RADARS® SYSTEM 2019

13TH ANNUAL SCIENTIFIC MEETING

Lessons from Opana® ER: Policy, Behavior, and Reality

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Roadmap

- Opana ER and its complicated history
- Policy changes and interventions
- Effects of policy on behavior and trends
- Lessons learned

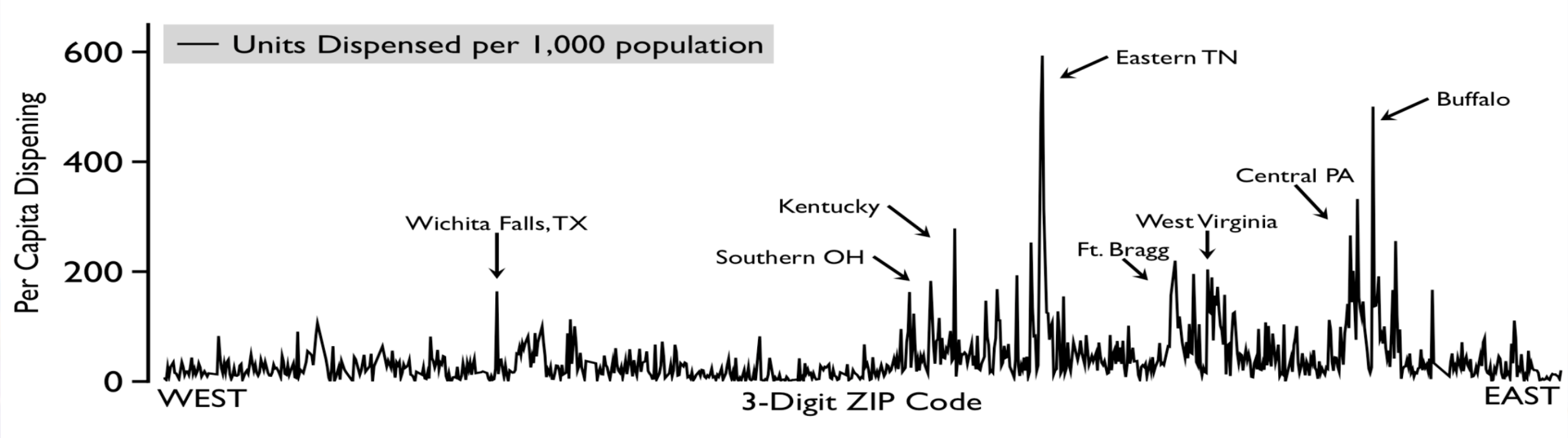
References: 10 pt.

Opana ER

- Extended-release oxymorphone
- Oxymorphone developed in Germany 1914
- Patented 1955
- Opana ER formulation Initially approved in 2006
- Indications: moderate to severe pain requiring around-the-clock treatment
- Geographic distribution

References: 10 pt.

Opana ER: Geographic distribution and heterogeneity

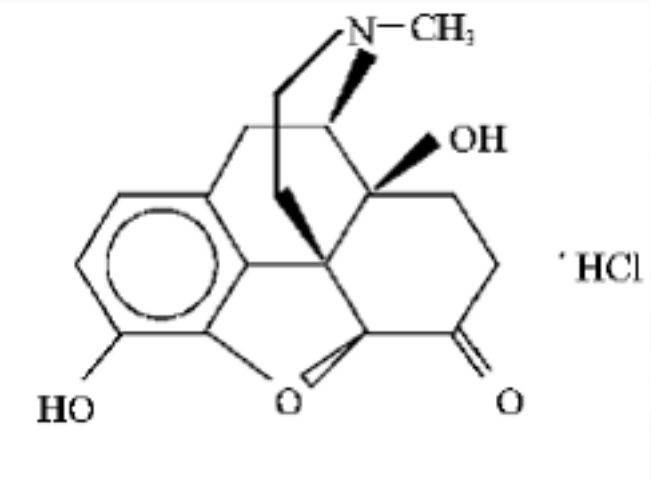


Time: 2009q3 – 2016q4
Source: IQVIA
N: 360,432,541 units dispensed
Analysis unit: 3-digit ZIP
Metric: cumulative population-adjusted rate

Oxymorphone

- Poor oral bioavailability
  - 10x more potent intravenously than orally

- Leads to unusual behaviors
  - Single 40mg pill = split into quarters
  - Each quarter = 2-4 users
  - Single pill leads to 8-16 doses intravenously
  - Each dose 50-75 MME



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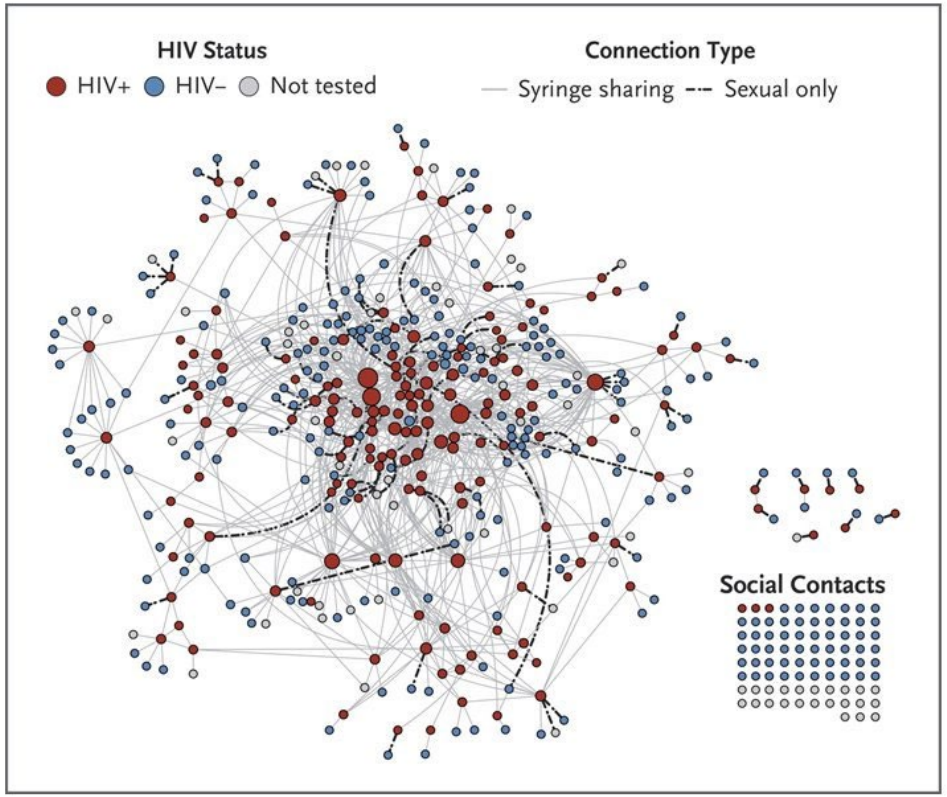
Oxymorphone

- Poor oral bioavailability
  - 10x more potent intravenously than orally
- Leads to unusual behaviors
  - Drug sharing
  - Unsafe injection practices
- Complications
  - HIV
  - Hepatitis C
  - TTP

Syringe-Sharing Network of Persons with Newly Diagnosed HIV Infection.



References: 10 pt.

Opana ER: Interventions and Policy Changes

- 2011: Reformulation approved
  - Released in 2012
  - Tamper resistant, but did not achieve ADF labeling
- Concern for transition from intranasal to intravenous abuse
- Outbreaks associated with oxymorphone

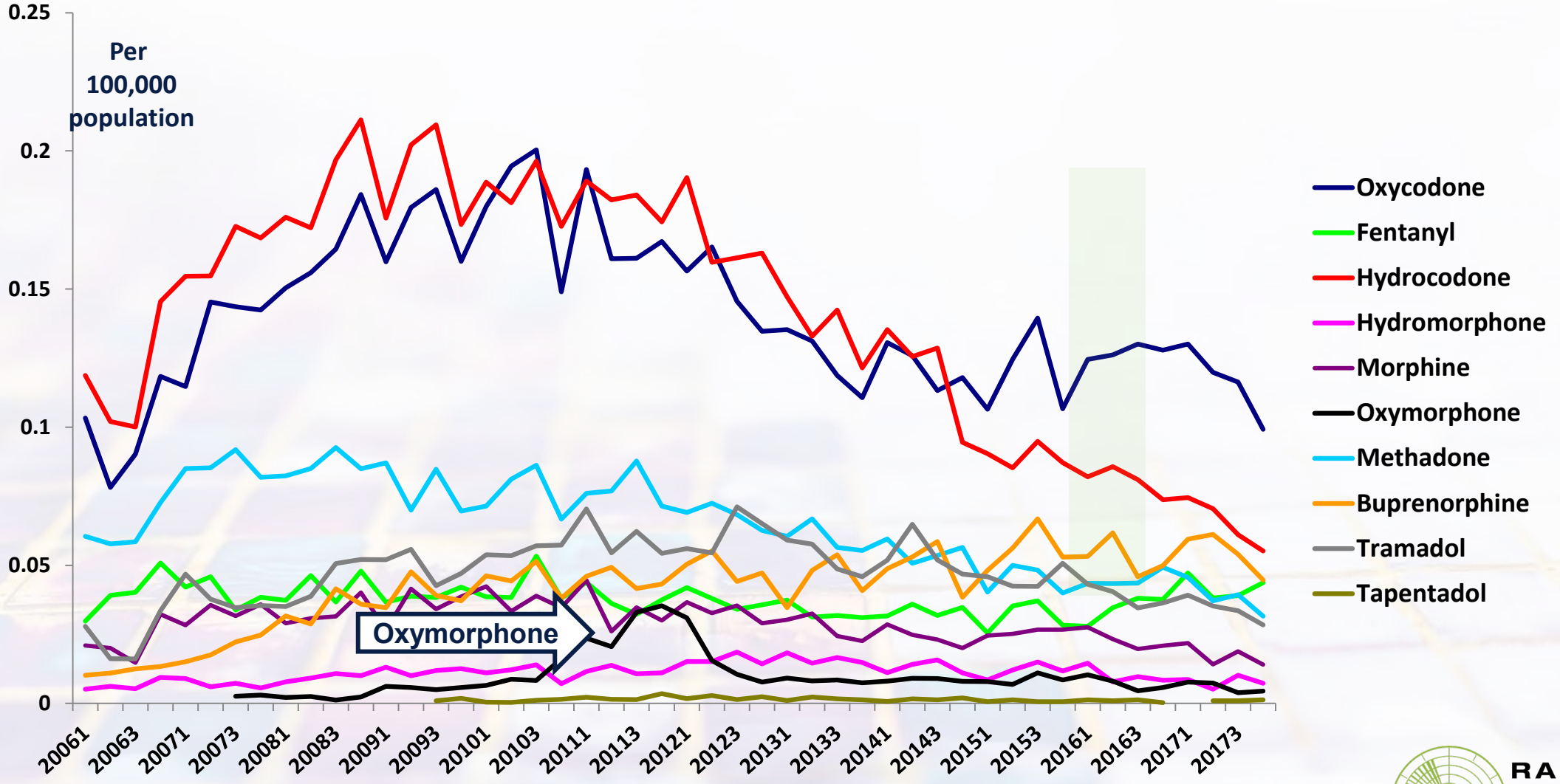
References: 10 pt.

Opana ER: Interventions and Policy Changes

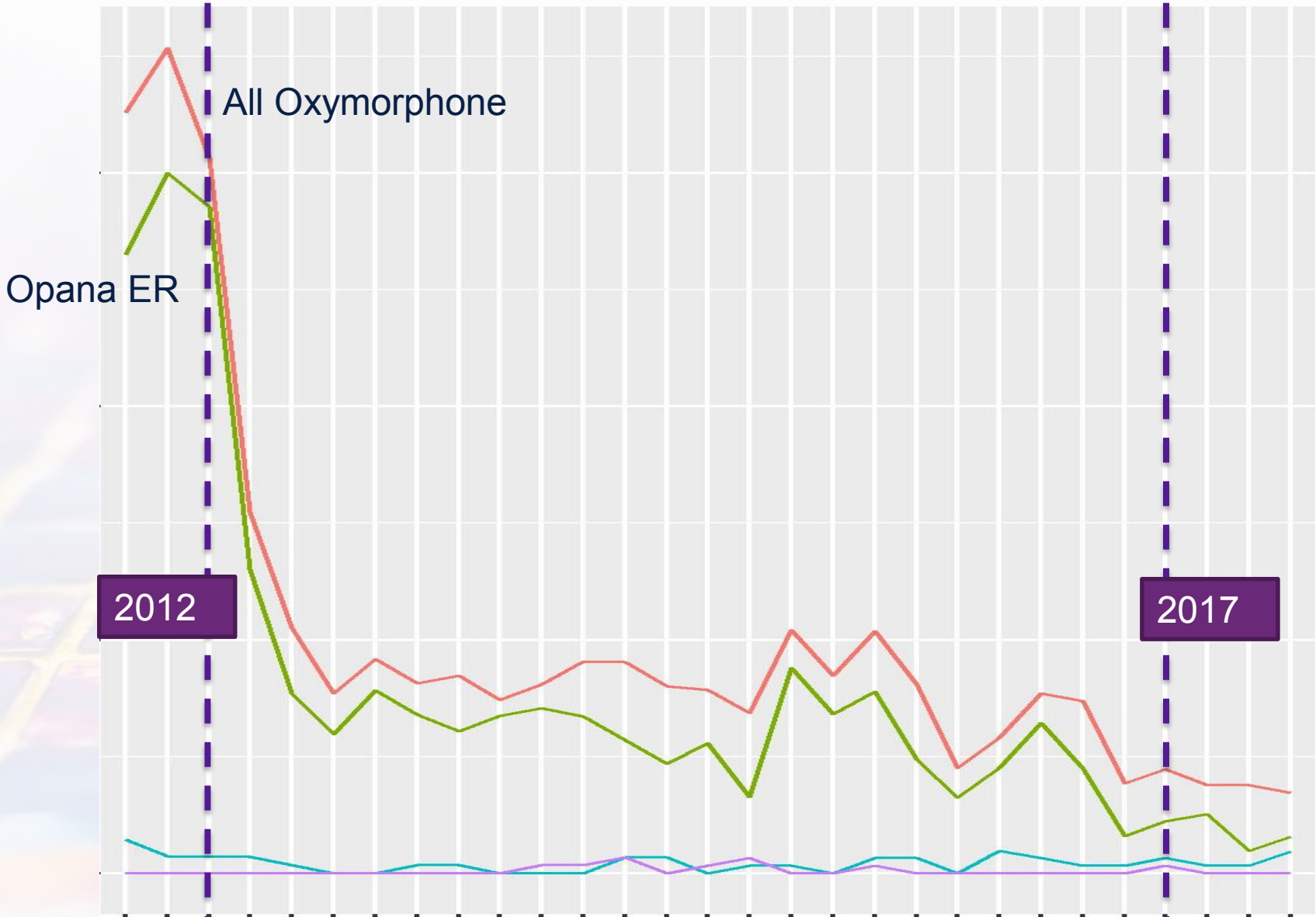
- March 2017:
  - FDA meeting
  - 18-8 vote, benefits no longer outweigh risks
- June 2017:
  - Recommended to be removed from market
- July 2017:
  - Opana ER removed
  - No change to generic forms or IR

References: 10 pt.

Oxymorphone: Big picture
Poison Center Program

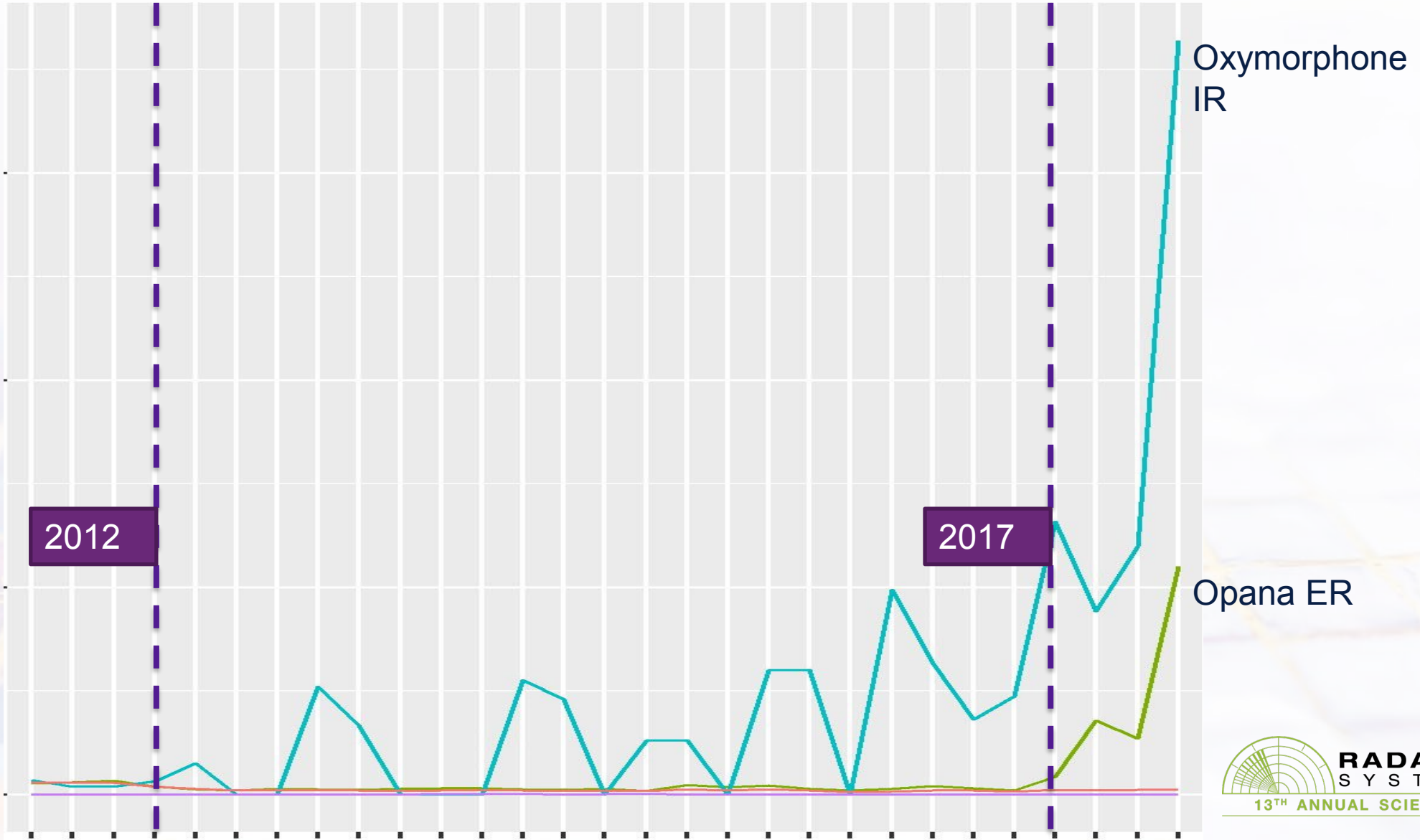


Opana ER: Effects of Policy on Behavior and Trends
Poison Center Program, rate per population



References: 10 pt.

Opana ER: Effects of Policy on Behavior and Trends
Poison Center Program, rate per prescriptions



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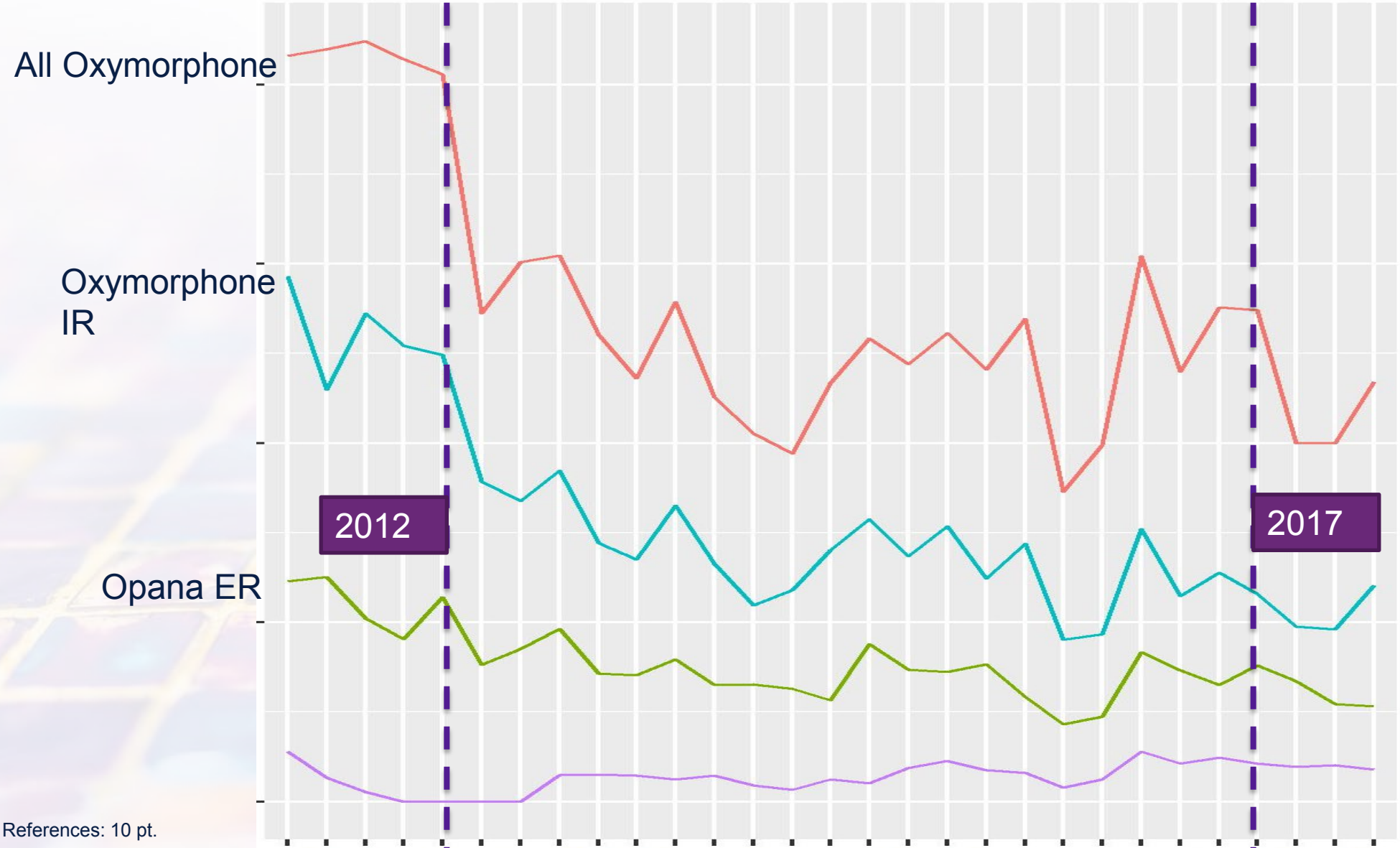
Opana ER: Effects of Policy on Behavior and Trends Treatment Center Programs, rate per population



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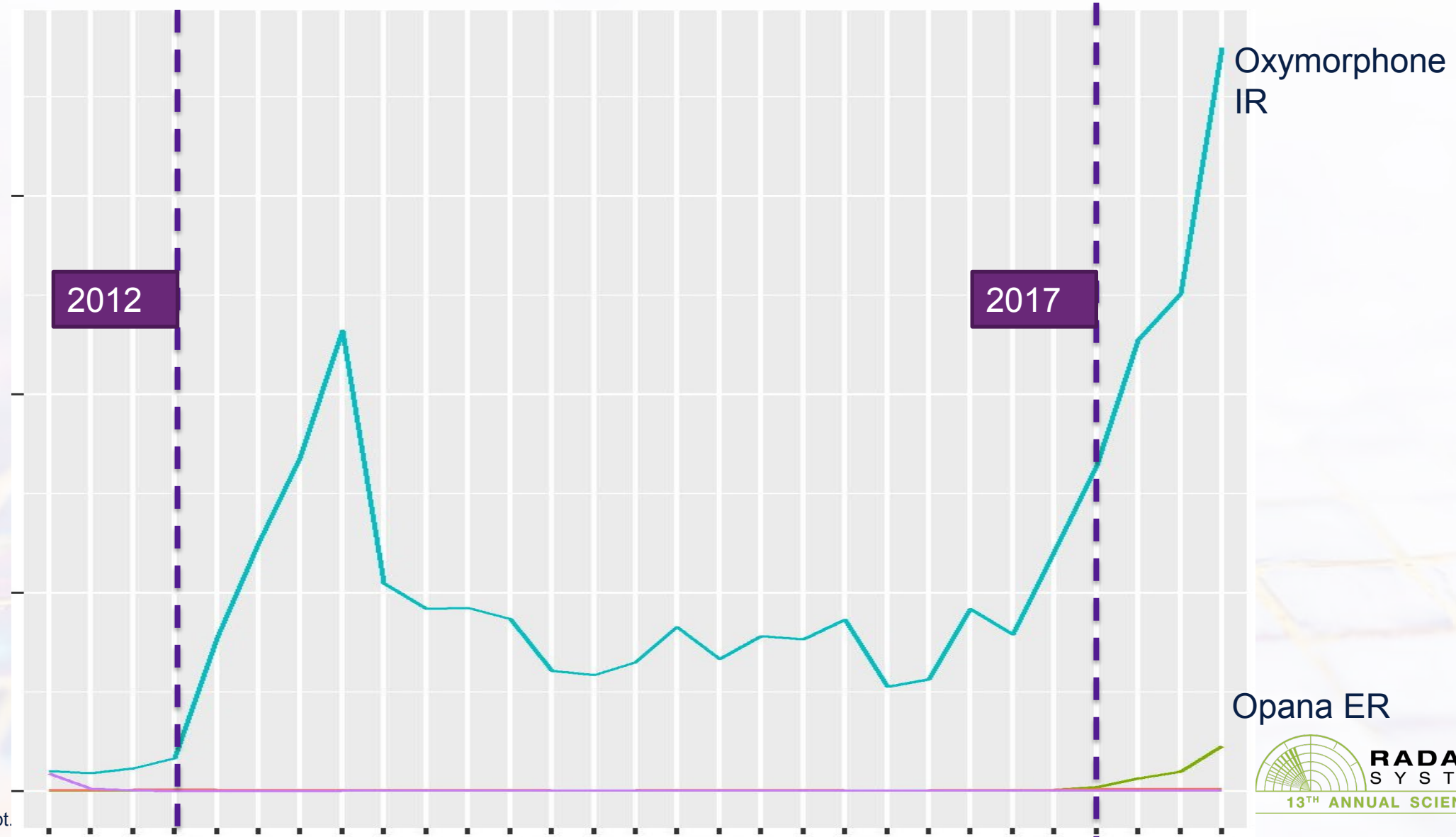

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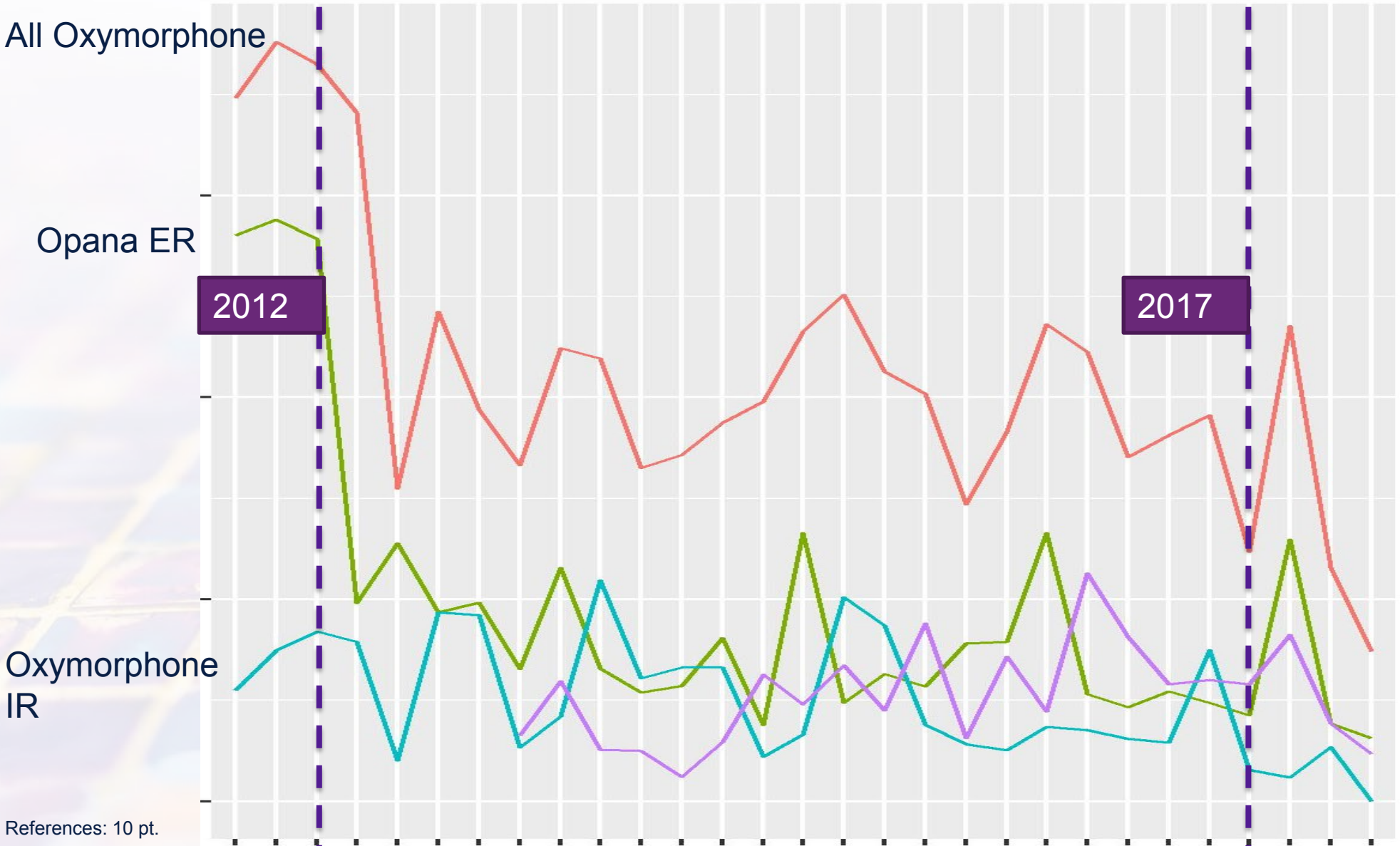
Opana ER: Effects of Policy on Behavior and Trends
Drug Diversion Program, rate per population



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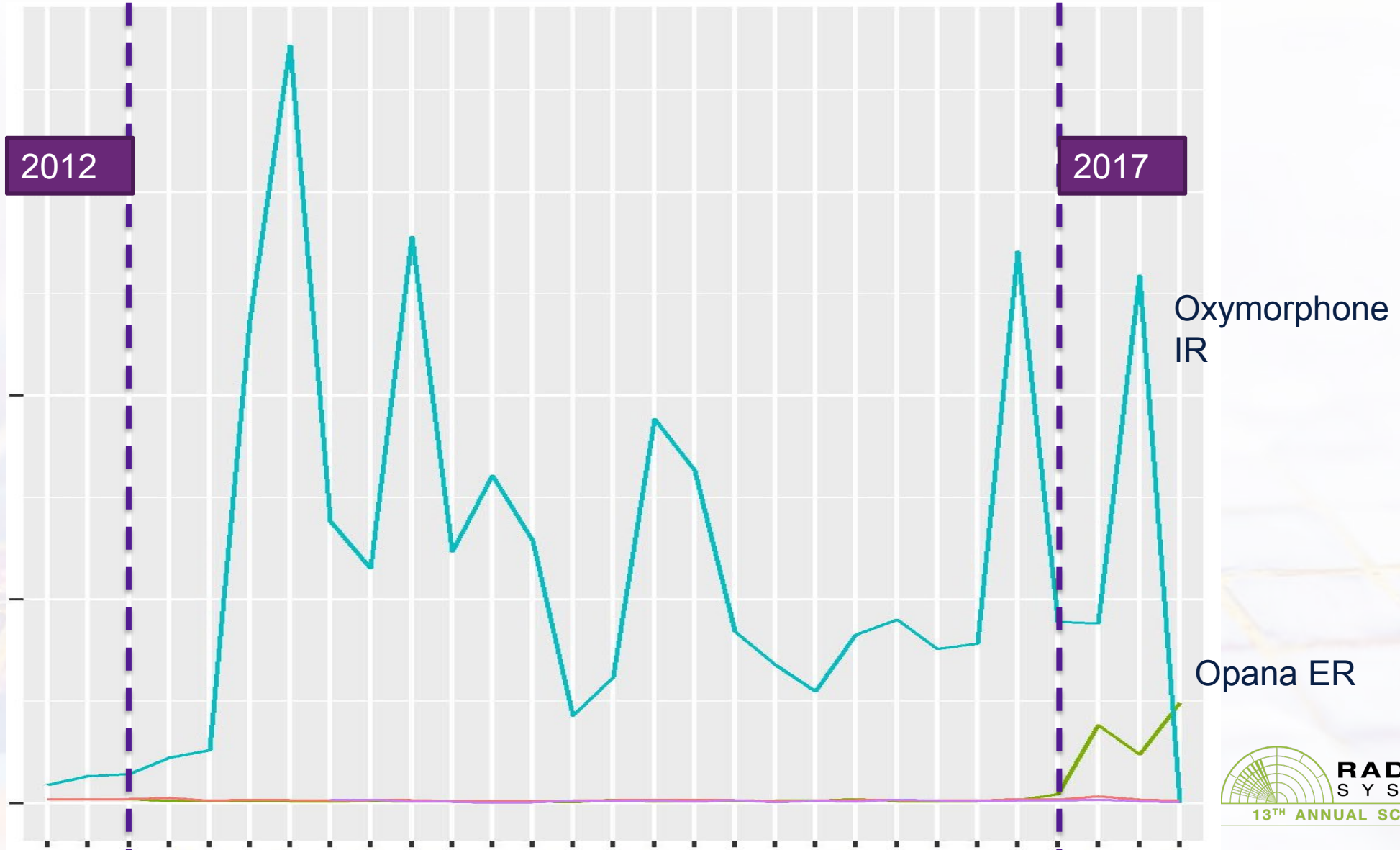
Opana ER: Effects of Policy on Behavior and Trends
Drug Diversion Program, rate per prescriptions



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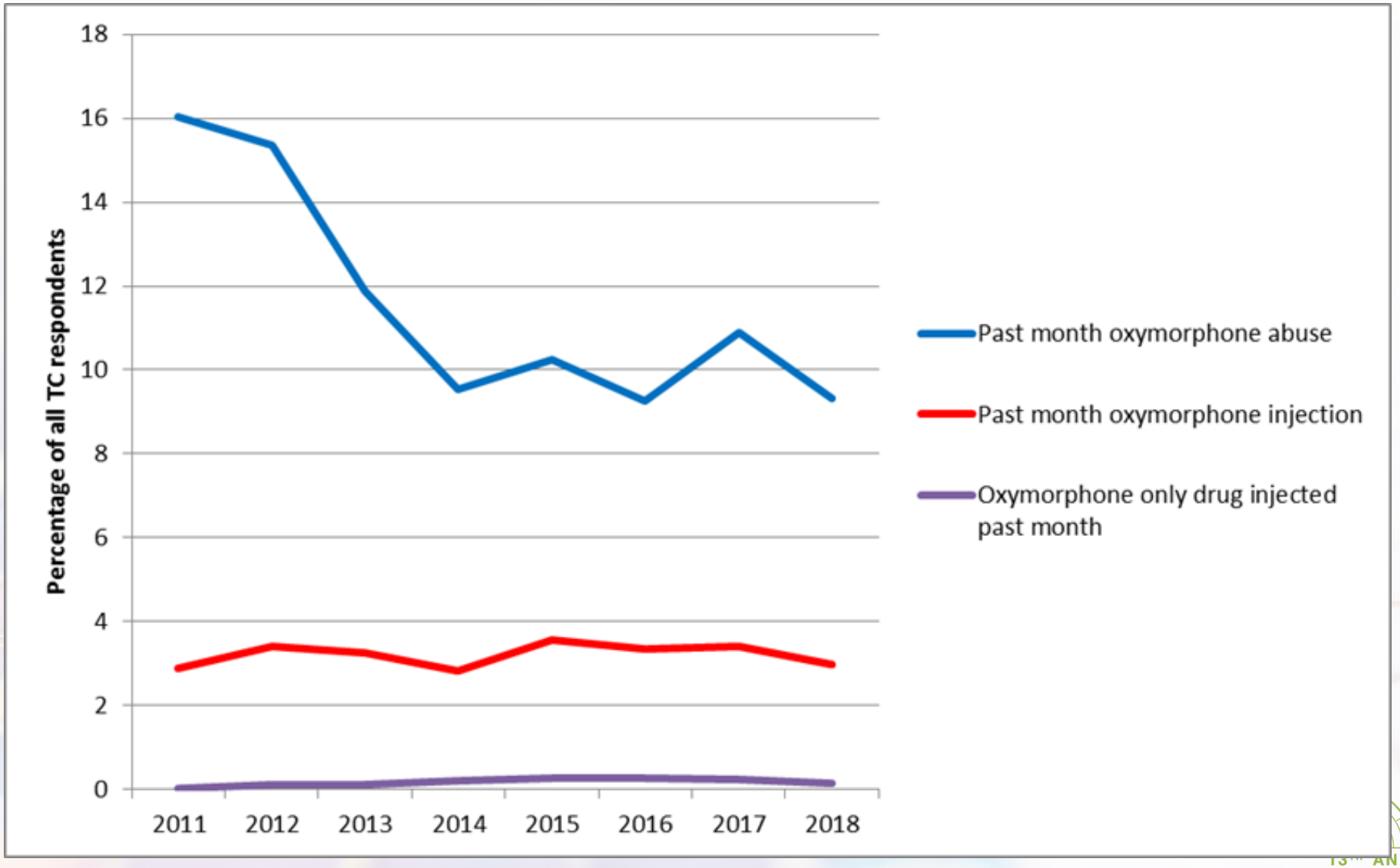
Opana ER: Effects of Policy on Behavior and Trends
Did injection behavior change?



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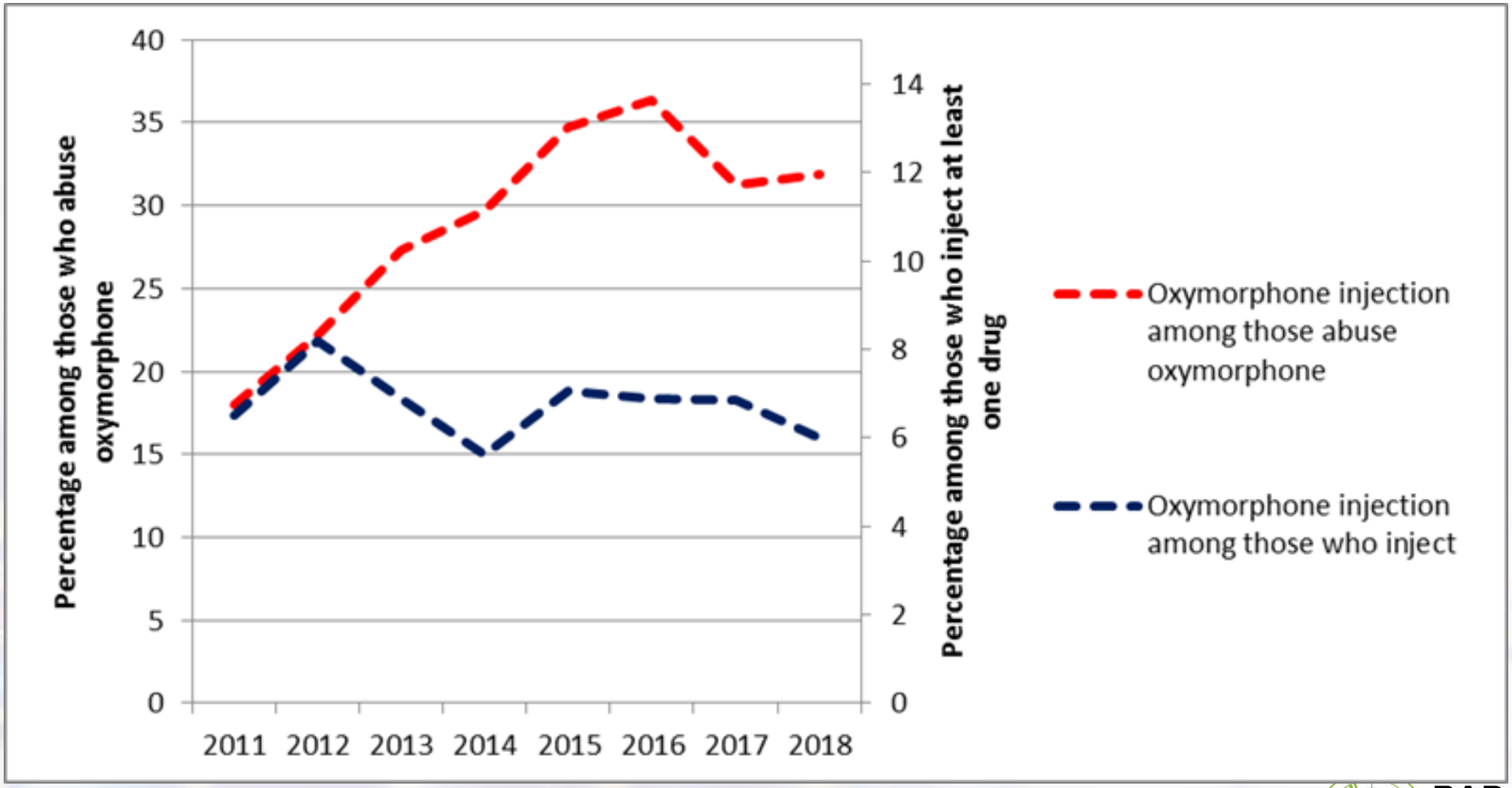

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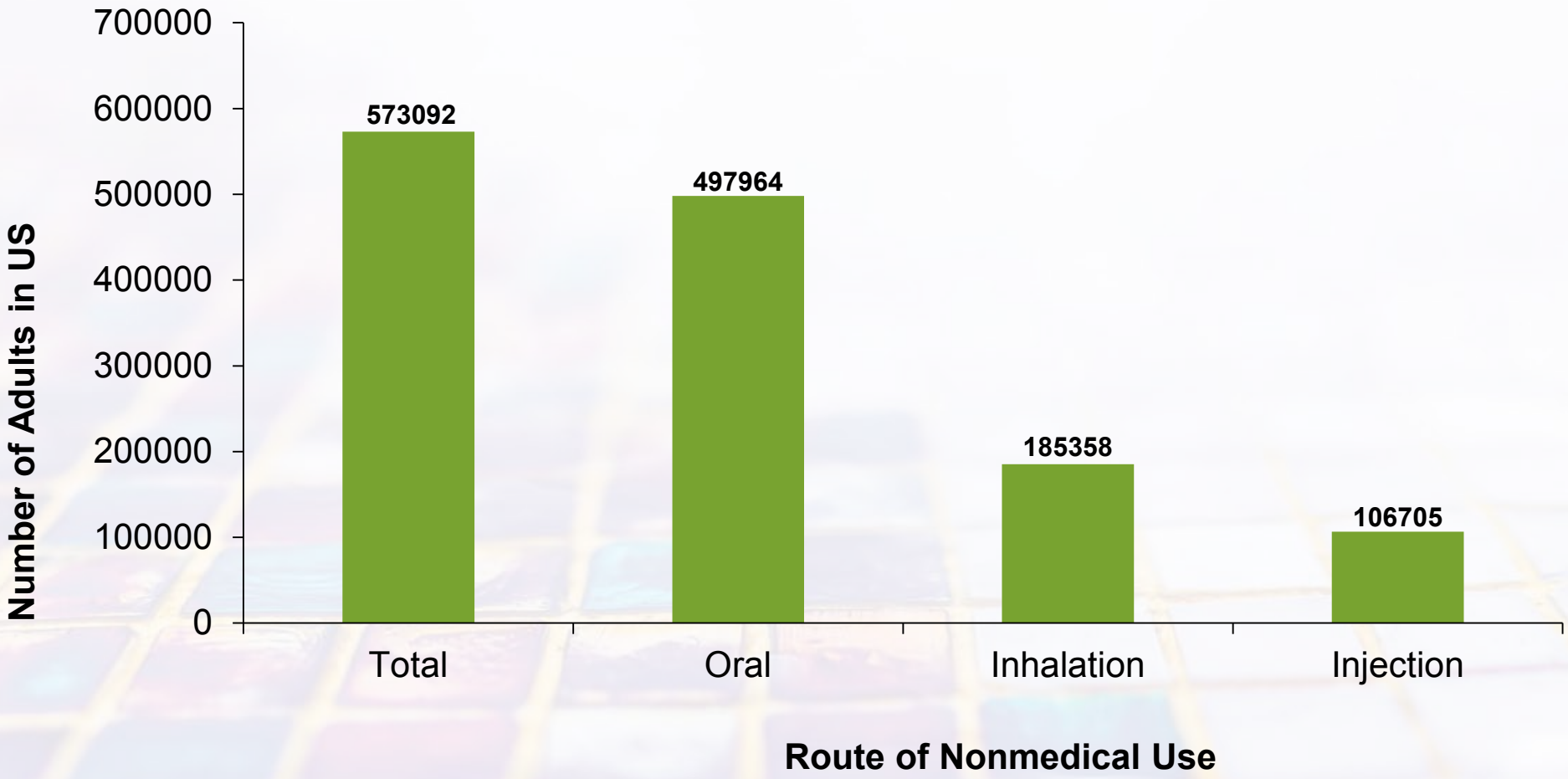
Opana ER: Effects of Policy on Behavior and Trends
Did injection behavior change? NMURx data



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Conclusions

- Oxymorphone as a molecule lends itself to dangerous behaviors
  - Low oral bioavailablity, high intravenous potency
  - Sharing behaviors are common
- Policy changes and interventions with Opana ER are a good first step
  - BUT do not seem to have impacted injection use as much as desired
- To see a significant impact, would likely need to take a step further
  - Is it worth considering removing all oxymorphone?
- Lessons learned

References: 10 pt.

Questions?

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