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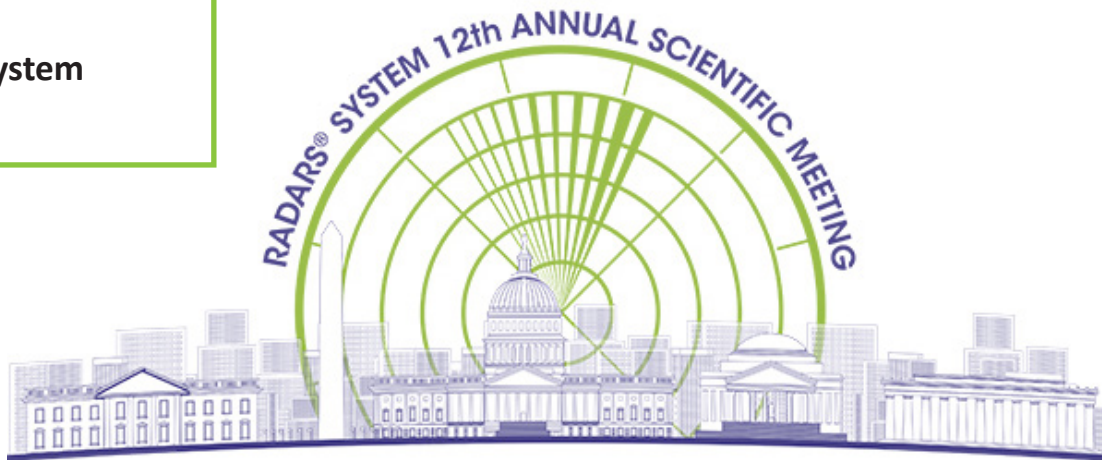


RADARS[®] SYSTEM 12th ANNUAL SCIENTIFIC MEETING

REGISTER

MAY 9-10, 2018

Westin Georgetown
2350 M Street NW
Washington, DC



WEDNESDAY, MAY 9, 2018

RADARS[®] System International Pre-Symposium

*International Landscape of Prescription
Medication 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

THURSDAY, MAY 10, 2018

RADARS[®] System 12th Annual Scientific Meeting

Evolution of the Opioid Overdose Epidemic

When:

Registration
7:30 am - 8:30 am
Annual Meeting
8:30 am - 3:30 pm

International Pre-Symposium

Wednesday, May 9, 2018



International Landscape of Prescription Medication Misuse

■ **Welcome and The Global Mosaic: Is Prescription Drug Misuse Really Different Among Countries?**

Janetta L. Iwanicki, MD

Associate Medical Director – Rocky Mountain Poison and Drug Center, Denver Health and Hospital Authority

■ **The Growing Nexus Between NARCOS and Counterfeit Medicines**

J. Aaron Graham

Executive Director – Brand Safety & Security, Boehringer Ingelheim Pharmaceuticals, Inc.

John J. Burke

President, Pharmaceutical Diversion Education Inc.
President and Co-Founder, International Health Facility Diversion Association

■ **Understanding the Evolution of the Opioid Epidemic in Canada, and the Risks of Poly-Substance Use**

Tara Gomes, PhD

Scientist, St. Michael's Hospital

■ **Acute Harms of Prescription Drug Misuse: What Can We Learn from the European Drug Emergencies Network (Euro-DEN) Plus Project**

David Wood, MD, FRCP, FACMT, FBPhS, FEAPCCT

Consultant Physician and Clinical Toxicologist, Guy's and St Thomas' NHS Foundation Trust and King's Health Partners

Reader in Clinical Toxicology, King's College London

12th Annual Scientific Meeting

Thursday, May 10, 2018

Evolution of the Opioid Overdose Epidemic

■ **Welcome and RADARS System 2017 Data Updates**

Richard C. Dart, MD, PhD

Executive Director – RADARS® System, Denver Health and Hospital Authority

■ **Thinking Outside the Opioid Box: Nonopioid Pharmaceutical Abuse**

Janetta L. Iwanicki, MD

Associate Medical Director – Rocky Mountain Poison & Drug Center, Denver Health and Hospital Authority

■ **The Illicit Injection of Prescription Opioids—Risks and Rewards**

Jon E. Zibbell, PhD

Senior Public Health Scientist – Behavioral Health Program, RTI International

■ **Understanding Changes in the US 'Heroin' Market: Notes from the Field**

Dan Ciccarone MD, MPH

Professor of Family and Community Medicine, UCSF
Principal Investigator, Heroin in Transition Study (NIH/NIDA)

■ **Getting to Category IV**

• **FDA's Current Approach to the Postmarket Evaluation of Opioid Analgesic Products with Properties Intended to Deter Abuse**

Tamra E. Meyer, PhD, MPH

Lead Epidemiologist, Division of Epidemiology II, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration

• **A Causal Approach to Understanding Abuse in the Community**

Nabarun Dasgupta, MPH, PhD

Senior Scientist – RADARS® System, Denver Health and Hospital Authority

John Schwarz, PhD

Director of Biostatistics – Rocky Mountain Poison & Drug Center, Denver Health and Hospital Authority

Featured Speakers



John J. Burke

President, Pharmaceutical Diversion Education Inc.
President and Co-Founder,
International Health Facility Diversion Association

Commander John J. Burke has been a law enforcement officer for over 49 years. He spent 32 years with the Cincinnati Police Department, the last nine years he formed and was in charge of the department's Pharmaceutical Diversion Squad.

He commanded the Greater Warren County Drug Task Force in Lebanon, Ohio, a HIDTA initiative that employs local, state, and federal agencies working toward the disrupting of high level drug trafficking, pharmaceutical diversion, and money laundering enterprises, for 16 years, retiring in October 2015.

He became the commander of the Brown County Drug & Major Crimes Task Force in Georgetown, Ohio in April 2016, and retired in May 2017.

Commander Burke is also the past national president of the National Association of Drug Diversion Investigators (NADDI) and is president and owner of Pharmaceutical Diversion Education Inc. He writes a monthly column on prescription drug abuse in Pharmacy Times magazine, and lectures nationally on the topics of pharmaceutical diversion to an audience that includes health professionals, law enforcement, health regulators, and others.

He is also the co-founder and President of the International Health Facility Diversion Association (IHFDA), www.ihfda.org a non-profit, 501C-3 organization dedicated toward the problems surrounding drug diversion within healthcare facilities.



Dan Ciccarone, MD, MPH

Professor of Family and Community Medicine, UCSF
Principal Investigator, Heroin in Transition Study (NIH/NIDA)

Dr. Dan Ciccarone, MD, MPH is a Professor in the Department of Family & Community Medicine at the University of California, San Francisco. Dr. Ciccarone has been

principal or co-investigator on numerous NIH sponsored public health research projects. He is currently leading the "Heroin in Transition" study which examines, utilizing an integrated multidisciplinary approach – ethnographic, economic and statistical modeling – the recent rise in heroin use and the expanding diversity of heroin source-forms and illicitly-made synthetic opioids (e.g. fentanyl) and their relationship to sharp increases in illicit opioid-involved morbidity and mortality. His publications have appeared in JAMA, NEJM, AJP, IJDP and PLoS Medicine. He is Associate Editor for the International Journal of Drug Policy and recently edited an IJDP special issue on the "triple wave crisis" of opioids, heroin and fentanyl in the US.



Tara Gomes, PhD

Scientist – St. Michael's Hospital

Dr. 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 125 peer-reviewed articles and over 50 policy reports in this area.

Dr. Gomes has worked closely with the Ontario Ministry of Health and Long-Term Care and the Canadian Network for Observational Drug Effect Studies (CNODES) to develop evidence to inform policies related to opioid use and abuse in Ontario and more broadly across Canada. She has also served as an expert for the US Food and Drug Administration and the US Department of Transportation in discussions related to opioid policies and regulations. In 2014, the ODPRN was awarded the Institute for Public Administration of Canada's Bronze Public Sector Leadership Award in Health and Education.



J. Aaron Graham
Executive Director – Brand Safety
& Security, Boehringer Ingelheim
Pharmaceuticals, Inc.

Aaron Graham is the Executive Director of Brand Safety & Security for Boehringer-Ingelheim Pharmaceuticals.

Prior to his current assignment, he served in similar senior security roles with global responsibility at Pfizer, Apple and Purdue Pharma.

Before transitioning to industry, Aaron began his federal law enforcement career as a Special Agent for the US Drug Enforcement Administration (DEA), where he conducted international undercover investigations and served on the SWAT team. He subsequently served as a senior special agent and team leader for the FDA-Office of Criminal Investigations, directing undercover investigations targeting global prescription drug trafficking organizations involving counterfeit, unapproved and misbranded medicines.

Aaron has appeared as an industry expert on NBC Dateline – “Bitter Pills,” National Geographic’s documentary “Illicit: The Dark Trade,” and numerous national newspapers and trade publications.

In March 2005, FBI LEEDA presented Aaron with their first-ever *Innovator Award*, acknowledging his leadership and exceptional contributions to the law enforcement community. In 2006, the American Police Hall of Fame presented Aaron with the *Presidents National Medal of Patriotism*. In March 2016, Aaron received PhRMA’s *We Work for Health Champions Award*.

Tamra E. Meyer, PhD, MPH
Lead Epidemiologist, Division of Epidemiology II,
Office of Surveillance and Epidemiology, Center
for Drug Evaluation and Research, Food and Drug
Administration

Dr. Tamra Meyer currently leads the prescription drug abuse team in the Division of Epidemiology, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Her team is responsible for evaluating the postmarket safety of drugs with respect to risks of misuse, abuse, addiction, and overdose. Dr. Meyer has served at FDA for four years as both an epidemiology reviewer and team lead across several therapeutic

areas. She previously served as a civilian epidemiologist for nearly four years with the Army Pharmacovigilance Center where she conducted large drug safety studies using the Military Health System electronic health data. Prior to her work in pharmacoepidemiology, Dr. Meyer studied genetic and cancer epidemiology while earning an MPH and PhD at the University of Texas Health Science Center and later as a postdoctoral fellow at the National Cancer Institute.



**David Wood, MD, FRCP,
FACMT, FBPhS, FEAPCCT**
Consultant Physician and Clinical
Toxicologist, Guy’s and St Thomas’
NHS Foundation Trust and King’s
Health Partners
Reader in Clinical Toxicology, King’s
College London

Dr. David Wood is Consultant Physician and Clinical Toxicologist at Guy’s and St Thomas’ NHS Foundation Trust and King’s Health Partners, London, UK and a Reader in Clinical Toxicology at King’s College London, London, UK. He has a clinical, research and academic interest in the epidemiology and patterns of use of and acute/chronic harms related to established recreational (illicit) drugs, new psychoactive substances (NPS) and misused prescription medicines. He has established a network of specialist European centres to monitor the acute harms associated with use of recreational drug/NPS and the misuse of prescription medicines (the European Drug Emergencies Network (Euro-DEN)), which continues as the Euro-DEN Plus project. In addition, together with the RADARS System, he undertakes UK based population level surveys through consumer marketing panels and sub-population level in situ surveys in nightclubs on the misuse of prescription medicines and UK web monitoring projects on discussion around their misuse. He is a co-opted member of the UK Advisory Council on the Misuse of Drugs (ACMD) and expert advisor to the European Monitoring Centre for Drugs and Drug Addiction (ECMDA) and the United Nations Office on Drugs and Crime (UNODC).

Speakers cont.



John E. Zibbel, PhD
Senior Public Health Scientist –
Behavioral Health Program, RTI
International

Jon E. Zibbell, PhD is a senior public health scientist in the Behavioral Health Program at the RTI International where he conducts behavioral epidemiological

research on risk factors and health outcomes associated with the opioid epidemic and injection drug use. Jon is a medical anthropologist with two decades of field experience in the areas of injection drug use, opioid use disorder, drug overdose and injection-related infectious disease. Before coming to RTI, Dr. Zibbell worked as a CDC health scientist in the Divisions of Viral Hepatitis and Unintentional Injury

Prevention conducting epidemiological and surveillance research on viral hepatitis and drug overdose while assisting States during outbreak investigations to respond to injuries and infections caused by drug use behaviors. In addition to research, Dr. Zibbell has conducted rapid ethnographic needs assessments for community-based syringe service and overdose prevention programs and continues to assist states and community organizations to develop evidence-based approaches to reduce morbidity and mortality associated with the opioid epidemic. His work has appeared in both academic and professional journals and he holds a joint, adjunct appointment in the Center for the Study of Human Health and the Department of Anthropology at Emory University.

Join us at our Networking Welcome Reception

for beverages and hors d'oeuvres

5:00PM to 7:00PM
Wednesday, May 9th



Westin Georgetown 2350 M Street NW Washington, DC



Recent Publications by RADARS® System

RADARS System Published in *Drug Safety*:

Comparative Rates of Mortality and Serious Adverse Effects Among Commonly Prescribed Opioid Analgesics

David L. Murphy Jacob A. Lebin, Stevan G. Severtson, Heather A. Olsen, Nabarun Dasgupta, Richard C. Dart

<https://doi.org/10.1007/s40264-018-0660-4>

Introduction

The epidemic of prescription opioid overdose and mortality parallels the dispensing rates of prescription opioids, and the availability of increasingly potent opioid analgesics.

Conclusions and Relevance

Potency of a prescription opioid analgesic demonstrates a significant, highly positive linear relationship with exposures resulting in SAEs per 100 kg drug dispensed reported to poison centers. Potency should be carefully considered from both individual provider and public health perspectives.

RADARS System Published in *The Journal of Pain*:

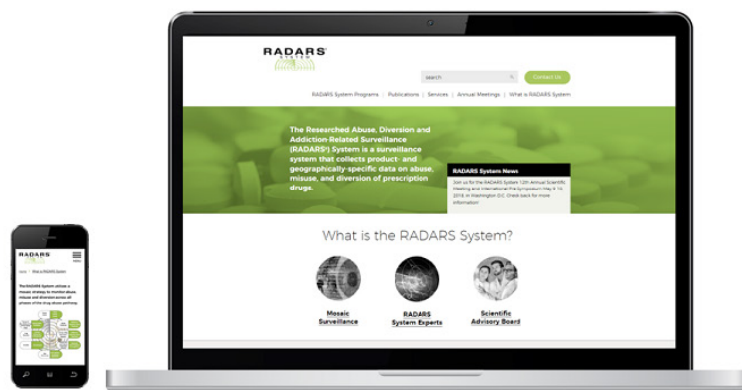
Assessment of Tapentadol API Abuse Liability With the Researched Abuse, Diversion and Addiction-Related Surveillance System

Suzanne K. Vosburg, S. Geoffrey Severtson, Richard C. Dart, Theodore J. Cicero, Steven P. Kurtz, Mark W. Parrino, Jody L. Green

<https://doi.org/10.1016/j.jpain.2017.11.007>

Highlights

- Abuse liability of the tapentadol active pharmaceutical ingredient (API) is compared with those of other scheduled opioids.
- Population-level event rates of tapentadol API abuse were lower than comparators.
- Drug availability adjusted event rates of tapentadol abuse were low but not lowest.
- Public health burden of tapentadol API appears to be low.



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 interpretations, and

See services available
through the RADARS® System

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.

