



Associations between pain clinic density and distributions of opioid pain relievers, drug-related deaths, hospitalizations, emergency department visits, and neonatal abstinence syndrome in Florida[☆]



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ABSTRACT

Background: Community-level associations between pain clinics and drug-related outcomes have not been empirically demonstrated.

Methods: To explore these associations we correlated overdose death rates, hospital-discharge rates for drug-related hospitalizations including neonatal abstinence syndrome, and emergency department rates for drug-related visits with registered pain clinic density and rate of opioid pills dispensed per person at the county-level Florida in 2009. Negative binomial regression was used to model the crude associations and associations adjusted for exposure measures and county demographic characteristics.

Results: An estimated 732 pain clinics operated in Florida in 2009, a rate of 3.9/100,000 people. Among the 67 counties in Florida, 23 (34.3%) had no pain clinics, and three had 90 or more. Adjusted negative binomial regression determined no significant association between pain clinic rate and drug-related outcomes. However, rates of drug-caused, opioid-caused, and oxycodone-caused death correlated significantly with rates of opioid and oxycodone pills dispensed per person in adjusted analyses. For every increase of one pill in the rate of oxycodone pills per person, there was a 6% increase in the rate of oxycodone-related overdose death.

Conclusions: Although pain clinics, some of which are “pill mills,” are clearly a source of drugs used nonmedically, their impact on health outcomes might be difficult to quantify because the pills they prescribe might be consumed in other counties or states. The impact of “pill mill” laws might be better measured by more proximal measures such as the number of such facilities.

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1. Introduction

In 2010, the number of drug overdose deaths ($n=38,329$) exceeded deaths from motor vehicle traffic crashes ($n=33,687$), the leading cause of injury death in the United States (Centers for Disease Control and Prevention, 2012a). Nationally, poisonings, the vast majority of which are drug overdoses (Warner et al., 2011), were the leading cause of injury death among people aged 25–64 years that year (Centers for Disease Control and Prevention, 2012b). Opioid pain relievers have been the primary driver of increases in overdose deaths since 1999 (Centers for Disease Control and Prevention, 2011a). The potential contribution of profit-motivated pain clinics, known as *pill mills*, to the increasing number and rate of overdoses involving prescription opioid pain relievers has been

noted in a growing number of states (Leinwand, 2011a). Such clinics typically see only patients reporting pain, perform minimal clinical evaluation, and routinely prescribe large quantities of opioid analgesics, often in combination with other drugs prone to abuse such as benzodiazepine sedatives or tranquilizers. Pill mills usually only accept cash payment, and the drugs they prescribe are frequently resold by their patients (Rigg et al., 2010). The Office of the Attorney General of Florida defines a pill mill as “a doctor’s office, clinic, or health care facility that routinely conspires in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice in the community or violates the laws of the state of Florida regarding the prescribing or dispensing of controlled prescription drugs” (Office of the Attorney General of Florida, 2011).

Pill mills have multiplied in Florida since 2007 (Satz, 2009), where in some counties they are reportedly more numerous than common fast food chain restaurants (Collins, 2010). Pill mills in Florida reportedly provide large quantities of oxycodone to their patients, often in combination with the benzodiazepine alprazolam (Hall, 2011) and have been blamed in the press for Florida’s

[☆] Supplementary material can be found by accessing the online version of this paper. See Appendix A for more details.

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rapid rise in prescription drug overdose deaths (Collins, 2010; Florida Department of Law Enforcement, 2010). From 2007 to 2009 the annual prescription drug overdose death rate in Florida increased 21.8% from 11.0 to 13.4 per 100,000 population (Centers for Disease Control and Prevention, 2011b), with a corresponding 68.4% increase in the rate of oxycodone-caused death from 3.8 to 6.4 per 100,000 population (Centers for Disease Control and Prevention, 2011b). In 2009, approximately eight drug overdose deaths occurred in Florida daily (Centers for Disease Control and Prevention, 2011b). Florida pill mills have also been blamed for a trifold increase in infants born with Neonatal Abstinence Syndrome (NAS) in the State ($n=354$ in 2006; $n=1374$ in 2010; Leinwand, 2011b). NAS has recently been associated with increasing rates of use of opioids by pregnant women (Patrick et al., 2012) and several adverse birth outcomes (Creanga et al., 2012).

To address the proliferation of hundreds of pain clinics that prescribe large quantities of oxycodone and alprazolam, some of which is used for nonmedical purposes (Centers for Disease Control and Prevention, 2011b), Florida became the third state to pass anti-pill mill legislation with the passage of Senate Bill 462 in 2009 (Florida Department of Health, 2010a). In addition, Sections 458.3265 and 459.0137 of the Florida Statutes (The Florida Legislature, 2010) provide that all privately owned pain-management clinics, facilities or offices that advertise for any type of pain management services or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the Department of Health beginning January 4, 2010 (The Florida Legislature, 2010). Additionally, Senate Bill 2272, passed in 2010, included changes that impacted the ownership and practice of pain management clinics in Florida (The Florida Senate, 2010), and effective July 1, 2011, CS/CS/House Bill 7095 closed loopholes in the prior laws including the dispensing of controlled substance from practitioners' offices; the prior law allowed a 72-h supply to be dispensed (Florida House of Representatives, 2011). It should be noted that not all registered pain clinics in Florida meet the definition of a "pill mill." There are legitimate pain clinics that provide an important service.

Publications have described problems with heroin and methadone in Florida (Graham et al., 2008; Wolf et al., 2004), but these reports antedate the current problem with pill mills. Johnson mapped Florida's prevalence of pain clinics and the incidence of prescription drug overdoses in an unpublished report (Johnson, 2010), but their relationship has not been explored in detail. In theory, a large number of "pill mills" in a community should increase the volume of drugs prone to abuse in that community and thereby increase the rates of adverse health outcomes associated with such abuse. However, an association between pain clinics and overdose deaths in a given community has not been empirically demonstrated in any jurisdiction. If such a relationship exists, it would support inferences that such laws will reduce overdose morbidity and mortality if they reduce the prevalence of pain clinics or pill mills and would provide additional justification for legislation restricting such inappropriate prescribing. Therefore, this study aims to determine whether pain clinic density or opioid distribution rates are associated with various drug-related health outcomes at the county level within Florida in 2009.

2. Methods

2.1. Data sources

Pain clinic density data were obtained from the Florida Department of Health (FLDOH), Division of Medical Quality Assurance. Pain clinics registered with the FLDOH on or before January 31, 2010 were used to estimate the number of pain clinics operating

in Florida in 2009. The number of opioid units distributed to dispensing physicians and pharmacies in Florida by county in 2009 was obtained from the Drug Enforcement Administration (DEA), Automation of Reports and Consolidated Orders System (ARCOS; US Department of Justice Drug Enforcement Administration, 2011). The phrase "number of pills" is used in this study for convenience, but some units were patches, liquids, etc., and pills had varying strengths. Eight opioids were included in the DEA ARCOS data: codeine, oxycodone, hydromorphone, hydrocodone, morphine, fentanyl base, methadone, and meperidine.

Health outcome data were obtained from the Florida Medical Examiners' (ME) Commission and the Florida Agency for Health Care Administration (AHCA). ME data provided the number of drug-caused deaths (a death in which a ME identified at least one of the following drugs as the cause (found at toxic/lethal level) of death: Amphetamines, Methamphetamine, MDMA, MDA, MDEA, Other Amphetamine, Alprazolam, Diazepam, Flunitrazepam, Other Benzodiazepine, Cannabinoids, Carisoprodol, Meprobamate, Cocaine, GHB, Difluoroethane, Freon, Zolpidem, Nitrous Oxide, Other Inhalant, Ketamine, Fentanyl, Heroin, Hydrocodone, Hydromorphone, Meperidine, Methadone, Morphine, Oxycodone, Propoxyphene, Tramadol, Other Opioid, Oxymorphone, Buprenorphine, and PCP); opioid-caused deaths (a death in which a ME identified at least one of the following opioids as the cause of death: oxycodone, hydromorphone, hydrocodone, morphine, fentanyl base, methadone, or meperidine) and oxycodone-caused deaths by the county of occurrence of the death. Individuals that died solely as a result of ethanol (i.e., no other drugs) were excluded ($n=160$). AHCA provided the number of drug-related hospitalizations (hospital records with any of the following codes: E codes: E850–E858, E950 (.0–.5), E962.0, or E980 (.0–.5) or ICD 9 codes: 960–979 or 304, 305), drug-related emergency department (ED) visits (ED records with any of the following codes: E850–E858, E950 (.0–.5), E962.0, or E980 (.0–.5) or ICD 9 codes: 960–979 or 304, 305) and NAS hospitalizations (Neonatal abstinence syndrome (NAS) hospitalizations = hospital records with ICD 9 Code 779.5: drug withdrawal syndrome in infant of dependent mother) by county in 2009. Denominator data for rate calculations were obtained through the Florida Department of Health's Florida Community Health Assessment Resource Tool Set (Florida CHARTS) (Florida Department of Health, 2010b).

2.2. Data analyses

Exposure rates and outcome variables for the state and by county were calculated and mapped. Rates were calculated per 100,000 population except for drug distribution data, where rates were calculated as pills distributed per person, and for NAS data, where rates were calculated per 1000 live births. Exposure rates were graphed by scatterplot. Descriptive statistics were used to provide state level outcome counts and percentages by sex, race (White, Black, Hispanic, Other), and age group.

Associations between exposures (rate of: pain clinics, opioid pills dispensed, and oxycodone pills dispensed) and outcomes (drug-caused death rate, opioid-caused death rate, oxycodone-caused death rate, drug-related hospitalization rate, drug-related ED visit rate, and NAS rate) by county were tested by using Spearman rank correlation and unadjusted and adjusted negative binomial regression. Negative binomial regression was adjusted for the rate of pain clinics (when the exposure was rate of opioid pills or oxycodone pills distributed), rate of opioid pills distributed (when the exposure was rate of pain clinics and the outcome was not oxycodone-caused death rate), or rate of oxycodone pills distributed (when exposure was the rate of pain clinics and the outcome was oxycodone-caused death rate); and the percentages of the county population that were aged 20–64 years, non-Hispanic

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