RADARS® SYSTEM

the Sweep

Researched Abuse, Diversion and Addiction-Related Surveillance System

First Quarter, 2017 | RADARS.org

SUBSCRIBE

In This Issue

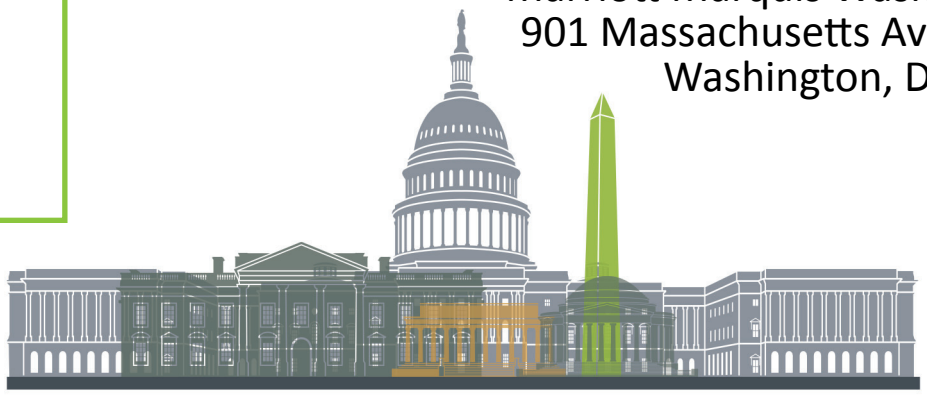
- 11th Annual RADARS System Scientific Meeting Info
- Annual Scientific Meeting Presentations and Speakers
- International Pre-Symposium Presentations and Speakers
- RADARS System Recent Publication
- FDA Advisory Committee Results
- RADARS System Services

RADARS® SYSTEM 11th ANNUAL SCIENTIFIC MEETING

REGISTER

MAY 11-12, 2017

Marriott Marquis Washington DC
901 Massachusetts Avenue NW
Washington, DC



THURSDAY, MAY 11, 2017

RADARS® System International Pre-Symposium
Global Insights in Prescription Drug Misuse

When:

Registration
12:00 pm - 1:30 pm

International Meeting
1:30 pm - 5:00 pm

Networking Reception
5:00 pm - 7:00 pm

FRIDAY, MAY 12, 2017

RADARS® System 11th Annual Scientific Meeting
Beyond the Label: Prescription Opioid Abuse

When:

Registration
7:30 am - 8:30 am

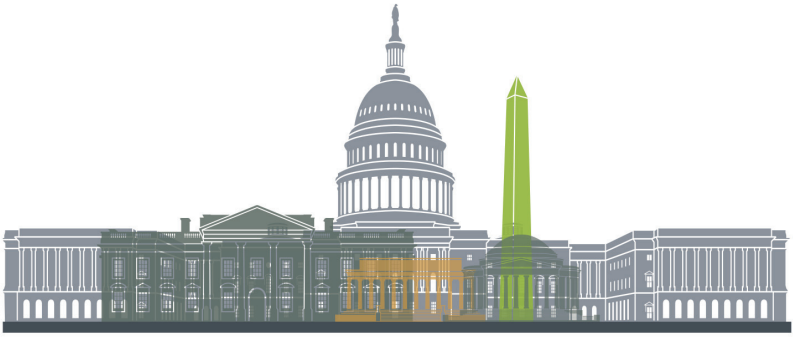
Annual Meeting
8:30 am - 3:30 pm

For questions, please contact Shiva Noorchashm at registration@radarsevent.com.

RADARS® SYSTEM

11th Annual Scientific Meeting

Friday, May 12, 2017
Marriott Marquis Washington DC



Beyond the Label: Prescription Opioid Abuse

Presentations

- ***Welcome and RADARS System 2016 Data Updates***
  Richard C. Dart, MD, PhD
  Executive Director, RADARS® System – Denver Health and Hospital Authority

- ***RAPID Analysis of Routes of Administration: Oral to Non-Oral Transitions***
  Theodore J. Cicero, PhD
  John P. Feighner Professor of Psychiatry, Department of Psychiatry – Washington University in St. Louis School of Medicine

- ***Findings from the Australian National Opioid Medications Abuse Deterrence (NOMAD) Study: Monitoring the Impact of a Potentially Tamper-Resistant Formulation of Controlled-Release Oxycodone, Reformulated OxyContin®***
  Louisa Degenhardt, PhD
  NHMRC Principal Research Fellow, National Drug & Alcohol Research Centre – University of New South Wales

- ***Evaluating the Impact of Abuse Deterrent Formulations: Methodological Challenges in Postmarketing Data***
  Judy Staffa, PhD, RPh
  Associate Director for Public Health Initiatives, Office of Surveillance and Epidemiology U.S. Food and Drug Administration

- ***Panel Discussion***
  Richard C. Dart, MD, PhD (Moderator)

- ***Darknet Drug Markets: Supply Chains, Stakeholders, and Opportunities for Public Health***
  Michael Gilbert, MPH
  Epidemico
  Nabarun Dasgupta, MPH, PhD
  Senior Scientist, RADARS® System – Denver Health and Hospital Authority

- ***Beyond Opioids: Emerging Drugs of Abuse***
  Jody L. Green, PhD, CCRP
  Director of Research Administration – Denver Health and Hospital Authority

- ***Behind the Opioid Epidemic – Fentanyl, Immediate-Release Opioids, and Mortality***
  Janetta L. Iwanicki, MD
  Associate Medical Director, Rocky Mountain Poison & Drug Center – Denver Health and Hospital Authority

- ***Panel Discussion***
  Richard C. Dart, MD, PhD (Moderator)

Featured Speakers

Judy Staffa, PhD, RPh

Associate Director for Public Health Initiatives, Office of Surveillance and Epidemiology – U.S. Food and Drug Administration

Judy Staffa, Ph.D., R.Ph., is the Associate Director for Public Health Initiatives at FDA, Center for Drug Evaluation and Research (CDER), Office of Surveillance and Epidemiology (OSE), where she is responsible for setting strategic direction for complex, multidisciplinary reviews related to opioid abuse – from a planning, scientific, and policy point of view. Prior to this role, Judy was the Director, Division of Epidemiology II, directing the regulatory review and research work of epidemiologists in CDER.

She has spent her FDA career serving in various roles as the office has evolved over the years. While in the role of the Associate Director for Regulatory Research she assisted in building OSE's epidemiologic research program, and prior to that she was an epidemiology reviewer and a drug utilization analyst team leader. Before joining FDA in 1999, Judy was a researcher at the Degge Group for ten years, conducting numerous pharmacoepidemiologic studies using both administrative claims data and electronic medical records data to investigate drug safety issues. Judy is a registered pharmacist who received her bachelor's degree in pharmacy from the University of Connecticut. She practiced community pharmacy prior to receiving her training in public health. She holds a master's degree in behavioral sciences from the Harvard School of Public Health, and a doctoral degree in epidemiology from the Johns Hopkins Bloomberg School of Public Health.

Louisa Degenhardt, PhD

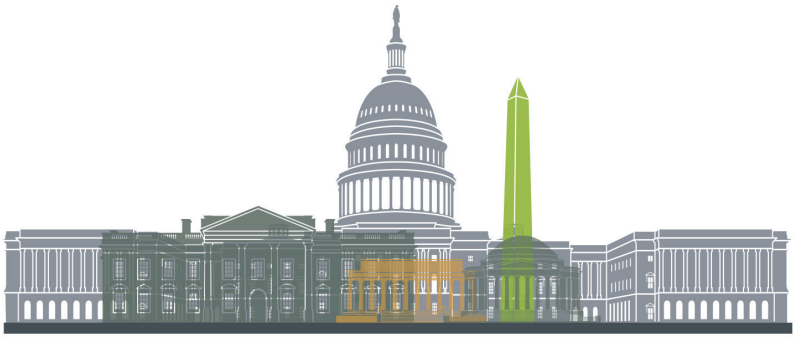
NHMRC Principal Research Fellow, National Drug & Alcohol Research Centre – University of New South Wales

Louisa is UNSW Scientia Professor and NHMRC Principal Research Fellow at the National Drug and Alcohol Research Centre (NDARC), Faculty of Medicine, UNSW. She was awarded her PhD in 2003, examining the comorbidity of drug use and mental disorders in the Australian population. She has honorary Professorial appointments at University of Melbourne's School of Population and Global Health, Murdoch Children's Research Institute, and University of Washington's Department of Global Health in the School of Public Health. Louisa conducts diverse epidemiological studies including analysis of large-scale community and clinical population surveys, data linkage studies focusing upon people with a history of drug dependence or chronic pain, and cohort studies of young people. Louisa has published over 460 peer reviewed papers, 120 technical reports and monographs, three books and 45 book chapters. Her H-index in Scopus is 64, and 84 in Google Scholar.

From 2001 to 2008 she established and expanded national drug surveillance systems across Australia. This work included the establishment of the National Illicit Drug Indicators Project (NIDIP), which comprises the analysis of routine data collections across Australia that collect data on drug use, harms and supply; she took over the running of the Illicit Drug Reporting System (IDRS) in 2001. She also expanded a pilot of the Ecstasy and related Drugs Reporting System (EDRS) into a national system in 2003, and oversaw all these systems until she took up an NHMRC Fellowship in 2008.

Louisa has been conducting increasingly diverse epidemiological studies, including examination of mortality related to opioid antagonist treatment; post marketing surveillance of new opioid agonist pharmacotherapies; cohort studies using data linkage methods of opioid treatment entrants; indirect prevalence estimation studies of opioid dependence; case-control studies of gene-environment interactions leading to opioid dependence; studies of drug overdose and international studies of the epidemiology of drug use and dependence. She is currently conducting a national prospective cohort study of entrants to pharmaceutical opioid use for the treatment of chronic non-cancer pain. She has more recently extended her focus upon the health of young people, and is currently involved in half a dozen local and national cohort studies, with a focus upon the incidence and course of risk behaviours of young people.

Louisa was the lead academic on the Secretariat for the Reference Group to the United Nations on Injecting Drug Use and HIV (2007-2010) and continues to work with WHO and UNAIDS examining epidemiology of illicit drug use and associated health risks across the globe. She co-chaired the Expert Group on mental disorders and illicit drug use for the 2010 Global Burden of Disease study and is on the core analytic team for GBD.



RADARS® SYSTEM

International Pre-Symposium

Thursday, May 11, 2017
Marriott Marquis Washington DC

Global Insights in Prescription Drug Misuse

Preceeding the 11th Annual Scientific Meeting, RADARS System will host an international pre-symposium, Global Insights in Prescription Drug Misuse. A networking reception will be held after the pre-symposium.

Presentations

- ***Welcome and introductions***
  Jody L. Green, PhD, CCRP
  Director – Canadian Consumer Product and Pharmaceutical Safety Inc.

- ***The Global Mosaic: RADARS® System International Program Updates***
  Jody L. Green, PhD, CCRP
  Director – Canadian Consumer Product and Pharmaceutical Safety Inc.

- ***Opioid Surveillance and Policy Evaluation: A Canadian Perspective***
  Tara Gomes
  Scientist – St. Michael's Hospital

- ***Comparative Assessments of the Prescription Drug Abuse Climate in the European Union and the United States: Scientific, Regulatory, and Cultural Factors***
  Scott P. Novak, PhD
  Director and Senior Research Scientist, Substance Abuse Research and Treatment, Public Health Center – Battelle Memorial Institute

- ***Trends in Pharmaceutical Opioid Use in Australia: Increasing Exposure, Increasing Risk***
  Louisa Degenhardt, PhD
  NHMRC Principal Research Fellow, National Drug & Alcohol Research Centre – University of New South Wales

- ***Panel Discussion***
  Jody L. Green, PhD, CCRP (Moderator)

Join us at our Networking Welcome Reception

for beverages and hors d'oeuvres

5:00PM to 7:00PM
Thursday, May 11th

Featured Speakers

Tara Gomes

Scientist – St. Michael's Hospital

Tara Gomes is an epidemiologist and Principal Investigator of the Ontario Drug Policy Research Network (ODPRN), a provincial network of researchers with expertise in pharmaceutical utilization, outcomes and policy who rapidly conduct research for drug decision-makers in Ontario and across Canada. She is also a Scientist in the Li Ka Shing Knowledge Institute of St. Michael's Hospital and the Institute for Clinical Evaluative Sciences and an assistant professor at the University of Toronto. Her research is focused on pharmacoepidemiology, drug safety and drug policy research leveraging large, administrative databases, and she has published over 120 peer-reviewed articles and over 50 policy reports in this area. She has also worked closely with policy makers and regulators across North America as an expert in discussions related to opioid policies and regulations.

Scott P. Novak, PhD

Director and Senior Research Scientist, Substance Abuse Research and Treatment, Public Health Center – Battelle Memorial Institute

Scott Novak, PhD, holds research interests in the causes, correlates, and consequences of prescription drug abuse, with a focus on the clinical and public policy implications. He currently works as a Director of Substance Abuse Research at Battelle Memorial Institute.

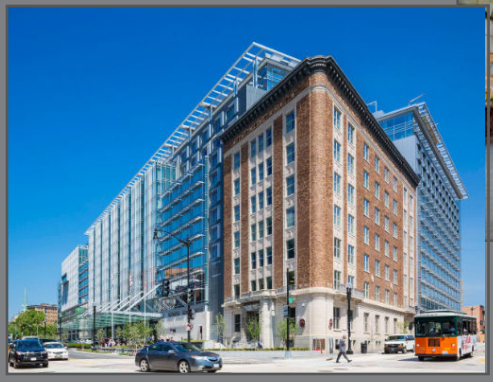
Dr. Novak's expertise is in novel statistical and methodological approaches to the analysis of epidemiological and clinical data, including extensions of the generalized linear mixed model (e.g., HLM) to classification, measurement, and diagnosis of disease. His methodological interests also involve the application of new social media technologies for data collection and analysis.

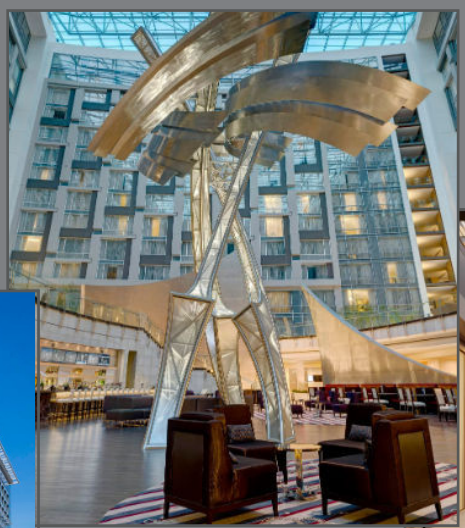
He is the principal investigator on several NIH grants and commercial projects, and has authored more than 100 papers and presentations. He has several funded projects examining characteristics of prescription drug abusers, including a project funded by the National Institute on Drug Abuse (NIDA), to understand the public health impact of state and local prescription drug access laws on prescription pain reliever abuse and heroin initiation.

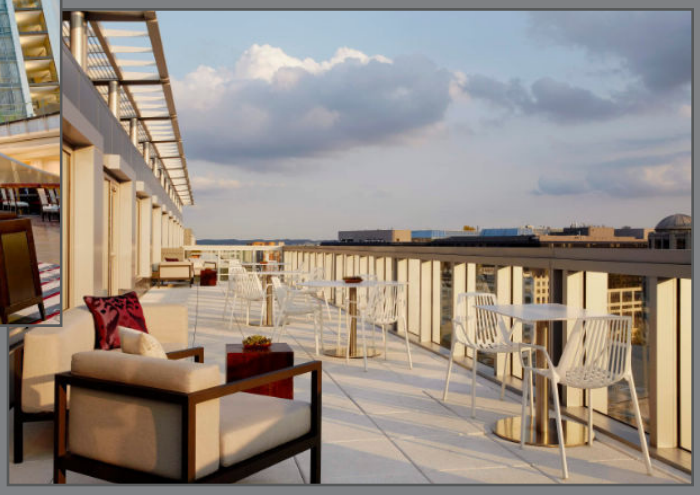
Marriott Marquis Washington DC

901 Massachusetts Avenue NW
Washington, DC

MAY 11-12, 2017







Recent Publication by RADARS® System

RADARS System Published in *Drug and Alcohol Dependence*:

Medical outcomes associated with prescription opioid abuse via oral and non-oral routes of administration

Jody L. Green, Becki Bucher-Bartelson, M. Claire Le Lait, Carl L. Roland, Elizabeth T. Masters, Jack Mardekian, J. Elise Bailey, Richard C. Dart.

2017; advance online publication. DOI: http://dx.doi.org/10.1016/j.drugalcdep.2017.01.039

Highlights

- The majority of poison center intentional abuse cases involve oral routes.
- Non-oral routes are reported and double the risk of life-threatening event.
- Abuse-deterrent formulations (ADFs) are relevant in reducing non-oral abuse but do not address oral abuse.
- ADF products are a small part of the overall prescription opioid market.
- Their public health impact may not be realized until they are more widely used.

Background

Prescription opioid abuse and misuse is a serious and growing public health issue. While the most common form of abuse is swallowing intact tablets/capsules, some abusers manipulate, or tamper with, these medications by altering the dosage form to allow for non-oral routes of administration (e.g., injection, inhalation) in order to achieve more rapid or enhanced psychoactive effects. Because administration of opioids via non-oral routes results in greater systemic availability and more rapid central nervous system penetration, we hypothesized that death and major medical outcomes occur more frequently with non-oral routes compared to oral route alone.

Methods

This retrospective cohort study analyzed data from the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System Poison Center Program to investigate relative risk of prescription opioid abuse via oral and non-oral routes.

Results

While the oral route was the most commonly reported route of abuse (64.0%), non-oral routes were reported in 14.6% exposures and unknown routes in 21.4% exposures. The relative risk of an exposure resulting in death or major effect was 2.43 (95% CI 1.97, 2.99) if non-oral routes were reported compared to exposures involving oral route only.

Conclusion

Analysis of acute health events recorded by poison centers indicates that death or major effects are twice as likely to occur with intentional abuse of prescription opioids via non-oral routes of administration than ingestion alone. Effective interventions to prevent abuse via non-oral routes of solid dosage forms of prescription opioids, such as abuse-deterrent formulations could have a significant public health impact.

FDA Advisory Committee Outcomes

Opana ER

On March 13-14, 2017, the Anesthetic and Analgesic Drug Products Advisory (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSRM) discussed safety issues with Opana ER (oxymorphone hydrochloride tablets) by Endo Pharmaceuticals Inc., pre- and post-marketing data about the abuse of Opana ER, and its overall benefit:risk.

Key Outcomes of Advisory Meeting

A majority of the Committee, 18 of 27 members, voted that the benefits of reformulated Opana ER do not continue to outweigh its risks.

RoxyBond

On April 5, 2017, the AADPAC and the DSRM Advisory Committee jointly supported the approval of RoxyBond, oxycodone immediate-release (IR) tablets, submitted by Inspirion Delivery Sciences, LLC with the proposed indication of management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Key Outcomes of Advisory Meeting

A majority of the Committee members, 19 of 20 members, voted that RoxyBond should be approved for the proposed pain indication. One Committee member abstained from voting.

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

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.

Take me to a list of domestic services

Take me to a list of international services