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The lock-in loophole: Using mixed methods to explain patient circumvention of a Medicaid opioid restriction program

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Abstract

Background: Lock-in programs are proliferating among private and public payers to restrict access to controlled substance prescriptions and enhance care coordination for patients exhibiting high-risk use of, primarily, opioids. Patients enrolled in lock-in programs are required to seek opioids from a designated provider and pharmacy for insurance coverage of their opioid and benzodiazepine prescriptions. Lock-in program restrictions are often circumvented by patients through out-of-pocket cash purchases of opioid prescriptions, undermining the program's intended function. This study sought to construct and explain trajectories of Medicaid-covered and cash pay opioid prescription fills among adults enrolled in an opioid lock-in program.

Methods: We used sequential explanatory mixed methods, which involved a quantitative retrospective cohort analysis of opioid fill trajectories using North Carolina Medicaid administrative claims data linked with state prescription drug monitoring program data, followed by qualitative semi-structured interviews with North Carolina pharmacists. The quantitative component included adults enrolled in the North Carolina Medicaid lock-in program between 10/

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½010–3/3½012. The qualitative component included a maximum variation sample of community pharmacists in North Carolina delivering care to lock-in patients. Quantitative outcomes included group-based trajectories of monthly Medicaid-covered and cash pay opioid prescription fills six months before and after LIP enrollment, and qualitative analyses generated themes explaining observed trajectories.

Results: Two-thirds of subjects exhibited reduced Medicaid-covered opioid prescription fills and no increase in cash pay fills after lock-in enrollment, with one-third exhibiting increased cash pay fills after lock-in. Pharmacists attributed increases in cash pay fills primarily to illicit behaviors, while some cash pay behavior likely reflected new unintended barriers to care.

Conclusions: Lock-in programs appear to reduce prescription opioid use for most enrolled patients. However, lock-in programs may have limited capacity to deter illicit behaviors among patients intent on abusing, misusing, or diverting these medications and may introduce new access barriers to necessary care for some.

Keywords

Opioids; lock-in program; patient review and restriction program; Medicaid; managed care; opioid policy; health services research; mixed methods; trajectory modeling

Introduction

Policymakers and payers are hurriedly implementing new strategies to curb prescription opioid abuse and overdose, which claimed over 17,000 lives in 2017.[1] Lock-in programs (LIP), also known as patient review and restriction programs, are proliferating among health plans to tighten controlled substance (CS) access and enhance care coordination for high-risk patients.[2,3] In these programs, patients exhibiting high-risk opioid use behaviors are “locked-in” to one pharmacy and prescriber for prescription coverage of select controlled substances, including opioid analgesics, benzodiazepines, and opioid replacement therapies for opioid use disorder.

LIPs are expanding despite the poor understanding of their effects on patient behaviors and outcomes[4–8] and limited knowledge of the role of the “lock-in loophole” on program effectiveness.[4] The lock-in loophole is an LIP design limitation where patients can circumvent the health plan’s enforcement of the LIP restrictions by purchasing non-compliant opioid and benzodiazepine prescriptions entirely out of pocket, which may be written by a non-LIP provider or filled at a non-LIP pharmacy. These out-of-pocket prescription purchases may undermine the LIP’s ability to achieve positive health outcomes by enabling doctor-and pharmacy-shopping behaviors and reducing care coordination between the LIP patient and their LIP providers.

Prior research provided initial evidence that, on average, LIP enrollment is associated with increased cash payments for CS prescriptions.[9,10] However, we do not know how cash pay behaviors vary within LIP populations or why patients circumvent the LIP with cash pay opioid and benzodiazepine prescriptions.[3,4,10] The objectives of this study were twofold: (1) to examine distinct patterns of cash pay opioid and benzodiazepine prescription fills among North Carolina (NC) Medicaid LIP patients, and (2) to explain underlying reasons for

observed cash pay behaviors. This knowledge is important for improving LIPs' effectiveness combatting opioid abuse, misuse, and overdose.

Methods

Overall study design

We conducted a sequential explanatory mixed methods study[11] with an initial quantitative retrospective cohort study of trajectories of cash pay and Medicaid-covered CS prescription fills among NC Medicaid LIP patients followed by qualitative semi-structured interviews with NC Medicaid LIP pharmacists to strengthen interpretation of quantitative findings. Finally, we compared quantitative and qualitative findings to propose explanations for observed cash pay fill patterns among LIP patients.

Quantitative component

Design and cohort—We constructed trajectories of monthly cash pay and Medicaid-covered CS prescription fills before and after LIP enrollment in a retrospective cohort of NC Medicaid LIP patients locked in between LIP implementation on October 1, 2010 and March 31, 2012.[10,12] Patients were eligible for enrollment if they had > 6 opioid claims, > 6 benzodiazepine claims, or > 3 unique prescribers of these drugs over two consecutive months. Lock-in patients were restricted to a single prescriber and pharmacy for 12 months for Medicaid coverage of opioid and benzodiazepine prescriptions. Patients with dual Medicare eligibility or cancer were excluded from the LIP. Our sample included LIP patients age 18–64 who had continuous NC Medicaid coverage for 12 months prior to and 6 months following their lock-in date to ensure a sufficient baseline period for patient characteristic measures and follow-up period for study outcomes.

Data—We linked NC Medicaid claims data with NC prescription drug monitoring program (PDMP) data. PDMP data included records of all dispensed controlled prescriptions in NC from October 1, 2009 through September 30, 2010, which were electronically submitted daily by NC pharmacies to the PDMP database. These linked data allowed us to observe all cash pay opioid and benzodiazepine prescriptions lacking a corresponding Medicaid claim.

Measures—We assessed two outcome measures for each patient in the six months before and after the lock-in period: (1) monthly count of cash pay opioid and benzodiazepine fills and (2) monthly count of Medicaid-covered opioid and benzodiazepine fills. In the six month baseline period before the outcome measures were measured, we assessed patient age at LIP enrollment, sex, race, metropolitan residence,[13] Charlson comorbidity score,[14] indicators of LIP eligibility criteria, and diagnoses of chronic pain, substance use disorder, anxiety disorder, depression, or other mental health condition.[15]

Analysis—Joint group-based trajectory modeling (GBTM) was used to detect and depict distinct longitudinal patterns of cash pay and Medicaid-covered opioid and benzodiazepine prescription fills. GBTM is a form of finite mixture modeling that assumes a cohort consists of distinct groups with a shared longitudinal pattern of an outcome.[9] GBTM estimates shapes of trajectories and predicts an individual's probability of being classified into a given

group.[16] Joint GBTM is an extension of this method that identifies groups of paired trends of distinct but related outcomes.[17,18] First, we estimated the unadjusted joint trajectories of the two study outcomes using a zero-inflated Poisson distribution. These were modeled beginning in the six months before through the six months after an individual's LIP enrollment date. We estimated up to four trajectory groups for each outcome (up to 16 joint trajectory groups), to facilitate practical interpretation. The number of groups and the polynomials dictating the shape of each trajectory were defined in the final joint GBTM model through an iterative process based on minimizing the Bayesian Information Criterion to maximize model fit.[19]

The final joint GBTM model estimated 16 joint trajectory groups. Joint trajectory groups exhibiting similar paired outcome trends over time were aggregated to enhance interpretation of subsequent analyses. Four aggregate joint trajectory groups were created. We used descriptive statistics to report patient characteristics within aggregate joint trajectory groups and modified Poisson generalized linear models (GLM) to estimate the association between patient characteristics and aggregate trajectory group membership.[20] We controlled for time with fixed effects for a quarter of LIP enrollment. All analyses were performed using STATA 13 and SAS version 9.4.[19]

Qualitative component—Using a grounded theory approach,[21] the follow-up qualitative component consisted of semi-structured interviews with NC pharmacists experienced delivering care to NC Medicaid LIP patients. An ideal qualitative follow-up study would have included LIP patients; however, patient interviews were not allowed by program administrators. Pharmacists are the best alternative because the responsibility for maintaining LIP integrity falls primarily on the pharmacist. LIP pharmacists also interface with LIP patients and prescribers and have rich knowledge of the system, provider, and patient-level factors affecting LIP patient behaviors.

Sampling—All licensed NC pharmacists were sent an informational email containing a link to a brief survey assessing basic information about their practice, LIP patient care experience, and interest in participating in a semi-structured interview. From a pool of 85 respondents, we included pharmacists who reported interaction with at least 5 LIP patients in the past two years, practiced in a community or outpatient pharmacy, worked full-time, and had been in practice for at least 2 years. We then applied a maximum variation purposeful sampling strategy to select pharmacist interviewees representing varied perspectives in terms of pharmacist gender, pharmacy type (chain, grocery, or independent), and geographic setting (rural, regional/suburban, or urban county).[22,23]

Interviews and analysis—Telephonic interviews were conducted using a short semi-structured interview guide designed to elicit conversation about the system, provider, and patient-level factors that explain the central phenomenon of LIP patients obtaining cash pay opioid and benzodiazepine prescriptions (Supplemental Figure 1). Specifically, pharmacists were questioned about the extent of their interaction with LIP enrollees, the underlying reason for patients' LIP enrollment (e.g. chronic pain, substance use disorder, or doctor shopping), their observed effects of LIP enrollment on patient behaviors, and program feedback received directly from LIP enrollees. Interviews lasted 20min and were recorded

and transcribed. Interview transcripts were coded and analyzed to generate themes using the constant comparative analysis method.[24,25] Given the limited scope, thematic saturation was reached at 13 pharmacist interviews.

Mixed component—The final phase of the sequential explanatory mixed-methods study involved comparing quantitative joint GBTM results with qualitative findings to generate empirical explanations of how LIP enrollment affects controlled substance-seeking behavior among Medicaid patients at high risk for preventable prescription drug abuse and misuse outcomes. This study was approved by the Creighton University Institutional Review Board.

Results

Quantitative findings

The final retrospective cohort included 1936 adult NC Medicaid LIP patients. Joint GBTM analysis identified four distinct trajectories for each of the Medicaid-covered and cash pay (Figure 1) opioid and benzodiazepine fill count outcomes. GBTM analysis performed well with trajectory group membership probabilities ranging from 0.83 to 0.94 (Supplemental Tables 2a and 2b).

All four trajectories of the Medicaid-covered fill outcome began to decline in the months preceding lock-in enrollment (Figure 1), leveling off after lock-in. Most patients exhibited a partial reduction in Medicaid-covered fills after lock-in (Groups M3, M4), while Medicaid-covered fills ceased shortly after lock-in enrollment among 31% of the cohort (Groups M1, M2). Regarding the cash pay outcomes, half had no cash pay opioid or benzodiazepine prescription fills (Figure 1, Group C1). Another 15% exhibited consistently low cash pay behavior (Group C2). One-third of patients exhibited new, rising cash pay fills post-lock-in after having negligible cash pay fills before LIP enrollment (Groups C3, C4).

Sixteen joint trajectory groups were identified by pairing a Medicaid-covered fill trajectory with a cash pay fill trajectory (Supplemental Figure 2 depicts all joint trajectory groups). The 4 aggregate joint trajectories based on comparable trends are shown in Figure 2. Half of the cohort belonged to a joint trajectory group in which Medicaid-covered opioid and benzodiazepine fills partially decreased after lock-in enrollment with minimal cash pay fills before and after lock-in (Aggregate Group 1). The rest of the cohort was fairly evenly distributed across the other three aggregate groups: Medicaid-covered fills stop and cash pay fills remain minimal (Aggregate Group 2, 17%); Medicaid-covered fills stop and cash pay fills increase (Aggregate Group 3, 14%); and Medicaid-covered fills partially decrease and cash pay fills increase (Aggregate Group 4, 21%).

Table 1 describes patient characteristics by aggregate joint trajectory group. Patients in groups in which Medicaid fills stopped were younger and lived in more metropolitan counties than those in which Medicaid-covered fills partially decreased. Aggregate Group 1 (“Medicaid stops, Cash pay minimal”) had a higher proportion of nonwhite patients than the other three aggregate groups (28% vs. 22–25%). Baseline anxiety disorder diagnosis was most prevalent among patients with partially decreasing Medicaid-covered fill and

increasing cash pay joint trajectories (54% vs. 36–48%). Patient characteristics by individual trajectory are shown in Supplemental Tables 3a and 3b.

Table 2 reports findings from GLM analysis estimating the association of patient characteristics with aggregate joint trajectory group membership. Patients in older age groups were significantly more likely to belong to a joint trajectory group in which Medicaid-covered fills stopped after lock-in (Aggregate Groups 1, 3). Older patients were more likely to exhibit a partial reduction in Medicaid-covered fills without cash pay behavior (Aggregate Group 2). Aggregate Group 1 membership, whose Medicaid-covered fills ceased and cash pay fills were minimal, was more probable among patients with a substance use disorder diagnosis and those who did not satisfy any of the NC Medicaid LIP eligibility criteria, indicating they were likely referred for enrollment by a provider. Patients with a baseline anxiety disorder or who became LIP-eligible from high benzodiazepine use were more likely to belong to Aggregate Group 4, where Medicaid-covered fills partially decreased while cash pay fills increased.

Qualitative findings

Characteristics of the 13 pharmacist interview respondents are reported in Supplemental Table 1. Most respondents were female (54%), were the pharmacist-in-charge (69%), and had been in practice for a median of 8 years. Thirty-eight percent practiced in rural counties and most were employed by national pharmacy chains. Nearly half of respondents had interacted with 25 or more LIP enrollees in the past 2 years. Qualitative analysis of interview transcripts with pharmacists produced five themes about the drivers of the cash pay phenomenon observed in quantitative analyses.

1. **The LIP works as intended for most patients.** Pharmacists commented that, while cash pay behavior among LIP patients was prevalent, most patients abided by LIP restrictions, particularly those receiving care through a pain clinic or substance use treatment clinic.

> You have patients that are really sick... and they understand and they do fine and we never hear from them again.

> Most of these folks that have gone to the substance abuse clinics or have chronic pain, they’re doing it out of necessity. It is not something where I think their goal is to divert the medicines or anything.

2. **LIP restrictions do not deter illicit behaviors.** When cash payments did occur, pharmacists primarily attributed it to illicit behaviors. They observed LIP restrictions were outmatched by the motivation and resourcefulness of patients intent on abusing or diverting these drugs. Also, the cash price of LIP-restricted prescriptions was much less than the potential revenue from their street sale.

> Regardless of what types of programs payers come up with, if a patient wants to get that medication because they feel that they need it, or they want it that bad—or maybe there might be a diversion issue where a patient is selling the medication—they are going to get that medication regardless.

> I think people underestimate how resourceful these patients are and that they are in survival mode.
>
> We have quite a few lock-in patients who . we can tell are abusing the system, because they come and already know the medication is not going to be paid for. They will say, 'I will just pay cash.'
>
> There's definitely going to be that patient that [price] doesn't matter. This is a source of income for them, and if they have to pay $30 versus $3, and they're going to sell it for $10 a pill, there's still money to be made.

3. **LIP restrictions introduce barriers to necessary care.** Pharmacists stated LIP patients often attempt to fill legitimate opioid or benzodiazepine prescriptions from non-LIP pharmacies for reasonable extenuating circumstances. For example, an LIP pharmacy with insufficient medication stock or limited hours of operation results in patients seeking legitimate prescriptions from non-LIP pharmacies. Or a patient may have been discharged with a prescription following an unexpected hospitalization and prefer to fill it at the closest pharmacy instead of their LIP pharmacy. In these circumstances, pharmacists attempting to fill a legitimate prescription for an LIP patient locked in elsewhere receive a Medicaid claim rejection. LIP patients are frustrated by the inflexibility of the program in these situations, and pharmacists must decide if they will allow cash payment.

> This patient was straightforward, honest. Everything made sense to them, so I didn't feel funny about [allowing cash payment].
>
> They weren't happy about it. But they, you know, felt they really needed it so they were okay to pay cash.
>
> I couldn't fill their prescription because it said they were locked in to another pharmacy. They said, 'Oh, I know, I know.' They did pay cash because they were closer to me. I did look them up [in the PDMP] and everything was legitimate.

Three pharmacists stated the majority of their LIP patients live out of town but are locked into their pharmacy because it is close to their lock-in prescriber's specialty pain or substance use disorder clinic. In this scenario, LIP patients must travel out of town to obtain Medicaid-covered prescriptions for any opioid or benzodiazepine therapy.

> I'll have folks locked in where they can only get their Suboxone or some of the other buprenorphine products at my pharmacy, but they live in [other nearby towns]. They're running into issues where they're trying to get their Xanax and they're locked in at my pharmacy.

LIP patients who frequently move, have limited transportation, or have limited means of communication struggle with navigating LIP restrictions. However, many pharmacists believed that most of the barriers to legitimate care are preventable by coordinating with program administrators.

> They're understanding that it takes some time to get things fixed and once it is fixed it works well.

> I would say [the LIP] worked more times than it was a failure. And if it was a failure, it was probably on the patient's part for moving and not notifying that they have moved 200 miles across the state.

Certain LIP technical logistics introduce barriers for patients and providers. Pharmacists cannot override an LIP claim rejection to process a legitimate prescription claim for an LIP patient unable to use their designated providers. Medicaid claim rejections for LIP patients do not inform the pharmacists to whom the patient is locked in. LIP patients can request provider changes from Medicaid only during normal business hours. Patients locked into a specialty prescriber for pain or addiction treatment were unable to designate another LIP prescriber for treatment of other conditions managed with benzodiazepines. This forces the patient to pay cash or delay necessary treatment.

> If someone comes to my pharmacy because I have Suboxone in stock or OxyContin or some of these other medicines they've been maintained on, I should be able to call Medicaid and say, 'Hey, their primary lock-in pharmacy does not have the medicine. I need an override.'

> There's a lot of pain management doctors that'll do a pain management medication, but they won't do a benzo. So if they need a benzo, then they're kind of left out in the cold.

4. **Patients lacking LIP program knowledge experience challenges.** Insufficient patient education about LIP restrictions, procedures, and purpose contribute to patients seeking care outside of their LIP providers. Patients who receive this training are better equipped to navigate the program.

> It really helps for somebody to pick up the phone, a nice voice on the other end that says, 'I understand that you got a letter from Medicaid. I'm here to help. What do you know about it? What can I answer for you? Do you mind if I explain it to you? Here's what you're going to do if you need to switch a provider. If you need help you need to let us know.' It makes a big difference to get them at the beginning.

5. **Engaged providers improve LIP integrity.** Pharmacists stressed the importance of establishing patient/provider relationships, the benefits of LIP providers taking the initiative to enforce the LIP restrictions, and assisting LIP patients experiencing access barriers. This helps mitigate cash pay behaviors and maintain the program's care coordination.

> We all know our customers. We know what days they come in. We know what other medicines they're on. We know how they're going to pay. Knowing our customers has helped the lock-in program work better for us.

> We do not allow them to pay cash, because that needs to be on the radar.

Mixing findings

We compared quantitative and qualitative findings to propose evidence-based explanations of the cash pay phenomenon among LIP patients.

Explanation 1: Most LIP patients do not pay cash for opioid and benzodiazepine prescription fills. Two-thirds of the retrospective cohort belonged to a joint trajectory group where Medicaid-covered opioid and benzodiazepine fills decreased post-lock-in, while cash pay behavior remained negligible (Aggregate Groups 1,2). Semi-structured interviews with LIP pharmacists agreed that most patients abide by the LIP (Theme 1).

Explanation 2: Most cash pay behavior is illicit in nature. While pharmacists did recall instances in which LIP enrollees sought to pay cash for legitimate opioid or benzodiazepine prescriptions because of reasonable extenuating circumstances, they attributed most cash pay prescription fills to abuse and diversion, combined with the program's inability to curb this behavior. Joint trajectory groups showing an increase in cash pay prescriptions following lock-in provide some observational evidence of this phenomenon. This notion was supported in trajectory analysis, primarily Aggregate Group 3 ("Medicaid stops; Cash pay increases"), which may have captured LIP patients that understood the LIP loophole and purposefully circumvented the program by paying cash for controlled medications intended for abuse or diversion.

Explanation 3: LIP restrictions can pose barriers to necessary care, particularly for patients with complex needs. Pharmacist interviews uncovered multiple patient-, pharmacy-, and program-specific factors that lead patients to seek necessary care from non-LIP providers. The cash pay behaviors of patients in these situations are likely depicted in Aggregate Group 4 ("Medicaid drops; Cash pay increases") joint trajectory groups. These patients continue to utilize their Medicaid coverage to obtain restricted prescriptions, but they engage in new cash pay behaviors after LIP restrictions are imposed. GLM analysis found that patients with anxiety disorders or who became eligible for LIP enrollment due to high benzodiazepine use were significantly more likely to belong to this group. This finding corroborates reports from pharmacists that LIP patients who are locked into a specialty provider for opioid management often struggle to secure Medicaid coverage of benzodiazepine prescriptions from non-LIP prescribers.

Discussion

Patients enrolled in the NC Medicaid LIP did not behave uniformly when faced with prescriber and pharmacy restrictions for opioid and benzodiazepine coverage. A recent study by Naumann, et. al. using similar data and methods identified heterogeneity in the trajectories of the amount of opioids patients received before and after enrollment in the NC Medicaid LIP, measured as milligram morphine equivalents.[26] However, our study is the first to examine the simultaneous patterns of Medicaid-covered and cash pay controlled substance prescription fills within an LIP population and explain the underlying factors driving the observed lock-in loophole behavior.

For most patients, the LIP appeared to achieve the intended effect on utilization—a decrease in opioid and benzodiazepine Medicaid claims without increasing cash pay behavior. This may demonstrate LIPs' potential to improve care coordination for most high-risk patients targeted for LIP intervention. However, the bulk of the decline in the Medicaid-covered fills occurred in the four months prior to LIP enrollment in each trajectory group. This may be

explained by a natural drop in use of these medications in the period between an acute healthcare event that led to their LIP eligibility and actual enrollment in the program, which was often delayed up to 6 months. Additionally, LIP enrollment spurred new opioid and benzodiazepine cash pay behavior in one-third of the cohort. Cash pay prescriptions undermine LIP providers' and administrators' ability to monitor and coordinate care for LIP patients. As LIPs proliferate, in Medicare Part D plans in 20 1 9,[27] it is important to mitigate unintended medication-seeking behaviors after LIP enrollment.

The first step is understanding why LIP patients pay cash for opioid and benzodiazepine prescriptions. In a previous study examining the effects of LIP enrollment on cash pay behaviors at the population level,[10] we speculated that cash pay prescriptions were driven by abuse or diversion and difficulties navigating LIP restrictions to obtain necessary care. In the present study, our mixed-methods approach allowed us to not only identify heterogeneous utilization patterns within an LIP population but it also largely verified our previous assertions.

According to NC pharmacists with experience delivering care to LIP enrollees, the motivations leading a patient to pay cash for an opioid or benzodiazepine prescription in the NC Medicaid LIP were multifactorial. In many cases, LIP patients pay cash to facilitate continued abuse or diversion of prescription opioids and benzodiazepines. Other LIP patients have a legitimate medical need for these prescriptions and pay cash because of the program's inability to accommodate reasonable extenuating circumstances. Both of these primary drivers of cash pay behavior in LIPs is exacerbated by insufficient education of LIP providers and patients about program operations and purpose.

Plans currently operating or preparing to implement a LIP should take practical measures to mitigate cash pay prescription fills occurring for legitimate reasons. First, the LIPs should be flexible enough to accommodate patients with complex clinical care or legitimate extenuating circumstances. LIPs should consider developing and evaluating protocols that would allow pharmacists to override claim rejections in appropriate circumstances when LIP patients urgently require a legitimate restricted prescription that was prescribed by a non-LIP provider or presented at a non-LIP pharmacy. A second lock-in prescriber or pharmacy should be allowed for patients receiving specialty pain or addiction treatment, especially when these specialty providers are not geographically proximal to the patient. Forthcoming Medicaid Part D LIPs will incorporate this flexibility.[27] Second, the scope of LIP functions should be expanded to provide necessary wraparound services. Connecting LIP patients to substance use disorder treatment and ancillary social services may help improve adherence to LIP restrictions and, subsequently, patient outcomes. Lastly, LIP education should be expanded to counsel patients and providers about how to anticipate and resolve situations where the LIP may pose a barrier to necessary care.

Our quantitative findings raise potential, and currently unverified, concerns that LIP restrictions on prescription opioids may inadvertently spur a small number of patients to increase illicit opioid use, such as heroin or illicit fentanyl. Of particular concern are patients in Aggregate Group 1 ("Medicaid stops; Cash pay minimal"), who comprised 17% of our sample, who ceased all observable prescription fill behavior in legal drug distribution

channels after lock-in. These patients were younger, more likely to have a substance use disorder, and more likely to be specifically referred for LIP enrollment by a provider. Given the alarming rise in heroin and fentanyl overdose since 2010,[28] further research into this potential unintended consequence of LIPs is paramount.

Our study has several limitations, including limited generalizability to other LIP populations because LIP design can vary substantially. Also, we allowed our group-based trajectory models to produce a maximum of 16 joint trajectory groups to facilitate meaningful interpretation. It is possible that allowing a greater number of trajectories could have altered our interpretation. We were also unable to contact current or former NC Medicaid LIP enrollees for this study due to NC Medicaid program privacy concerns. We recognize pharmacist interviews cannot substitute for the perspectives and experiences of LIP enrollees, and future research should seek to interview or survey LIP enrollees about their experiences in the LIP. Moreover, our quantitative data sources were unable to observe out-of-state prescription fills, the ultimate end user of dispensed medications, and potential unmeasured confounders, including NC Medicaid coverage category. Lastly, we did not examine opioid and benzodiazepine use separately in quantitative analyses; however, our prior work has demonstrated that opioid use is overwhelmingly more prevalent than benzodiazepine use before and after LIP enrollment.[10,26]

Lock-in programs are blunt tools affecting a high-risk patient population with diverse needs and motivations for using opioids and benzodiazepines. LIPs capture high-risk patients with legitimate, complex clinical needs as well as individuals engaged in abuse or diversion. Our findings should inform targeted LIP improvements that mitigate access to opioids and benzodiazepines for abuse and diversion while connecting these patients to treatment. At the same time, LIPs must be flexible enough to allow patients to obtain legitimate medical care while enhancing care coordination between providers.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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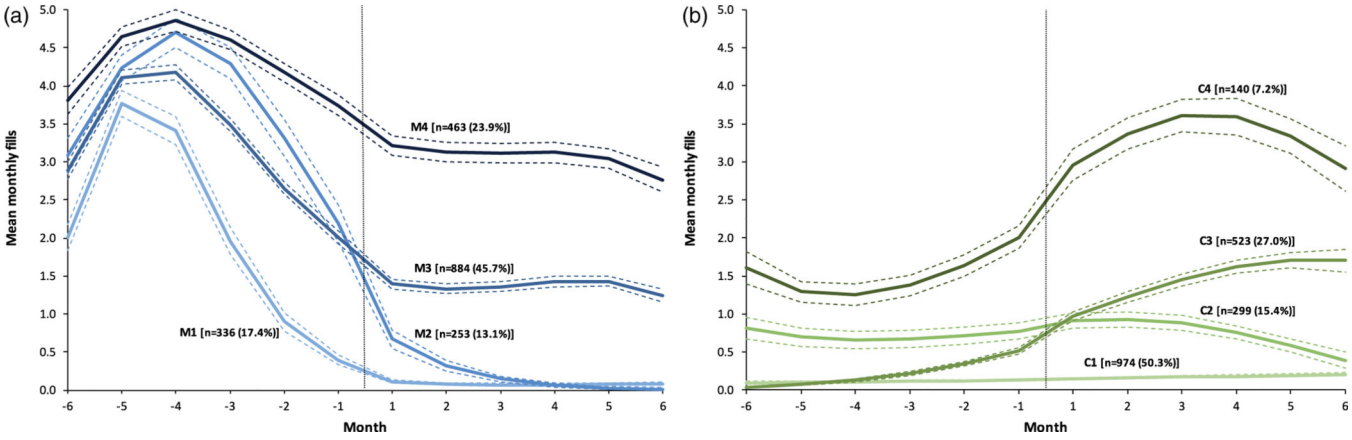

Figure 1.

Individual group-based trajectories of (a) monthly Medicaid-covered opioid and benzodiazepine prescription fills and (b) monthly cash pay opioid and benzodiazepine prescription fills among lock-in program patients. *Note.* The vertical dotted line represents date of lock-in program enrollment. The paired dotted lines encompassing each trajectory indicate 95% confidence intervals. Trajectories were estimated with joint group-based trajectory modeling using a Poisson distribution for the count outcome measure of number of (a) Medicaid-covered opioid or benzodiazepine prescription fills and (b) cash pay opioid or benzodiazepine prescription fills in a month of observation.

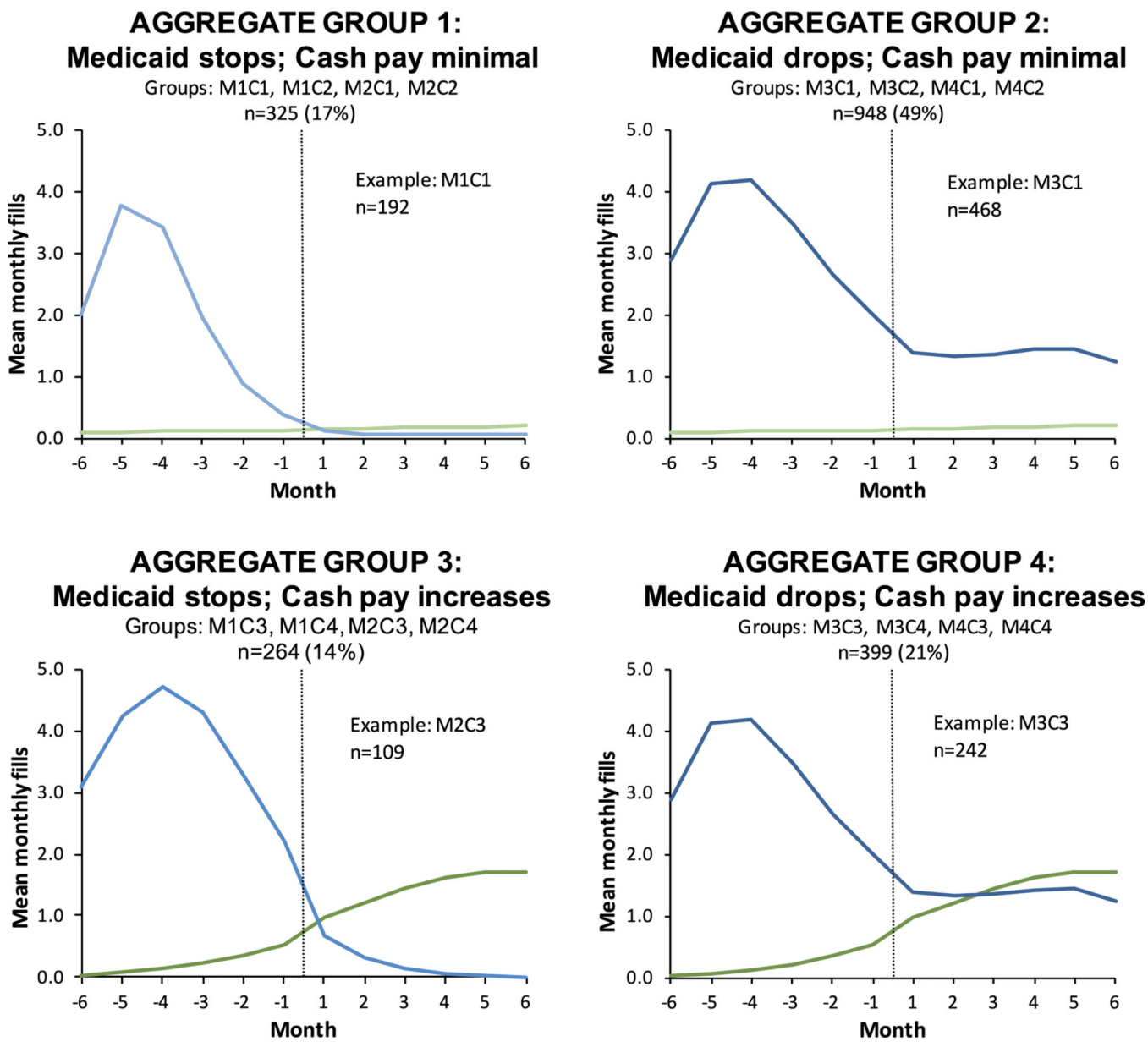

Figure 2.

Joint group-based trajectories of Medicaid-covered and cash pay opioid and benzodiazepine fills, aggregated into similar joint trajectory patterns. *Note.* M*x*C*x* group notations indicate a joint trajectory group, which pairs a Medicaid-covered opioid and benzodiazepine fill trajectory group (M1-M4) with a cash pay opioid and benzodiazepine fill trajectory group (C1-C4) depicted in Figure 1. The four joint trajectories depicted represent the most frequent joint trajectory within each aggregate group. The vertical dotted line represents date of lock-in program enrollment

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Table 1.

Cohort characteristics, by aggregate joint trajectory group.

	Aggregate Group 1 Medicaid stops; Cash pay minimal	**Aggregate Group 2 Medicaid drops; Cash pay minimal**	**Aggregate Group 3 Medicaid stops; Cash pay increases**	**Aggregate Group 4 Medicaid drops; Cash pay increases**
Joint trajectory groups included	M1C1, M1C2, M2C1, M2C2	M3C1, M3C2, M4C1, M4C2	M1C3, M1C4, M2C3, M2C4	M3C3, M3C4, M4C3, M4C4
n (%)	325 (16.8%)	948 (49.0%)	264 (13.6%)	399 (20.6%)
Age, mean (SD)	35.9 (10.7)	41.2 (10.2)	36.7 (10.3)	39.8 (10.5)
Age categories, *n* (%)				
18–30	125 (38.5%)	159 (16.7%)	85 (32.2%)	95 (23.8%)
31–40	100 (30.8%)	288 (30.4%)	96 (36.4%)	115 (28.8%)
41–50	58 (17.9%)	306 (32.3%)	52 (19.7%)	125 (31.3%)
51–64	42 (12.9%)	195 (20.6%)	31 (11.7%)	64 (16.0%)
Female, *n* (%)	223 (68.6%)	681 (71.8%)	191 (72.4%)	289 (72.4%)
Race, *n* (%)				
White	235 (72.3%)	731 (77.1%)	206 (78.0%)	300 (75.2%)
Black	69 (21.2%)	154 (16.2%)	43 (16.3%)	74 (18.6%)
Other	21 (6.5%)	63 (6.7%)	15 (5.7%)	25 (6.3%)
Metropolitan residence[a], *n* (%)	242 (74.5%)	670 (70.7%)	203 (76.9%)	287 (71.9%)
Baseline diagnoses, *n* (%)				
Substance use disorder	135 (41.5%)	318 (33.5%)	109 (41.3%)	151 (37.8%)
Chronic pain	271 (83.4%)	881 (92.9%)	246 (93.2%)	376 (94.2%)
Anxiety disorder	116 (35.7%)	443 (46.7%)	126 (47.7%)	216 (54.1%)
Depression	98 (30.2%)	418 (44.1%)	124 (47.0%)	191 (47.9%)
Other mental illness	119 (36.6%)	374 (39.5%)	125 (47.4%)	159 (39.9%)
Charlson comorbidity score[b], *n* (%)				
0	199 (61.2%)	456 (48.1%)	150 (56.8%)	187 (46.9%)
1	82 (25.2%)	257 (27.1%)	68 (25.8%)	106 (26.6%)
2 or more	44 (13.5%)	235 (24.8%)	46 (17.4%)	106 (26.6%)
LIP eligibility				
Opioid Rx fills	256 (78.8%)	799 (84.3%)	220 (83.3%)	348 (87.2%)

	Aggregate Group 1 Medicaid stops; Cash pay minimal	Aggregate Group 2 Medicaid drops; Cash pay minimal	Aggregate Group 3 Medicaid stops; Cash pay increases	Aggregate Group 4 Medicaid drops; Cash pay increases
Benzodiazepine Rx fills	3 (0.9%)	30 (3.2%)	8 (3.0%)	21 (5.3%)
Pharmacy shopping	240 (73.9%)	630 (66.5%)	206 (78.0%)	297 (74.4%)
No criteria met[c]	34 (10.5%)	53 (5.6%)	14 (5.3%)	14 (3.5%)

Note. SD: Standard deviation; Rx: Prescription. M*x*C*x* group notations indicate a joint trajectory group, which pairs Medicaid-covered opioid and benzodiazepine fill trajectory group (M1-M4) with a cash pay opioid and benzodiazepine fill trajectory group (C1-C4) depicted in Figure 1.

[a] Residence in a county with a Rural-Urban Continuum Code designation of 1–3.

[b] Charlson scores were calculated using the Quan modification.[14]

[c] Subject did not meet any of the three LIP eligibility criteria based on claims data review. We assumed these subjects were referred for LIP enrollment by a healthcare provider.

Table 2.

Results of generalized linear models estimating likelihood of aggregate joint trajectory group membership.

	Aggregate Group 1 Medicaid stops; Cash pay minimal *n* = 325 (17%) RR	**Aggregate Group 2 Medicaid drops; Cash pay minimal *n* = 948 (49%) RR**	**Aggregate Group 3 Medicaid stops; Cash pay increases *n* = 264 (14%) RR**	**Aggregate Group 4 Medicaid drops; Cash pay increases *n* = 399 (21%) RR**
Age				
18–30 (reference)				
31–40	0.68**	1.38**	0.89	0.91
41–50	0.48**	1.58**	0.56**	1.06
51–64	0.55**	1.63**	0.57**	0.90
Female	0.84	1.07	0.92	1.04
Nonwhite	1.26*	0.91	0.97	1.05
Metropolitan residence[a]	1.12	0.91	1.28	0.97
Baseline clinical diagnoses				
Substance use disorder	1.29*	0.87**	1.12	1.00
Chronic pain	0.63**	1.07	1.43	1.31
Anxiety disorder	0.77*	1.01	0.90	1.29**
Depression	0.67**	1.02	1.22	1.14
Other mental illness	1.01	0.99	1.27	0.87
Charlson comorbidity index[b]				
0 (reference)				
1	0.95	1.02	0.94	1.05
2 or more	0.72*	1.05	0.80	1.21
LIP eligibility				
Opioid Rx fills	0.91	0.94	0.91	1.32
Benzodiazepine Rx fills	0.35	0.92	0.91	1.76**
Pharmacy shopping	1.25	0.85**	1.32	1.16
No criteria met[c]	1.68*	0.78	1.09	0.93

** *Note.* $p < .01$,

* $p < .05$; RR: Relative risk; Rx: Prescription. M*x*C*x* group notations indicate a joint trajectory group, which pairs a Medicaid-covered opioid and benzodiazepine fill trajectory group (M1 -M4) with a cash pay opioid and benzodiazepine fill trajectory group (C1 -C4) depicted in Figure 1. Relative risks were estimated in each model using modified Poisson generalized linear models estimating the association of patient characteristics with membership in an aggregate joint trajectory group, compared to all other aggregate joint trajectory groups.

[a] Residence in a county with a Rural-Urban Continuum Code designation of 1 −3.

[b] Charlson scores were calculated using the Quan modification.[14]

[c] Subject did not meet any of the three LIP eligibility criteria based on claims data review. We assumed these subjects were referred for LIP enrollment by a healthcare provider.