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Impact of prescription drug monitoring programs and pill mill laws on high-risk opioid prescribers: A comparative interrupted time series analysis

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ABSTRACT

Background: Prescription drug monitoring programs (PDMPs) and pill mill laws were implemented to reduce opioid-related injuries/deaths. We evaluated their effects on high-risk prescribers in Florida.
Methods: We used IMS Health's LRx Lifelink database between July 2010 and September 2012 to identify opioid-prescribing prescribers in Florida (intervention state, N: 38,465) and Georgia (control state, N: 18,566). The pre-intervention, intervention, and post-intervention periods were: July 2010–June 2011, July 2011–September 2011, and October 2011–September 2012. High-risk prescribers were those in the top 5th percentile of opioid volume during four consecutive calendar quarters. We applied comparative interrupted time series models to evaluate policy effects on clinical practices and monthly prescribing measures for low-risk/high-risk prescribers.
Results: We identified 1526 (4.0%) high-risk prescribers in Florida, accounting for 67% of total opioid volume and 40% of total opioid prescriptions. Relative to their lower-risk counterparts, they wrote sixteen times more monthly opioid prescriptions (79 vs. 5, $p < 0.01$), and had more prescription-filling patients receiving opioids (47% vs. 19%, $p < 0.01$). Following policy implementation, Florida's high-risk providers experienced large relative reductions in opioid patients and opioid prescriptions (−536 patients/month, 95% confidence intervals [CI] −829 to −243; −847 prescriptions/month, CI −1498 to −197), morphine equivalent dose (−0.88 mg/month, CI −1.13 to −0.62), and total opioid volume (−3.88 kg/month, CI −5.14 to −2.62). Low-risk providers did not experience statistically significantly relative reductions, nor did policy implementation affect the status of being high- vs. low- risk prescribers.
Conclusions: High-risk prescribers are disproportionately responsive to state policies. However, opioids-prescribing remains highly concentrated among high-risk providers.

1. Introduction

Prescription opioid addiction and non-medical use are significant public health problems, responsible for about 44 daily overdose deaths in the United States (Kolodny et al., 2015; United States Department of Health and Human Services, Centers for Disease Control and Prevention, 2015). From 2000 to 2010, large increases in opioid prescription among ambulatory and emergency visits coincided with reductions in use of non-opioid analgesics and

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an unchanging prevalence of pain among patients (Chang et al., 2014; Daubresse et al., 2013). The burden of opioid-related morbidity has increased markedly over the past decade, with a 153% increase in the rate of opioid-related emergency department visits between 2004 and 2011 (Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, 2013). Similarly, the age adjusted death rate attributable to prescription opioids quadrupled between 1999 and 2009, surpassing that of stimulants, heroin, and other prescription drugs (Calcaterra et al., 2013). These problems are not limited to the United States; the United Kingdom and other European countries also face increasing use of opioids for non-cancer pain (Stannard, 2013), high number of individuals estimated to be addicted to prescription drugs (Dhalla et al., 2011b), and an increase in drug-related deaths (Dhalla et al., 2011b; Giraudon et al., 2013).

Although there are no magic bullets to address these issues, policy makers play an important role in shaping regulatory, payment and public health policies to reduce opioid-related injuries and deaths (Dhalla et al., 2011b; Franklin et al., 2015; Giraudon et al., 2013; Lyapustina et al., 2016; Stannard, 2013; Stewart and Basler, 2013). Prescriber-oriented interventions, such as updating the guidelines on opioid prescription, have been adopted in many countries, but their penetration is unknown and following the guidelines is not mandatory (Giraudon et al., 2013). Establishing regulatory monitoring of prescription opioids has also been proposed in the United Kingdom (Stewart and Basler, 2013), and implemented at many states in the United States (Florida Office of the Attorney General, 2015; United States Department of Justice, Drug Enforcement Administration, 2011). For example, state policy-makers in the United States have used prescription drug monitoring programs (PDMPs) and "pill mill" laws to address the prescription opioid epidemic. Although these state-sponsored programs are used for a variety of clinical, regulatory and educational purposes, a primary function of PDMPs is to give physicians, pharmacists and other health care providers access to patients' prescription histories to improve identification and management of individuals at high risk of opioid abuse or diversion (United States Department of Justice and Drug Enforcement Administration, 2011). In contrast, pill mill laws establish state-level regulatory oversight of pain management clinics, including the establishment of prescribing and dispensing requirements, and create penalties for those who do not comply with their requirements (United States Department of Health and Human Services, Centers for Disease Control and Prevention, 2012). While there is growing evidence regarding the effect of these approaches on opioid sales (Haegerich et al., 2014; Rutkow et al., 2015), overdoses (Sauber-Schatz et al., 2013), and deaths (Delcher et al., 2015), less is known about how they affect specific groups of prescribers. This is important, as approximately 20% of U.S. physicians are responsible for prescribing 80% of all opioid analgesics (Blumenschein et al., 2010; Dhalla et al., 2011a; Swedlow et al., 2011).

We previously demonstrated that Florida's PDMP and pill mill law were associated with modest decreases in opioid prescribing concentrated among providers with higher baseline opioid volume (Rutkow et al., 2015). However, in that analysis, which focused on Florida because of disproportionate levels of opioid-related morbidity and mortality in the state, we used a crude measure to characterize high-volume prescribers and limited our analysis to a select number of prescribing outcomes. In the current analysis, we use a rigorous method of identifying several groups of high-risk prescribers and, in addition to more fully characterizing them, we evaluate the effect of Florida's policies on their clinical practices, such as their total number of prescription-filling patients with an opioid prescription. Furthermore, we characterize the concentration of opioid volume and prescriptions among this group of prescribers as well as how the policies of interest impact these measures.

2. Material and methods

2.1. Data

Using data from IMS Health's LifeLink LRx database, we examined anonymized, individual-level prescription claims, which represented approximately 65% of all retail prescription transactions in the United States. The data are automatically transmitted to IMS Health on a weekly basis from pharmacies in retail and food stores, as well as independent and mass merchandiser pharmacies. Claims data include National Drug Code (NDC)-level product information, quantity dispensed, days supply, payment source (Medicare, Medicaid, commercial insurer, or cash), and the five digit zip code of the dispensing pharmacy. Patient information includes sex, year of birth, and date of first entry into the data set. Prescriber information, derived from the American Medical Association masterfile, includes prescriber specialty and zip code.

2.2. Time segments and cohort derivation

Our analysis was based on a 12-month pre- and post-intervention observation period. The pre-intervention period extended from July 2010 through June 2011. The policy implementation period (i.e., intervention period) included the 3 months between July 2011 through September 2011, representing the time during which Florida's PDMP and relevant aspects of its pill mill law were put into effect. The post-intervention period spanned October 2011 through September 2012.

Approximately 12 million individuals who filled at least one prescription in Florida or Georgia from July 2010 to September 2012 were identified. Among these individuals, we excluded 3.6 million individuals who filled prescriptions from stores that did not consistently report data to IMS Health throughout the study period (no reported data within the first three and last three month of the study period). We also excluded 4.3 million individuals (36%) without any pharmacy claims within three months of the first and last months of the study period. Furthermore, we excluded approximately 2% of transactions with erroneous or extreme values (e.g., negative quantities dispensed or transactions with morphine milligram equivalents (MME) exceeding 360 milligrams [mg] per transaction). In the end, we included 12.02 million eligible opioid prescriptions in the analysis.

From these opioid prescriptions, we identified 57,031 prescribers who had prescribed at least one opioid in Florida or Georgia in the 12-month pre-intervention period. Although we included non-physician prescribers such as dentists and nurse practitioners, we excluded 336 veterinarians. To define high-risk prescribers, we divided the 12-month pre-intervention period into four quarters and calculated each prescriber's total opioid volume, the sum of MME associated with every transaction, during each quarter. In each state, we flagged prescribers who were in the top 5th percentile of opioid volume in each calendar quarter, and we defined high-risk prescribers as those who were flagged for each of the four pre-intervention quarters. Low-risk prescribers were defined as those who did not qualify for the high-risk category. We also examined two subsets of high-risk prescribers: (1) "high-risk/high-prescription": high-risk prescribers who were also in the top 5th percentile of the *proportion of all prescriptions* dispensed as opioids, across all four quarters during the pre-intervention period, and (2) "high-risk/high-patient": high-risk prescribers who were also in the top 5th percentile of the *proportion of all prescription-filling patients* receiving opioids, across all four