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RADARS[®] SYSTEM

News

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

VOL. 2, ISS. 4

JULY / AUGUST 2007

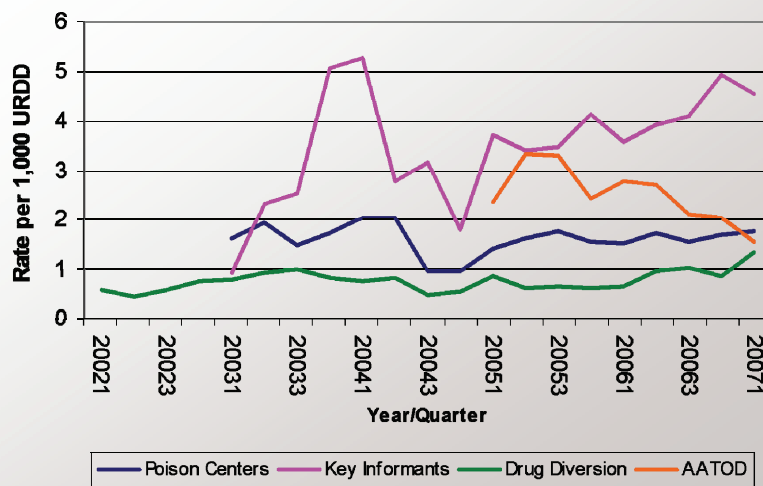
RADARS System Presents at SAMHSA Methadone-Associated Mortality Meeting

On July 20, the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA) hosted a meeting to review current knowledge of methadone-associated deaths and review the progress of action items established in 2003 following the release of the SAMHSA report, *Methadone-Associated Mortality*. The meeting included epidemiologists, clinicians, educators, regulatory and enforcement officials, patient advocates and policy-makers.

Richard C. Dart, M.D., Ph.D. and Executive Director of the RADARS System, was among the professionals invited to attend and participate in the meeting and presented on current trends in methadone misuse, abuse and diversion using data from the RADARS System. For all

methadone contacts reported to any of the RADARS System signal detection programs (Drug Diversion, Key Informant, Opioid Treatment Program, Poison Center), methadone exposures have been relatively unchanged in recent years (Figure 1).

Figure 1. Methadone Abuse, Misuse and Diversion Rates by Signal Detection System Unique Recipients of a Dispensed Drug (URDD)



In an analysis of methadone-associated deaths reported to poison centers from 2003-2006, the RADARS System found that a total of 132 deaths occurred, with 20-29 year olds accounting for the largest proportion of those deaths. Researchers also identified that pediatric methadone-associated deaths (ages 0-5 years) accounted for approximately 2.5 percent of the total methadone-associated

deaths for the three year period. (See Figure 2).

See **Methadone Mortality** page 2



Did You Know?

- The RADARS System Poison Center Signal Detection System now includes the entire state of Nevada. This signal detection system now gathers data for an additional population 86,304 people.
- In an evaluation of 2006 data, the RADARS System found 93 percent of reporting three-digit ZIP codes had at least one case of prescription drug abuse, misuse or diversion. Visit www.radars.org to read the full press release.

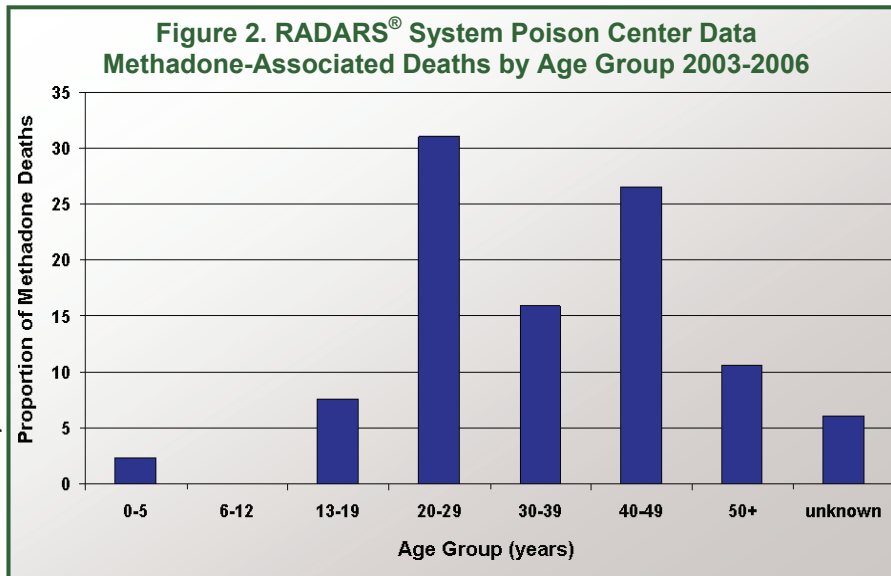
Methadone Mortality from page 1

Findings from the 2003 SAMHSA report showed an increase in methadone-associated deaths, which paralleled the increasing trends in deaths after exposure to other opioid analgesics. The report also found that many of those deaths were linked to the use of the methadone for pain treatment, rather than for addiction treatment.¹ Presentations at the 2007 meeting indicate that the mortality rate continues to increase.

Additionally, the report found that a majority of methadone-associated deaths typically occur from three scenarios: 1) an accumulation of methadone to toxic levels at the start of treatment for pain or addiction, 2) misuse of diverted methadone by individuals who had little or no tolerance, and 3) synergistic effects of

methadone used in combination with other drugs.¹

The 2003 meeting outlined a specific need for more useful data in analyzing methadone abuse, misuse, diversion and outcomes. Every quarter, the Poison Center Signal Detection System of the RADARS System gathers data on acute and chronic exposures for all ages and tracks their outcomes. In addition to actively gathering data on methadone, the RADARS System gathers data for eight other substances from 92 percent of three-digit ZIP codes in the nation.



1. A National Assessment of Methadone-Associated Mortality: Background Briefing Report. 2003. Available at <http://www.dpt.samhsa.gov/medications/methadone.htm>

College on Problems of Drug Dependence Meeting *Addresses Opioid Analgesic Abuse and Intervention Strategies*

The College on Problems of Drug Dependence (CPDD) held its 69th Annual Meeting in Quebec City, Canada June 16-21, 2007. The CPDD was established in 1929 and is the longest standing group in the nation addressing problems of drug dependence. The annual meeting brings together scientists and clinical investigators from industry, academia, and governmental agencies as well as representatives from regulatory agencies and other professionals in diverse disciplines of drug dependence.

Herbert Kleber, M.D., member of the RADARS System Scientific Advisory Board and Meredith Smith, Ph.D., M.P.A., Director of Risk Management and Health Policy for Purdue Pharma L.P., led a workshop titled, *Reducing Opioid Analgesic Abuse: Models for Successful Collaboration among Government, Industry and other Key Stakeholders*. The five presen-

tations in this workshop included examples of how pharmaceutical companies are working with the FDA to monitor opioid products and creating interventions to curb abuse.

The symposium, *Prescription Opiate Abuse: Deviating from the Script*, provided an overview and analysis of current trends in prescription opioid abuse and data collection and monitoring methods. A presentation given by Elise Bailey, MSPH, of the RADARS System provided an overview of current abuse and diversion rates for buprenorphine, methadone, hydrocodone and oxycodone.

The 70th Annual Scientific Meeting of the CPDD will be held June 14-19, 2008, in San Juan, Puerto Rico. Please visit www.cpdd.vcu.edu for more information.

Food and Drug Administration Holds Public Workshop on the Implementation of Risk Minimization Action Plans

On June 25 and 26, 2007, the Food and Drug Administration (FDA) held a public workshop, *Implementation of Risk Minimization Action Plans (RiskMAPs) to Support Quality Use of Pharmaceuticals: Opportunities and Challenges*. Speakers at the workshop included representatives from the FDA, industry and prescription drug researchers.

A presentation focusing on the design and implementation of opioid risk management plans was given by Patricia Robinson, M.D., and Aparna Mohan, M.D., Ph.D. of Johnson and Johnson. This presentation mentioned that a thoughtful surveillance program will assess the plan's effectiveness by directly measuring risks.

The development of a RiskMAP for an opioid or stimulant product poses some unique challenges for drug makers who monitor the safe and illegal use of their products. According to the presentation, a comprehensive plan will employ a system that has the ability to translate risks into measurable terms by using standardized data collection methods and will use trend analysis to identify changes over time. Us-

ing these data collection methods will allow drug manufacturers to measure the effectiveness of any interventions or educational programs that have been conducted.

"Calculating rates for abuse, misuse and diversion is especially important in evaluating the safety of opioid and stimulant products. Specialized surveillance systems, like the RADARS System, are able to capture data for abuse, misuse, and diversion every quarter and offer the opportunity for drug manufacturers to track trends over time and measure the effectiveness of any intervention efforts that may be underway" said Richard C. Dart, M.D., Ph.D. and Executive Director of the RADARS System.

The FDA reports that from October 2002 to December 2006, 130 RiskMAPs have been submitted for review and approval. As of February 2007, approximately 30 drugs were approved in conjunction with a suitable RiskMAP plan.

For more information on this public workshop and to view all presentations, please visit <http://www.fda.gov/cder/meeting/riskMAPs.htm>

Recent Publications & Events

Using RADARS System Data

- Richard C. Dart, M.D., Ph.D., Executive Director of the RADARS System, recently participated in an article for the June 25 issue of *Alcoholism and Drug Abuse Weekly*. The article, *Trial of OxyContin: An Opportunity for Treatment Field to Educate*, focuses on treatment options for substance abusers and current trends in prescription drug abuse.
- Cicero TJ, Dart RC, Inciardi JA, Woody GE, Schnoll S, Munoz A. The Development of a Comprehensive Risk-Management Program for Prescription Opioid Analgesics: Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS). *Pain Medicine*. 2007; 8:157-170.

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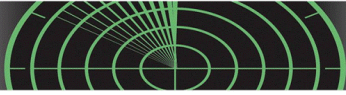
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Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS[®]) System

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

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.

RMPDC 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 and Hospital Authority (DHHA). The RMPDC has been in operation for more than 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.

