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
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
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
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.
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
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
Oxymorphone: Big picture
Poison Center Program

Per 100,000 population

20061 20062 20063 20064 20065 20066 20067 20068 20069 20070 20071 20072 20073

- Oxycodone
- Fentanyl
- Hydrocodone
- Hydromorphone
- Morphine
- Oxymorphone
- Methadone
- Buprenorphine
- Tramadol
- Tapentadol

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

All Oxymorphone

Opana ER

2012

2017

References: 10 pt.
Opana ER: Effects of Policy on Behavior and Trends
Poison Center Program, rate per prescriptions

2012

2017

Oxymorphone IR

Opana ER

References: 10 pt.
Opana ER: Effects of Policy on Behavior and Trends Treatment Center Programs, rate per population
Opana ER: Effects of Policy on Behavior and Trends Treatment Center Programs, rate per prescriptions

References: 10 pt.
Opana ER: Effects of Policy on Behavior and Trends
Drug Diversion Program, rate per population

References: 10 pt.
Opana ER: Effects of Policy on Behavior and Trends
Drug Diversion Program, rate per prescriptions

References: 10 pt.
Did injection behavior change?

![Graph showing percentage of all TC respondents over the years.]

- Past month oxymorphone abuse
- Past month oxymorphone injection
- Oxymorphone only drug injected past month

References: 10 pt.
Opana ER: Effects of Policy on Behavior and Trends
Did injection behavior change?
Opana ER: Effects of Policy on Behavior and Trends
Did injection behavior change? NMURx data

Route of Nonmedical Use

Number of Adults in US

<table>
<thead>
<tr>
<th>Route of Nonmedical Use</th>
<th>Number of Adults in US</th>
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<tbody>
<tr>
<td>Total</td>
<td>573092</td>
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<tr>
<td>Oral</td>
<td>497964</td>
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<tr>
<td>Inhalation</td>
<td>185358</td>
</tr>
<tr>
<td>Injection</td>
<td>106705</td>
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References: 10 pt.
Conclusions

• Oxymorphone as a molecule lends itself to dangerous behaviors
  – Low oral bioavailability, 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
Questions?

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