

Behind the Opioid Epidemic – *Expanding the Horizons of Drug Surveillance* Fentanyl, Immediate Release Opioids, and Mortality

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Roadmap

- Behind the opioid epidemic
- Hidden threats
 - Threats to health and safety
 - Threats to data interpretation
- Immediate release opioids
- Mortality data and product specificity
- Directions forward

The IR Opioid Threat

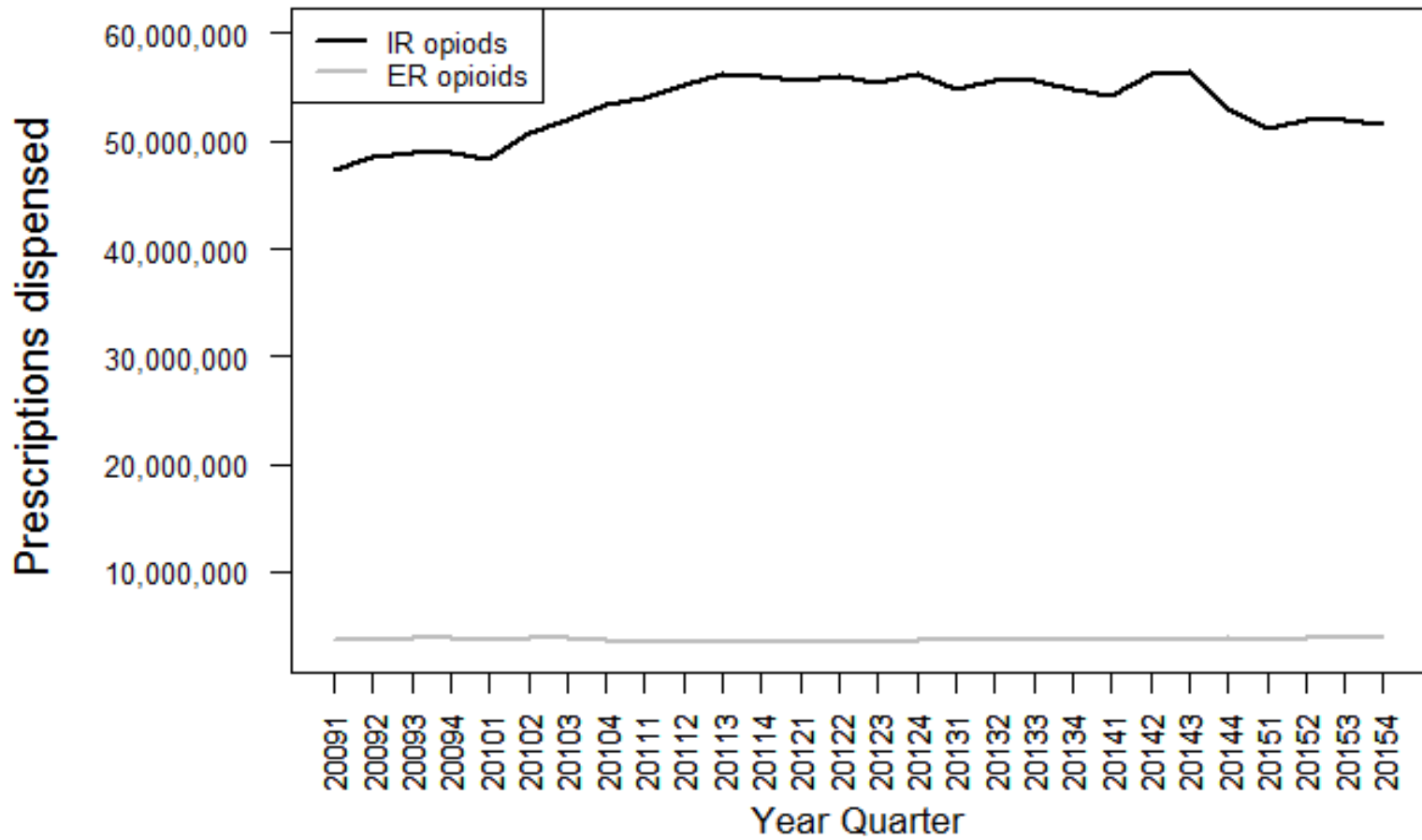
- Strong regulatory focus on extended release (ER) medication abuse
 - US FDA concerned for potential increased risk of serious side effects
 - Risk Evaluation and Mitigation Strategy (REMS)
 - Current abuse deterrent formulations (ADFs)

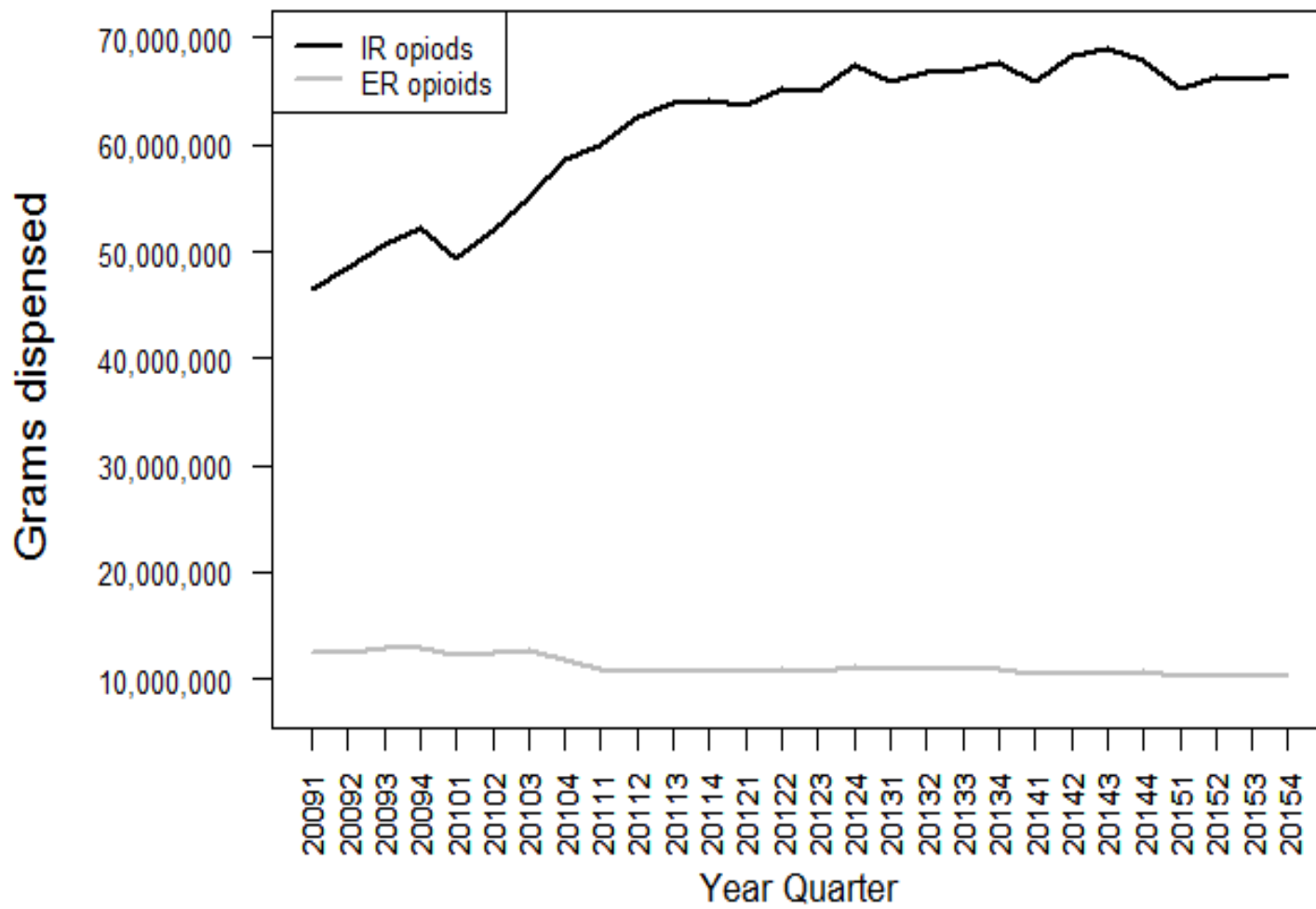
The IR Opioid Threat

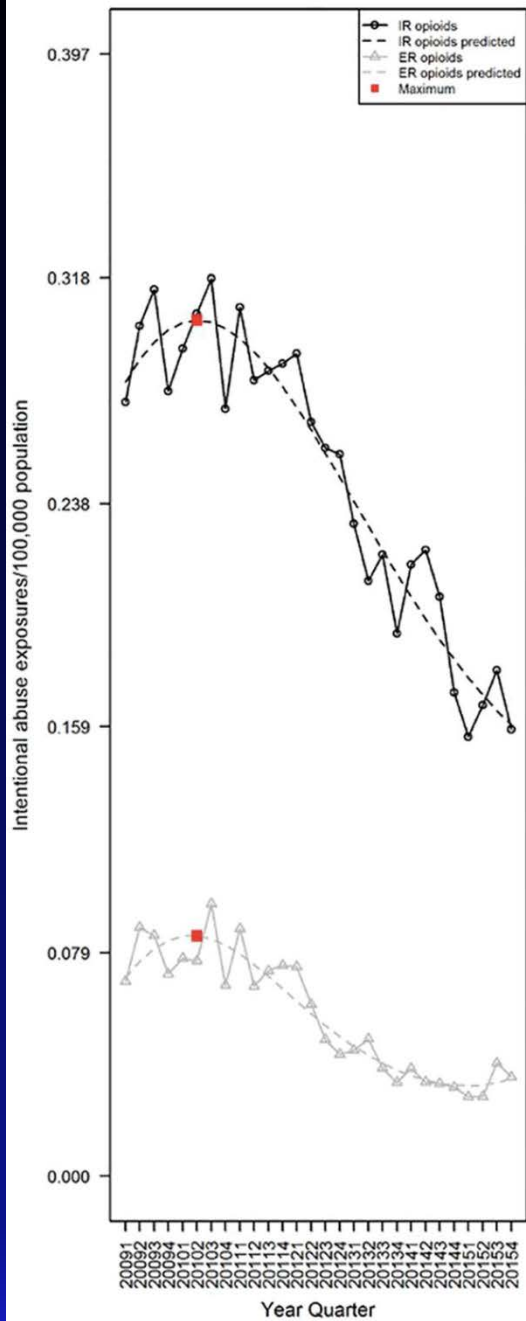
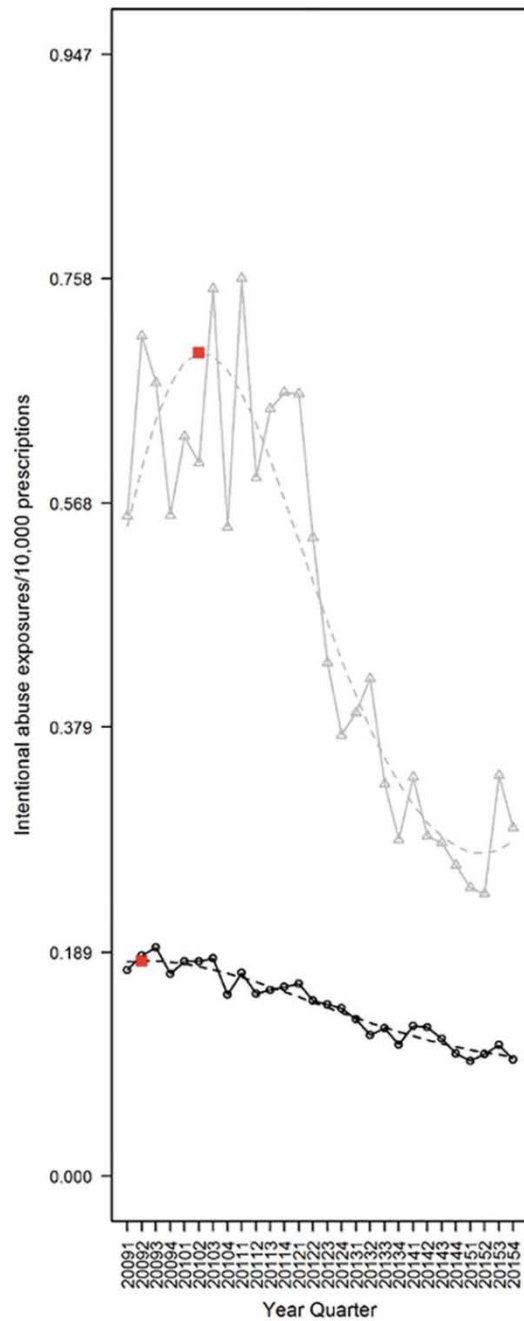
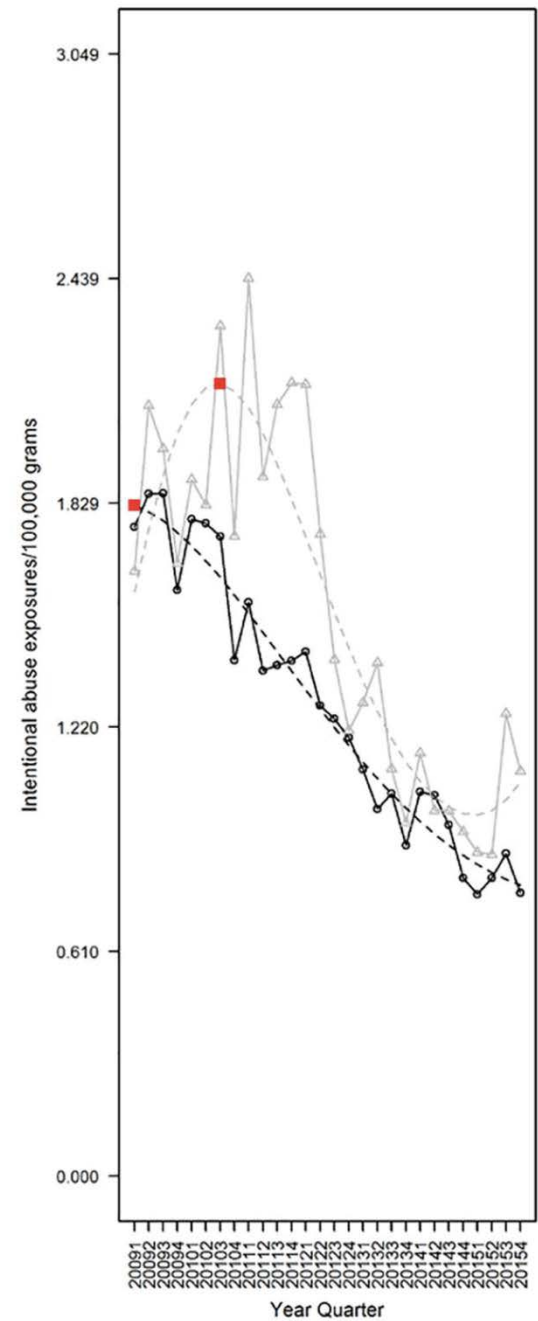
- However, immediate release (IR) opioids may be the bigger public health issue
 - 90% of opioid analgesic prescriptions dispensed
 - Majority of abusers initiate abuse with IR
 - Not currently subject to REMS or similar regulation
 - No currently available ADFs

The IR Opioid Threat

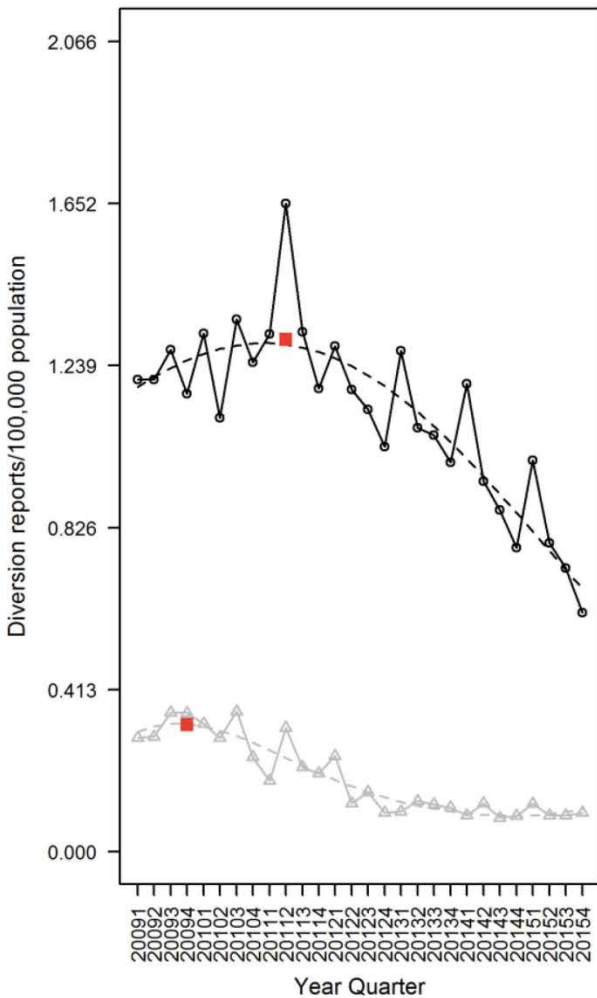
- IR opioids are prescribed at a rate 12-16 times higher than ER
- IR opioids are dispensed in 3-7 times greater gram quantities than ER



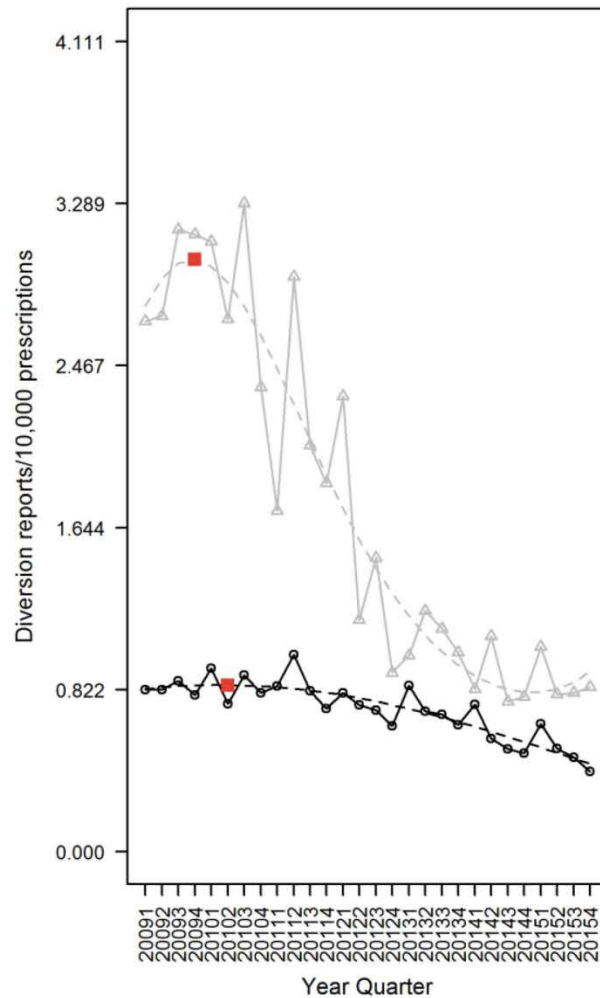


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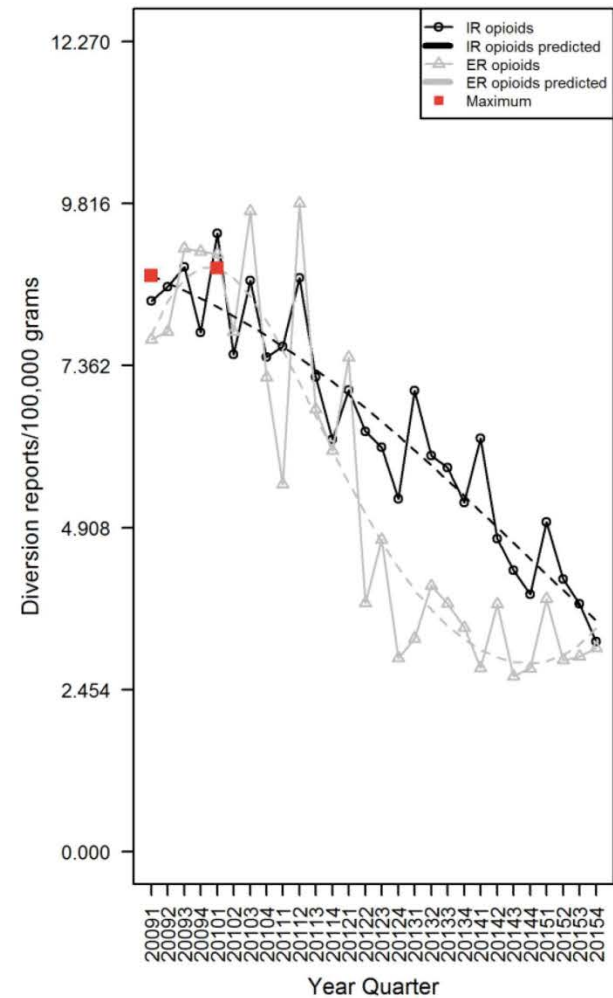
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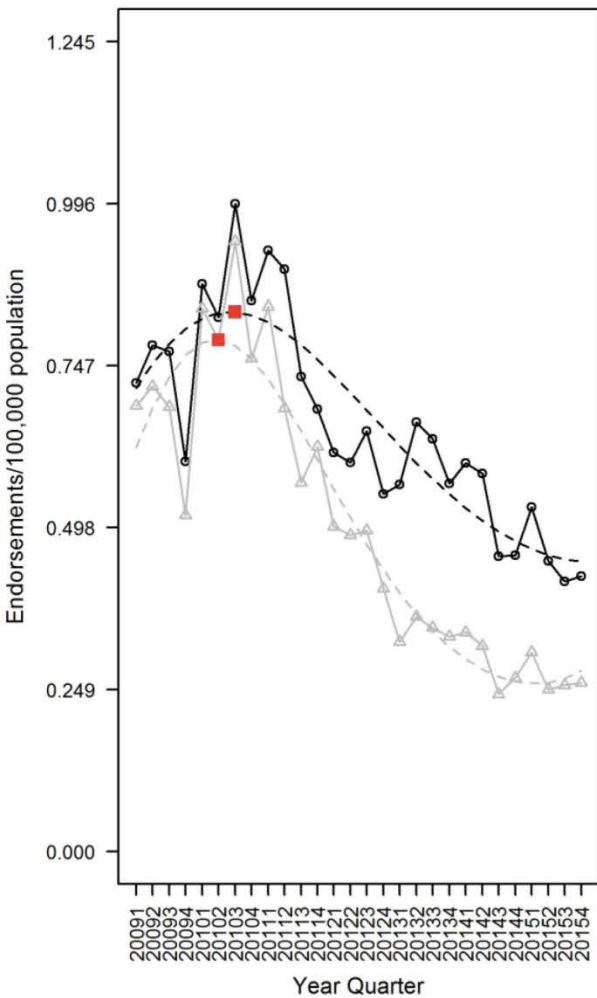
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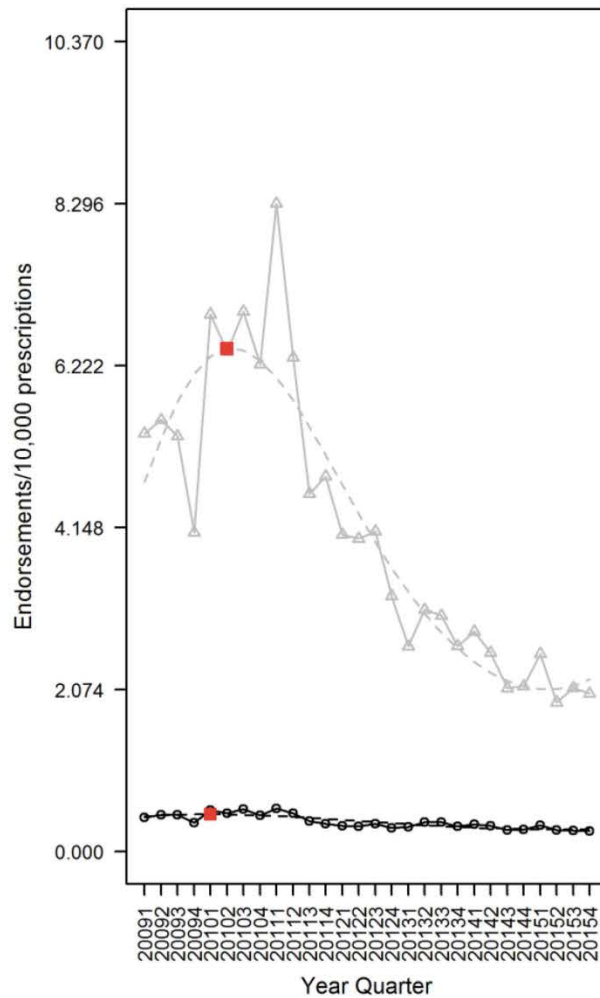
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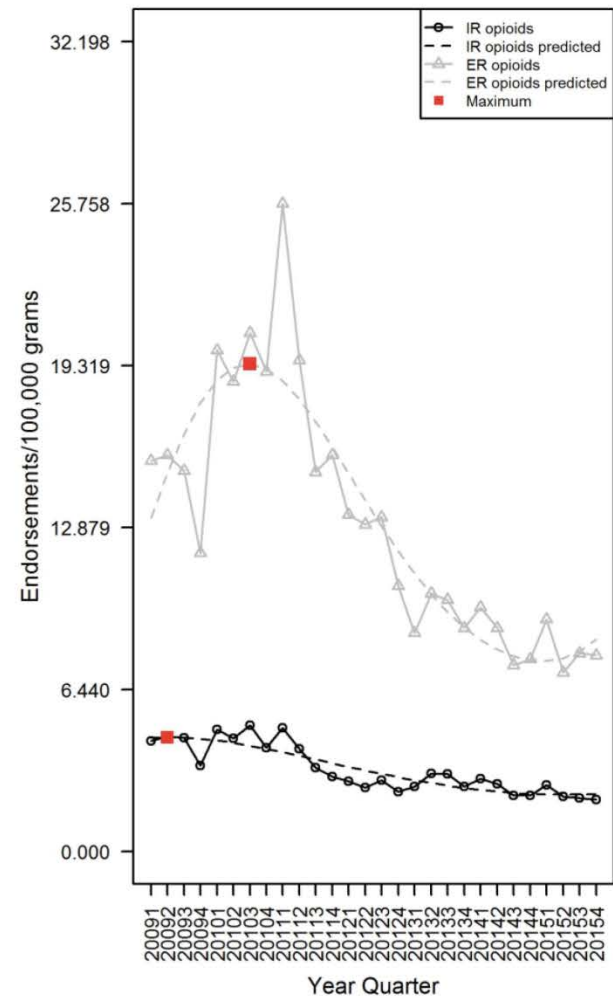
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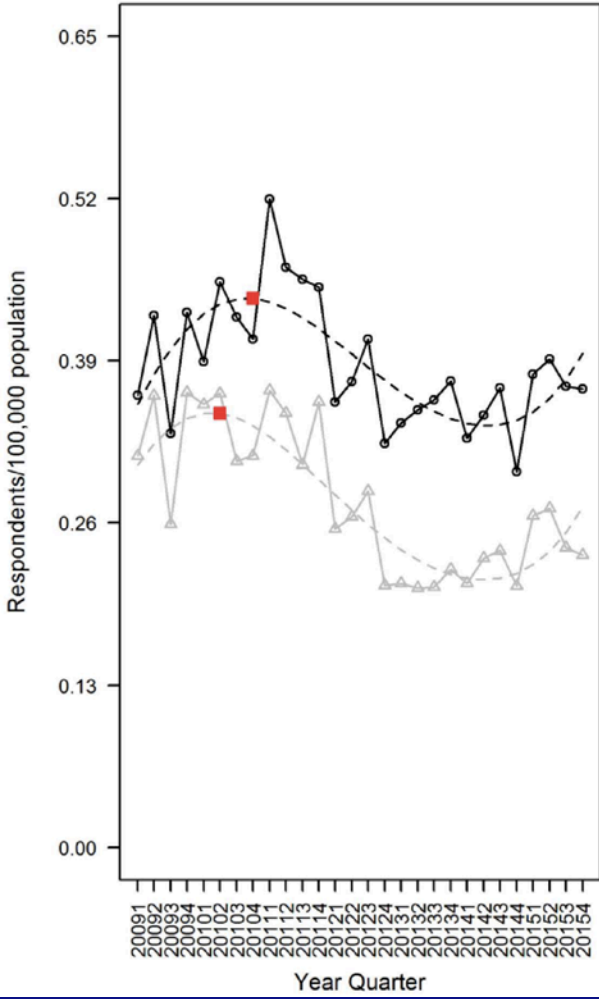
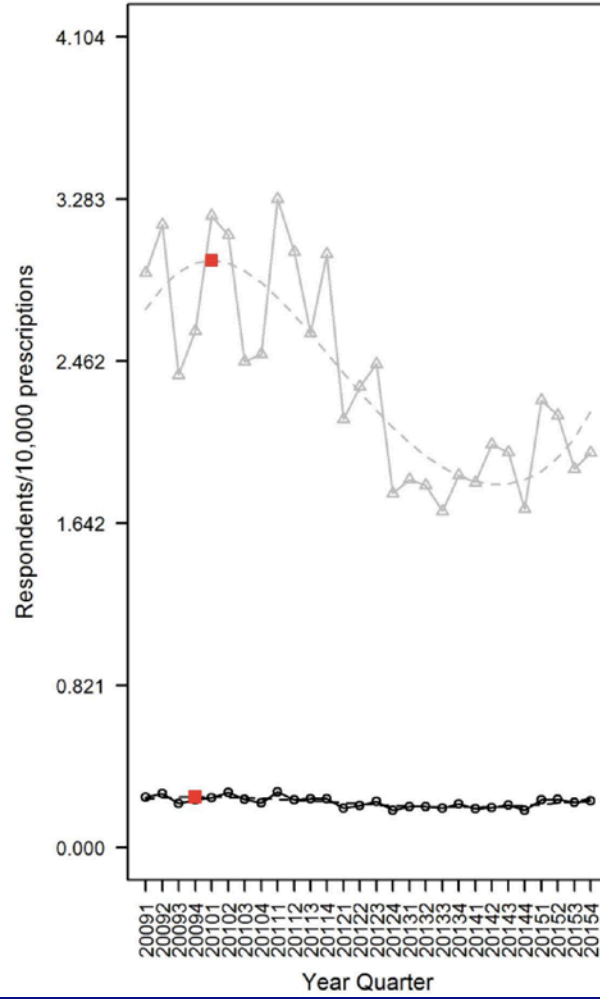
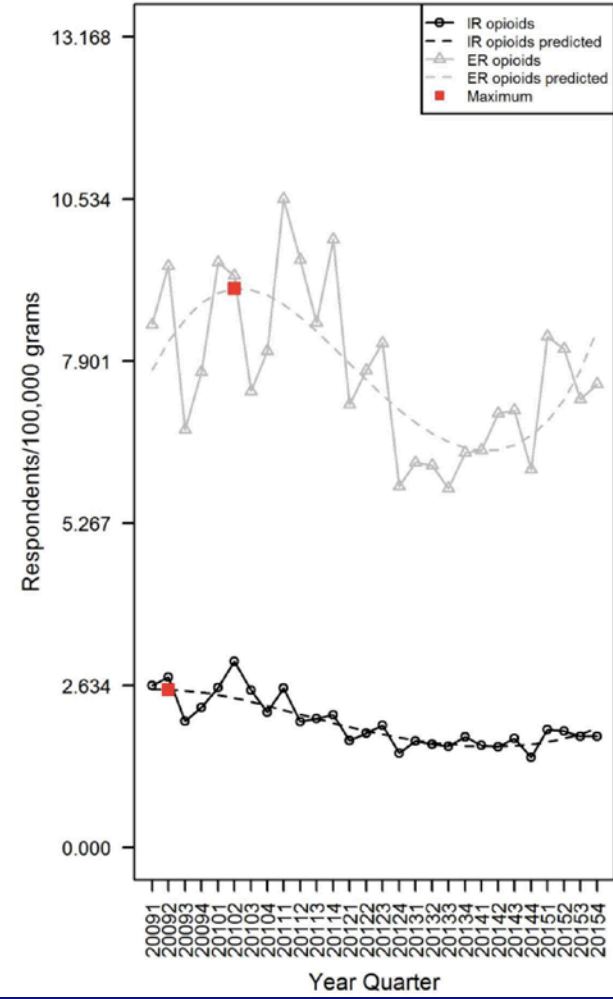


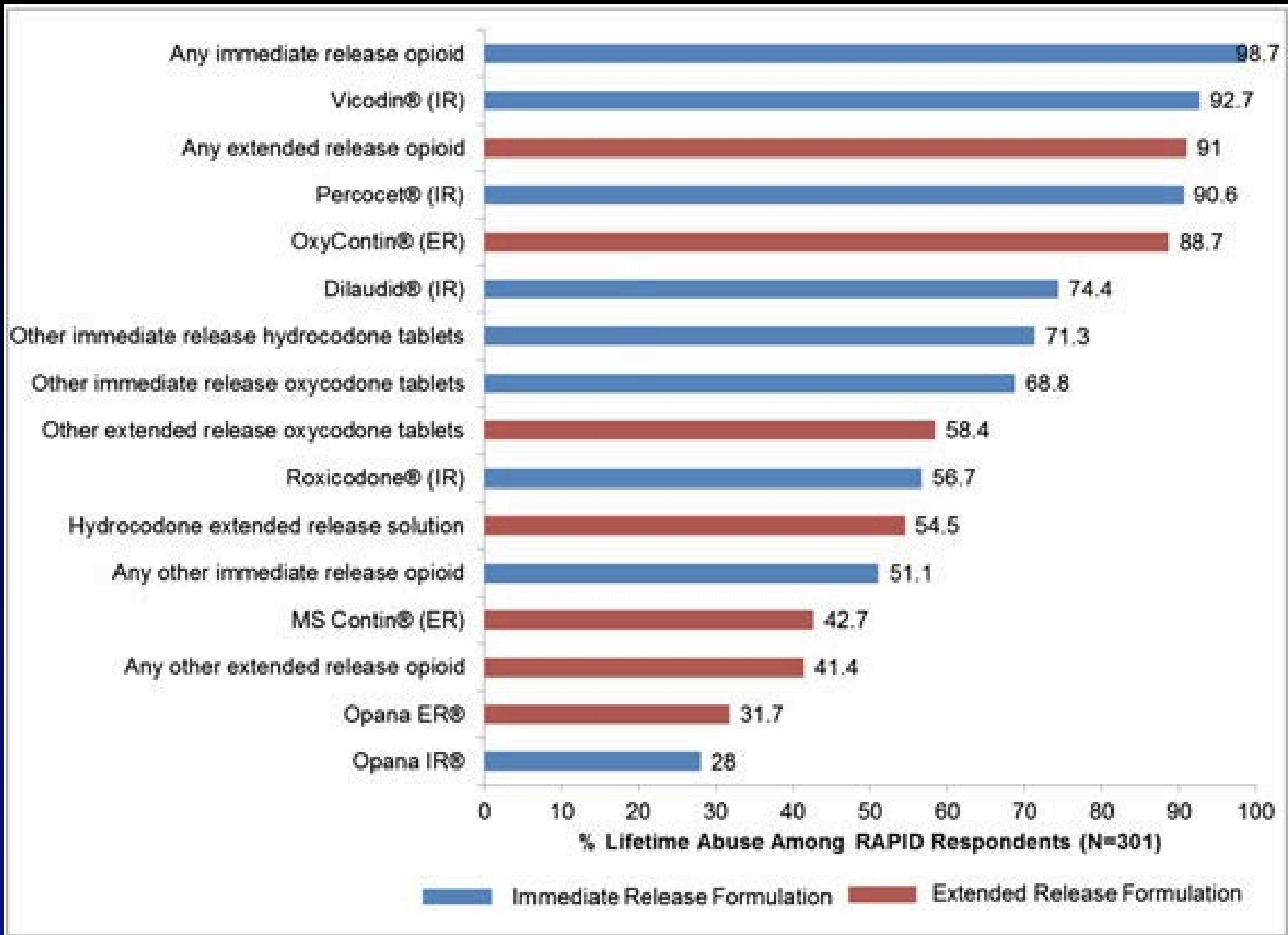
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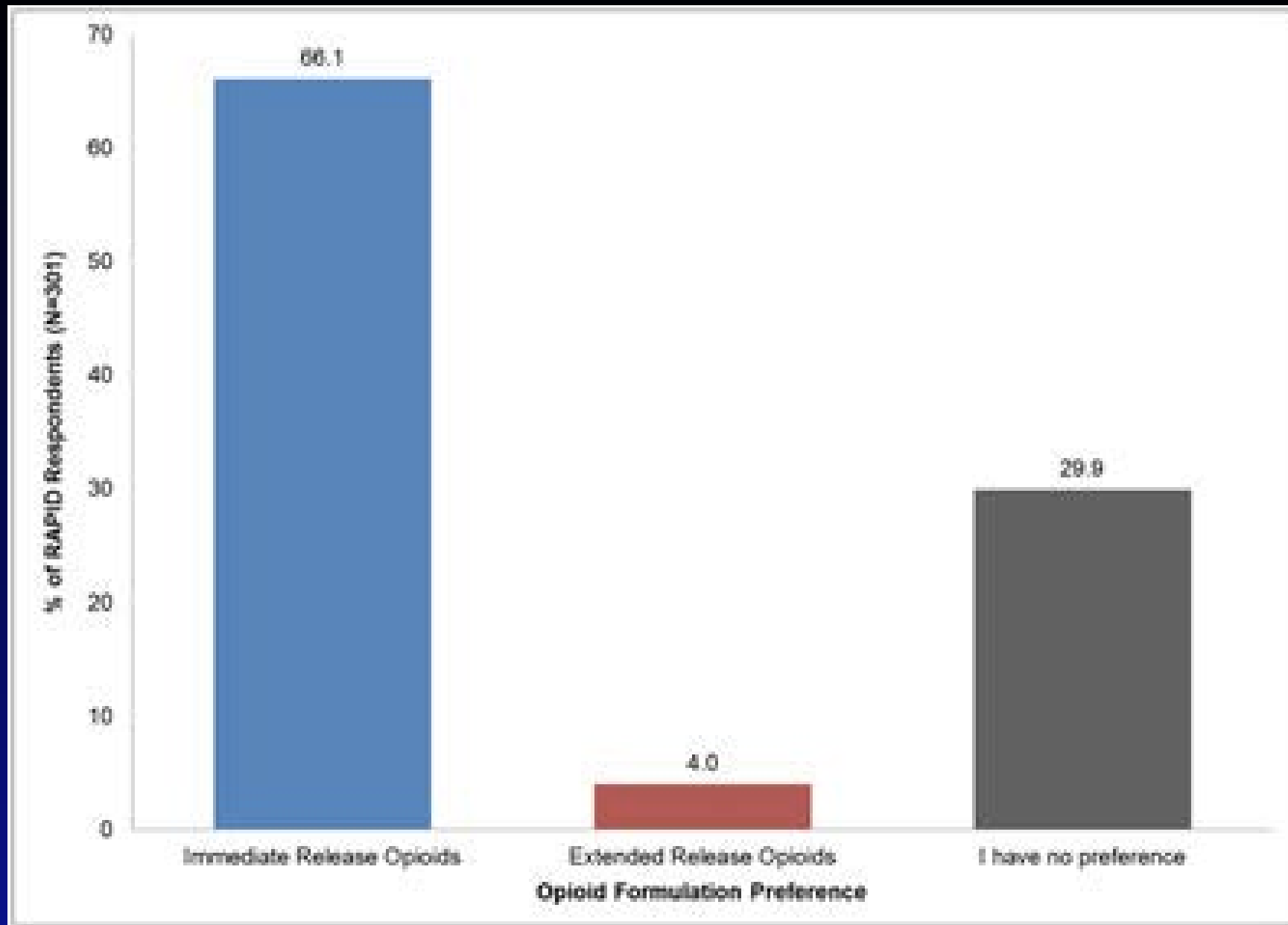


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The IR Opioid Threat

- IR opioid abuse and diversion impact a much larger absolute number of individuals than ER opioids
- More prescribing = more reported abuse
- Population rates higher for IR than ER
- IR more preferred formulations by those who abuse opioids

The IR Opioid Threat

- Current US policy misses a prime opportunity for intervention
 - Focusing on IR formulations impacts more individuals
 - Many may be early in process of initiation of abuse
 - Targeting both IR and ER decreases “squeezing the balloon” effect

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National Vital Statistics System (NVSS)

- US Centers for Disease Control (CDC)
- Multiple cause-of-death mortality files
- Official national statistics reported by each state and US territory
- Cause of death classified using ICD-10 multiple cause-of-death codes
 - Opioids classified in “buckets”

FIGURE 1. Age-adjusted rate* of drug overdose deaths† and drug overdose deaths involving opioids§,¶ — United States, 2000–2014

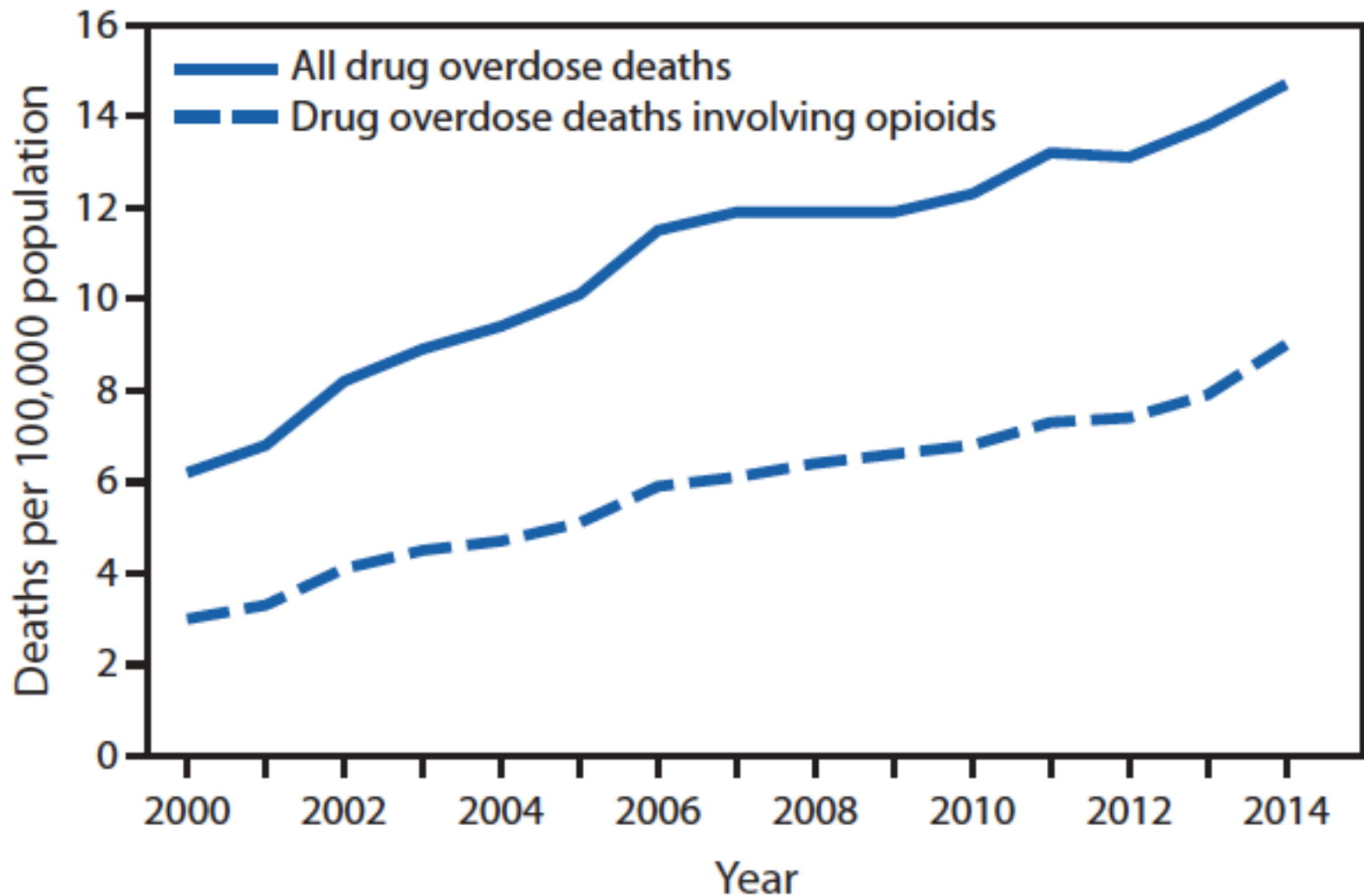
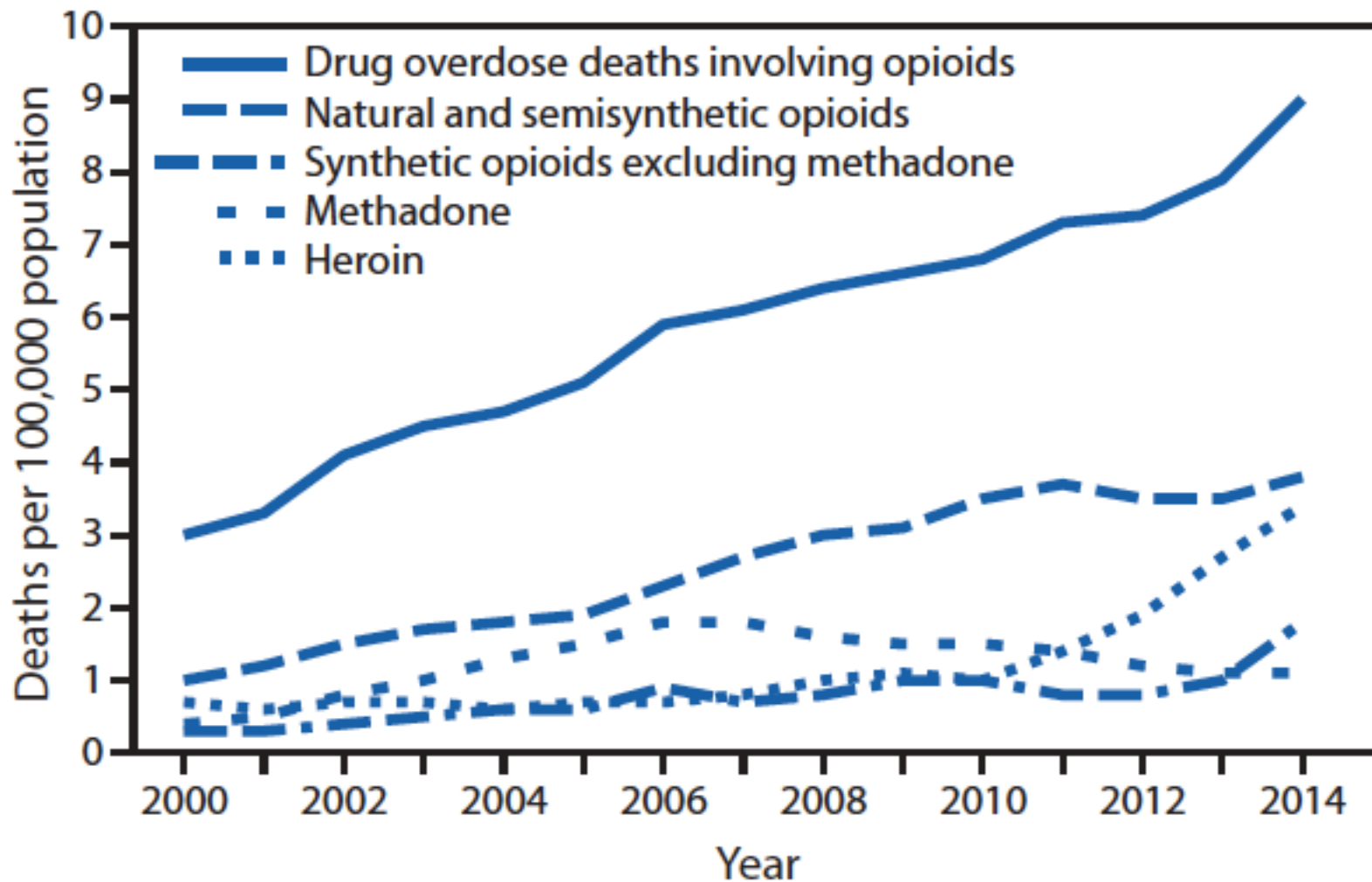
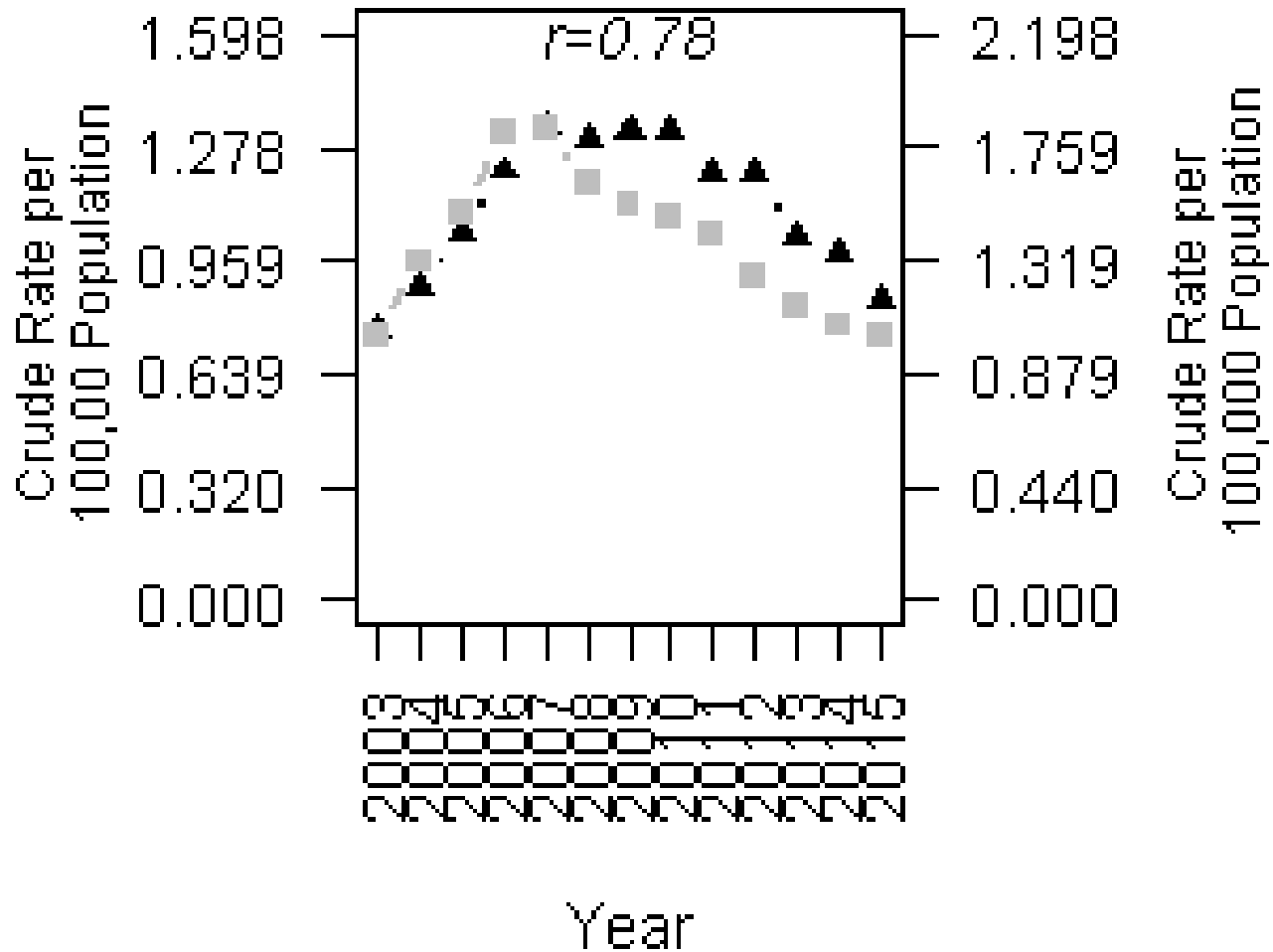


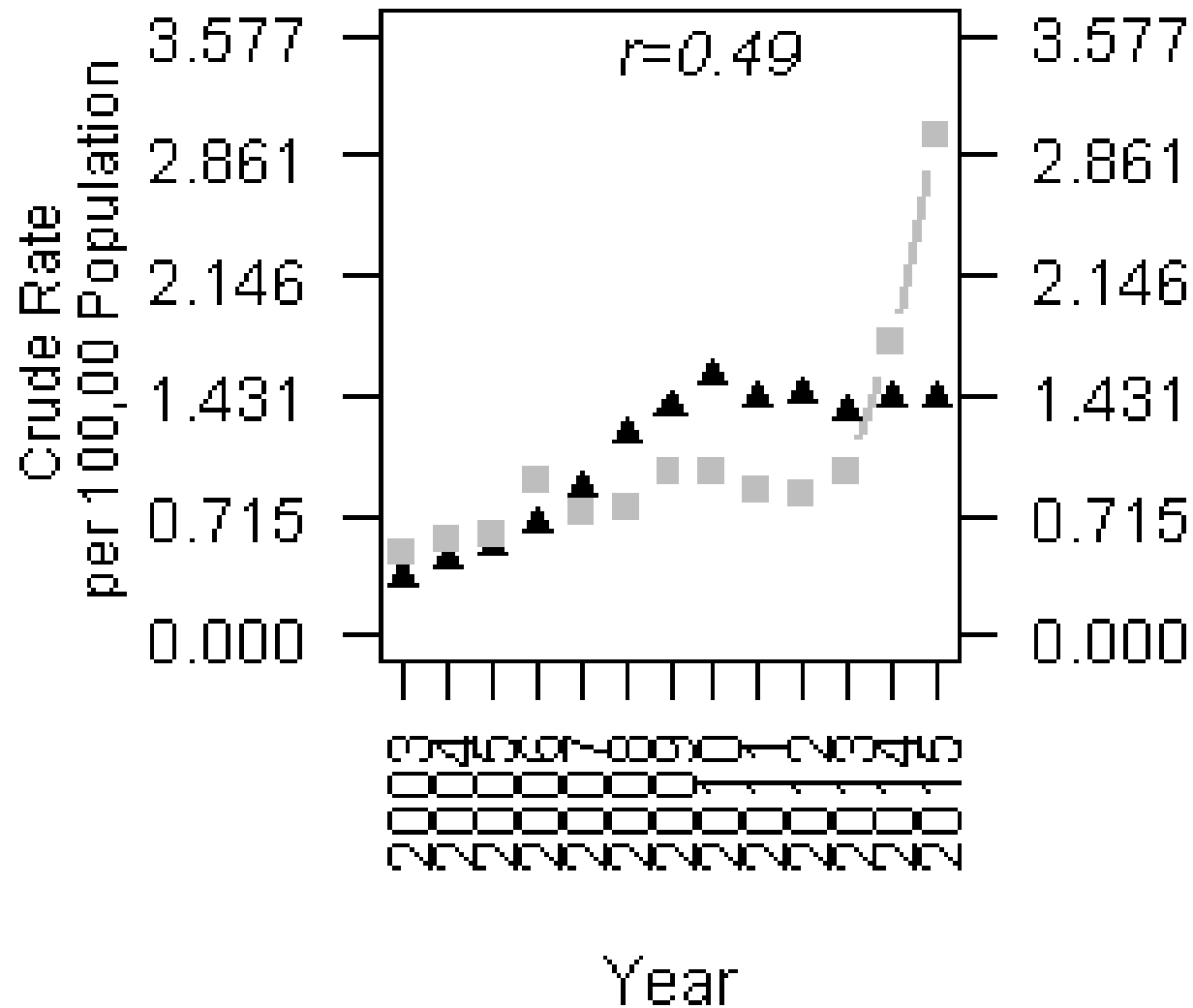
FIGURE 2. Drug overdose deaths* involving opioids,^{†,§} by type of opioid[¶] — United States, 2000–2014



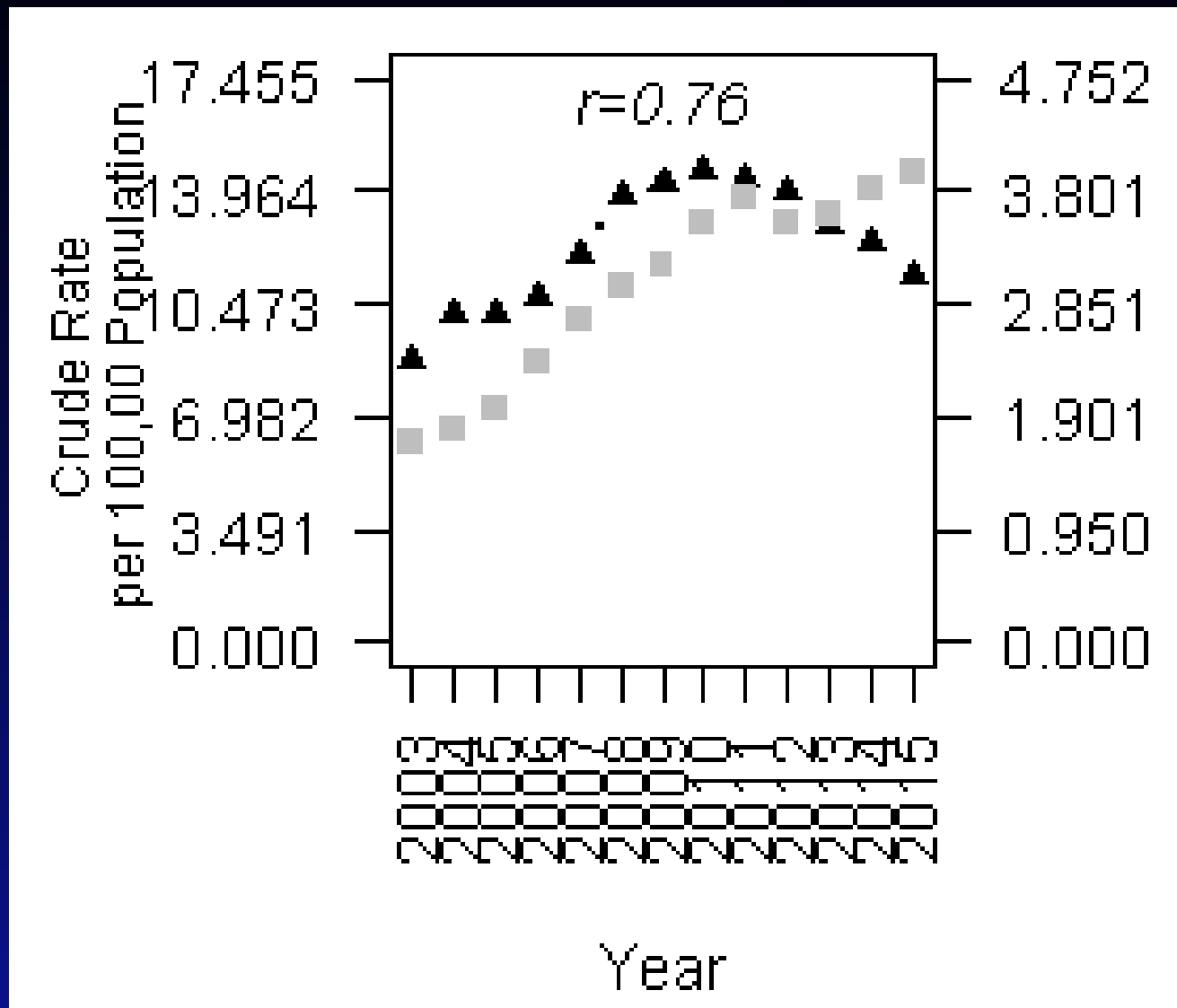
Methadone



Synthetic Opioids

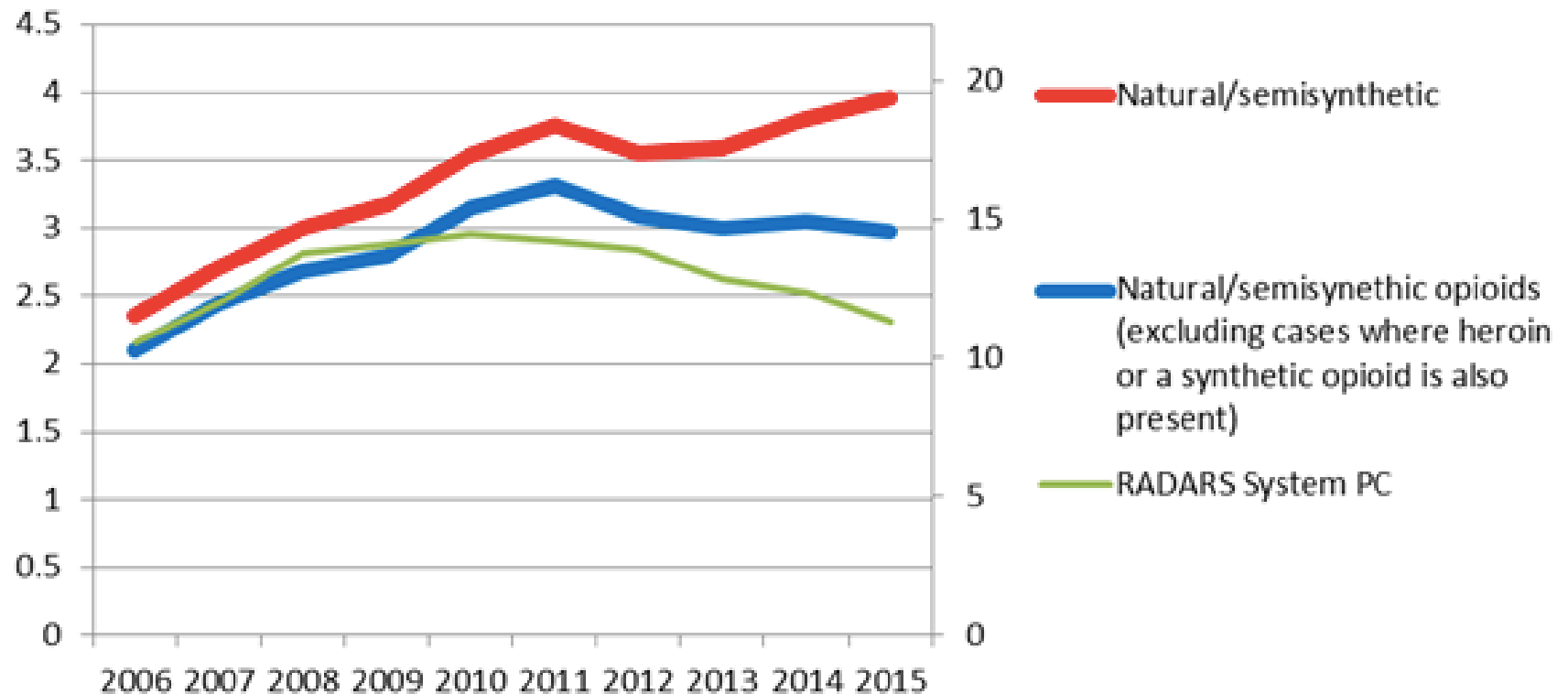


Natural/Semisynthetic



Heroin Interactions

NVSS death rates per 100,000



Mortality Data

- NVSS data are comprehensive, but lacks granularity
- RADARS System Poison Center data track well with NVSS
 - Exceptions may be related to increased specificity
- Poison Center data is more timely and specific

The Path Forward?

- IR medication abuse impacts a much larger absolute number of individuals in the US than ER
- For the greatest public health impact, interventions to decrease prescription opioid abuse in the US should include both IR and ER formulations

The Path Forward?

- NVSS mortality data has significant limitations in interpretation
- Appropriate and timely interventions require product specificity and earlier data availability
- Adding complementary Poison Center data may provide specificity, nuance, and earlier intervention

Questions?

