapy, including OUD and overdose
- Intended for primary care physicians
- Not intended for patients receiving active cancer treatment, palliative care, or end-of-life care
- Not intended to dictate Standard of Care
- <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

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### Diverse Spectrum of Pain Management/OUD Stakeholders

- Physicians, dentists, podiatrists, non-physician prescribers
- Pharmacists and pharmacies
- Pain/Addiction research
- Pain management professional organizations
- Mental health treatment community
- OUD/Addiction treatment community
- Pain advocacy groups, including patients/families/employers
- Overdose treatment/reversal initiatives
- Federal regulatory bodies
- State medical boards et al regulatory agencies
- Active-duty military and veterans
- Minority health communities
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### Diverse Efforts Aimed at Rx Opioids, OUD, Overdose

- IOM/NAM Pain in America Report 2011
- National Pain Strategy
- CDC Guideline for Prescribing Opioids for Chronic Pain
- HHS Five-Point Strategy to Combat the Opioid Crisis
- Pain Management Best Practices Inter-Agency Task Force
- Behavioral Health Coordinating Council
- Drug Enforcement Administration / Food and Drug Administration
- Interagency Pain Research Coordinating Committee
- NIH HEAL Initiative
- Multiple Congressional Committees: House and Senate
- CMS / AMA / specialty organizations (AAPM/APS, ASCO, etc)

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### Rx Opioids Management

- Multidisciplinary-Multimodal treatment approaches
- Comprehensive evaluations of pain and collateral issues – physical, psychosocial, spiritual, situational
- Opioid Risk Assessment/Mitigation/Management Strategies – ORAMMS
- Risk stratification / Follow-up structure
- Serial menus vs Cafeteria approach
- Adherence / Compliance monitoring
- Expected outcomes / Unanticipated results / Unintended consequences
- Unknown Unknowns?

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### Evolution towards a comprehensive biopsychosocial model of pain and treatment

- Beecher: the personal meaning of pain was a determinant of pain complaints (1951).
- Melzack, Wall: published the Gate Control Model of pain (1965).
- Fordyce: encouraged consideration of social and environmental factors on pain (1973).
- IASP's definition of pain as a sensory and emotional experience (1979).
- Turk et al.'s demonstration of the influence of psychological factors on pain experience (1983).
- WHO 3-step Ladder
- ACGME's multi-disciplinary guidelines (2006).
- ..... AAPM/APS, ASCO, CDC, IOM/NAM, NIH, HHS, etc... 2019

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