



Third Quarter 2015 Newsletter

SAVE-THE-DATE

You are cordially invited to attend

RADARS® SYSTEM 10th ANNUAL SCIENTIFIC MEETING

MAY 5-6, 2016

Westin Georgetown 2350 M Street, NW Washington, DC



THURSDAY, MAY 5, 2016

INTERNATIONAL PRE-SYMPOSIUM AND NETWORKING WELCOME RECEPTION

FRIDAY, MAY 6, 2016 MAIN ANNUAL CONFERENCE SIC MEETING

For questions, please contact Shiva Noorchashm at registration@radarsevent.com.

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RADARS System Mission Statement

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

Did You Know?

Did you know October was National Substance Abuse Prevention Month?

Scientific Advisory Board Retirement Announcement



It is with great gratitude and regret that we announce the retirement of Dr. Alvaro Muñoz from the RADARS System Scientific Advisory Board.

Alvaro Muñoz is Professor of Epidemiology with joint appointments in the Departments of Biostatistics and Environmental Health Sciences at the Johns Hopkins University Bloomberg School of Public Health. He received his M.S. (1977) and Ph.D. (1980) degrees in Statistics from Stanford University. From 1980-1985, he was an Instructor at the Channing Laboratory of the Harvard Medical School when his research focus was on Pulmonary disease and on Infectious Disease Epidemiology.

In 1986 Muñoz was appointed to the post of Assistant Professor in the Department of Epidemiology, with a joint appointment in the Department of Biostatistics at the Johns Hopkins University Bloomberg School of Public Health. He was promoted to Associate Professor in 1987 and to full Professor in 1993. He was awarded an additional joint appointment in the Department of Environmental Health Sciences in

1994.

In 1995, he was Chair of the Section on Epidemiology of the American Statistical Association and was elected to fellow of the association in 1999. Muñoz was elected to fellow of the American College of Epidemiology in 1997. Muñoz has received the Golden Apple for Excellence in Teaching at the Johns Hopkins Bloomberg School of Public Health in 2003, 2006 and 2010. Dr. Muñoz has been a member of the Editorial Boards of the journals AIDS (2000-2003), Cancer Epidemiology Biomarkers and Prevention (1995-1998) and Statistics in Medicine (1994-2001).

Muñoz' research interests are in statistical methods in observational studies, particularly survival and longitudinal data analysis. He has been intimately involved in large cohort studies of the epidemiology of HIV/AIDS and of kidney disease. Following his role as the original Principal Investigator of the Data Coordinating Centers of the Multicenter AIDS Cohort Study (MACS) and the Women's Interagency HIV Study (WIHS), Muñoz began his research (in 2005) as Principal Investigator of the data center for the CKiD study (Children's Kidney Disease). From 1995 to 2006, he directed the Epidemiology/Biostatistics Center of a postmarketing surveillance program to assess the abuse liability of Ultram® and Ultracet®. Dr. Muñoz participated as part of the RADARS System since its inception in 2001. With his colleagues (Michael Schneider and Kelly Townsend) at Johns Hopkins University, they established a standard approach to concatenate all sources of data collected by the RADARS System programs into summary files that were simple yet comprehensive as they incorporate the three primary domains of the data: time (on a quarterly basis), location (at the three digit zip codes level) and drug. For the drugs, the Hopkins team also took the lead to develop a taxonomy of the drugs which was comprehensive, simple and conducive to carry out analyses at different levels (e.g., from specific product to active pharmaceutical ingredient). The summary files conceptualized and produced by the Hopkins team have provided the common basis for the issuing of reports to different subscribers and at the same time they have formed the basis for data of RADARS System publications. Methodologically, Dr. Muñoz has enjoyed the interactions and implementations of novel methods in collaboration with the biostatisticians and epidemiologists at Denver Health.

Dr. Muñoz has written or participated in the writing of one book, twelve chapters and more than 275 publications in prestigious peer-reviewed scientific journals. He has also actively participated in more than 40 scientific meetings, and has been an invited lecturer more than 60 times (often as key note speaker), both in the United States and internationally.

We thank Dr. Muñoz for his contributions.

RADARS System Abstracts RADARS System Conference Attendance: July 2015 – October 2015

31st International Conference on Pharmacoepidemiology & Therapeutic Risk Management August 22, 2015 – August 26, 2015



The annual ICPE meeting provides a forum for open exchange of scientific information and for the development of policy, education and advocacy for the field of pharmacoepidemiology, including pharmacovigilance, drug utilization research, outcomes research, comparative effectiveness research, and therapeutic risk management. The conference was attended with academicians, clinicians, industry, and regulatory officials from the United States and internationally. Prescription opioid abuse was recognized as a

major public health problem in the United States and as a serious and growing concern in countries outside the United States. Many sessions during the conference focused on topics surrounding prescription drug abuse.

RADARS System was proud to present an abstract with data from the United Kingdom Survey of Non-Medical Use of Prescription Drugs this year, which reported on the non-medical use of opioids only, benzodiazepines only, and both opioids and benzodiazepines when taken together.

Please see next page to learn more about our presentation.





Non-Medical Use of Benzodiazepines and Opioids: an Online National Survey in the United Kingdom

J.L. Green¹, A.C Besharat¹, E.M. Goodman¹, B. Bucher Bartelson¹, D.M. Wood², P.I. Dargan²

¹Rocky Mountain Poison & Drug Center, Denver Health, Denver, CO, US

²Clinical Toxicology, Guy's and St. Thomas' NHS Foundation Trust and King's Health Partners, London, UK

Background

- The online National Survey Program was developed to study rates of non-medical use (NMU) of prescription drugs and associated behaviors among the general population in the United Kingdom (UK)
- Data on poly-drug use and NMU of prescription drugs in Europe are limited
- This is important given the high prevalence of prescription drug abuse in the United States (US)

Methods

- The online national survey is deployed biannually through a survey administration company. Respondents age 16 and older living in the UK are eligible. The sample was stratified to reflect the geographical and gender distribution of the UK
- The survey was launched on July 16th, 2014 and in field for 9 days. Data from this launch were analyzed. 2,504 respondents completed the survey; 5 respondents were excluded for reporting all opioid active pharmaceutical ingredients for NMU or all illicit drugs in the last 7 days
- Lifetime use and NMU of prescription drugs (use without doctor's prescription or for any reason other than recommended by a doctor), illicit drug use, chronic pain (pain lasting at least 3 months that occurs constantly or flares up frequently), and Drug Abuse Screening Test (DAST-10) were analyzed
- Chi Square tests and Kruskal-Wallis for statistical differences were performed

Figure 1. Non-Medical Use of Opioids, Benzodiazepines, and Both

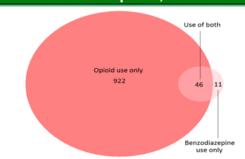
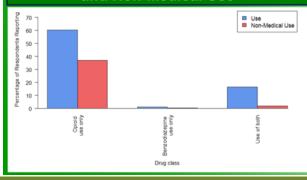


Figure 2. Respondents Reporting Use and Non-Medical Use



Objective

 To report use and NMU of opioids only, benzodiazepines only, and opioids and benzodiazepines (both) in a UK national survey

Results

- · 2,499 respondents completed eligible surveys
- 1,509 (60.4%) reported opioid use only, 31 (1.2%) benzodiazepine use only, and 412 (16.5%) use of both
- · 922 (36.9%) respondents reported NMU of an opioid only
- 979 (39.2%) respondents reported NMU of an opioid or benzodiazepine and most (94.2%) reported NMU of opioids only
- However, 80.7% of those reporting NMU of benzodiazepines also reported NMU of opioids (19.3% reported NMU of benzodiazepines only)
- Compared with the opioid only or benzodiazepine only groups, respondents reporting NMU of both had the:
 - Highest proportion of chronic pain (69.6%, p=0.0045)
 - · Highest proportion of illicit drug use (71.7%, p<0.0001)
 - Highest median DAST-10 (3, p<0.0001)

Table 1. Demographics Among Those Reporting Non-Medical Use

| | Opioids only | Benzodiazepines only | Both N=46 | |
|---------------|-------------------|----------------------|-------------------|--|
| | N=922 | N=11 | | |
| Age | | | | |
| Median (IQR) | 49.0 (35.0, 62.0) | 37.0 (27.0, 59.0) | 37.5 (30.0, 46.0) | |
| Gender, N (%) | | | | |
| Male | 503 (54.6) | 4 (36.4) | 25 (60.9) | |
| Female | 419 (45.4) | 7 (63.6) | 18 (39.1) | |

Table 2. Chronic Pain, Illicit Drug Use, and DAST-10

| | Non-Medical Use | | | |
|------------------------|-----------------------|------------------------------|--------------|----------|
| | Opioids only N=922 | Benzodiazepines only N=11 | Both N=46 | p-value |
| Chronic pain, % | | | | |
| Yes | 51.5 | 18.2 | 69.6 | 0.0045 |
| No | 48.5 | 81.8 | 30.4 | 0.0045 |
| Illicit drug use, % | | | | |
| Yes | 33.2 | 45.5 | 71.7 | < 0.0001 |
| No | 66.8 | 54.5 | 28.3 | |
| DAST-10 [median (IQR)] | 0 (0-1) | 1 (0-2) | 3 (0-5) | < 0.0001 |

Conclusions

- Data suggest a high prevalence of NMU of opioids in the UK; although the prevalence of NMU of benzodiazepines was lower
- Respondents reporting NMU use of opioids only were the group least likely to report illicit drug use
- Amongst those reporting lifetime NMU of benzodiazepines, opioids were often also reported
- This study confirmed poly-drug NMU may indicate severe health consequences related to drug abuse
- Understanding poly-drug NMU is important to inform interventions

Financial Support: The RADARS® System is part of Denver Health and Hospital Authority, a division of the State of Colorado. It is supported by subscriptions from pharmaceutical manufacturers.









RADARS System Abstracts

RADARS System Conference Attendance: July 2015 – October 2015

PAIN*Week* September 6th, 2015 – September 10th, 2015

PAINVVEEK®

PAINWeek is the largest pain conference in the United States for those interested in pain management. This dynamic conference emphasizes patient care and science simultaneously, bringing together experts across the world with varying backgrounds and perspectives on pain.

RADARS System actively participated in this year's PAINWeek with 3 abstract presentations, highlighting our integral research on prescription drug abuse. Data from the RADARS System Poison Center Program, the RADARS System Opioid Treatment Program, the RADARS System Drug Diversion



Program, the RADARS System Survey of Key Informants' Patients Program and the Survey of Non-Medical Use of Prescription Drugs were utilized. For further information on our abstracts, please see below:

Medical outcomes associated with unintended routes of prescription opioid abuse. Bucher Bartelson B, Le Lait MC, Dart RC, Roland CL, Masters ET, Mardekian J, Green JL.

<u>Chronic pain and non-medical use of opioids, benzodiazepines, and pregabalin in the United Kingdom.</u>

Dart RC, Dargan PI, Wood DM, Besharat AC, Goodman EM, Iwanicki JL, Green JL.

Abuse deterrent reformulation of controlled release oxycodone is associated with persistently declining rates of abuse and diversion by both oral and non-oral routes. Iwanicki JL, Severtson SG, Green JL, Besharat AC, Dart RC

RADARS System Abstracts

RADARS System Conference Attendance: July 2015 – October 2015

International Society of Addiction Medicine (ISAM) Dundee, Scotland

October 5th, 2015 – October 8th, 2015



Falling rates of prescription opioid abuse and death in the United States: Formulations and ramifications. (Symposium)

Iwanicki JL

North American Congress of Clinical Toxicology (NACCT) San Francisco, CA

October 8th, 2015 – October 12th, 2015



Fischer LJ, Severtson SG, Dart RC



<u>Characterization of Chronic Pain in College Students as Reported to an Online Survey</u>
Fix CM, Besharat AC, Dart RC

Rates of Suicide Involving Prescription Opioids Before, During and After the Great Recession Lavery SA, Le Lait MC, West NA, Dart RC

<u>Trends of suspected suicide involving prescription opioids by 4 United States regions</u> Lavery SA, West NA, Le Lait MC, Dart RC

Non-medical Use of Prescription and Illicit Drugs in Public versus Private Colleges & Universities Margolin Z, Besharat AC, Nelson SK, West NA, Bucher Bartelson B, Green JL, Dart RC

<u>Decrease in Exposure Calls to Poison Centers: A Look at Opioid and Stimulant Drug Classes Over time By Age Group</u>

Marquess SA, McDaniel HA, West NA, Dart RC

Non-Dermal Routes Used in Fentanyl Patch Intentional Exposures

Nickless JR, Le Lait MC, West NA, Coulter MS, Dart RC

Upcoming RADARS System Conference Attendance: November 2015 – December 2015

Canadian Centre on Substance Abuse (CCSA) Montreal, Quebec

November 16th, 2015– November 18th, 2015



Monitoring the Street Price of Diverted Opioids in Canada with StreetRx.com

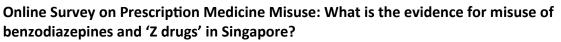
Partnership. Knowledge. Change.

Chronic Pain and Non-Medical Use of Prescription Opioids in a United Kingdom National Survey Iwanicki JL, Besharat AC, Goodman EM, Dargan PI, Wood DM, Dart RC, Green JL

Dart RC, Goodman EM, Karin McBride KE, Margolin Z, Dasgupta N, Menone CM, Green JL, Iwanicki JL

Asian Pacific Association of Medical Toxicology (APAMT) Perth, Australia

December 1st, 2015 – December 4th, 2015



Wood DM, Besharat AC, McDaniel H, Green DL, Dargan PI



American Academy of Addiction Psychiatry (AAAP) Huntington Beach, CA

December 3rd, 2015 – December 6th, 2015



Severtson SG, Bucher-Bartelson B, Green JL, Besharat AC, Cicero T, Ellis M, Kurtz SP, Rosenblum A, Dart RC

Unintentional Exposures to Buprenorphine/Naloxone Tablets and Oral Film Among Children Less Than Six Years Old Through 2014

Severtson SG, Bucher-Bartelson B, Green JL, Besharat AC, Dart RC

Learn More About Our Domestic and International Services...

Please click for more information:



The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARSB) System is a surveillance system that collects product- and geographically-specific data on abuse, misuse and diversion of

The RADARS® System provides prescription drug abuse data to a variety of organizations, offering surveillance and consulting vices that have helped dozens of clients meet their business and regulatory requirements

Who We Are

RADAR/88 System data have been used by manufacturers, regulatory agencies as well as medical and public health officials to characterize and manifor prescription drug obuse, misuse and diversion. The data have been used for an array of purposes including submission of reports to the U.S. Food and Drug Administration (FDA), new drug applications, labeling claims, post market requirements and filts: Evaluation and Mitigation Strategies (REA) assessment. Data can also be used for the development and evaluation of interventions (i.e. abuse deterent formulations), and to monitor ever-changing market trends.

The RAD ARS® System is a nonprofit operation of the Pocky Mountain Poison & Drug Center RMPDC1, a division of Denver Health

Services

- Surveillance data for risk management activities

- Field research and targeted investigations of emerging topics FDA Advisory Committee preparation and/or presentation Development and execution of publication stategies Review of materials for regulatory submissions
- Consultation with experts on the RADARS® System Scientific Advisory Board
- Coordination of Industry Advisory Board to gather stakeholder needs and harmonize surveillance strategy
- Annual site visits by RADARS® System Clinicians and Scientists
 - Uterature surveillance
 - Drug information and safety reporting contact
- Adverse event and periodic safety reporting
 Advisory Board participation and general consulting

RADARS® System Programs: Mosaic Approach

ion allowing for early and ongoing monitoring of newly approved drugs as well as the

The RADARS® System utilizes a mosaic strategy to detect misuse, abuse and diversion at all phases of the

Data from all RADARS® System programs are triangulated to provide a more complete picture of prescription drug suse, abuse and dive

This approach has been used in many fields of research and is especially useful in the study of hard to reach or hidden populations, such as those who use, misuse, or divert prescription drugs. It is not abute, misure, or divert prescription drugs. Il is not hypically possible to study such behavior in controlled settings (e.g., randomized, controlled frails). Instead, researchers often rely on multiple convenience samples, each abtained from a different perspective on the hidden population being studied. No single on the hidden population being studied, No single data source is expected to provide complete and representative information about the covert behaviors but, considered together, multiple data sources strengthen the credibility of findings, reduce the risk of folse interpretations, and provide a more complete and comprehensive perspective.

The RADARS® System is composed of a mosaic of which torget diverse populations uphout the United States and abroad. They are duct-specific and sensitive to geographic

Mosaic Approach

intended to monitor rates of misuse, abuse and diversion of prescription drugs and provide experienced and expert analysis interpretation of the data. Our consulting services are customized to the business and regulatory requirements of our clients. The RADARS® System is a nonprofit operation of the Rocky Mountain Poison & Drug Center (RMPDC), a division of Denver Health

International Services

- Surveillance data for risk management activities Development and execution of publication strategies
- Field research and targeted investigations of emerging topics

 Other traditional post-market surveillance services

RADARS

Who We Are

- Preparation and/or presentation for meetings with regulatory agencies

- Literature surveillance
- Drug information and safety reporting contact center

International Surveillance of Prescription Drug Misuse, Abuse, and Diversion

Adverse event and periodic safety reporting

International Programs: Mosaic Approach

The RADARS® System utilizes a mosaic strategy to detect misuse, abuse and diversion at all phases of the drug abuse pathway.

The Researched Abuse. Diversion and Addiction-Related Surveillance (RADARS®) System international surveillance services are

Data from all RADARS® System programs are triangulated to provide a more complete picture of prescription drug misuse, abuse and diversion.

This approach has been used in many fields of research and is especially useful in the study of hard to reach or hidden populations, such as those who abuse populations, such as those who abuse, misuse, or divert prescription drugs. It is not typically possible to study such behavior in controlled settings (e.g. randomized, controlled trails). Instead, researchers often rely on multiple convenience samples, each obtained from a different perspective on the hidden population being studied. No single data source is expected to provide complete and representative information about the covert behaviors but, considered together, multiple data sources strengthen the credibility of findings, reduce the risk of false interpretations, and provide a more complete and comprehensive



The RADARS® International System is composed of a mosaic of programs which target diverse populations throughout Europe Canada and Australia. They are product-specific and sensitive to geographic location allowing for early and ongoing monitoring of newly approved drugs as well as those already on the market.

RADARS® System Quarterly Technical Report

Abuse Prevalence and Preference of Immediate Release versus **Extended Release Opioids**

RADARS® System in Social Media – Get Connected!



Follow us at @RADARS System. You can find news relating to prescription drug surveillance and abuse in the US and abroad. RADARS® System tweets include publication announcements, conference attendance, program updates and more.



Publication and conference attendance news can be found on our LinkedIn site (www.linkedin.com/company/radars-system).



Visit www.RADARS.org for active links to presentations, conference and manuscript abstracts.

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.

Contact Information

Account, Subscription, Program or Data Inquiries:

business@radars.org (303) 389-1233

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. The RMPDC has been in operation for more than 50 years, making it one of the oldest poison control centers in the nation. Denver Health 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.







RADARS® System • 777 Bannock Street • Mail Code 0180 Denver, CO 80204-4507 Questions or comments?

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