



Effectiveness of ~~ADFs~~ Opioid Analgesic Products with Properties Intended to Deter Abuse in the Real World

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Do abuse deterrent opioid formulations work?

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Systematic Review

- *Does the introduction of an opioid analgesic with abuse deterrent properties result in reduced overall abuse of the drug in the community?*
- Included opioid analgesics with labelled abuse deterrent properties (hydrocodone, morphine, **oxycodone**)
- Results categorized using Bradford-Hill criteria.

Systematic Review

- 44 articles containing original data

| Hill Factor | Description |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Strength (<u>effect size</u>): | Effect size positive, ranging from 27% to 90% reduction in a measure of abuse. |
| Consistency (<u>reproducibility</u>): | Strikingly similar results in 3 different countries after reformulation in 2010 (US), 2012 (Canada), 2014 (Australia) |
| Specificity | Variety of comparators used – all significantly different from reformulated oxycodone ER |
| Temporality | Reduction in a variety of endpoints after introduction of reformulated oxycodone ER |
| Plausibility | FDA Categories 1-3 |
| Coherence | All results to date are coherent with Category 1-3 studies |
| Biological Gradient, Experiment, Analogy: | N/A |
| Additional Criteria | |
| Confounding and/or Bias | No plausible alternative explanation for events at 3 different times in 3 different countries |

Systematic Review

| Hill Factor | Description |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Strength (<u>effect size</u>): | Effect size varied by study, ranging from 27% to 90% reduction in a measure of abuse. |
| Consistency (<u>reproducibility</u>): | Decrease in measures of abuse was strikingly similar results in 3 different countries after reformulation in 2010 (US), 2012 (Canada), 2014 (Australia) |
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| Specificity | Variety of comparator drugs were used – consistently different from reformulated oxycodone ER |
| Temporality | Reduction in a variety of endpoints after introduction of reformulated oxycodone ER |
| Plausibility | FDA Categories 1-3 |
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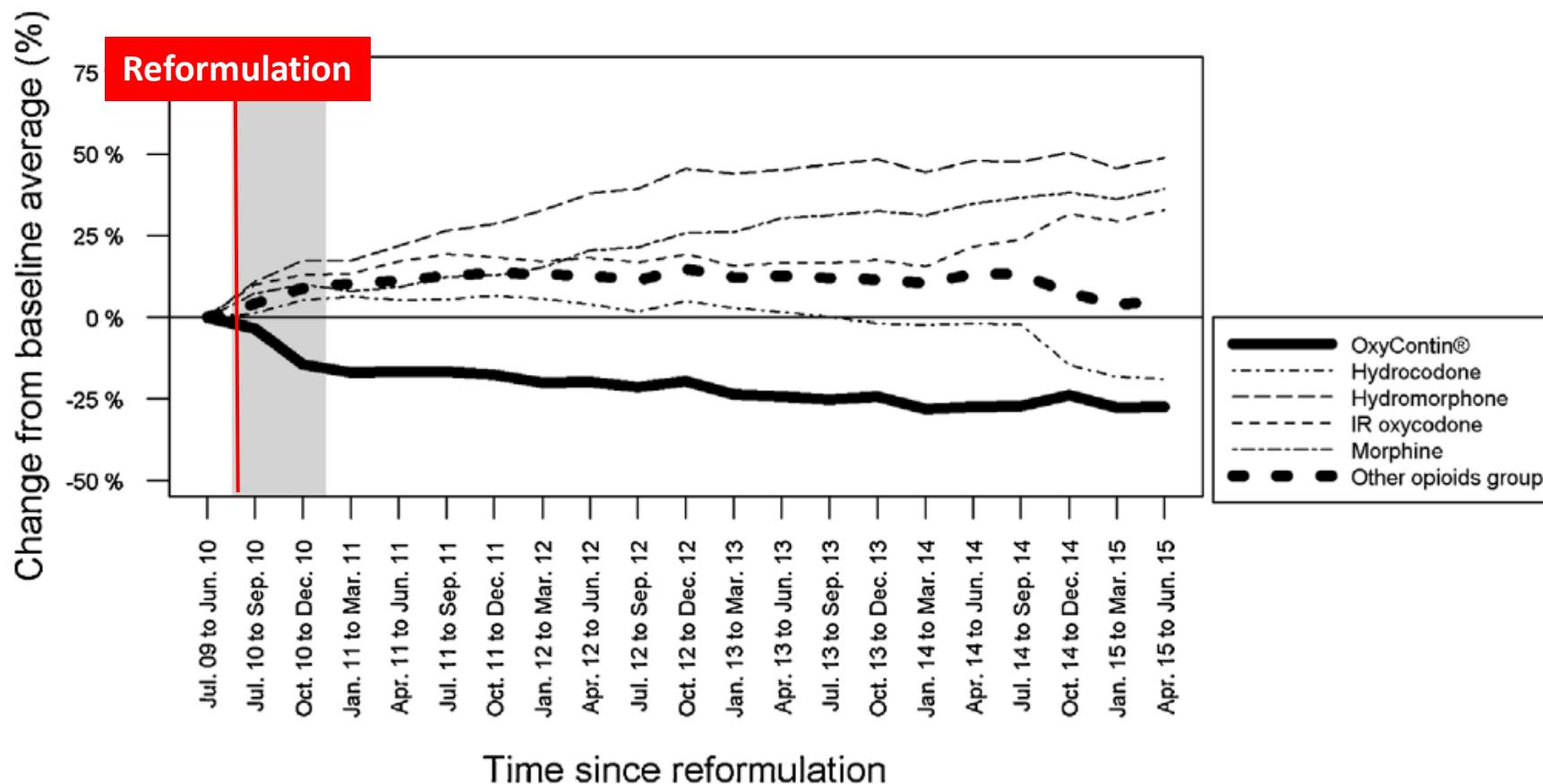
Systematic Review

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| Specificity | Variety of comparators used – all significantly different from reformulated oxycodone ER |
| Temporality | Reduction in a variety of endpoints temporally related to introduction of reformulated oxycodone ER |
| Plausibility | FDA Categories 1-3 |
| Coherence | All results to date are coherent with Category 1-3 studies |
| Biological Gradient, Experiment, Analogy: N/A | |
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Systematic Review

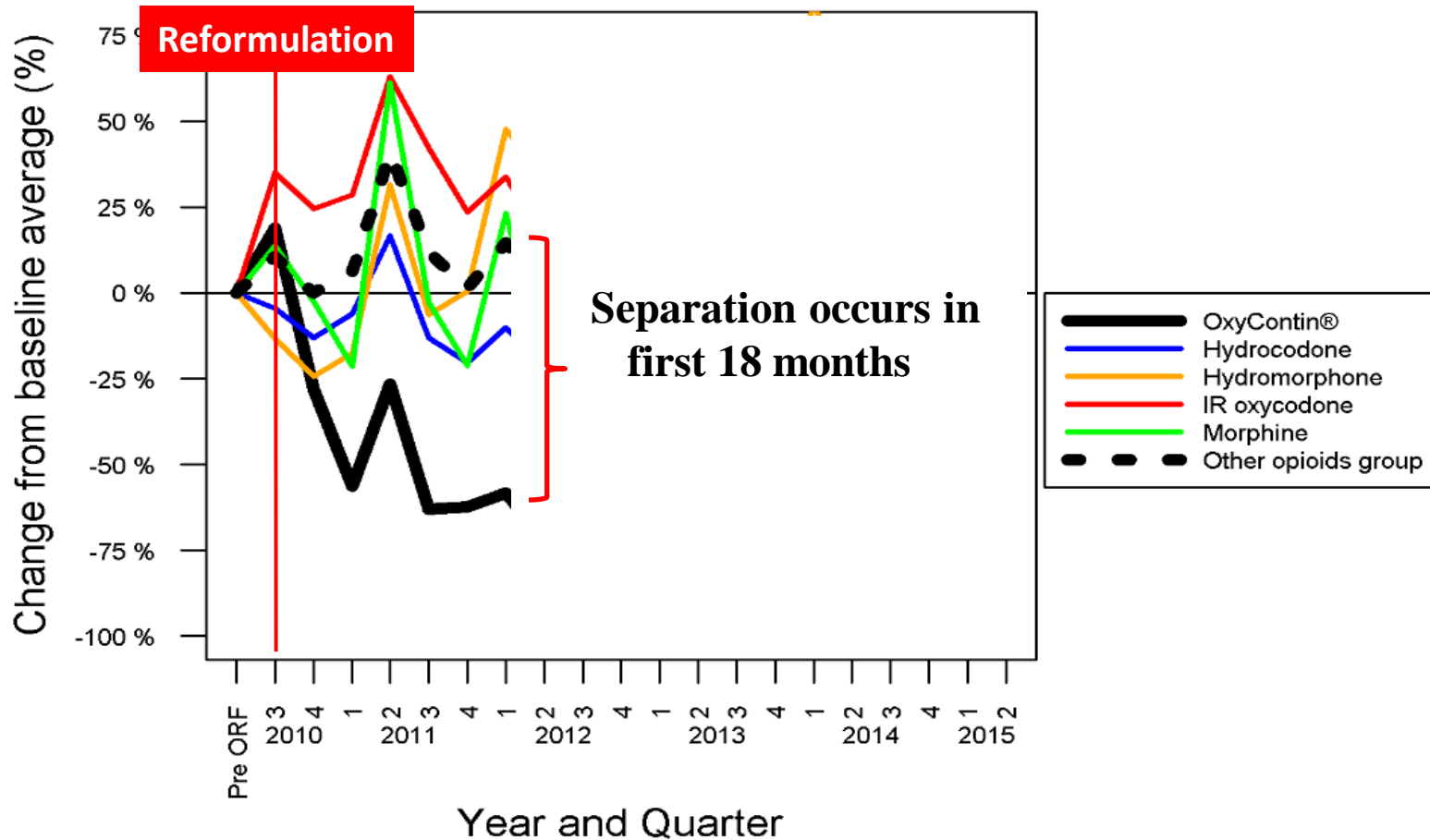
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Opioid Analgesic Prescriptions Dispensed in the US, April 1, 2009 to June 30, 2015

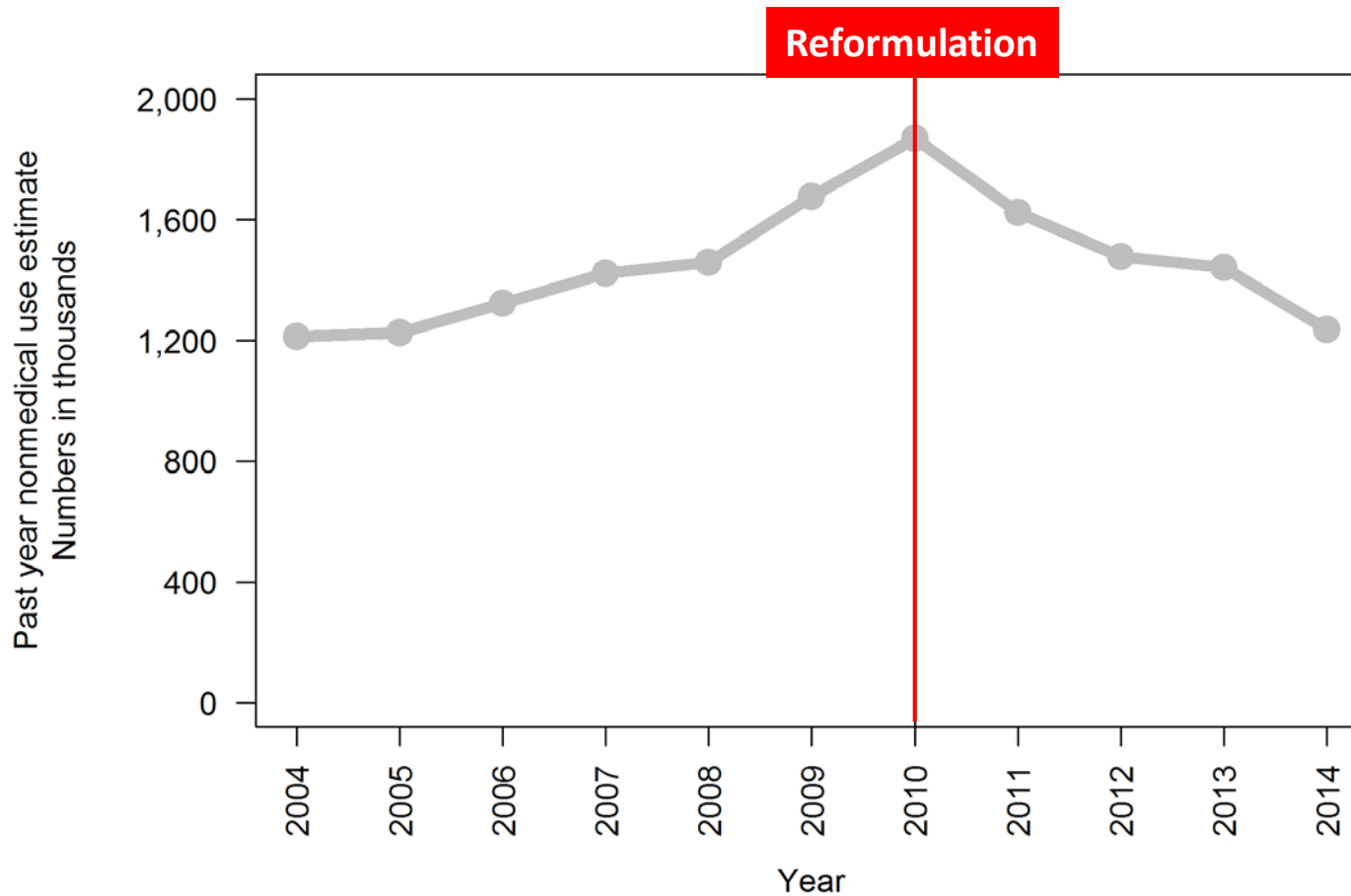


Opioid Treatment Program, Drugs Used in Past 30 Days, 2009 - 2015

- 115 Substance abuse treatment programs in 37 states

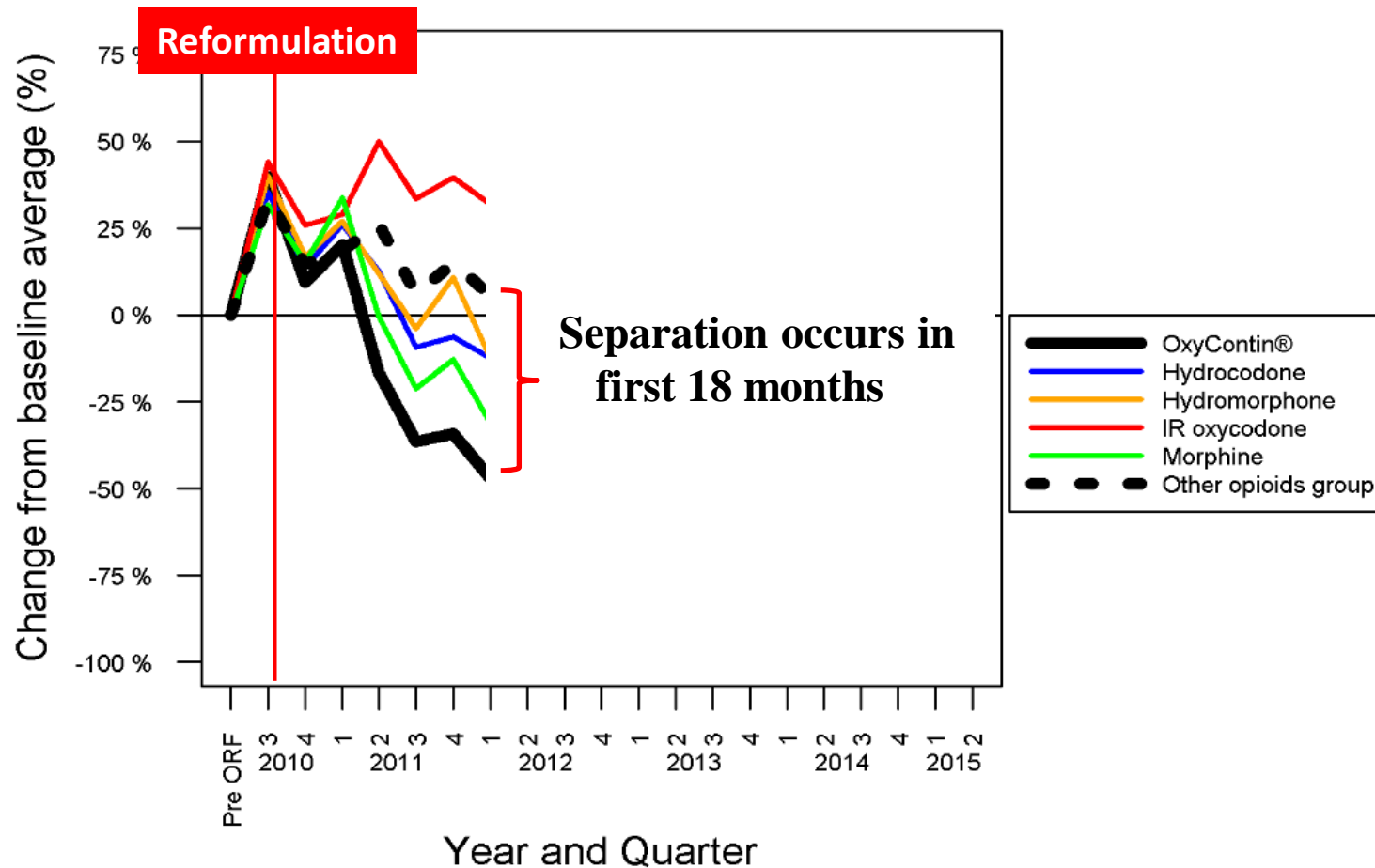


Past Year Nonmedical Use of OxyContin[®], National Survey of Drug Use and Health, 2006 – 2014



Drug Diversion Program, Drugs Involved in Investigations, 2009 - 2015

- 250 law enforcement investigators in 49 states



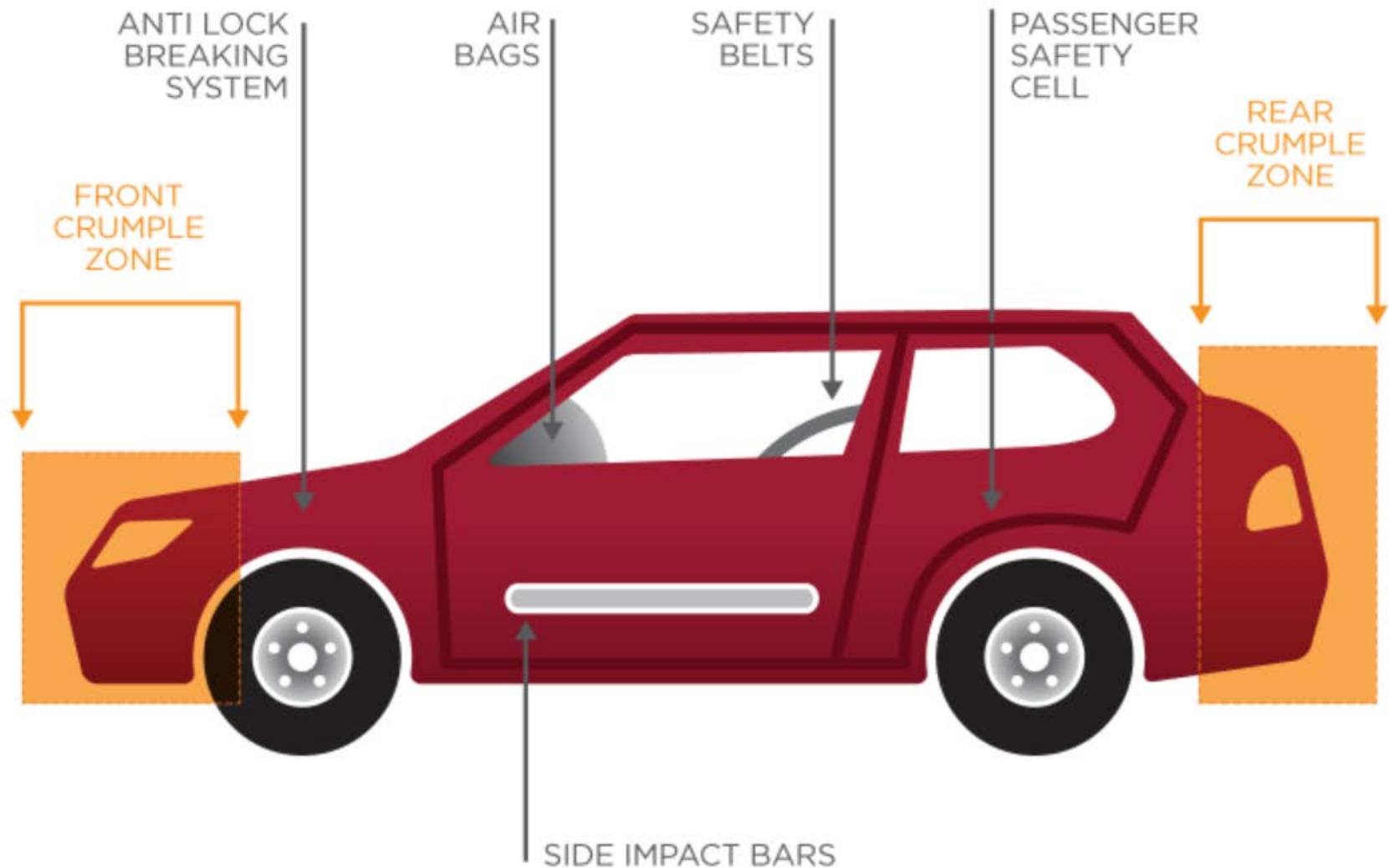
What's New Since 2017

- **Person-level changes in oxycodone use after the introduction of a tamper-resistant formulation in Australia**
 - “The reformulation had a greater impact on opioid access patterns of people less than 65 years of age who were using higher strengths of oxycodone CR.”
 - *Schaffer et al. CMAJ* 2018 March 26;190:E355-62. doi: 10.1503/cmaj.170666
- **The effect of a potentially tamper-resistant oxycodone formulation on opioid use and harm: main findings of the National Opioid Medications Abuse Deterrence (NOMAD) study**
 - “This formulation of controlled-release oxycodone reduced tampering with pharmaceutical opioids among people who inject drugs, but did not affect population-level opioid use or harm.”
 - Larance et al. *Lancet Psychiat*. [http://dx.doi.org/10.1016/S2215-0366\(18\)30003-8](http://dx.doi.org/10.1016/S2215-0366(18)30003-8)

Why Are ADFs Opposed in the United States?

- There are “no data” to show opioid analgesic products with properties intended to deter abuse are effective
- They can’t stop oral abuse
- They don’t change overall or even API prescription drug abuse
- They may “force” an OUD patient to use other opioids like heroin
- They may encourage doctors to prescribe ER opioids unwisely
- They are expensive
- Most critiques are written by authors with undeclared COI, usually financial (especially PBMs, insurers), but also philosophical (no one should be treated with an opioid)

Automotive Safety as a Model for Prescription Opioids

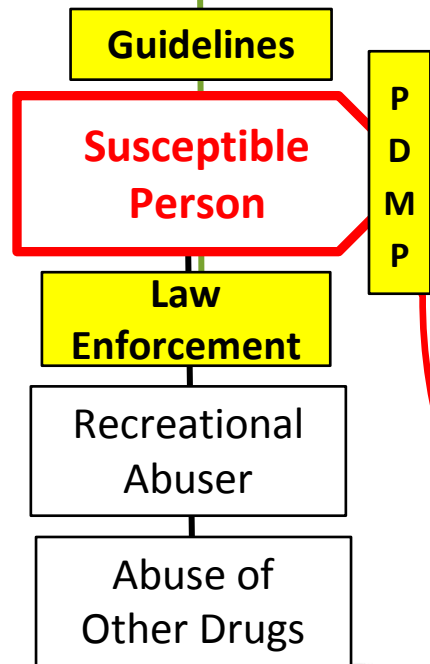


Automotive Safety as a Model for Prescription Opioids, 1998 vs 2015 Toyota

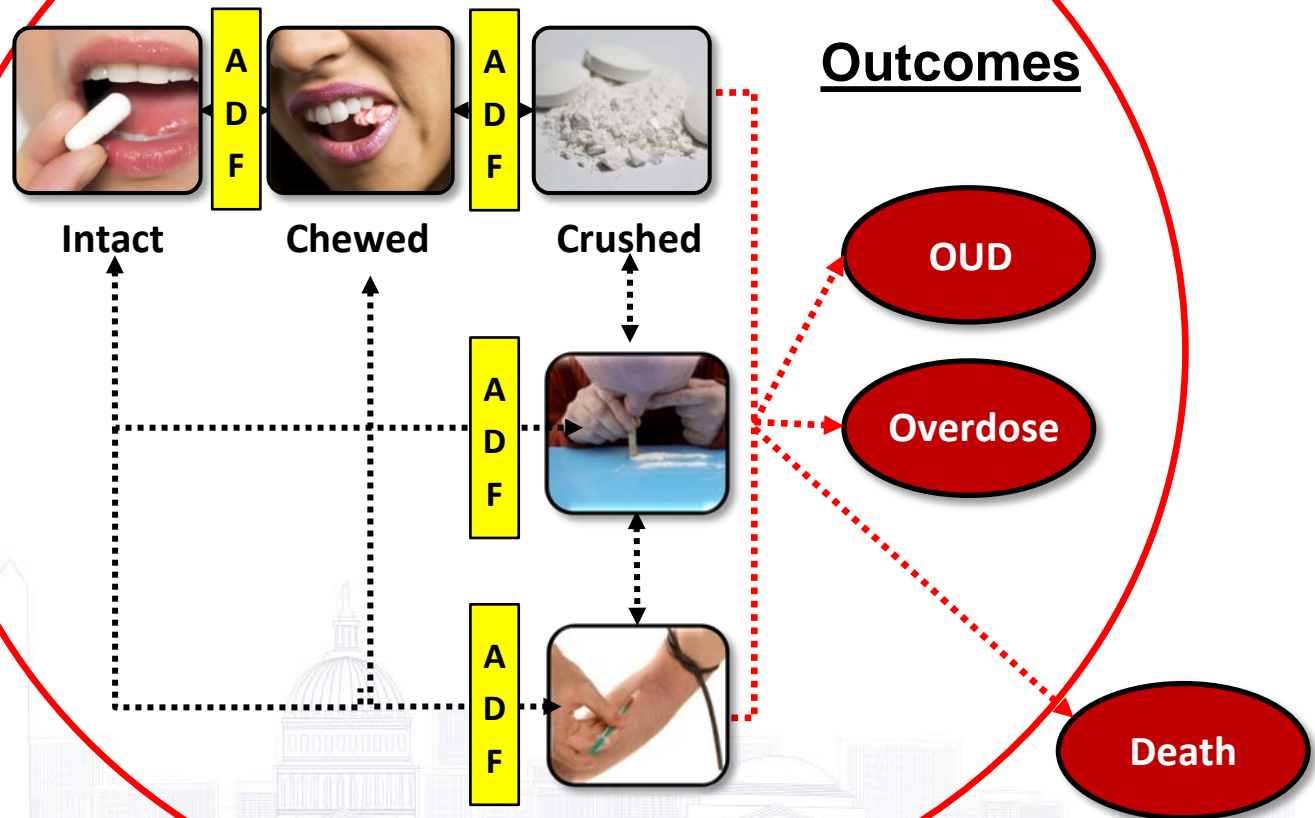


Progression of Prescription Opioid Abuse

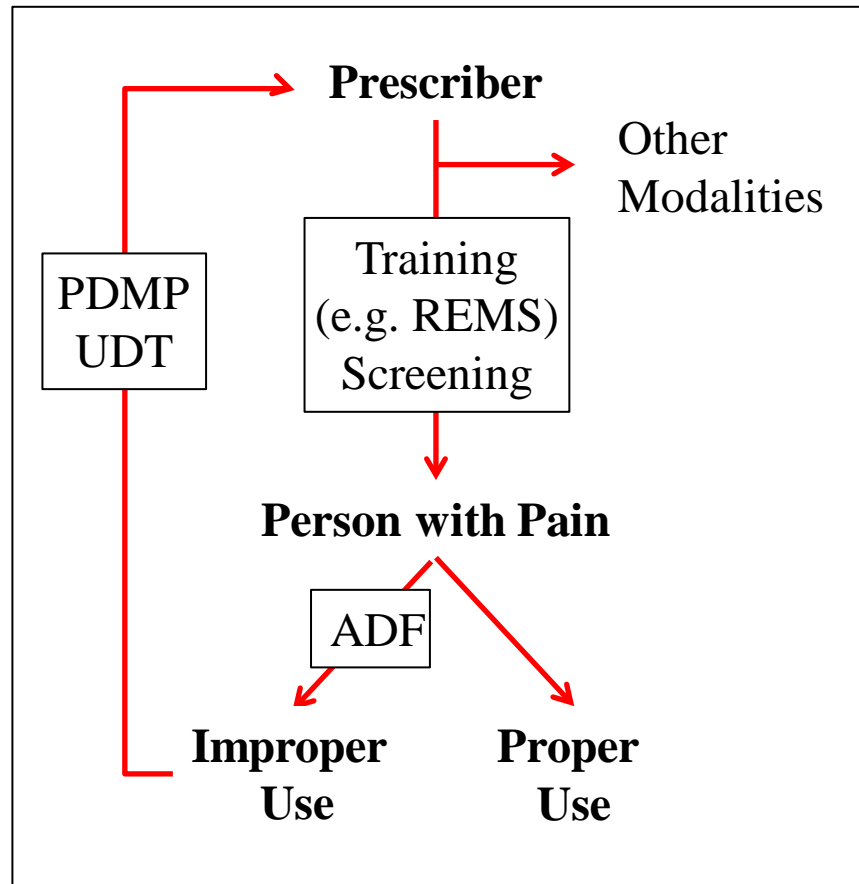
ICER: Adult NC CP
Patients Newly
Prescribed ADF vs.
Non-ADF ER Opioid



The Balloon



A Prescriber Needs Several Tools to Treat Chronic Pain



Carter Introduces Legislation to Remove Barriers to Abuse Deterrent Opioids

Washington, April 23, 2018

Congressman Earl L. "Buddy" Carter (R-Ga.) introduced legislation today to remove barriers to abuse deterrent opioids.

Abuse deterrent formulations (ADFs) represent a breakthrough technology that helps prevent the crushing, snorting, and injection of painkillers.

Currently, many prescription drug plans present access barriers for chronic pain patients to ADFs including cost-sharing tiers, fail-first requirements, and prior authorization requirements. Instead of receiving ADFs, often patients are limited to using traditional opioids that can be easily diverted, crushed, snorted, and injected.

Carter's legislation, the *Abuse Deterrent Access Act of 2018*, directs the Secretary of Health and Human Services to conduct a study on barriers to accessing abuse deterrent opioid formulations for chronic pain patients enrolled in Medicare.

...As the only pharmacist in Congress, I believe we must find solutions to combat this crisis that prevent opioid diversion while maintaining legitimate patient access for those who truly need it. ADFs ensure those who legitimately need pain medication are able to access it while helping to prevent misuse."

Original cosponsors include Representatives Dave Loebsack (D-Ia.) and Tom Reed (R-Ny.).

End

