Behind the Opioid Epidemic – 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
The graph shows the trend of grams dispensed over time, categorized into IR opioids (black line) and ER opioids (gray line). The y-axis represents the grams dispensed, ranging from 0 to 70,000,000. The x-axis represents the year and quarter, ranging from 2009 to 2015. The data indicates a steady increase in the dispensed grams of IR opioids over the years, with some fluctuations. The ER opioids show a much lower trend, remaining relatively stable.
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
The IR Opioid Threat

• Current US policy misses a prime opportunity for intervention
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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

- Drug overdose deaths involving opioids
- Natural and semisynthetic opioids
- Synthetic opioids excluding methadone
- Methadone
- Heroin

Synthetic Opioids

Graph showing the trend of crude rate per 100,000 population over the years with a correlation coefficient of 0.49.
Natural/Semisynthetics
Heroin Interactions

![Graph showing NVSS death rates per 100,000]

- **Natural/semisynthetic**
- **Natural/semisynthetic opioids (excluding cases where heroin or a synthetic opioid is also present)**
- **RADARS System PC**

Y-axis: NVSS death rates per 100,000
X-axis: Years 2006 to 2015
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?