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RADARS[®] System Presentation Highlights

Prescription Drug Monitoring Programs: Evidence for Effectiveness

Eric Lavonas, MD is scheduled to present at the FDA Drug Safety and Risk Management Advisory Committee Meeting in Silver Spring, MD on January 24-25, 2013. 43 states currently operate Prescription Drug Monitoring Programs (PDMP). Prior to 2005, there were no observed effects of PDMPs on overdose mortality or sales (Paulozzi; *Pain Med* 2011; 12:747-54). RADARS[®] System Poison Center data (2003-2012) and Treatment Center data (2005-2012) were used to analyze abuse trends in hydrocodone and other schedule II opioids in states with and without PDMPs (Figures 1 & 2). In conclusion, opioid abuse rates rise less quickly in states with PDMPs versus states without PDMPs making them a valuable tool along with other interventions to combat opioid abuse in the United States.

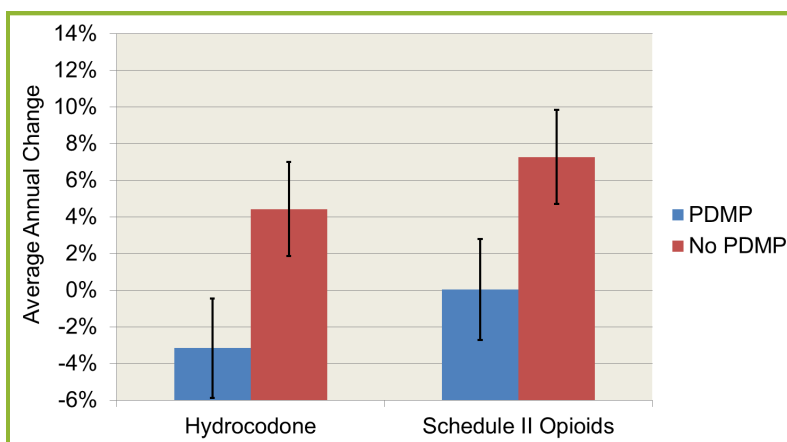


Figure 1: Poison Center Program abuse exposures, adjusted for drug supply

Save the Date!

The 17th Annual RADARS[®] System Scientific Meeting is scheduled for April 18, 2013 at the Hilton Washington DC / Rockville Meeting Center in Rockville, MD.

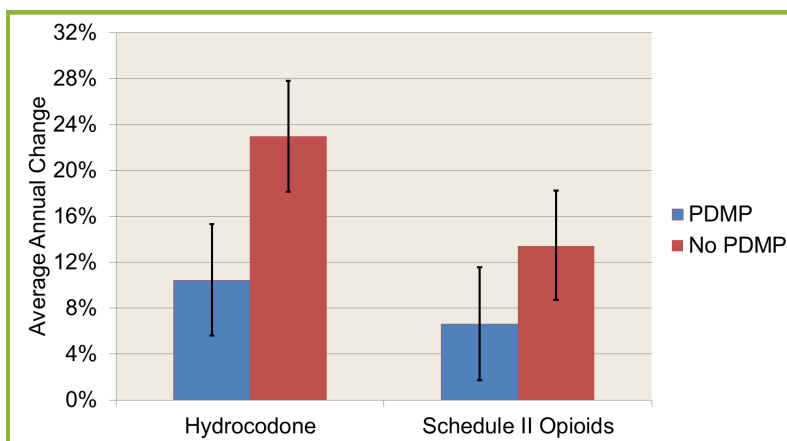


Figure 2: Treatment Center Program opioid abuse mentions, adjusted for drug supply



Cont.

Intentional and Unintentional Prescription Opioid Exposures in Australia, Italy, Germany and the United States

Jody Green, Ph.D. presented the platform titled above at the North American Congress of Clinical Toxicology Annual Meeting in Las Vegas, NV, October 1-6, 2012. The data from 2007-2011 was collected through collaboration with the following:

RADARS® System Poison Centers - JL Green, RC Dart, B Bucher-Barelson

GIZ-Nord Poisons Centre, University Medical Center Göttingen, Germany - H Desel , G Ochsenfahrt

Poison Control Centre of Milan, Italy - F Sesana, G Milanesi

NSW Poisons Information Centre, Sydney Australia - N Gunja, J Brown

Global Toxicsurveillance Network (GTNet)

Key rates of intentional and unintentional exposure calls per 100,000 were calculated for oxycodone, buprenorphine and methadone. Data show increasing rates of oxycodone exposures are not limited to the US and methadone intentional exposure rates were higher than oxycodone in NW Germany and Italy (Figures 1-4). While rates across countries should not be compared as data collection methods differ between centers, changes in rates of prescription opioid abuse are changing worldwide.

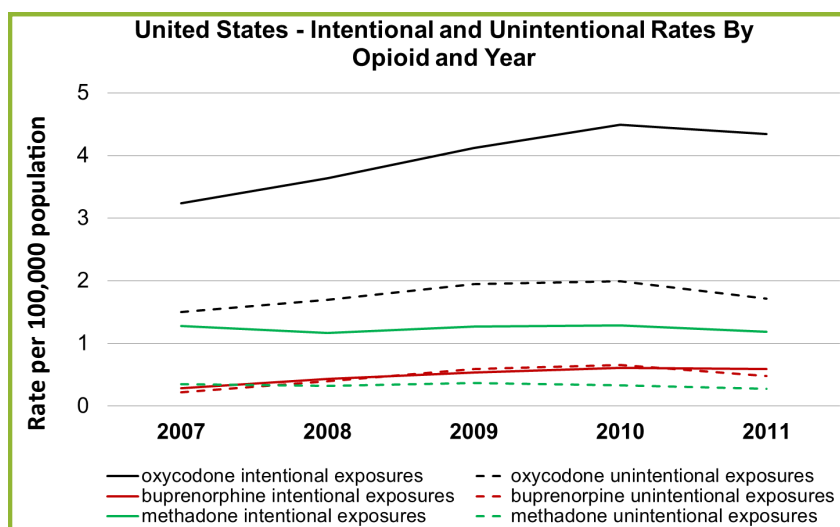


Figure 1: United States - Intentional and Unintentional Rates by Opioid and Year

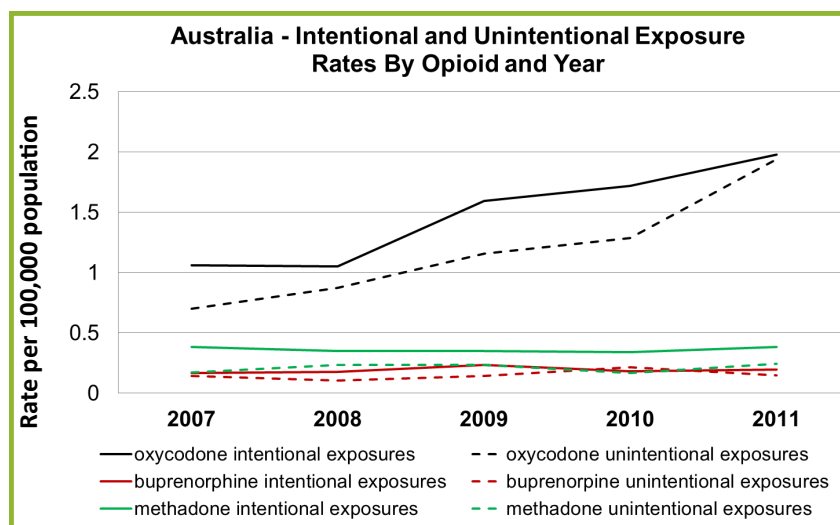


Figure 2: Australia - Intentional and Unintentional Exposure Rates by Opioid and Year

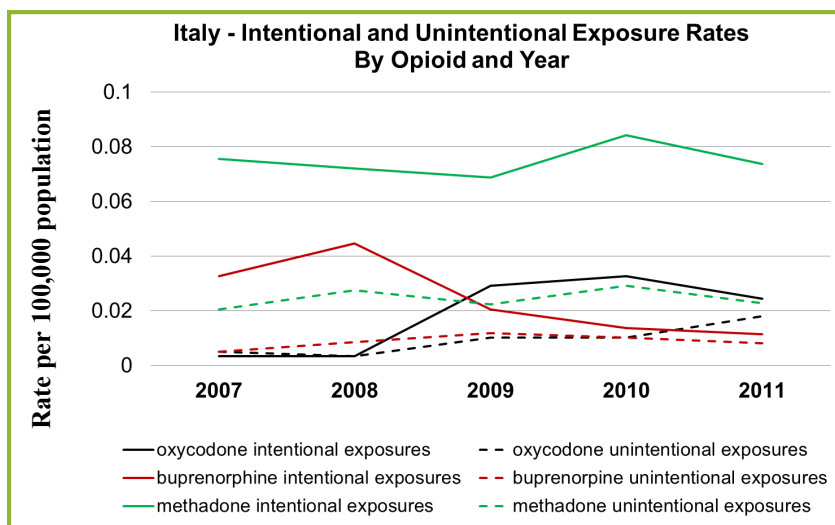


Figure 3: Italy - Intentional and Unintentional Exposure Rates by Opioid and Year

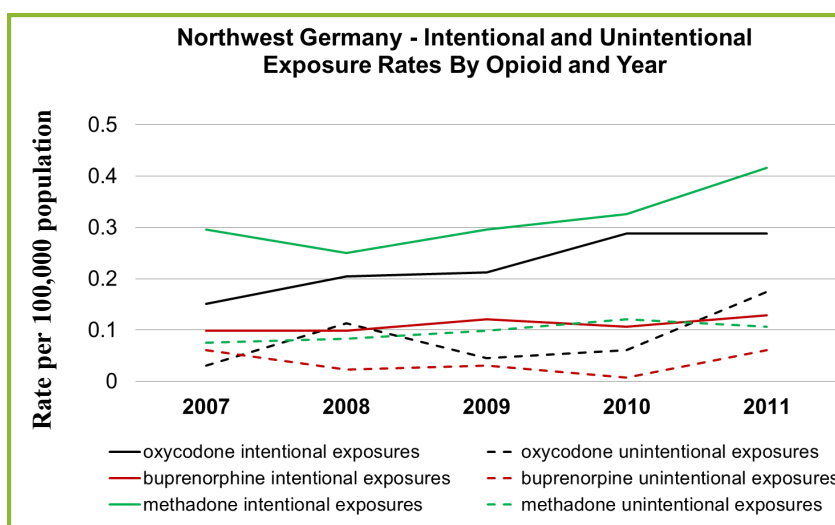
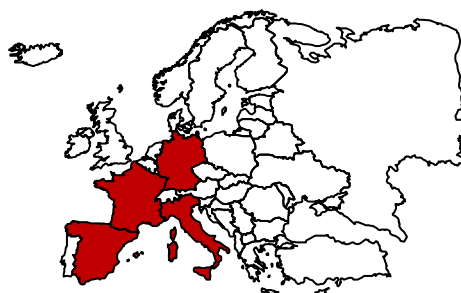


Figure 4: Northwest Germany - Intentional and Unintentional Exposure Rates by Opioid and Year

In addition to the platform, the following poster was presented “International Perspective on Prescription Stimulant Exposures Reported to Poison Centres from 2007-2011”.

Trends of opioid misuse and diversion: lessons for Europe from the USA

In keeping with the international theme, Dr. Green also presented during a satellite symposium at the International Society of Addiction Medicine in Geneva, Switzerland, on October 16th, 2012. The presentation began with a review the RADARS® System programs and methods and provided an overview of opioid abuse and mortality trends by drug class in the US. The presentation continued with analysis of the positive impact of tamper and abuse resistant modifications applied to oxycodone, hydromorphone and buprenorphine products using data from RADARS® System programs. The final portion of the presentation introduced the Global Toxicsurveillance Network (GTNet), a collaboration with the US, United Kingdom, Germany, Italy, Netherlands, Switzerland and Australia with the goal of harmonizing poison center data.. And, a pilot study to collect data from opioid treatment facilities in Italy, Spain, France and Germany was described. This collaboration of RADARS® System and the European Opiate Addiction Treatment Association (Europad) is being led by Professoress Icro Maremmanni from the University of Pisa, Italy.



Suboxone® Tablets from Reckitt Benckiser to be Discontinued

On September 25, 2012, Reckitt Benckiser (RB) broadcast a press release announcing plans to remove Suboxone® (buprenorphine and naloxone) sublingual tablet products from the market. RB submitted an analysis to the FDA on September 18, 2012 in response to data received from RADARS System Poison Centers which found “consistently and significantly higher rates of accidental unsupervised pediatric exposure with Suboxone® Tablets...than reported with Suboxone® [sublingual] Film”. In addition, RB issued a Citizen’s Petition to the FDA requesting that all manufacturers of buprenorphine products be required to create safeguards to reduce the risk of pediatric exposure.

Although a definitive root cause was not determined, RB believes the child resistant unit-dose packaging unique to the Suboxone® Film is part of what contributes to the lower exposure rates when compared to Suboxone® Tablets – which are distributed in 30-count bottles with child-resistant caps.

Immediately after the press release, questions arose as to the impact on the generics market. Suboxone® Tablets no longer are patent-protected; however, the film is under patent protection. Analysts predict this “could spark legal challenges by companies or US health insurers, including Medicaid, since it would make it more difficult for generic companies to launch lower-cost versions”.¹

To read the entire press release, please use the following link:

www.rb.com > Home>Investors & media>Announcements>2012>Reckitt Benckiser Pharmaceuticals Inc. to Voluntarily Discontinue the Supply of Suboxone Tablets

Please copy the web address into your web browser to view

Reference: <http://www.thepharmaletter.com/file/116756/reckitt-benckiser-pharma-to-voluntarily-discontinue-suboxone-tablet-supply-in-usa.html>

Rankings 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) Unique Recipient of Dispensed Drug (URDD) per 100 Population: number of individual opioid prescriptions filled (excluding refills), calculated with 2010 US Census data.

(2) Intentional Exposures per 100,000 Population: intentional exposures* reported to RADARS System Poison Centers per 100,000 persons, calculated using 2010 US Census data.

(3) Intentional Exposures per 1000 URDD: intentional exposures* reported to RADARS System Poison Centers per 1000 persons based on individual prescriptions for opioids (excludes refills), calculated with data from IMS.

Rank	Unique Recipient of Dispensed Drug (URDD) per 100 Population		Intentional Exposures per 100,000 Population		Intentional Exposures per 1000 URDD	
1	TN	24.67	AZ	7.30	MN	0.602
2	KY	24.32	ME	6.63	SD	0.573
3	AL	23.23	KY	6.24	AZ	0.480
4	OR	21.25	SD	6.02	MD	0.413
5	MS	19.78	VT	5.59	IA	0.410

Cont.

Higher rates indicate higher risk. According to our 2012 Q2 RADARS® System data:

#1 for patients filling a prescription for opioids is Tennessee

- In our last report Alabama was #1 (22.52)

#1 for intentional opioid exposures reported to poison centers based on population is Arizona

- In our last report West Virginia was #1 (9.67); regrettably we don't have 2Q data from WV but we will for 3Q, so stay tuned for results in the next newsletter!

#1 for intentional opioid exposures reported to poison centers based on Unique

- Recipient of Dispensed Drug rate is Minnesota
Minnesota also was #1 in our last report (0.706)

* Intentional 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.

Recent RADARS System Publications and Presentations

Manuscripts:

- Zosel A, Bartleson BB, Bailey JE, Lowenstein S, Dart RC. Characterization of adolescent prescription drug abuse and misuse using the Researched Abuse Diversion and Addiction-Related Surveillance (RADARS®) System. *American Academy of Adolescent and Child Psychiatry*. In Press

Abstracts/Posters/Platforms:

- Brown KR, Severtson SG, Dart RC, RADARS® System Poison Center Group. RADARS® System poison center intentional exposures to OxyContin®: a look at the differences in rates of abuse via unintended routes before and after reformulation intervention. North American Congress of Clinical Toxicology Congress. Las Vegas, NV. October 2012.
- Davis JM, Bucher-Bartelson B, Severtson SG, Dart RC, RADARS® System Poison Center Group. Regional differences in seasonal trends in suicide exposures to prescription opioids as reported to poison centers participating in the RADARS® System. North American Congress of Clinical Toxicology Congress. Las Vegas, NV. October 2012.

Cont.

- Davis J, Severtson SG, Bartelson BB, Muñoz A, Schneider MF, Surratt H, Chilcoat H, Coplan P, Green JL, Dart RC. Changes in diversion rates following the introduction of a reformulated extended release oxycodone product. American College of Emergency Physicians Scientific Assembly. Denver, CO. October 2012.
- Davis J, Severtson SG, Bartelson BB, Muñoz A, Schneider MF, Surratt H, Chilcoat H, Coplan P, Green JL, Dart RC. Changes in diversion rates following the introduction of a reformulated extended release oxycodone product. American Academy of Physical Medicine and Rehabilitation Annual Meeting. Atlanta, GA. November 2012.
- Fischer LJ, Davis JM, Bucher-Bartelson B, Poppish L, Dart RC, RADARS® System Poison Center Group. Prescription opioid and stimulant use among pregnant women: surveillance by poison control centers participating in the RADARS® System. North American Congress of Clinical Toxicology Congress. Las Vegas, NV. October 2012.
- Green JL. The impact of tamper resistant formulations on prescription drug abuse. National Association of State Controlled Substance Authorities (NASCA) Conference. Scottsdale, AZ. October 2012.
- Green JL. Intentional and Unintentional Prescription Opioid Exposures in Australia, Italy, Germany and the United States. North American Congress of Clinical Toxicology Congress. Las Vegas, NV. October 2012.
- Green JL, Bucher-Bartelson B, Desel H, Ochsenfahrt G, Sesana F, Milanese G, Brown J, Gunja N, Dart RC. International Perspective on Prescription Stimulant Exposures Reported to Poison Centres from 2007-2011. North American Congress of Clinical Toxicology Congress. Las Vegas, NV. October 2012.
- Lavonas E. Abuse, Misuse, and Diversion of Prescription Opioids: Evaluating the Problem and Proposed Solutions. Ontario Methadone Prescribers Conference. Toronto, Canada. November 2012.
- Lavonas EJ, Severtson G, Murrelle EL, Ruby J, Bucher-Bartelson B, Dart RC. Unintentional exposures to buprenorphine/naloxone tablets and oral film among children less than 6 years old: initial experience from the RADARS® System Poison Center Program. Association for Medical Education and Research in Substance Abuse Annual Meeting. Bethesda, MD. November 2012.
- Lavonas EJ, Severtson G, Murrelle EL, Ruby J, Bucher-Bartelson B, Dart RC. Unintentional exposures to buprenorphine/naloxone tablets and oral film among children less than 6 years old. International Society for Pharmacoeconomics and Outcomes Research European Congress. Berlin, Germany. November 2012.
- Lavonas EJ, Severtson G, Murrelle EL, Ruby J, Bucher-Bartelson B, Dart RC. Unintentional exposures to buprenorphine/naloxone tablets and oral film among children less than 6 years old. American Academy of Addiction Psychiatry Annual Meeting. Aventura, FL. December 2012.
- Maremanni I, Green JL. Trends of opioid misuse and diversion: lessons for Europe from the USA. International Society of Addiction Medicine (ISAM) RBP Sponsored Symposium. Geneva, Switzerland. October 2012.
- Severtson SG, Bartelson BB, Davis J, Muñoz A, Schneider MF, Coplan P, Chilcoat H, Green JL, Dart RC. Difference in rates of abuse following reformulation of extended release (ER) oxycodone using data from the RADARS® System Poison Center program. American College of Emergency Physicians Scientific Assembly. Denver, CO. October 2012.
- Severtson SG, Bartelson BB, Davis J, Muñoz A, Schneider MF, Coplan P, Chilcoat H, Green JL, Dart RC. Difference in rates of abuse following reformulation of extended release (ER) oxycodone using data from the RADARS® System Poison Center program. American Academy of Physical Medicine and Rehabilitation Annual Meeting. Atlanta, GA. November 2012.
- Winter EJ, Davis JM, Bucher-Bartelson B, Westberry R, Green JL, Lavonas EJ, Dart RC, RADARS® System Poison Center Group. Systematic misclassification in product-specific coding of poison center data: the example of buprenorphine in the RADARS® System poison center program. North American Congress of Clinical Toxicology Congress. Las Vegas, NV. October 2012.

RADARS System Presentations

- North American Congress of Clinical Toxicology Annual Meeting. Las Vegas, NV. October 1-6, 2012.
- American College of Emergency Physicians Scientific Assembly. Denver, CO. October 8-11, 2012.
- International Society of Addiction Medicine Satellite Symposium. Geneva, Switzerland. October 14-18, 2012.
- National Association of State Controlled Substance Authorities Conference. Scottsdale, AZ. October 22-26, 2012.
- Ontario Methadone Prescribers Conference. Toronto, Canada. November 9, 2012.
- Association for Medical Education and Research in Substance Abuse Annual Meeting. Bethesda, MD. November 1-3, 2012.
- International Society for Pharmacoeconomics and Outcomes Research European Congress. Berlin, Germany. November 3-7, 2012.
- American Academy of Physical Medicine and Rehabilitation Annual Meeting. Atlanta, GA. November 15-18, 2012.
- American Academy of Addiction Psychiatry Annual Meeting. Aventura, FL. December 6-9, 2012

RADARS System Quarterly Technical Reports

RADARS System Technical Report #2012Q4-1

Age trends in the abuse of prescription opioids

Please copy the web address into your web browser to view the pdf:

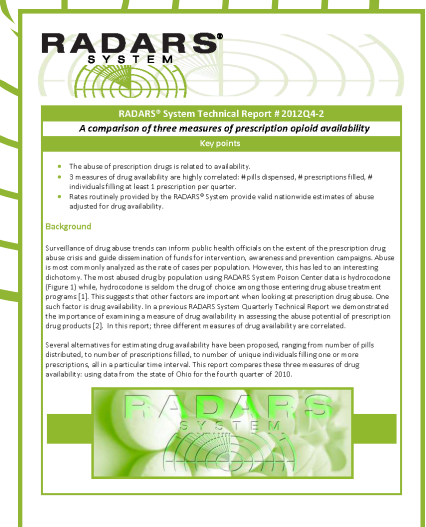
[http://www.radars.org/Portals/1/Age trends in the abuse of prescription opioids.pdf](http://www.radars.org/Portals/1/Age%20trends%20in%20the%20abuse%20of%20prescription%20opioids.pdf)

RADARS System Technical Report #2012Q4-2

A comparison of three measures of prescription opioid availability

Please copy the web address into your web browser to view the pdf:

[http://www.radars.org/Portals/1/A comparison of three measures of prescription opioid availability.pdf](http://www.radars.org/Portals/1/A%20comparison%20of%20three%20measures%20of%20prescription%20opioid%20availability.pdf)



Did You Know?

The Medical Association of Georgia has developed the initiative called "Think About It". The program takes a three-pronged approach: creating legislation, educating health care professionals, and providing safe places to dispose of and store prescription drugs

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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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