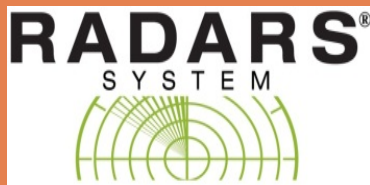


RADARS® System: Mosaic Approach to Opioid Surveillance & REMS Evaluation

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DIA
2012
Collaborate
to Innovate



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Objectives

- Describe the RADARS[®] System
 - The “mosaic” approach
 - Utilization for safety and risk mitigation analysis
- Prescription Drug Surveillance & REMS Evaluation
 - Importance of measuring the right outcome



RADARS System Fundamentals

- RADARS System History
 - 2001: Founded by Purdue Pharma
 - 2006: Independently owned and operated by Denver Health & Hospital Authority (Rocky Mountain Poison and Drug Center)
 - 2012: Serving 10 subscribers
- Independent Scientific Advisory Board
- Monitor over 120 different products



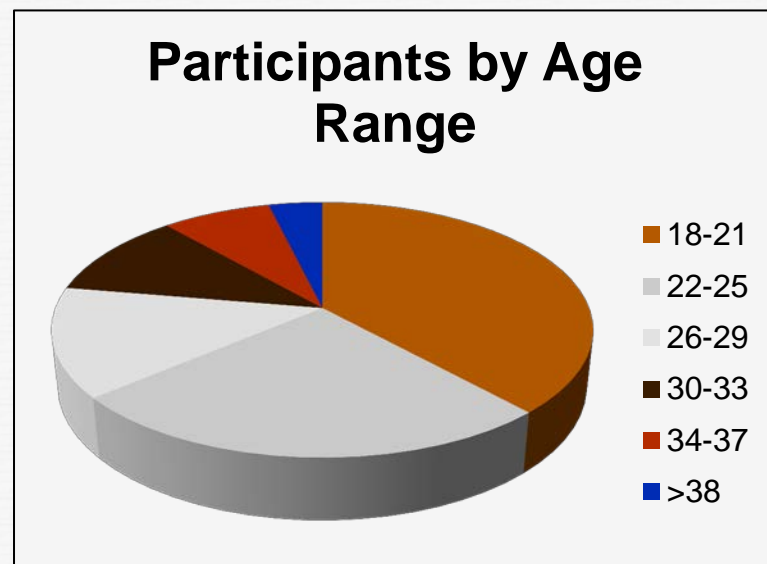
RADARS System Goals

- Measure rates of misuse, abuse and diversion of prescription drugs
- Identify sentinel events involving the misuse, abuse and diversion of prescription drugs nationwide
- Provide experienced and expert analysis and interpretation of the data



College Survey

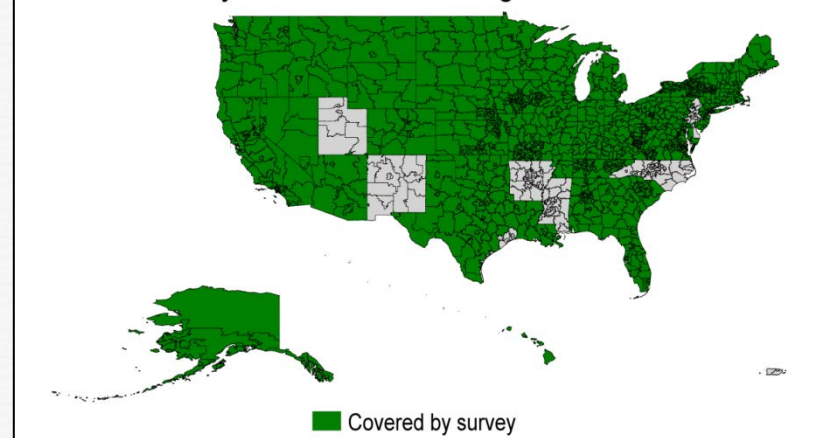
- **Population**
 - College students (traditional and non-traditional)
- **Definition/Type of Cases**
 - Self-reported nonmedical use of prescription drugs in previous semester
- **Coverage**
 - 6,000 responders/year
 - 50 states across 4 regions
- **Reporting Timeframe**
 - Fall / Spring / Summer



Poison Center (PC)

- **Population**
 - young children, adolescents, adults, elderly
- **Definition/Type of Cases**
 - Spontaneous reports of intentional exposure mentions of acute medical events associated with one or more prescription drugs
- **Coverage**
 - 50 of 57 PCs
- **Reporting Timeframe**
 - quarterly

3DZs covered by Poison Center during the 4th Quarter of 2011



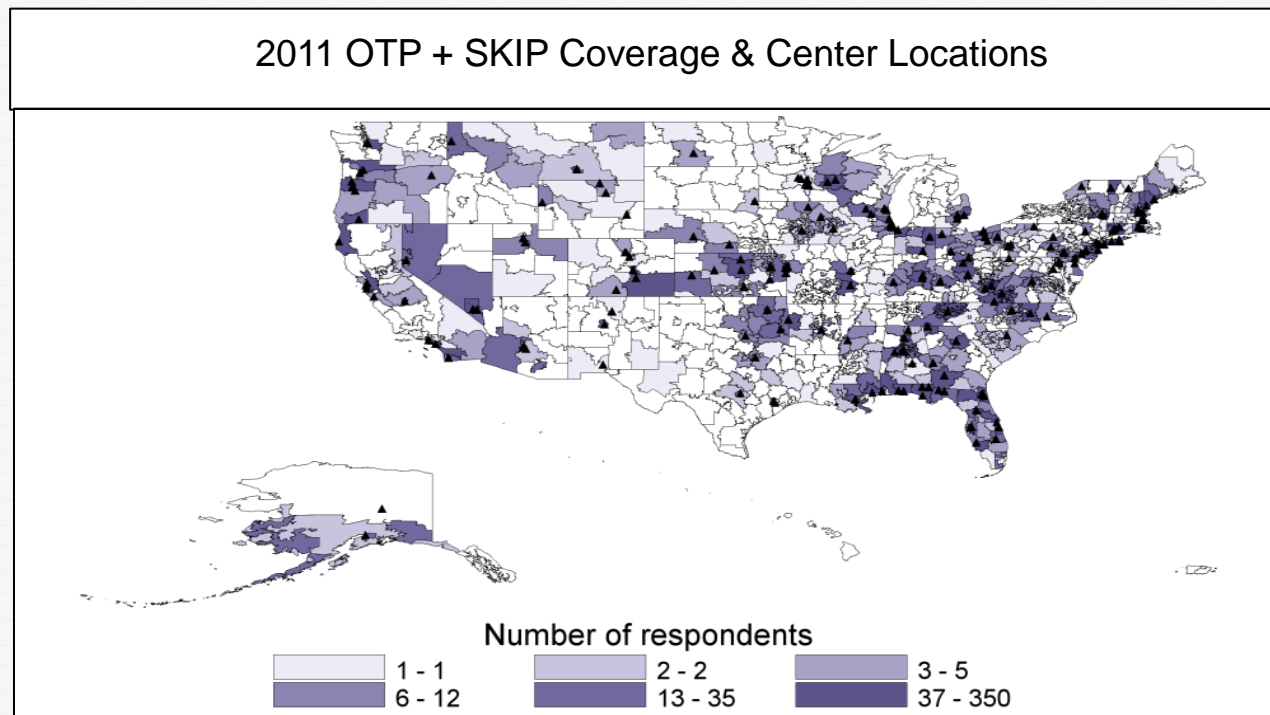
Opioid Treatment Programs (OTP & SKIP)

- **Population**
 - Opioid dependent persons seeking treatment at public/private opioid treatment programs (OTP) and private substance abuse treatment programs (SKIP)
- **Definition/Type of Cases**
 - Self-reported use of prescription or illicit opioids to “get high” in the past 30 days



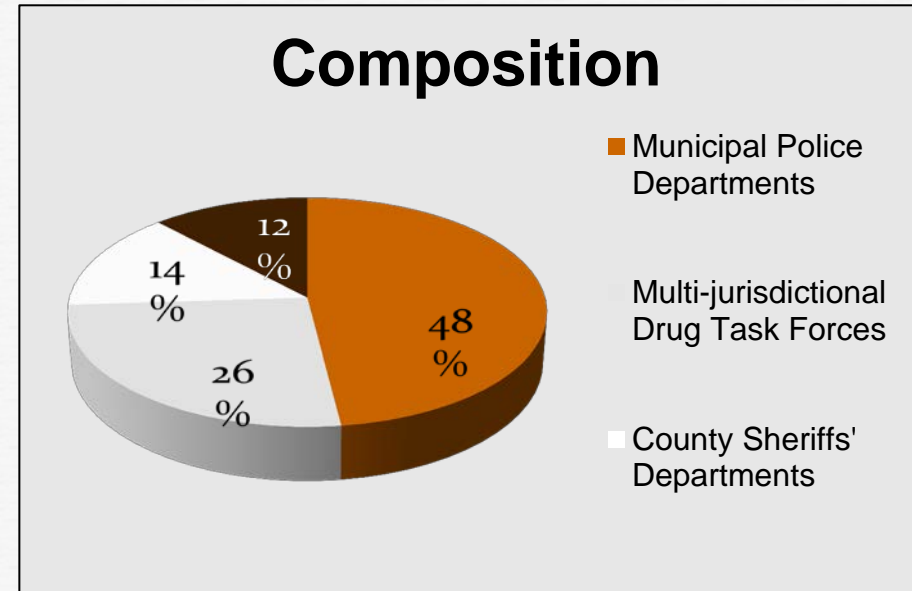
Opioid Treatment Programs (OTP & SKIP)

- Coverage
 - See map
- Reporting Timeframe
 - quarterly



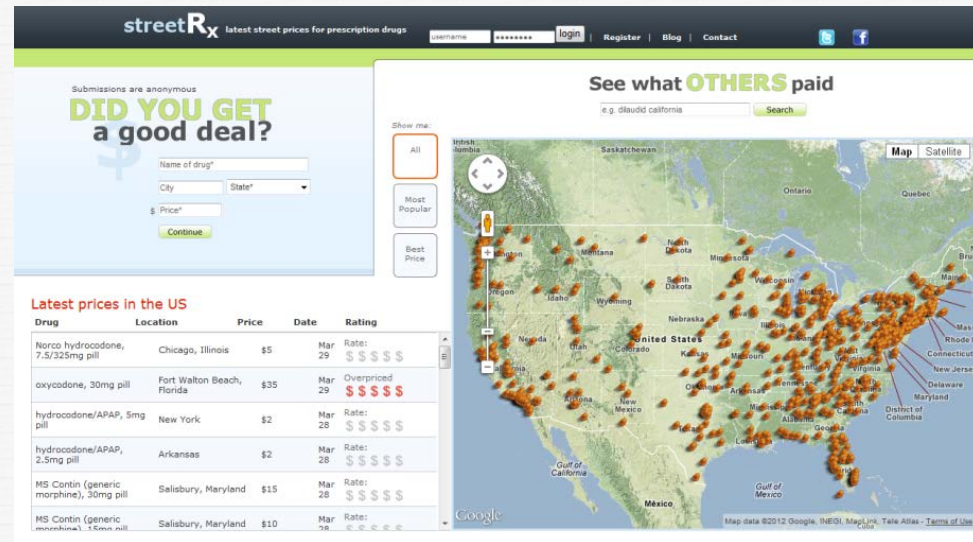
Drug Diversion (DD)

- **Population**
 - Cases of prescription drug diversion
- **Definition/Type of Cases**
 - Number of new instances of pharmaceutical diversion investigated by drug diversion units or reported to state regulatory boards
- **Coverage**
 - 280 reporters from 50 states
- **Reporting Timeframe**
 - quarterly



StreetRx (www.streetrx.com)

- **Population**
 - Any person in US with access to the internet
- **Definition/Type of Cases**
 - Utilize crowdsourcing methodology to calculate average price of specific prescription drug in particular location
 - Validated by DD
- **Coverage**
 - All 50 states
- **Reporting Timeframe**
 - Quarterly



StreetRx (www.streetrx.com)

streetRx latest street prices for prescription drugs

username

password

login

Register

Blog

Contact



Submissions are anonymous

DID YOU GET

See what **OTHERS** paid

e.g. dilaudid california

Search

Prices for Dilaudid, Exalgo, generic Dilaudid, hydromorphone, hydromorphone (generic Dilaudid), Palladone — USA

Drug	Location	Price	Date	Rating
Dilaudid, 8mg pill	Mesa, Arizona	\$15	May 1	Pricey \$ \$ \$ \$ \$
Dilaudid, 8mg pill	Mesa, Arizona	\$10	May 1	Reasonable \$ \$ \$ \$ \$
Exalgo, 16mg pill	Cincinnati, Ohio	\$50	Apr 27	Rate: \$ \$ \$ \$ \$
Dilaudid, 2mg pill	Banning, California	\$1.50	Apr 24	Not Bad \$ \$ \$ \$ \$
hydromorphone (generic Dilaudid), 4mg	Knoxville, Tennessee	\$5	Apr 22	Rate: \$ \$ \$ \$ \$
Dilaudid, 2mg pill	Brewster, New York	\$15	Apr 21	Rate: \$ \$ \$ \$ \$

Latest prices
Drug

Norco hydrocodone
7.5/325mg pill

oxycodone, 3

hydrocodone
pill

hydrocodone
2.5mg pill

MS Contin (generic
morphine), 3

MS Contin (generic
morphine), 1



RADARS[®] System Mosaic Approach

College
Survey

Early
Experimenters

Poison
Center

Acute Events

OTP
(Opioid Tx
Program)

Patients in
Treatment

SKIP
(Survey of Key
Informant Pts)

Patients in
Treatment

Drug
Diversion

Criminal Justice/
Law Enforcement

Street
Price

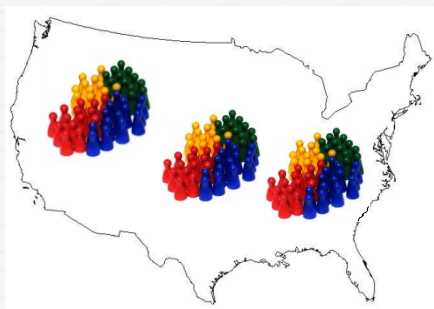
Users/Buyers



RADARS® System Process: A Tale of Two Denominators

COUNTS BY SYSTEM

**UNITED STATES
POPULATION**



= POPULATION RATE

- Disease burden on whole population
- Does not account for drug availability

COUNTS BY SYSTEM

URDD



**= UNIQUE RECIPIENTS OF
DISPENSED DRUG (URDD)
RATE**

- Number of unique people filling prescription for drug

Application of RADARS System Data

- Development of Interventions
 - How drugs are being abused, misused, diverted
 - Geographic specificity
- Ongoing surveillance
 - Monitoring trends over time due to market or regulatory changes
- Impact Assessment of Interventions – REMS Evaluation
 - Measuring the right outcome with product and geographic specificity



2011 RADARS System Opioid Abuse Trends

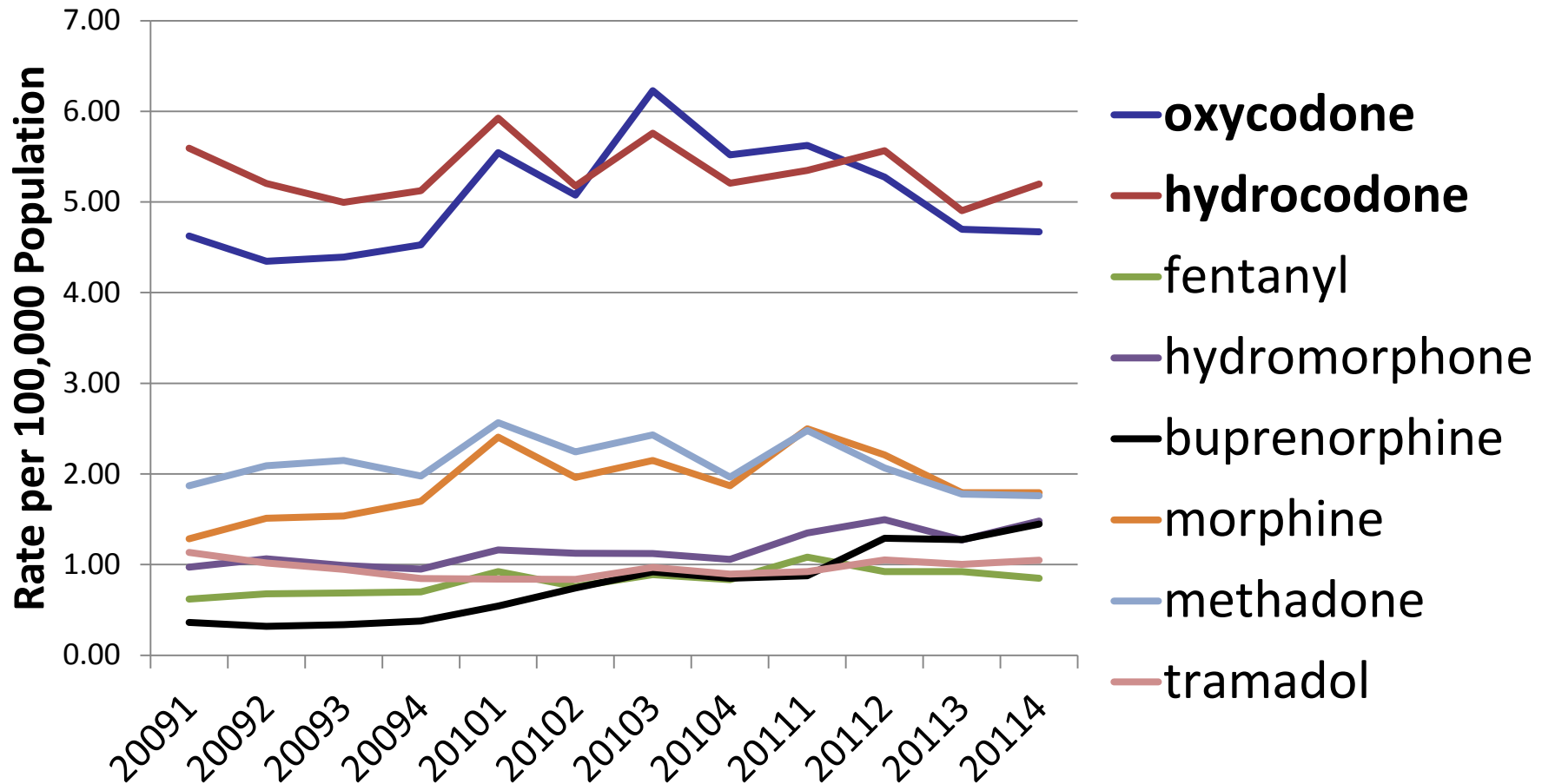
Population Rate (Ranked Highest-Lowest)

Rank	College Survey	Poison Center	Survey of Key Informant Pts	Opioid Treatment	Drug Diversion
1	hydrocodone	hydrocodone	hydrocodone	oxycodone	oxycodone
2	oxycodone	oxycodone	oxycodone	hydrocodone	hydrocodone
3	morphine	tramadol	morphine	methadone	morphine
4	tramadol	methadone	hydromorphone	morphine	buprenorphine
5	fentanyl	morphine	methadone	hydromorphone	methadone
6	methadone	buprenorphine	buprenorphine	buprenorphine	hydromorphone
7	buprenorphine	fentanyl	fentanyl	fentanyl	tramadol
8	hydromorphone	hydromorphone	tramadol	tramadol	fentanyl



RADARS System Programs*

Population Rates by API (2009 1Q to 2011 4Q)



*Includes College Survey, Poison Center, Opioid Treatment Program (OTP), Survey of Key Informants' Patients (SKIP), and Drug Diversion.



2011 RADARS System Opioid Abuse Trends

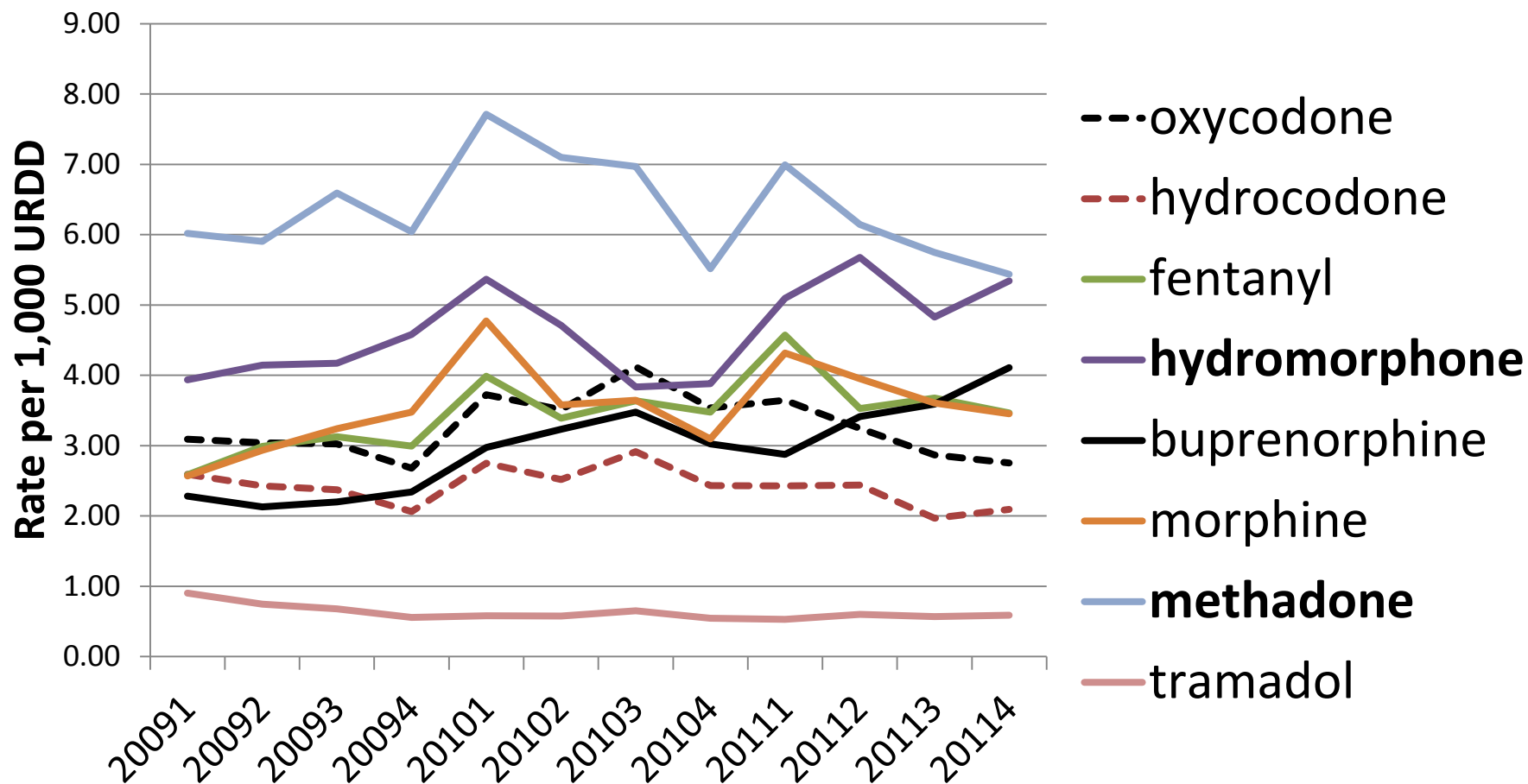
URDD Rates (Ranked Highest-Lowest)

Rank	College Survey	Poison Center	Survey of Key Informant Pts	Opioid Treatment	Drug Diversion
1	methadone	methadone	hydromorphone	methadone	methadone
2	hydromorphone	buprenorphine	methadone	hydromorphone	hydromorphone
3	morphine	morphine	morphine	morphine	buprenorphine
4	fentanyl	hydromorphone	buprenorphine	buprenorphine	morphine
5	buprenorphine	fentanyl	fentanyl	fentanyl	oxycodone
6	oxycodone	tramadol	oxycodone	oxycodone	fentanyl
7	hydrocodone	oxycodone	hydrocodone	hydrocodone	hydrocodone
8	tramadol	hydrocodone	tramadol	tramadol	tramadol



RADARS System Programs

URDD Rates by API (2009 1Q to 2011 4Q)



*Includes College Survey, Poison Center, Opioid Treatment Program (OTP), Survey of Key Informants' Patients (SKIP), and Drug Diversion.



Reformulated OxyContin[®]: Pre and Post-Analysis



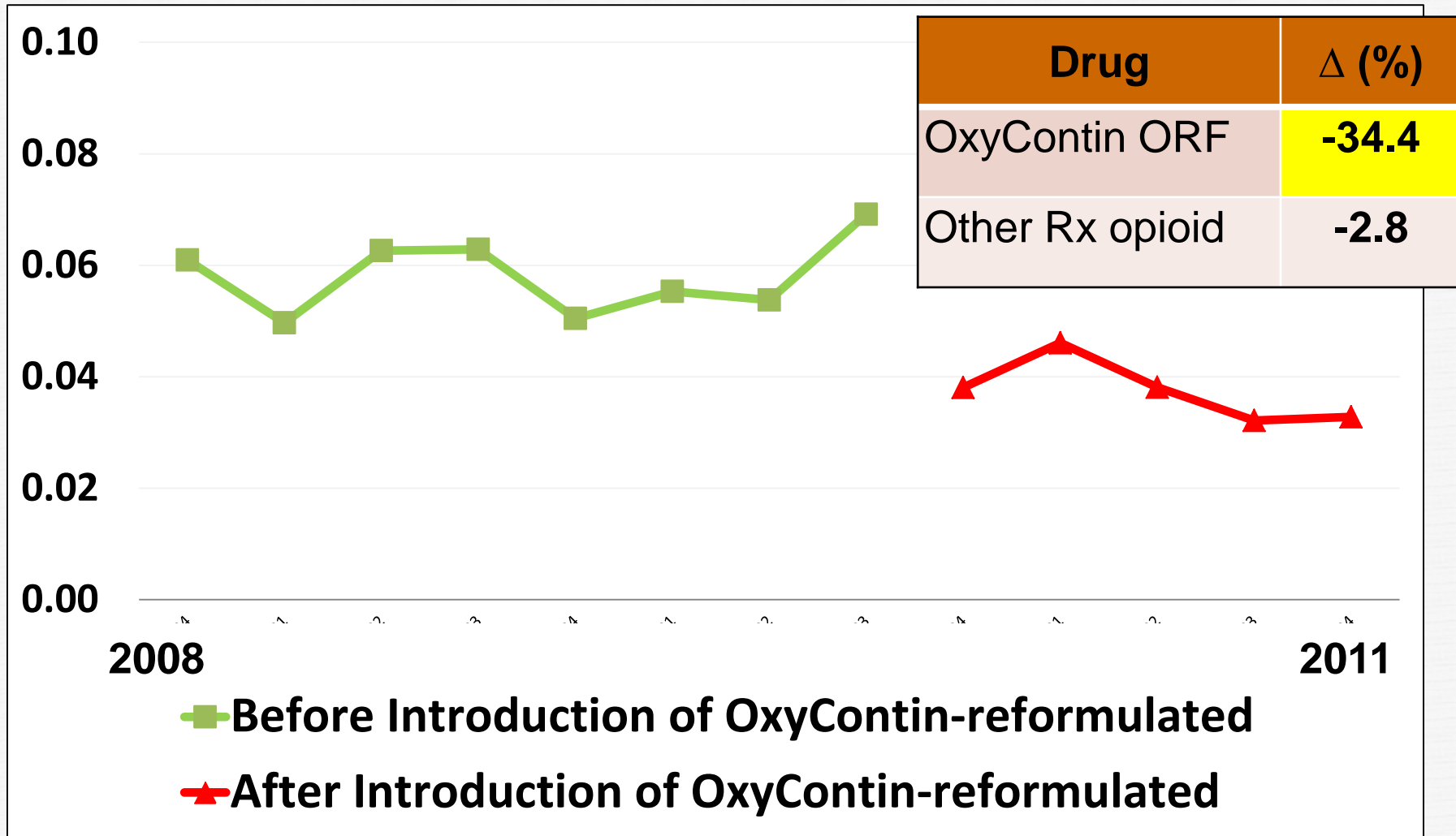
**OxyContin
OC**



**OxyContin
OP**

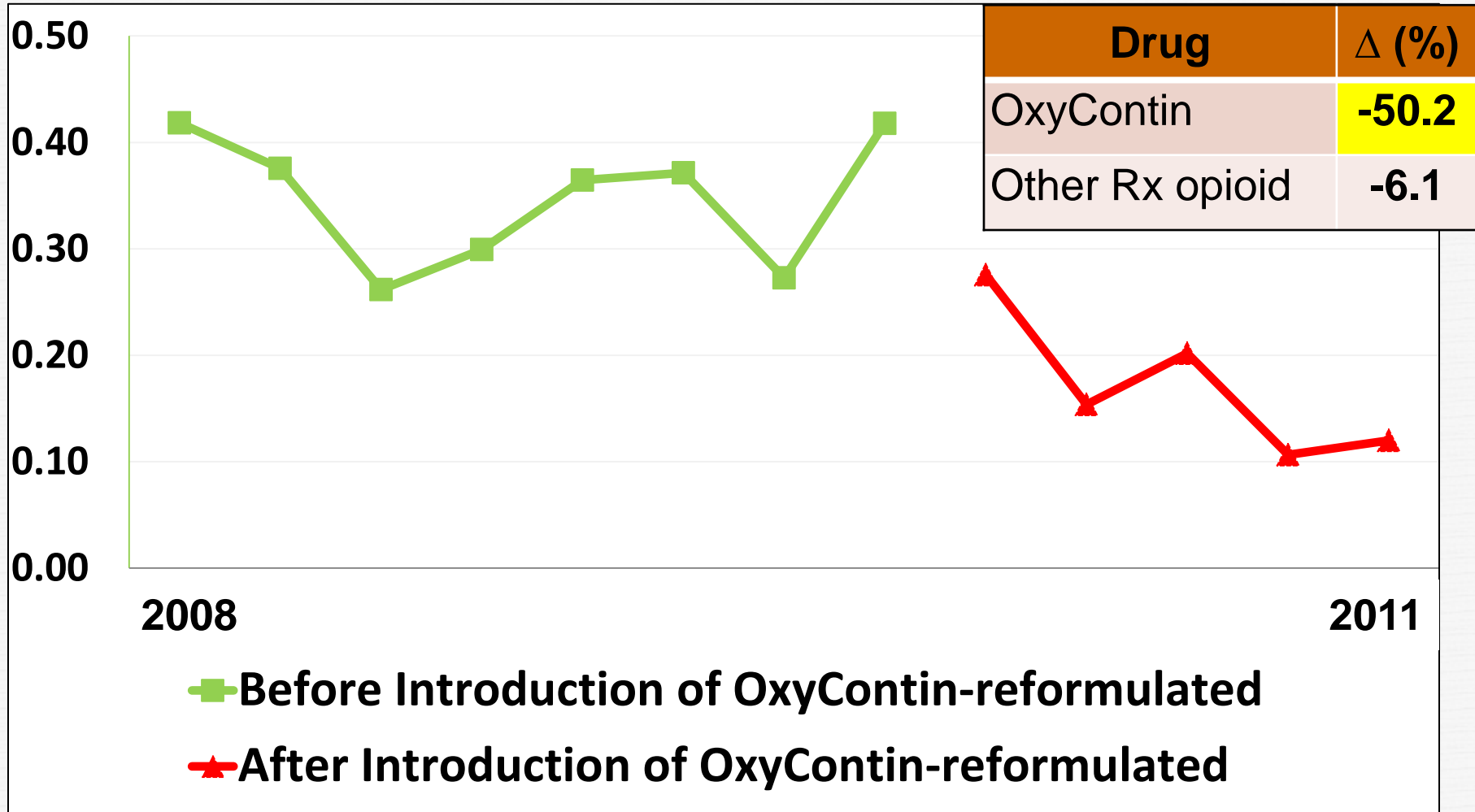
Poison Center Program - Intentional Abuse

Population Rate for OxyContin (2008 Q4 - 2011 Q4)



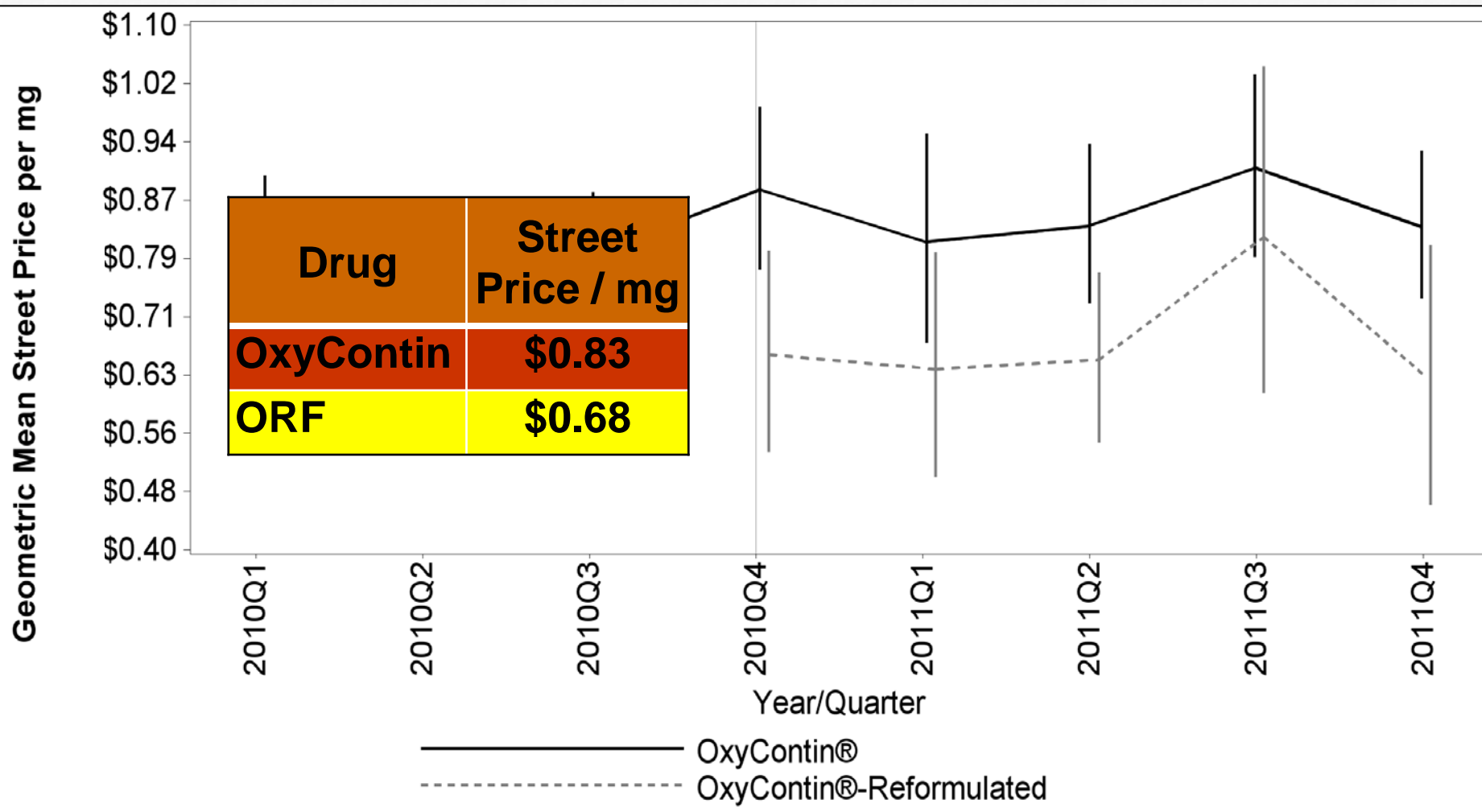
Drug Diversion Program

Population Rate for OxyContin (2008 Q4 - 2011 Q4)



Drug Diversion Program

OxyContin Street Price (2010 Q1 - 2011 Q4)



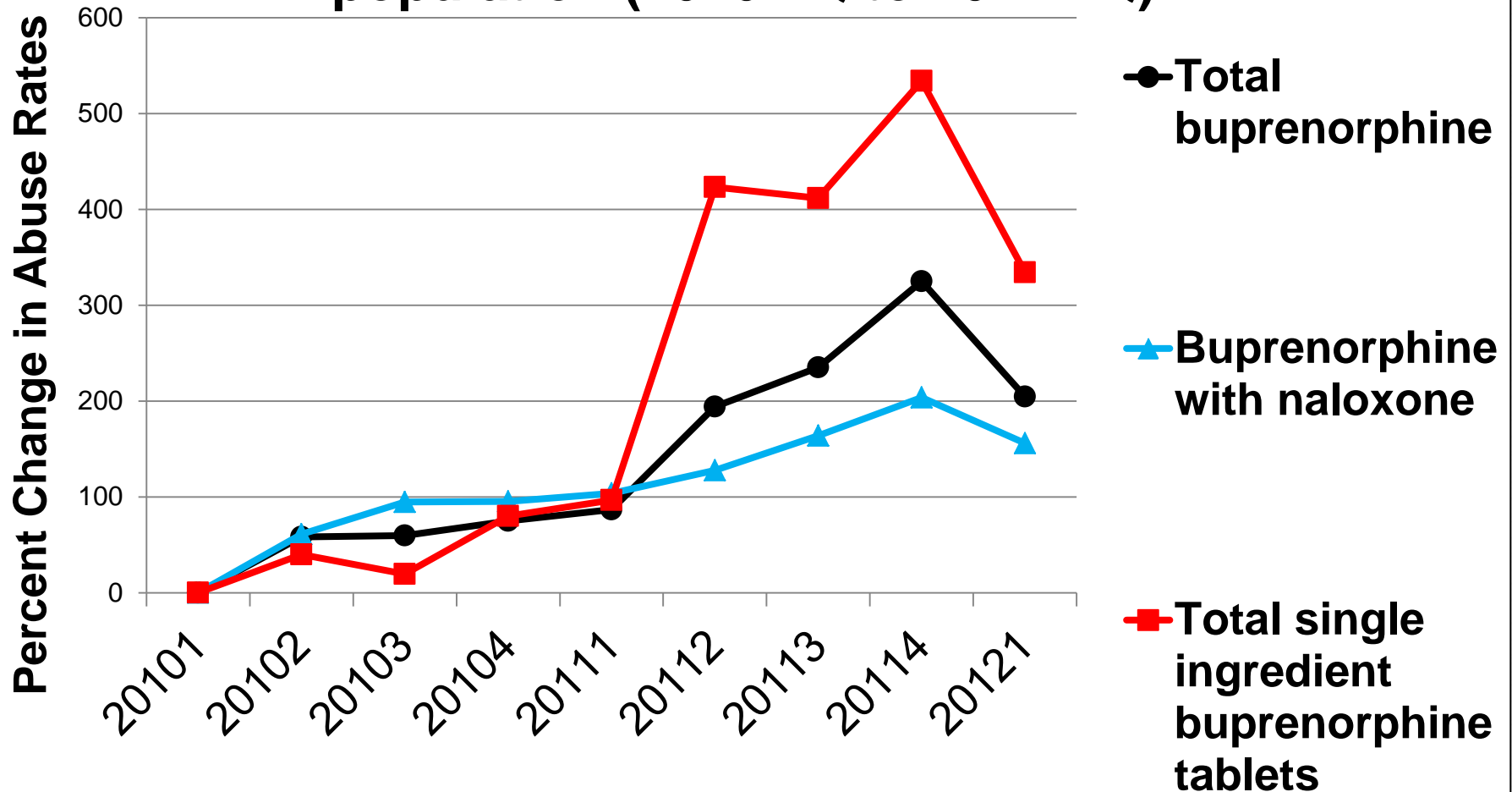
REMS Evaluation

- Class-wide REMS
 - Measuring active pharmaceutical ingredient (API) level data
 - Indicative of overall trends for a class of drugs
 - NOT indicative of contributions of different formulations, routes or platforms



The RADARS® System SKIP Program

Percent Change in Abuse Rates per 100,000 population (2010 1Q to 2012 1Q)



Key Elements of the RADARS System

- 11 years of data
 - Maximum lag: 3 months
- Multifaceted (“mosaic”) approach
 - Diversion & illicit sale
 - Misuse/Abuse/Addiction/Overdose
 - Medical outcomes
- Product & Geographic Specificity
 - National coverage of over 120 products
- Valuable system for surveillance and REMS evaluation

