RADARS® SYSTEM News

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

First Quarter 2008 **Volume 3, Issue 1**

In this Issue

Did You Know?

- ***The RADARS System currently monitors 11 drug substances and can easily add others as needed.***

  These drug substances include 77 specific products or subcategories, each of which may be reported on at the request of the subscriber.

- ***The RADARS System newsletter is also available electronically.***

  The e-newsletter is a fast and easy way to receive news, updates and announcements from the RADARS System.

  Visit www.radars.org to subscribe to the electronic distribution list.

Prescription Monitoring Programs: An Overview

According to the National Alliance for Model State Drug Laws, 36 states have operating PMPs or have approved PMP legislation—all with the goal of detecting and preventing abuse and diversion of pharmaceutical products.

All PMPs gather the same basic information including patient name, address, type and amount of drug dispensed, prescribing physician's name, pharmacy name, date of dispensing, and prescription number. Other pertinent information is also gathered depending on individual state needs. This information is housed in a state database where prescribers, law enforcement agencies and state officials can detect abuse, misuse or diversion of pharmaceutical products.

Though PMPs collect similar data and share the same goals, their overall operational procedures remain a function of each individual state. PMPs can be run by various state agencies including public health departments, law enforcement agencies or boards of pharmacy; the schedules of drugs that are monitored can vary; the reporting timeframes can vary from monthly to daily; and the ways in which the information is used can vary as well and research into which methods of use are more effective in curbing abuse, misuse and diversion of pharmaceutical products continues.

A 2004 report by the U.S. General Accounting Office, *State Monitoring May Help to Reduce Illegal Diversion,* stated that monitoring programs have been effective in reducing prescription drug diversion, but also noted that as drug diverters became increasingly aware of a state's ability to track a person's drug history, those diverters tended to relocate their diversion activities elsewhere, usually to neighboring states. For this reason, the Department of Justice is currently funding pilot projects for state PMPs to share data.

An article in the January 2006 edition of

[PMP continued on page 3]

Specific Purposes of PMPs

- **Education and information**—PMPs provide feedback to physicians and pharmacists about prescribing and dispensing. PMPs also produce prescription drug abuse data which can raise public awareness.
- **Public health initiatives**—PMP data are used to implement new programs, evaluate current programs and establish health policies.
- **Intervention and prevention**—Patient specific data allow health care professionals to distinguish between legitimate medical concerns and instances of potential drug abuse.
- **Investigation and law enforcement**—PMP data provide law enforcement agencies with information that can aid in the prosecution of crimes involving prescription drugs.
- **Protection and confidentiality**—Even though most PMPs predate the Health Insurance Portability and Accountability Act, all PMPs already incorporated extensive security measures to protect patient confidentiality and no breaches of security have been documented to date.

Interview with RADARS System Scientific Advisory Board Member, Danna Droz, R.Ph., J.D.

Danna Droz, R.Ph., J.D.

Danna Droz is the Prescription Monitoring Program (PMP) Administrator for the Ohio State Board of Pharmacy with primary responsibility for the Ohio Automated Prescription Reporting System and currently serves as a member of the RADARS System Scientific Advisory Board. She developed and implemented KASPER (Kentucky All Schedule Prescription Electronic Reporting), a nationally recognized PMP and is a frequent lecturer on drug law topics including pharmacy drug law, drug law for practitioners, PMPs, federal drug law, drug diversion and legal issues in pain management.

Q. Please tell us about your current work.

In 2005, Ohio's governor signed legislation authorizing the Board of Pharmacy to implement a PMP. Previously, I administered the KASPER program in Kentucky which seemed to influence a large number of individuals to travel to Ohio to see physicians and obtain prescriptions. Knowing that I had retired in 2003, the Board invited me to develop a similar program for Ohio. I'm very passionate about PMPs and their value to health care practitioners as well as law enforcement so I moved to Columbus, OH. We opened OARRS, the Ohio Automated Rx Reporting System, in October 2006. After 14 months, we are processing nearly 1000 requests for information every weekday, with 79% of these coming from prescribers and 17% from pharmacists. I'm not aware of another state that has experienced this rate of growth. The Ohio Board and the staff have been incredibly supportive. Their support and a great staff of two are helping us to build a first class PMP.

Q. Many states have implemented a PMP. How can these data be used by various parties?

First, states vary widely in who has access to the data. Some states allow only physicians and some allow only law enforcement and the rest are somewhere in the middle. Most states that allow physician access also allow pharmacists to obtain information. In addition, numerous other entities are identified in individual state laws including the Medicaid programs, the state's attorney general, or researchers (using de-identified data). So, not every program will allow every group to use the data.

Secondly, most of the programs provide a list of prescriptions obtained by the patient, not an assessment. Thus the person receiving the list of prescriptions can evaluate it, in light of other information such as the patient's diagnosis, physical symptoms, and other non-PMP drugs. The same list of prescriptions might indicate abuse or misuse in a chronic pain patient but be perfectly legitimate in a cancer patient. It is impossible to make good judgments based only on PMP data.

Physicians are the primary clients of every PMP that allows physicians to obtain patient prescription information. The physicians can use the report to validate the patient-provided drug history or to evaluate compliance with their treatment plan. For example, is the patient getting all the prescriptions filled at the appropriate intervals? Are they obtaining similar drugs from other physicians? Is the patient in compliance with any agreement to use only one or two pharmacies? Does the patient need drug abuse counseling or other types of drug abuse/addiction treatment?

Pharmacists are an extension of the physician, but many times they have access to additional information that a physician does not have, such as when patients utilize multiple pharmacies for their prescriptions. The pharmacists are drug experts and often detect early refills, duplicate therapies, or forged prescriptions. They can then consult with the prescriber(s) to ensure that the patient receives appropriate treatment.

State and federal regulators are responsible for protecting the public from health care professionals. When someone complains that a physician is "over-prescribing" or prescribing inappropriately, the licensing board needs to obtain detailed prescription information about a large number of patients. With a PMP report, the initial phase of the investigation can be done very quickly and substantiate the complaint or provide a reasonable basis to close the case.

Law enforcement officers use PMP information to focus their investigations. Typically, an officer receives a complaint that an individual is forging prescriptions or obtaining prescription by deception, both of which are criminal activity. Without a PMP, the officer must contact every pharmacy in the area to try to locate the prescriptions that become evidence of the crime. With a PMP report, the officer can contact only the specific pharmacies where the evidence is likely to be located. PMP information does not alter the investigation that is required; it simply streamlines it.

Q. Are there any limitations to PMP data?

Yes, states typically restrict the data in

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Save the Date!

RADARS System 2008 Annual Scientific Meeting

Thursday, May 1, 2008 ❍ Bethesda, Maryland

See page 4 for more information.

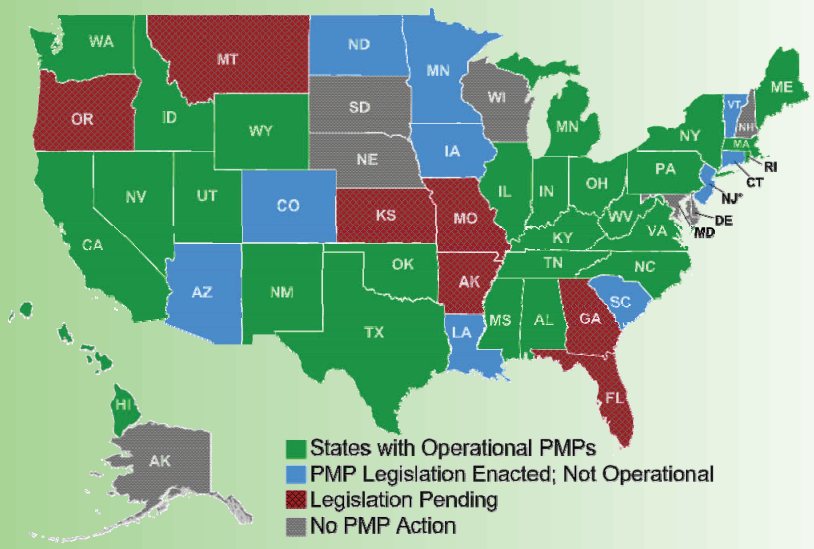
[PMP from page 1]

Legisbrief, from the National Conference of State Legislatures noted that PMPs are effective in gathering information for their own state, but remain unable to share information across state lines which make evaluating prescription drug abuse trends at a regional or national level difficult.

Given that PMPs continue to emerge throughout the nation, it is necessary to scientifically confirm their effectiveness and value to the medical community and general public.

The RADARS System is able to evaluate and measure rates of prescription drug abuse, misuse and diversion over specific time spans and can report data at a three-digit ZIP code level to evaluate the effectiveness of interventions and programs such as PMPs.

Status of Prescription Monitoring Programs



Information for graphic obtained from: Drug Enforcement Administration. *A Closer Look at Prescription Monitoring Programs.* Available at http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm. Current as of December 2007.

*New Jersey PMP law passed on January 4, 2008. Program not yet operational.

Q&A

Q. Can RADARS System data be used to analyze the effectiveness of local, state and national interventions?

A. Yes, RADARS System data can provide an analysis of current trends in prescription drug abuse, misuse and diversion and can measure the effectiveness of interventions.

A recent analysis of Kentucky's Operation UNITE (Unlawful Narcotics Investigations, Treatment and Education) found that the program decreased prescription drug abuse in the 29 counties of Kentucky's fifth congressional districts.

To complete the analysis, RADARS System researchers analyzed poison center intentional exposures involving prescription opioid abuse before and after the initiation of Operation UNITE.

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a number of ways to protect patient confidentiality. Primarily, states restrict the purpose for which an individual can obtain the data. A good example is that a pharmacist may only obtain a report on a patient, i.e. someone who has, at a minimum, presented a prescription. They may not use a PMP report for pre-employment screening purposes.

Another restriction is the length of time that the PMP can retain the patient's identifying information. The data has value in healthcare and law enforcement for only for 2 to 3 years. So there's no reason to retain that data any longer. (There is, however, value in retaining de-identified data for longer periods for research purposes.)

Probably the most important limitation is remembering that this data is subject to errors that are inherent in the pharmacy process. Pharmacy personnel make data entry errors such as reversing the digits on a birth date or attributing a prescription to the wrong prescriber. Other times the patient may decide to pick up a prescription at a different pharmacy after it was telephoned in and prepared for dispensing. If the first pharmacy already reported the prescription to the state PMP, the drug may appear to have been dispensed twice. Understanding the pharmacy workflow and record-keeping is a major key to understanding what the data may or may not mean.

What opportunities for research are there using PMP data?

PMP data are a rich resource for current dispensing patterns. I'm working with some researchers in Ohio to see if we can correlate prescription drug dispensing patterns with street availability of prescription drugs. It may not be possible but we don't know until we study it. Another researcher wants to study the effects of marketing on certain products. Yet another is discussing differences in narcotic use by specific populations. In addition, PMP data could be used to validate other research or data sources. Of course, all of this is using de-identified data.

PMP data might answer numerous other questions. Some states do not allow research with PMP data at all and not every state collects all the same data elements. Yet, since 36 states now have a PMP or are in the process of developing it, the next few years can be very exciting in terms of the research that can be done.

RADARS System to Host Second Annual Scientific Meeting on Prescription Drug Abuse: *From Signals to Interventions*

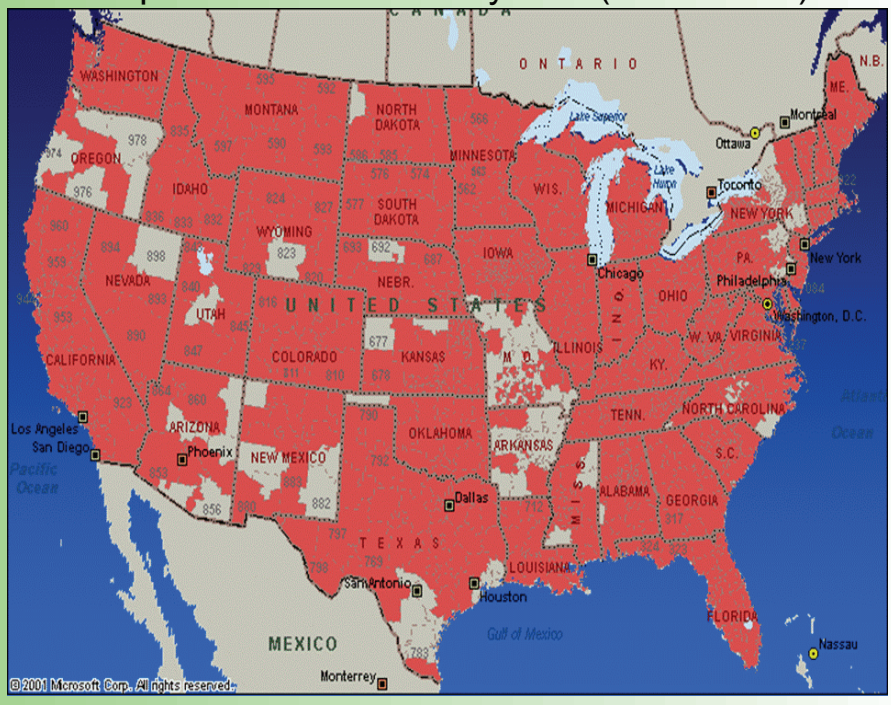
Research on the abuse, misuse and diversion of prescription drugs continues to provide essential information concerning prescription drug safety in the nation. In an effort to continue to contribute to the understanding of prescription drug abuse, misuse and diversion, the RADARS System will host its second annual scientific meeting: *From Signals to Interventions* on May 1, 2008 in Bethesda, Maryland.

The second annual scientific meeting will focus on new developments in prescription drug abuse research and interventions. In addition, an overview of newly developed signal detection systems and annualized 2007 data will be presented. Speakers will include experts in public health interventions and in prescription drug abuse and interventions. To date, three speakers have been confirmed and will be presenting on the following topics:

- Dr. Jennifer Sabel from the Washington State Department of Health will present on *Prescription Opiate Deaths in Washington State and Potential Solutions*
- Patrizia Carrieri from the French National Institute from Health and Medical Research will present on *The Importance of Measuring Drug Related Harms and Benefits of Treatment in Post-Marketing Surveillance: Lessons from Buprenorphine*
- Commander John Burke from the National Association of Drug Diversion Investigators will present on *Law Enforcement and the Pharmaceutical Industry-Collaboration for Success*

In 2007, annual meeting attendees included several pharmaceutical manufacturers; representatives from U.S. government regulatory agencies including the Drug Enforcement Agency, Food and Drug Administration; the Substance Abuse and Mental Health Services Administration; as well as representatives from several organizations such as the National Association of Drug Diversion Investigators and the American Association for the Treatment of Opioid Dependence; and researchers in the field of prescription drug abuse. Detailed information is posted at www.radars.org.

2006 Prescription Drug Abuse or Diversion Cases Reported to RADARS System (shaded red)



Key findings presented at the 2007 Annual Scientific Meeting include:

- Prescription opioid abuse is widespread, affecting nearly all areas of the United States (see map).
- No community is immune to prescription opioid abuse: 93 percent of reporting three-digit ZIP codes had at least one case of prescription opioid abuse, misuse or diversion in 2006.
- The highest pockets of abuse, misuse and diversion occur in the Appalachian Region and the Northeast.
- Levels of abuse are high and still increasing in some areas, though may be flattening out in other areas.
- No single prescription opioid is responsible for the problem. RADARS System data indicate that abusers typically take advantage of multiple opioids.
- According to data from the Poison Center Signal Detection System, there were 9,240 exposures to prescription opioids in young children from January 2003 to July 2006.

Study Provides Overview of Prescription Drug Diversion Trends

While national surveys have documented prescription drug abuse and misuse as a widespread problem, few studies have focused on the problem of prescription drug diversion where regulated pharmaceuticals are moved to the illicit marketplace. A study using data gathered from the Drug Diversion Signal Detection System was published in a recent issue of *Law Enforcement Executive Forum*.

The Diversion of Prescription Opioid Analgesics by James A. Inciardi, et al., provides an overview of prescription drug diversion and highlights the need to understand where and how prescription drug diversion occurs.

Drug Diversion survey data reported in the article revealed that from January 2002 through December 2006, "a total of 64,655 investigations of prescription drug diversion were initiated...and typically, more than one drug was involved in each case." Furthermore, survey data found that despite the recent media focus on the Internet as a primary source for diversion, drug abusers typically avoid the Internet as a source for prescription drugs.

These findings are an important step towards understanding how therapeutic medications are moved to the illegal marketplace, however RADARS System researchers note that more studies are required to fully understand this problem.

The Drug Diversion Signal Detection System, one of the first signal detection systems developed under the RADARS System, continues to research current prescription drug diversion trends across the nation providing a unique look at one of the facets of the prescription drug abuse spectrum for the RADARS System.

RADARS System Publications

1. Inciardi JA, Surratt HL, Lugo Y, Cicero TJ. The Diversion of Prescription Opioid Analgesics. *Law Enforcement Executive Forum*. 2007; 7.

2. Cicero TJ, Inciardi JA, Surratt HL. Trends in the Use and Abuse of Branded and Generic Extended Release Oxycodone and Fentanyl Products in the United States. *Drug and Alcohol Dependence.* 2007; 91: 115-120.

Please visit www.radars.org for a complete list of publications.

Meetings of Interest

- The Center for Substance Abuse Treatment hosted the 2008 Buprenorphine Summit on February 21-22, 2008. The meeting, *Buprenorphine in the Treatment of Opioid Addiction: Balancing Medication Access with Quality Care*, brought together experts in the field of opioid addiction treatment to review current patterns of buprenorphine use in the treatment of opioid addiction.

  Nabarun Dasgupta, MPH, doctoral candidate in epidemiology at the University of North Carolina at Chapel Hill attended the meeting and presented RADARS System data on current trends in buprenorphine abuse, misuse and diversion.

- The American Society of Addiction Medicine will host its 39th Annual Medical-Scientific Conference April 10-13, 2008 in Toronto, Ontario, Canada.

  Richard C. Dart, M.D., Ph.D., Executive Director of the RADARS System will attend and present at a seminar held Sunday, April 13, 2008. *Buprenorphine and Office-Based Treatment of Opioid Dependence* will cover the efficacy and safety of buprenorphine treatment. Dr. Dart's presentation will present prescription drug abuse, misuse and diversion data from the RADARS System.

- The College of Problems of Drug Dependence will host its 70th Annual Scientific Meeting June 14-19, 2008 in San Juan, Puerto Rico.

- The Drug Information Association will host its 44th Annual Meeting June 22-26 in Boston, MA.

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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.

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 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.