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RADARS[®]

S Y S T E M

Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS[®]) System

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RADARS System Quality Assurance Practices

Quality Assurance (QA) programs are a crucial component of any program. A good quality assurance program consists of planned and systematic actions that ensure the project is performed and data are generated, documented and reported in accordance with Standard Operating Procedures (SOPs) and applicable regulations.

The RADARS System has an established quality assurance program that incorporates a clear set of quality control steps. The following is an overview of some of the quality control steps undertaken by the Drug Diversion, Key Informant, Poison Center and Opioid Treatment Program Signal Detection Systems within the RADARS System QA program.

Data Entry Verification

Data entry verification provides a reliable start to the entire data collection process by guaranteeing that only accurate data are entered.

The RADARS System verifies data entry accuracy in multiple ways.

- Data submitted by informants to the Drug Diversion and Key Informant Signal Detection Systems are first entered manually by a research assistant and then verified by a second research assistant.
- Each US poison center utilizes a standardized electronic data collection process (established by the American Association of Poison Control Centers), irrespective of participation in the RADARS System. Trained and nationally certified poison center staff enter data at the time that the exposure is being managed on the phone and complete the fields in the data collection software utilizing standardized definitions.
- Opioid Treatment Program questionnaires are completed anonymously by patients and faxed to the coordinating site using a dedicated toll-free number. These questionnaires are scanned into data recognition software which has a quality control module used to review the data to ensure that hand written responses have been correctly recognized and converted into electronic text.

Data Validation

While data entry verification ensures that reported data are entered correctly, additional checks for correctness and compliance with applicable standards, rules and conventions (i.e. data validation) are performed.

The RADARS System validates data in the following ways.

- Each signal detection system performs either manual or computer reviews to identify missing, inconsistent or inaccurate data and to detect unusual trends and patterns that are developing.
- All discrepancies are documented and sent to appropriate personnel for resolution.

Ensuring Data Integrity

Security measures ensure consistent, correct, secure, and accessible data that do not become corrupt over time.

The RADARS System ensures data integrity in multiple ways.

- Data at each signal detection system are stored in databases with access limited to authorized individuals.
- Electronic data transmission is performed through the use of encryption software or dedicated fax machines as needed.
- Data from each signal detection system are uploaded into a secure central database; the central database is compared to the signal detection systems' local databases to ensure they are identical.

Final Report Verification

The RADARS System conducts final report verifications to ensure that subscribers receive accurate data. Reports are generated using signal detection system data (numerator data) in conjunction with data provided by outside vendors (denominator data). Additional quality control checks are employed to check denominator data for inconsistencies and verify data outputs and statistical analyses.

The entire quality assurance program ensures accurate data are sent to subscribers and are used in research submitted for publication to peer reviewed journals.

RADARS System Appoints New QA Manager

Janet Pulver, M.S., R.A.C., C.Q.A. has been appointed the Quality Assurance Manager of the RADARS System. In this position, Pulver will be responsible for standard operating procedures to comply with regulations and standards, maintaining a training compliance program for all staff and overseeing all quality assurance operations of the RADARS System.

“We are very excited to have such an experienced person to coordinate the QA procedures to ensure that the RADARS System is always in compliance with

regulations,” said Elise Bailey, M.S.P.H., Business Manager of the RADARS System.

Before joining the RADARS System team, Pulver worked in Food and Drug Administration regulated industries since 1997, has held positions in clinical research, and senior positions in quality assurance and regulatory affairs. She also obtained her Regulatory Affairs Certification from the Regulatory Affairs Professionals Society (RAPS) and is a Certified Quality Auditor by the American Society for Quality (ASQ).

Journal of Addictive Diseases Publishes RADARS System Manuscript: *Abuse of Buprenorphine in the United States 2003-2005*

According to a recent evaluation of a subset of RADARS System Poison Center Signal Detection System cases from 4th quarter 2003 through 4th quarter 2005, buprenorphine has a low rate of abuse when compared to the number of prescriptions written. There were seventy-seven abuse cases involving buprenorphine; 7.8 percent involved Subutex[®], the buprenorphine product used during the initiation phase of opioid dependence treatment, and 92.2 percent involved Suboxone[®], the buprenorphine-naloxone product used during the maintenance phase of treatment.¹

Though buprenorphine is a heavily controlled opioid, its increased medical availability has resulted in increased concern regarding its abuse potential. In

Finland, abuse of buprenorphine “has been reported among untreated intravenous users,” however, “to date, little is known concerning the abuse of these sublingual buprenorphine products in the U.S.”¹

Results of this study suggest that while cases of abuse involving buprenorphine do exist, “the level of such abuse is low relative to the number of prescriptions dispensed;” however “ongoing monitoring of these new products is vital in order to determine whether these trends will continue.”¹

1. Smith MY, Bailey JE, Woody GE, Kleber HD. Abuse of Buprenorphine in the United States: 2003-2005. *Journal of Addictive Diseases*. 2007; 26:107-111.

RADARS System Researcher Receives APHA Award

Nabarun Dasgupta, doctoral candidate in epidemiology at the University of North Carolina at Chapel Hill, has received an Alcohol, Tobacco and Other Drugs (ATOD) award for Best Student Abstract. Dasgupta’s abstract, *Poison Center Intentional Exposure Calls Predict Mortality Due to Prescription Opioids*, analyzes RADARS System poison center intentional exposure cases from 2003 showing that RADARS System data provides a more timely way of predicting mortality due to prescription opioid overdoses.

The ATOD award is given by the American Public Health Association (APHA) to individuals chosen for

their noteworthy contribution to the field and commitment to reducing alcohol, tobacco and other drug use.

The award and abstract will be presented at the APHA annual meeting November 3-7, 2007, in Washington, DC.

Congratulations to Nab and many thanks for his work with the RADARS System.

**The RADARS System poster, *Effectiveness of the Kentucky Operation UNITE (Unlawful Narcotics Investigations, Treatment and Education) as Evaluated by RADARS[®] System Poison Centers*, will also be presented at the APHA meeting.

Upcoming Meetings of Interest

- The National Association of State Controlled Substances Authorities (NASCSA) will host its annual meeting October 16-20, 2007, in Albuquerque, New Mexico. NASCSA is a non-profit organization dedicated to providing regulated industries and professions a mechanism to work to increase the effectiveness and efficiency of state and national efforts to prevent and control drug abuse. Mark Parrino, President of the American Association for the Treatment of Opioid Dependence (AATOD) and Principal Investigator of the RADARS System Opioid Treatment Program Signal Detection System will present, *Myths and Realities of Methadone (proper dosing)*. For more information, please visit www.nascsa.org
- The American Association for the Treatment of Opioid Dependence (AATOD) will host its national conference October 20-24, 2007, in San Diego, California. The AATOD conference will provide new information in the field of opioid treatment and will demonstrate techniques for improving treatment. For more information, please visit www.aatod.org
- The National Association of Drug Diversion Investigators (NADDI) will hold its 18th annual meeting November 13-16, 2007, in the Tampa Bay area. NADDI is an organization whose members are involved in investigating and prosecuting pharmaceutical drug diversion. Presentations at the meeting will include an overview of prescription drug abuse and an overview of the RADARS System Drug Diversion Signal Detection System. For more information, please visit www.naddi.org

Recent Publications & Events

Using RADARS System Data

- Campagna E, Bailey JE, Kirtland M, Spiller H, Dart RC. Effectiveness of the Kentucky Operation UNITE (Unlawful Narcotics Investigations, Treatment and Education) as Evaluated by RADARS[®] System Poison Centers. American Public Health Association Annual Meeting. Washington, DC. November, 2007.
- Cicero TJ, Surratt H, Inciardi JA, Munoz A. Relationship between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States. *Pharmacoepidemiology and Drug Safety*. 2007; 16:827-840.
- Dasgupta N, Bailey JE, Dart RC, Jonsson MF. Poison Center Exposure Calls Predict Mortality Due to Prescription Opioid Poisoning. American Public Health Association Annual Meeting. Washington, DC. November, 2007.
- Smith MY, Bailey JE, Woody GE, Kleber HD. Abuse of Buprenorphine in the United States: 2003-2005. *Journal of Addictive Diseases*. 2007; 26:107-111.

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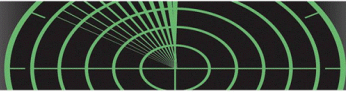
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Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS[®]) System

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RADARS System Mission Statement

The RADARS System provides timely and geographically-specific data to the pharmaceutical industry, regulatory agencies, policymakers and medical/public health officials to aid in understanding trends in the abuse, misuse, and diversion of prescription drugs in the United States.

RMPDC and Denver Health

The RADARS System is a governmental nonprofit operation of the Rocky Mountain Poison and Drug Center (RMPDC), an agency of Denver Health (DH). The RMPDC has been in operation for more than 50 years, making it one of the oldest poison control centers in the nation. DH is the safety net hospital for the City and County of Denver. DH is the Rocky Mountain region's academic Level I trauma center and includes Denver Public Health, Denver's 911 emergency medical response system, nine family health centers, 12 school-based clinics, NurseLine, correctional care, Denver CARES, the Denver Health Medical Plan, and the Rocky Mountain Center for Medical Response to Terrorism, Mass Casualties and Epidemics.

