



Researched Abuse, Diversion and Addition-Related Surveillance System

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10th Annual RADARS® System **Scientific Meeting**

esearchers from all over the globe met in Washington D.C. in May for the 10th Annual RADARS® System Scientific Meeting, calling it everything from phenomenal to the most informative meeting attended. The 2016 meeting aimed to present and discuss **Diverging Perspectives of Prescription** Opioid Abuse and accomplished the task with the assistance of presenters who are leaders in their fields.

The meeting addressed intriguing and important issues head-on, including those surrounding the understanding of political factors affecting abuse deterrent opioids, trends in nonmedical use of prescription opioids, drug overdose mortality through the National

Vital Statistics System and more. The more than 100 attendees found time to network, ask and answer **auestions**

See a complete and up-todate list of all **RADARS System** publications

relating to some of the issues facing the industry and benefitted from a wealth of expertise provided by those from a variety of backgrounds. Of specific note to attendees was the opportunity to take in perspectives of others in attendance.

For the third year in a row, the meeting



was preceded by an International Pre-Symposium, this year asking: Prescription Drug Misuse - A Global Crisis? As the RADARS® System continues to grow and expand to meet the needs of the

international prescription drug market, the international presymposium becomes increasingly valuable to those with an interest in learning about international prescription drug misuse.

10th Annual RADARS® System Scientific Meeting Welcomes Speakers from Around the World

Download Agenda

- John Burke
- Theodore Cicero, PhD
- Dan Cohen, MALS
- Richard Dart, MD, PhD
- Nabarun Dasgupta, MPH, PhD
- Jody Green, PhD, CCRP
- Professor Raymond Hill, BPharm, PhD, DSc (Hon), FMedSci
- Christopher Jones, PharmD, MPH
- Steven Kurtz, PhD
- Lewis Nelson, MD
- Scott Novak, PhD
- Margaret Warner, PhD
- David Wood, MD, FRCP, FEAPCCT, FACMT, FBPhS



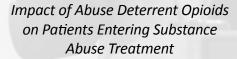
Burke

Impact of Abuse Deterrent Opioids on Drug Diversion Investigators

Full Presentation Here

Conclusions:

- Reformulated OxyContin® can be abused
- Must swallow multiple pills intact to achieve "high"
- Hardened addicts most likely to OD and die will not use intact
- They need the jolt of injection or snorting
- Difficult and time consuming to accomplish this with the ADF OxyContin®





Conclusions:

- ADFs have the potential to reduce abuse, primarily through non-oral routes of administration
- ADFs can result in some shifts to other drugs of abuse
- ADFs should be considered for immediate-release as well as extended-release opioids



Cohen



The Political Factors Affecting the Abuse Deterrent Formulations

Full Presentation Here

- ADFs are being recognized as a valuable component in the combat against Rx drug abuse – Opioids & Stimulants
- FDA increasingly acknowledges its responsibility to provide guidance to industry for ADF development and to bring more ADF products (incl. IR opioids) to market
- Real-life incentives are still missing and adequate labeling and support from payers are key hurdles
- Working with all relevant stakeholders to create awareness, acceptance and incentives is still to be improved and intensified





Dart

Welcome and RADARS® System 2015
Data Updates

Full Presentation Here

Abuse Deterrent Opioids: Lessons for the "Downward Spiral"

Full Presentation Here

Conclusions:

- Lots of controversy
 - Cost
 - Fear of increased prescribing
 - Alternatives are plentiful
- Won't be able to tease out the minor differences until most of the market is ADF
- Then the fun will begin
 - But only if health care payers decide to pay

Street Prices

Full Presentation Here

Conclusions:

 StreetRx provides an overview of what opioids are selling for on the street and the demographics of those reporting prices





Green

International Pre-Symposium: Welcome and Introduction & RADARS® System International Data Updates by Region

Full Presentation Here

Conclusions:

- A mosaic approach to surveillance provides valuable insight from multi-dimensional perspectives
- Each of the programs presented target different facets of prescription opioid abuse, misuse, and diversion
- While magnitude and patterns vary, heroin, THC, prescription opioids and benzodiazepines commonly abused/misused in many countries



Hill

International Pre-Symposium: Misuse of Medications in the UK and Related Advisory Council on Misuse of Drugs (ACMD) Activities

Full Presentation Here

Conclusions:

- The 2014/15 Crime Survey for England and Wales found that 5.4% of the 16 – 59 age group and 7.2% of the 16 – 24 age group had misused a prescription painkiller in the past 12 months
- The rise in prescribing of opioid medication in the UK is almost wholly attributable to increased prescribing for chronic pain
- New guidelines advise against this practise for most patients
- More than 30% of drug related deaths across the UK involve ingestion of more than one substance including ethanol



Jones

Prescription Opioid and Heroin
Abuse in the United States

Full Presentation Here

- Trends in Rx opioid and heroinrelated morbidity and mortality continue to change
- More research needed to track patterns of use and overdose and the impacts (intended and unintended) of policy and practice change on prescribing, use, and health outcomes
- Data support a comprehensive approach that focuses on improving prescribing practices, expanding access to evidencebased treatment for opioid use disorders, and increasing use of naloxone





Kurtz

International Pre-Symposium: Non-Prescription Fentanyl: Canadian Fentanyl Trends Moving to the US

Full Presentation Here

Conclusions:

 Canada and US have different but complementary drug trafficking routes - Illicit drug trade adapts to Rx opioid misuse trends and control measures

Most worrisome -

- high potency illicit fentanyl analogues are easily camouflaged and transported
- mass produced counterfeit Rx products



Nelson

Setting the Stage: Are Abuse Deterrent Formulations Ready for Prime Time?

Full Presentation Here

Conclusions:

- The many moving parts make it difficult to discern causality of interventional effectiveness
- Epidemiologic proof of abuse or addiction reduction should be obtained to allow advanced labeling claims
- Needed to justify the increased expense of ADF, especially branded
- We must continue to educate patients and prescribers about ADFs and opioids in general
- Rationalize expectations
- Harm reduction efforts
- Need to focus on primary prevention
- ADF have a role, but we cannot rely on engineering controls to fix the epidemic of opioid abuse and addiction

Public health policy issues -

- International cooperation
- Systematic surveillance, including Rx counterfeits and substitutes
- Law enforcement efforts to control illicit trade
- Prevention measures targeted to young people
- Pain management treatments that work
- Treatments with low abuse liability
- Access to opioids for patients that need them
- Drug treatment access
- Harm reduction, including needle exchange, safe injection sites, and OD reversal



Novak

NSDUH Trends in Nonmedical Use of Prescription Opioids

Full Presentation Here

- Methodological challenges in national data sources
- Rx abuse and heroin drive by a lifecourse history, rather than specific exposure (e.g. prescription for pain via iatrogenic addiction)
- Post-Marketing Surveillance of therapeutic classes and specific drugs will be easier with NSDUH redesign, but new methods are needed to capture new and emerging products and behaviors (non-injection routes of tampering
- Non-probability methods and enriched population surveillance methods (e.g., substance abuse treatment centers) have utility for estimating early trends and relationships to key variables of interest





Warner

Understanding Drug Overdose Mortality Using the National Vital Statistics System

Conclusions:

- Over 47,000 drug poisoning deaths in the US in 2014
 - Drug poisoning is the leading cause of injury death in the US

 More than the number of deaths from motor vehicle traffic or from firearms

- Data are collected from death certificates filled out by medical examiners and coroners
- Projects underway to address some limitations

Look for a save the date for the 11th Annual RADARS® System Scientific Meeting to come this fall.



Wood

International Pre-Symposium: Trends of Prescription Drug Misuse in the UK and Singapore

Full Presentation Here

- Increasing evidence and concern about non-medical use of prescription medicines
 - ↑opioid prescribing, particularly tramadol
 - Predominately opioids and benzodiazepines
 - Less commonly with GABAergics
- In UK appears associated with certain 'sub-populations'
 - Clubbers, MSM community, those with chronic pain
- Less information on prescription medicine use in Asia
 - Prescribing of opioids much lower than US and UK
 - Internet surveys suggest however there is an issue
- These internet surveys suggest prescription medicine misuse is a potential concern in the UK and Singapore
- Further work is required in both regions to explore
 - Geographical and demographic patterns
 - Sources of drugs
 - Motivations for use
 - Potential association with chronic pain and/or chronic illness
 - This will help inform appropriately targeted primary and secondary interventions



John Burke directs the attention of attendees toward the screen during his presentation on Impact of Abuse Deterrent Opioids on Drug Diversion Investigators.



Attendees engage in a panel discussion with experts in their fields during the 10th Annual RADARS® System Scientific Meeting.



Dr. David Wood, as part of the international panel, addresses questions asked during the interactive session during the 10th Annual RADARS® System Scientific Meeting.



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.

Take me to a list of international services

