



Researched Abuse, Diversion and Addiction-Related Surveillance System

Fourth Annual Scientific Meeting: *Risk Management of Scheduled Drugs – Evaluation of REMS for Opioids*

RADARS® System Fourth Annual Scientific Meeting
Risk Management of Scheduled Drugs – Evaluation of REMS for Opioids
Wednesday, April 14, 2010
Hyatt Regency (Bethesda, Maryland)

The RADARS System Fourth Annual Scientific Meeting was organized to address the evaluation of Opioid Risk Evaluation and Mitigation Strategies (REMS), using data-based decision making and a multiple-perspective approach.

Attendees (n=76) included researchers and speakers, pharmaceutical representatives, federal research/regulatory agency representatives and policymakers.

Richard C. Dart, MD, PhD, Director of the Rocky Mountain Poison & Drug Center (RMPDC) at Denver Health & Hospital Authority in Denver, Colorado, and Executive Director of the RADARS System, presided over the meeting. The RADARS System, which was acquired by Denver Health and Hospital Authority from Purdue Pharma L.P. January 1, 2006, is now an independent operation of RMPDC and completed its 8th year of data collection in December 2009.

After a brief overview of RADARS System annual data from 2009, the meeting focused on strategies and methods for evaluating the effectiveness of REMS for opioids and fulfilling the requirements set forth by recent FDA mandates under FDAAA (2007). A summary of each of presentation is provided below.

Report of RADARS System 2009 Data

Richard C. Dart, MD, PhD

*Rocky Mountain Poison & Drug Center, Denver Health and Hospital Authority
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RADARS System data offer multiple perspectives on prescription drug abuse, misuse, and diversion through the use of six programs (Drug Diversion, Poison Center, Opioid Treatment, Survey of Key Informants' Patients, Impaired Health Care Worker, and College Survey). These programs collect and provide data rapidly with geographic specificity to the 3-digit ZIP code level. The six RADARS System Programs provide unique perspectives and offer opportunities to monitor prescription drug abuse, misuse and diversion in distinct populations, providing a unique mosaic of current drug use patterns.

The RADARS System Programs provide excellent geographical coverage. Ninety-nine percent of 3-digit ZIP codes in the US report to at least one RADARS System Program, with 90% covered by 2 or more and 65% covered by 3 or more. In 2009, the 3-digit ZIP codes reporting to at least one RADARS System Program increased in Pennsylvania but decreased in New Mexico.

RADARS System 2009 publications and new lines of research in 2009 consist of:

- 6 published manuscripts



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- 7 posters/oral presentations at scientific conferences
- Pilot study of Drug Diversion Street Price Survey
- Data provided directly to US FDA

A complete list of RADARS System related publications is provided in Appendix A.

In addition, RADARS System representatives gave presentations to the following groups in 2009:

- IMMPACT-X
- College on Problems in Drug Dependence
- American Academy of Pain Medicine
- Food and Drug Administration

For 2009, RADARS System Programs report continued high prevalence of and geographic penetration of abuse, misuse and diversion cases of prescription opioids of interest (buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and tramadol).

Trends over time for RADARS System prescription opioids of interest and for each RADARS System Program demonstrate that rates adjusted for population are increasing over time, while rates adjusted for availability of prescription opioids in a community (Unique Recipients of Dispensed URDD [URDD]) are not increasing over time. Therefore, as availability of prescription opioids of interest increases, abuse, misuse and diversion of these prescription opioids increase proportionally to the availability of those opioids.

Trends over time for RADARS System prescription stimulants of interest (amphetamines and methylphenidate) have remained relatively stable over time.

The RADARS System is able to evaluate the effectiveness of interventions, and Dr. Dart presented the results of an analysis of RADARS System Poison Center Program data in states with and without state-based prescription monitoring programs (PMPs). State-based PMPs mitigate opioid intentional exposure rates over time as evidenced by slower increases in RADARS System Poison Center intentional exposure rates per 1,000 URDD in states with PMPs compared to states without PMPs (states with PMPs report a 0.3% increase in intentional exposure rates per quarter while states without PMPs report a 2.2% increase in intentional exposure rates per quarter).

In conclusion, RADARS System data from 2009 demonstrate the following:

- Prescription opioid abuse, misuse and diversion rates are increasing
- Every state has evidence of abuse, misuse and diversion of prescription opioids
- All prescription opioids are abused and are often abused in combination with other prescription opioids
- The RADARS System can detect changes in rates of abuse, misuse and diversion



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Risk Evaluation and Mitigation Strategies (REMS): An Overview

Mary Willy, PhD

Deputy Director, Division of Risk Management

Office of Surveillance and Epidemiology, Food and Drug Administration

In 2007, the Food and Drug Administration Act (FDAAA) established REMS, requiring sponsors to develop and comply with risk evaluation and mitigation strategies to ensure the benefits of a drug outweigh the risks to the public. These provisions took effect on March 25, 2008.

REMS can be required at time of drug approval or post-approval with new safety information. REMS require both the REMS plan itself and a supporting document. REMS elements may include such items as medication guides or package inserts, communication plan, elements to assure safe use (ETASU), and an implementation system.

All REMS must include a timeline for assessments which should take place at a minimum at 18 months, 3 years and 7 years after REMS approval, although FDA may specify assessments at different frequencies. REMS assessment plans may include the following elements:

- Proposed evaluation methods and rationales for the chosen measures
- Targeted values for each measure and the timeframe for achieving them
- Type of data that will be collected
- Plans to assess unintended and/or favorable consequences of the REMS following implementation
- Conclusion about whether goals have been met

FDA will then review the assessments and determine whether the REMS is meeting its goals and whether modifications to the REMS are required.

Assessment of opioid REMS in particular may include evaluation of patient understanding of serious risks, evaluation of prescriber understanding of serious risks and safe use, an analysis and summary of surveillance and monitoring activities for abuse, misuse, overdose and addiction, an analysis to evaluate utilization patterns, and an assessment of the extent to which ETASU are meeting the goals or whether the goals should be modified.

REMS are approved for 107 products which are available on FDA website along with the draft guidance documents for REMS development

(<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm>).

FDA is hoping to finalize guidance on the format and content of a REMS and publish a draft guidance on REMS assessments and modification. In addition, an advisory committee will convene to help develop opioid-specific REMS.

Options for Measuring the Impact of Opioid REMS on Non-Patients



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Non-patients are defined as those who intentionally use opioids for psychotropic effects outside of medical supervision, unintentional pediatric exposures, and individuals with pain who are not under the care of a physician. Societal expectations, FDAAA citation and foreseeable (unintended) consequences of opioid exposures are all cited as reasons for measuring non-patients in REMS for opioids. Evaluating the impact of REMS for opioids on non-patients is dependent on the final design of the REMS for opioids and on how exposure to the REMS is measured. With REMS for opioids, one might expect better patient selection through prescriber education, less diversion through patient education, and increased public awareness.

A “balloon effect”, the concept that decreased availability of one drug will lead to increases in the use/abuse of other pharmacologically similar drugs assuming no major change in demand, is possible as seen in the example of temazepam gel caps in Australia (Degenhardt L, et al. The effects of the market withdrawal of temazepam gel capsules on benzodiazepine injecting in Sydney, Australia. *Drug Alcohol Rev.* 2008 Mar; 27(2): 145-51).

The evaluation of drug use/abuse outcomes post-REMS for opioids will be observational (sometimes naturalistic) studies, which should adhere to the guidelines set by FDA Guidance for Industry on Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, International Society for Pharmacoepidemiology (ISPE) Guidelines for Good Pharmacoepidemiology Practices, and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. Currently, FDA-mandated data sources cited in the Draft Guidance for the Development of REMS do not adhere to these guidelines.

The definition of patients and non-patients for the purposes of evaluating the impact of REMS for opioids is difficult to define, therefore multiple data sources should be considered. Further, a distinction between actual and perceived availability of opioids and the confounding effect of various factors should be considered. REMS for opioids will increase the scrutiny of data sources used in future policy-making, and combining small, well-conducted studies and data from national sources will provide a better breadth of data than any single system alone.

The DSM Approach to Diagnosis of Addiction

Charles O'Brien, MD, PhD
University of Pennsylvania

The identification of substance use disorders is challenging, as is determining the severity of these disorders. The revised Diagnostic and Statistical Manual (DSM V) will address these substance use-related topics as well as consider for inclusion other non-substance addictions.



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In the DSM III, a substance abuse continuum was defined, with a progression from use to abuse to addiction. Few data were available pertinent to the abuse stage. Currently, there is increased emphasis on levels of addiction severity and understanding the neuroplastic changes produced by addiction. Repeated drug use results in two distinct (and often discrete) states: physical dependence and compulsive drug-seeking behavior (which varies based on the specific drug used). In the DSM IV, tolerance and withdrawal were determined to be insufficient to make a diagnosis of substance abuse disorder, so “craving” was added.

Predicting who is at greater risk than others of developing addiction is difficult; more patients are being treated currently than in the past, but quantification of the increase in risk is also challenging. Additionally challenging is assessment of the interaction between psychological issues, substance abuse and chronic pain, particularly with regard to treatment plans. The development of a new prospective cohort study is underway to assess risk factors for aberrant drug use behaviors. The study will be an observational/naturalistic study and will aim to address the following:

- Under-treatment of pain
- Prescribing habits of doctors
- Further refinement of “craving” definition
- Adverse drug effects vs. actual side effects

The development of the DSM V will acknowledge that comorbidities are the rule (not the exception), and, as a result, evaluations will be cross-cutting.

Unintended Consequences of Drug Risk Communication: The Example of Antidepressants

Robert Valuck, PhD, RPh
University of Colorado

Important lessons from drug risk communications for prescription antidepressants are applicable to drug risk communications for opioids, such as REMS for opioids because many commonalities exist between the two drug classes (concerns exist in both drug classes for overuse and underuse; serious side effects may occur in either drug class; both drug classes have experienced increased regulatory scrutiny in recent years). Assessing the impact of drug risk communications presents a challenges designing the evaluations and measuring such effects; quick access to relevant data sources as well as large study samples and longer follow-up periods are needed.

To address concerns about antidepressant use and suicidality in children and adolescents, FDA issued a Black Box Warning in October 2004 and expanded this warning to include young adults (aged 19-24 years) in December 2005. While some of the intended effects were achieved, broad, persistent unintended effects were identified:

- The diagnosis of depression, bipolar, and anxiety decreased (fewer cases of new diagnoses)
- While the Black Box Warning was targeted to patients younger than 25 years, adults 25 years and older were impacted as demonstrated by decreases in antidepressant prescription rates



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- Individual-level substitution to anxiolytics (pediatric and adult patients) and stimulants (adult patients) were observed
- Primary care physicians responded to the drug risk communication sooner and in greater numbers than psychiatrists

The boxed warning as a drug risk communication strategy is a “blunt instrument” which needs further refining through targeted communications, examination of unintended consequences and optimizing data streams. DARTNet (Distributed Ambulatory Research in Therapeutics Network) provides one such opportunity to collect data on antidepressant prescribing patterns through an alternative network of clinicians. Determining how patients best receive and retain risk communication information is also important, and DARTNet incorporates various data streams to allow for such assessment.

Evaluation of Opioid REMS Using RADARS System Data

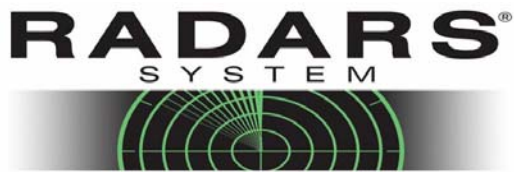
Richard C. Dart, MD, PhD

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Non-REMS opioids (immediate-release opioid products) are prescribed in much higher volumes than REMS opioids. Due to large quantities of prescriptions for non-REMS opioids and the greater risk of medical consequences associated with REMS opioids, it is important to evaluate the data utilizing both population and URDD rates to understand the overall phenomenon.

Objectives for the analysis of REMS and non-REMS opioids using RADARS System data are as follows:

- Effect of REMS for opioids on overall rates abuse, misuse and diversion: if REMS for opioids is effective, two hypotheses are that abuse, misuse and diversion of REMS opioids will decrease and that abuse, misuse and diversion of an individual REMS opioid product will decrease.
- Administration route: if REMS for opioids is effective, two hypotheses are that higher risk routes of abuse of REMS opioids will decrease and that higher risk routes of abuse of an individual REMS opioid product will decrease.
- Medical consequences: if REMS for opioids is effective, two hypotheses are that major events and deaths associated with REMS opioids will decrease and that major events and deaths associated with an individual REMS opioid product will decrease.
- Ages of individuals involved in abuse and misuse: if REMS for opioids is effective, two hypotheses are that frequency of abuse, misuse and diversion will decrease for all age groups for REMS opioids without a corresponding increase in non-REMS opioids and that frequency of abuse, misuse and diversion will decrease for all age groups for an individual REMS opioid product.
- Source of drug abused: if REMS for opioids is effective, two hypotheses are that frequency of diversion will decrease for REMS opioids without a corresponding increase in diversion of non-



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REMS opioids and that frequency of diversion will decrease for an individual REMS opioid product.

- Street price: if REMS for opioids is effective, a difference in street price between REMS opioids and non-REMS opioids may indicate the demand for one drug formulation over another.
- To evaluate natural experiments: natural experiments will be identified for additional analyses after the launch of REMS for opioids.

Baseline data from the RADARS System were presented for the first five of these analysis objectives. The RADARS System offers a way to evaluate some of the anticipated and unanticipated effects of REMS for opioids. However, evaluations will not be simple depending on the outcome measure chosen. While results will be available rapidly (within 5 months of the end of the quarter in question), how should the results be interpreted and applied? Further discussion on this is warranted.



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Appendix A: RADARS System Publication List

Manuscripts

Bailey JE, Barton PL, Lezotte D, Lowenstein SR, Dart RC. The Effect of FDA Approval of a Generic Competitor to OxyContin® (Oxycodone HCl Controlled-Release) Tablets on the Abuse of Oxycodone. *Drug and Alcohol Dependence*. 84:182-187, 2006.

Bailey JE, Campagna E, Dart RC. Reporting for the RADARS® System Poison Center Group. The Underrecognized Toll of Prescription Opioid Abuse on Young Children. *Annals of Emergency Medicine*. 53:419-424, 2009.

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Rosenblum A, Parrino M, Schnoll SH, Fong C, Maxwell C, Cleland C, Magura S, Haddox D. Prescription Opioid Abuse Among Enrollees into Methadone Maintenance Treatment. *Drug and Alcohol Dependence*. 90:64-71, 2007

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Abstracts Continued

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Abstracts Continued

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