RADARS® SYSTEM News

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

Third Quarter 2008 Volume 3, Issue 3

## In This Issue



## Did You Know?

The RADARS System captures data for all age groups, including young children.

Please read the story on pediatric exposures to see how many children were exposed to opioid medications from January 2003 through June 2006 according to RADARS System data.

## Save the Date!

The 2009 RADARS System Annual Scientific Meeting will be held Thursday, April 23, 2009, in Bethesda, Maryland.

More information on the meeting's topic will be announced at a later date.

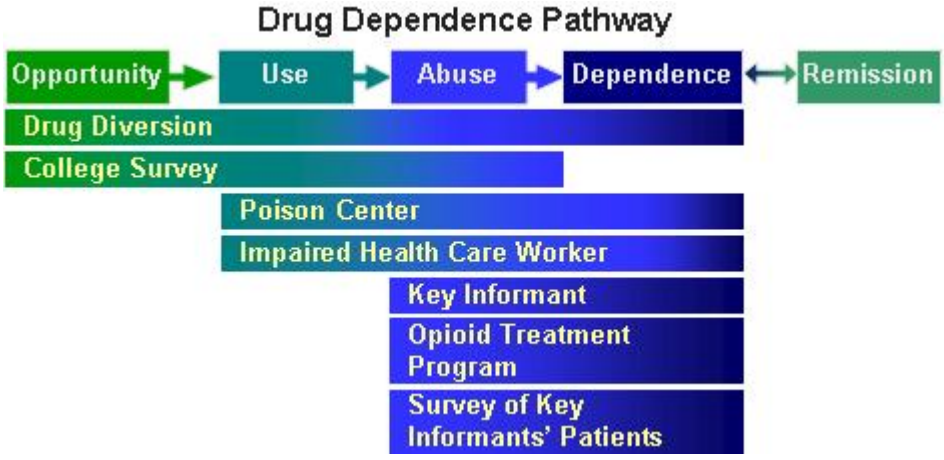
## RADARS System Presents to the FDA

On August 4, 2008, Richard C. Dart, M.D., Ph.D., Executive Director of the RADARS System traveled to Washington, DC, to present an overview of the RADARS System to approximately 40 employees of the U.S. Food and Drug Administration (FDA). Attendees included employees from the Office of Surveillance and Epidemiology, the Division of Anesthesia, Analgesia and Rheumatology, and Controlled Substances. The presentation provided regulatory officials with a better understanding of the RADARS System and its signal detection systems, with examples of research that can be performed using RADARS System data, and with an overview of the quarterly RADARS System data provided to pharmaceutical companies as part of their risk management reporting obligations to the FDA.

"This was an excellent opportunity to present the RADARS System to the FDA. It was important to show examples of RADARS System data and to show how pharmaceutical companies can, and are, using these data to fulfill their regulatory obligations," said Dr. Richard C. Dart. "I look forward to working more closely with the FDA to understand current regulations and ensure that the RADARS System adapts to the changing regulatory environment."

As part of the presentation, Dr. Dart showed how RADARS System data are useful for identifying trends during each stage of the drug dependence pathway prior to remission, which includes five stages: opportunity, use, abuse, and dependence. When monitoring a specific medication, it is important for the manufacturer to track its product in a variety of populations who may be at risk for drug dependence; this enables the company to develop appropriate interventions.

*The graphic below demonstrates how the signal detection systems monitor various populations along the drug dependence pathway.*




Sources: Chilcoat HD, Johanson CE. Vulnerability to Cocaine Abuse. Higgins ST, Ed. *Cocaine Abuse: Behavior, Pharmacology, and Clinical Applications.* San Diego, CA: Academic Press; 1998: 313-341.

Institute of Medicine – Committee on Opportunities in Drug Abuse Research. *Pathways of Addiction*. Washington, DC: National Academy Press; 1996.

TOP

## Effective Interventions Needed to Prevent Nonmedical Pediatric Exposures to Opioid Medications

While national surveys such as the 2006 Monitoring the Future continue to identify prescription drug abuse as a major public health concern for adolescents, few sources for information on prescription drug abuse and its effects on young children exist. The RADARS System captures detailed data for all age groups and recently conducted a study to understand the impact of prescription opioid abuse on young children.

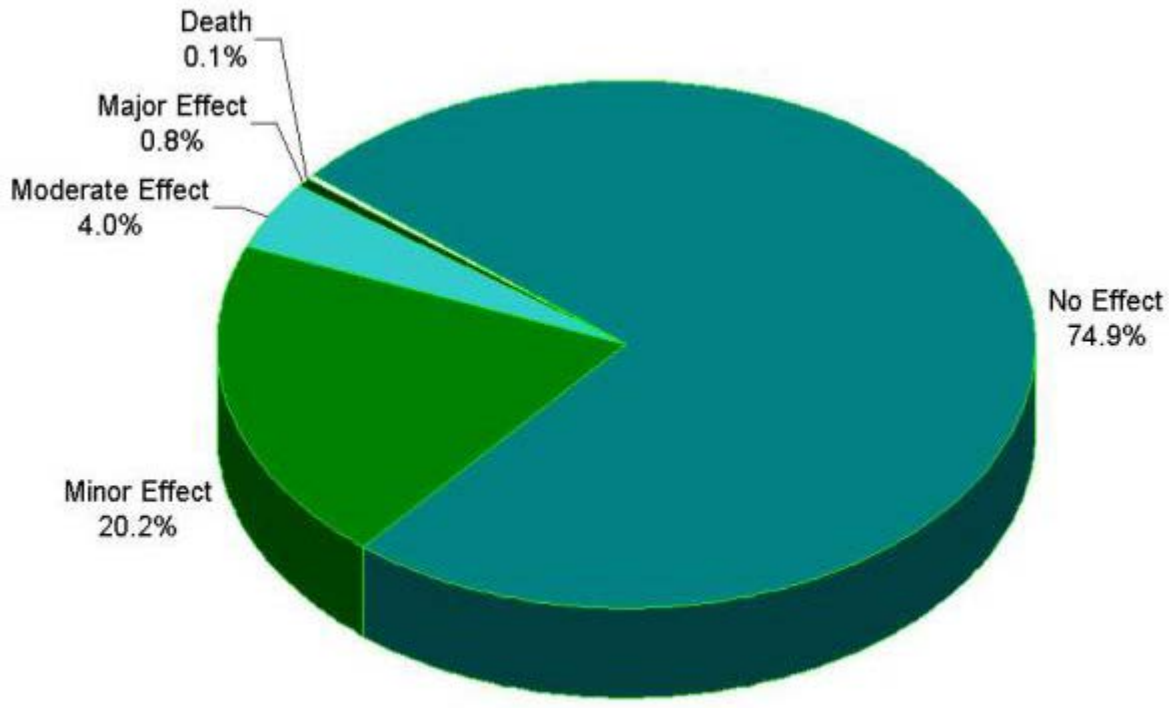
*The Under Recognized Toll of Prescription Opioid Abuse on Young Children* analyzed all pediatric exposures, intentional and unintentional/other, as reported to the Poison Center Signal Detection System. These exposure reasons capture data on both the administration of a drug to a child by an adult, therapeutic errors, and other events where a child came in contact with a medication while exploring the home environment, among other reasons

During the study period (January 2003—June 2006), 9,240 exposure mentions to opioid medications in children under the age of six were identified, with the median age of exposure being two years. Nearly all of the exposures involved unintentional ingestions occurring within the child's home and eight exposures resulted in death.

"The volume of pediatric exposures involving prescription opioids is alarming. In just three-and-a-half-years, more than nine thousand kids came in contact with a prescription opioid medication, and most exposures occurred in their own home," commented Richard C. Dart, MD, PhD, Executive Director of the RADARS System. "Understanding how children come in contact with prescription medications is the first step in developing interventions to safeguard children from medications found in households across the nation."

This study was conducted by the RADARS System in an ongoing effort to conduct research for the benefit of the scientific community and the general public. *The Under Recognized Toll of Prescription Opioid Abuse on Young Children* has been accepted for publication in the *Annals of Emergency Medicine*.

**Prescription Opioid Exposures by Known Outcome in Children Under the Age of Six:**
**Data from RADARS System Poison Centers**
**January 2003—June 2006**




TOP

## RADARS System Launches its Seventh Signal Detection System: A Survey of College Students

The RADARS System has successfully launched the College Survey Signal Detection System. The seventh signal detection system surveys self-identified college students enrolled in two- or four- year programs nationwide.

The survey is conducted via an online questionnaire completed at the end of fall and spring semesters/quarters and at the end of the summer.

The RADARS System began collecting data from this signal detection system during the summer of 2008.

TOP

## RADARS System Summary of Characteristics

The RADARS System has completed a table of characteristics which summarizes the main data collection elements of the entire system and has also created a table outlining the characteristics of each signal detection system. This provides potential and current subscribers with an easy reference about the RADARS System. Please visit the RADARS System Characteristics page.

### General Characteristics of the RADARS System

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|---|---|
| **Rate calculations** | Unique Recipients of Dispensed Drug (URDD) or population, per quarter or year, by Signal Detection System |
| **Reporting frequency to subscribers** | Quarterly, more frequently by request |
| **Publications** | 17 publications in peer reviewed journals and 39 abstracts presented at scientific conferences |
| **Signal determination methodology** | Rate thresholds of 2- or 5- cases per 100,000 population<br>Conditionally autoregressive (CAR) statistical model with Bayesian hierarchical model specification (under development) |
| **Geographic specificity** | 3-digit ZIP code of patient or case<br>Coverage of 876 of 930 3-digit ZIP codes in the nation (94%) |
| **Product Specificity** | Drug class (e.g. buprenorphine, fentanyl, oxycodone, hydrocodone, methylphenidate, morphine) and specific product (e.g. Suboxone®, Concerta®, Kadian®) |
| **Quality Assurance** | • Document development and change control<br>• Implementation of Standard Operating Procedures (SOPs) for all Signal Detection Systems<br>• Quality control steps including data entry verification, data validation, data verification, and final report verification<br>• Database controls including validation, central database internal system data validation, database backup and disaster recovery processes, and audit trails<br>• Electronic systems controls including security and data transmission<br>• Corrective action processes<br>• Quality audits and monitoring including database quality audits, monitoring visits at Signal Detection System sites, internal audits, and contractor audits<br>• Training program and documentation for all RADARS System staff<br>• Central database 21 CFR part 11 compliant |

### Characteristics of Individual Signal Detection Systems (SDS)

| | Population | Definition/ Types of Cases | Coverage | Reporting Timeframe | Initiation of Data Collection |
|---|---|---|---|---|---|

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| **Drug Diversion** | Cases of prescription drug diversion | Number of new instances of pharmaceutical diversion reported to or investigated by diversion units or regulatory boards | 300 reporters from 50 states | 3 months | 2002 |
| **Key Informant** | Clinicians, Epidemiologists, Treatment counselors and other experts in substance abuse in a position to know about emerging drug abuse problems in their areas | Use to get high or use as a substitute for other drugs of abuse as reported by health care professionals | 196 reporters from 46 states | 3 months | 2002 |
| **Poison Center** | Young children<br>Adolescents<br>Young Adults<br>Adults<br>Elderly | Spontaneous reports of cases of acute medical events | 44 states, 83% of US population covered | 1 week | 2003 |
| **Opioid Treatment Program** | Opioid dependent treatment seekers entering methadone maintenance (public & private) | Self-reported use to get high in last 30 days | 75 programs from 33 states and 25,646 questionnaire responders | 1 week | 2005 |
| **Impaired Health Care Worker** | Early adopters to newly available pharmaceutical controlled substances | Self-reported health care workers, cases investigated by regulatory agencies, or patients of impaired health care programs identified in any of the SDSs | As a subset of the other SDSs, coverage reflects that of the other SDSs | 3 months | 2007 |
| **Survey of Key Informants' Patients** | Patients of Key Informants who are seeking treatment | Self-reported use to get high in last 30 days | 400 questionnaire responders from 25 states | 1 week | 2008 |
| **College Survey** | College students, recent initiates | Self-reported non-medical use in previous semester | 2,000 questionnaire responders from 50 states each quarter/semester | Quarter/Semester | 2007 |

TOP

## Regulatory News

On May 22, 2008, the U.S. Food and Drug Administration (FDA) launched the Sentinel Initiative to create "a national, integrated, electronic system for monitoring medical product safety."

The new system will allow the FDA to query multiple data sources including medical claims and health records to monitor adverse events for a product through its entire life cycle.

For more information, please visit the FDA's Sentinel Initiative website and read *The Sentinel Initiative—A National Strategy for Monitoring Medical Product Safety.*

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Public Relations


## Recent RADARS System Publications and Presentations

- Bailey JE, Campagna E, Dart RC, Reporting for the RADARS System Poison Center Group. The Under Recognized Toll of Prescription Drug Abuse on Young Children. *Annals of Emergency Medicine*. In Press.
- Hays BD, Klein-Schwartz W, Doyon S. Toxicity of Buprenorphine Overdoses in Children. *Pediatrics*. 2008; 121: 782-786.
- Kirtland MN, Lemon S, Bailey JE, Dart RC. Effectiveness of a Poison Center Intervention on Product Coding. 2008 North American Congress of Clinical Toxicology. September, 2008.
- Kirtland MN, Bailey JE, Dart RC. Prescription Opioid Associated Death Rates Using RADARS System Data. American Academy of Addiction Psychiatry Conference. December, 2008.
- Montoya AM, Bailey JE, Dart RC. Current Nonmedical Prescription Drug Use Among College Students: Analysis of RADARS System Data. The American Academy of Addiction Psychiatry Conference. December, 2008.

Complete Publication List
TOP

## Upcoming Meetings of Interest

- The National Association of State Controlled Substances Authorities will host its annual meeting October 21-25 in Fort Lauderdale, Fla. Dr. Richard C. Dart of the RADARS System will present, *The Impact of Prescription Opioid Abuse on Young Children (<6 years old): Report of Poison Center Data.*
- The International Association for Pain and Chemical Dependency will host its annual meeting October 29 through November 1 in Philadelphia, Pa. H. Westly Clark of the Center for Substance Abuse Treatment will present, *CSAT Report: A National Assessment of Prescription Drug Abuse* at the meeting.
- The National Association of Drug Diversion Investigators (NADDI) will hold its 19th annual conference on November 11-14, 2008 in Nashville, Tenn. NADDI is a membership organization whose members are responsible for investigating and prosecuting pharmaceutical drug diversion.
- The Food and Drug Law Institute will host an Introduction to Drug Law and Regulation: Understanding How the FDA Regulates the Drug Industry November 20-21 in Washington, DC.
- The American Academy of Addiction Psychiatry will host its annual meeting December 4-7 in Boca Raton, Fla. Two RADARS System abstracts will be presented.

TOP

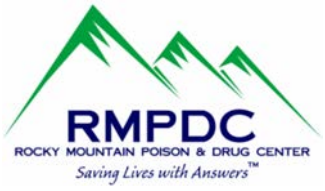
## RADARS System Mission Statement

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.

TOP

## Rocky Mountain Poison and Drug Center and Denver Health

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.



TOP

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