Reducing Opioid Misuse: Evaluation of a Medicaid Controlled Substance Lock-In Program

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Abstract

Opioid misuse, abuse, and overdose are a rapidly growing public health epidemic. Medicaid Lock-In Programs (MLIPs) are designed to prevent overutilization of controlled substances by Medicaid patients. However, despite widespread use, there is little information on their effect. Using North Carolina (NC) Medicaid claims data from October 2008 through June 2013, we examined changes in Medicaid-reimbursed opioid prescriptions by patients enrolled in NC's MLIP. We used mixed effects models to examine the effect of MLIP enrollment on monthly opioid claims, number of pharmacies, total days' supply, total units (ie, pills), and total Medicaid payments for opioids. In our sample of 6,148 MLIP patients, the odds of having any opioid claim in a given month was 84% lower during MLIP enrollment relative to the period before enrollment (odds ratio = .16). MLIP enrollment also corresponded with a reduction in monthly number of opioid prescriptions by 1.13, monthly number of pharmacies by .61, and monthly Medicaid expenditures by $22.78. Although MLIPs may constitute a successful component of comprehensive efforts to reduce the potential overutilization of opioids, care should be taken to ensure that programs such as MLIPs do not constrain patients' legitimate needs for analgesic medications.

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Keywords

Opioids; Medicaid; controlled substances; utilization; managed care

Opioid misuse and abuse constitute the fastest growing drug problem in the United States, making it a costly contributor to the nation's morbidity and mortality.[24] Sales of prescription opioid analgesics increased by >300% between 1999 and 2010, during which time the number of overdose deaths attributed to prescription opioids increased by 312%.[5,18] According to the Centers for Disease Control and Prevention, in 2014 >47,000 deaths were attributed to drug overdose in the United States in 2014, 19,000 of which involved prescription opioids.[23] An even greater number of people survive unintentional overdoses, leading to impairments, disabilities, and dependency. In addition to the human toll, the misuse and abuse of prescription opioids results in $53 to $56 billion in societal costs each year.[3,12] This burden falls on the health care system and state resources, including law enforcement.[12]

Patients' use of multiple prescribers presents a difficult issue for their physicians, who must navigate changing dosages and potentially risky drug interactions, while also providing compassionate care and working to manage chronic pain.[16] Increased prescribing of and greater access to opioids has also led to a range of abuses and dangerously uncoordinated care for many patients.[8] Recent analyses of Medicare data indicated that patients prescribed opioids had an average of 52 prescriptions per year from approximately 10 drug classes (ie, opioid prescriptions, as well as other prescriptions), risking multiple drug interactions.[19] Moreover, research has suggested that opioid prescribing by multiple prescribers is not only a common practice but is also associated with increased rates of opioid-related hospital admissions.[14] Even in the absence of diversion or other illicit use, continuity of care is critical to addressing the misuse of opioids.

The misuse and abuse of opioids, as well as other controlled substances (CSs) including benzodiazepines, has led many states to develop programs that seek to reduce CS abuse and to improve continuity of care for those needing CS medication therapy. In part because mortality from overdoses in the Medicaid-eligible population is 5 to 7 times that of the general population,[9] and in part because opioid misusers are more likely to be covered by Medicaid,[2] states are increasingly managing CS abuse by means of Medicaid Lock-In Programs (MLIPs). MLIPs are designed to identify Medicaid patients at risk of health-related issues caused by the potential overutilization of CS and tightly regulate their access, generally by requiring that patients use a single prescriber and/or pharmacy to obtain certain CS prescriptions for a specified period of time. The use of MLIPs has been recommended by the Centers for Medicare and Medicaid Services (CMS).[6] Specifically, the CMS recommends including providers and pharmacies in MLIPs, because this helps to improve the monitoring of CS use across multiple points in the health care system.

The North Carolina (NC) Recipient Management MLIP, implemented in October 2010,[10] was developed in response to a US Government Accountability Office audit that reported that NC was 1 of 5 states with an unusually large number of claims for CS prescriptions.[26] The NC MLIP was intended to reduce fraudulent prescription claims for opioids and

antianxiety CS medications, while improving continuity of treatment among patients with high utilization of CS prescriptions. Additionally, because of the known association of dependency and overdose with an individual's total number of prescriptions and the number of providers from whom they secure prescriptions,[11] the NC MLIP may result in significant improvements in care utilization, health outcomes, and quality of life.

Despite the widespread use of MLIPs, little information can be found in the published literature that directly assesses their outcomes.[22] To date, programs like the NC MLIP have been developed from a paradigm focusing on cost savings, with improved health outcomes seemingly considered as a secondary benefit. Recently, the US Senate voted in favor of S.524, the Comprehensive Addiction and Recovery Act of 2016, which includes a provision for lock-in programs in Medicare.[25] If enacted, such a provision would have a sweeping effect on many Medicare beneficiaries. Current research provides minimal insight into the effect, positive or negative, of MLIPs on patients.

Because of the need to better understand the effects of MLIPs on prescription drug utilization, we sought to identify changes in the number of Medicaid-reimbursed opioid prescriptions filled, and the number of pharmacies from which these prescriptions were obtained, by individuals participating in the NC MLIP. Among patients enrolled in the MLIP, we hypothesized that we would find reductions in the number of 1) prescriptions for opioids this population filled and 2) pharmacies each enrollee visited for the opioid prescriptions they received while enrolled, compared with the period before enrollment.

Methods

This study was approved by the Institutional Review Board at the University of NC at Chapel Hill. The requirement for individual informed consent was waived because this study used existing administrative claims data.

Overall Design

This study was a single group, interrupted time series design of individuals enrolled in the MLIP at any point during the 33 months after the program's implementation on October 1, 2010. We analyzed Medicaid-covered prescription drug utilization over a 57-month period (October 1, 2008–June 30, 2013) encompassing 24 months before (October 1, 2008–September 30, 2010) through 33 months after (October 1, 2010–June 30, 2013) NC MLIP implementation. The population eligible for Medicaid, enrollment in the MLIP, and prescription fill and provider utilization outcomes were assessed for each calendar month, beginning on the first day of the month and ending with its last day.

Data Source

Our data were comprised of NC Medicaid claims provided by the NC Division of Medical Assistance, which manages the State's Medicaid program. Data were structured to provide total opioid prescriptions according to month for each Medicaid-enrolled individual. Any given individual could have provided up to 57 months of data. To ensure that pre-MLIP enrollment data were limited to the months when an individual was "at risk" of an opioid prescription, we excluded all months before the individual's first month in which Medicaid

paid for an opioid prescription they filled. For example, if an individual only began receiving opioid prescriptions after a specific event, this would exclude the time period before the onset of opioid use. To ensure we did not capture residual and potentially altered effects related to disenrollment from the MLIP, we excluded any months after an individual was no longer enrolled in the program.

Population

The NC Division of Medical Assistance enrolled patients in the MLIP on a monthly basis. Program staff determined MLIP eligibility on a monthly basis by examining the number of opioid and benzodiazepine prescriptions filled and the number of providers from which such prescriptions were obtained in the previous 2 months. Specifically, patients were eligible for enrollment if in a consecutive 2-month period they obtained more than 6 opioid prescriptions, obtained more than 6 benzodiazepine prescriptions, or received opioid or benzodiazepine prescriptions from more than 3 unique prescribers. Medical histories of eligible patients were reviewed by MLIP staff, and patients with certain diagnoses (eg, cancer, terminal illnesses) were determined exempt from enrollment. Approximately 200 patients were enrolled in the MLIP each month. Enrolled patients were restricted to using 1 prescriber and 1 pharmacy location to obtain their opioids and other specific CS prescriptions for a 12-month period. After the 12-month period, patients were disenrolled from the MLIP.

Our initial sample included 6,221 individuals (representing 445,549 claims) who were enrolled in the MLIP at any time between October 2010 and June 2013, inclusive. We excluded a small number of individuals who were younger than 18 or older than 65 years at the time of enrollment (n = 17), or who were not in a private living environment (n = 38), to avoid confounding factors of dual eligibility and differing care environments. Because our goal for this analysis was to examine changes in opioid prescriptions, we also excluded individuals who received only benzodiazepine prescriptions (n = 18), and were thus enrolled in the MLIP on that basis alone.

Measures

The primary exposure for this analysis was enrollment in the MLIP, which we assessed each month. Outcomes of interest included various measures related to the utilization of opioids, which were defined by Medicaid using specific therapeutic and generic class codes. Specifically, we used the First Data Bank therapeutic class codes: H3A, H3H, H3J, H3M, H3N, H3U, and H3X, and excluded generic codes for tramadol: 07221, 26387, 50417, 50427, 13909, because tramadol was not included under MLIP restrictions until after our study period ended. We used these codes to create an indicator of whether a given claim represented an opioid, and then added these within enrollees to create a total number of opioid prescriptions for each individual according to month. Using these indicators, we also created total values for each enrollee for the monthly amount paid by Medicaid for these prescriptions, as well as the days' supply obtained and units (ie, pills) dispensed.

Pharmacies were identified by their unique identification number in Medicaid claims data. We identified the first instance of each unique pharmacy according to month, then summed

these to create a total number of pharmacies each individual visited to obtain Medicaid-reimbursed opioid prescriptions each month.

Covariate information included individual-level data from Medicaid claims (age, sex, race, ethnicity, and living arrangement) and county-level data, which included prescriber and pharmacy density. Prescriber density was defined as the number of actively practicing medical professionals, including physicians, physician assistants, and nurse practitioners, who had CS prescribing authority in each patient's county of residence. The number of actively practicing medical professionals was obtained from the 2010 NC Health Professions Data file and was linked to each patient's county of residence in his or her Medicaid data.[21] Pharmacy density was defined as the number of licensed community and outpatient pharmacies in each patient's county of residence. The number of pharmacies was obtained from the CMS National Provider Identifiers 2012 master file.[7]

Analysis

We used mixed effects models that took advantage of the longitudinal nature of the data. Our models differed depending on the outcome, but all allowed for varying numbers of months in the period before and during MLIP enrollment, as well as for months with no data (ie, for months in which an individual was not enrolled in Medicaid). Our models provided an average effect of enrollment in the MLIP on each of the outcomes specified previously, controlling for individual and county-level covariates. For the binary outcome of any opioid prescription in a month, we used generalized least squares logistic regression models with random effects to account for within-person correlation over time. For the nonbinary (ie, continuous, count) outcomes, we also used mixed effects models with random effects but used restricted maximum likelihood estimation and specified an autoregressive correlation structure on the error terms. We considered Poisson mixed effects models for the count variables (ie, number of prescriptions and pharmacies). However, the resulting effect size estimates for the Poisson models were nearly equivalent to those obtained when we used the linear mixed effects models. Therefore, because of the easier interpretation of linear parameters, we chose these models for all nonbinary outcomes. All models included fixed effect terms for months to control for population trends over time.

Results

Our final sample included 6,148 NC MLIP enrollees who collectively had 211,666 months of data during our study period. The mean age of MLIP participants at their time of enrollment was 35 years, and they were predominantly female (69%) and white (78%).

Almost two-thirds (64%) of all enrollees' months included at least 1 claim for an opioid (Table 1). The number of months including at least 1 opioid claim differed markedly before (70%) and after (47%) a participant's enrollment in the MLIP. The mean number of opioid prescription claims (including months with no prescriptions) was 1.62 before enrollment in the MLIP and .84 after enrollment. We also found reductions in the mean number of pharmacies used, mean total days' supply received, and mean total units dispensed during MLIP enrollment, compared with before enrollment.

In multivariable analysis, the odds of having any opioid claim in a given month was 84% lower during MLIP enrollment relative to the period before enrollment (adjusted odds ratio = .16; 95% confidence interval [CI], .15–.16; Table 2). Enrollment in the MLIP also corresponded with a reduction in the number of opioid prescriptions participants secured each month by 1.13 (95% CI, –1.16 to –1.11), the number of pharmacies they visited each month by .61 (95% CI, –.62 to –.60), and total Medicaid payments per month by $22.78 (95% CI, –$27.88 to –$17.69). Reductions in total days' supply received and total units dispensed per month were also observed.

Discussion

Confirming our study's hypotheses, we found that enrollment in the MLIP resulted in reductions in the average of the number of opioid prescriptions filled per month and the number of pharmacies visited to obtain those prescriptions. After accounting for key individual and county-level covariates, we found that the odds of having an opioid prescription in any given month while enrolled in the program was 84% lower than before enrollment. We also found that each month, on average, patients received approximately 1 fewer opioid prescription and visited fewer pharmacies to obtain these opioids. As expected, these differences further corresponded with reductions in the total days of supply received (mean difference: –9.6) and the total units dispensed (mean difference: –40.3) each month. Finally, our study showed that the MLIP reduced the program's drug costs by an average each month of $22.78 per MLIP patient. These findings would appear to provide clear evidence of the program's effectiveness in reducing Medicaid-covered opioid prescriptions, at least in NC.

The large reduction in the odds of filling any prescription for opioids after enrollment in the NC MLIP raises questions about whether enrollees were denied access to needed medications. Concerns have been expressed that restrictions on MLIP participants' access to providers and dispensers—particularly providers—may lead to needless and preventable suffering. For example, participants may receive CS prescriptions from providers with different specialties (eg, from psychiatrists and orthopedists) for entirely defensible reasons, one relating to mental health and the other for pain management. There is also legitimate reason for concern that MLIP enrollees who experience acute incidents before the scheduled closing of their designated provider's office or pharmacy (eg, for a long holiday weekend) may suffer needlessly, especially if they lack access to emergency care. There is thus a need for more research on patients' experiences as enrollees, and particularly the effects of enrollment on their quality of life and their access to CSs in response to legitimate needs. The guiding principle of primum non nocere applies here as it does to all other aspects of the health care system; particularly because of the relative vulnerability of Medicaid populations.[17]

Recent pilot programs supported by the Association for Community Affiliated Health Plans may provide a starting point for research and evaluation on enhanced MLIP models with the potential to better serve patient needs.[1] Specifically, 2 enhanced MLIP pilot programs integrated into Medicaid managed care plans in New Jersey and Ohio took innovative approaches of building comprehensive case management care for those enrolled. For

example, recognizing that MLIP patients often have a range of unmet health- and quality of life-related needs, case managers in a New Jersey Medicaid health plan assess MLIP patients' pain management care and evaluate their critical resource needs (eg, food, transportation, and housing). In Ohio, the largest Medicaid managed care plan in the state integrated a case management "wraparound" with its MLIP. This "wraparound" component similarly involves case managers who work closely with patients to address a full range of patient needs, connecting them with community resources, social services, and health care professionals. Additionally, case managers are trained in strategies designed to help build long-term, supportive relationships with patients, including helping them acknowledge potential substance abuse issues and engage in treatment as appropriate. Further research on these and other MLIP models that work to address all patient needs are warranted to optimize outcomes from the perspectives of patients, providers, and Medicaid.

The US Senate has recently approved a bill supporting lock-in programs for Medicare.[25] Our findings suggest that although such a policy might reduce costs, there may be unintended consequences. Assessing the full effect of such programs is essential to ensuring patients receive needed care. Additionally, further research on the effect of programs designed to reduce prescription opioid misuse on the concurrent increase in heroin use and overdose is warranted because of the recent secondary epidemic of heroin use and overdose and the widespread reporting by heroin users their opioid use was initiated with prescription opioids.[13,15,20] Research on the extent to which MLIP restrictions affect or trigger illicit opioid use could include urine toxicological screening data on patients, behavioral interviews, and/or a more complete assessment of dispensed prescription medications using prescription drug monitoring program data.

Limitations

We acknowledge several limitations to this study. First, we relied exclusively on the claims data that are available to program administrators. These do not capture any outside sources of opioid prescriptions, such as participants who pay dispensers in cash. Second, as a single group longitudinal study in which each participant serves as his or her own control, we cannot exclude the possibility that our findings may reflect either current secular trends or regression to the mean. The latter source of bias is particularly problematic in that MLIP enrollees are identified for lock-in because they exceeded a state-defined threshold of high opioid utilization. However, the staggered enrollment across the first 2 years of the program should reduce the impact of any secular trends on MLIP effect. Our analysis also only examined individuals younger than 65 years of age. Although this is appropriate because of the near-universal Medicare coverage in this age group, our findings may differ for other populations, such as older Medicare enrollees. Finally, we are unable to identify "doctor-shopping" in these claims, which would provide additional context to the patterns of prescriptions. Prescriber identification is not a required field for submission of pharmacy claims, and extensive missing data did not allow for a reliable indicator of each prescription's prescriber.

Conclusions

The misuse and abuse of prescription drugs, particularly opioids, has become a problem at all levels of the health care system. Misuse can result in excessive use of medical services, and the costs of these opioid medications often represent one of the largest portions of Medicaid pharmacy expenditures.[4] MLIPs may constitute a successful component of comprehensive efforts to reduce misuse of opioids and other prescription medications. Care should be taken, however, to ensure that programs, such as MLIPs, do not constrain patients' legitimate needs for analgesic medications. Additional research will also need to examine the extent to which individuals react to the restriction of MLIPs by obtaining opioids without using Medicaid coverage, or through illicit means.

Acknowledgments

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Perspective:

Enrollment in NC's MLIP reduced the likelihood that patients would present a claim for an opioid prescription, and the number of opioid prescriptions patients secured each month. MLIPs may constitute a successful strategy for reducing the misuse, abuse, and diversion of prescription opioids. However, further research is needed to examine the program's potential unintended consequences.

Table 1.

Average Number and Characteristics of Prescription Opioids Dispensed to Patients Per Month During Pre-Enrollment and Enrollment Periods in the NC MLIP (NC Medicaid Claims Data, October 2008–June 2013)

	Overall (SD)	Pre-Enrollment in MLIP (SD)[*]	During MLIP Enrollment (SD)[*]
Any opioid claim per mo, %	64.2 (47.9)	69.9 (45.9)	46.9 (49.9)
Mean opioid claims per mo	1.43 (1.56)	1.62 (1.63)	.84 (1.16)
Mean pharmacies used per mo	.84 (.81)	.95 (.85)	.48 (.53)
Mean total days' supply received per mo	22.41 (26.27)	23.36 (26.20)	19.48 (26.27)
Mean total units received per mo	85.13 (119.73)	90.59 (121.67)	68.31 (111.88)
Mean total Medicaid payments per mo, $	102.88 (396.25)	99.60 (400.96)	112.99 (381.20)

[*]
All differences between pre-MLIP enrollment and MLIP-enrollment periods had $P < .001$.

Table 2.

Unadjusted and Adjusted Estimates Comparing Changes In Monthly Opioid Utilization Measures Between Pre-Enrollment And Enrollment Periods in the NC MLIP (NC Medicaid Claims Data, October 2008–June 2013)

	UNADJUSTED			ADJUSTED*		
	ESTIMATE†	SE	95% CI	ESTIMATE†	SE	95% CI
Odds ratio for having any opioid claim in a mo	.23	.003	.23–.24	.16	.003	.15–.16
Mean difference in number of opioid claims per mo	−1.15	.012	−1.18 to −1.13	−1.13	.013	−1.16 to −1.11
Mean difference in number of pharmacies used per mo	−.62	.006	−.63 to −.61	−.61	.006	−.62 to −.60
Mean difference in total days' supply received per mo	−9.92	.189	−10.29 to −9.55	−9.62	.190	−9.99 to −9.25
Mean difference in total units received per mo	−41.22	.880	−42.95 to −39.50	−40.31	.888	−42.05 to −38.57
Mean difference in total Medicaid payments per mo	−23.50	2.558	−28.52 to −18.49	−22.78	2.599	−27.88 to −17.69

Abbreviations: SE, standard error; CI, confidence interval.

*
Adjusted analyses control for individual-level (ie, race, ethnicity, sex, age, and living arrangement) and county-level (ie, prescriber and pharmacy density) covariates.

†
$P < .001$ for all effect estimates.