

Wanted: a public health approach to prescription opioid abuse and diversion

David E. Joranson MSSW* and Aaron M. Gilson PhD

Pain & Policy Studies Group, Comprehensive Cancer Center, School of Medicine and Public Health, University of Wisconsin, Madison, WI, USA

Response to "Increasing deaths from opioid analgesics in the United States". Leonard J. Paulozzi, Daniel S. Budnitz and Yongli Xi. *Pharmacoepidemiology and Drug Safety* 2006;15: (in press). DOI: 10.1002/pds.1276.

In this issue, Paulozzi, Budnitz, and Xi of the Centers for Disease Control and Prevention describe mortality data from the National Center for Health Statistics and retail sales of controlled substances from the U.S. Drug Enforcement Administration (DEA). The authors attribute rising opioid analgesic mortality to their medical use and "aggressive" pain management. Although these findings add to the growing body of evidence that describes adverse health consequences associated with increased abuse of prescription pain medications,¹⁻⁷ they do not explain how prescribing or pain management relate to mortality. Evidence of causal relationships would be necessary to determine that a particular drug or prescriptions for pain management caused a death.

The media often picks up such analyses and the result is that complex underlying problems of abuse and addiction are attributed to prescription drugs and their prescribers. Unwittingly, publicity about simple associations can exacerbate fears of appropriate medical use of prescription drugs among pain patients and the public, trigger more drug control, and increase fears of regulatory scrutiny among legitimate pre-

scribers and dispensers. All of these can lead to further under-treatment of pain.

Abuse of prescription pain medicines leads to tragic consequences for individuals, families, and society, and has profound implications for those involved in pain management, addiction medicine, and diversion control. Here we argue that a public health approach is necessary to understand prescription opioid abuse and diversion and we discuss several elements we believe are essential.

First, we need better data. Databases that are now in use, such as those analyzed by Paulozzi *et al.*, cannot attribute the cause of a death to a particular drug. A recent Substance Abuse and Mental Health Services Administration report addressing methadone-associated mortalities points to the difficulty of using postmortem examinations to reliably distinguish methadone toxicity deaths from those where the presence of methadone is incidental.⁸ Because mortality often occurs in the presence of poly-substance use,^{9,10} it becomes even more difficult to determine a specific cause of death, let alone the user's intent or the source of drug.

In particular, we need information about the motivations for drug use. For example, it is important to know whether those who die from drug-related causes were pain patients using medications for which they had a legitimate prescription for pain. Indeed, literature suggests that much of the abuse of opioid analgesics is by recreational and street users and individuals with co-morbid psychiatric conditions.^{1,11,12} Yet, the most widely used databases for estimating incidence or prevalence of abuse and non-medical use of opioid analgesics, such as the Drug Abuse Warning Network,¹³ Monitoring the Future,¹⁴

* Correspondence to: D. E. Joranson, Pain & Policy Studies Group, Comprehensive Cancer Center, School of Medicine and Public Health, University of Wisconsin, Madison, WI, USA.
E-mail: joranson@wisc.edu

and the National Survey of Drug Use and Health,¹⁵ do not collect extensive data, if at all, about motivations for use, which could include pain relief, euphoria, blocking withdrawal, suicide, or self-medication of co-morbid conditions such as anxiety or depression. A public health approach also requires that we know more about the sources of abused drugs. Major databases, like those cited above, do not collect information about the sources, or vectors, of the drugs leading to morbidity or mortality. We have already made recommendations to improve data collection.^{2,3}

We should bear in mind that it is those who are involved in abuse, addiction, and related trafficking that drive a powerful demand to divert prescription drugs. Indeed, drug abuse data systems should be seen as an important source of information about unmet treatment needs for a range of populations who create the demand, including those with mental health and substance use disorders.

While treatment for opioid analgesic abuse and addiction has expanded to save lives and reduce demand,¹⁶ epidemiologists should examine how people manage to divert prescription drugs from the drug distribution system. Reports indicate opioid analgesics are stolen from medicine cabinets, sold by patients, obtained from "pill mills," the internet, forgery, and "doctor-shopping."¹⁷⁻¹⁹ All of these activities are illegal and are not legitimate medical care or "pain management."

Another category of crimes to divert prescription controlled substances is when individuals steal from the supply chain, for example, pilferage from hospital medical inventories, pharmacy robberies, and night break-ins. Until recently, there has been little evidence of the extent that opioid analgesics are diverted by this (or any other) method.^{2,17,20-22} We filed a Freedom of Information Act request to obtain a DEA database containing federally required reports of the amounts stolen from businesses that hold DEA registrations.²³ For unknown reasons, this national database includes reports from less than half of the states and, thus, significantly under-reports national incidence and quantities.

Our preliminary analysis reveals that there were almost 13,000 incidents of prescription controlled substances diverted by theft from 2000 to 2003. In 2003 alone, 2 million dosages of six opioid analgesics that we studied were reported stolen from the supply chain, mainly from retail pharmacies;²⁴ these were all FDA-approved Schedule II prescription opioid analgesics: fentanyl, hydromorphone, meperidine, methadone, morphine, and oxycodone. The amounts of hydrocodone, a Schedule III opioid

analgesic, that were diverted in this manner were approximately twice as much as the total of all six study drugs.

It is now apparent that there are significant non-medical sources of diversion. Consequently, we cannot automatically interpret that mortality involving prescription opioids means that the person was using a "prescribed" opioid or that pain management was involved. Clearly, the tremendous amounts of "prescription" opioid analgesics reported stolen from the supply chain reached the illicit market without ever having been prescribed by a physician or dispensed by a pharmacist to a patient. The fact that large quantities of abused opioid analgesics are diverted directly from the supply chain, completely bypassing the involvement of ordinarily conscientious healthcare professionals, underscores the need to develop abuse-resistant medications.

To be sure, the Paulozzi *et al.* study should prompt more investigation of the prevalence of iatrogenic drug abuse and addiction, but we also need to know the case characteristics and motivations of those who exhibit aberrant drug behaviors that end in overdose and death²⁵⁻²⁸ so that evidence-based interventions can be developed and tested. In high-incidence areas, targeted ethnographic studies could provide information that would stimulate efforts to address the underlying causes of prescription drug abuse at the community level to relieve the devastating burdens associated with abuse and addiction. Meanwhile, we should support state medical regulatory authorities who have been working for a decade to achieve balance at the state level by taking disciplinary action against those few practitioners who divert prescription pain medications, and by adopting policies that encourage pain management and better education of practitioners to take necessary precautions when prescribing opioid analgesics.²⁹⁻³¹ Working more closely with national organizations charged with measuring the national incidence and prevalence of adverse health consequences from prescription opioid abuse, we could develop an evidence base for understanding the complex relationships between unintentional poisoning, prescription drug abuse and diversion, and the medical use of opioid analgesics.

Clearly, we must not allow the drug abuse problem, illegal activities, and a very small minority of careless, misinformed, or mal-intended health professionals to interfere with the public health goal of relieving pain and improving the quality of life in patients with a legitimate need for a prescription opioid. We fully concur with the authors that efforts to reduce mortality from opioid analgesics must be balanced³² (i.e.,

targeting interventions at those who cause the problem while not impeding appropriate and effective patient care). However, targeting interventions requires information about why prescription controlled drugs are misused, how they are diverted, and who diverts them. This area continues to be ripe for a public health examination.

REFERENCES

- Cicero TJ, Inciardi JA, Munoz A. Trends in abuse of Oxycontin and other opioid analgesics in the United States: 2002–2004. *The J Pain* 2005; **6**(10): 662–672.
- Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997–2002. *J Pain Symptom Manage* 2004; **28**(2): 176–188.
- Joranson DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. *JAMA* 2000; **283**(13): 1710–1714. (Available at <http://www.medsch.wisc.edu/painpolicy/jama.htm>).
- Novak S, Nemeth WC, Lawson KA. Trends in medical use and abuse of sustained-release opioid analgesics: a revisit. *Pain Med* 2004; **5**(1): 59–65.
- Sees KL, Di Marino ME, Ruediger NK, Sweeney C, Shiffman S. Non-medical use of OxyContin tablets in the United States. *J Pain Palliat Care Pharmacother* 2005; **19**(2): 13–23.
- Tolle SW, Hickman SE, Tilden VP, Bubalo JS, Fromme EK. Trends in opioid use over time: 1997–1999. *J Palliat Med* 2004; **7**(1): 39–45.
- Zacny J, Bigelow G, Compton P, et al. College on problems of drug dependence taskforce on prescription opioid non-medical use and abuse: position statement. *Drug Alcohol Depend* 2003; **69**: 215–232.
- Substance Abuse and Mental Health Services Administration. *Methadone-Associated Mortality: Report of a National Assessment*. Rockville, MD: U.S. Department of Health and Human Services; 2004.
- Cone EJ, Fant RV, Rohay JM, et al. Oxycodone involvement in drug abuse deaths: a DAWN-based classification scheme applied to an oxycodone postmortem database containing over 1000 cases. *J Anal Toxicol* 2003; **27**: 57–67.
- Cone EJ, Fant RV, Rohay JM, et al. Oxycodone involvement in drug abuse deaths. II: evidence for toxic multiple drug-drug interactions. *J Anal Toxicol* 2004; **28**(4): 217–225.
- Hays LR. A profile of OxyContin addiction. *J Addict Dis* 2004; **23**(4): 1–9.
- Kurtz SP, Inciardi JA, Surratt HL, Cottler L. Prescription drug abuse among ecstasy users in Miami. *J Addict Dis* 2005; **24**(4): 1–16.
- Substance Abuse and Mental Health Services Administration—Office of Applied Studies. *DAWN Emergency Department Table 5.2.0—ED Drug Episodes by Episode Characteristics: Estimates for the Conterminous U.S. by Year*. Rockville, MD: 2003. (Available at http://dawninfo.samhsa.gov/pubs_94_02/edpubs/2002final/).
- Johnston LD, O'Malley PM, Bachman JG, Schulenberg JE. *Monitoring the Future national results on adolescent drug use: overview of key findings*. 2004. NIH Publication No. 05-5726.
- Substance Abuse and Mental Health Services Administration. *Results from the 2004 National Survey on Drug Use and Health: National Findings*. NSDUH Series H-28, DHHS Publication No. SMA 05-406.
- O'Connor P. Methods of detoxification and their role in treating patients with opioid dependence. *JAMA* 2005; **294**(8): 961–963.
- Council of State Governments. *Trends Alert: Drug Abuse in America—Prescription Drug Diversion*. Lexington, KY: 2004.
- Drug Enforcement Administration—Office of Diversion Control. *The Diversion of Drugs and Chemicals—A Descriptive Report of the Programs and Activities of DEA's Office of Diversion Control*. Washington, DC: Drug Enforcement Administration; 1999. (Available at <http://www.deadiversion.usdoj.gov/pubs/program/activities/index.html>).
- Trescott AM, Boswell MV, Athuri SL, et al. Opioid guidelines in the management of chronic non-cancer pain. *Pain Physician* 2006; **9**(1): 1–39.
- Brushwood DB, Kimberlin CA. Media coverage of controlled substance diversion through theft or loss. *J Am Pharmacists Assoc* 2004; **44**(4): 439–444.
- Drug Enforcement Administration—Office of Diversion Control. *OxyContin[®] Theft and Loss Incidents—Data From the DEA Drug and Loss System*. 2003. (Available at http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxycodone.htm).
- National Center on Addiction and Substance Abuse at Columbia University. *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* New York, NY: Center on Addiction and Substance Abuse; 2005. (Available at http://www.casacolumbia.org/Absolutem/articlefiles/380-final_report_not_embargoed.pdf).
- Code of Federal Regulations. *Title 21 CFR §1301.76(b)*. (Available at http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr1301_03.html).
- Joranson DE, Gilson AM. Drug crime is a source of abuse pain medications in the United States [letter]. *J Pain Symptom Manage* 2005; **30**(4): 299–301.
- Glantz MD, Colliver JD. Drug use, drug abuse, and heterogeneity. *Bull Narc* 2002; **54**(1&2): 45–59.
- Michna E, Ross EL, Hynes WL, et al. Predicting aberrant drug behavior in patients treated for chronic pain: importance of abuse history. *J Pain Symptom Manage* 2004; **28**(3): 250–258.
- Passik SD, Kirsh KL, McDonald MV, et al. A pilot survey of aberrant drug-taking attitudes and behaviors in samples of cancer and AIDS patients. *J Pain Symptom Manage* 2000; **19**(4): 274–286.
- Passik S, Kirsh KL, Whitcomb L, Dickerson PK, Theobald DE. Pain clinicians' rankings of aberrant drug-taking behaviors. *J Pain Palliat Care Pharmacother* 2002; **16**(4): 39–49.
- Federation of State Medical Boards of the United States Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX: Federation of State Medical Boards of the United States Inc; 1998. (Available at <http://www.fsmb.org>).
- Federation of State Medical Boards of the United States Inc. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Dallas, TX: Federation of State Medical Boards of the United States Inc.; 2004. (Available at <http://www.fsmb.org>).
- Gilson AM, Joranson DE. Controlled substances and pain management: changes in knowledge and attitudes of state medical regulators. *J Pain Symptom Manage* 2001; **21**(3): 227–237. (Available at <http://www.medsch.wisc.edu/painpolicy/publicat/01jpsm/index.htm>).
- Joranson DE. Why is a balanced policy important, and do we have it now? In *Balancing the Response to Prescription Drug Abuse, Report of a National Symposium on Medicine and Public Policy* (1st edn), Wilford BB (ed.). American Medical Association, Department of Substance Abuse: Chicago, IL; 1990; 1–6.