

RADARS® System

Abuse Deterrent Formulations (ADFs) Analyses

***CDC/PCF Meeting on Drug Reformulation
February 21, 2012***

Jody Green, PhD
Director of Research - RMPDC



Discussion Objectives

- Introduction of RADARS® System
- Present OxyContin® ADF Analysis
 - Provide details for each of the RADARS System programs
 - Show the latest signal detections for OxyContin in specific programs



RADARS® System Background

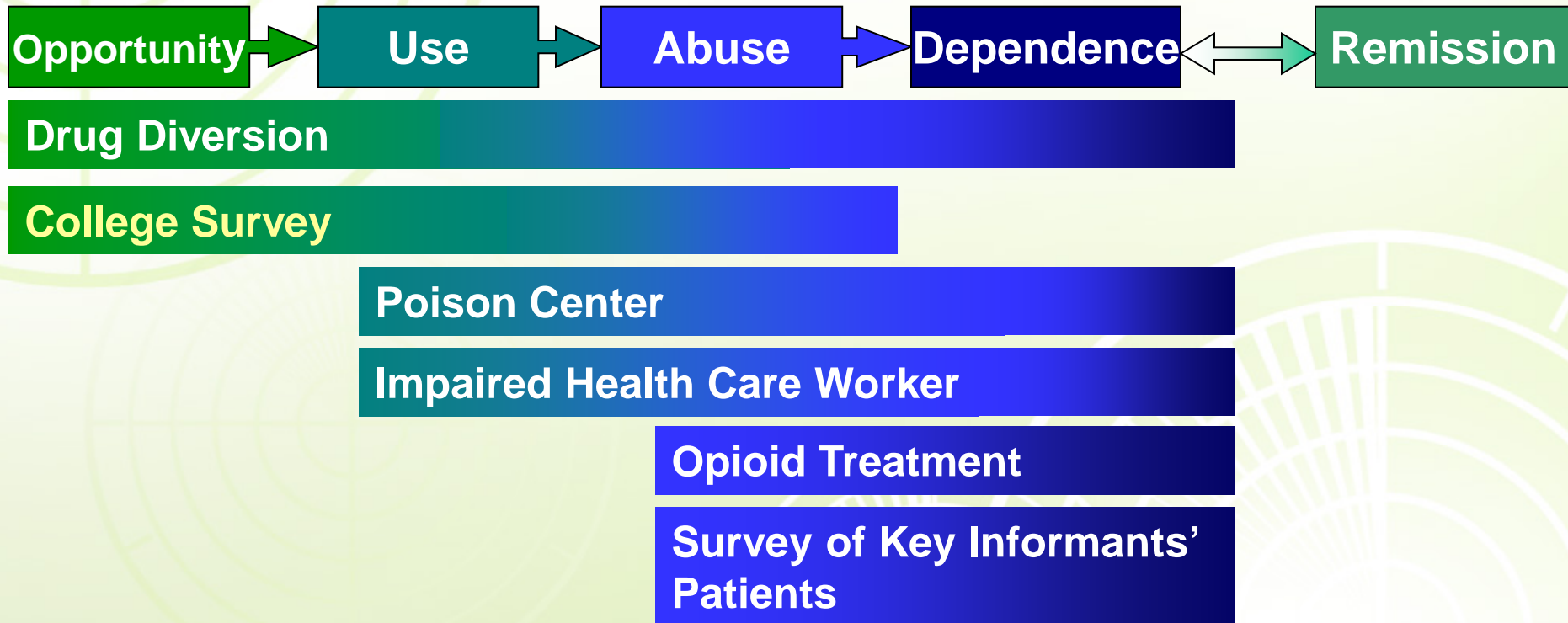
What is the RADARS® System?

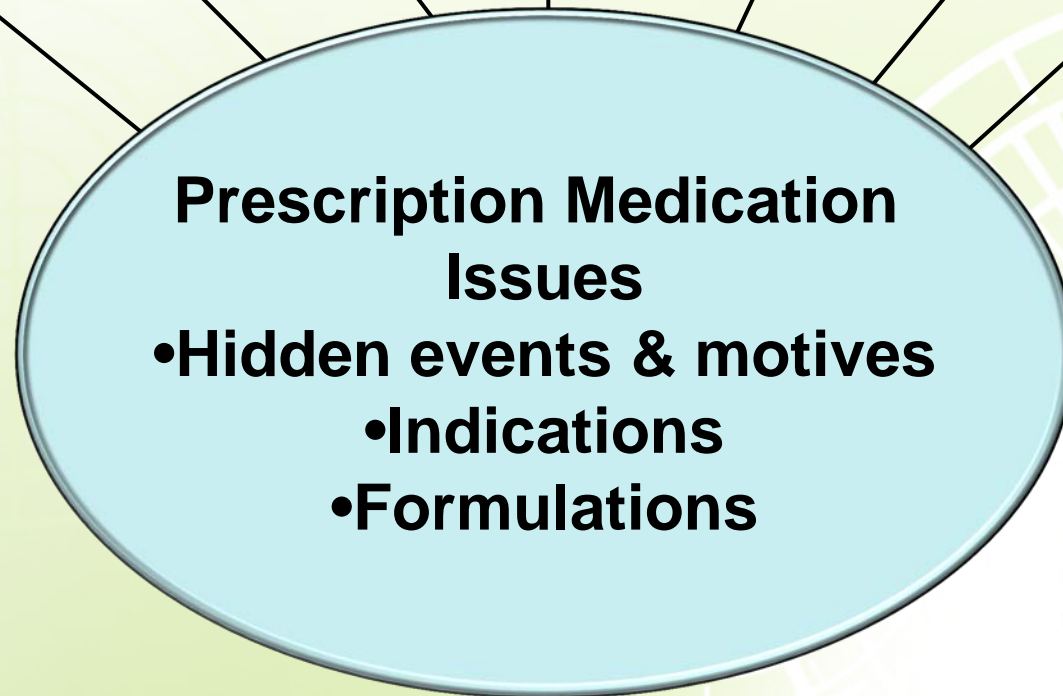
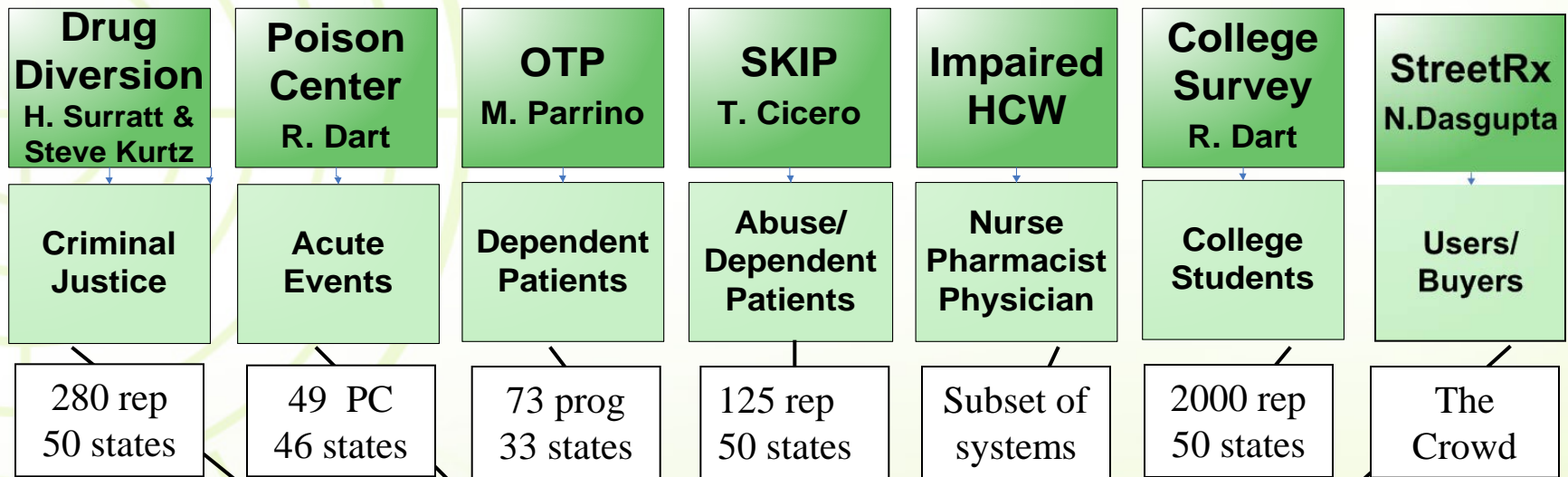
- History of the RADARS® System
 - Purdue Pharma, L.P. 2002
 - Transfer to Denver Health and Hospital Authority, 2006
 - Independent program
 - Denver Public Safety Net Hospital for 150 years
 - State sanctioned independent authority
 - Top community health program in the country
 - Among most influential health care leader
 - Financially stable

RADARS[®] System Goals

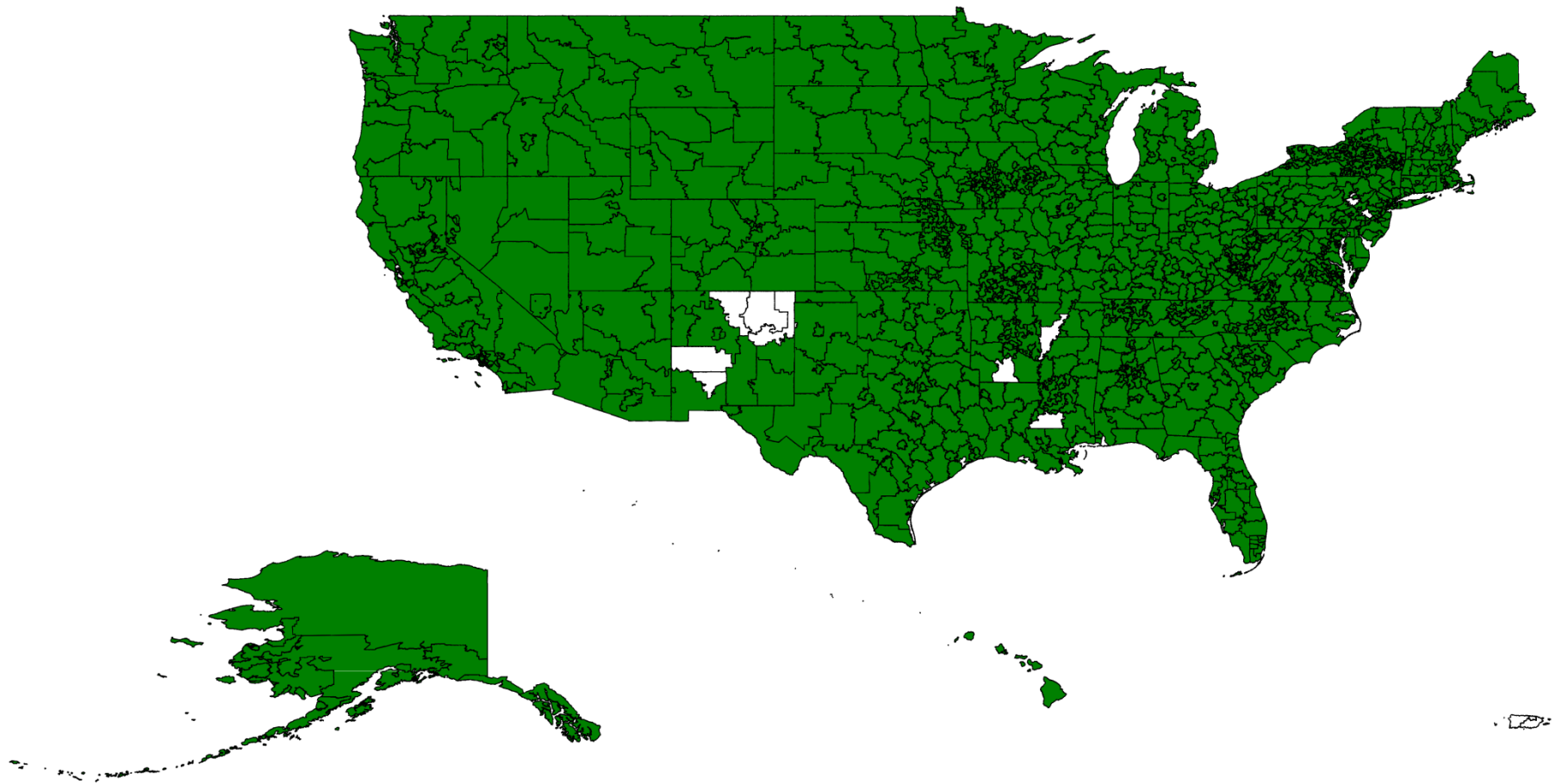
- Identify sentinel events involving the misuse, abuse and diversion of prescription drugs nationwide
- Measure rates of misuse, abuse and diversion of prescription drugs
- Provide experienced and expert analysis and interpretation of the data

Drug Dependence Pathway





3DZs covered by at least one RADARS System during the 3rd Quarter of 2011

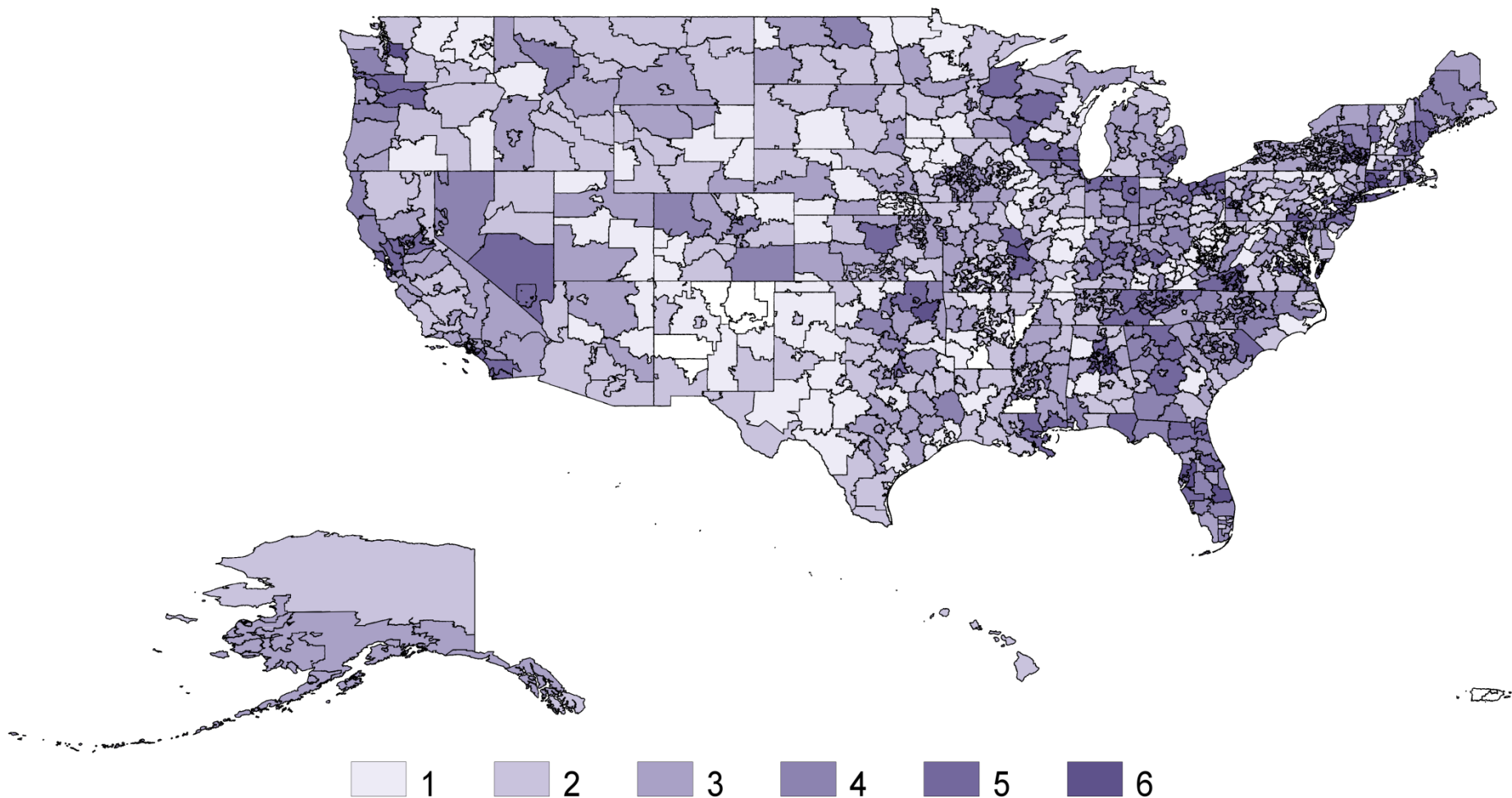


Covered by a RADARS Program



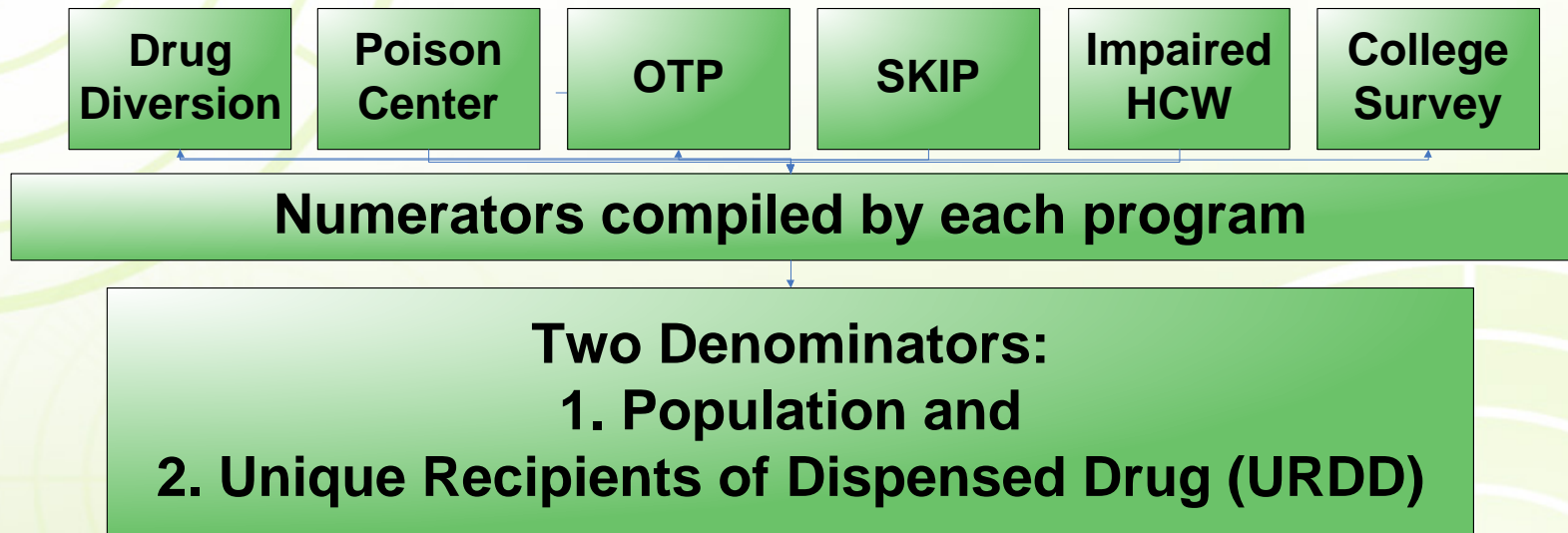
Covered by survey

Number of systems covering each 3DZ in the United States during the 3rd Quarter of 2011



RADARS® System Process

Adding the Denominator



Tale of Two Denominators

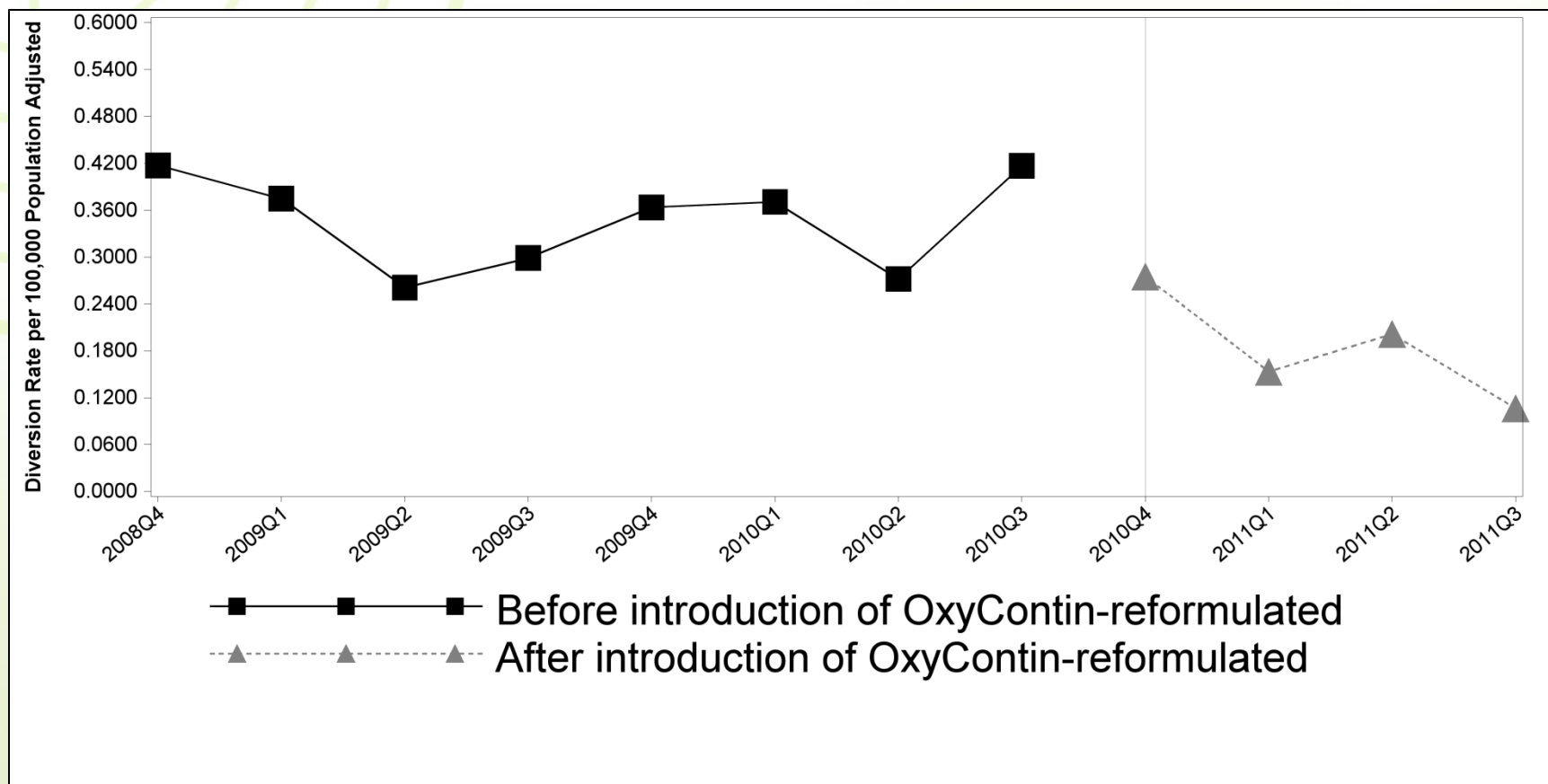
- **Population**
 - Tried and true - Disease burden on whole population
 - Does not account for drug availability
- **Unique Recipients of Dispensed Drug (URDD)**
 - Number of unique people filling prescription for drug
 - Accounts for availability of drug in community
 - Relates events to corresponding patient benefit
 - Alternatives – pill count, total mgs of drug

RADARS® System Individual Program OxyContin ADF Analysis

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**
 - 3 months

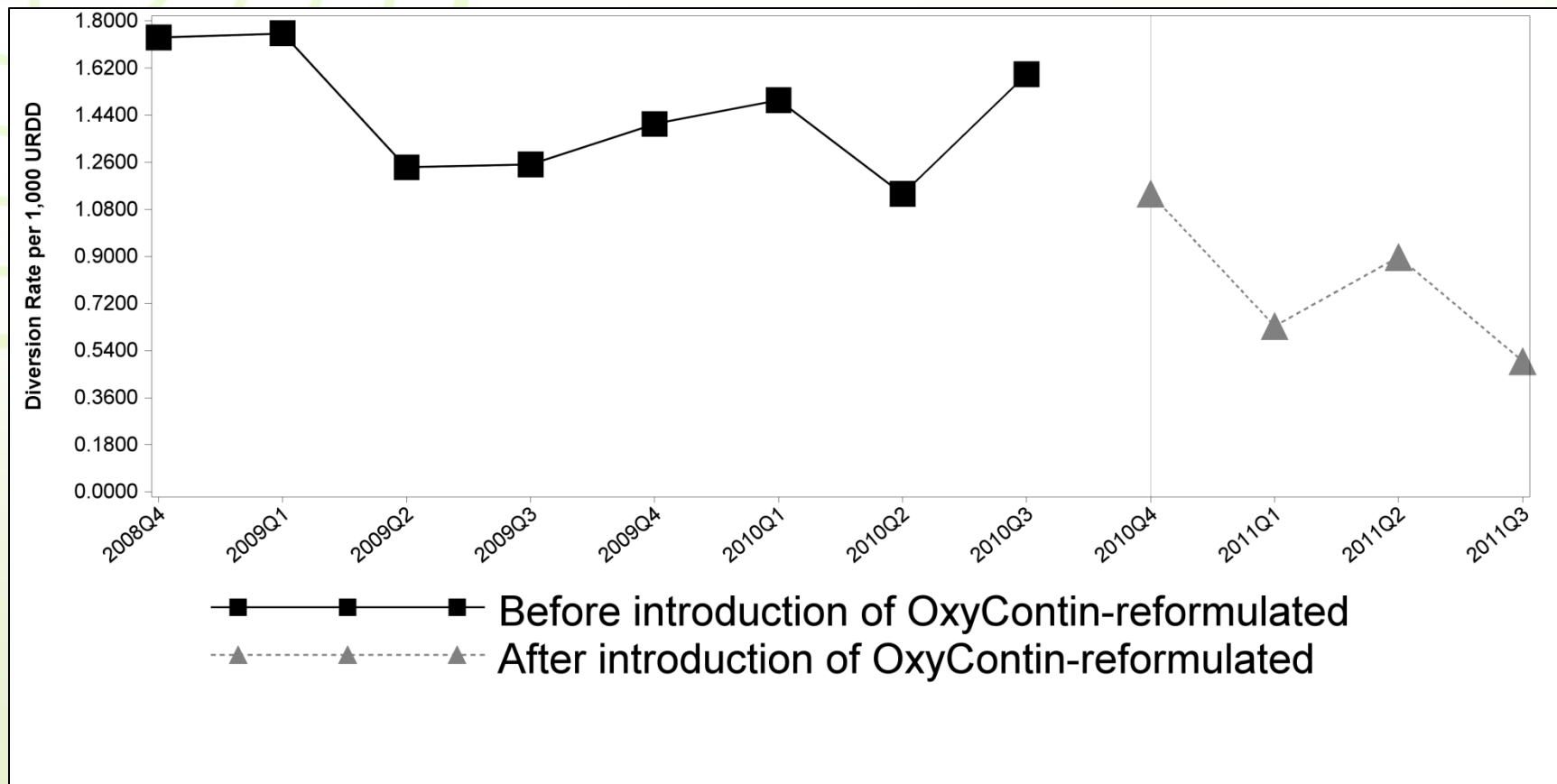
The RADARS® System Drug Diversion Program – Diversion Population rate for OxyContin 2008 Q4 through 2011 Q3 by time period



The RADARS® System Drug Diversion Program – Diversion Population rate for OxyContin 2008 Q4 through 2011 Q3 by time period

Drug	Adjusted Population Rate before ORF transition	Adjusted Population Rate after ORF transition	Percent change in Rates (95% CI)	p-value for change	p-value for difference from OxyContin change
OxyContin	0.3394	0.1789	-47.27% (-51.02% to -43.24%)	<.0001	.
Other prescription opioids	2.7284	2.6796	-1.79% (-3.79% to 0.26%)	0.0862	<.0001

The RADARS® System Drug Diversion Program – Diversion URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period

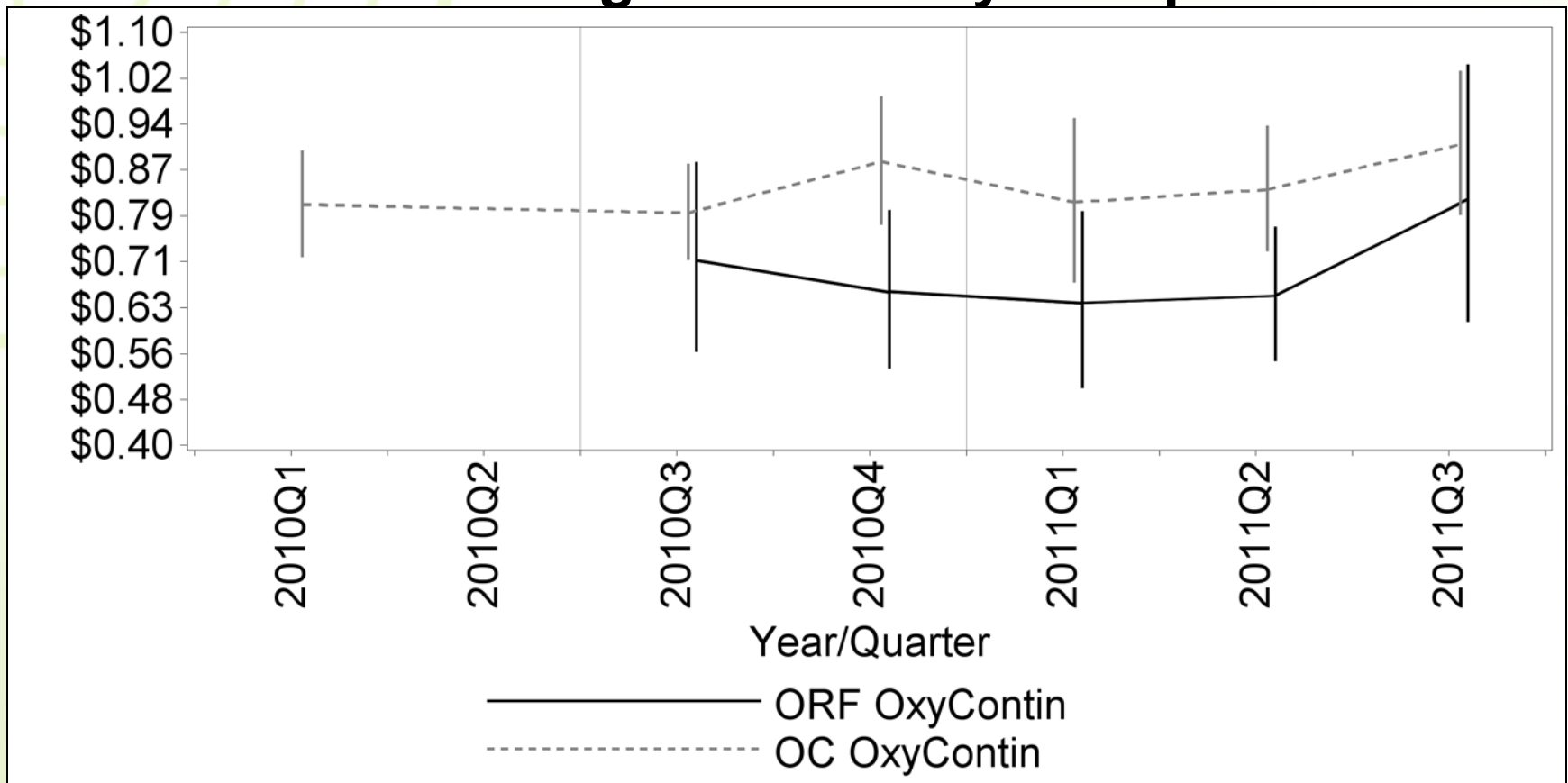


The RADARS® System Drug Diversion Program – Diversion URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period

Drug	URDD Rate before ORF transition	URDD Rate after ORF transition	Percent change in Rates (95% CI)	p-value for change	p-value for difference from OxyContin change
OxyContin	1.4277	0.7806	-45.33% (-49.21% to -41.15%)	<.0001	.
Other prescription opioids	0.2564	0.2284	-10.93% (-12.75% to -9.07%)	<.0001	<.0001

The RADARS® System Street Price Program – Geometric mean street price for OxyContin by formulation

2010 Q1 through 2011 Q3 by time period



The RADARS® System Street Price Program – Geometric mean street price for OxyContin by formulation 2010 Q1 through 2011 Q3 by time period

Drug	Geometric Mean(95% CI)	Ratio of Geometric Mean to ORF (95% CI)	p-value for Ratio of Geometric Means to ORF
OxyContin Reformulated	\$0.68 (\$0.62 to \$0.75)		
OxyContin	\$0.83 (\$0.78 to \$0.89)	-18.48% (-8.61% to -27.29%)	0.0005

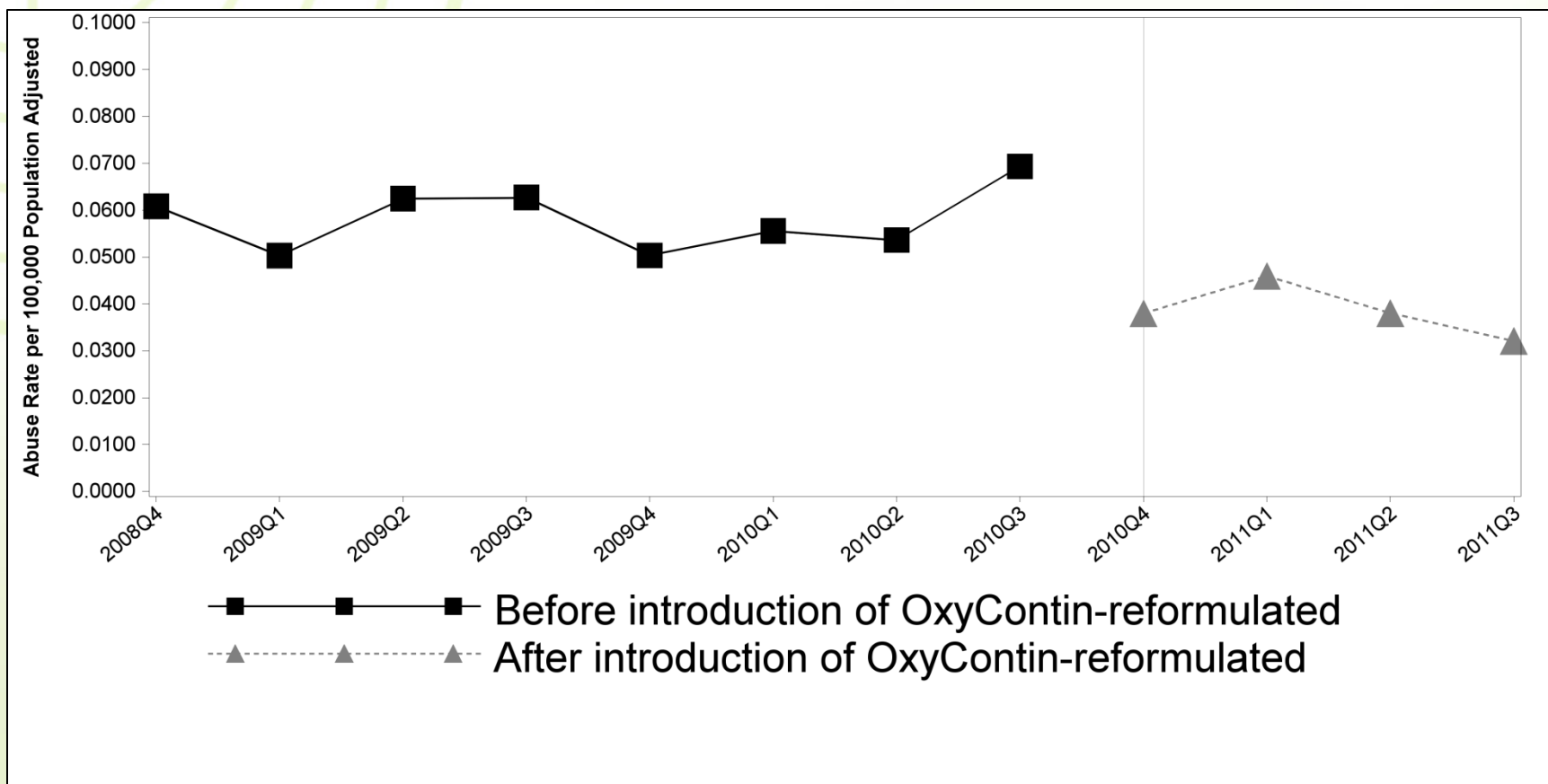
Drug Diversion Summary

- Pre- and Post-ORF analysis of shows significant decreases in diversion rates
 - Percent decrease in abuse rates for ORF much larger than abuse rates for other prescription opioids
- Street Price for ORF dropped 18.5% compared to original OC
 - \$0.15 less per milligram
 - Indicates less demand for ORF on the street

Poison Center (PC)

- **Population**
 - young children, adolescents, young adults, adults, elderly
- **Definition/Type of Cases**
 - Spontaneous reports of intentional exposure mentions of acute medical events associated with one or more prescription drug of interest
- **Coverage**
 - 49 of 57 poison centers
- **Reporting Timeframe**
 - weekly

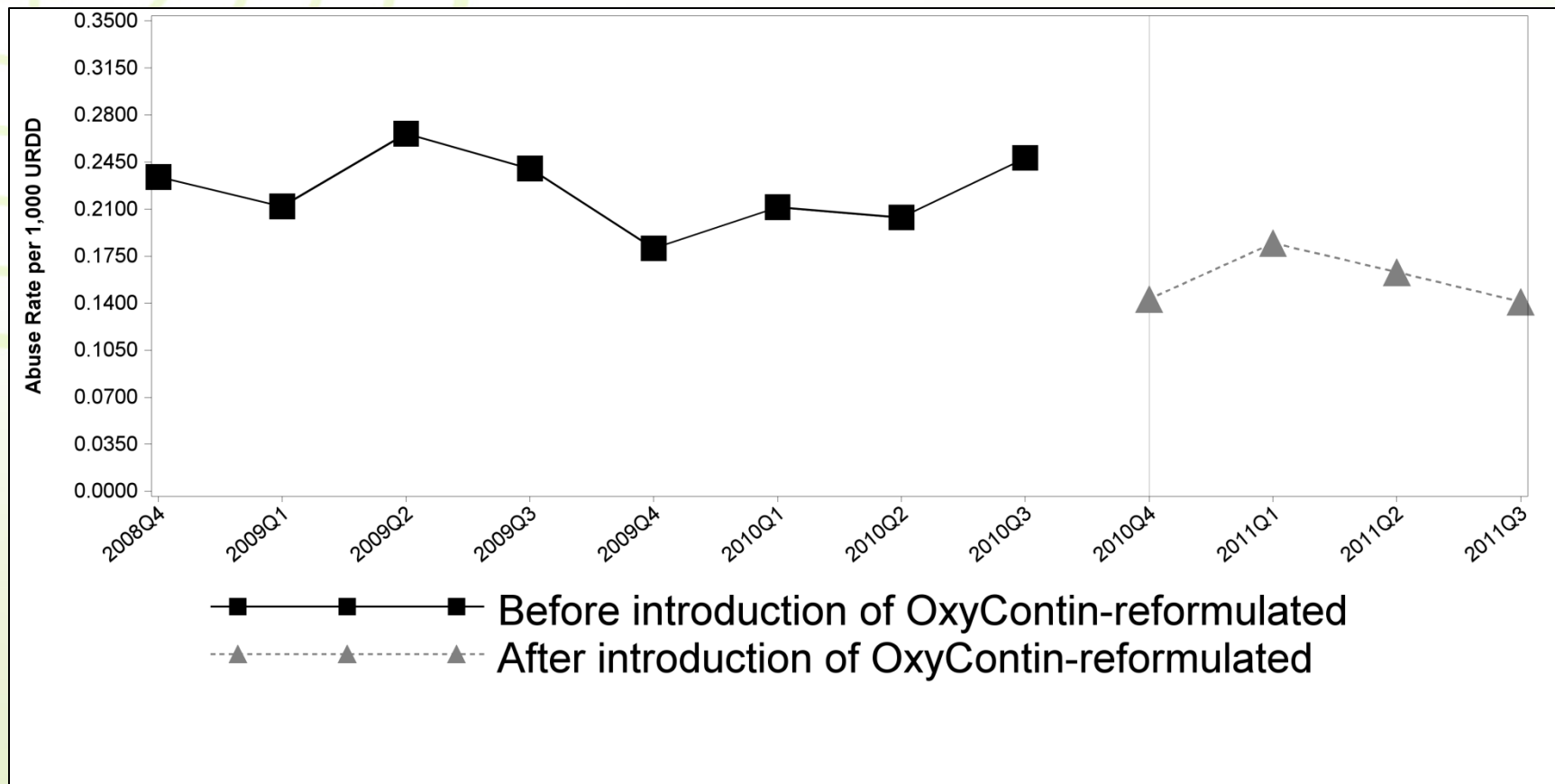
The RADARS® System Poison Center Program – Intentional Abuse Population rate for OxyContin 2008 Q4 through 2011 Q3 by time period



The RADARS® System Poison Center Program – Intentional Abuse Population rate for OxyContin 2008 Q4 through 2011 Q3 by time period

Drug	Adjusted Population Rate before ORF transition	Adjusted Population Rate after ORF transition	Percent change in Rates (95% CI)	p-value for change	p-value for difference from OxyContin change
OxyContin	0.0582	0.0384	-33.92% (-40.88% to -26.14%)	<.0001	.
Other prescription opioids	0.5434	0.5378	-1.02% (-4.10% to 2.15%)	0.5225	<.0001

The RADARS® System Poison Center Program – Intentional Abuse URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period



The RADARS® System Poison Center Program – Intentional Abuse URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period

Drug	URDD Rate before ORF transition	URDD Rate after ORF transition	Percent change in Rates (95% CI)	p-value for change	p-value for difference from OxyContin change
OxyContin	0.2240	0.1578	-29.53% (-36.96% to -21.24%)	<.0001	.
Other prescription opioids	0.0490	0.0443	-9.59% (-12.40% to -6.69%)	<.0001	<.0001

Poison Center Summary

- Pre- and Post-ORF analysis of shows significant decreases in intentional abuse rates.
 - Percent decrease in abuse rates for ORF much larger than abuse rates for other prescription opioids
- RADARS System data current through 3rd Quarter of 2011
 - Provided updated assessment of ORF intervention more rapidly than any other prescription drug abuse data set

Opioid Treatment Program (OTP)

- **Population**

- Opioid dependent persons seeking treatment at public and private opioid treatment programs

- **Definition/Type of Cases**

- Self-reported use of prescription or illicit opioids to “get high” in the past 30 days

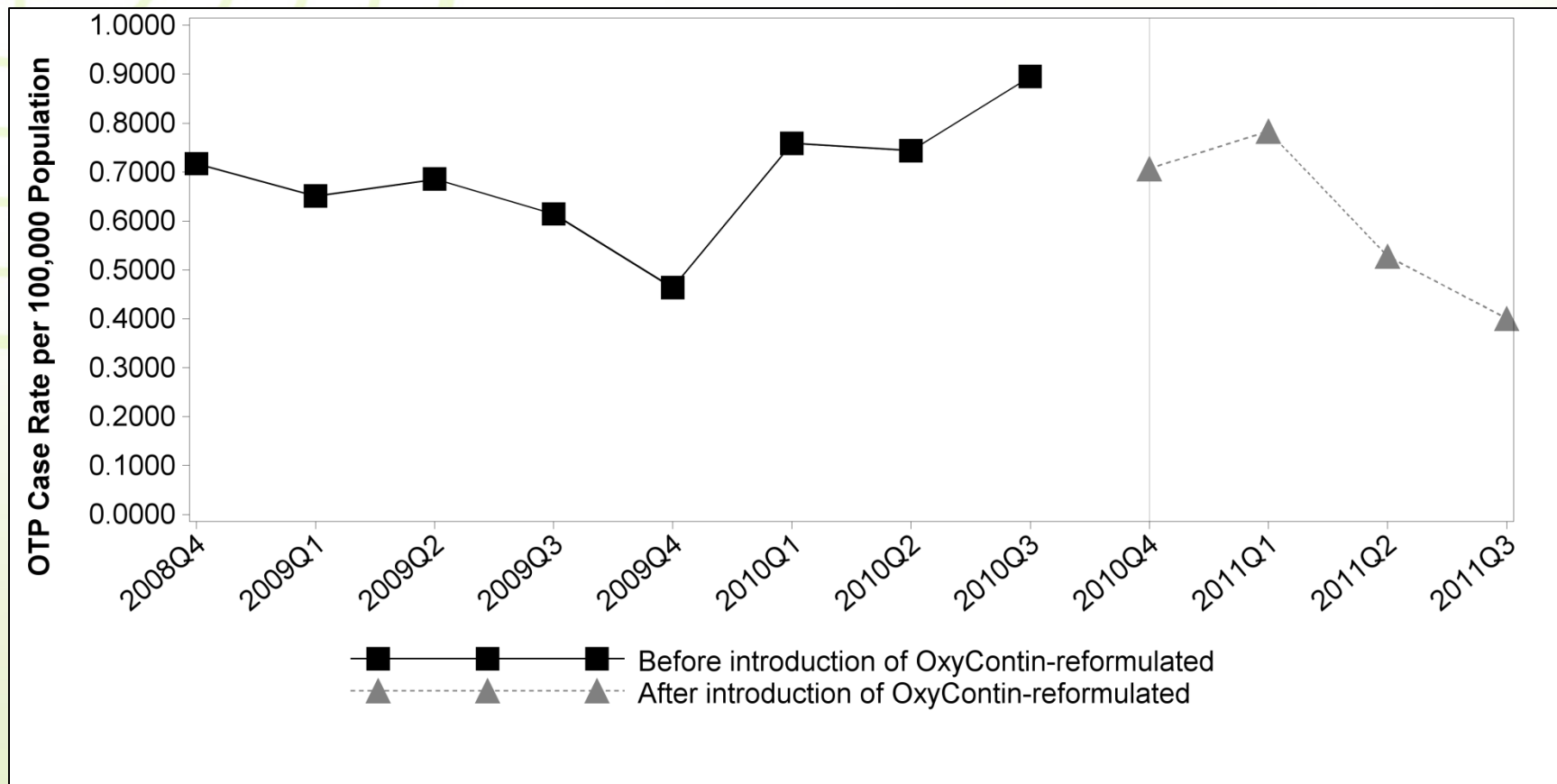
- **Coverage**

- 73 programs from 33 states and 29,594 questionnaire responders

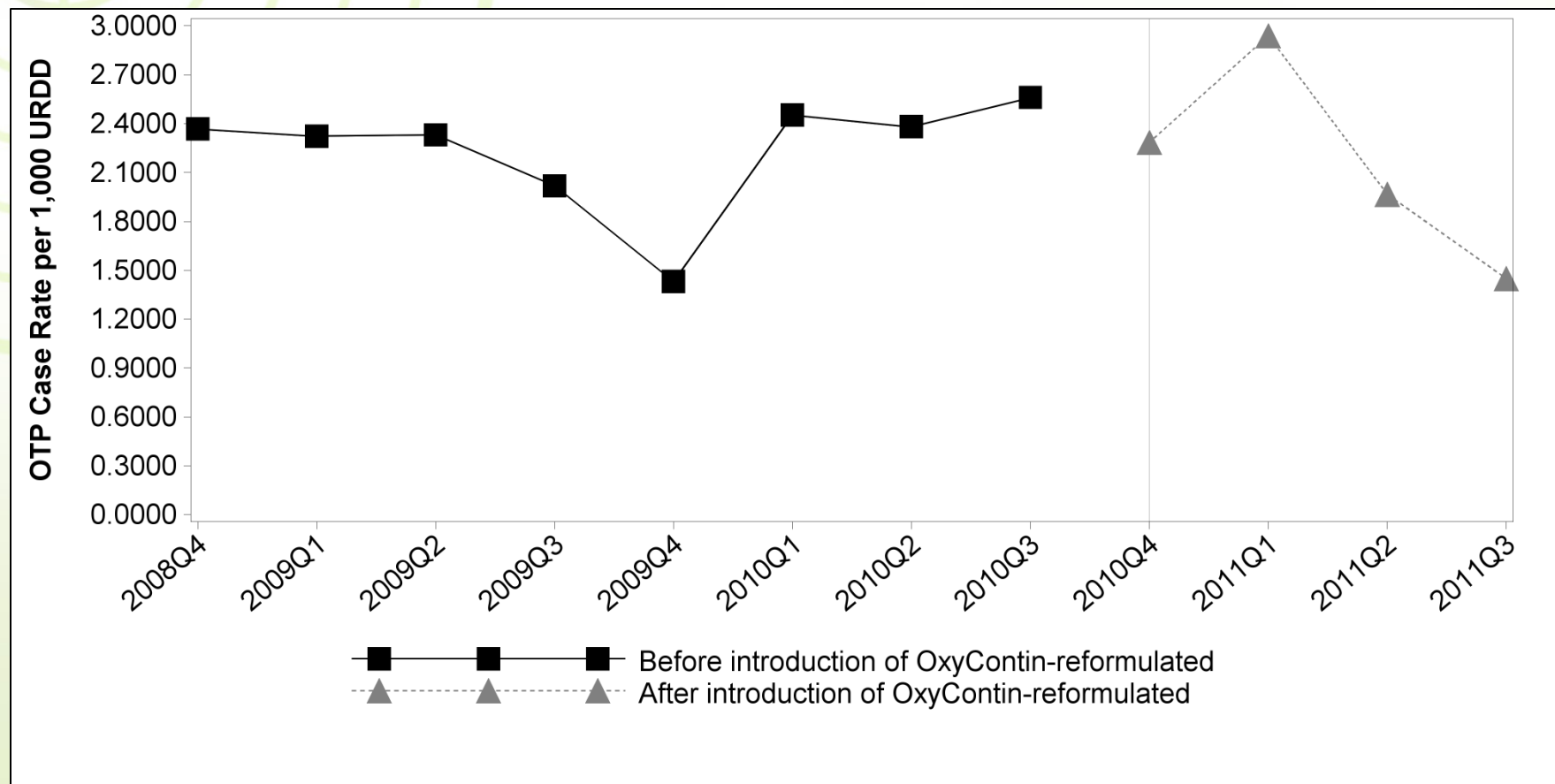
- **Reporting Timeframe**

- weekly

The RADARS® System Opioid Treatment Program – Population rate for OxyContin 2008 Q4 through 2011 Q3 by time period



The RADARS® System Opioid Treatment Program – URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period



Survey of Key Informant's Patients (SKIP)

- **Population**

- Opioid dependent persons seeking treatment at primarily private substance abuse treatment programs

- **Definition/Type of Cases**

- Self-reported use of prescription or illicit opioids to “get high” in the past 30 days

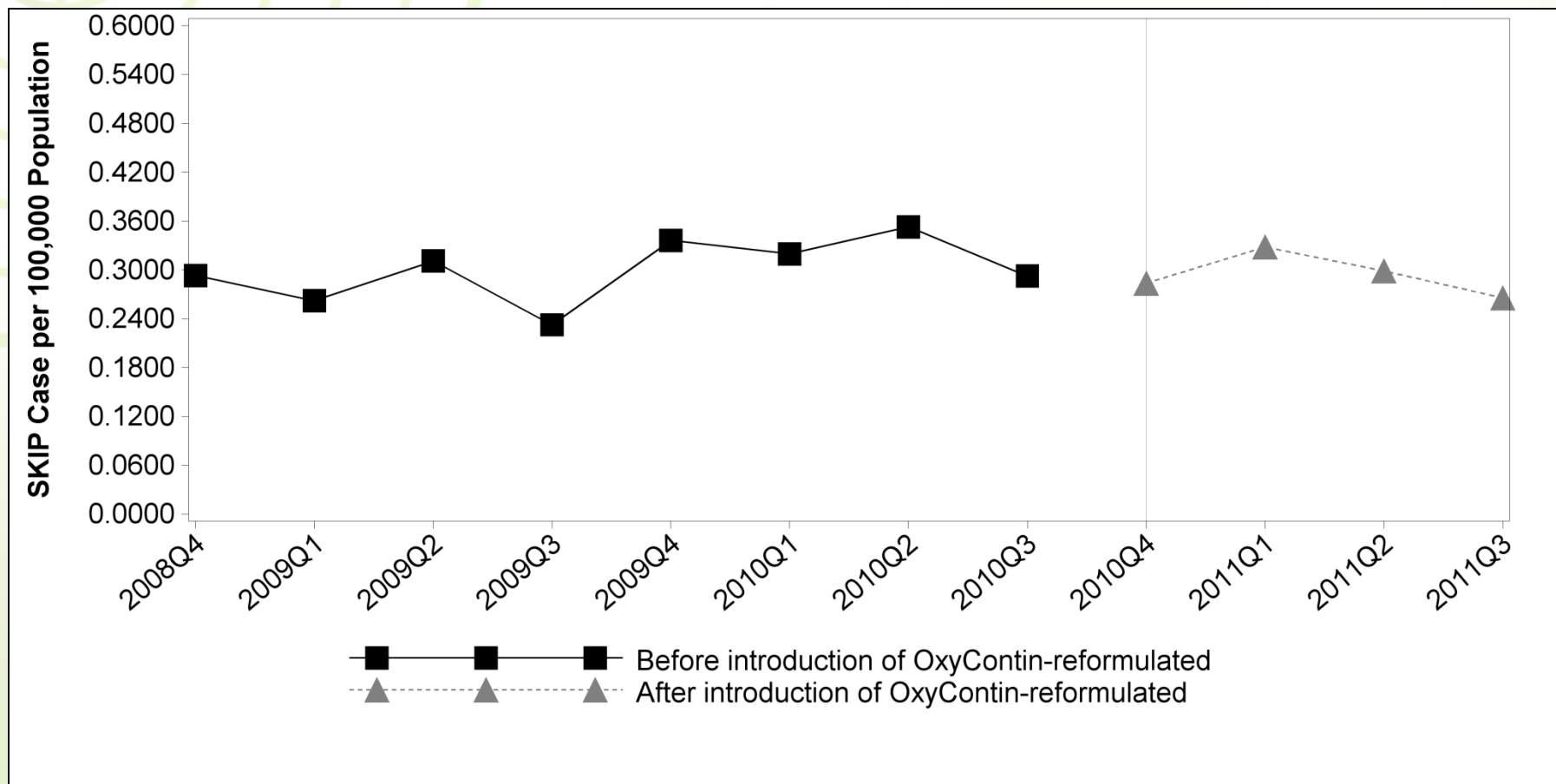
- **Coverage**

- 125 Informants yielding 2,760 questionnaire responders from 50 states

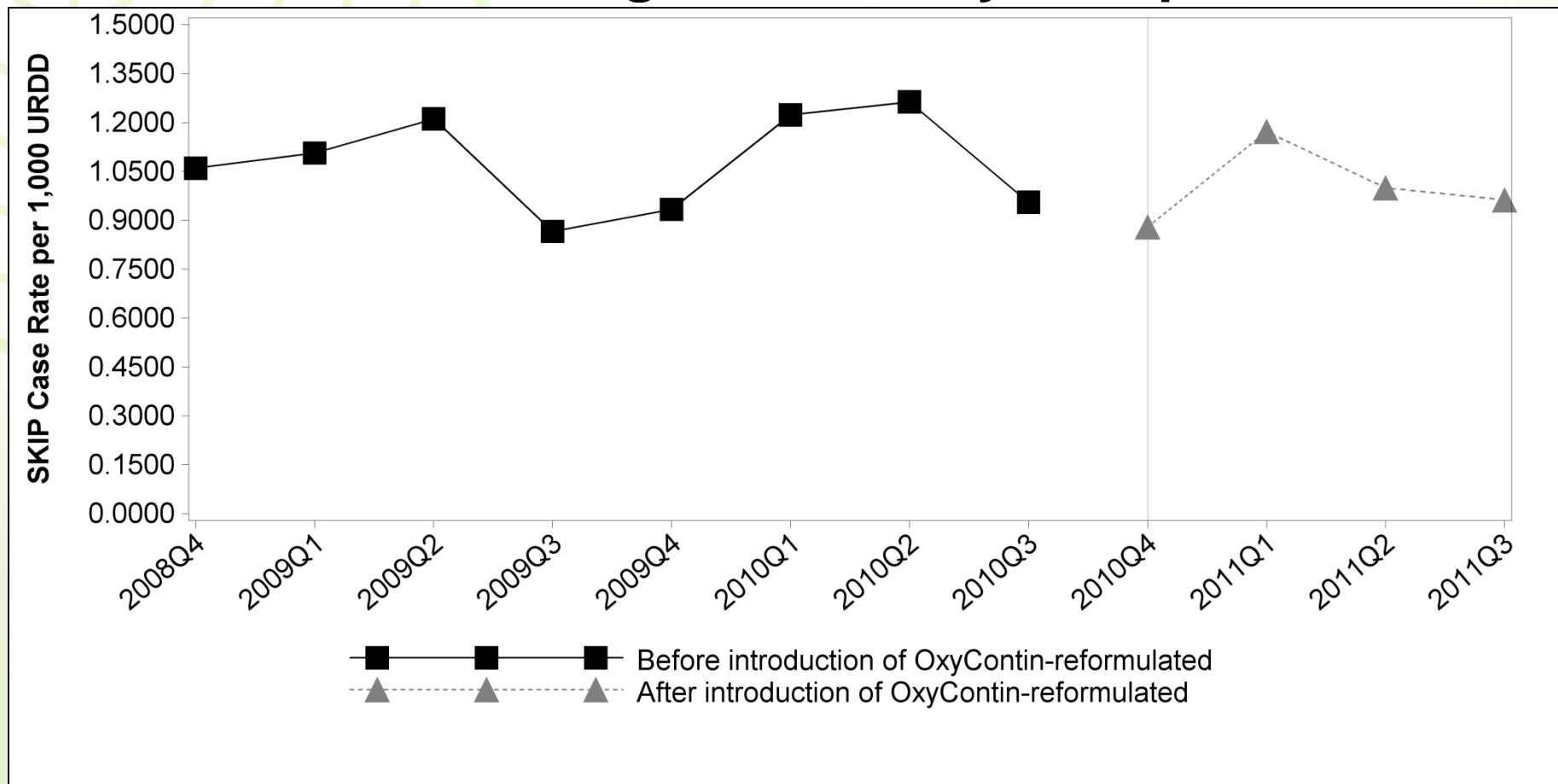
- **Reporting Timeframe**

- weekly

The RADARS® System Survey of Key Informants' Patients – Population rate for OxyContin 2008 Q4 through 2011 Q3 by time period



The RADARS® System Survey of Key Informants' Patients – URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period



College Survey

- **Population**
 - College students (traditional and non-traditional)
- **Definition/Type of Cases**
 - Self-reported nonmedical use of prescription drugs in previous semester
- **Coverage**
 - Approximately 2,000 questionnaire responders from 50 states each semester/summer
- **Reporting Timeframe**
 - Fall Semester / Spring Semester / Summer

RADARS® System Summary

- 10 years of data
- Capture data on multiple facets of drug abuse (mosaic)
- Product Specificity – over 150 drugs of interest
- Geographic specificity
- Quality assurance
- Offer comparator data to other prescription opioids over the same period of time
- Provide data that are timely and comprehensive

Questions?