



In This Issue

Coming Up: The Annual RADARS[®] System Scientific Meeting

Opioid Labeling Panel

Ranking by State

RADARS System Goes Social!

RADARS System Quarterly Technical Report

Denver Health Employee of the Month - Kimberly Brown!

Recent RADARS System Publications and Presentations

Conferences Attended

Contact Information

Mission Statement

RMPDC and DHHA

Did You Know?

On January 24-25, 2013, the FDA held an Advisory Committee Meeting in which a panel voted 19-10 to place Vicodin[®] and other hydrocodone products under greater restrictions.

Coming Up: The Annual RADARS[®] System Scientific Meeting

Please join us for the 7th Annual RADARS[®] System Scientific Meeting on April 18th, 2013 to be held at the Hilton Washington D.C./Rockville. The theme for this year's meeting is "Formulating a Solution to Misuse and Abuse" and will focus on the impact of abuse- and tamper-deterrent formulations from a variety of perspectives. Complete 2012 RADARS System data will be presented including an in-depth look at recent pre- and post-abuse deterrent trend analyses covering multiple products. In-depth commentary on the latest draft guidance for industry issued by the FDA regarding abuse-deterrent opioid evaluation and labeling will be offered.

In addition, leaders in the fields of drug diversion, pain management, opioid dependence treatment, pharmacoeconomics and prescription drug surveillance will provide insight into the impact (positive or negative) of these technologies in their areas of expertise.

Featured talks to include:

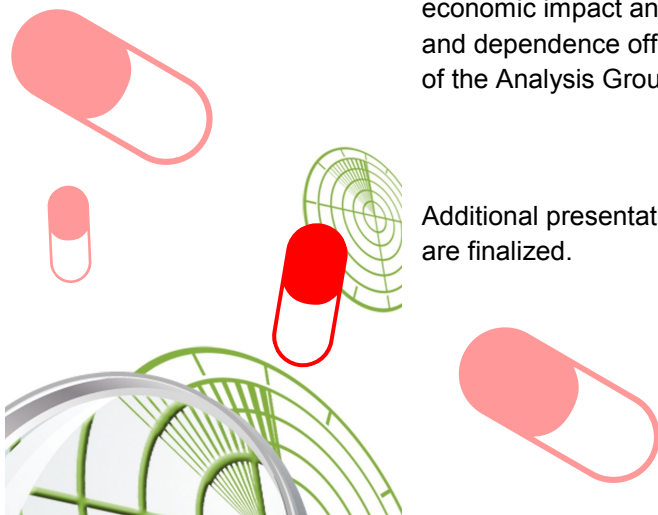
A clinician's perspective on reducing tampering and subsequent abuse of long-acting opioids offered by Dr. Steven P. Stanos, Medical Director of the Center for Pain Management at the Rehabilitation Institute of Chicago and Assistant Professor at the Feinberg School of Medicine at Northwestern University in Chicago, Illinois.



A managed care perspective on opioid abuse detailing the economic impact and societal costs of opioid misuse, abuse and dependence offered by Dr. Alan G. White, Vice President of the Analysis Group in Boston, Massachusetts.



Additional presentations to be added to the agenda as speakers are finalized.



Opioid Labeling Panel

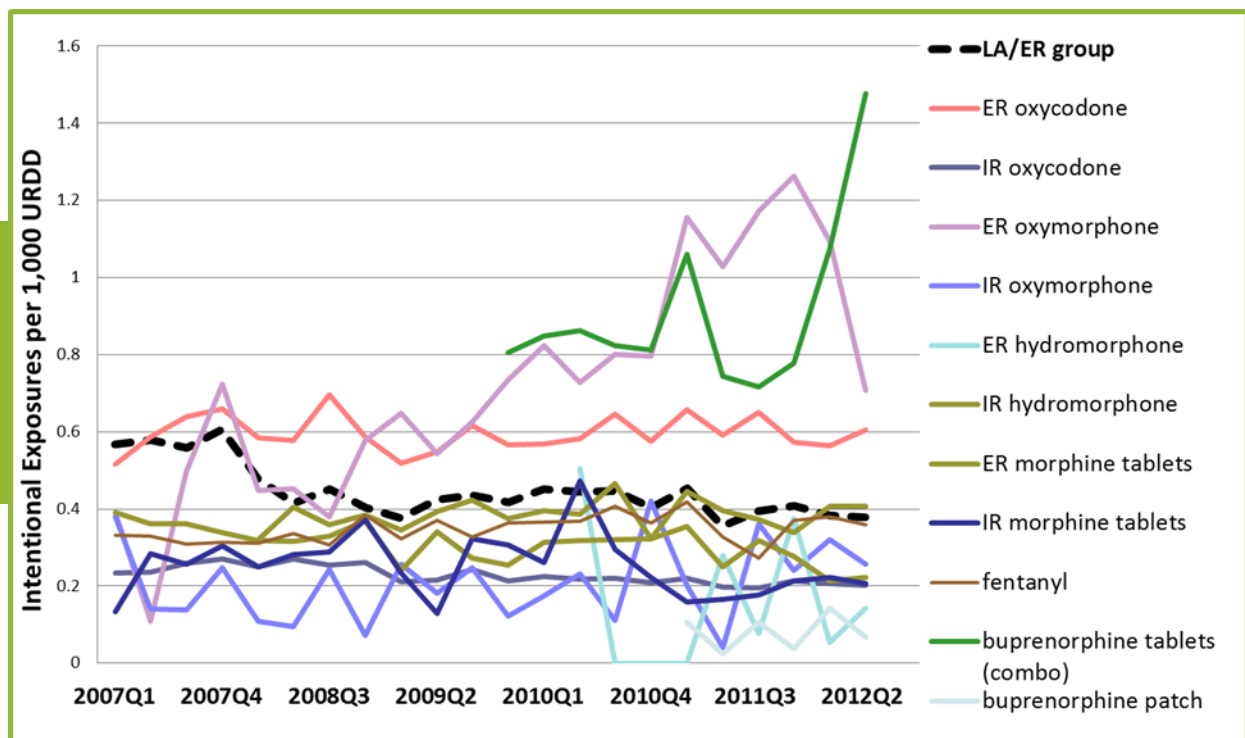
On February 7-8, 2013, the FDA held the following public meeting “Impact of Approved Drug Labeling on Chronic Opioid Therapy Part 15” to obtain information, particularly scientific evidence, such as study data or peer-reviewed analyses, on issues pertaining to the use of opioid drugs in the treatment of chronic pain. This hearing was, in part, to discuss a Citizen’s Petition submitted by Physicians for Responsible Opioid Prescribing (PROP) on July 25, 2012 to make opioid labeling more restrictive. The citizen’s petition requested 3 specific actions:

1. Strike the term “moderate” from the indication for non-cancer pain.
2. Add a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain.
3. Add a maximum duration of 90-days for continuous (daily) use for non-cancer pain.

Dr. Jody Green, PhD (Director of Research Administration, RMPDC) presented “Impact of Approved Drug Labeling on Chronic Opioid Therapy: RADARS® System Findings” for the panel. She presented the following 3 key points:

1. All prescription opioids are abused, both long-acting extended-release and immediate-release
2. Abuse and diversion of specific products has been reduced with abuse deterrent formulations
3. Proposed prescription limits must ensure continued access to these important therapies for legitimate pain patients

This chart illustrates the disparity in intentional exposure rates reported to the RADARS system poison centers, after accounting for drug availability. The heavy black dotted line is the LA/ER opioid group. You see many other opioid groups above and



A webcast of the meeting can be found on the FDA website:

<http://www.fda.gov/Drugs/NewsEvents/ucm326450.htm>

Ranking by State

Which states are most at risk for abuse, misuse and/or diversion based on prescription and/or exposure trends? RADARS System data can help identify the top “at risk” states. Presented below are the top five “at risk” states based on three different analyses:

- (1) URDD Prescriptions Filled = Unique Recipient of Dispensed Drug (URDD) per 100 Population: number of individual opioid prescriptions filled (excluding refills), calculated with data from IMS and 2010 US Census data.
- (2) Population Rate Intentional Abuse Exposures = Intentional exposures* reported to RADARS System Poison Centers per 100,000 persons, calculated with 2010 US Census data.
- (3) URDD Intentional Abuse Exposures = Intentional exposures* reported to RADARS System Poison Centers per 1000 persons based on individual prescriptions for opioids (excludes refills), calculated with data from IMS and 2010 US Census data.

Rank	URDD Prescriptions Filled		Pop. Rate Intentional Abuse Exposures		URDD Intentional Exposures	
1	TN	24.29	WV	8.62	SD	0.59
2	WV	23.89	SD	6.27	MN	0.56
3	AL	23.08	AZ	6.18	MD	0.47
4	KY	21.67	ME	6.17	IA	0.45
5	OR	20.36	MD	5.68	IL	0.42

Higher rates indicate higher risk. According to our 2012 Q3 RADARS System data:

#1 for patients filling a prescription for opioids is Tennessee

- Tennessee also was #1 (24.67) in our last report

#1 for intentional opioid abuse exposures based on population rate per 100,000 is West Virginia

- In our last report Arizona was #1 (7.30); 2Q data was not available from WV

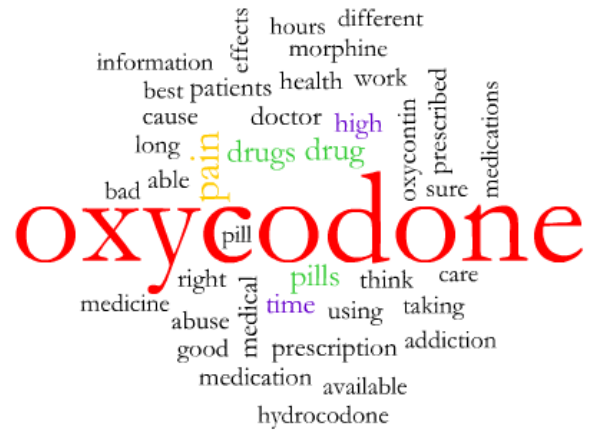
#1 for intentional opioid abuse exposures based on Unique Recipient of

- Dispensed Drug rate per 1000 is South Dakota
Minnesota was #1 (0.602) for the last 2 quarters reported

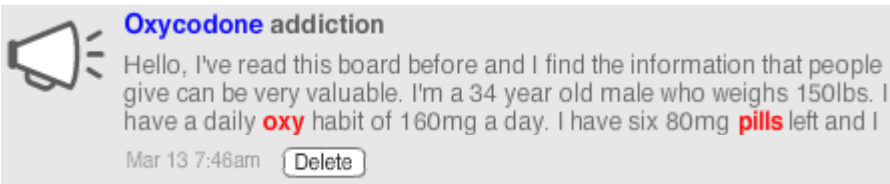
** Intentional Abuse Exposure is defined as a purposeful action resulting from the intentional improper or incorrect use of a substance where the victim was likely was attempting to gain a high, euphoric effect or some other psychotropic effect, includes recreational use.*

We've started using Radian⁶ Analysis Dashboard to track trends on the internet for prescription drugs in the RADARS System taxonomy. Radian⁶ allows the RADARS team to review forums, blogs and social media posts to determine which drugs people are talking about, how often they are posting, how they might be abusing and or obtaining them, where they are located regionally and basic demographic information, such as age and gender of the people who are posting. These insights provide useful information into specific drugs of choice, changes in trends of use over time and demographic- and geographic-specific trends per drug. Some output examples are provided:

Country	Count	Percentage
Canada	76	38.2%
United Kingdom	55	27.6%
Netherlands	24	12.1%
Other (7 more)	11	5.5%
Australia	14	7.0%
Germany	9	4.5%
Italy	7	3.5%
Norway	3	1.5%



And you can dig deeper into forums and blogs to read the actual conversation threads...these social media mentions not only highlight abuse, but frequently involve people talking about responsible ways to use their medications – sharing stories and suggestions for other people in pain.



RADARS® System has also has a Twitter Handle: [@RADARS_System](#), come follow us!

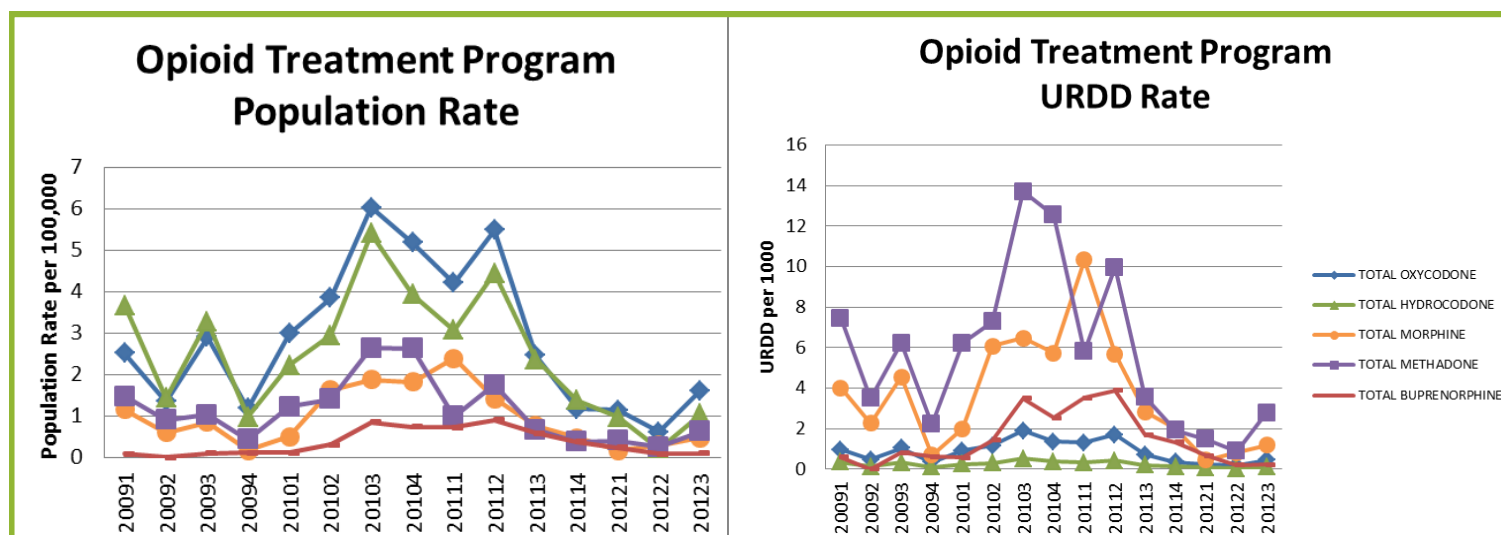


RADARS® System Technical Report # 2013Q1-1

Kentucky-Impact of Opioid Abuse Deterrent Policies**Key Points**

- RADARS® System programs can help illustrate the impact of Prescription Drug Monitoring Programs (PDMPs)
- By population rate and URDD, buprenorphine, methadone, morphine and oxycodone showed declines after 2Q2011 in the RADARS® System Opioid Treatment Program.
- In the RADARS® System Drug Diversion program, hydrocodone showed a decline in population rate after 1Q2012 but URDD rates remained stable.

Figure 1: Opioid Treatment Program Population and URDD Rates in Kentucky from Q1 2009 – Q3 2012

**Background**

Prescription Drug Monitoring Programs (PDMPs) are statewide databases that gather information from pharmacies on dispensed prescriptions of controlled substances. These databases were implemented to address the prescription drug abuse epidemic [1]. Kentucky implemented their PDMP program in January 1999 with the online startup of KASPER (Kentucky All Schedule Prescription Electronic Reporting) [2]. Data collection processes were enhanced in February 2008 [2]. Kentucky has instituted satisfaction surveys to document the role PDMPs play in clinical practices and provides quarterly reports to show prescribing patterns by geographic areas [1]. In 2012, a statute mandating PDMP enrollment and use by prescribers was enacted with the immediate result of a crack-down on “pain management clinics” [3]. In October, the press was already reporting success with the new statute: “so far, 10 pain management clinics have closed and the amount of pain killers being prescribed has dropped sharply since the law took effect [4].

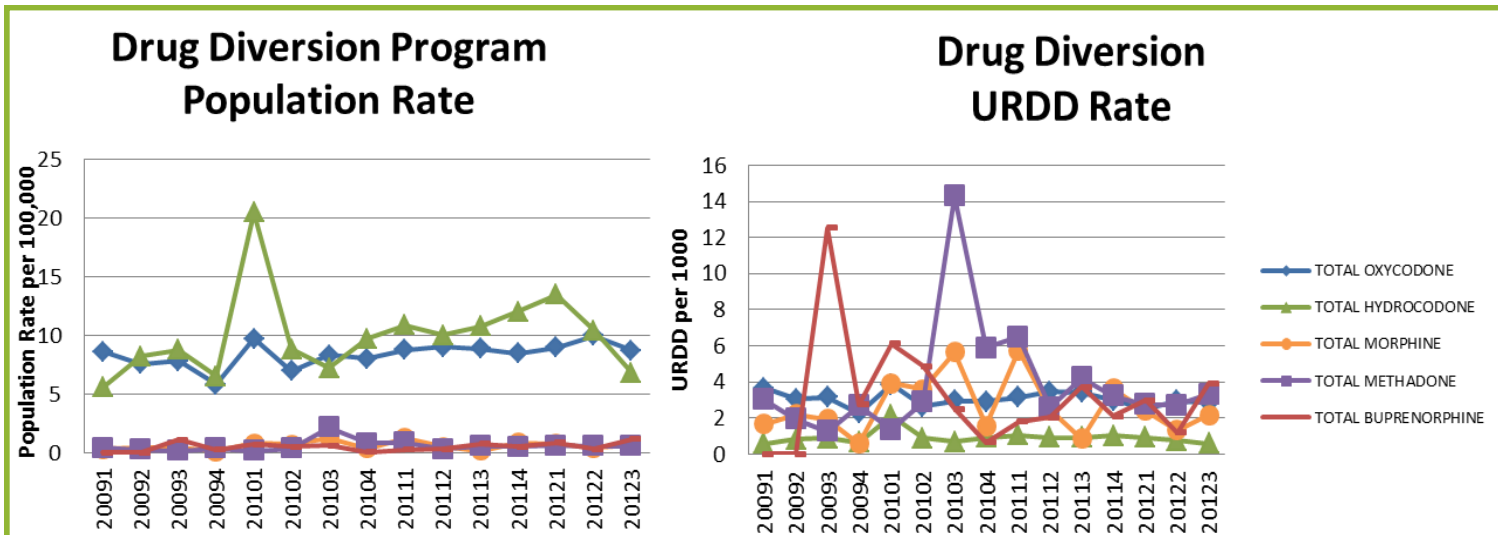
Methods

Data was restricted to Kentucky based zip codes for RADARS® System Opioid Treatment Program (OTP) and Drug Diversion (DD) Programs for buprenorphine, hydrocodone, methadone, morphine and oxycodone. The number of cases, Unique Recipient of Dispensed Drug (URDD), and population for every 3-digit zip code in the state were summed by drug and year quarter. The sum of the cases then was divided by the summed URDD and summed population and multiplied by 1,000 and 100,000, respectively, to obtain the URDD and population rates for each drug and year quarter.

Results

Data from OTP showed declines for buprenorphine, methadone, morphine and oxycodone after 1Q2011 for both population and URDD rates (see figures above on pg1). Hydrocodone only declined by population rate. By comparison, DD data does not show such dramatic decreases across the 5 products. Hydrocodone diversion decreased after 1Q2012 by population rate but not by URDD (see figures below).

Figure 2: Drug Diversion Program Population and URDD Rates in Kentucky from Q1 2009 – Q3 2012



Conclusions

RADARS® System programs can show the impact of the PDMP instituted in Kentucky over time. In particular, noteworthy declines in population and URDD rates are seen for buprenorphine, hydrocodone, methadone, morphine and oxycodone in the Opioid Treatment Program. Such dramatic decreases were not evident in the Drug Diversion Program.

Suggested citation:

Lowitz K, Le Lait MC, Severtson SG, Dart RC (2013). Kentucky – Impact of Opioid Abuse Deterrent Policies. RADARS System Technical Report, 2013Q1-1.

References

1. Clark T, Eadie J, Kreiner, P, Strickler G. Prescription Drug Monitoring Programs: An assessment of the evidence for best practices. Report: September 20, 2012. The Prescription Drug Monitoring Program Center of Excellence, Heller School for Social Policy and Management, Brandeis University.
2. KASPER (Kentucky All Schedule Prescription Electronic Reporting). Kentucky Cabinet for Health and Family Services. <http://www.chfs.ky.gov/os/oig/KASPER.htm>.
3. Brammer J. New prescription drug law prompts four pain clinics to close. Published July 24, 2012. www.kentucky.com/2012/07/24/2269205/four-pain-clinics-to-close-in.html.
4. Schreiner B. Beshear sees successes in fight against drug abuse. Published October 29, 2012. www.sfgate.com/news/article/Stumbo-sees-successes-in-fight-against-drug-abuse-3991111.php.

Denver Health Employee of the Month — Kimberly Brown!

It is our pleasure to announce that Kimberly Brown, a researcher on the RADARS® System project who has been with Denver Health for 5 years, was named the Employee of the Month for February by the Denver Health Employee of the Month Committee. The Committee reviews nominations submitted from department personnel across the Denver Health and Hospital Authority system. With her selection, Kim becomes the Research Department's first recipient of this honor. One of the key successes highlighted in the nomination was her role as a project team leader on a short-term consulting project with one of our RADARS System subscribers. Kim worked with client partners to develop the project plan, coordinate all components (from data collection to analysis and reporting), assemble and train the project team and follow up on task assignments at every stage. She went above and beyond by working many long hours to obtain the information, guidance and staffing needed to propel the project forward to completion. She was recognized at the Denver Health Commitment Awards Ceremony on Wednesday, February 27th.

Recent RADARS System Publications and Presentations

Manuscripts:

- Dart RC, Cicero TJ, Surratt HL, Rosenblum A, Bartelson BB, Adams EH. Assessment of the abuse of tapentadol immediate release: The first 24 months. *Journal of Opioid Management*. 2012;8(6):395-402.
- Zosel A, Bucher Bartelson B, Bailey E, Lowenstein S, Dart R. Characterization of adolescent prescription drug abuse and misuse using the Researched Abuse Diversion and Addiction-Related Surveillance (RADARS®) System. *Journal of the American Academy of Child and Adolescent Psychiatry*. 2013;52(2):196-204.

Abstracts/Posters/Platforms:

- Green JL. Impact of Approved Drug Labeling on Chronic Opioid Therapy: RADARS® System Findings. Impact of Approved Drug Labeling on Chronic Opioid Therapy Part 15. Silver Spring MD. February 7-8, 2013.
- Lavonas E. Prescription Drug Monitoring Programs: evidence for effectiveness. FDA Drug Safety and Risk Management Advisory Committee Meeting. Silver Spring, MD. January 23-24, 2012

Conferences Attended

- FDA Drug Safety and Risk Management Advisory Committee Meeting. Silver Spring, MD. January 24-25, 2013.
- Impact of Approved Drug Labeling on Chronic Opioid Therapy Part 15. Silver Spring MD. February 7-8, 2013.

Did You Know?

In January 2013, the FDA introduced the following draft "Guidance for Industry: Abuse-Deterrent Opioids — Evaluation and Labeling" with the Agency's current thinking on clinical study design to support abuse-deterrent properties and approvable labeling claims.

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RADARS System Mission Statement

The RADARS System provides timely, product specific and geographically-precise data to the pharmaceutical industry, regulatory agencies, policymakers and medical/public health officials to aid in understanding trends in the abuse, misuse, and diversion of prescription drugs in the United States.

Rocky Mountain Poison and Drug Center and Denver Health and Hospital Authority

The RADARS System is a governmental nonprofit operation of the Rocky Mountain Poison and Drug Center (RMPDC), an agency of Denver Health (DH). The RMPDC has been in operation for more than 50 years, making it one of the oldest poison control centers in the nation. DH is the safety net hospital for the City and County of Denver and is the Rocky Mountain region's academic Level I trauma center and includes Denver Public Health, Denver's 911 emergency medical response system, nine family health centers, 12 school-based clinics, NurseLine, correctional care, Denver CARES, the Denver Health Medical Plan, and the Rocky Mountain Center for Medical Response to Terrorism, Mass Casualties and Epidemics.



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