



Published in final edited form as:

Drug Alcohol Depend. 2018 January 01; 182: 112–119. doi:10.1016/j.drugalcdep.2017.10.001.

Evaluating short- and long-term impacts of a Medicaid “lock-in” program on opioid and benzodiazepine prescriptions dispensed to beneficiaries

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Abstract

Background—Insurance-based “lock-in” programs (LIPs) have become a popular strategy to address controlled substance (CS) (e.g., opioid) misuse. However, little is known about their impacts. We examined changes in CS dispensing to beneficiaries in the 12-month North Carolina Medicaid LIP.

Methods—We analyzed Medicaid claims linked to Prescription Drug Monitoring Program (PDMP) records for beneficiaries enrolled in the LIP between October 2010 and September 2012 (n= 2,702). Outcomes of interest were 1) number of dispensed CS prescriptions and 2) morphine milligram equivalents (MME) of dispensed opioids while a) locked-in and b) in the year following release.

Results—Compared to a period of stable CS dispensed prior to LIP enrollment, numbers of dispensed CS during lock-in and post-release were lower (count difference per person-month:

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Contributors: RBN designed the study, conducted all analyses, and was primarily responsible for writing the manuscript. NCG, JLL, SWM, CLR, and ACS provided conceptual feedback on the study design and analysis, contributed to the interpretation of findings, and reviewed and provided contributions to manuscript drafts. All authors have approved the final version of the manuscript.

Conflict of interest: No conflicts to declare.

–0.05 (95% CI: –0.11, 0.01); –0.23 (95% CI: –0.31, –0.15), respectively). However, beneficiaries' average daily MMEs of opioids were elevated during both lock-in and post-release (daily mean difference per person: 18.7 (95% CI: 13.9, 23.6); 11.1 (95% CI: 5.1, 17.1), respectively). Stratification by payer source revealed increases in using non-Medicaid (e.g., out-of-pocket) payment during lock-in that persisted following release.

Conclusions—While the LIP reduced the number of CS dispensed, the program was also associated with increased acquisition of CS prescriptions using non-Medicaid payment. Moreover, beneficiaries acquired greater dosages of dispensed opioids from both Medicaid and non-Medicaid payment sources during lock-in and post-release. Refining LIPs to increase beneficiary access to substance use disorder screening and treatment services and provider use of PDMPs may address important unintended consequences.

Keywords

Medicaid; opioid; narcotic; lock-in; prescription drug abuse; controlled substance

1. Introduction

Between 2000 and 2015, half a million Americans died from a drug overdose, and the majority of these deaths involved an opioid (57%) (CDC, 2016). The rapid escalation in opioid deaths during this period was due to multiple factors, one of which was that previous perceptions and cautions related to the risks and addictive potential of opioid prescription drugs were inappropriately dismissed, and opioid prescribing rapidly escalated (Van Zee, 2009).

Several policies and programs have been implemented in an attempt to curb opioid misuse, abuse, and addiction. One strategy used by insurers across the U.S., and especially by Medicaid, is a “lock-in” program (LIP). LIPs are designed to identify beneficiaries demonstrating potential overutilization of opioids and other controlled substance (CS) prescription drugs (e.g., benzodiazepines) and to limit the beneficiaries' access, typically by requiring them to use a single prescriber and/or pharmacy to obtain CS for a specified period of time, such as 12 months (CDC, 2012; Roberts and Skinner, 2014).

Because LIPs are designed primarily to reduce waste and abuse of CS prescriptions in healthcare systems, evaluations have largely been limited to understanding changes in prescription utilization and cost savings to insurers (Beaubien, 2005; Blake, 1997; CDC, 2012; Chinn, 1985; Dreyer et al., 2015; Hladilek et al., 2004; Mitchell, 2009; Singleton, 1977). However, studies to date have failed to provide a comprehensive picture of LIP impacts from a beneficiary perspective, including a clear understanding of short and long-term LIP impacts on beneficiaries' CS prescription regimens.

Our team has been evaluating North Carolina's (NC) Medicaid LIP with the goal of providing a more complete understanding of LIP impacts on beneficiaries (Roberts et al., 2016; Skinner et al., 2016). However, analyses to date have been limited to the “lock-in” period, and focused mainly on numbers of dispensed CS during this period. While examining dispensed CS prescriptions can provide insight into overall prescription

coordination within this population, understanding total dosages received helps us more closely assess beneficiary treatment regimens and the potency of all prescriptions acquired. Thus, the purpose of this study was to: 1) expand estimation of LIP effects by exploring sustained LIP effects in the year following release from the program, and 2) estimate both immediate and sustained LIP effects on the dosage of opioid prescriptions dispensed to beneficiaries, in terms of average daily morphine milligram equivalents (MMEs).

2. Methods

2.1 Study design

Using an observational prospective cohort study design, we established and followed a cohort of independently living adults (e.g., excluding those living in residential facilities) between the ages of 18 and 64 who were enrolled in the NC Medicaid LIP between October 2010 and September 2012. In order to obtain a more complete picture of LIP effects, we used NC Medicaid claims linked to records from the NC Controlled Substance Reporting System (CSRS), the state's Prescription Drug Monitoring Program (PDMP). To understand sustained LIP influence, we included up to 12 months of person-time on beneficiaries following release from the program. We estimated program effects while locked-in and following LIP release on numbers of dispensed CS per person-month and average daily MMEs of dispensed opioids per person.

2.2 NC's Medicaid LIP

The NC Medicaid LIP was first implemented in October 2010 (NC DHHS, 2010). Medicaid beneficiaries were eligible for the LIP if they filled, within two consecutive calendar months: (1) more than six opioid prescriptions, (2) more than six benzodiazepine prescriptions, or (3) opioid or benzodiazepine prescriptions that were written by more than three different prescribers (NC DHHS, 2010). Each month, LIP-eligible beneficiaries, as determined from Medicaid prescription dispensing information for the previous two months, were prioritized for LIP enrollment using a proprietary algorithm combined with a review process by pharmacists. Based on this prioritization, approximately 200 of the highest-ranking beneficiaries were selected for LIP enrollment each month due to administrative resource constraints (i.e., not all LIP-eligible beneficiaries were enrolled). Beneficiaries were notified of their selection for program enrollment and that LIP enrollment restricted them, for a one-year period, to using one prescriber and one pharmacy location to obtain opioids or benzodiazepines. Beneficiaries were given 30 days to choose a preferred prescriber and pharmacy before restrictions began. If they did not choose a preferred prescriber and pharmacy, they were assigned one of each. Additional details of the implementation and administration of NC's Medicaid LIP have been previously provided (Naumann et al., 2017).

2.3 Linked Medicaid claims and Prescription Drug Monitoring Program data

Our research team linked NC Medicaid claims to records from the NC CSRS. Linked data for the period of October 2009 through June 2013 were obtained for beneficiaries enrolled in the LIP between October 2010 and September 2012. NC Medicaid claims included beneficiaries' demographics, periods of Medicaid enrollment, adjudicated pharmacy and

medical claims, and assigned LIP enrollment and release dates. NC CSRS records included data on all CS (schedules II-V) dispensed to LIP beneficiaries, regardless of source of payment (e.g., Medicaid-reimbursed, out-of-pocket). Additional details on the linkage have been previously documented (Roberts et al., 2016).

2.4 Study subjects

To estimate the association between LIP-related periods and numbers of CS (specifically, opioids and benzodiazepines) dispensed per person-month, we followed beneficiaries in our cohort from the first day they received any opioid or benzodiazepine prescription on or after October 1, 2009, throughout their period of lock-in, and up to one year following program release or until June 30, 2013, whichever came first. To estimate the association between LIP-related periods and average daily MMEs of dispensed prescription opioids per person, we followed beneficiaries in the same manner, except that their start of follow-up was the first day of receiving any opioid prescription, as opposed to any opioid or benzodiazepine prescription.

To avoid conflating program effects for those who remained continuously enrolled in the LIP and those who exited the LIP prior to completion (Naumann et al., 2017), we restricted this analysis to those who remained in the LIP for a full 12 months or were administratively censored in June 2013, the last month for which we had data. We defined continuous enrollment as no more than a 7-day gap in coverage. These beneficiaries constituted 62% of all beneficiaries ages 18–64 years with an independent living arrangement who were ever enrolled in the LIP between October 2010 and September 2012. There were no requirements regarding continuous Medicaid coverage in the time prior to LIP enrollment or in the year after LIP release. However, previous analyses indicated that those with continuous coverage while enrolled in the LIP had, on average, close to complete Medicaid coverage prior to enrollment as well (Naumann et al., 2017).

2.5 “Lock-in” status as a time-dependent measure

To examine changes in the numbers of CS dispensed per person-month and average daily MMEs of dispensed opioids per person, we divided time into four segments: two pre-enrollment periods (>6 months pre-enrollment, or “pre-spike,” and 0–6 months pre-enrollment, or “spike”), a 12-month program period (“lock-in”), and a period (up to 12 months) after program release (“post-release”). Descriptive analyses revealed a specific period with large spikes in numbers and dosages of CS dispensed in the months just prior to program enrollment. This spike period precipitated LIP enrollment for many beneficiaries. During this period, a sudden escalation was met by a similar de-escalation in the six months prior to LIP enrollment, resulting in dispensing that appeared to largely return to pre-spike levels just prior to actual enrollment (Figure 1). Moreover, additional analyses revealed that this pattern of escalation, triggering of LIP criteria, and a nearly equal de-escalation was not unique to the LIP-enrolled population. It also occurred in Medicaid beneficiaries who were never enrolled in the LIP but met the LIP enrollment criteria. While this spike period reveals critical information regarding the average CS utilization trajectory leading to eligibility for the LIP, this volatile period of utilization is likely not the most appropriate reference period for LIP effect estimation. Rather, understanding the extent to which the LIP was associated

with CS utilization during and upon release, as compared to a more stable utilization period prior to program enrollment, provides a more suitable comparison. Therefore, we stratified pre-enrollment time into pre-spike and spike periods and focused our LIP effect estimation on dispensing during lock-in and post-release periods as compared to the pre-spike period.

2.6 Outcome measures

We examined monthly numbers of dispensed CS prescriptions by payer source— Medicaid-reimbursed, not Medicaid-reimbursed (e.g., out-of-pocket), and those paid for by any source. While several different types of drugs are classified as CS, our use of the term CS in this study only includes opioid and benzodiazepine prescriptions, the CS regulated by the LIP. In addition to examining LIP effects on numbers of CS obtained, we also quantified the effect on the average dosage of dispensed opioid prescriptions. Average daily MME is a research measure commonly used to compare diverse opioid medication regimens using a standardized unit, morphine equivalents (Brandeis University, 2013). To calculate the average daily MME of a given opioid prescription, we multiplied the drug's strength by the quantity received and a medication-specific MME conversion factor and divided by the days' supply received (CDC, 2015). The average daily MME for each prescription was then applied to all days for which the prescription was active (i.e., all days in which the prescription was to be taken, according to the days' supply). If a beneficiary had more than one opioid prescription active on a given day, the MMEs for that day were summed. Average daily MMEs were also stratified by source of payment. Prescriptions for medication-assisted treatment (e.g., Suboxone) were included neither in the assessment of LIP eligibility, nor in outcome measure calculations.

Similar dosing equivalencies for benzodiazepines are less evidence-based, poorly described, and often based on expert opinion. Moreover, the majority of CS prescriptions received by LIP-enrolled beneficiaries consisted of opioids (approximately 75–80%). For these reasons we did not calculate similar dosage estimates for benzodiazepines.

2.7 Covariates

To elucidate potential sources of confounding that could impact our estimation of LIP effects on CS prescription utilization, we developed a conceptual figure based on the best available literature and our understanding of factors affecting LIP exposure and the outcome measures of interest (see online supplement). The figure included demographic, Medicaid eligibility-related, and clinical characteristics, which we evaluated as sources of confounding. Demographic and Medicaid-related characteristics were assessed at the time of LIP enrollment and included age, sex, race, urbanicity of the beneficiary's county of residence, overdose death rate in the beneficiary's county of residence, and Medicaid aid category and class code. Clinical characteristics were assessed using a one-year lookback period from the date of LIP enrollment and included history of alcohol or other substance use-related disorders, history of medication-assisted treatment for opioid addiction, history of an overdose event, number of unique pharmacies visited, number of emergency department visits, number of inpatient admissions, history of specific pain-related diagnoses (e.g., arthritis, back, neck, headache/migraine, fibromyalgia, sickle cell), history of specific mental health-related diagnoses (e.g., depression, anxiety, bipolar, schizophrenia), and Charlson

comorbidity index. Details on variable categories and claims-related codes used to define potential confounders can be found in the online supplementary material.

To help control for confounding by time due to changes in awareness and CS prescribing culture and use during this time, we developed temporal trend measures that allowed us to control for changes in outcomes occurring over calendar time. We generated these measures from temporal trends in outcome measures in the population of Medicaid beneficiaries who were eligible to enter the LIP, but who were never enrolled. These temporal trend measures were included in all models. For further details, see online supplementary material.

2.8 Statistical Analyses

We calculated the prevalence of demographic and clinical characteristics of beneficiaries included in the analytic cohort. For categorical variables, we obtained counts and percentages. For continuous variables, we calculated means and 25th, 50th (median), and 75th percentiles. To visualize changes in the outcomes across pre-spike, spike, lock-in, and post-release periods, we plotted outcome means across these LIP-related time periods and according to payer source. To further descriptively examine and compare outcome measures over time, we calculated crude means of average daily MMEs per dispensed opioid per person by LIP-related time period and payer source.

We used generalized estimating equations (GEE) to estimate measures of association between LIP-related time periods (compared to the pre-spike referent period) and the average number of CS prescriptions dispensed per person-month and average daily MMEs of dispensed opioids per person. To examine changes in numbers of CS dispensed per person-month, we used both linear-Poisson and log-Poisson GEE models to estimate count differences and count ratios, respectively, with 95% confidence intervals (95% CI). A linear regression GEE (identity link, Gaussian residual distribution) was used to estimate changes in average daily MMEs per person while locked-in and in the year post-release, as compared to the pre-spike period.

All models were specified with an exchangeable correlation matrix and used restricted cubic spline terms with five knots to adjust for temporal trend. While measures of association should be largely robust to the effects of time-independent confounders due to our design, we checked the influence of potential confounders in all models. For each model, the impact of confounding was assessed by including each potential confounder described above in a one-at-a-time manner (due to modeling constraints) and examining measures of association for meaningful changes, defined as more than a 10% change in the beta estimates for measures of association. However, we observed no meaningful changes; therefore, these variables were not included in final models. Temporal trend measures described above were included in all models, including those in which we assessed confounding.

This study was approved by the University of North Carolina at Chapel Hill's Institutional Review Board.

3. Results

Between October 2010 and September 2012, 2,702 beneficiaries were enrolled in the LIP and remained enrolled in the LIP for a full one-year period (or remained continuously enrolled prior to being administratively censored in June 2013). Beneficiaries were largely white (74%), female (70%), and had a mean age of 39 years (Table 1). Nearly half received Medicaid due to a disability, and they exhibited a high prevalence of pain and mental health-related diagnoses (e.g., more than half had a diagnosis of depression) in the year prior to LIP enrollment.

3.1 Pre-modeling results

Figure 1 displays crude means of monthly CS dispensed per person and average daily MMEs dispensed per person across LIP-related time (i.e., months/days from LIP enrollment) and by prescription payment source. The overall pattern in the mean numbers of all CS dispensed, paid for using any payment source, indicated a stable mean of just over 2 prescriptions per month in the pre-spike period. This more than doubled to 5.2 prescriptions per month at the peak of the spike period, followed by a sudden decline just prior to LIP enrollment. There was with a slight decline while locked-in, and the mean post-release was similar to the pre-spike mean.

Crude means of average daily MMEs across program time revealed a similar pattern in terms of the spike and general stabilization of means during lock-in (Figure 1b). However, the pattern was dissimilar in that mean average daily MMEs increased across both pre-spike and post-release periods.

When stratified by payment source, crude means indicated an increase in the proportion of dispensed CS obtained through non-Medicaid sources while locked-in, which then largely, although not completely, reverted to pre-spike levels in the post-release period. However, for mean average daily MMEs, the increase in using non-Medicaid payment sources did not appear to revert to pre-spike levels in the post-release period.

Crude means of average daily MMEs per dispensed opioid per person from all payer sources indicated a steady increase in the mean across LIP-related periods (Table 2). However, stable medians suggested that the mean increase was largely driven by a smaller subset of beneficiaries at the upper end of the distribution. Stratification by payment source revealed a similar finding for non-Medicaid reimbursed opioids, in that a substantial increase in the mean was observed post-release while the median remained similar to other LIP-related periods. Finally, results for Medicaid-reimbursed opioids indicated an upward shift in the mean and median while enrolled in the LIP.

3.2 Frequency and dosage of dispensed CS

Controlling for temporal trend in dispensed CS prescriptions, numbers of CS dispensed per person-month during lock-in and post-release were slightly lower than the pre-spike period (count difference per person-month: -0.05 ; 95% CI: $-0.11, 0.01$ and -0.23 ; 95% CI: $-0.31, -0.15$, respectively) (Table 3). Stratification by payer source revealed that large decreases in Medicaid-reimbursed prescriptions during lock-in and post-release were considerably offset

by increases in non-Medicaid-reimbursed prescriptions during these periods. For example, compared to the pre-spike period, there were 0.61 (95% CI: -0.66, -0.55) and 0.38 (95% CI: -0.45, -0.31) fewer Medicaid-reimbursed prescriptions per person-month during lock-in and post-release, respectively. However, non-Medicaid-reimbursed prescriptions increased by 0.56 (95% CI: 0.52, 0.59) and 0.12 (95% CI: 0.08, 0.16) per person-month during lock-in and post-release, respectively. Similar patterns were observed in analyses restricted to opioids alone.

The average daily MME of opioids dispensed to beneficiaries was elevated during lock-in and post-release relative to pre-spike (daily mean difference per person: 18.7; 95% CI: 13.9, 23.6 and 11.1; 95% CI: 5.1, 17.1, respectively) (Table 4). Similar to dispensed CS, there were notable increases in reimbursement using non-Medicaid payment sources. Compared to the pre-spike period, 6.6 (95% CI: 4.8, 8.5) more average daily MMEs per person were purchased using non-Medicaid payment during lock-in and 6.2 (95% CI: 3.7, 8.6) more post-release.

4. Discussion

4.1 Key Findings

Consistent with previous research, we found that from an insurance-based perspective, LIPs appear to reduce CS prescriptions dispensed to beneficiaries enrolled in a state's Medicaid LIP (Beaubien, 2005; Blake, 1997; CDC, 2012; Chinn, 1985; Dreyer et al., 2015; Hladilek et al., 2004; Mitchell, 2009; Roberts et al., 2016). This paper provides the first evidence that such reductions, although somewhat attenuated, persist in the year following disenrollment. For example, the average number of Medicaid-reimbursed CS dispensed per person-month was 31% lower during lock-in and 18% lower post-release, as compared to a stable period of dispensing prior to lock-in.

A strength of this study was access to information on prescriptions obtained through Medicaid and non-Medicaid payment sources, which revealed insights on intended and unintended consequences of the LIP. We found that while CS dispensing decreased overall, beneficiaries acquired more CS prescriptions outside of the Medicaid payment system while locked-in, compared to prior to LIP enrollment. The increased acquisition of CS from non-Medicaid sources persisted following program release. Concerns about increased acquisition of CS from non-Medicaid sources during lock-in have previously been noted (Roberts et al., 2016); however, this is the first study to indicate that these effects persist post-release.

We also found that beneficiaries received larger dosages of opioids in terms of average daily MMEs during lock-in and post-release, regardless of payment source. The percent of average daily MMEs dispensed while locked-in increased by approximately 28% relative to the pre-enrollment (and pre-spike) period, and by about 17% post-release. While the majority of average daily MMEs were acquired through Medicaid payment, there were large increases in average daily MMEs obtained outside of the Medicaid payment system during these periods. Approximately 12% of all average daily MMEs were paid for using non-Medicaid sources prior to enrollment, which increased to roughly 20% during lock-in and post-release.

The overall decline in numbers of dispensed CS and opioids and parallel increases in average daily MMEs suggests that opioids acquired during LIP and following release were characterized by greater average daily MMEs per prescription, relative to those obtained prior to the LIP. Descriptive analyses supported this finding but also revealed that increases may have been driven by select beneficiaries at the upper end of the dosage per prescription distribution.

From an insurance-based perspective, the increase in average daily MMEs per Medicaid-reimbursed opioid during lock-in could signal improved care coordination for some beneficiaries. In other words, LIP restrictions may have encouraged lock-in providers to more carefully assess beneficiaries' prescriptions regimens, reducing numbers of prescriptions (e.g., continuous 30-day prescriptions rather than multiple shorter-term prescriptions), while not reducing overall MMEs. Moreover, overall increases in MMEs dispensed to certain beneficiaries during lock-in and following release could indicate a natural progression of opioid tolerance in a population with a high prevalence of chronic pain. However, this increase may also indicate increases in average overdose risk for this population. Given that research suggests a dose-dependent relationship between average daily MMEs and opioid overdose risk (Bohnert et al., 2011; Dasgupta et al., 2016; Dunn et al., 2010), future studies should explore potential changes in overdose risk across LIP-related periods.

Our finding that average daily MMEs per opioid obtained outside of the Medicaid system increased post-release may signal that some beneficiaries began acquiring more potent opioids outside of the purview of the Medicaid system following release from the program. Future research exploring heterogeneity underlying these population-level averages may help further disentangle subgroups experiencing potential unintended LIP effects.

4.2 Implications for LIP designs and policies

Our findings of LIP impacts on CS prescription measures provide key indications for intervention and LIP improvements. First, our finding that a substantial proportion of beneficiaries' average daily MMEs were obtained outside of the Medicaid payment system highlights the need for increased use of PDMPs. We lack data on how often NC Medicaid LIP providers, specifically, accessed the CSRS during this time. However, a 2012 evaluation of the CSRS indicated that prescribers and pharmacists used the CSRS less than 6% of the time that a CS was either prescribed or dispensed (NC GA, 2014), suggesting a missed opportunity to provide better informed care. The recent passage of NC's Strengthen Opioid Misuse Prevention (STOP) Act of 2017 might help address this issue (NC GA, 2017). Under this Act, prescribers will soon be required to check the CSRS prior to prescribing Schedule II or III opioids. Furthermore, as of 2020, electronic prescriptions will be required for specific CS in NC, which could also reduce the risk that beneficiaries may visit multiple pharmacies and obtain CS outside of the Medicaid payment system.

Second, given our finding of increased acquisition of MME dosages during lock-in and findings that nearly a third of LIP enrollees had a diagnosis of a substance use-related disorder in the year prior to enrollment, further research is needed on access to substance use disorder treatment, such as medication-assisted therapy, prior to, during, and following LIP

release. If found to be underutilized, providing opportunities to discuss substance use behaviors (e.g., motivational interviewing) with LIP enrollees, a strategy that has been included in previous LIP models (ACAP, 2015), and ensuring access to substance use disorder treatment could potentially improve care and health outcomes. Additionally, given the high and increasing average daily MME dosages observed across program-related periods, LIP administrators might consider increased communication with providers of LIP-enrolled patients about overdose risk reduction strategies, such as potential opioid tapering, utilization of alternative or complementary pain therapy approaches, and possession of naloxone (Dowell et al., 2016).

Finally, our findings indicate that beneficiary behavior changes occurring during lock-in tend to persist following program release. Investment in a more comprehensive LIP model could produce benefits realized by both beneficiaries and insurers that are not limited to the one-year lock-in period. In addition to the elements discussed above, LIP models that incorporate case managers to help manage the complex and unique needs (Naumann et al., 2017) of LIP enrollees (e.g., through connection to alternate pain therapy services, mental health disorder treatment) may produce improved outcomes (ACAP, 2015).

4.3 Limitations

Our results should be viewed in light of four main limitations. First, we did not have linked claims-CSRS data on persons who were never enrolled in the LIP. While this group would have been useful as a control, we compensated by incorporating a novel method to control for changes in secular trend over time using Medicaid claims data from those eligible but never enrolled in the LIP.

Second, while the CSRS database captures almost all CS dispensed to these beneficiaries, there are some gaps in understanding beneficiaries' complete CS use. We do not have information on CS prescriptions acquired across state lines or from pharmacies located on military bases or veterans' administration hospitals, or CS that beneficiaries obtained through illicit sources (diversion). If these CS acquisitions increased during lock-in and post-release, our measures of association would be underestimated.

Third, administrative censoring resulted in loss of follow-up in the one-year post-release period. It is possible that losses to follow-up were related to our outcome measures and could have introduced some bias when estimating measures of association involving the post-release period.

Finally, given rapid changes in prescribing knowledge and culture, availability and use of illicitly-manufactured opioids (e.g., heroin, fentanyl), and overall changes in public awareness concerning the potential risks of opioid use, our findings might not be entirely generalizable to today's environment (Dowell et al., 2016; Guy et al., 2017; Rudd et al., 2016). For example, current LIP-enrolled beneficiaries may obtain fewer prescriptions using out-of-pocket payments at pharmacies than what we observed, but may instead obtain more illicit substances. Still, even with a rapidly changing environment, our findings emphasize the need to take a broader view of program effects on beneficiaries, both in terms of alternate payment sources and the persistence of program effects.

4.4 Conclusions

NC's Medicaid LIP reduced overall numbers of CS prescriptions dispensed during lock-in, and this reduction was sustained in the year following program release. However, the LIP was associated with acquiring a greater proportion of CS prescriptions using non-Medicaid payment sources both during lock-in and post-release. Beneficiaries also acquired greater dosages of dispensed opioids, in terms of average daily MMEs, from both Medicaid and non-Medicaid payment sources, both during lock-in and post-release. Refining LIPs to increase provider utilization of PDMP data, ensure access to substance use disorder treatment services, and incorporate complementary beneficiary support services may help address important unintended consequences (e.g., increases in non-Medicaid payment) and increase the overall utility of these programs. Future research is needed as to the short- and long-term impacts of alternate LIP designs and more comprehensive LIP models, incorporating measures that assess program impacts from both insurer and beneficiary perspectives. Additionally, future research exploring the potential heterogeneity underlying average population effects may help further refine and target LIPs to those most likely to benefit.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

The authors thank the NC Division of Medical Assistance and the Division of Mental Health, Developmental Disabilities, and Substance Abuse for their support in obtaining the data.

Role of funding source: This research was supported by Cooperative Agreement U01 CE002160-01 from the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (NCIPC/CDC) and award R49-CE001495 to the University of North Carolina for an Injury Control Research Center from NCIPC/CDC. Ms. Naumann received fellowship support from the University of North Carolina's Royster Society of Fellows. Dr. Gottfredson received support through an award from NIH (K01 DA035153). The funding sources had no additional role in study design; data collection, analysis, interpretation of the data; nor in the writing, preparation, and submission of the manuscript.

References

- Association for Community Affiliated Plans (ACAP), 2015 Strategies to reduce prescription drug abuse: lessons learned from the ACAP SUD collaborative. Washington (DC): ACAP Available online: http://www.communityplans.net/Portals/0/Fact%20Sheets/ACAP_Substance_Use_Disorder_Toolkit.pdf Accessed on June 26, 2017.
- Beaubien JM, 2005 Effectiveness of recipient restriction programs in Medicaid managed care organizations. University of Rhode Island [Dissertation].
- Blake SG, 1997 The impact of the Louisiana Medicaid lock-in program on the process and clinical and economic outcomes of recipient care. Northeast Louisiana University [Dissertation].
- Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, Blow FC, 2011 Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA* 305, 1315–1321. [PubMed: 21467284]
- Brandeis University, Heller School for Social Policy and Management, 2013 Technical assistance guide No.01–13: calculating daily morphine milligram equivalents. Waltham, MA: Brandeis University Available online: http://www.pdmpassist.org/pdf/BJA_performance_measure_aid_MME_conversion.pdf Accessed on June 26, 2017.

- Centers for Disease Control and Prevention (CDC), 2012 Patient review and restriction programs: lessons learned from state Medicaid programs. CDC Expert Panel Meeting Report. Atlanta, GA: CDC Available online: https://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf Accessed on June 26, 2017.
- Centers for Disease Control and Prevention (CDC), 2015 Centers for Disease Control and Prevention's compilation of opioid analgesic formulations with morphine milligram equivalent conversion factors, 2015 version. Atlanta, GA: CDC.
- Centers for Disease Control and Prevention (CDC), 2016 Wide-ranging Online Data for Epidemiologic Research: National Vital Statistics System mortality data. Atlanta, GA: CDC Available online: <https://wonder.cdc.gov/> Accessed on June 26, 2017.
- Chinn FJ, 1985 Medicaid recipient lock-in program--Hawaii's experience in six years. *Hawaii Med. J.* 44, 9–18. [PubMed: 3918957]
- Dasgupta N, Funk MJ, Proescholdbell S, Hirsch A, Ribisl KM, Marshall S, 2016 Cohort study of the impact of high-dose opioid analgesics on overdose mortality. *Pain Med.* 17, 85–98. [PubMed: 26333030]
- Dowell D, Haegerich TM, Chou R, 2016 CDC guideline for prescribing opioids for chronic pain—United States, 2016. *MMWR Recomm Rep.* 65, 1–49.
- Dreyer TR, Michalski T, Williams BC, 2015 Patient outcomes in a Medicaid managed care lock-in program. *J. Manag. Care Pharm.* 21, 1006–1012.
- Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M, 2010 Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann. Intern. Med.* 152, 85–92. [PubMed: 20083827]
- Guy GP Jr., Zhang K, Bohm MK, Losby J, Lewis B, Young R, Murphy LB, Dowell D Vital Signs: changes in opioid prescribing in the United States, 2006–2015, 2017. *MMWR* 66, 697–704.
- Hladilek MK, Howe MJ, Carr RM, 2004 An overview of Wisconsin Medicaid quality. *Wis. Med. J.* 103, 58–62.
- Mitchell L, 2009 Lock-in program promotes appropriate use of resources. *J. Okla. State Med. Assoc.* 102, 276. [PubMed: 19750820]
- Naumann RB, Marshall SM, Lund JL, Skinner AC, Ringwalt C, Gottfredson NC, 2017 Attributes of Medicaid beneficiaries eligible, enrolled, and retained in a controlled substance “lock-in” program. Under review.
- North Carolina Department of Health and Human Services (NC DHHS), 2010 Implementation of a recipient management lock-in program. August 2010 North Carolina Medicaid Bulletin. Raleigh, NC: NC DHHS.
- North Carolina General Assembly (NC GA), Program Evaluation Division, 2014 North Carolina needs to strengthen its system for monitoring and preventing the abuse of prescribed controlled substances. Raleigh, NC: NC GA Report No. 2014–05. Available online: http://www.ncleg.net/PED/Reports/documents/Rx/Rx_Report.pdf Accessed on June 26, 2017.
- North Carolina General Assembly (NC GA), 2017 Strengthen Opioid Misuse Prevention (STOP) Act. Session Law 2017–74. House Bill 243.
- Roberts AW, Farley JF, Holmes GM, Oramasionwu CU, Ringwalt C, Sleath B, Skinner AC, 2016 Controlled substance lock-in programs: examining an unintended consequence of a prescription drug abuse policy. *Health Aff.* 35, 1884–1892.
- Roberts AW, Skinner AC, 2014 Assessing the present state and potential of Medicaid controlled substance lock-in programs. *J. Manag. Care Pharm.* 20, 439–446c.
- Rudd RA, Seth P, David F, Scholl L Increases in drug and opioid-involved overdose deaths—United States, 2010–2015, 2016 *MMWR* 65, 1445–1452. [PubMed: 28033313]
- Singleton TE, 1977 Missouri's lock-in: control of recipient misutilization. *J. Medicaid Manage.* 1, 10–17. [PubMed: 10297488]
- Skinner AC, Ringwalt C, Naumann RB, Roberts AW, Moss LA, Sachdeva N, Weaver MA, Farley J, 2016 Reducing opioid misuse: evaluation of a Medicaid controlled substance lock-in program. *J. Pain* 17, 1150–1155. [PubMed: 27497767]
- Van Zee A, 2009 The promotion and marketing of oxycontin: commercial triumph, public health tragedy. *Am. J. Public Health* 99, 221–227. [PubMed: 18799767]

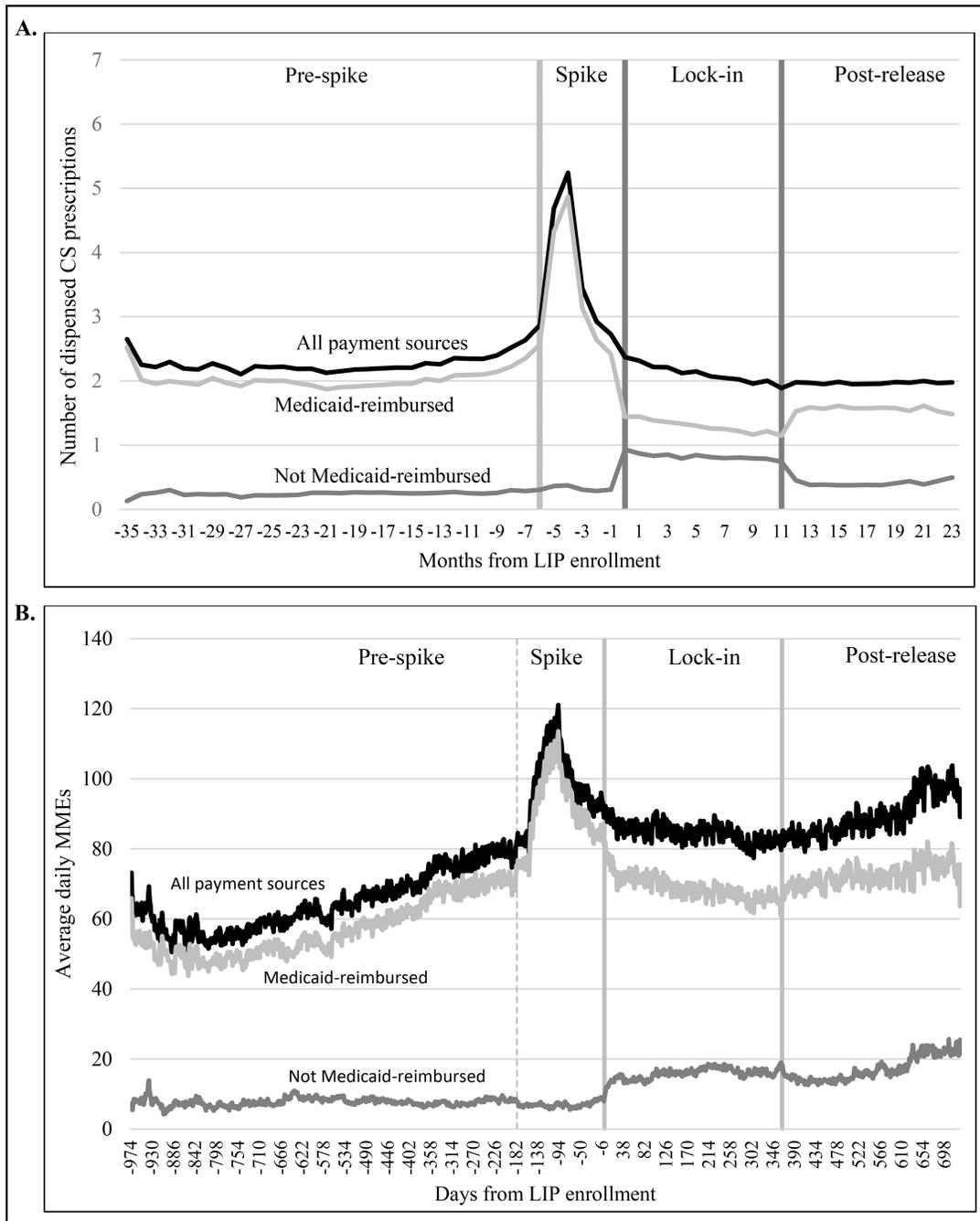


Figure 1. Average number of dispensed controlled substance (CS) prescriptions per person per month[^] (Panel A) and average daily morphine milligram equivalents (MMEs) of dispensed opioid prescriptions (Panel B) per person across pre-spike, spike, lock-in, and post-release periods* among North Carolina Medicaid “lock-in” program (LIP) enrollees (n=2702), October 2009–June 2013

[^] Includes CS prescriptions regulated by the LIP, specifically opioids and benzodiazepines

*Pre-spike period= more than 6 months prior to LIP enrollment; Spike period= 0–6 months prior to LIP enrollment; lock-in period= months enrolled in the LIP (up to 12 months); Post-release period= months after disenrollment from the LIP (up to 12 months following release)

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TABLE 1.

Characteristics of North Carolina Medicaid “lock-in” program (LIP) enrollees (n=2,702), October 2009-June 2013

Characteristics	N (%); mean (25th, 50th, 75th pcts)
DEMOGRAPHIC*	
Age (years)	38.7 (30, 38, 47)
Gender	
Women	1,897 (70.2)
Men	805 (29.8)
Race	
White	2,000 (74.0)
Black	550 (20.4)
Other	152 (5.6)
Medicaid eligibility category	
Aid to families with dependent children	1,390 (51.4)
Aid to disabled	1,282 (47.5)
Aid for other reasons (e.g., aid to blind)	30 (1.1)
SUBSTANCE USE-RELATED†	
Alcohol-related disorder	174 (6.4)
Other substance-related disorder	871 (32.2)
Medication-assisted treatment	274 (10.1)
Medication or drug-related overdose	193 (7.1)
HEALTH CARE UTILIZATION†	
Number of unique pharmacies from which Medicaid-reimbursed prescriptions were obtained	4.2 (2, 4, 6)
Emergency department visits	9.8 (2, 6, 13)
Inpatient admissions	1.3 (0, 1, 2)
PAIN-RELATED DIAGNOSES†	
Any joint pain or arthritis	2,453 (90.8)
Back pain	2,253 (83.4)
Neck pain	1,124 (41.6)
Headache/migraine pain	589 (21.8)
Fibromyalgia, chronic pain, or fatigue	1,443 (53.4)
Rheumatoid arthritis or osteoarthritis	706 (26.1)
Sickle cell	50 (1.9)
MENTAL HEALTH-RELATED DIAGNOSES†	
Depression	1,675 (62.0)
Anxiety disorder	1,185 (43.9)
Other serious mental health disorder (e.g., bipolar, schizophrenia)	751 (27.8)
COMORBID CONDITION INDEX†	
Mean Charlson comorbidity index	0.920, 0, 1)

Pcts=percentiles.

Note: please see online supplement for detailed information on variable definitions.

* Assessed at time of “lock-in” program enrollment

† Assessed using a one-year lookback period from time of “lock-in” program enrollment

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Means of average daily morphine milligram equivalents (MMEs) per dispensed opioid prescription per person among North Carolina Medicaid “lock-in” program (LIP) enrollees (n=2,702) by LIP-related time period[#] and payer source, October 2009–June 2013

TABLE 2.

Period [#]	All payer sources	Medicaid-reimbursed	Not Medicaid-reimbursed
	Mean (25 th , 50 th , 75 th percentile)		
Pre-spike	58 (33, 44, 63)	58 (32, 44, 62)	58 (30, 43, 64)
Spike	62 (36, 48, 69)	62 (36, 48, 69)	59 (30, 45, 64)
Lock-in	67 (34, 47, 77)	75 (34, 55, 94)	55 (31, 41, 60)
Post-release	69 (32, 46, 83)	70 (31, 46, 86)	68 (30, 45, 75)

[#]Pre-spike period= more than 6 months prior to LIP enrollment; Spike period= 0–6 months prior to LIP enrollment; Lock-in period= months enrolled in the LIP (up to 12 months); Post-release period= months after disenrollment from the LIP (up to 12 months following release)

TABLE 3.

Means, count differences, and count ratios of monthly numbers of controlled substance prescriptions[§] dispensed to North Carolina Medicaid “lock-in” program (LIP) enrollees (n=2,702) by payer source and LIP-related time period[#], October 2009-June 2013

Period [#]	All payer sources			Medicaid-reimbursed			Not Medicaid-reimbursed		
	Model-estimated mean (95% CI) [^]	Count difference (95% CI) [*]	Count ratio (95% CI) [*]	Model-estimated mean (95% CI) [^]	Count difference (95% CI) [*]	Count ratio (95% CI) [*]	Model-estimated mean (95% CI) [^]	Count difference (95% CI) [*]	Count ratio (95% CI) [*]
Pre-spike	2.30 (2.24, 2.35)	Ref	Ref	2.01 (1.96, 2.05)	Ref	Ref	0.28 (0.26, 0.29)	Ref	Ref
Spike	3.65 (3.60, 3.70)	1.41 (1.36, 1.47)	1.63 (1.60, 1.67)	3.32 (3.28, 3.37)	1.37 (1.32, 1.42)	1.71 (1.75, 1.83)	0.32 (0.30, 0.35)	0.05 (0.03, 0.07)	1.20 (1.12, 1.29)
Lock-in	2.11 (2.06, 2.16)	-0.05 (-0.11, 0.01)	0.98 (0.95, 1.01)	1.29 (1.25, 1.34)	-0.61 (-0.66, -0.55)	0.69 (0.67, 0.71)	0.82 (0.79, 0.86)	0.56 (0.52, 0.59)	3.16 (2.92, 3.42)
Post-release	1.87 (1.81, 1.93)	-0.23 (-0.31, -0.15)	0.90 (0.86, 0.93)	1.47 (1.42, 1.52)	-0.38 (-0.45, -0.31)	0.82 (0.78, 0.85)	0.39 (0.36, 0.42)	0.12 (0.08, 0.16)	1.56 (1.41, 1.73)

[§] Includes controlled substance prescriptions regulated by the LIP, specifically opioids and benzodiazepines

[#] Pre-spike period= more than 6 months prior to LIP enrollment; Spike period= 0–6 months prior to LIP enrollment; Lock-in period= months enrolled in the LIP (up to 12 months); Post-release period= months after disenrollment from the LIP (up to 12 months following release)

[^] Estimated with linear Poisson GEE model, used average value of secular trend variable for each LIP time period

^{*} Estimated with GEE model, adjusted for secular trend

TABLE 4.

Means and changes in average daily morphine milligram equivalents (MME) of opioid prescriptions dispensed to North Carolina Medicaid “lock-in” program (LIP) enrollees (n=2,702) by payer source and LIP-related time period[#], October 2009–June 2013

Period [#]	All payer sources			Medicaid-reimbursed			Not Medicaid-reimbursed		
	Model-estimated mean (95% CI) [^]	Mean difference (95% CI) [*]	Model-estimated mean (95% CI) [^]	Mean difference (95% CI) [*]	Model-estimated mean (95% CI) [^]	Mean difference (95% CI) [*]			
Pre-spike	66.2 (60.4, 72.0)	Ref	58.0 (52.5, 63.6)	Ref	8.2 (7.0, 9.3)	Ref			
Spike	98.2 (91.7, 104.7)	32.3 (28.4, 36.1)	91.2 (84.9, 97.5)	34.2 (30.4, 38.0)	7.0 (6.1, 7.8)	-1.9 (-3.2, -0.7)			
Lock-in	84.6 (79.0, 90.1)	18.7 (13.9, 23.6)	68.8 (63.7, 74.0)	12.1 (7.4, 16.8)	15.7 (14.1, 17.4)	6.6 (4.8, 8.5)			
Post-release	77.4 (71.6, 83.3)	11.1 (5.1, 17.1)	62.0 (56.9, 67.1)	5.0 (-0.9, 10.8)	15.4 (12.8, 18.1)	6.2 (3.7, 8.6)			

[#] Pre-spike period= more than 6 months prior to LIP enrollment; Spike period= 0–6 months prior to LIP enrollment; Lock-in period= months enrolled in the LIP (up to 12 months); Post-release period= months after disenrollment from the LIP (up to 12 months following release)

[^] Estimated with GEE model, used average value of secular trend variables for each LIP time period

^{*} Estimated with GEE model, adjusted for secular trend