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Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System

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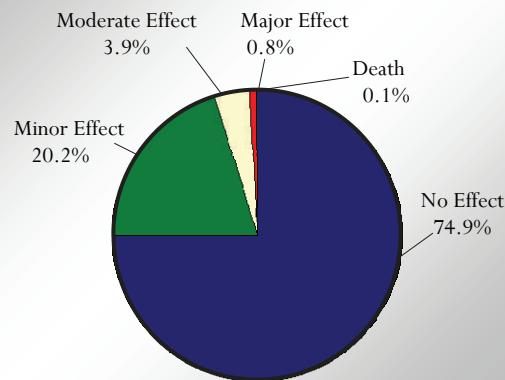
Pediatric Exposures: *Data from the Poison Center Signal Detection System*

The RADARS System Poison Center Signal Detection System consists of 42 of 60 (70%) total poison centers in the United States. These participating centers are geographically dispersed, providing coverage of rural, urban and suburban areas of the U.S., and servicing a total population of approximately 210 million (74% of the total U.S. population).

The 42 participating poison centers are all certified by the American Association of Poison Control Centers (AAPCC), and data collection is standardized across AAPCC – certified centers through the use of Toxic Exposure Surveillance System (TESS) fields. Poison information specialists at the centers receive calls from health-care professionals and the general public either to report an exposure or to request assistance with the management of an exposure. During these calls, the specialists gather information on the patient's exposure history, first aid measures, assessment, treatment recommendations and outcome. Each week, the participating poison centers submit data related to the RADARS System drugs of interest to the coordinating center (RMPDC) where product identification and reason codes are verified for each case. These data are then reported to subscribers on a quarterly basis.



Pediatric Exposures by Known Outcome
January 2003-June 2006



Data from this signal detection system offers valuable information regarding prescription opioid abuse and misuse. The wide range of callers to poison centers enables the Poison Center Signal Detection System to capture data on pediatric exposures, recreational drug users/abusers, chronic

users, and accidental exposures. Like the other RADARS System signal detection systems, the Poison Center Signal Detection System is able to provide timely, geographically-specific data.

Another valuable aspect of the Poison Center Signal Detection System is its ability to report data on pediatric exposures. Pediatric exposures are worrisome because the primary source of drug exposures in infants and toddlers is inappropriate access to the medications of adults in the household. If these medications are prescription drugs of abuse, then the potential health effects for these children are serious and can include death.

There were 9,241 pediatric exposures reported to RADARS System poison centers from January 2003 through June 2006 related to the RADARS System drugs of interest (buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone, morphine and oxycodone). Seven pediatric exposures (0.08%) resulted in death, and 45 (0.5%) resulted in a major outcome. The overall exposure rate per 100,000 persons was highest for hydrocodone (4.6) and lowest for hydromorphone (0.06), while the overall exposure rate per 1,000 URDD (Unique Recipients of Dispense Drugs) was highest for

buprenorphine (7.5) and lowest for fentanyl (0.4). "Many people do not realize that prescription opioids inadvertently end up in the hands of children. These cases can, and do, have tragic ends," said Richard C. Dart, M.D., Ph.D., Executive Director of the RADARS System.



Richard C. Dart M.D., Ph.D.

In January 2006, the RADARS System was acquired by the Rocky Mountain Poison and Drug Center of Denver Health, and Dr. Dart was named the Executive Director of the RADARS System as well.

Principal Investigator of the Poison Center Signal Detection System

Richard C. Dart, M.D., Ph.D. is the Director of the Rocky Mountain Poison & Drug Center (RMPDC) of Denver Health and Hospital Authority (DHHA). Dr. Dart is also a Professor of Surgery (Emergency Medicine), Medicine and Pharmacy at the University of Colorado Heath and Sciences Center in Denver, is an officer of the American Association of Poison Control Centers (AAPCC), serves on the editorial board of *Annals of Emergency Medicine*, is board certified by the American Board of Emergency Medicine and the American Board of Medical Toxicology, and is active in the American College of Medical Toxicology (ACMT), the American Academy of Clinical Toxicology and the American College of Emergency Physicians.

Dr. Dart has earned numerous awards for his teaching, research and leadership endeavors.

Notable achievements include:

- The 2004 recipient of the American College of Medical Toxicology Matthew J. Ellenhorn Award for Excellence in Medical Toxicology
- Inaugural member of the Medical Toxicology sub-board of the American Board of Emergency Medicine
- Recognition by the Commissioner of the U.S. Food and Drug Administration with a special citation (2002)

He is also the editor of *The 5-Minute Toxicology Consult* and *Medical Toxicology 3rd edition*, a well known text for medical toxicologists and has published more than 150 papers, chapters, reviews, editorials and letters and is frequently invited to lecture to health care and regulatory audiences. For additional information on Dr. Dart, please refer to his biography on the RADARS System website at www.radar.org.

RADARS System Data

In Response to the SAMHSA Report on Nonmedical Users of Rx Pain Relievers

A recent report from the Substance Abuse and Mental Health Services Administration (SAMHSA) reports on the prevalence of pain reliever misuse in the United States from 2002 to 2004. The report also named Colorado, Kentucky, and Washington State as the top three states having the "highest prevalence of pain reliever misuse for persons aged 12 or older."¹ The RADARS System has compiled data through the second quarter of 2006 regarding prescription opioid intentional exposures to the RADARS System's nine monitored substances. Poison Center Signal Detection

System data indicate that the intentional exposure rate for prescription opioids in the United States for January through June 2006 is 7.8 per 100,000 population. Additionally the RADARS System has identified hydrocodone and oxycodone as the two prescription opioids with the highest population-based intentional exposure rates in the first half of 2006.

1. Substance Abuse and Mental Health Services Administration. *Federal Report Shows New Nonmedical Users of Prescription Pain Relievers Outnumbered New Marijuana Users between 2002 and 2004*. Available at <http://www.samhsa.gov/newsroom/advisories/061102misuse5701.aspx>

Rank Order RADARS System Opioids 1 st and 2 nd Quarter 2006

- | |
|---|
| <ol style="list-style-type: none"> 1. Hydrocodone 2. Oxycodone 3. Tramadol 4. Methadone 5. Morphine 6. Fentanyl 7. Hydromorphone 8. Buprenorphine |
|---|

*Based on rates per 100,000 population



Did You Know?

The RADARS System newsletter will now be produced on a bi-monthly schedule in 2007. The January/ February issue will highlight the Methadone Clinic (AATOD) Signal Detection System.

RADARS System Researcher

Quoted in Press Release

The RADARS System is actively involved in publishing RADARS System data in peer reviewed journals. Recently, "The Effect of FDA Approval of a Generic Competitor to OxyContin® (oxycodone HCl controlled-release) Tablets on the Abuse of Oxycodone", by Elise Bailey, Phoebe Barton, Dennis Lezotte, Steven Lowenstein and Richard Dart, was published in the journal, *Drug and Alcohol Dependence*. Results from this study were highlighted in a recent press release. The original news release, titled. *U.S. FDA*

approval of OxyContin Generic did not Affect Oxycodone Abuse Patterns was released on November 12, 2006 by NewsRx.com, a pay-per-view service. Congratulations to Elise and her co-authors. This is very exciting news for the RADARS System.

Press Release available by subscription at <http://www.newsrx.com/newsletters/Medical-Letter-on-the-CDC-and-FDA/2006-11-12-291112200652DC.html>

Also available on public internet sites such as www.pharmacychoice.com

Recent Publications

Using RADARS System Data

The RADARS System is committed to publishing RADARS System data in peer reviewed journals. For a complete listing of current publications, please visit WWW.RADARS.ORG

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Did You Know?

The Methadone Clinic (AATOD) Signal Detection System gathers data directly from patients who are admitted to methadone treatment centers; the RADARS System has received more than 15,000 questionnaires from across the country since its inception.



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Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System

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Mission Statement

The RADARS System provides timely and geographically-specific 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.



RMPDC and Denver Health

The RADARS System is an independent, not-for-profit, operation of the Rocky Mountain Poison and Drug Center (RMPDC), an agency of Denver Health and Hospital Authority (DHHA). The RMPDC has been in operation for 50 years, making it one of the oldest poison control centers in the nation. DHHA is the safety net hospital for the City and County of Denver. DHHA 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.

