



Researched Abuse, Diversion and Addition-Related Surveillance System

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Opioid Analgesics with Abuse-Deterrent Properties: Current Data and Future Opportunities



r. Richard Dart was one of a handful of invited speakers at the National Academy of Medicine's pain management and regulatory strategies committee meeting in September. Dr. Dart presented data on current and future opportunities for opioid analgesics with abuse-deterrent properties (ADF).

While patients prescribed opioid analgesics typically swallow intact pills, many abusers chew or crush the pills, which allows faster absorption into the bloodstream and a quicker high. Medications that have abusedeterrent properties make it difficult to crush or dissolve the drug for snorting or injection.

During his presentation, Dr. Dart used oxycodone extended release (ER; OxyContin®), reformulated in 2010 with tamper-resistant properties, as an example of abuse and diversion trends before and after ADF reformulation.

"If the drug's properties make it less attractive for abuse," Dr. Dart said, "we expect to see a decrease in patients requesting prescriptions for that drug." Three months after OxyContin's

reformulation in 2010, prescriptions dispensed for oxycodone ER decreased by roughly 15 percent, while prescriptions for other opioids increased. Where poison center data showed an increase for poisoning from other opioids, oxycodone ER decreased by about 40 percent. Data from law enforcement offices showed that diversion of other opioids increased in the first few months after reformulation while oxycodone ER decreased. At first, oxycodone dropped by 50 percent, but ultimately fell by 90 percent after reformulation. Data from both RADARS System substance abuse treatment programs showed the same trend, listing oxycodone ER decreasing by 60 and 40 percent, respectively.

Reformulation of more opioid medications with abuse-deterrent properties, combined with prescribing guidelines and prescription drug monitoring programs (PDMP's) can help prevent the development of opioid abuse.

View the complete presentation here:
Opioid Analgesics with Abuse-Deterrent
Properties: Current Data and Future
Opportunities.

RADARS® System Adds Survey of Non-Medical Use of Prescription Drugs Program to Mosaic

Key to the RADARS® System's success is its mosaic approach, which allows for the collection of data from many different populations to paint a comprehensive picture of prescription drug abuse, misuse and diversion. In July of 2016, the RADARS System bolstered its repertoire by launching, for the first time in the United States, its new Survey of Non-Medical Use of Prescription Drugs Program (NMURx), a general population survey under the direction of principal

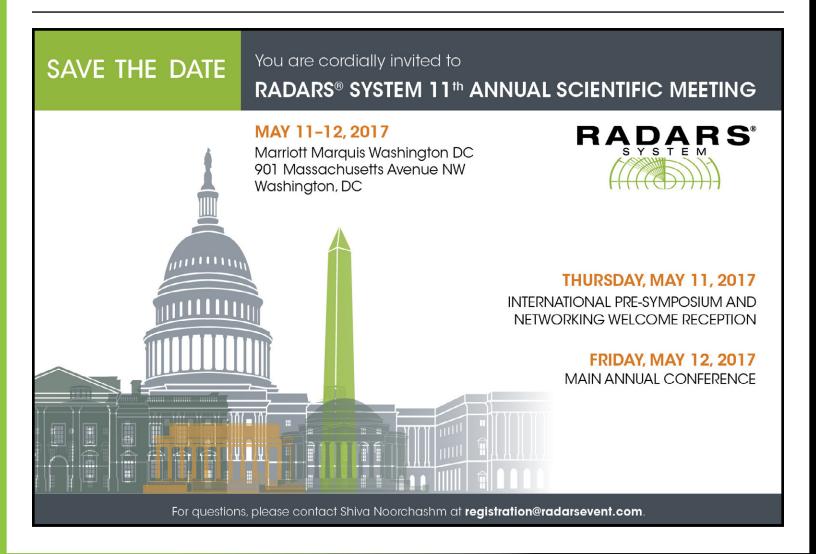
investigator Dr. Jody L. Green.

The NMURx Program's scope makes it unique. NMURx launches twice annually and reaches 30,000 adults per launch. While other RADARS System programs survey targeted at-risk populations, such as patients entering treatment programs, the NMURx survey collects data from the general population related to lifetime as well as recent non-medical use of prescription drugs.

The NMURx Program defines

non-medical use as use of a drug without a prescription or outside of a doctor's recommendation. Although it centers around the non-medical use of prescription drugs, questions about over the counter drugs and illicit drugs are also included.

NMURx launched in the U.S. in July 2016, but has also successfully been launched in the UK, Canada and Singapore. To learn more about the NMURx program, send an e-mail to business@radars.org.





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Study Shows that Impact of Reformulated OxyContin® Has Continued for 5 Years

The RADARS® System recently published a study examining the sustainability of observed reduction in OxyContin® abuse and diversion after its 2010 abuse-deterrent reformulation in Drug and Alcohol Dependence. The results of this study are important because previous research found 32 feasible recipes to overcome the tamper-

resistant properties of the

reformulated OxyContin®

available on the internet.

After its

reformulation,

OxyContin® abuse, including both oral and non-oral routes, and diversion declined significantly, and this decline persisted for five years. During this time, other opioid analgesics experienced increased rates of abuse initially and subsequently

declined, but not to the extent of OxyContin. Additionally, the street price of reformulated OxyContin dropped to 36 percent below its original street price.

For this study, the RADARS System used data acquired through its Poison Center, Drug Diversion, Opioid Treatment,

> Survey of Key Informants' Patients and StreetRx Programs. **RADARS System** researchers calculated population-based and drugutilizationbased rates and compared average quarterly OxyContin abuse and diversion rates from before

In the midst of a major health problem attributed to misuse and abuse of prescription analgesics,

2015.

reformulation to the

rates in second quarter

abuse-deterrent formulations are becoming increasingly important. OxyContin, an extended release (ER) oxycodone tablet, was reformulated in 2010 to make it difficult to crush. This makes crewing, snorting, smoking and injecting more difficult.

One concern surrounding abuse-deterrent formulations is a tendency for physicians to underestimate the drugs' potential for abuse and overprescribe. RADARS System results do not support this concern. In fact, prescriptions dispensed for OxyContin decreased progressively through the first five years after reformulation.

One explanation suggested for the decrease in dispensed prescriptions for reformulated OxyContin is decreased demand -- less doctor shopping, or attempting to secure a prescription for a drug by pretending to have a painful condition. Between 1996, OxyContin's launch into the marketplace, and 2010, prescription volume increased greatly.

To read the full open-access manuscript, visit Drug and Alcohol and Dependence:

Severtson SG, Ellis MS, Kurtz SP, Rosenblum A, Cicero TJ, Parrino MW, Gilbert MK, Buttram ME, Dasgupta N, Bucher Bartelson B, Green JL, Dart RC. Sustained reduction of diversion and abuse after introduction of an abuse deterrent formulation of extended release oxycodone. Drug Alcohol Depend 2016;168:219-229.

More Than

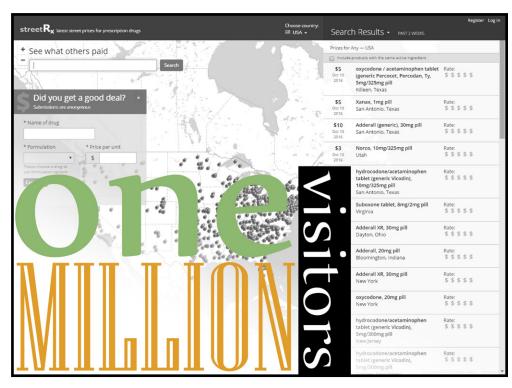
1 MILLION

Visit StreetRx During 2015

One of the RADARS® System's most unique programs, the StreetRx Program (streetrx.com), hit a milestone in 2015, registering hits from more than a million visitors. The crowdsourcing website, designed to anonymously collect prices paid for drugs purchased on the street, is projected to eclipse the 1.4-million mark in 2016.

The StreetRx Program has been live for more than five years and continues to grow each year. During 2015, the program received more than 65,000 black-market price reports and is projected to receive a fresh 80,000 by the end of 2016. To provide some growth perspective, StreetRx has logged 160,000 reports since its inception. RADARS® System personnel keep StreetRx up to date as new drugs and formulations hit the market. This data and trends provide unique insight.

"A greater understanding of the underground market for prescription medications can give manufacturers, regulators and patient advocates insight into the effectiveness of the pharmaceutical industry's ongoing attempts to produce drugs that are more difficult to crush, snort or inject," said Christopher Menone, the StreetRx project manager.



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-Christopher Menone, StreetRx project manager

"At the same time, the data collected through StreetRx increases our knowledge of the geographic patterns in the black market for prescription drugs, providing insight into the efficacy of harm-reduction efforts at the local and state levels." StreetRx not only allows for submission of information but also allows

visitors to view a limited number of other submissions.

StreetRx is operated by Epidemico, a public health software and data analytics company, under contract from the RADARS System. For more information on the StreetRx Program, send an e-mail to business@radars.org.



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RADARS® System Offers Wide Range of Services Both Domestically and Internationally

The RADARS® System data have been utilized by manufacturers, regulatory agencies and medical and public health officials to characterize and monitor prescription drug abuse, misuse and diversion.

The data have been presented at several US Food and Drug Administration (FDA) advisory committee meetings and scientific meetings as well as in reports to the FDA, new drug applications, labeling claims, post market requirements, and Risk Evaluation and Mitigation Strategies (REMS) evaluations. Data may also be used for the development of interventions, to assess the impact of interventions and to monitor ever-changing market trends.

The RADARS® System is composed of a mosaic of programs which target diverse populations. Data from these RADARS® System programs are triangulated to provide a comprehensive picture of prescription drug abuse, misuse and diversion. Triangulation is an approach used in many fields of research and is especially useful in the study of hard to reach or hidden populations, such as prescription drug abusers. No single data source is expected to provide complete and representative information about a given population, but when considered together, multiple data sources strengthen the credibility of findings, reduce the risk of false

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See services available through the RADARS® System

interpretations, and provide a more complete and comprehensive perspective on the behaviors of the covert population.

The RADARS® System has helped clients meet pre- and post-market regulatory and business requirements since 2006. These services are customized to meet specific regulatory and business needs and may include but are not limited to the development of studies, formal epidemiological studies including protocol and statistical analysis plan development, quarterly and annual surveillance reports, and ad hoc analyses/reports as requested.

The RADARS® System publishes several articles each year in noteworthy peer-reviewed journals, including the New England Journal of Medicine, JAMA Psychiatry, the Journal of Pediatrics, Drug and Alcohol Dependence and the Clinical Journal of Pain. Further, RADARS® System data are regularly presented at scientific conferences throughout the world.

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