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## Features of prescription drug monitoring programs associated with reduced rates of prescription opioid-related poisonings



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#### ABSTRACT

*Background:* The United States is in the midst of an opioid epidemic. In addition to other system-level interventions, all states have responded during the crisis by implementing prescription drug monitoring programs (PDMPs). This study examines associations between specific administrative features of PDMPs and changes in the risk of prescription opioid-related poisoning (RxORP) over time.

Methods: This longitudinal, observational study utilized a 'natural experiment' design to assess associations between PDMP features and risk of RxORP in a nationally-representative population of privately-insured adults from 2004 to 2014. Administrative health claims data were used to identify inpatient hospital admissions and emergency department visits related to RxORP. Generalized estimating equation Poisson regression models were used to examine associations between specific PDMP features and changes in relative risk (RR) of RxORP over time.

Results: In adjusted analyses, states without PDMPs experienced an average annual increase in the rate of RxORP of 9.51% over the study period, while states with operational PDMPs experienced an average annual increase of 3.17%. The increase in RR of RxORP over time in states with operational PDMPs was significantly less than increases in states without PDMPs. States with specific features, including those that monitored more schedules or required more frequent data reporting, experienced stronger protective effects on the RR of RxORP over time. Conclusion: This study examined associations between specific PDMP features and RxORP rates in a nationally-representative population of privately-insured adults. Results of this study may be used as empirical evidence to guide PDMP best practices.

#### 1. Introduction

From 1999 to 2010, opioid analgesic prescriptions in the US increased approximately 4-fold (Centers for Disease Control and Prevention, 2011). Increasing use of opioid analgesics has been associated with a corresponding increase in rates of prescription opioid-related poisonings (RxORPs) (Paulozzi et al., 2006). Deaths involving RxORPs quadrupled from 1999 to 2015, killing more than 183,000 people (Rudd et al., 2016). Opioid-related, inpatient hospital admissions and emergency department (ED) visits also increased substantially from 2005 to 2015 (Weiss et al., 2017). In February 2011, the US Centers for Disease Control and Prevention (CDC) labeled recent increases in RxORPs as "a US epidemic", and in October 2017, President Trump declared the crisis a national public health emergency (Centers for Disease Control and Prevention, 2012; Executive Office of the President, 2017; Naylor and Keith, 2017).

A variety of system-level interventions have been deployed to combat the epidemic, including crack downs on 'pill mills' in certain states as well as the development of abuse deterrent formulations of oxycodone and other prescription opioids. Policy makers have responded during the ongoing crisis by establishing prescription drug monitoring programs (PDMPs). PDMPs are state-based programs that track the prescribing and dispensing of controlled substances (CS) to consumers with a goal of mitigating misuse and diversion. PDMP data may assist prescribers and pharmacists in their decision-making at the point of care and may also assist law enforcement and licensure boards in the identification of potentially aberrant prescribing and dispensing practices. Ideally, PDMPs offer the opportunity for providers to adequately manage pain with opioid analgesics while also preventing opioid misuse and opioid-related morbidity and mortality. At present, 49 states and the District of Columbia have implemented PDMPs (National Alliance for Model State Drug Laws, 2016). In recent years,

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PDMPs have expanded internationally, and programs have been implemented in Canada, Australia, and parts of Europe (Furlan et al., 2014; Islam and McRae, 2014).

A number of previous studies have examined associations between PDMP implementation and changes in rates of opioid-related morbidity and mortality with varying results (Bao et al., 2016; Brady et al., 2014; Curtis et al., 2006; Delcher et al., 2015; McAllister et al., 2015; Meara et al., 2016; Patrick et al., 2016; Paulozzi et al., 2011; Paulozzi and Stier, 2010; Reifler et al., 2012; Reisman et al., 2009; Simeone and Holland, 2006; Simoni-Wastila and Qian, 2012; Wastila and Bishop, 1996). The variable findings observed in the current PDMP literature may be due, in part, to the fact that many of these studies have failed to take into account the heterogeneity of PDMP administrative features between states (Finley et al., 2017).

Specific PDMP features may have important impacts on the efficacy of individual programs. For example, a PDMP that monitors all CS, requires dispensers to report CS dispensing on a daily basis, and requires prescribers to query the data before issuing CS prescriptions, may allow for easier detection of potential medication misuse relative to less comprehensive programs (Dowell et al., 2016; Haffajee et al., 2015; National Alliance for Model State Drug Laws, 2015). To our knowledge, only two studies to date have assessed the impacts of specific PDMP features on opioid-related mortality (Pardo, 2017; Patrick et al., 2016).

As state and federal funding is appropriated to assist in the assessment and enhancement of PDMPs, empirical evidence is needed to both understand their effectiveness and guide their evolution (Ashburn, 2016; Davis et al., 2014). Accordingly, this study: 1) Assesses associations between PDMP status and rates of RxORP in a nationally representative sample of privately-insured adults; 2) Examines the marginal effects of different PDMP features on the relative risk (RR) of RxORP over time; and 3) Estimates the adjusted RR of RxORP in the most recent month of data available in states with varying PDMP features.

#### 2. Material and methods

#### 2.1. Study design

This observational longitudinal study employed a 'natural experiment' design to assess associations between PDMP features and RxORP rates in a nationally-representative sample of privately-insured adults. Changes in PDMP features—including timing of initial legislation enactment and program implementation, or alterations to specific functionality—were assessed monthly in all 50 states and the District of Columbia from January 2004 to December 2014. PDMP status was assessed on a monthly basis as changes in PDMP features occurred frequently and at irregular times during the study period. The outcome of interest was the number of RxORPs among the beneficiary population in each state-month. Given that this study was observational and relied on de-identified data collected for research purposes, it was deemed exempt from review by the University of Kentucky IRB.

#### 2.2. Data

This study utilized data from multiple sources. Data for clinical events and demographic characteristics were obtained from Truven Health Marketscan\* administrative claims data (Truven, 2017). These data are nationally-representative of the privately-insured and employed US population, and include all provider, facility and pharmaceutical claims for eligible privately-insured adults. Truven collects data from a wide variety of insurance providers as well as large self-insured employers and includes data on approximately 20–30 million individuals each year. All individuals aged 18 or over and enrolled for at least one full month with medical benefits in the period 2004–2014 were included.

Data regarding PDMP features in each state-month were identified

from two separate sources—the National Alliance of Model State Drug Laws (NAMSDL), and the Prescription Drug Abuse Policy System (PDAPS) (National Alliance for Model State Drug Laws, 2016; Prescription Drug Abuse Policy System, 2016). The NAMSDL and PDAPS data were both used to assess the timing of PDMP legislation enactment and program operation. Data regarding the status of specific PDMP features, and dates that these features were implemented, were obtained from PDAPS.

#### 2.3. Outcome and covariate measures

The outcome of interest in this study was the number of RxORPs in each state-month. We chose to focus on RxORPs as we hypothesize that PDMPs have a proximal effect on this injury outcome. RxORPs were identified from inpatient hospital admissions and ED claims where at least one diagnostic code for an RxORP was listed. This study was specifically interested in opioid-related poisonings from prescription drugs, so only claims with ICD-9-CM codes relevant to prescription opioid-related poisonings as defined by the CDC were identified (965.00, 965.02, 965.09, E85.01, E85.02) (Centers for Disease Control and Prevention, 2013). Because individuals experiencing a RxORP may have multiple claims with this code resulting from a single event, only one RxORP was counted per patient per day. RxORP diagnoses observed in outpatient claims were required to have the place of service listed as the ED. Hospital admission claims including a RxORP diagnosis that had the same admission date as a preceding RxORP admission's discharge date were not counted, as these likely represent hospital transfers.

Demographic covariates of interest included potential RxORP risk factors and were defined as the percentage of the Truven population in each state-month that were male, the percentage that were aged 25–35 years old, and the US Census Bureau region. Data on race/ethnicity of the study population were not available. Individual patient claims were aggregated to calculate rates and percentages at the state-month level. For these measures, the denominator was the total number of personmonths of eligibility observed in each state-month. For example, the number of male-person months was divided by total number of personmonths observed in a given state-month to determine percentage of the population that were male in each state-month. The rate of diagnosed substance-use disorders (SUDs) in each state-month was included as a clinical covariate. SUD diagnoses were defined according to Clinical Classification Software (CCS) grouping 661 from the Healthcare Cost and Utilization Project, 2016).

Enactment of PDMP legislation may change prescribing practices before the programs are formally operational (Patrick et al., 2016). Thus, to assess this possibility, this study examined the date that PDMP legislation was enacted as well as the date that programs became operational. PDMPs were defined as operational when they allowed data access to either prescribers or law enforcement officials. Dates of PDMP enactment and operation are available from both NAMSDL and PDAPS (National Alliance for Model State Drug Laws, 2014; Prescription Drug Abuse Policy System, 2016). The earliest reported date of PDMP legislation enactment and the latest reported date of user access were used when these sources conflicted. The PDAPS data were used when the dates were not available from NAMSDL (National Alliance for Model State Drug Laws, 2014).

This study examined five features of PDMPs: 1. Whether the PDMP was operational—defined as prescribers or law enforcement having access to the data; 2. CS Schedules monitored by the PDMP (II only or II–III, II–IV, and II–V); 3. Frequency of data reporting from dispensers to the PDMP central server (monthly or less, weekly, and daily); 4. Requirement for unsolicited reporting of patients' CS prescription history to in-state prescribers or licensure boards; and 5. Mandated (as defined by PDAPS) prescriber query of PDMP data prior to prescribing in certain circumstances. Other PDMP features of interest, including mandatory registration with the PDMP and PDMP utilization rate by

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