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

Opportunity → Use → Abuse → Dependence → Remission

Drug Diversion

College Survey

Poison Center

Impaired Health Care Worker

Opioid Treatment

Survey of Key Informants’ Patients

Prescription Medication Issues
• Hidden events & motives
• Indications
• Formulations
Number of systems covering each 3DZ in the United States during the 3rd Quarter of 2011.
RADARS® System Process
Adding the Denominator

Numerators compiled by each program

Two Denominators:
1. Population and
2. Unique Recipients of Dispensed Drug (URDD)
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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adjusted Population Rate before ORF transition</th>
<th>Adjusted Population Rate after ORF transition</th>
<th>Percent change in Rates (95% CI)</th>
<th>p-value for change</th>
<th>p-value for difference from OxyContin change</th>
</tr>
</thead>
<tbody>
<tr>
<td>OxyContin</td>
<td>0.3394</td>
<td>0.1789</td>
<td>-47.27% (-51.02% to -43.24%)</td>
<td>&lt;.0001</td>
<td></td>
</tr>
<tr>
<td>Other prescription opioids</td>
<td>2.7284</td>
<td>2.6796</td>
<td>-1.79% (-3.79% to 0.26%)</td>
<td>0.0862</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>
The RADARS® System Drug Diversion Program – Diversion URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period

Before introduction of OxyContin-reformulated

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

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<th>Drug</th>
<th>URDD Rate before ORF transition</th>
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<tr>
<td>OxyContin</td>
<td>1.4277</td>
<td>0.7806</td>
<td>-45.33% (-49.21% to -41.15%)</td>
<td>&lt;.0001</td>
<td></td>
</tr>
<tr>
<td>Other prescription opioids</td>
<td>0.2564</td>
<td>0.2284</td>
<td>-10.93% (-12.75% to -9.07%)</td>
<td>&lt;.0001</td>
<td>&lt;.0001</td>
</tr>
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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

<table>
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<tr>
<th>Drug</th>
<th>Geometric Mean (95% CI)</th>
<th>Ratio of Geometric Mean to ORF (95% CI)</th>
<th>p-value for Ratio of Geometric Means to ORF</th>
</tr>
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<tr>
<td>OxyContin</td>
<td>$0.68</td>
<td>-18.48%</td>
<td>0.0005</td>
</tr>
<tr>
<td>Reformulated</td>
<td>($0.62 to $0.75)</td>
<td>( -8.61% to -27.29%)</td>
<td></td>
</tr>
<tr>
<td>OxyContin</td>
<td>$0.83</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>($0.78 to $0.89)</td>
<td>( -8.61% to -27.29%)</td>
<td></td>
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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

![Graph showing Abuse Rate per 100,000 Population Adjusted]

- **Before introduction of OxyContin-reformulated**
- **After introduction of OxyContin-reformulated**
The RADARS® System Poison Center Program – Intentional Abuse Population rate for OxyContin 2008 Q4 through 2011 Q3 by time period

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<tr>
<td>OxyContin</td>
<td>0.0582</td>
<td>0.0384</td>
<td>-33.92% (-40.88% to -26.14%)</td>
<td>&lt;.0001</td>
<td></td>
</tr>
<tr>
<td>Other prescription opioids</td>
<td>0.5434</td>
<td>0.5378</td>
<td>-1.02% (-4.10% to 2.15%)</td>
<td>0.5225</td>
<td>&lt;.0001</td>
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The RADARS® System Poison Center Program – Intentional Abuse URDD rate for OxyContin 2008 Q4 through 2011 Q3 by time period

Before introduction of OxyContin-reformulated

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

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<tr>
<td>OxyContin</td>
<td>0.2240</td>
<td>0.1578</td>
<td>-29.53% (−36.96% to −21.24%)</td>
<td>&lt;.0001</td>
<td></td>
</tr>
<tr>
<td>Other prescription opioids</td>
<td>0.0490</td>
<td>0.0443</td>
<td>-9.59% (−12.40% to −6.69%)</td>
<td>&lt;.0001</td>
<td>&lt;.0001</td>
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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

- Before introduction of OxyContin-reformulated
- After introduction of OxyContin-reformulated
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

- Before introduction of OxyContin-reformulated
- After introduction of OxyContin-reformulated
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?