



Researched Abuse, Diversion and Addiction-Related Surveillance System

Third Annual Scientific Meeting: *Risk Management of Scheduled Drugs: Where Are We Now? Where Are We Headed?*

RADARS[®] System Third Annual Scientific Meeting
Risk Management of Scheduled Drugs- Where Are We Now? Where Are We Headed?
April 23, 2009, Hyatt Regency in Bethesda, Maryland.

Attendees (n=96) included researchers and speakers, pharmaceutical representatives, federal research or regulatory agency representatives, and policymakers.

The meeting was organized to discuss Risk Evaluation and Mitigation Strategies (REMS) in light of recent FDA announcements regarding monitoring of many Schedule II opioids.

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 7th year of data collection in December 2008.

After a brief overview of RADARS System annual data from 2008, the meeting focused on bridging the gap between curbing prescription drug abuse while maintaining access to prescription opioids for those who need them and fulfilling the requirements set forth by recent FDA mandates under FDAAA of 2007. A summary of each of presentation is provided below.

Report of RADARS System 2008 Data

RADARS System data offer multiple perspectives on the subject of prescription drug misuse, abuse and diversion through the use of seven signal detection systems (Drug Diversion, Key Informant, Opioid Treatment Program, Poison Center, Impaired Healthcare Worker, College Survey , and our latest addition, Survey of Key Informants' Patients). These systems collect and provide data rapidly with geographic specificity down the to 3-digit ZIP code level. The coverage area addresses the rural nature of misuse, abuse and diversion of prescription opioids and also has the ability to identify non-abuser victims of the prescription drug abuse problem, such as accidental ingestions by children.

These seven signal detection systems provide unique perspectives and offer opportunities to monitor prescription drug abuse, misuse and diversion along the spectrum of the drug dependence pathway (opportunity, use, abuse, and dependence).

The RADARS System provides timely and geographically specific data to aid in understanding trends in abuse, misuse, and diversion of prescription drugs in the United States. Current RADARS System prescription drug substances of interest are buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, tramadol, amphetamine, methylphenidate, and carisoprodol.

Goals of the RADARS System:



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- Identifying sentinel events involving the misuse, abuse and diversion of prescription drugs nationwide
- Measure rates of misuse, abuse and diversion of prescription drugs
- Provide experienced and expert analysis and interpretation of the data

Nationally, average RADARS System opioid rates per 1,000 unique recipients of dispensed drug (URDD – an indicator of drug availability) demonstrate stabilizing trends through 2007. Yet these trends appear to be increasing slightly during 2008. The average stimulant rates per 1,000 URDD appear stable over the entire time period of data collection (3rd quarter 2007 through 4th quarter 2008).

Dr. Dart discussed the complexity of the prescription drug problem and the fact that prescription drugs are necessary and effective; however, when abuse arises, pharmaceutical companies are held accountable and this leads to attention from the FDA. Most recently the FDA announced a mandate for Risk Evaluation and Mitigation Strategies (REMS) for several Schedule II narcotics: all extended release opioids, methadone and fentanyl patches.

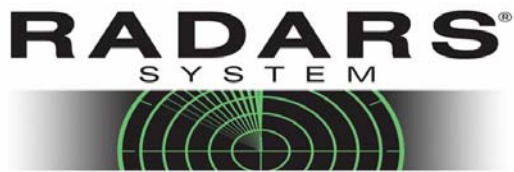
One of the challenges presented by REMS is the evaluation of their effectiveness on the misuse, abuse and diversion of the affected products. The RADARS System is able to evaluate the effectiveness of interventions, and Dr. Dart presented the results of an analysis of RADARS System data before and after the Kentucky UNITE (Unlawful Narcotics Investigations, Treatment and Education) intervention effort. This intervention was initiated in 2004 within the 29 counties in Eastern Kentucky. The program focuses on undercover investigations, substance abuse treatment, support networks for those impacted by drug abuse, and education on the dangers of drug abuse. Funding efforts from state and federal grants are also included for treatment and other areas.

RADARS System Poison Center data demonstrate higher average intentional exposure rates per 1,000 URDD in Eastern Kentucky than in the rest of Kentucky from 1st quarter 2003 through 4th quarter 2008. However, Kentucky UNITE's impact is demonstrated within RADARS System Poison Center data as decreasing average intentional exposure rates per 1,000 URDD since Kentucky UNITE's initiation in 2004. After the intervention, the rates in Eastern Kentucky are decreasing to rates similar approaching those in the rest of Kentucky (where rates are steadily increasing). The increase in rates in the other regions of Kentucky may be a result of people avoiding the UNITE intervention in Eastern Kentucky and simply moving their abuse activities to counties where they are "safe."

The RADARS System Plan for Assessment of REMS

With the implementation of REMS, it is essential to maintain access to opioid analgesics to legitimate patients while reducing misuse, abuse, addiction, and overdose associated with these products. The potential evaluations of REMS that the RADARS System can provide include the following:

1. Impact on reducing misuse, abuse, addiction, and overdose



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- a. Changes in RADARS System rates over time: Do misuse, abuse, and diversion rates increase for products not listed as a part of the class-wide REMS? Do rates decrease for products listed as a part of class-wide REMS?
2. Routes of administration
 - a. Does route of administration change if tamper deterrent formulations are on the market?
 - i. Four RADARS System signal detection systems currently report route of administration.
 1. In 2008, 43.1% of Opioid Treatment Program and Survey of Key Informants' Patients respondents reported injecting their primary drug
 2. In 2008, College Survey respondents endorsed injection and inhalation as routes of administration for non-medical use of prescription drugs
3. Sources
 - a. Will REMS lead to less doctor shopping yet increase access to prescription drugs through other sources?
4. Costs
 - a. Does the cost of REMS drugs go up?
 - i. The Drug Diversion Signal Detection System collects the street price of prescription drugs.

Key Points:

- All prescription opioids and stimulants are abused.
- Data indicate that multiple prescription opioids and stimulants are misused and abused in conjunction with each other.
- RADARS System data demonstrate evidence of abuse, misuse and diversion stabilizing in 2006 – 2007, but increasing throughout 2008.
- RADARS System data can detect rapid changes in rates of abuse, misuse and diversion of products and can assist in the assessment of REMS.

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

Community-Oriented Interventions and Roles of Pharmaceutical Industry

Nabarun Dasgupta, MPH

University of North Carolina – Chapel Hill

The RADARS System

Wilkes County, North Carolina, is a small county in the rural foothills of Appalachia which has poisoning mortality rates 3 to 4 times higher than the state average and 5 times higher than the national average. One of the unique aspects of Wilkes County that lent itself to high rates of poisoning mortality is the blue-collar nature of work in the area, which leads to work-related injury, pain and need for pain management using narcotics. In addition, there is steep elevation change across the county, which can delay 911 response times, often resulting in the death of patients who otherwise may have survived if they had received care in an appropriate timeframe.



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An overdose intervention program called “The Chronic Pain Initiative & Project Lazarus” was designed and implemented in Wilkes County aimed at preventing overdose deaths. The design of the intervention involves a core of community knowledge and coalitions with surveillance, prevention, rescue and evaluation. The coalition is uniquely suited to this task because they have a stake in pain management, addiction treatment and reduction of poisoning mortality in their home county. The coalition was first started because the county wanted to lower hospital admissions related to overdoses and thereby reduce hospital costs; while the admission rate and hospital costs have declined in Wilkes County, the death rate has yet to decline.

The components of the intervention are as follows:

1. Create a “Pharmacy Home” which is as close to a patient registry as the coalition could get
 - a. Patients must have access to a single physician who also must be registered with Pharmacy Home.
 - b. Patients must also use the same pharmacy for filling each prescription.
 - c. To aid in this effort, the emergency departments cut down on narcotic dispenses. Emergency department physicians now provide a small 24 hour supply of a narcotic to the patients and ask them to follow-up with the registry physician for a full script.
2. Grant provided for supply of naloxone to be distributed to patients which will aid in necessary rescue efforts during opioid overdoses.
3. DVD on patient education was developed for use in community clinics and physician offices. This short video explains the proper use of prescription drugs and the danger of misuse and abuse.
4. Customized Healthcare Worker Toolkit was developed by the coalition which is centered on the specific needs of Wilkes County. The homegrown process of developing this toolkit helped the coalition understand what the county really needed. The critical lesson from this process is that communities would prefer to work together to develop a customized solution rather than be handed a pre-made solution.
5. An unintended consequence of this intervention effort is that while rates of hospital admissions related to overdose are declining in Wilkes County, rates in all surrounding counties have increased.

The intervention effort has recently extended its efforts to the Outer Banks of North Carolina, and this intervention is demonstrating similar results.

Maine Attempts to Treat Pain and Addiction – Is Treatment Part of the Problem?

Karen Simone, PharmD, DABAT

Jennifer Bubar, BSN, BA

Northern New England Poison Center

The Northern New England Poison Center (serving Maine, New Hampshire and Vermont) receives over 110,000 calls each year; over one quarter of these calls are related to substance abuse. Poison



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center calls are self-reports from the public and health care providers. Calls related to substance abuse may either involve exposures or may just be information-seeking. Calls for new and unusual substances or exposures often predominate as opposed to cases involving straightforward issues that have been around for a long time (for example, a cocaine overdose does not often merit a call to the poison center).

In May 2001, Maine instituted a methadone take home policy that was more liberal than the policy suggested by SAMHSA. When the new take home policy went into place, Maine saw a parallel increase in deaths associated with methadone exposure, and the poison center saw an increase in calls involving methadone. One particular peak in calls was seen after a "problem" clinic opened with lax prescribing practices. In response to the increasing number of deaths, the regulations were changed in June 2002, stopping all take home doses for an interim period of time, requiring clinics to be open 7 days a week, and creating new restrictions on take home doses.

The question arose: Are methadone associated deaths the result of clinic dosing or methadone that is out in community? Calls to the poison center requesting information on methadone very rarely involve liquid methadone, which is dispensed by clinics, and nearly always involve methadone tablet formulations. It is therefore difficult to assess whether there is excess methadone available in the community because the patients receiving the methadone are not using it for legitimate pain relief.

Another trend captured by the Northern New England Poison Center followed the implementation of the preferred Medicaid drug list in 2003. The list specified that preferred ER formulations included Kadian, Avinza, generic morphine and methadone; MSContin and OxyContin were not on the list. The preferred drug list is an attempt at cost savings, favoring the use cheaper drugs, and requires a great deal of paperwork for the prescription of a non-preferred drug.

In general, information calls to the Northern New England Poison Center are mostly about opioids; of the opioids, oxycodone is involved in a majority of the calls. After the implementation of the 2003 Medicaid preferred drug list, calls about MSContin dropped while those for Kadian increased, most likely linked to the preferred drug list. There was a slight increase in calls about OxyContin which is not on preferred list, but the increased call volume may be linked to a lawsuit with Mallinckrodt over patent rights that coincided with the preferred drug list; it is possible that people had not been using OxyContin for a while but were stocking up on OxyContin supplies in the event that the lawsuit changed what would be available on the street.

When a new drug is introduced on the market, a temporal increase in calls is often seen, likely because physicians are prescribing the new drug, but eventually the calls level off. The same trend is seen when a brand name product goes generic.

As demonstrated by prescription monitoring program and Northern New England Poison Center data, the increasing trends of use and diversion of buprenorphine are still lower than the increase in number of prescriptions; hopefully this demonstrates buprenorphine getting into the hands of patients



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who need it. The Northern New England Poison Center is still receiving calls for buprenorphine involving pediatric poisonings. These exposures are most often the result of accidental ingestions and may represent people who are careless with their medications. The danger with buprenorphine is that the children do not become drowsy immediately and can be presumed symptom free until it is too late. However, the exposures seen by the Northern New England Poison Center were not deliberate and to date have not resulted in any deaths.

Poison centers are very instrumental in identify trends regarding prescription medications; data are captured from before the drug is launched and includes changes in route of administration to demographic data after a product is launched.

New Developments and Challenges in Risk Management of CII Opioids

Juergen Schmider, MD, PhD
Cephalon, Inc

The struggle currently facing the pharmaceutical companies is the need to maintain adequate pain management for patients versus protecting public health and has been brought on by the perception of prescription opioid abuse and diversion and the increase in prescriptions paralleling the increase in non-medical use. The specific issue at play is that of prescribing the right drug to the right patient. The potency of a particular opioid compared to the extent to which a patient is used to the drug (tolerance) and the use of breakthrough pain medications versus long acting opioids are the core of this issue.

The FDA mandated that all controlled release opioids and methadone will require a REMS under a single system in an effort to maintain access to these medications while reducing misuse, abuse and diversion; civil action is possible for not following this mandate. The requirements for REMS aim to control distribution and bring down diversion, certify prescribers/pharmacists, document safe-use conditions, create a database of enrolled doctors, pharmacists and patients and monitor distribution and prescription data.

The options for developing a REMS are wide open. They may include escalation of intervention efforts, label changes, education in the form of CME or additional tools for healthcare workers, reminder systems to key stakeholders, prescribers and pharmacists on safe use conditions via safety letters, and lastly, performance linked access systems (PLAS) (when availability of a drug is linked to a prescriber/pharmacist) to select the correct patients for a given drug. Some examples of PLAS include the tracking system for thalidomide and iPLEDGE.

The challenge to the implementation of these systems is the fact that the healthcare system is not equipped to accommodate the REMS requirements. Instead, the system should be should be built into the current healthcare system. One way to do this would be a single class registry; yet it would be difficult to make the requirements the same for all drugs because not all drugs in a class fit the same mold. Also, if a system were put into place, it may eventually become difficult to integrate new



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products that have different risks into that system. The alternative to a single class registry is individual registries that fit FDA guidelines; however, this is problematic for other stakeholders (e.g. doctors and pharmacists). Moving forward with individual drug registries would lead to duplicate efforts when generics for a given product reached the market.

Another option is the closed distribution of prescription medications which would require a central agent to verify distribution of medications, potentially making reimbursement to healthcare facilities extremely difficult and delaying availability of medications to those who need them. Alternatively, a community pharmacy allows for decentralization in a given community but has to rely on pharmacists to cooperate while only allowing for limited control of distribution. Finally, a community based distribution system with full control, in the form of an e-verification system would be ideal as this avoids the need for pharmacists to remember unique requirements for given drugs. This system would still fulfill FDA requirements while not burdening the healthcare system. Unfortunately at this time, there is no current viable technology in place; the development of such a system will require significant time and money.

Even if an ideal system is put into place, there are still hurdles to measuring the effectiveness of the program such as assuring the proper proportion of appropriate patients receive products. Overall, the scale of monitoring these 21 million prescriptions for CII immediate and extended release products each year is monumental, and everyone involved must be cognizant that patients must continue to receive appropriate pain care.

FDA's "Class-Wide" Risk Evaluation and Mitigation Strategies for Opiates: A Legal Perspective

Josephine Torrente

Hyman, Phelps and McNamara, P.C.

The FDA may request a REMS as a part of an NDA prior to the approval of drugs to ensure that the benefits outweigh the risks. In many instances, serious or unexpected risks are discovered post-approval; therefore, the FDA may require a REMS to ensure the benefits outweigh the newly discovered risks and to address any new safety information that has arisen after the product was launched.

To assure safe use of a product any known risks that would otherwise make the drug unavailable must be assessed, and these risks must be well understood in order to develop a proper tracking system. In addition, REMS requirements cannot burden patient access, must conform to similar drugs with similar risk profiles and must be compatible with current dispensing practices and other healthcare policies.

Suggestions for REMS include certification for doctors and pharmacists with follow-up training, doctor/patient agreements that include a checklist for discussion of important information regarding improper use of the medications and a database of enrolled entities (doctors, pharmacists and



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patients) which would be monitored constantly.

One interesting aspect of the new REMS requirements is that REMS were originally created to monitor new serious risks that were discovered; however the monitoring of abuse and diversion of prescription opioids is not a new risk; instead, it was known at the time of drug approvals. One could argue that the new risk is the continued increase in rates of abuse, yet the difficulty lies in the fact that manufacturers only have so much control over the root of the abuse problem; the pharmaceutical companies nor the FDA have control over patients who play a huge part in creating and maintaining rates of abuse and who will continue to do as they please.

The FDA has created a difficult argument for class-wide REMS because only controlled release and breakthrough pain products have been named; therefore the term "class-wide" does not really hold true as the mandate is for specific formulations within a class. Moving forward, it will be extremely difficult to get new drugs approved if they do not fit neatly into the guidelines. The delays may keep abuse deterrent formulations from hitting the market depending on where they fit into the schema. Additionally, the FDA can, in essence, require that companies have the same REMS, but the FDAAA statute gives generic companies different provisions if the generic companies cannot come to an agreement with the original manufacturer.

Compliance Issues with Class-Wide Risk Evaluation and Mitigation Strategies: A Pharmacist's Perspective

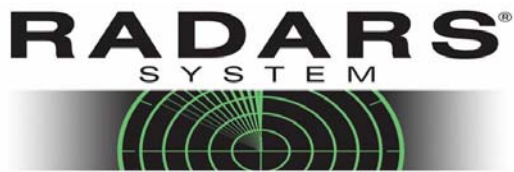
Ernest Boyd, RPh, MBA

Ohio Pharmacists Association

Patients need to select pharmacists in the same way they select their doctors, they need to form a relationship with them. If a pharmacist does not explain things to a patient, then the patient should find a new pharmacist!

Most medications are taken by seniors, a population with difficulty reading bottles and sorting through pamphlet information; the duty of a pharmacist is to provide clarity. Pharmacists must be the ones to ask the questions and not wait for patients to ask because in many cases, patients do not know where to begin with their questions. The environment of pharmacies is changing which creates inherent difficulties and worries for pharmacists.

Due to their first line knowledge, pharmacists can provide insight to pharmaceutical companies as decisions are made regarding REMS. Moving forward with REMS may generate additional information to be handed to patients, however this is insufficient. Considering how many different medications one person can be on, handing out endless streams of paper almost guarantees non-compliance due to the creation of fear of side effects and ramifications of taking prescribed doses. Companies should focus on providing a single page of critical information that is likely to be overlooked and information that is most common instead of describing side effects that occur in 1 of 100 patients.



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Items from the pharmacist's perspective to consider for REMS include:

- Current registry programs are cumbersome, time consuming and difficult, often leading to pharmacies not carrying those drugs which require a registry program. Yet not carrying opioids is not an option.
- A patchwork of REMS (i.e. different programs for different companies and different products) will be confusing; streamlining to a uniform REMS will have the best outcomes. Keep in mind that restricted distribution of one drug will likely shift the problem to another drug with similar issues.
- Current monitoring programs that require pharmacists to check patient identification cards leads to patients filling prescriptions online or via mail order. Certain restrictions and guidelines cause closures of pharmacies because they become afraid of the ramifications if rules are not followed or if they fail to make enough sales. Pharmacy closures mean less access for patients, which can become deadly to patients who need to fill life saving medications as soon as possible.
- Finally, companies must ensure that solutions are cost effective and do not create additional burden on pharmacies; if not, pharmacies could close their doors.

Balanced Policy and Practice in Risk Management: The Pain Patient Perspective

Will Rowe

American Pain Foundation

The American Pain Foundation stresses the importance of protecting opioids within the realm of risk management. There is already a large problem of the under treatment of pain in this country as 76.5 million Americans are in pain and 57% report that their pain has lasted more than one year. In contrast, the misuse and abuse of prescription opioids is a well-known issue. Chronic pain and addiction are equally painful and pervasive, so seeking a balance is difficult.

Balance between two ideals is a familiar regulatory concept. Take the idea of the EPA and the environment: the government has strived to create regulations that protect the environment while allowing businesses to work within a set of guidelines that prevents their demise. Similarly, regulations must be set forth to prevent prescription drug misuse and abuse while protecting the rights of patients who need the medications for their daily survival. Now is the time to strategize in order to fully anticipate outcomes of a policy, develop an analytical process to monitor it and identify any necessary protective measures.

The American Pain Foundation believes that if doctors are given a set of standards and practice guides that they understand and know, they would be safe from investigation and scrutiny and it would be effective in providing patients the pain management they need.

It is difficult to measure access to pain medications. Policy efforts are underway that measure in the form of report cards individual states' success in these areas.



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Appendix A

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.
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Manuscripts Continued

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Abstracts Continued

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