



Researched Abuse, Diversion and Addiction-Related Surveillance System

Fourth Ouarter, 2016 | RADARS.org

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Immediate Release Opioids Account for the Most Abuse of Prescription Opioids

mmediate Release Opioids Account for the Most Abuse of Prescription Opioids Opioid abuse and diversion continues to draw focus from regulatory bodies. Right now, most regulations and interventions are focused on the abuse and diversion of extended release opioids. However, a new RADARS System study published in PLoS ONE compared abuse and diversion rates between extended release and immediate release opioids. The study found immediate release opioids, not extended release, should be monopolizing regulation.

According to the study, physicians prescribed immediate release opioids, such as Vicodin, at a rate 12 to 16 times higher than extended release opioids, such as OxyContin, from 2009 to 2015. It also noted 90 percent of all opioids sold in the U.S. were immediate release.

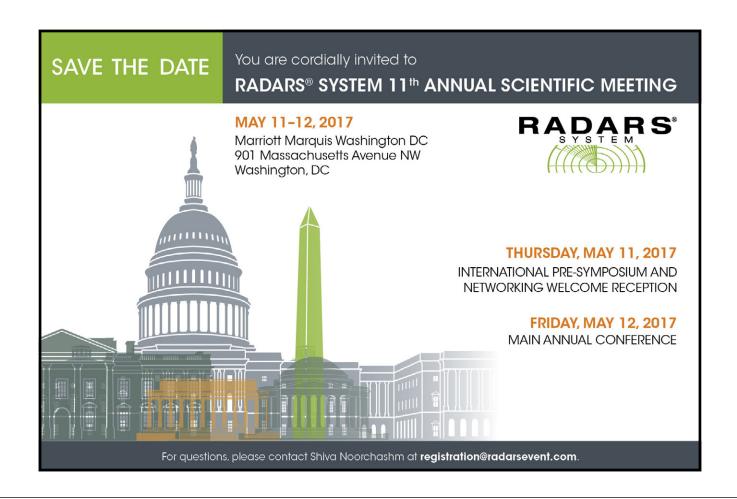
"Extended release opioids have name recognition," lead author Janetta Iwanicki explained. "They also receive a lot of focus because of their potency. However, the largest amount of abuse and diversion occurs with immediate release drugs, not extended release opioids."

The study showed abuse and diversion rates were significantly higher with immediate release drugs.

The study pulled data from four RADARS System programs: the Poison Center, Drug Diversion, Opioid Treatment and Survey of Key Informants' Patients (SKIP) programs. Data from all four programs, in some manner, indicated immediate release opioids were abused at a higher rate than extended release.

In particular, the Drug Diversion program showed immediate release opioids were diverted at a rate 6.1 fold higher than extended release when adjusted for population.

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Survey of Non-Medical Use of Prescription Drugs Program Sneak Peak at 2016 U.S. Launch

In 2016, the RADARS® System launched its newest program in the United States, the Survey of Non-Medical Use of Prescription Drugs (NMURx) Program. Under the direction of principal investigator Dr. Jody L. Green, this program surveys the general population about lifetime use and recent non-medical use of prescription drugs as well as reasons for non-medical use, routes of administration and source of drug acquisition.

The initial U.S. launch returned data from more than 30,000 respondents, which the RADARS® System weighted by region, age and gender to represent more

than 247 million adults from the general population. Preliminary results from the survey show selfreported, lifetime non-medical use (use without a prescription or for any reason other than what was recommended by a doctor) was highest among opioids (13.1%; 95% Confidence Interval (CI): 12.7-13.5), followed by stimulants (4.3%; 95% CI: 4.0-4.5), sedatives (3.4%; 95% CI: 3.2-3.6) and GABA analogues (0.4%; 95% CI: 0.6-0.8). Additionally, among those who reported non-medical use of an opioid at any point, two-thirds (66.3%) also reported using an illicit drug at least once.

The NMURx Program's scope makes it unique. The survey will be administered twice a year in the U.S. and collect 30,000 responses per wave. While many other RADARS® System programs survey targeted at-risk populations, such as patients entering treatment programs, the NMURx Program collects data from the general population related to lifetime and recent non-medical use of prescription and over-the-counter drugs, as well as alcohol, tobacco and illicit drug use.

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RADARS® System Data One of Two U.S. Data Sources Used in Advisory Council on the Misuse of Drugs Report in U.K.

mid-December report and letter to the U.K. Home Secretary and the Secretary of State for Health about the diversion and illicit supply of medicines referenced RADARS® System data as the only U.S. data source other than the Drug Enforcement Agency. The Advisory Council on the Misuse of Drugs (ACMD) report and letter, authored by Professor Les Iversen, chair of the ACMD, and Professor Ray Hill, chair of the Diversion and Illicit Supply of Medicines Inquiry, explored the potential for medical and social harms arising from the illicit supply of medicines.

The report was initiated in response to a commissioning letter from the Home Secretary in September of 2013 and identifies the key differences between the situation in the U.K. and consideration of the situation in other countries, particularly the U.S.

RADARS® System data, specifically, contributed to a couple of important conclusions. In the Displacement section, item 6.2.6, reads, "Use of prescription medicines to manage the 'come down' from illicit stimulant drugs seems to involve purchase of the drugs from a 'friend' who may have obtained them by legitimate

prescription. Existing drug addiction issues create a ready market for prescribed medicines, such as benzodiazepines, methadone, and other opiates, whether diverted or illicit."

The RADARS® System has the ability to gather user-submitted information on street prices of diverted prescription drugs through its StreetRx Program. Visitors can anonymously view, post and rate submissions in a format that offers price transparency to an otherwise opaque black market, while providing a novel data set for public health surveillance. This provides a unique look at the street prices of diverted prescriptions drugs in the U.S. and internationally.

Patients in Europe entering opioid addiction treatment programs can fill out paperbased and self-administered questionnaires through the RADARS® System's EUROPAD program. These data allow the RADARS® System to estimate prevalence and injection rate of prescription and illicit opioid and non-opioid drugs used to get high. In the report's section titled "Comparison with the US and comment on other countries", item 9.13.7 reads, "The most frequently abused drugs were codeine,

tramadol and fentanyl. Opioid substitution drugs (methadone and buprenorphine) were also prone to misuse. When 309 patients who were attending opioid treatment programmes in Germany or Italy were surveyed, 36% reported that prescription opioids were the primary drugs used to get high including buprenorphine and methadone."

The RADARS® System has nearly a dozen programs that collect timely productand geographically-specific data relating to prescription drug abuse, misuse and diversion. It measures rates of abuse, misuse and diversion, contributing to the understanding of trends and aiding the development of effective interventions.

According to gov.uk, the Advisory Council on the Misuse of Drugs makes recommendations to government on the control of dangerous or otherwise harmful drugs, including classification and scheduling under the Misuse of Drugs Act 1971 and its regulations.

To read the letter or the full report, visit gov.uk: https://www.gov.uk/government/publications/diversion-illicit-supply-of-medicines.



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A second RADARS System study by lead author Theodore Cicero supported the need immediate release opioid regulation. The study, recently published in Pharmacoepidemiology and Drug Safety, also compared immediate release and extended release drugs, This study pulled data from the SKIP program and utilized the Researchers and Participants Interacting Directly (RAPID program), where it asked about 300 participants to compare the two types of opioids directly. All participants had used both immediate release and extended release opioids, and most preferred immediate release. The study revealed participants found immediate release opioids to provide a quicker high, even if take non-orally, and easier to abuse through non-oral routes.

Results showed two-thirds of the SKIP sample indicated abuse of at least one immediate release opioid in the past month, while less than half admitted to abusing an extended release opioid during that time. The RAPID sample also reported lifetime abuse and nearly the entire group, 98.7 percent, reported abuse of an immediate release opioid at



least once. Ninety-one percent reported abuse of an extended release opioid. In the end, the participants were asked to choose between immediate release and extended release opioids and only four percent indicated preference for extended release while nearly two-thirds, 70.3 percent, preferred immediate release.

To learn read in full and learn the details of the studies, click the following links: Abuse and Diversion of Immediate Release Opioid Analgesics as Compared to Extended Release Formulations in the United States (Iwanicki JL, Severtson SG, McDaniel H, Rosenblum A, Fong C, Cicero TJ, et al. (2016) Abuse and Diversion

of Immediate Release Opioid Analgesics as Compared to **Extended Release Formulations** in the United States. PLoS ONE 11(12): e0167499. doi:10.1371/ journal.pone.0167499) and Relative preferences in the abuse of immediate-release versus extended-release opioids in a sample of treatmentseeking opioid abusers (Cicero, T. J., Ellis, M. S., and Kasper, Z. A. (2016) Relative preferences in the abuse of immediate-release versus extended-release opioids in a sample of treatmentseeking opioid abusers. Pharmacoepidemiol Drug Saf, doi: 10.1002/pds.4078).

To learn more about RADARS System programs, visit <u>radars</u>. <u>org/home2/programs</u>.

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NMURx launched in the U.S. in July 2016 and has successfully been launched in the United Kingdom, Canada and Singapore as well. In 2017, the NMURx Program will collect more than 190,000 surveys, and with its anticipated expansion to Germany, France, Italy and Spain, the NMURx Program's survey could surpass one of the largest existing

online drug surveys in terms of number of respondents -- the Global Drug Survey (GDS).

To learn more about the NMURx program, e-mail business@radars. org.



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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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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