RADARS® SYSTEM News

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

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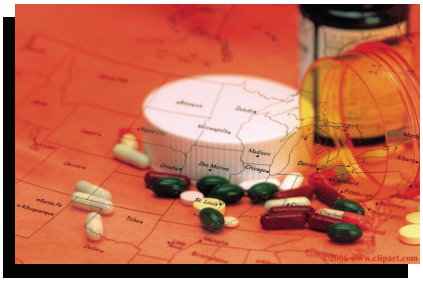


Key Informant Network
of the RADARS System

In 2000 and 2001, reports of abuse of opioid analgesics began to surface in the media and in several federally funded surveys. These reports suggested that prescription drug abuse was a growing epidemic in the United States.[2,3,4] These growing concerns prompted the Food and Drug Administration (FDA) to develop a task force to evaluate post-marketing surveillance and drug safety. This task force recommended that the FDA "work with drug sponsors to develop proactive risk management strategies that would better protect the public by obtaining 'real-time' evidence of emerging problems."[4]

In response to the need for post-marketing surveillance, the RADARS System was developed to monitor prescription drug abuse, misuse and diversion through the use of four signal detection systems. One of the first signal detection systems to be developed was the Key Informant Network System. This system proactively surveys drug abuse experts. Key informants were identified as individuals "who would be in a strong position to assess, at the very earliest possible time, whether prescription drugs were being abused in their communities and why."[1] These key informants include NIDA grantees, impaired health care professionals, addiction treatment specialists, pain management specialists, and others who are in positions to know about prescription drug abuse in their communities and who have proven to be a "rich source of data on the emergence of abuse of prescription drugs at a local, community level."[1]

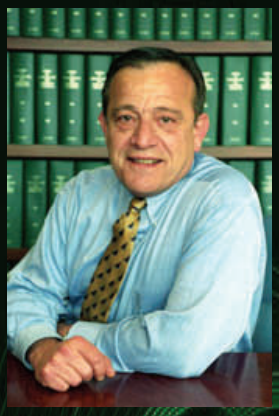
Key informants in all regions of the United States were originally selected based on their qualifications and experience with recognizing problematic substance use or abuse.

Every quarter, key informants are invited to participate in a survey that inquires about the number of individuals known by the key informant to be abusing particular drugs of interest. The survey does not inquire about any individual information that could potentially identify the key informant's clients or patients, thereby preserving confidentiality.

Under the leadership of it principal investigator, Theodore J. Cicero, Ph.D., the Key Informant Network System has been successful in identifying signal sites for drugs of interest every quarter. A signal site is a three-digit zip code with five or more cases per 100,000 persons. Study results from 2002-2004 detected an increasing trend in prescription drug abuse that federally-based data collection systems such as the Treatment Episode Data Set (TEDS) and Community Epidemiology Work Group (CEWG), which are passive registers that lack timeliness in reporting, also later described. This concordance in results indicates that the Key Informant Network is able to provide timely information about the incidence of abuse sooner than the more passive and somewhat "historical" federally funded data collection systems.[1]

Today, the signal detection system has approximately 200 key informants who report from 25 percent of three-digit zip codes in the nation. The RADARS System is working to expand the geographic coverage of this system and is actively recruiting informants in additional regions of the country.

1. Cicero, TJ., Inciardi, JA, Munoz, A. Trends in Abuse of OxyContin® and Other Opioid Analgesics in the United States: 2002-2004. *The Journal of Pain.* 2005; 6(10): 662-672.
2. Substance Abuse and Mental Health Services Administration: Results from the 2002 National Survey on Drug Use and Health: National Findings. Rockville, MD, Office of Applied Studies, NHSDA Series: H22, DHSS Publication No. SMA 03-3836, 2003
3. Substance Abuse and Mental Health Services Administration: Emergency Department Trends from the Drug Abuse Warning Network, Final Estimates 1995-2002. Rockville, MD, Office of Applied Studies. NHSDA Series: D-24, DHSS Publication No. SMA 03-3780, 2003
4. Government Accounting Office (GAO) Report to Congressional Requesters: Prescription Drugs: OxyContin abuse and diversion and efforts to address the problem, Washington, D.C.; GAO-04-0110, 2003
5. U.S. Dept. of Health and Human Services, Food and Drug Administration May 1999. (Henney Report): Managing the risks from medical product use: creating a risk management framework. Available at: http://www.fda.gov/cder/present/dia-699/opdral-dia/opdral-dia.PPT#4. Accessed April 5, 2005.



Theodore J. Cicero, Ph.D.

Principal Investigator

Of the Key Informant Network System

Theodore J. Cicero, Ph.D., principal investigator of the Key Informant Network System and member of the scientific advisory board, is known as a distinguished researcher in the field of drug abuse. He most recently served as Vice Chancellor for Research at Washington University and is a life fellow of the American College of Neuropsychopharmacology.

In addition to his academic, university and scientific roles, Dr. Cicero was past president of the College on Problems of Drug Dependence, served on the Board of Scientific Counselors of the National Institute for Drug Abuse, was an expert advisor to the World Health Organization Substance Abuse Advisory Group, and served as chairperson of the Food and Drug Administration Drug Abuse Advisory Panel for ten years.

Dr. Cicero has devoted much of his research to the development of risk management programs for new drugs with abuse potential including development of a post-marketing surveillance program for tramadol.

Now, Dr. Cicero's participation in the RADARS System has expanded his research and risk management efforts to include other opiates with high abuse potential and with his involvement, the Key Informant Network System effectively detects abuse rates for the monitored drug substances of the RADARS System.

Profile

Drug Enforcement Administration

Proposes New Policy for Prescribing Painkillers

The Drug Enforcement Administration (DEA) has overturned their policy regarding the prescribing methods for morphine-based painkillers. The new rule allows doctors who treat chronic pain sufferers to write three 30-day prescriptions at a time; two of the prescriptions are to be post-dated to be filled one month apart. Previously, doctors were only allowed to write a single prescription for a 30-day supply, which would often require patients to visit their doctor each month to receive a new prescription—an office visit that many felt was unnecessary.

Morphine is one of the nine drug substances monitored by the RADARS System and the data gathered may provide insight into the relationship between prescribing practices and abuse rates.

"This proposed rule…is intended to make sure patients get the pain relief they need, and that doctors have the latitude to prescribe in a manner consistent with their sound medical judgment, while enabling DEA to fulfill its legal obligation to prevent drug abuse and diversion."

Working Together: DEA and the Medical Community

Available at http://www.usdoj.gov/dea/pubs/pressrel/pr090606.html

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Did You Know?

The Poison Center System collects data on pediatric exposures to the RADARS System monitored drug substances. The December issue of the RADARS System newsletter will provide more information on this signal detection system.

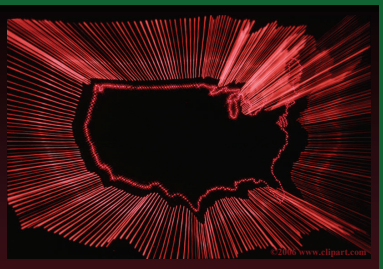
Institute of Medicine Report Suggests
Surveillance of New Prescription Medications

On September 22, 2006, the Institute of Medicine (IOM), an independent committee selected by the Food and Drug Administration (FDA) released its findings titled, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*. The committee was assembled to assess the U.S. drug safety system and to make recommendations to improve risk assessment, surveillance and the safe use of drugs. Among the recommendations was one concerning new prescription medications and public safety *following* the release of a drug. The FDA does not currently require any post-marketing surveillance for prescription drugs. However, the IOM report specifically recommends that the FDA have the ability to require post-marketing risk assessment and risk management programs to monitor and ensure safe use of prescription drugs.[1]

If these recommendations are enacted, prescription drug companies may need to enhance their current risk management efforts to include post-marketing surveillance regarding the use of their prescription drug products. Such post-marketing surveillance has been completed to satisfy FDA requirements without hindering the release of a drug into the marketplace.

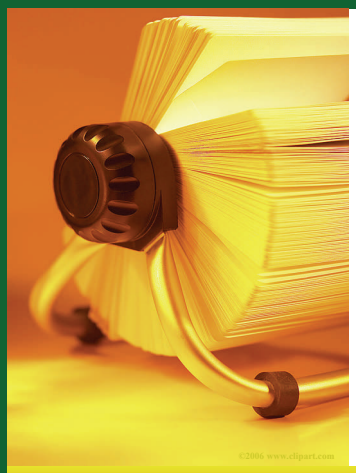
In 1994, Theodore J. Cicero, Ph. D., now a member of the RADARS System scientific advisory board and principal investigator of the RADARS System Key Informant Network System, proposed a plan to the FDA that a new drug, tramadol—HCl (Ultram®), which had very limited abuse potential, could be marketed as a non-scheduled drug provided that an aggressive post-marketing surveillance program was implemented and overseen by an Independent Steering Committee (ISC). Ultram was approved by the FDA as a non-scheduled drug and the RADARS System continues to monitor tramadol today. Such post-marketing surveillance and risk management efforts have been *encouraged* by the FDA in the past, and now, following the IOM report, may soon be *required* by the FDA.

1. Institute of Medicine Committee on the Assessment of the U.S. Drug Safety System. The Future of Drug Safety: Promoting and Protecting the Health of the Public. The National Academy of Sciences, 2006. http://www.nap.edu



"The committee's vision of a transformed drug safety system has at its core a life-cycle approach to drug risk and benefit—not a new concept, but one that has been implemented, at best, in a limited and fragmented manner."

The Future of Drug Safety: Promoting and Protecting the Health of the Public



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Did You Know?

The RADARS System currently has four signal detections systems and is in the process of developing new signal detection systems which will collect data from additional populations within the United States. These systems will be spotlighted in future newsletters.

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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.

DENVER HEALTH
Level One Care for ALL

RMPDC
ROCKY MOUNTAIN POISON & DRUG CENTER
Saving Lives with Answers for 50 Years™