The Good, the Bad and the Ugly

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October 26,2017

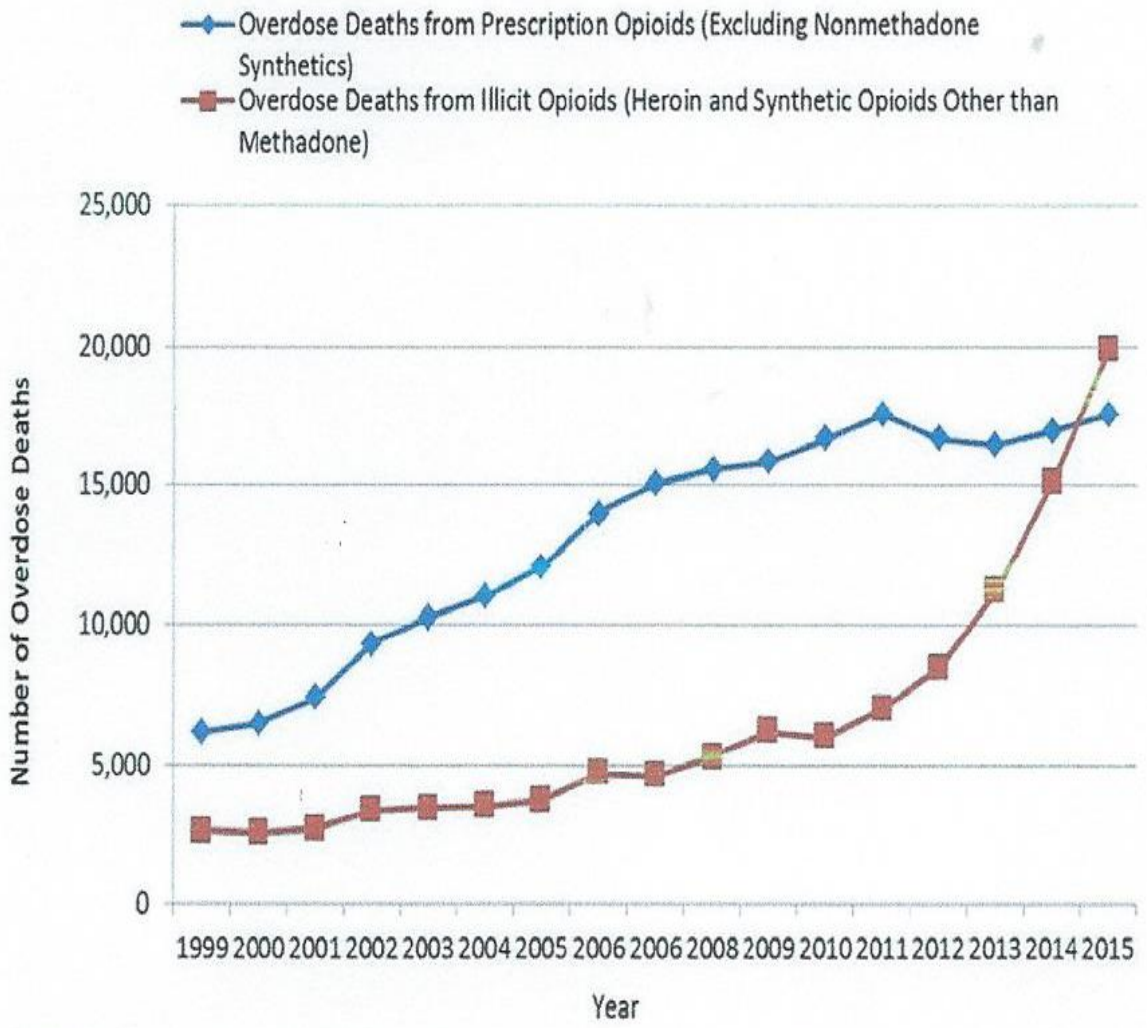

FIGURE S-1 Number of overdose deaths from prescription and illicit opioids, United States, 1999–2015.

Annals of Internal Medicine ORIGINAL RESEARCH

Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health

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Background: Despite the continuing epidemic of opioid misuse, data on the prevalence of prescription opioid use, misuse, and use disorders are limited.

Objective: To estimate the prevalence of prescription opioid use, misuse, and use disorders and motivations for misuse among U.S. adults.

Design: Survey.

Setting: The 2015 National Survey on Drug Use and Health (NSDUH).

Participants: 72 600 eligible civilian, noninstitutionalized adults were selected for NSDUH, and 51 200 completed the survey interview.

Measurements: Prescription opioid use, misuse, and use disorders.

Results: Weighted NSDUH estimates suggested that, in 2015, 91.8 million (37.8%) U.S. civilian, noninstitutionalized adults used prescription opioids; 11.5 million (4.7%) misused them; and 1.9 million (0.8%) had a use disorder. Among adults with prescription opioid use, 12.5% reported misuse; of these, 16.7% reported a prescription opioid use disorder. The most commonly reported motivation for misuse was to relieve physical pain (63.4%). Misuse and use disorders were most commonly reported in adults who were uninsured, were unemployed, had low income, or had behavioral health problems. Among adults with misuse, 59.9% reported using opioids without a prescription, and 40.8% obtained prescription opioids for free from friends or relatives for their most recent episode of misuse.

Limitation: Cross-sectional, self-reported data.

Conclusion: More than one third of U.S. civilian, noninstitutionalized adults reported prescription opioid use in 2015, with substantial numbers reporting misuse and use disorders. Relief from physical pain was the most commonly reported motivation for misuse. Economic disadvantage and behavioral health problems may be associated with prescription opioid misuse. The results suggest a need to improve access to evidence-based pain management and to decrease excessive prescribing that may leave unused opioids available for potential misuse.

Primary Funding Source: U.S. Department of Health and Human Services.

Ann Intern Med. doi:10.7326/M17-0865 **Annals.org**
For author affiliations, see end of text.
This article was published at Annals.org on 1 August 2017.

The United States is experiencing an epidemic of prescription opioid misuse, with prescription opioid overdose deaths more than quadrupling between 1999 and 2015 (1–4). Misuse is defined as use of a psychotropic medication without a prescription; for a reason other than as directed by a physician; or in greater amounts, more often, or longer than prescribed. The potential for misuse complicates prescription of opioids (5, 6). Several studies based on local data (7–11) or national samples of high school seniors (12, 13) have examined motivations for medication misuse. However, an examination of the prevalence of prescription opioid use, misuse, and use disorders and motivations for misuse in the U.S. adult population has been lacking. Such data could inform efforts to reduce prescription opioid misuse and related morbidity and mortality.

Based on a nationally representative sample of U.S. adults, this study examined the 12-month prevalence of prescription opioid use by sociodemographic characteristics, health conditions, and behavioral health status; the prevalence of misuse and use disorders among prescription opioid users by sociodemographic characteristics, health conditions, and behavioral health status; motivations for misuse; and sources of prescription opioids among adults with misuse and use disorders.

METHODS

Survey Methods and Study Population

The 2015 National Survey on Drug Use and Health (NSDUH) was a face-to-face household interview survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA). The NSDUH used a stratified, multistage area probability sample that was designed to be representative of the nation as a whole as well as each of the 50 states and the District of Columbia. Under a stratified design, with states serving as the primary strata and state sampling regions serving as the secondary strata, census tracts, census block groups, segments within census block groups, and dwelling units within segments were selected using probability-proportional-to-size sampling. After dwelling units were selected, an interviewer visited each unit to obtain a roster of all persons residing there. The roster information obtained from an eligible member of the dwelling unit was used to select 0 to 2 people for the survey.

See also:
Editorial comment 1
Summary for Patients 2

Prescription Opioid Use, Misuse and Use Disorders in US Adults

2015 National Survey on Drug Use and Health

Results:

- 91.8 million (37.8%) US civilians use prescription opioids
- 11.5 million (4.7%) misused them
- 1.9 million (0.8%) had a use disorder

Han et al Ann. Inter Med 2017

Misuse and Use Disorders Associated with the following factors

- Among adults with prescription opioid use: 12.5% report misuse

  16 % of them reported a prescription use disorder

Reasons for misuse:

- 63.4 % to treat physical pain

Misuse and Use Disorders Associated with the following factors

- Uninsured
- Unemployed
- Low income
- Behavioral health problems

Conclusion

- Need to improve access to evidenced -based pain management
- Decrease excess prescribing that may leave unused opioids available for potential abuse

Population Based North Carolina Study Das Gupta et al 2016

- North Carolina Prescription Drug Monitoring Program 2010 analysis:
- 2,182,374 patients received opioid prescriptions
- Dose dependent opioid overdose risk not at 100 mg/day average daily MME
- slight influence at 200 mg/day
- 24% of overdoses had no prescription for opioids

- 679 overdose deaths ½ of whom had an active prescription on the day of death
- 80 % had co prescribing of benzodiazepines

Brookings Work Force Study

- 47 % of the men in the non working labor force reported taking an opioid in the past day
- Ages 35 to 55 years predominately white
- Live in rural areas
- High suicide rate (81%)
- Regions that voted for Trump

Case et al PNAS 2016

Trends in Medical Opioid Use

- 1990-1996 increase in medical use of opioid analgesics did not contribute to health consequences
- 1997-2002 some influence
- 2004-2011 close relationship to opioid use and inappropriate use and abuse

Sensationalism and Pain

- Pain Killer: A “Wonder” Drug Trail of Addiction and Death Barry Meier
- Dreamland: The True Tale of America’s Opiate Epidemic Sam Quinones
- American Pain: How a Young Felon and His Ring of Doctors Unleashed America’s Deadliest Drug Epidemic John Temple

Treating Pain in 1970's

- Physicians reluctant to prescribe opioids
- No clinical guidelines existed
- No oral opioids available except codeine, meperidine, hydrocodone and oxycodone with acetaminophen or aspirin
- Drugs on a q 4 -6 hr basis given im
- Placebos commonly used
- Strict state laws limited opioid prescribing

Improvement in Cancer Pain Management 1980's-90's

- Availability of oral morphine products:
  Oral tablet, liquid and slow release formulations
- Development of guidelines for cancer pain management by ACS and APS
- Morphine vs heroin controversy resolved
  ACS ,ASCO and NHPCO advocated for access to opioid analgesic drugs for cancer patients
- WHO Cancer Unit developed "Freedom from Cancer Pain" initiative as a public health issue

Portenoy and Foley Pain 1986

- Retrospective case series on chronic non-cancer pain
- 38 patients Rx for at least 4 years
- 2/3 <20mg MED/Day
- 4 >40mg MED/day
- 24/38 acceptable pain relief
- No gain in social function or employment
- Role of opioids unclear

Range of Cancer Pain Initiatives

- Creation of State Cancer Pain Initiatives
- Changes in state laws and regulations with Intractable Pain Acts to allow physician to prescribe opioids
- Multiple studies on physician- related, patient- related and regulatory- related barriers

1990'sPalliative Care and Pain

- Support study findings.
- IOM Reports: Approaching Death 1997
  When Children Die 2003
  Improving Palliative Care for Cancer 2001
- Undertreatment of pain in the elderly and in nursing homes
- Pain as a "Fifth Vital Sign "

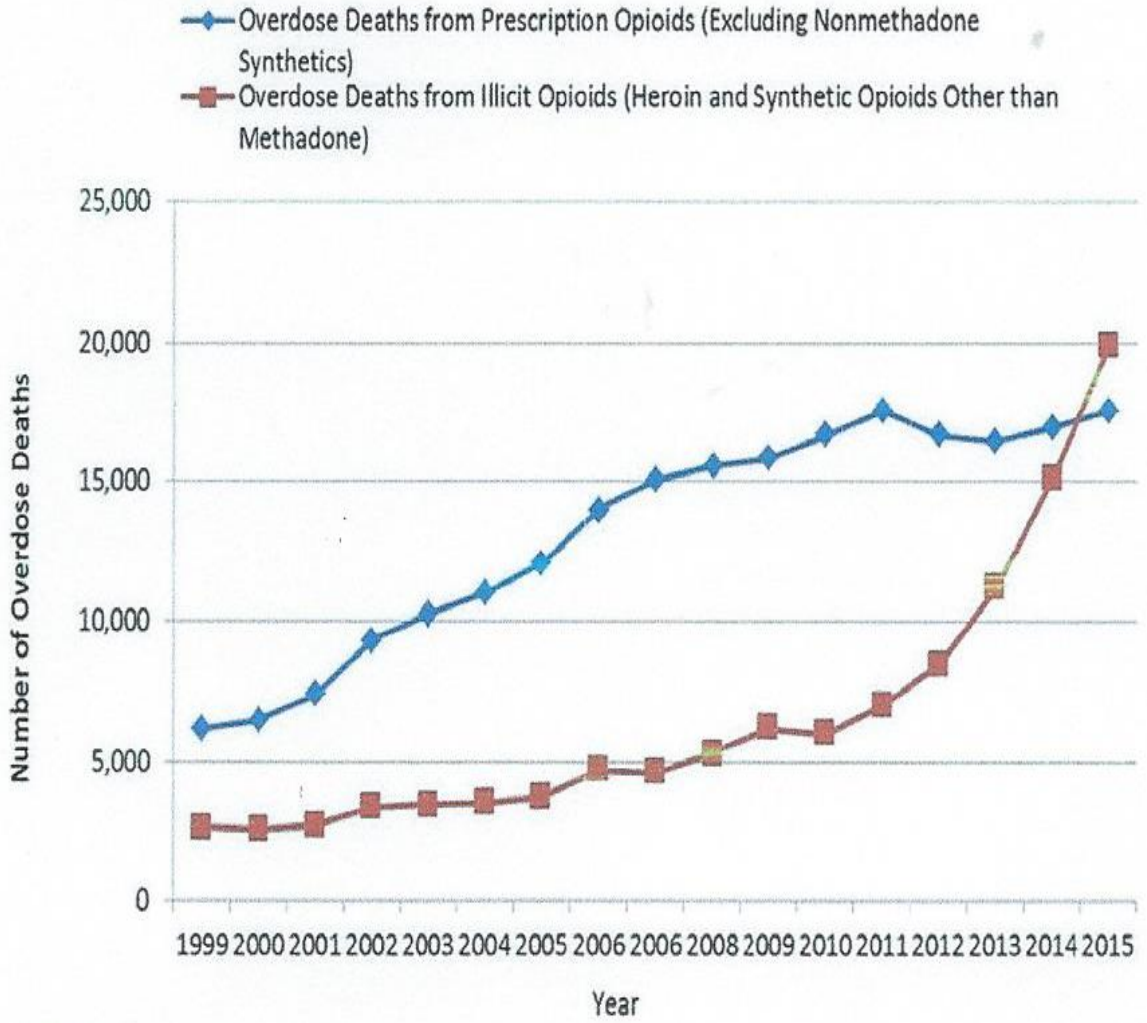


FIGURE S-1 Number of overdose deaths from prescription and illicit opioids, United States, 1999–2015.

2012 US Senate Investigation

- Allegations of a “network” of national organizations and researchers including physicians, pain societies, and regulatory agencies with financial connection to makers of narcotic pain killers
- These players helped create a body of dubious information favoring opioids

Citizens Petition by PROP

- July 25,2012 signed by 36 physician leaders
- Requested FDA to prohibit marketing of opioids for conditions in which their use has not been proven safe and effective

FDA Response to PROP

- ER/LA Opioids no longer indicated for moderate pain
- FDA recommended to DEA to reschedule hydrocodone from Schedule III to Schedule II
- Opana ER removed from the market

Interventions to Control the Opioid Crisis

- Prescription drug monitoring programs
- Strengthening pain clinic laws
- Improvement in access to naloxone
- Physician training and education REMS program
- CDC Guidelines to limit prescribing

Harvard Educated Doctors Prescribe Fewer Opioids

Data from 2006-2014:

- Physicians trained at the lowest ranked US medical schools prescribe 3x as many opioids compared to Harvard graduates
- Harvard trained general practitioners wrote 180 prescriptions/year compared to 550 prescriptions/year for the lowest ranked graduates

Schnell and Currie NBER 2016

CDC Guidelines

Opioid Selection Dose, Duration, Discontinuance:

- when prescribing opioids at any dose, assess risk and benefits and should carefully reassess risk

when increasing to >50 morphine milligram equivalents (MME)/day and avoid increasing dose to >90 morphine milligram equivalents (MME)/day or carefully justify a decision to escalate dose

- Clinicians should prescribe the lowest effective dose of immediate release opioids possible and should prescribe no greater quantity than the amount needed for the expected duration of pain severe enough to require opioids
- Three days or less should be sufficient, more than seven days will rarely be needed.

Undertreatment of Cancer Pain in United States

- 2011 : Medical oncology outpatient survey:

  67% reported pain, 33% received inadequate prescribing

- 2011: Medical Oncologists survey:

  Response to two vignettes: 60% and 80% responded inadequately

Undertreatment of Cancer Pain

- Numerous studies suggest under treatment in 50 % of patients with active cancer
- Risk Factors:

  -Over 65 years of age

  -African American

  -Hispanic

Paice et al JCO 2014

US Efforts to Improve Cancer Pain

2011: IOM Report: Relieving Pain in America

2013: Development of a National Pain Strategy

-Funding to the NIH Pain Consortium

2014: IOM Report: Dying in America

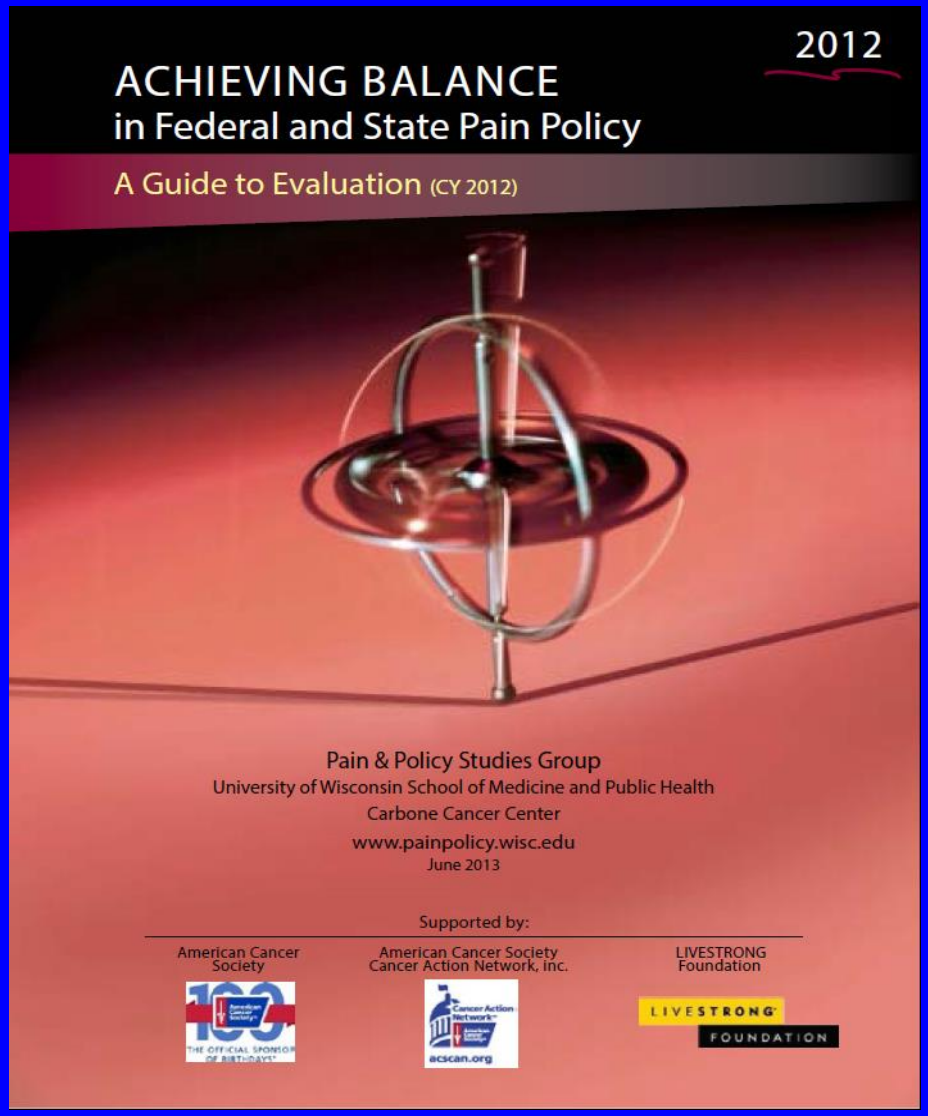
2016: Pain Management and Opioid Prescribing:

-Balancing Societal and Individualized Benefits and Risks of Prescription Opioid Use

US Efforts to Improve Cancer Pain

- PAINS Alliance: Pain groups to improve pain care for all
- ACS Quality of Life Initiative
- Achieving Balance in State Pain Policy: State Report Cards published by Pain and Policy Study Group at the University of Wisconsin

http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/evalguide2012.pdf



ASCO Policy Statement on Opioid Therapy:

Protecting Access to Treatment for Cancer-Related Pain

www.asco.org

ASCO Clinical Practice Guideline 2016

Management of Chronic Pain in Survivors of Adult Cancer

http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2016.68.5206

Barriers to Opioid Availability

Access Limitations:

- Obtaining prescriptions from prescribers
- Few pharmacy carry opioids or limited supply impacting e-prescribing
- Patients given partial fill requiring new prescription for remaining supply
- Pharmacies refusing to honor 3 day emergency supply

Barriers to Opioid Availability

Access Limitations:

- Limits on number of tablets/patches per fill.

  -Many patients limited to 100 per fill
- Limits on number of opioids (usually 2)dispensed in 30 days
- When titrating dose up cannot obtain next higher dose prior to 30 days or need prior authorization.

Barriers to Opioid Availability

Access Limitations:

- Patients report being treated as drug seekers by some pharmacies

Barriers to Opioid Availability

Reimbursement/Insurance Limitations:

- Requirements for prior authorizations for many opioids is increasing, not just for more expensive opioids
- Prior authorizations can take up to 72 hours (business days only)or longer to obtain: expedited review 24-48 hours; pts without meds or pay out of pocket then need new prescription

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Barriers to Opioid Availability

Reimbursement/Insurance Limitations:

- Very difficult to access insurance companies on Friday afternoon not available on weekends complicating hospital discharges

Challenges to Opiod use in Hospice and Palliative Care

- Diversion and misuse in hospice care
- Justifying opioid pain management for patients in palliative care with insurers
- Unintended consequences of the CDC Guidelines on physician prescribing
- Lack of targeted educational programs to differentiate patient groups
- Dual Loyalty of physicians tested in the treatment of pain