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Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Meeting Summary

The RADARS System Second Annual Scientific Meeting, *From Signals to Interventions*, was held May 1, 2008, at the Hyatt Regency, Bethesda, Maryland. Attendees (n=80) included researchers and speakers, pharmaceutical representatives, federal research or regulatory agencies, and policymakers.

The meeting was organized to inform and promote discussion among users of RADARS System data: regulatory agencies, policymakers, medical/public health officials and the pharmaceutical industry. The RADARS System provides timely and geographically specific data to aid in understanding trends in abuse, misuse, and diversion of prescription drugs in the United States. Current RADARS System drug classes of interest are buprenorphine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone and tramadol.

Richard C. Dart, M.D., Ph.D., Director of the Rocky Mountain Poison and Drug Center (RMPDC) at Denver Health and Hospital Authority in Denver, Colorado, and Executive Director of the RADARS System, presided over the meeting. The RADARS System, which was acquired by Denver Health and Hospital Authority from Purdue Pharma L.P. by RMPDC January 1, 2006, is an independent operation of RMPDC, and completed its 6th year of data collection in December 2007.

After an initial brief overview of RADARS System annual data for 2007, the meeting focused on stimulating discussion regarding what prescription drug abuse, misuse and diversion interventions entail and what are realistic expectations for these interventions. To perform risk management, one must evaluate the risk, manage the risk, and finally measure the effect of their risk management and interventions. A summary of each of the presentations by experts in the field of public health interventions is provided below. Participants were also encouraged to browse the RADARS System posters available for review in the meeting room and provided with "Quantifying morbidity associated with the abuse and misuse of opioid analgesics: A comparison of two approaches" recently published in *Clinical Toxicology*. A complete list of RADARS System related publications is provided in Appendix A.

Report of RADARS System 2007 Data

RADARS System data offer multiple perspectives through the use of six unique signal detection systems (Drug Diversion, Key Informant, Opioid Treatment Program, Poison Center, Impaired Health Care Worker, and College Survey Signal Detection Systems) that collect and provide data rapidly and with geographic specificity (3-digit ZIP code level), address the rural nature of prescription opioid abuse, misuse and diversion, and include data on non-abuser victims.

RADARS System new developments in 2007 include piloting two new signal detection systems, bringing the number of signal systems within RADARS System to six. The Impaired Health Care Worker Signal Detection System, a subset of all of the RADARS System signal detection systems, reports prescription drug abuse, misuse and diversion data on self-identified health care workers. This signal detection system may serve to detect early adopters of prescription drug abuse, misuse

RADARS[®] SYSTEM

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and diversion who work in the health care industry. The College Survey Signal Detection System surveys self-identified college students regarding their abuse and misuse of prescription drugs during the previous semester and over the summer. These data may represent experimentation with prescription drug abuse and offer an early abuser's perspective.

These six signal detection systems provide unique perspectives and offer opportunities to monitor prescription drug abuse, misuse and diversion along the spectrum of the drug dependence pathway (opportunity, use, abuse, and dependence).

Goals of the RADARS System are as follows:

- Identifying sentinel events involving the misuse, abuse and diversion of prescription drugs nationwide
- Measure rates of misuse, abuse and diversion of prescription drugs
- Provide experienced and expert analysis and interpretation of the data

Nationally RADARS System 2007 data trends are similar to previous years. Per 100,000 persons, hydrocodone and oxycodone are consistently the highest abused, misused, and diverted. Per 1,000 unique recipients of dispensed drug (URDD), an indicator of drug availability, buprenorphine, methadone, and hydromorphone are the most highly abused, misused and diverted.

While no one system covers the entire United States, 94% of the 3-digit ZIP codes report into at least one of the signal detection systems. In 2007, 97% of these 3-digit ZIP codes reported at least one case of abuse, misuse and diversion to RADARS System drugs of interest.

Key findings from the annual report:

- No community is immune to prescription drug abuse.
- Prescription drug abuse, misuse and diversion are widespread, affecting nearly all areas of the United States.
- Evidence of abuse, misuse and diversion is increasing in total, but the abuse, misuse and diversion standardized by number of people receiving a prescription for the drugs of interest is not increasing.
- All opioid drugs are abused.

Communities That Care: Model for Community-Level Substance Abuse Prevention

Michael Arthur, Ph.D.

Social Development Research Group

Seattle, WA

The goal of Communities That Care is to empower communities to choose effective prevention policies and programs matched to community needs. Communities That Care not only tracks rates of abuse, but also focuses on prevention and the precursors of abuse. Effective prevention is based on

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Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Meeting Summary

the premise that to prevent a problem before it happens, the factors that predict the problem must be changed.

The Communities That Care strategic prevention planning system guides a community through a process where a coalition is formed and stakeholders from the community are selected. Community levels of protection and risk are then measured by surveying young people themselves. Finally, tested, effective actions are matched against the community's profile of risk and protection. This prevention planning system process is designed to fit locally as communities select what they believe will work for them. If a community is not meeting its goals, interventions can be adjusted mid-stream to fit new goals.

Communities That Care initiates its work with adolescents long before they are exposed to drugs or start abusing them. Interventions are often geared towards elementary school-aged children that focus on interactions that promote social bonds and parental influence on children and their decisions.

Communities That Care is currently conducting a randomized controlled trial of 24 of its communities to test the effectiveness of their methodology in reducing risk levels, increasing protection levels, and reducing health and behavior problems in early adolescence. Twelve paired communities were randomly assigned to Communities That Care or control conditions in 2003. Results indicate that adoption of the Communities That Care system helped:

- Foster community action grounded in data from the community's young people
- Collaboration among key stakeholders
- Installation of new tested and effective programs in all 12 communities in the Communities That Care condition
- Reduce targeted risk factors in the Communities That Care communities relative to the controls
- Reduce initiation of delinquent behavior in the Communities That Care communities relative to controls.

Prescription Opiate Deaths in Washington State and Potential Solutions

Jennifer Sabel, Ph.D.

Washington State Department of Health

Olympia, WA

In recent years, several data sources have indicated that Washington State may have a higher prevalence of prescription drug abuse. Substance Abuse and Mental Health Administration (SAMHSA) data indicate that Washington State is one of the top 10 states for persons reporting non-medical use of pain relievers in the National Survey of Drug Use and Health (NSDUH) survey. In addition, Drug Enforcement Administration (DEA) data for the state of Washington demonstrate that the volume of prescription opiates distributed in pharmacies and hospitals has increased dramatically

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Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Meeting Summary

between 1997 and 2005. The Health Youth Survey showed that 10% of 10th graders and 12% of 12th graders used a painkiller to get high in past 30 days, compared to 15% and 20%, respectively for cigarette use. While a majority of teens say they misuse prescription narcotics to relieve pain, 30% say they use the prescription narcotics to get high.

Data from the Washington State Injury and Violence Prevention Program from 1980 through 2006 demonstrate that 90% of poisoning deaths are the result of drug overdoses, and 42% of the drug overdoses are among the Washington State Medicaid clients. To better understand these data, the Washington State Health Department manually reviewed death certificates, and deaths were classified as definitely, probably or possibly related to prescription opiate use. In 1995, 24 deaths were identified as either definitely or possibly related to opiate use; this number increased 17-fold to 475 in 2006. A majority of death certificates identified more than one substance (2.5 on average), and methadone was listed most frequently.

Prevention strategies were then implemented with the intention of decreasing these poisoning deaths as the result of drug overdoses.

- One prevention strategy involved the development of opioid guidelines to assist clinicians in prescribing opioids in a safe and effective manner.
- Another prevention strategy involved clinical interventions in Medicaid clients. These clinical interventions include:
 - Narcotic Review Program: clients who receive ten or more prescriptions a month have their prescription histories shared with all of their providers
 - Toolkit: resource for providers with information about chemical dependency treatment, screening, and referral pocket card, among others
 - Patient Review and Restriction Program: restricts overusing clients to one provider, one pharmacy, one narcotic prescriber, and one hospital for non-emergent issues
- Care Coordination is another prevention strategy which is based on professional partnerships and collaborations between emergency departments, primary care providers and pharmacists.
- Finally, one recently implemented intervention is the Washington Screening, Brief Intervention and Referral and Treatment project which screens patients in emergency rooms for substance abuse disorders.

The outcomes of these prevention strategies include a significant reduction in the number of narcotic scripts filled, doubling of alcohol and drug treatment rates, a reduction in emergency department and physician visits, a decrease

The Importance of Measuring Drug Related Harms and Benefits of Treatment in Post-Marketing Surveillance: Lessons from Buprenorphine

Patrizia Carrieri

INSERM (French National Institute for Health and Medical Research)

Marseilles, France

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Second Annual Scientific Meeting: From Signals to Interventions

Meeting Summary

Ms. Carrieri discussed the benefits of access to drug abuse treatment in France and the benefits to society that result from increased access. The World Health Organization lists buprenorphine and methadone as essential drugs because they prevent HIV and overdose deaths; however, critics assert that buprenorphine is often trafficked and that buprenorphine injection spreads HIV. Data presented demonstrate that:

- As access to buprenorphine and methadone increased, the number of nationally distributed syringes (a proxy for intravenous drug use) decreased.
- After access to these drugs increased, heroin overdose deaths and the number of heroin-related arrests both declined.
- The proportion of drug users living with HIV has declined dramatically over the last decade.
- While one issue regarding drug abuse treatment is doctor shopping, the leading causes of doctor shopping for buprenorphine were low dosages or patients who were unhappy with their level of care. Once patients started receiving adequate drug abuse treatment, doctor shopping decreased.

To explore the drug abuse treatment debate in the United States, the *Baltimore Sun* article written by Fred Schulte and limited access to drug abuse treatment in the United States was discussed. According to Ms. Carrieri, the *Baltimore Sun* article ignored the French experience over the last 12 years and failed to describe the public health benefits of buprenorphine. A result of the limited access to drug abuse treatment in the United States is that new HIV cases continue to occur in intravenous drug users. This differs from France where the number of new cases is declining.

Other countries have also instituted drug policies, and several public health benefits associated with these policies have been reported. France's needle exchange program and access to buprenorphine has reduced HIV and overdose deaths, but Hepatitis C has not decreased. Amsterdam's full harm reduction program focused on needle exchange programs and increased access to methadone, both of which reduced HIV, Hepatitis C and overdose deaths. The Swiss model found that when treatment coverage reaches saturation levels, the black market for these drugs disappears.

Law Enforcement and the Pharmaceutical Industry – Collaboration for Success

John Burke

National Association of Drug Diversion Investigators (NADDI)

Hamersville, OH

The National Association of Drug Diversion Investigators (NADDI) provides education to its members on the subject of pharmaceutical drug diversion. Through collaboration with pharmaceutical industry and health regulatory personnel, NADDI aims to develop more effective measures to combat pharmaceutical drug diversion. In addition, NADDI members are pain patient advocates; they work to educate pain management physicians on relevant issues.

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Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Meeting Summary

Collaboration between NADDI and pharmaceutical companies has led to useful intervention efforts. Examples of key law enforcement and pharmaceutical industry collaborations include:

- Purdue Pharma L.P. funds Rx Patrol (www.rxpatrol.org), a database for law enforcement documenting reports of pharmacy robbery, burglary and crime. Thefts in one jurisdiction which has been reported to Rx Patrol have been linked to thefts in other jurisdictions, improving the effectiveness of the investigation.
- Purdue Pharma L.P. has provided NADDI with both unrestricted grants and grants directed to law enforcement
- Purdue Pharma L.P. funded the development of brochures for the identification of pharmaceuticals
- Purdue Pharma L.P. funded two undercover websites to sell fake OxyContin[®]. This website attracted a major international counterfeiter who purchased 2,000 OxyContin placebos from an undercover officer, offered to sell 60,000 Cialis[®], and was subsequently arrested.
- Purdue Pharma L.P. provided significant resources that resulted in the largest undercover purchase of OxyContin[®] in U.S. history- 3,000, 80mg. tablets for \$105,000. This has resulted in the arrests and dismantlement of a large interstate prescription drug operation based in the Midwest
- Abbott Labs funds seed grants offered to law enforcement entities willing to dedicate at least one investigator to full-time diversion work for at least one year. NADDI personnel also mentor these entities during the grant period.
- Alpharma funded the “Practical Guide for Prescribing Controlled Substances”, distributed to prescribers and dispensers, which describes common sense measures to reduce or stop drug diversion.

Getting to Intervention – Getting Past Prevention in Planning Risk Minimization Action Plans (RiskMAPs) and Risk Evaluation and Mitigation Strategies (REMS)

Curtis Wright, M.D., M.P.H.

Star Pharmaceuticals

Gloucester, MA

Risk assessment, event rate monitoring, risk and loss prevention are all non-controversial aspects of risk management. Intervention, the process of taking an active part in the remediation of loss or injury, is a far more controversial area. Putting together a risk management plan with no provision for intervention is like buying a watchdog with no teeth, but intervention is seen as a slippery slope fraught with administrative, practical and legal perils. However, this does not have to be the case.

Every commercial activity produces a mixture of intended beneficial effects and unintended adverse consequences. Likewise, every society struggles with how to control the unintended adverse consequences. Any industry who has unintended adverse consequences associated with the use of its products has a social responsibility to mitigate or remediate the resulting injury. The result is a dilemma: commercial firms have an obligation not to engage in social welfare projects at the expense

RADARS[®] SYSTEM

Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Meeting Summary

of legitimate profits, and society has an obligation not to impose injury and costs on the public to protect the profits of commercial firms. This problem is especially severe for health care.

Society expects that in addition to the benefit, every reasonable effort will be made to prevent, deter, detect, and minimize the risks to the public and will hold a firm responsible for any casualties *perceived* to be associated with the product to the extent to which the company could have reasonably acted to prevent or mitigate the injury. To this end, all firms must assess the risk of such events and manage risks throughout its product's life cycle. This must occur even if no formal risk management plan was "required", and this process must be transparent – at every step, every document, discussion, memorandum, meeting and e-mail must reflect a clear, coherent, and reasoned profile of product benefits and risks.

If a firm's product becomes associated with a problem, calls are immediately placed to the firm, asking:

- Did you foresee this happening?
- What did you do to prevent it?
- Is it happening to others?
- How bad is it (or will it get)?
- *What do you intend to do about it?*

Every firm should have a plan in place to address the final question. This plan should be simple, prescriptive, specific (time, place, population at risk, exact intervention proposed), and supported by evidence of effectiveness. If a firm has planned

- What you are going to measure
- What your action thresholds are
- What actions you will take
- Who to tell
- What to say

IN ADVANCE, the firm will do all right.

Appendices

A: RADARS System Publication List

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Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Appendix A: RADARS System Publication List

Peer Reviewed Journals

Bailey JE, Barton PL, Lezotte D, Lowenstein SR, Dart RC. The Effect of FDA Approval of a Generic Competitor to OxyContin® (Oxycodone HCl Controlled-Release) Tablets on the Abuse of Oxycodone. *Drug and Alcohol Dependence*. 2006; 84:182-187.

Cicero TJ, Dart RC, Inciardi JA, Woody GE, Schnoll S, Munoz A. The Development of a Comprehensive Risk-Management Program for Prescription Opioid Analgesics: Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS). *Pain Medicine*. 2007; 8:157-170.

Cicero TJ, Inciardi JA, Munoz A. Trends of Abuse of OxyContin® and Other Opioid Analgesics in the United States: 2002-2004. *The Journal of Pain*. 2005; 6:662-672.

Cicero TJ, Inciardi JA, Surratt HL. Trends in the Use and Abuse of Branded and Generic Extended Release Oxycodone and Fentanyl Products in the United States. *Drug and Alcohol Dependence*. 2007; 91: 115-120.

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.

Hughes AA, Bogdan GM, Dart RC. Active Surveillance of Abused and Misused Prescription Opioids Using Poison Center Data: A Pilot Study and Descriptive Comparison. *Clinical Toxicology*. 2007; 45:144-151.

Inciardi JA, Goode JL. OxyContin® and Prescription Drug Abuse. *Consumers' Research*. 2003; 7:17-21.

Inciardi JA, Surratt HL, Kurtz SP, Burke JJ. The Diversion of Prescription Drugs by Health Care Workers in Cincinnati, Ohio. *Substance Use and Misuse*. 2006; 41:255-264.

Inciardi JA, Surratt HL, Lugo Y, Cicero TJ. The Diversion of Prescription Opioid Analgesics. *Law Enforcement Executive Forum*. 2007; 7.

Inciardi, JA., Cicero, TJ, Munoz, A, Adams, EH, Geller, A, Senay EC, Woody, GE. The Diversion of Ultram®, Ultracet®, and Generic Tramadol HC1. *Journal of Addictive Diseases*. 2006; 25:53-58.

Rosenblum A, Parrino M, Schnoll SH, Fong C, Maxwell C, Cleland C, Magura S, Haddox D. Prescription Opioid Abuse Among Enrollees into Methadone Maintenance Treatment. *Drug and Alcohol Dependence*. 90: 64-71, 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.

Smith MY, Dart RC, Hughes AA, Geller A, Senay EC, Woody GE, Colucci S. Clinician Validation of Poison Control Center Intentional Exposure Cases Involving Prescription Opioids. *American Journal of Drug and Alcohol Abuse*. 2006; 32:465-478.

Smith MY, Schneider MF, Wentz A, Hughes A, Haddox JD, Dart RC. Quantifying Morbidity Associated with the Abuse and Misuse of Opioid Analgesics: A Comparison of Two Approaches. *Clinical Toxicology*. 2007; 45:23-30.

RADARS[®] SYSTEM

Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Appendix A: RADARS System Publication List

Abstracts

- Bailey JE, Bogdan GM, Dart RC. Adolescent Prescription Opioid Abuse and Misuse. The Colorado Public Health Association Conference.
- Bailey JE, Bogdan GM, Dart RC. Extended Release Versus Immediate Release Morphine: Difference in Abuse and Medical Outcome. North American Congress of Clinical Toxicology Conference. San Francisco, CA. October, 2006.
- Bailey JE, Dart RC. Exposures to Oxycodone: Demographic Differences by Formulation. American College of Emergency Physicians. New Orleans, LA. October, 2006.
- Bailey JE. Demographic Difference in the Misuse and Abuse of Oxycodone Formulations: Poison Center (PC) Surveillance. Drug Information Association (DIA) Annual Meeting. Philadelphia, PA. June, 2006.
- Campagna E, Bailey JE, Kirtland M, Spiller HA, 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.
- Campagna EJ. Prescription Opioid Abuse in Urban Versus Rural Areas Using RADARS System Data. 69th Annual College on Problems of Drug Dependence Meeting. Quebec City, Canada. June 16, 2007.
- Cram LM, Bailey JE, Dart RC. Description of buprenorphine, methadone, hydrocodone and oxycodone abuse and diversion rates using RADARS[®] System data. Oral Presentation. 69th Annual College on Problems of Drug Dependence Meeting. Quebec City, Canada. June 20, 2007.
- Dart RC, Hughes AA. Adolescent Prescription Opioid Abuse and Misuse: Surveillance by Poison Centers. The College of Problems of Drug Dependence Conference. Scottsdale, AZ. June, 2006.
- Dart RC, Hughes AA. Reporting for the RADARS[®] System Poison Control Centers. Public Health Disparities in Rural Areas: High Rates of Prescription Opioid Abuse. The American Public Health Association Conference. Philadelphia, PA. December, 2005.
- 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.
- Graham A, Smith MY, Haddox JD, Wright C. Reducing the Potential for Diversion of Prescription Opioids: Tested Interventions. The College on Problems of Drug Dependence Conference. Orlando, FL. June, 2005.
- Haddox JD, Schnoll SH. The Standards for Risk Management Plans for High Abuse Potential Medications. The College on Problems of Drug Dependence Conference. Washington, DC. April, 2005.
- Haddox JD, Smith MY, Colucci S, Rosenblum A, Fong C, Maxwell C, Parrino M. Pain as a Reason for Seeking Admission to Methadone Treatment. The College of Problems of Drug Dependence Conference. Scottsdale, AZ. June, 2006.
- Hughes AA, Bogdan GM, Bond R, Dart RC. Increase in OxyContin[®] Abuse or Media Hype? Journal of Toxicology: Clinical Toxicology. 2002; 40:656-657.

RADARS[®] SYSTEM

Researched Abuse, Diversion and Addiction-Related Surveillance System

Second Annual Scientific Meeting: From Signals to Interventions

Appendix A: RADARS System Publication List

Abstracts (cont.)

Hughes AA, Bogdan GM, Dart RC. Comparative Rates of OxyContin[®] Abuse: Anecdotal Highs. *Journal of Toxicology: Clinical Toxicology*. 2003; 41:746-747.

Hughes AA, Dart RC, Bailey JE. Reporting for the RADARS[®] System Poison Control Centers. Lick or Stick: The Common Routes of the Misuse and Abuse of Fentanyl. The North American Congress of Clinical Toxicology Conference. Orlando, FL. September, 2005.

Hughes AA, Dart RC. Reporting for the RADARS[®] System Poison Control Centers. Prescription Drug Abuse Epidemic: Surveillance of Opioid Abuse Using Poison Centers. The American Public Health Association Conference. Philadelphia, PA. December, 2005.

Hughes AA, Dart RC. Reporting for the RADARS[®] System Poison Control Centers. Demographic Differences of the Misuse and Abuse of Oxycodone Formulations. The Colorado Public Health Association Conference. Denver, CO. September, 2005.

Hughes AA, Dart RC. Reporting for the RADARS[®] System Poison Control Centers. Surveillance of the RADARS[®] System by Poison Control Centers. The College on Problems of Drug Dependence Conference. Orlando, FL. June, 2005.

Hughes AA, Dart RC. Reporting for the RADARS[®] System Poison Control Centers. Seasons of Abuse? Temporal Trends of Prescription Opioids. *Journal of Toxicology: Clinical Toxicology*. 2004; 42:762-763.

Inciardi JA, Surratt HL. The Diversion of Prescription Opioids in the US. The College of Problems of Drug Dependence Conference. Scottsdale, AZ. June, 2006.

Kline AT, Smith MY, Haddox JD, Rosenblum A, Fong C, Parrino M, Maxwell C. Abuser-reported Sources of Illegally Obtained Opioid Analgesic Medications. The College of Problems of Drug Dependence Conference. Scottsdale, AZ. June, 2006.

Senay EC, Geller A, Woody G, Dart R, Hughes A, Smith MY. Patterns of Abuse, Dependence and Misuse of Prescription Opioid Analgesics, Benzodiazepines and Carisoprodol in 7792 calls to Poison Control Centers. The College on Problems of Drug Dependence Conference. Orlando, FL. June, 2005.

Smith MY, Dart R, Hughes A, Geller A, Senay E, Woody G, Colucci S. Clinician Validation of Poison Control Center Intentional Exposure Cases Involving Prescription Opioids. The College on Problems of Drug Dependence Conference. Orlando, FL. June, 2005.

Smith MY, Haddox JD. Measuring Rates of Nonmedical Use - Dimensions and Denominators. The College on Problems of Drug Dependence Conference. Washington, DC. April, 2005.

Smith MY, Irish W, Wang J, Haddox JD, Dart RC. Relative Rate of Opioid Analgesic Abuse in Communities in the U.S. The College of Problems of Drug Dependence Conference. Scottsdale, AZ. June, 2006.

Smith MY, Schneider MF. Measuring Rates of Prescription Opioid Abuse and Misuse-Dimensions and Denominators. The College on Problems of Drug Dependence Conference. Washington, DC. April, 2005.