

Opioids and a Path Forward

Abuse Deterrent Formulations: Current Data and Future Opportunities

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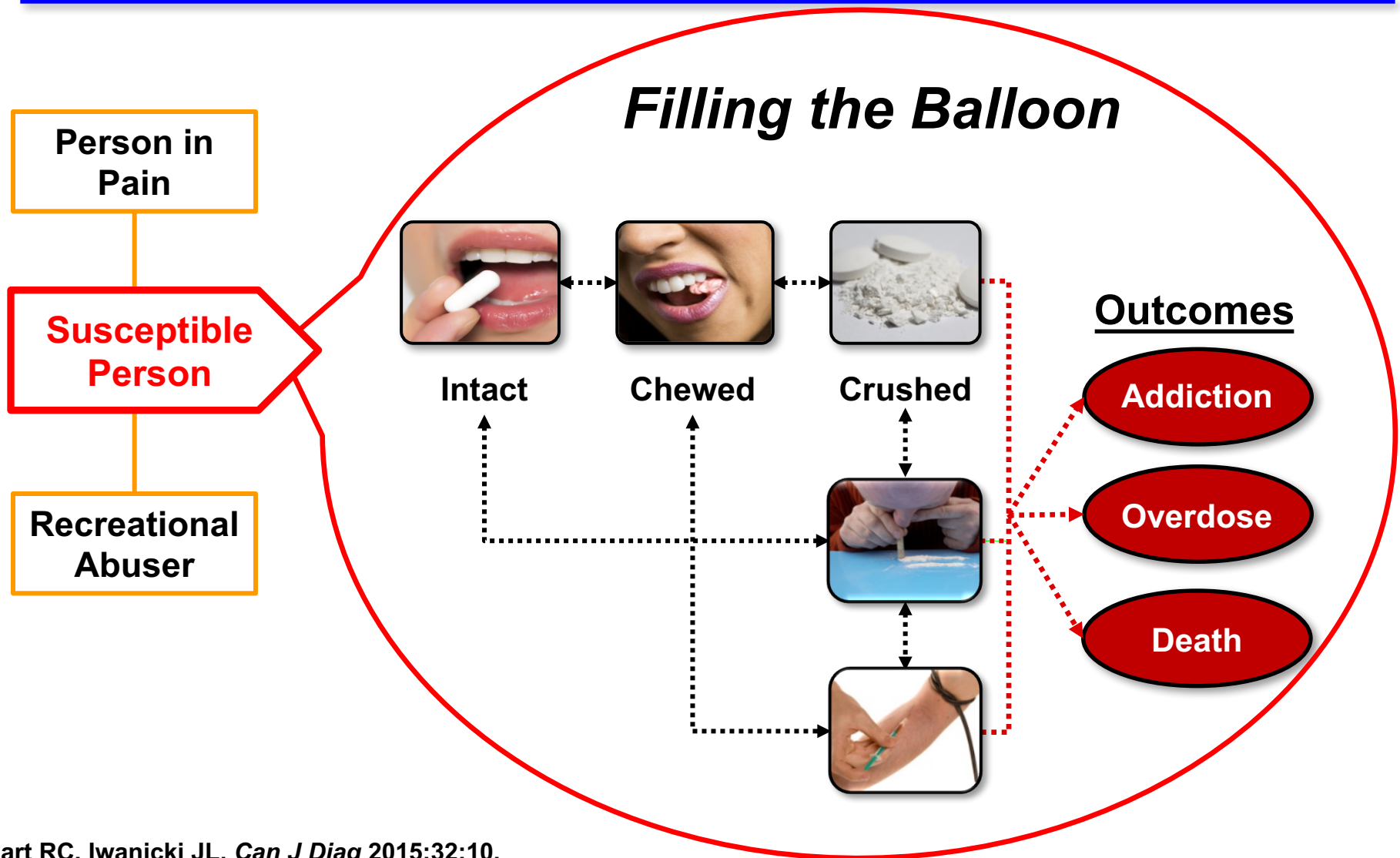
Roadmap

- How do abuse deterrent formulations (ADFs) work?
- What data do we have to show effectiveness of ADFs?
- What are the current challenges and gaps in knowledge?
- What are the next steps?

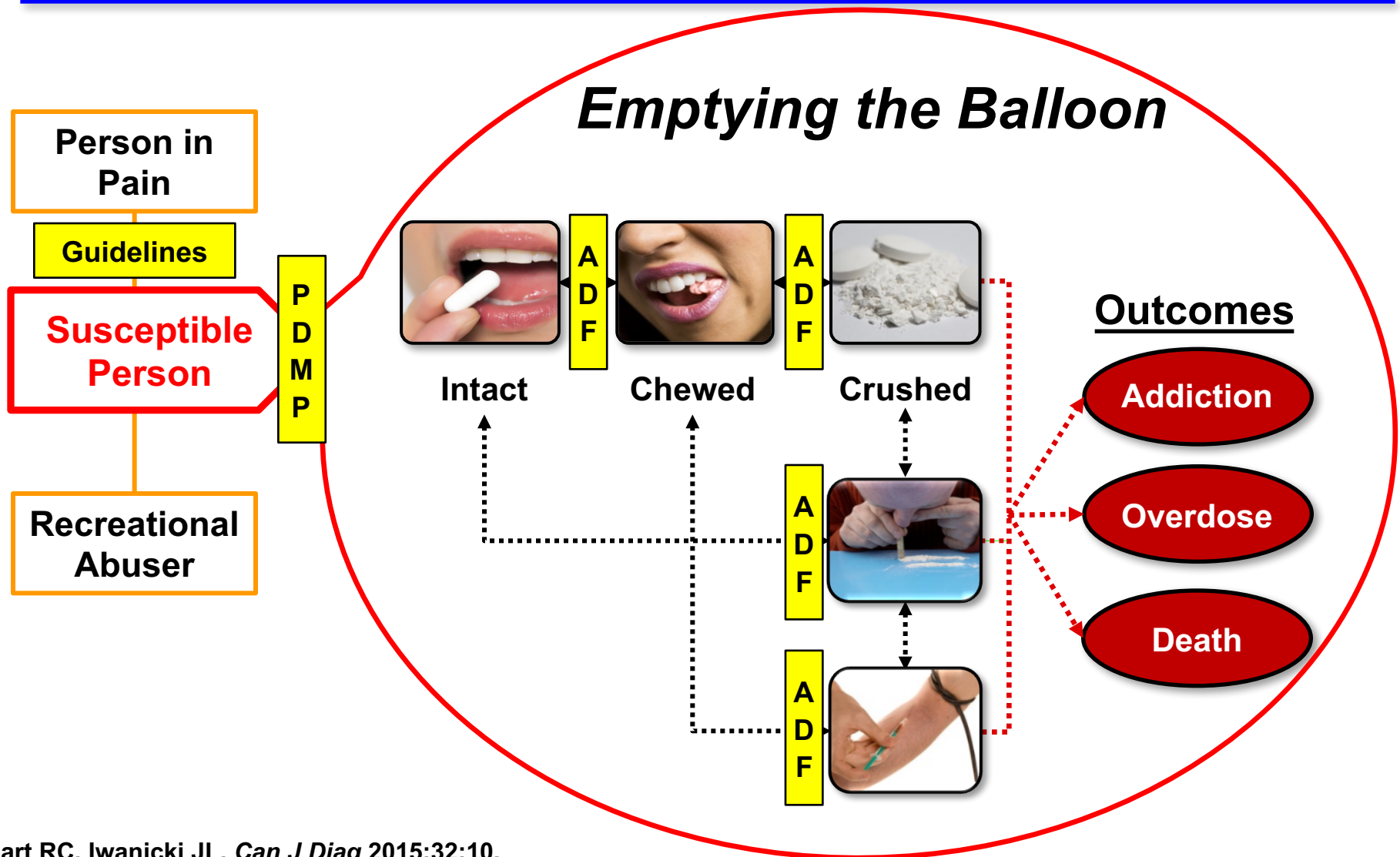
How do abuse deterrent formulations (ADFs) work?

- Prescription drug abuse is like other drug abuse, except with an additional “route” of abuse:
 - Oral = intact + ***chewed or crushed***
 - Intranasal
 - Intravenous (IV)
- Importance of using the drug in unintended ways
 - Crucial transition
 - Changes perception of heroin use¹
 - Risk of overdose, addiction, infections, death higher after intranasal or IV abuse than oral abuse

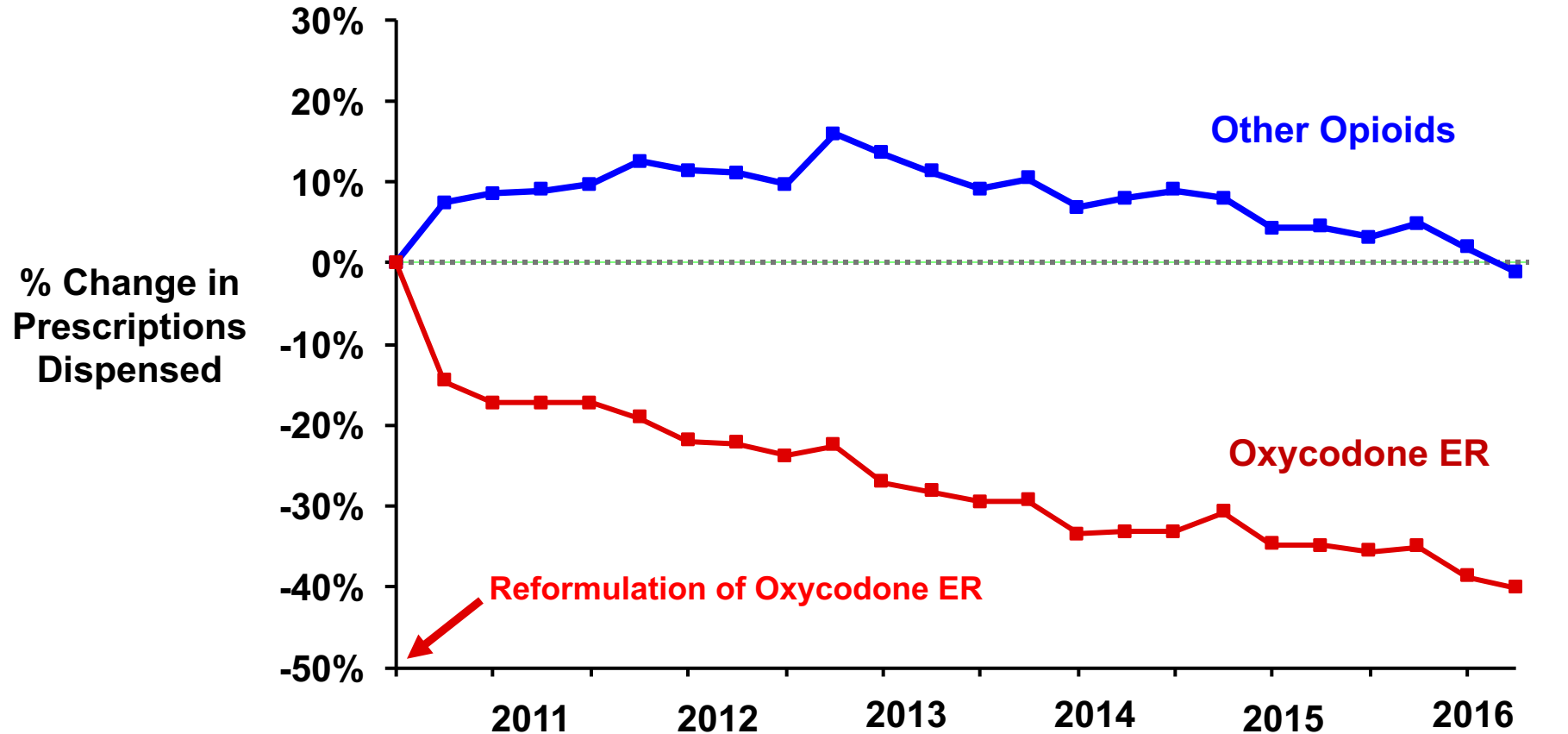
How do ADFs work?



Intervening in Prescription Drug Abuse



Oxycodone ER Prescriptions Dispensed Decreased Promptly After Reformulation



Other Opioids = Oral dosage forms of opioid analgesics: hydrocodone, hydromorphone, morphine, oxymorphone, tramadol, tapentadol, and IR oxycodone

RADARS® System Surveillance of Prescription Drug Abuse

- Independent postmarketing surveillance program focusing solely on prescription drug abuse
- Most manufacturers of prescription opioids are subscribers
 - Limited to use for regulatory and risk-management use

Acute Health Events

Entering Treatment

New Initiates



Web Monitoring

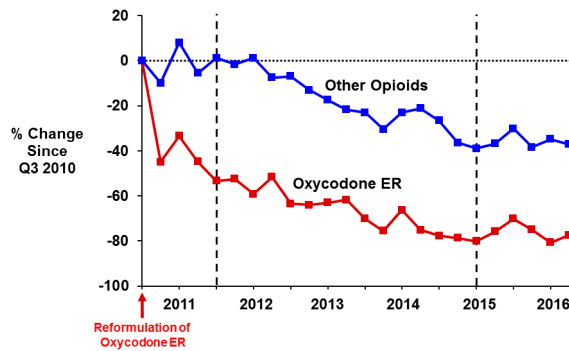
Drug Transactions

Entering Treatment

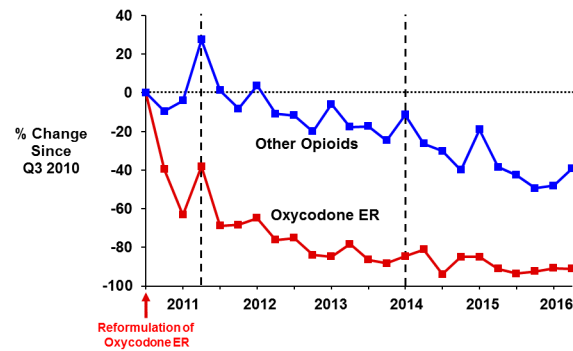
Illicit Market Price

Oxycodone ER Abuse and Diversion Decreased After ADF Introduction

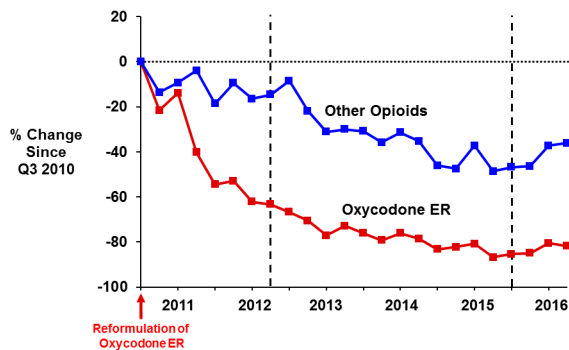
Poison Center – Intentional Abuse



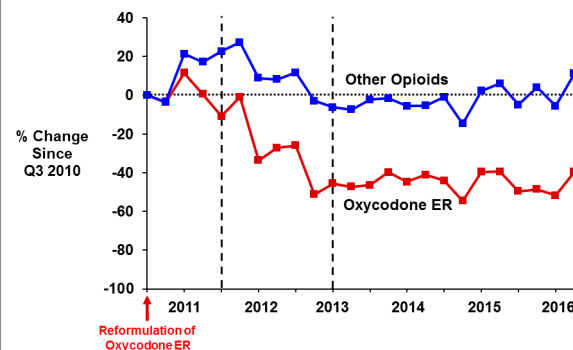
Drug Diversion Investigations



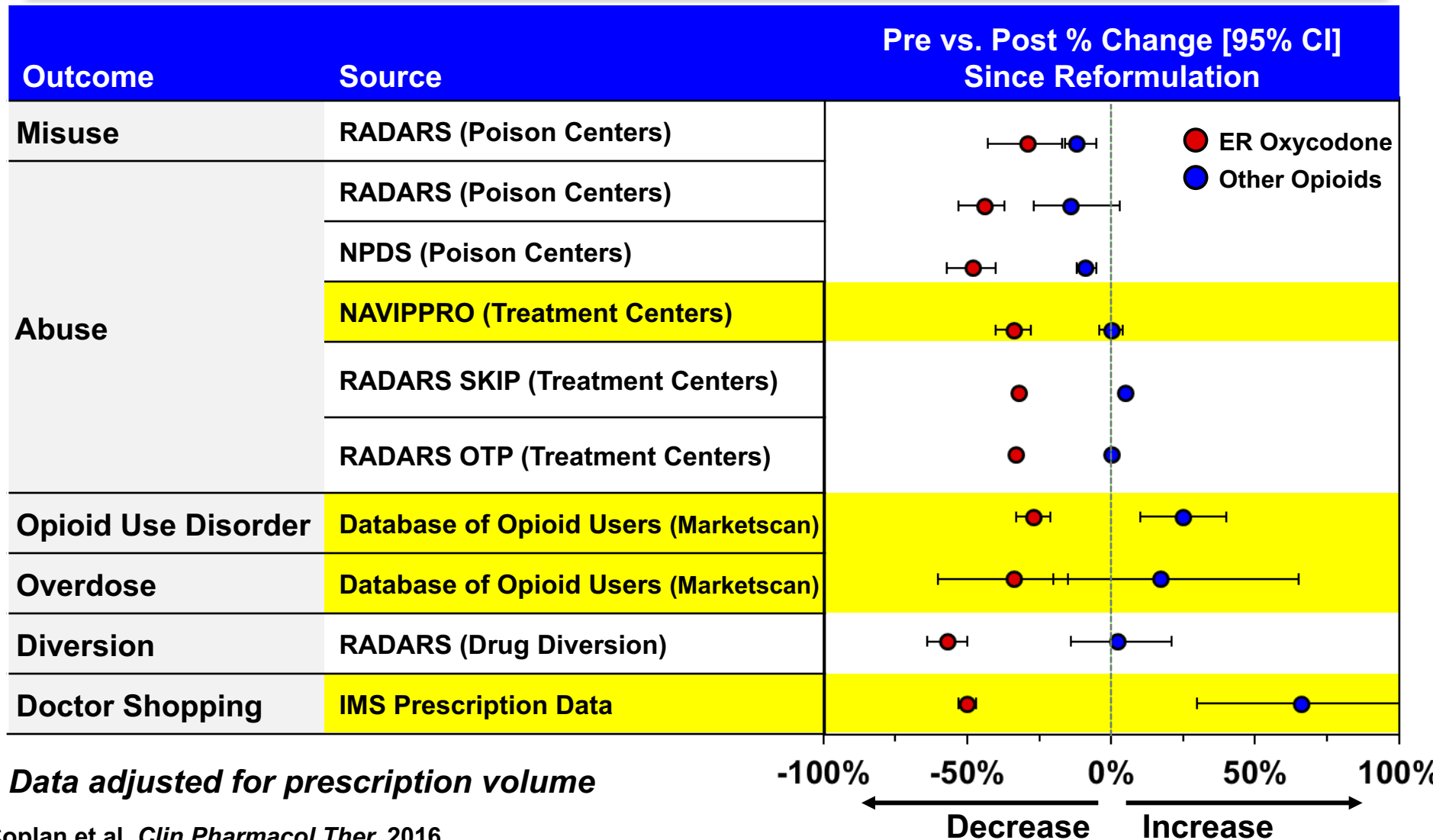
Opioid Treatment – Abuse



Survey Key Informant Patients – Abuse

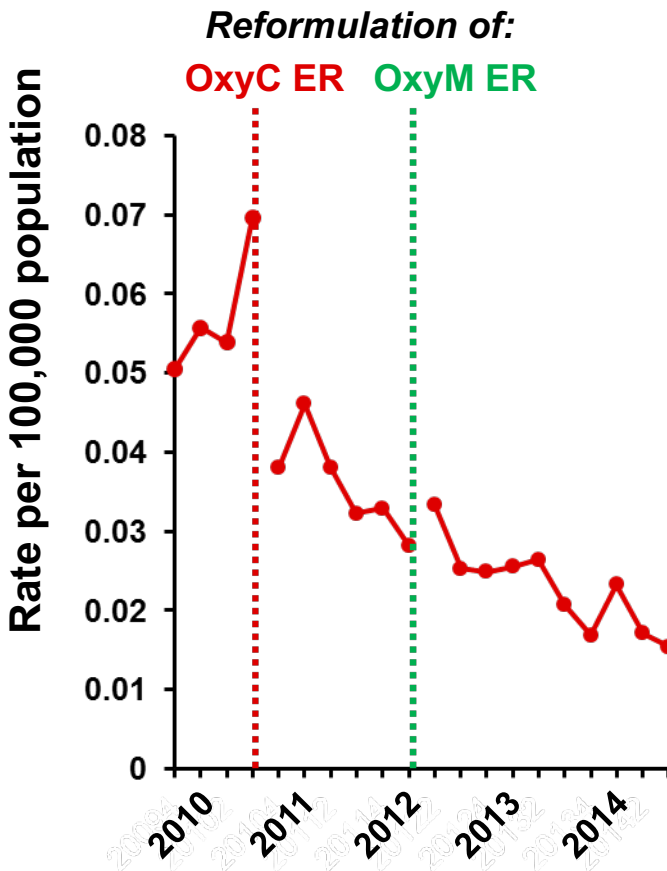


Consistency: Oxycodone ER Associated with Lower Rates Across Many Data Sources

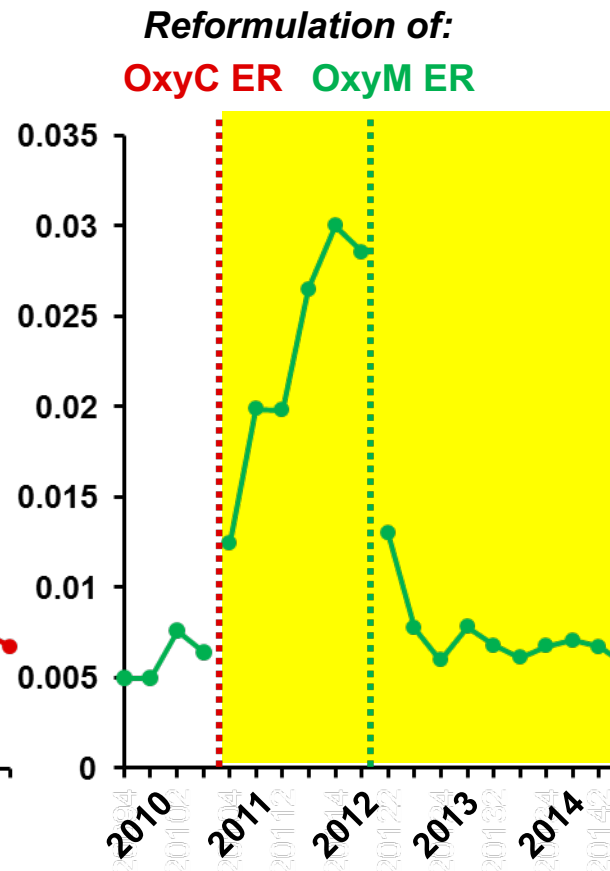


Poison Center Cases: Response to Reformulation of Oxycodone ER and Oxymorphone ER

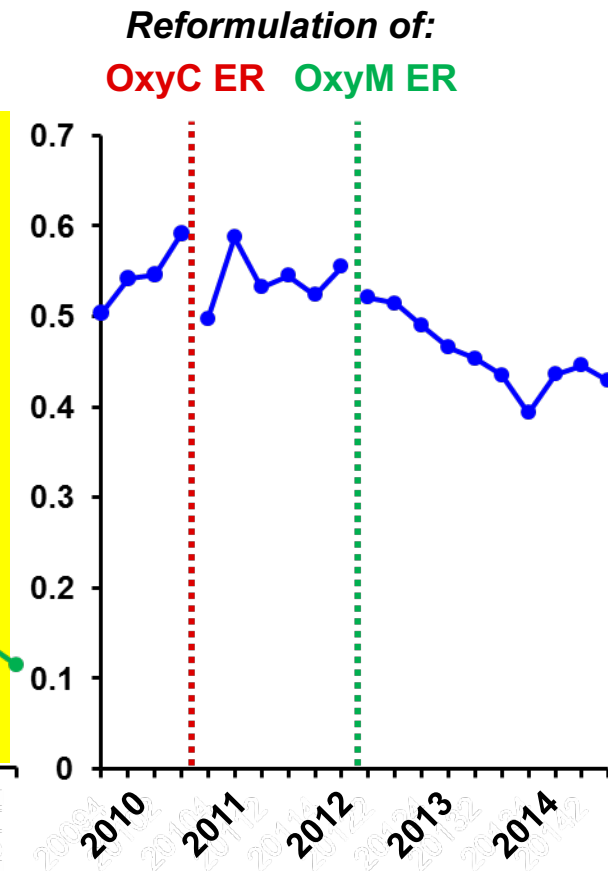
Oxycodone ER



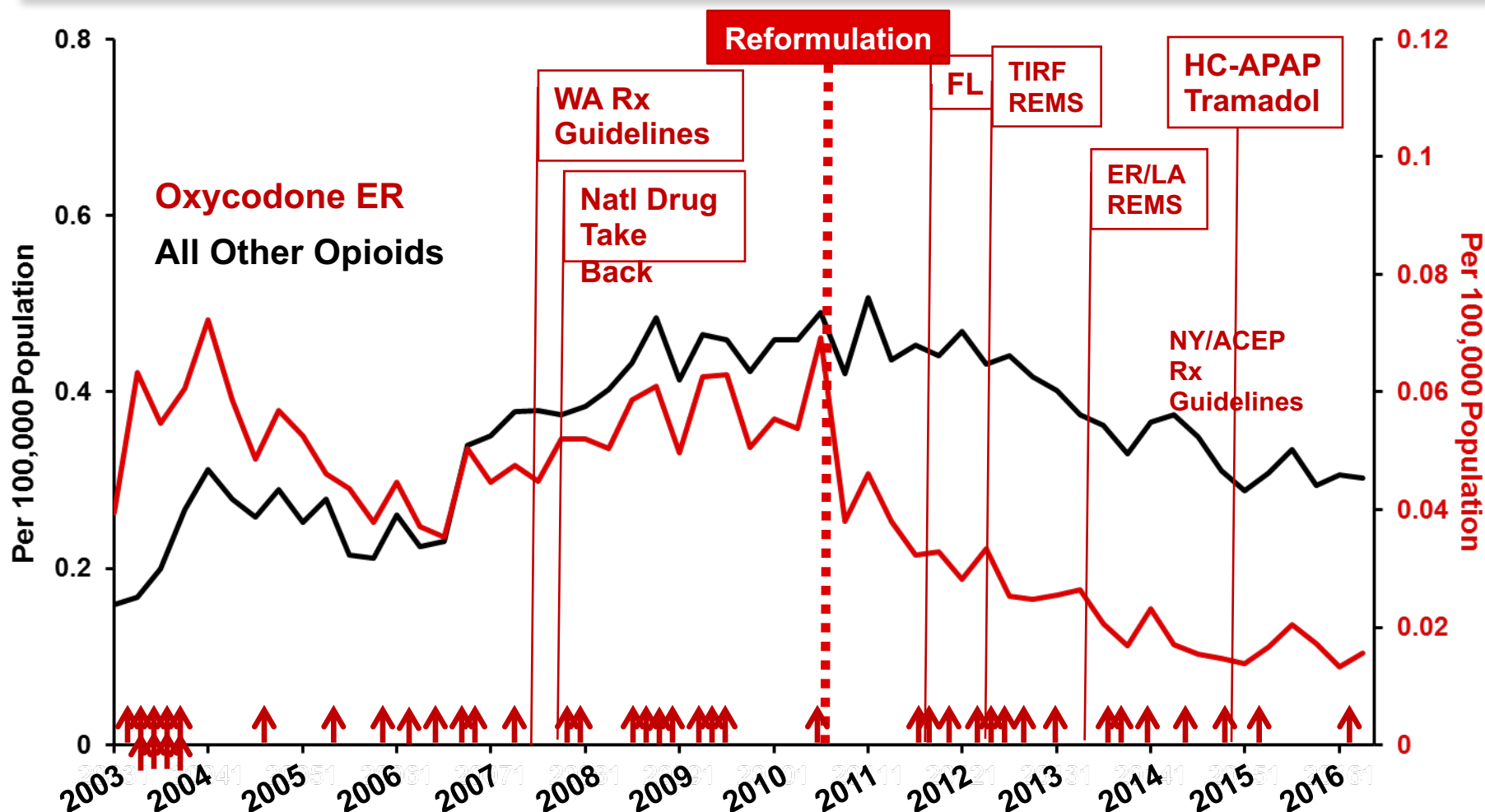
Oxymorphone ER



Other Opioids



Alternate Explanations Fail to Explain Changes



↑ PDMP Initiation

Effects of ADFs on the Community

- Extended release (ER) products have a small part of opioid market
- ER products account for small portion of total abuse
- Oxycodone ER can reduce its own abuse, not entire market
- For full impact, need both immediate release (IR) and ER medications to be abuse deterrent

Conclusions and Implications

- Abuse deterrent opioids are likely to be effective in reducing abuse and its outcomes
- Widespread use would reduce prices and reduce the crucial transition from intact swallowing to crushing
- Opportunity for important legislative intervention to allow early access to ADFs
- Education, training, and other interventions needed as well