RADARS® SYSTEM News

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

Fourth Quarter 2010 Volume 5, Issue 4

In This Issue

Did You Know?

The RADARS System will be holding its 5th Annual Meeting on April 28 2011 in Bethesda, Maryland.

Save the Date!

The RADARS® System at the FDA Abuse Deterrent Formulation Advisory Committee Meeting

Due to growing concerns regarding the misuse and abuse of prescription opioids, the FDA and pharmaceutical companies have been assessing new Abuse Deterrent Formulation (ADF) opioid products. As part of this assessment, the FDA recently held an Advisory Committee meeting to address how postmarketing studies accurately demonstrate whether specific opioid products "intended to deter misuse and abuse actually result in a decrease in the risks of misuse and abuse."

At the meeting, committee member Dr. Robert Kerns, director of the pain management program at Yale University, told FDA officials, "We're a long way away from making any kind of conclusion about abuse deterrence." Since there is no current consensus on a path forward and "not a specific metric or surveillance system in place" to answer all ADF questions, Dr. John Mendelson, senior scientist in the California Pacific Medical Center, offered a product by product standard. Dr. Mendelson expanded on the point that an agreement on consensus methodologies to measure these new formulations would take years.

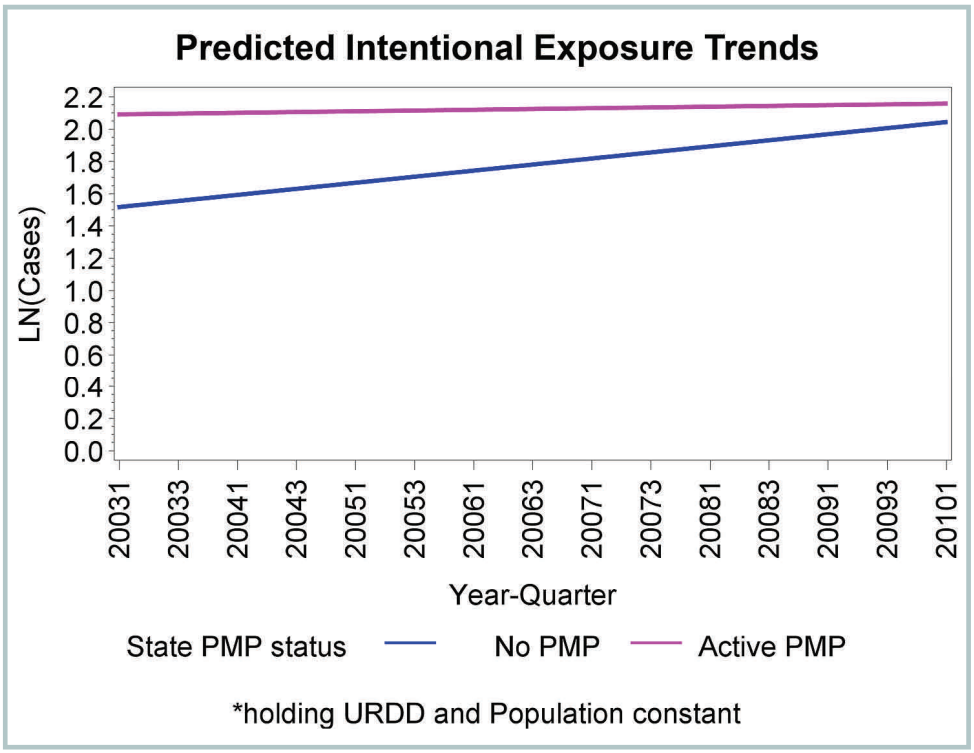
The Advisory Committee concluded that current data sources, both public and private would be satisfactory to measure the effectiveness of abuse deterrent formulations. Reports of abuse and misuse behaviors; emergency events and hospitalizations; and outcomes such as overdoses all comprise sources of data which can be used to evaluate trends related to non-medical drug use. Since each data source has strengths and limitations, the inclusion of data from multiple sources can contribute to the overall evaluation of these new abuse deterrent formulations. The committee members recommended companies utilize existing monitoring programs on an every 6 month basis, for a minimum study period of three years using a comparison to other similar products that are on the market.

RADARS® System was asked by Purdue Pharma, Inc. and King Pharmaceuticals Research and Development, Inc. to participate in the FDA Advisory Committee meeting in order to outline their capabilities in evaluating two new ADF opioid formulations, OxyContin® and Embeda®. RADARS System will provide both Purdue and King surveillance data from its numerous programs, allowing the companies to effectively meet the requirements outlined in the Advisory Committee recommendations. Data collected by the RADARS System will be brand specific, incorporate generic competitors and provide a basis of comparison for population rates and indices of drug availability. Data will include routes of administration, a key factor in determining the overall effectiveness of abuse deterrent formulations. The RADARS System will be integral in assisting both companies in assessing and measuring "the exact form of abuse and misuse that their product was designed to deter and then demonstrate efficacy of their strategy in a human population."

Using RADARS® System Poison Center Data To Examine Opioid Abuse/Misuse Rates Relationship To State Prescription Monitoring Programs

Prescription Monitoring Programs (PMPs) are statewide databases, containing patient-level prescription data on select drugs, intended for medical professionals or other officials to use in identifying patients with prescription drug abuse history or providers engaging in illegal activities. Most states have implemented PMPs in attempt to curb prescription drug abuse and diversion; however, assessment of their impact, if any, on drug abuse is only beginning. We aimed to evaluate the relationship between PMPs and state opioid abuse and misuse rates over time.

Six and a half years (2003-mid 2009) of RADARS System Poison Center Program (PC) intentional exposure data were used as a measure of opioid abuse and misuse. A repeated measures negative binomial regression was used to assess the association between states' intentional exposures and PMP presence.



Even after controlling for factors such as population, drug availability, state PMPs were a significant factor in predicting intentional exposures. Further, results support that states with active PMPs have a slower increase over time in intentional exposures than states without such programs. PMP states' intentional exposures increase 1.0% (CI -2.0 to 4.1%) annually, where as states without monitoring programs have an average increase of 7.9% (CI 4.2 to 11.6%) annually.

PC observational data offer preliminary support that PMPs are effective. Future efforts will evaluate the effectiveness based on PMPs' characteristics across states, medical professional utilization, and drug abuse populations most impacted.

RADARS.org Site Launch

The RADARS System will be re-launching RADARS.org in January 2011. The site will feature new content, better navigation and an updated contemporary look. The redesign is part of an ongoing effort to enhance communications between the RADARS System, our subscribers, government agencies and industry.

Recent RADARS System Publications and Presentations

- Varughese S, Rosen S, Lindholm A, Ertischek MD, Sembower MA, Schnoll S. Non-medical use surveillance and signal identification of lisdexamfetamine dimesylate, a pro-drug stimulant for the treatment of ADHD. American Academy of Child and Adolescent Psychiatry Annual Meeting. New York, NY. October, 2010.

Upcoming Meetings of Interest

- DIA Pharmacovigilance and Risk Management, January 9-12, 2011. Washington, District of Columbia.
- ExL Pharma Events 3rd Risk Evaluation and Mitigation Strategies Summit, January 24-25, 2011. Arlington, Virginia.
- Food and Drug Law Institute Conferences, January 25-26, 2011. Washington, District of Columbia.
- American Academy of Forensic Sciences, February 21-22, 2011. Chicago, Illinois.
- DIA Excellence in Pharmacovigilance, February 21-25, 2011. London, United Kingdom.
- American Society for Clinical Pharmacology and Therapeutics, March 2-5, 2011. Dallas, Texas.
- Society of Toxicology, March 6-10, 2011. Washington, District of Columbia.
- NIDA Clinical Trials Network, March 15-17, 2011. Bethesda, Maryland.
- American College of Medical Toxicology Spring Conference, March 13-20, 2011. Clearwater, Florida.
- American Academy of Pain Medicine, March 24-27, 2011. Washington, District of Columbia.
- Drug Information Association Euro Meeting, March 2-5, 2011. Geneva, Switzerland.

Did You Know?

Richard Dart M.D., Ph.D. was sworn in as the president of the American Association of Poison Control Centers (AAPCC).

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RADARS System Mission Statement

The RADARS System provides timely, product specific and geographically-precise 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 and Hospital Authority

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.

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