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Evaluation of a Medicaid Lock-in Program:

Increased Use of Opioid Use Disorder Treatment but No Impact on Opioid Overdose Risk

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Abstract

Background: “Lock-in” programs (LIPs) identify beneficiaries demonstrating potential overutilization of opioids, and other controlled substances, and restrict their access to these medications. LIPs are expanding to address the opioid crisis and could be an effective tool for connecting people to opioid use disorder treatment. We examined the immediate and sustained effects of a Medicaid LIP on overdose risk and use of medication-assisted treatment (MAT) for opioid use disorder.

Methods: We analyzed North Carolina Medicaid claims from July 2009 through June 2013. We estimated daily risk differences and ratios of MAT use and overdose during lock-in and following release from the program, compared with periods before program enrollment.

Results: The daily probability of MAT use during lock-in and following release was greater, when compared with a period just before LIP enrollment [daily risk ratios: 1.50, 95% confidence interval (CI): 1.18–1.91; 2.27, 95% CI: 1.07–4.80; respectively]. Beneficiaries’ average overdose risk while enrolled in the program and following release was similar to their risk just before enrollment (daily risk ratios: 1.01, 95% CI: 0.79–1.28; 1.12, 95% CI: 0.82–1.54; respectively).

Discussion: North Carolina’s Medicaid LIP was associated with increased use of MAT during enrollment, and this increase was sustained in the year following release from the program. However, we did not observe parallel reductions in overdose risk during lock-in and following release. Identifying facilitators of MAT access and use among this population, as well as potential barriers to overdose reduction are important next steps to ensuring effective LIP design.

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Keywords

controlled substance; lock-in; Medicaid; opioid

Between 2000 and 2016, >300,000 people died from an opioid overdose with a death rate in 2016 > 4 times that of 2000 (3.0 vs. 13.3 per 100,000 population).¹ Parallel increases in opioid use disorders (OUDs) have been documented.²

Several policies and programs have been implemented in an attempt to reduce OUD and overdose.³ In some cases, established programs for controlling health care utilization have been reframed to address the current public health emergency. For example, beneficiary “lock-in” programs (LIPs) originated in Medicaid in the 1970s as a tool to reduce fraud, waste, and abuse of Medicaid resources.^{4,5} LIPs were implemented to identify beneficiaries exhibiting high use of prescription-controlled substances and to control access to these medications by requiring them to use, typically, a single prescriber and/or pharmacy to obtain these drugs for a specified period of time (eg, 1–2 y). As opioid use, OUD, and overdose increased, LIPs received renewed attention and their use proliferated as a means to reduce not only fraud and waste, but also OUD and overdose.^{4,5} Although research indicates that LIPs reduce controlled substance prescription claims and plan expenditures for beneficiaries enrolled in the LIP,^{4,6–13} their larger impact as a repurposed tool to improve patient and public health outcomes is unknown.

We previously reported on the impacts of North Carolina’s (NC) Medicaid LIP on opioid prescriptions dispensed to those enrolled in the program. We found that the program was associated with reductions in numbers of Medicaid claims for opioid prescriptions per person per month.^{14,15} However, our findings also suggested that numbers of opioids obtained through out-of-pocket payment increased.^{15,16} Furthermore, average dosages of opioids dispensed [in terms of average daily morphine milligram equivalents (MMEs)] to beneficiaries were elevated during LIP enrollment.¹⁵ The increases in out-of-pocket payments and average daily MMEs among LIP enrollees raise concerns about patient clinical outcomes and public health effects of LIPs related to OUD and overdose. Therefore, the objective of this study was to examine impacts of NC’s Medicaid LIP on overdose risk and use of medication-assisted treatment (MAT) for OUD among beneficiaries. We assessed both immediate (during program enrollment) and sustained (following program release) impacts of the program on these outcomes.

METHODS

NC’s Medicaid LIP

The NC Medicaid LIP was implemented in October 2010.¹⁷ Medicaid beneficiaries were eligible for the LIP if they had, within 2 consecutive calendar months: (1) >6 opioid claims, (2) >6 benzodiazepine claims, or (3) opioid or benzodiazepine claims prescribed by > 3 different prescribers.¹⁷ A prioritization process resulted in about 200 LIP-eligible beneficiaries selected for enrollment each month. Once enrolled, beneficiaries were restricted to using 1 prescriber and 1 pharmacy location to receive NC Medicaid coverage of

opioid and benzodiazepine prescriptions for a 1-year period. Additional details of the implementation and administration of NC's Medicaid LIP, as well as how the NC Medicaid population compares with other Medicaid populations, have been previously reported.¹⁸

Data, Study Design, and Cohort

Data included NC Medicaid claims from July 2009 through June 2013. We established and followed a cohort of independent-living adults, aged 18–64, who became eligible for the LIP between June 2010 and June 2013. Because the objective was to examine the association between the program and the outcomes of MAT and overdose, we included beneficiaries who became eligible for the LIP by meeting the opioid-specific criterion (> 6 opioid prescriptions). Approximately 97% of those enrolled in the LIP met this criterion.¹⁸ We included those who became eligible for the LIP between June 2010 and June 2013 because the first assessment period for program eligibility was June–July 2010 (for the first LIP enrollment in October 2010) and we had data through June 2013. We followed beneficiaries in our cohort from the first day they received any opioid prescription in our data, throughout their period of lock-in, and up to 1 year following program release or until the end of our dataset, whichever came first. This study was approved by the University of North Carolina at Chapel Hill's Institutional Review Board.

Classification of LIP Observation Periods

To examine immediate and sustained associations between the LIP and outcomes, we divided beneficiaries' observation time into 4 segments: 2 pre-program enrollment periods ("pre-LIP eligibility" and "post-LIP eligibility"), a 12-month program period (lock-in), and a period after program release (release). We divided pre-program time into 2 periods to allow for comparisons to 2 distinct periods of interest to the LIP: (1) a "pre-LIP eligibility" period included time from a beneficiary's first opioid prescription in our claims data until they met the LIP opioid eligibility criterion and (2) a "post-LIP eligibility" period included time from meeting LIP eligibility until actual program enrollment, if enrolled. As noted above, due to the LIP prioritization process, some beneficiaries met LIP criteria but were never enrolled. The "lock-in" period included up to 12 months of program time, and the "release" period included up to 12 months following program release.

Outcomes

We estimated the daily probability of MAT use for an OUD and the risk of overdose across LIP-related periods. Receipt of MAT was defined as having an active prescription for a buprenorphine product indicated for use of OUD treatment on a given day or any mention of CPT code H0020 for methadone treatment on a given day.^{19,20} Overdose, was defined using the following ICD-9-CM codes 960–979 or E-codes: E850–E858, E950.0–E950.5, E962.0, E980.0–E980.5.^{21,22} See Supplementary Material, Supplemental Digital Content 1, (<http://links.lww.com/MLR/B676>) for additional details on outcome assessment and sensitivity analyses.

Covariates and Propensity Scores

To isolate the effects of the LIP on outcomes and control for potential confounding, we identified a comparison group of NC Medicaid beneficiaries that met LIP eligibility criteria but were not enrolled in the program due to program capacity limitations. We constructed propensity scores estimating the probability of LIP enrollment conditional on baseline covariates using logistic regression.²³ Covariates included demographic characteristics, health care utilization, and medical diagnoses.^{15,18} Specific information on claims-related codes used to define characteristics and a figure displaying the propensity score distribution for LIP-enrolled and not enrolled groups are available in the Supplement, Supplemental Digital Content 1 (<http://links.lww.com/MLR/B676>).

Statistical Analyses

We compared the prevalence of demographic characteristics, health care utilization, and medical diagnoses among LIP-enrolled and not enrolled groups. For categorical variables, we calculated percentages, and for continuous variables, means and SDs.

We examined crude counts and rates of MAT and overdose by LIP-related periods. We used generalized estimating equations to estimate measures of association (daily risk differences and ratios) between lock-in and release periods, compared with the pre-LIP enrollment reference periods, and the average risk of MAT and overdose. We included stabilized inverse probability of LIP enrollment weights (calculated using the propensity scores described above) in models.²³ See Supplement for additional details, Supplemental Digital Content 1 (<http://links.lww.com/MLR/B676>). Models also included linear secular trend variables to help control for changes in awareness and opioid prescribing culture and use during this time.

RESULTS

Between June 2010 and June 2013, 17,823 NC Medicaid beneficiaries were eligible for enrollment in the LIP, and 31% (n = 5479) were enrolled. Crude rates of MAT and overdose generally increased across pre-LIP, during, and release periods (Table 1).

Table 2 compares the demographic characteristics, health care utilization, and medical diagnoses of those enrolled versus not enrolled in the LIP. See Supplement, Supplemental Digital Content 1 (<http://links.lww.com/MLR/B676>) for comparisons after inverse probability of LIP enrollment weighting.

Including inverse probability of enrollment weights and adjusting for temporal trend, the daily probability of MAT use during lock-in and post-release was greater, compared with time before meeting LIP criteria (Table 3; Fig. S2 in Supplement, Supplemental Digital Content 1, <http://links.lww.com/MLR/B676>). Moreover, the daily probability of MAT use during lock-in and following release remained greater, when compared with a period after program criteria had been met, but before program enrollment (post-LIP eligibility period). Compared with the post-LIP eligibility period, 9 more beneficiaries per 1000 accessed MAT per day during lock-in [95% confidence interval (CI): 3.80–14.18] and 25 more following release (95% CI: –5.14 to 54.29).

Beneficiaries' average overdose risk was also elevated while enrolled in the program and following release when compared with their risk before meeting program criteria (Table 4; Fig. S2 in Supplement, Supplemental Digital Content 1, <http://links.lww.com/MLR/B676>). However, overdose risks during the program and following release were similar to that observed after meeting program eligibility criteria but before enrollment [daily risk ratios: 1.01, 95% CI: 0.79–1.28; 1.12, 95% CI: 0.82–1.54, respectively].

DISCUSSION

Among a population characterized by high opioid use, we found that LIP enrollment was associated with increased use of MAT for OUD, when compared with a period just before program enrollment (post-LIP eligibility). However, there were no corresponding reductions in average overdose risk. Both of these findings were sustained in the year following release from the program.

Although previous research has documented high opioid overdose death rates among those enrolled in a LIP, this is the first study to specifically examine daily overdose risk across program-related periods.²⁴ Ideally, LIPs would result in improved care coordination, connection to appropriate OUD treatment as needed, and reduction in overdose. Although findings suggested an average increase in MAT use for OUD, these increases did not couple with overdose decreases. However, given previous analyses indicating an increase in average daily MMEs across LIP enrollment and release periods, when compared with pre-program time, a reduction in overdose risk would have been incongruous.¹⁵ In addition, the extent to which LIP restrictions may induce enrollees to obtain substances outside of the health care system is unknown and could also affect overdose risk across these periods. Further research looking at specific opioids involved in overdoses among LIP enrollees, particularly during the more recent increase in synthetic opioid-related (eg, fentanyl) deaths, is also warranted.

Our findings suggest that LIPs may provide a useful framework for connecting high-risk patients with diagnosed or undiagnosed OUD with MAT. Although there are examples of LIPs applying an intensive case management approach to ensure the provision of MAT and other necessary ancillary medical services, many still do not.^{25,26} Specifically, use of motivational interviewing, peer-to-peer support, and assessment and connection to resources for treatment of comorbid conditions (eg, mental health disorders) and other critical needs (eg, transportation resources to MAT) are examples of promising starting points. Evaluations of programs that include such a tailored approach, including estimation of their effects on key public health outcomes and on short-term and long-term costs and benefits, would provide critical information to LIP administrators.

This study was subject to at least 4 limitations. First, we did not have information on overdoses that did not generate a Medicaid claim. Second, we did not have information on out-of-pocket payments made at methadone clinics or for out-of-pocket MAT-related buprenorphine prescriptions. To assess the impact of this, we examined data on out-of-pocket payments for buprenorphine prescriptions, obtained through linkage to the state's prescription drug monitoring program, for those enrolled in the LIP (we only had access to linked data on the LIP-enrolled group). We found that out-of-pocket payments constituted a

small proportion of all buprenorphine dispensed, with little change across LIP-related periods. Third, the presence of diagnoses and health care utilization measures in the year before meeting LIP eligibility may be underestimated for some, given variable amounts of data available on those before LIP eligibility. However, research suggests that inclusion of any available data in a lookback period to assess presence of covariates results in less misclassification than restricting to a common lookback period.²⁷ Fourth, administrative censoring resulted in loss of follow-up in the 1-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.

NC's Medicaid LIP was associated with increased use of MAT during enrollment, and this increase was sustained in the year following release from the program. However, we did not observe parallel reductions in overdose risk during lock-in and following release, when compared with just before LIP enrollment. Identifying facilitators of MAT access and use among this population, as well as potential barriers to overdose reduction are important next steps to ensuring effective LIP design.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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TABLE 1.

Counts and Rates of MAT and Overdose Among Beneficiaries Eligible for the North Carolina Medicaid ‘‘Lock-in’’ Program by Period, July 2009 to June 2013 (N = 17,823)

Program-related Period	Total Person-days	MAT			Overdose	
		Total Days of MAT Administration	MAT Administration Rate Per 1000 Person-days (SD)	Total Overdose Events	Overdose Event Rate Per 1000 Person-days (SD)	
Pre-LIP eligibility	7,350,138	79,028	10.75 (103.13)	1094	0.15 (12.20)	
Post-LIP eligibility	7,038,308	107,318	15.25 (122.54)	1265	0.18 (13.41)	
Lock-in	1,340,032	41,825	31.21 (173.89)	357	0.27 (16.32)	
Release	581,566	22,978	39.51 (194.81)	149	0.26 (16.00)	

LIP indicates ‘‘lock-in’’ program; MAT, medication-assisted treatment.

TABLE 2.

Characteristics of North Carolina Medicaid Beneficiaries Eligible for the LIP by Program Enrollment Status, July 2009 to June 2013 (N = 17,823)

	Percentage or Mean (SD)	
	Enrolled (N=5479)	Not Enrolled (N=12,344)
Demographics *		
Age group (y)		
18-24	11.0	9.3
25-34	34.9	26.7
35-44	28.7	25.6
45-54	18.6	24.6
55-64	6.8	13.8
Women	69.3	64.2
Race		
White	76.5	74.9
Black	17.9	19.9
Other (eg, Asian, Pacific Islander)	3.4	2.6
Unreported	2.2	2.6
Medicaid aid category code		
Aid to families with dependent children	61.3	52.2
Aid to disabled	35.2	44.4
Other (eg, aid to blind)	3.5	3.5
Health care utilization †		
Medical care utilization		
No. emergency department visits	7.4 (9.7)	3.9 (5.1)
No. inpatient admissions	3.6 (9.4)	3.5 (9.2)
Pharmacy utilization		
Unique pharmacies visited	3.9 (2.5)	2.8 (1.8)
No. opioid prescriptions when LIP criteria met	8.0 (1.3)	7.6 (1.0)
Medication-assisted treatment		
Any methadone treatment	1.7	0.8
Any buprenorphine prescription dispensed ‡	3.1	0.9
Medical diagnoses †		
Pain-related diagnoses		
Any joint pain or arthritis	81.5	77.0
Back pain	74.7	61.2
Neck pain	32.8	26.2
Headache/migraine	18.4	13.5
Fibromyalgia, chronic pain, or fatigue	36.7	29.5
Rheumatoid arthritis or osteoarthritis	17.2	15.9
Mental health diagnoses		

	Percentage or Mean (SD)	
	Enrolled (N=5479)	Not Enrolled (N=12,344)
Depression	49.3	40.5
Bipolar disorder	15.4	10.4
Personality disorder	2.8	1.3
Anxiety disorder	31.4	21.3
Posttraumatic stress disorder	5.2	3.1
Substance use-related diagnoses		
Any overdose	5.0	3.0
Alcohol-related disorder	5.9	5.7
Other substance-related disorder	20.6	12.0
Other comorbid conditions		
Mean Charlson comorbidity index	0.7 (1.4)	1.5 (2.7)
Cancer	0.6	12.9

* Assessed at time of meeting LIP eligibility.

† Assessed using a 1-year look-back period from point of meeting LIP eligibility.

‡ Buprenorphine prescription indicated for treatment of substance use disorder.

LIP indicates “lock-in” program.

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TABLE 3.

Average Adjusted* Daily Risks, Risk Differences, and Risk Ratios of Medication-assisted Treatment Administration Comparing LIP-related Periods, July 2009 to June 2013 (N = 17,823)

Program-related Period	Model-estimated Daily Risk Per 1000 Pop (95% CI) [‡]	Reference Period: Pre-LIP Eligibility Period		Reference Period: Post-LIP Eligibility Period	
		Daily Risk Difference Per 1000 Pop (95% CI)	Risk Ratio (95% CI)	Daily Risk Difference Per 1000 Pop (95% CI)	Risk Ratio (95% CI)
Pre-LIP eligibility	9.35 (5.90–14.81)	Ref	Ref		
Post-LIP eligibility	16.09 (10.29–25.14)	3.03 (–0.11 to 6.18)	1.33 (1.04–1.69)	Ref	Ref
Lock-in	24.86 (17.33–35.66)	12.02 (6.83–17.22)	1.99 (1.51–2.63)	8.99 (3.80–14.18)	1.50 (1.18–1.91)
Release	40.41 (18.56–88.01)	27.61 (–2.04 to 57.26)	3.01 (1.40–6.46)	24.58 (–5.14 to 54.29)	2.27 (1.07–4.80)

* Inverse probability of enrollment weighted and adjusted for secular trend.

[‡] Estimated from adjusted log-binomial generalized estimating equation model, using median value of secular trend for each period.

CI indicates confidence interval; LIP, “lock-in” program; Pop, population; Ref, reference.

TABLE 4.

Average Adjusted* Daily Risks and Risk Ratios[†] of Overdose Comparing LIP-related Periods, July 2009 to June 2013 (N = 17,823)

Program-related Period	Reference Period: Pre-LIP Eligibility Period		Reference Period: Post-LIP Eligibility Period
	Model-estimated Daily Risk Per 1000 Pop (95% CI) [‡]	Risk Ratio (95% CI)	Risk Ratio (95% CI)
Pre-LIP eligibility	0.16 (0.14–0.19)	Ref	
Post-LIP eligibility	0.22 (0.18–0.28)	2.04 (0.99–4.21)	Ref
Lock-in	0.22 (0.18–0.26)	2.06 (1.10–3.86)	1.01 (0.79–1.28)
Release	0.22 (0.16–0.29)	2.29 (0.95–5.46)	1.12 (0.82–1.54)

* Inverse probability of enrollment weighted and adjusted for secular trend.

[†] Linear-binomial generalized estimating equation models for overdose risk had convergence issues; therefore, risk differences are not presented.

[‡] Estimated from adjusted log-binomial generalized estimating equation model, using median value of secular trend for each period.

CI indicates confidence interval; LIP, “lock-in” program; Pop, population; Ref, reference.