Targeting Key Outcomes for Measuring the Impact of Interventions

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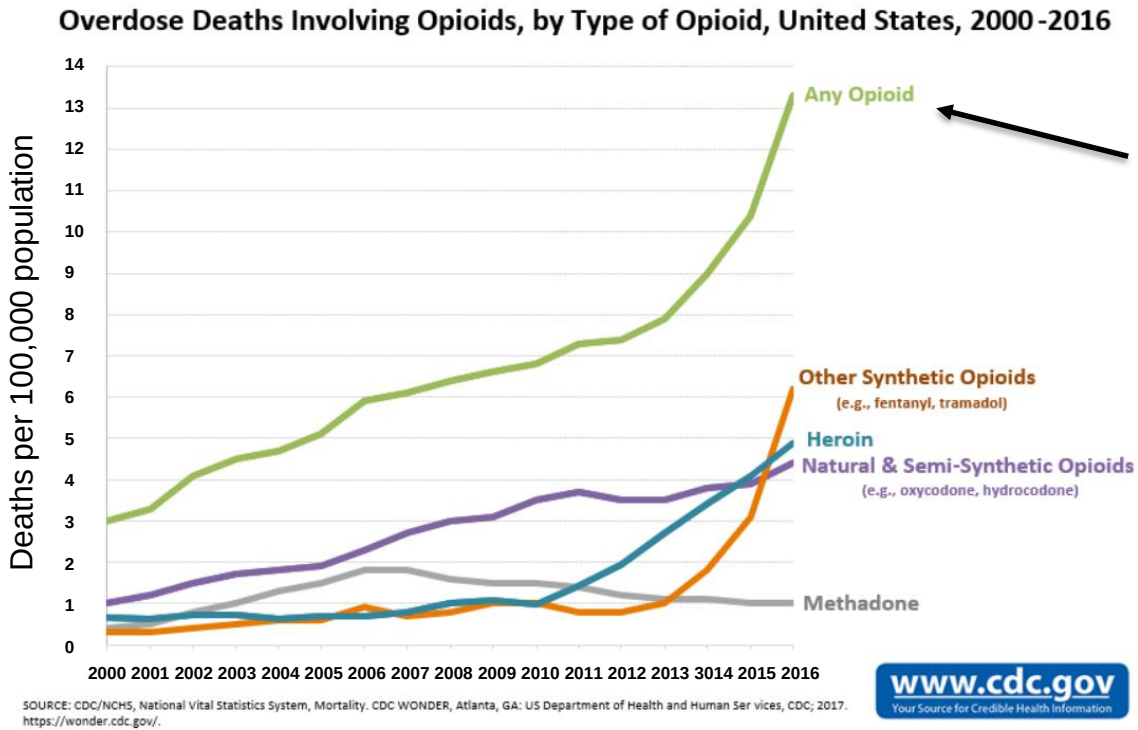
Need For Action: Opioid Overdose Deaths Increasing



Overdose rates involving an opioid continue to rise in the U.S.

https://www.cdc.gov/drugoverdose/data/index.html

A Wide Range of Entities are Implementing/Recommending Prescribing Limits

Federal

CDC

VA | U.S. Department of Veterans Affairs

Insurance Providers

MASSACHUSETTS

KAISER PERMANENTE
SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP

Health First COLORADO
Colorado's Medicaid Program

State/Locality

Washington State Department of Health

NYC Health
THE NEW YORK CITY DEPARTMENT of HEALTH and MENTAL HYGIENE

Ohio MHAS
MENTAL HEALTH & ADDICTION SERVICES
Promoting wellness and recovery

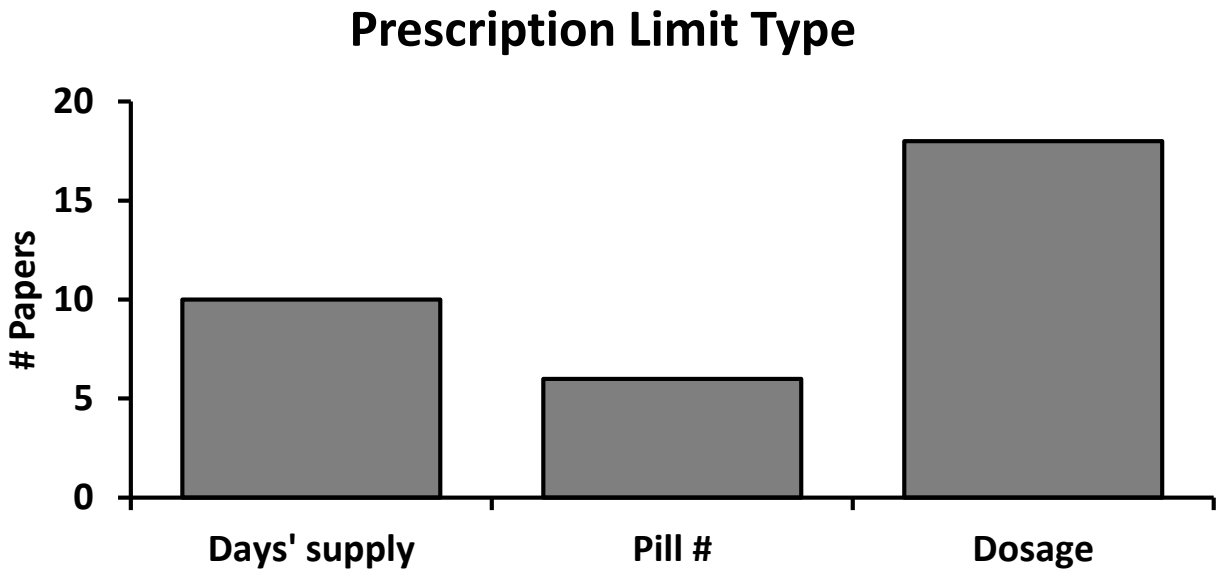
UTAH DEPARTMENT OF HEALTH

Professional Societies

ACOEM
AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

AMERICAN ACADEMY OF EMERGENCY MEDICINE

Many States, Jurisdictions, Health Systems, and Insurance Companies Already Limit Prescribing

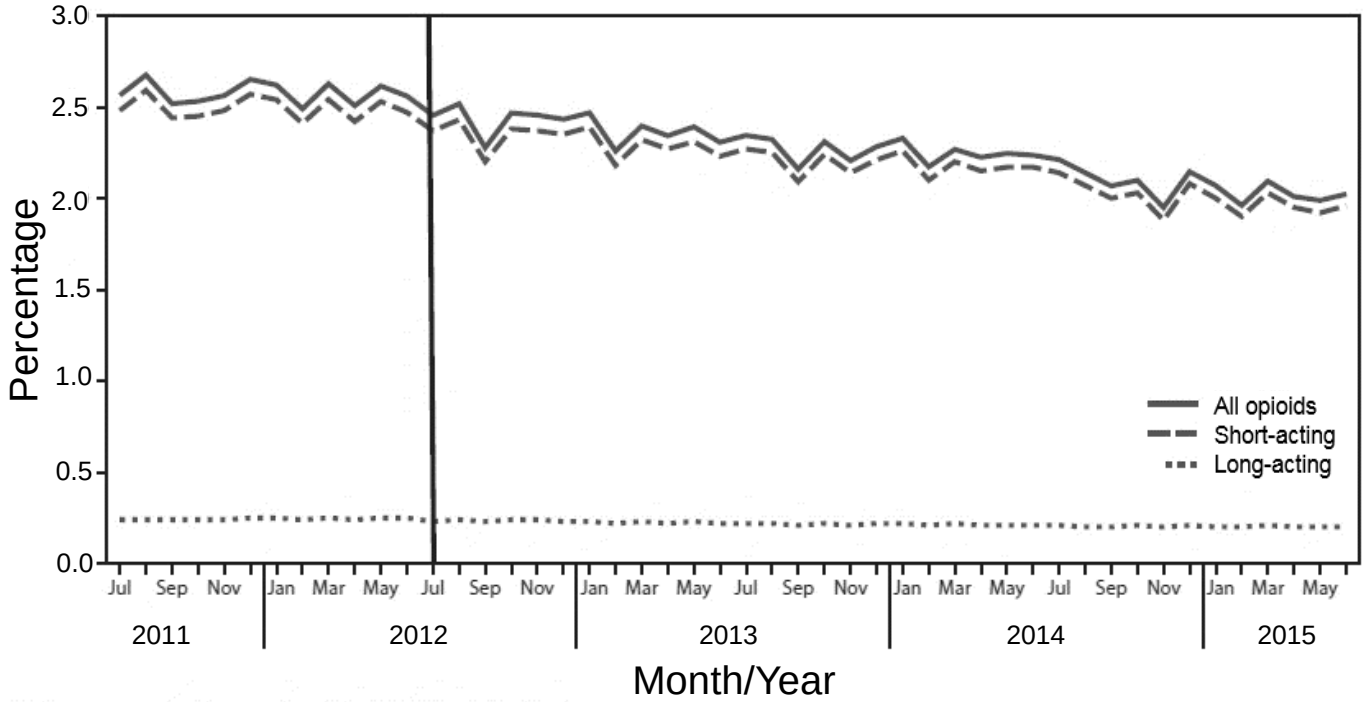


*Of 29 published program evaluations with prescription limits (through 9/2017)

Key Outcomes of Interest

Outcomes Currently Being Assessed: Rx Rates

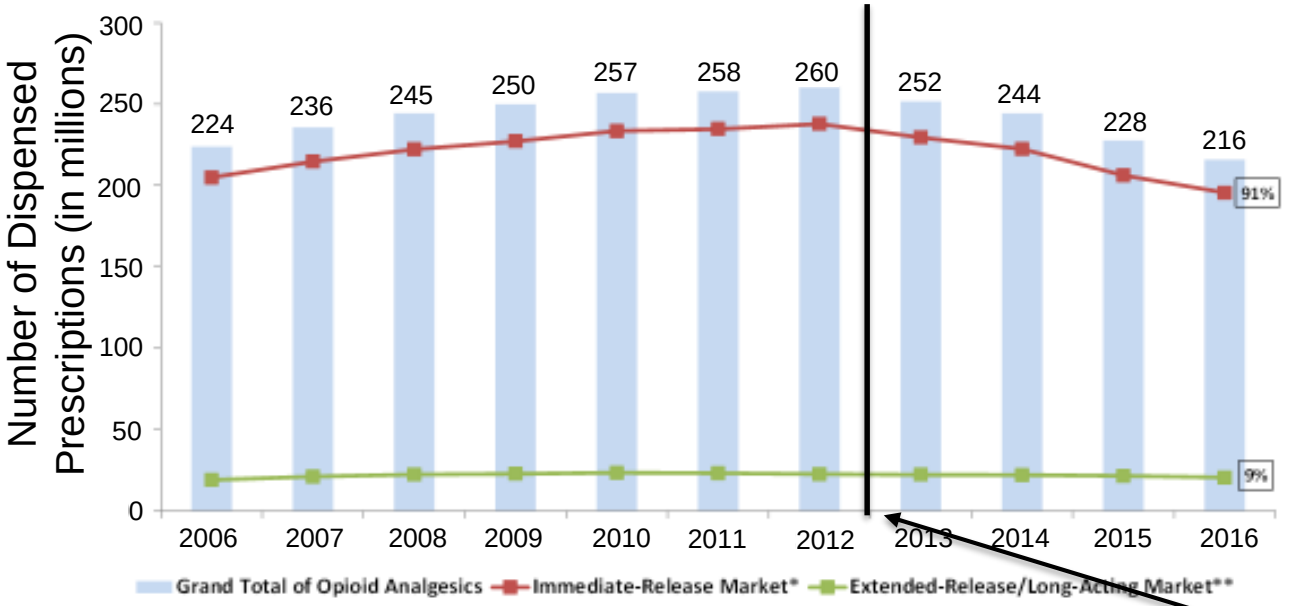
Figure 2. Percentage of members with opioid prescriptions – Blue Cross Blue Shield Massachusetts (BCBSMA), *July 2011-June 2015



*July 1, 2012, marked the start of the date of the BCBSMA opioid utilization program

MMWR, Garcia 2016

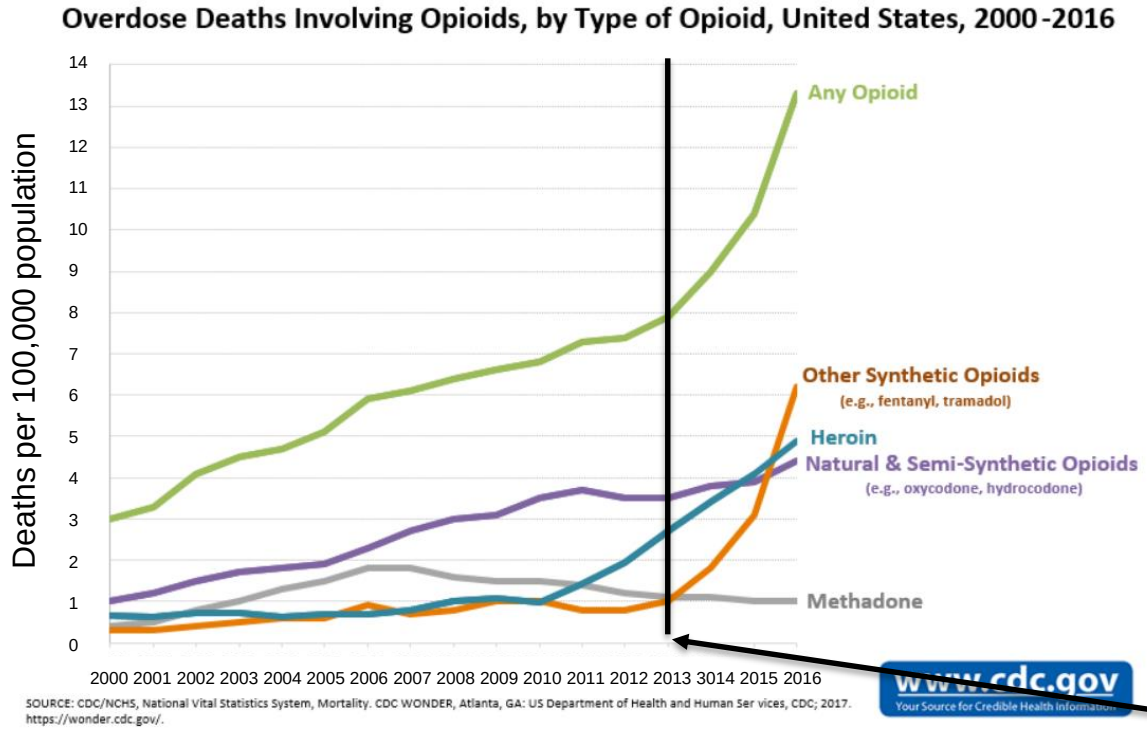
Nationally Estimated Number of Prescriptions Dispensed for Opioid Analgesics Products from U.S.



Source: National Prescription Audit (NPA) and static data 2006-2011. January 2006-December 2016 Extracted March 2017.
*Immediate-Release formulations include oral solids, oral liquids, rectal, nasal, and transmucosal.
**Extended-Release/Long-Acting formulations include oral solids and transdermal patches.
Note: Include opioid analgesics only, excluding injectable formulations as well as opioid-containing cough-cold products and opioid-containing medication-assisted treatment (MAT) products

Prescribing dropped

Overdose Rates Continue to Rise Despite Decreasing Prescribing of Opioid Analgesics



Prescribing dropped

https://www.cdc.gov/drugoverdose/data/index.html

Unintended Consequences: Creating Barriers to Proper Pain Management

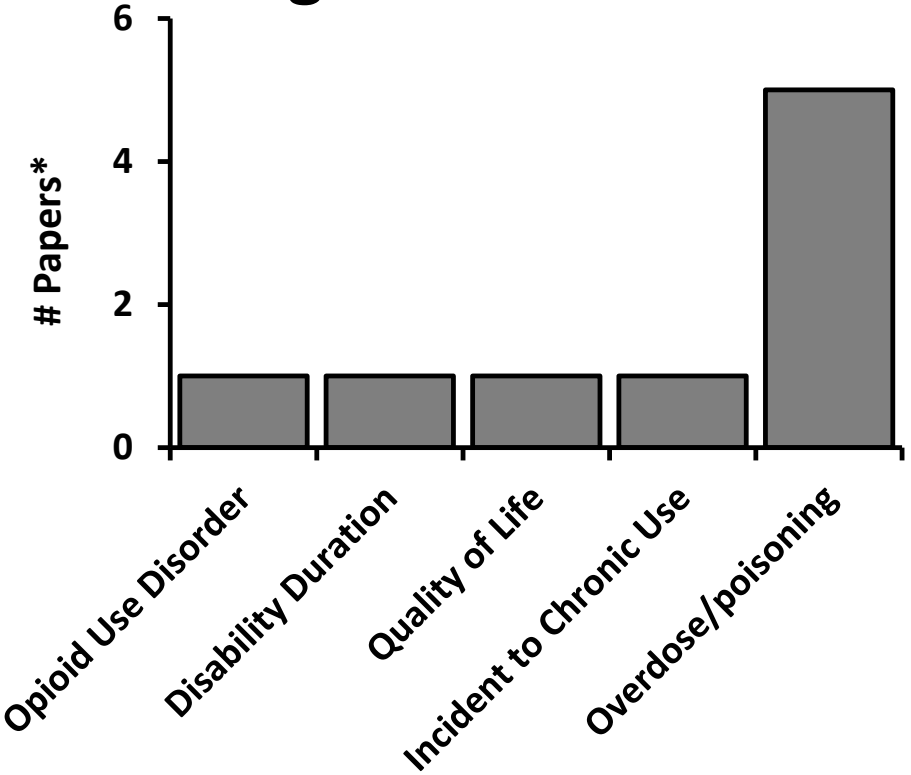
- **Patient**
  - Forced tapers/dose reductions
  - Denial of prescriptions
  - Increasing disability
  - Harms to patient access
  - Suicide
- **Prescribers, Pharmacists**
  - “Chilling effect”- Fear of liability
  - Barriers (e.g., documentation, extra steps)

Unintended Consequences: Creating Barriers to Proper Pain Management

"As a chronic pain patient, the pendulum has swung too far on the side of access to opioid pain medication. I have been a chronic pain patient for over 20 years. In that time I have tried every therapy, injections & 10 major surgeries to try to reduce my pain. It is only after all these treatments did I start opioid medication. It has been a true life saver for me, although I am deemed totally disabled, I have some quality of life again. I can watch my grandchildren, do some light housework & enjoy being alive! Before the medication, my life was miserable, pain ruled my ability to do anything. Do you know that urgent care facilities do not treat pain? **When you phone a doctors office for an appointment, the first question they ask is, Are you on pain medicine? or We do not prescribe narcotics.** The number one complaint of patients is pain. We are in a crisis, a crisis of the under treatment of pain in America. **The rights for the disabled, chronic pain patients & the elderly are being disregarded & disrespected**."

~FDA docket comment: FDA-2017-N-6502-0054

Patient Outcomes Assessed in Published Program Evaluations



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Is Overdose Too Distal to the Implementation?

Majority of program evaluations looking at patient outcomes used overdose as patient outcome.

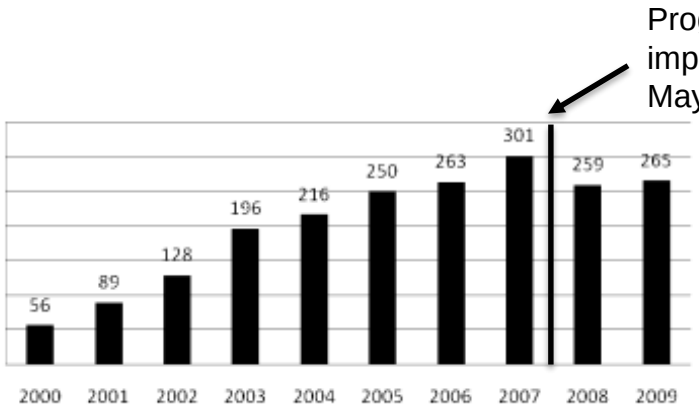


Figure 4 Number of unintentional drug overdose cases involving at least one prescription opioid by year: Utah, 2000–2009.

Johnson et al., Pain Medicine, 2011

Do Program Evaluations Need to Focus More on Proximal/Patient Outcomes?

Quality of Life

Pain Level

Refill Rate

Abuse

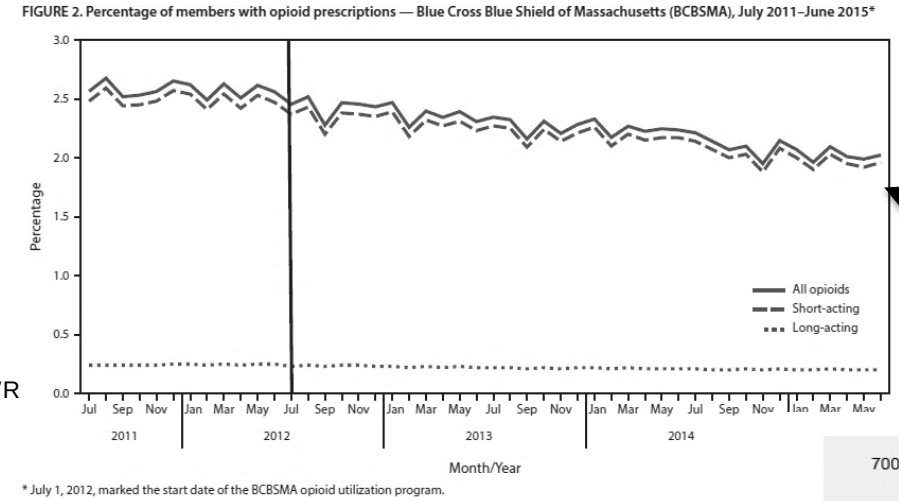
Addiction

Misuse

Reduction in Unnecessary Prescriptions/ Dose

Methodological Considerations

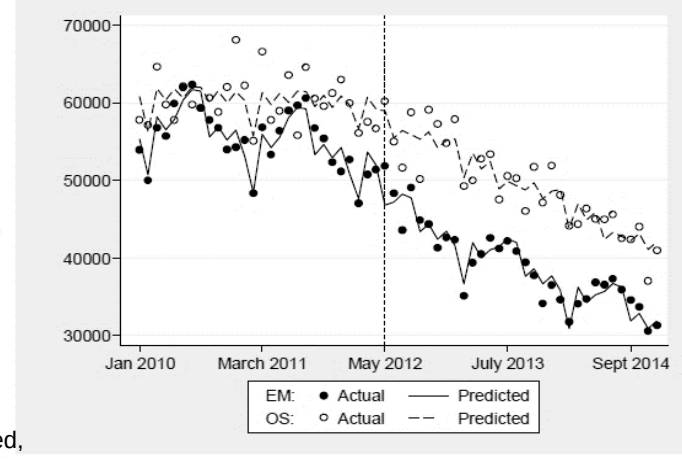
Non-Program Comparator Groups Needed



Garcia, 2016, MMWR

Most studies compared trends before and after program start but did not account for secular trends.

- Only 5 studies* that assessed trends over time included a **non-program comparison group** to adjust for secular trends.

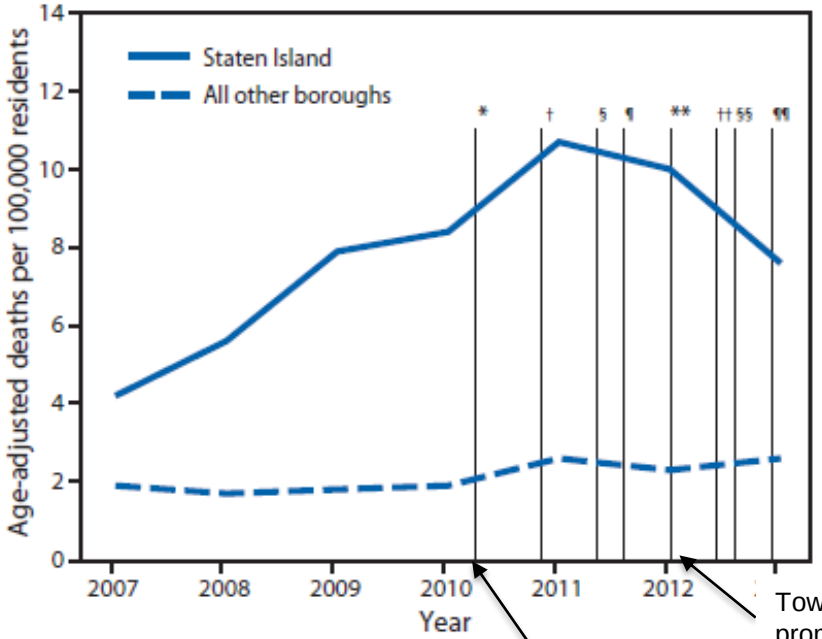


*Of 29 published program evaluations with prescription limits (through 9/2017)

Weiner, 2017, Ann Emerg Med,

How can We Assess Individual Components of the Programs?

FIGURE. Age-adjusted rate of unintentional drug poisoning (overdose) deaths involving opioid analgesics, by borough of residence, and New York City public health interventions — 2007–2013



- Built in Staggering?
- Natural Experiments?

Town halls convened in Staten Island. Implemented detailing campaign to promote opioid prescribing guidelines to prescribers in Staten Island.

Citywide data brief highlighting overdose mortality and Rx use in Staten Island.

Paone et al., MMWR, 2015

Takeaways

Can We Develop Best Practices for Program Evaluations?

1) Plan for and integrate evaluation from the beginning.
2) In addition to prescribing rates, include proximal and distal patient outcomes as well as unintended consequences, along with measures of misuse/abuse
3) Include a non-program comparator group to adjust for secular trends.
4) Plan ways to assess different components of the program, such as prescribing limits.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