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Retrospective Review

Consumer/Patient Encounters with Prescription Drug Monitoring Programs: Evidence from a Medicaid Population

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Background: Prescription drug monitoring programs issue reports about a patient's controlled substance prescription history upon request to physicians, law enforcement officials, and pharmacists. The dual purposes of these programs are to reduce the abuse and diversion of controlled substances while not preventing access to these medications for legitimate medical need.

Objective: The purpose of this study was to examine the experiences of Medicaid patients with Kentucky's Prescription Drug Monitoring Program (PDMP).

Study Design: A random sample of Medicaid patients was surveyed in 2010; respondents were matched with patient retrospective claims data from 6 months prior to the survey's administration.

Study Setting: Kentucky Medicaid patients from across the state.

Methods: A combination of patient surveys and Medicaid claims data was used to test the relationship between patient characteristics and patient-reported interactions with physicians regarding their PDMP reports and whether they experienced difficulty obtaining or filling a prescription for a controlled substance due to a PDMP report.

Results: Most Medicaid patients are unaffected by the PDMP; however, patients diagnosed with chronic non-cancer pain conditions and patients reporting a Hispanic ethnicity are significantly more likely to have a physician discuss their PDMP report with them. Patients diagnosed with chronic non-cancer pain conditions are also significantly more likely to report difficulty obtaining a prescription for a controlled substance than patients that have not been diagnosed with chronic non-cancer pain conditions. Patients living in rural areas are significantly less likely than patients in urban areas to report difficulty obtaining a prescription for a controlled substance.

Limitations: The utilization of controlled substance prescriptions by respondents was not measured or monitored. The Medicaid population examined in this study may not be representative of the population as a whole.

Conclusions: These results suggest that more attention to the consumer/patient perspective is warranted in maintaining a balanced approach to decreasing drug abuse and diversion while not limiting access to controlled substances in cases of legitimate medical need

Key words: Prescription Drug Monitoring Program, Medicaid, controlled substances, chronic pain patients, patient experiences, KASPER

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Prescription drug misuse compromises the health and well-being of numerous individuals worldwide, and the problem is considered an epidemic in the United States (1). An equally devastating crisis is undertreated or untreated pain (2). The common denominator for both of these problems is controlled substance medications, including opioid pain relievers, anxiolytics, and sedatives. Controlled substance consumption, of opioids in particular, has been on the rise for both nonmedical and therapeutic users (3). The use of opioids to manage non-cancer chronic pain is somewhat medically controversial, due to the possible deleterious effects associated with long-term opioid use and increased risks for abuse (4,5). A further complication of opioid use in the management of chronic pain is assessing misuse in patients who are prescribed opioid therapies for legitimate medical need (6).

Many states have implemented prescription drug monitoring programs (PDMPs) to address the problems of controlled substance abuse and diversion. Although programs vary, PDMPs allow health care professionals who prescribe or dispense controlled substances to easily access PDMP databases at the point of care. Patients' use of scheduled medications can be confirmed by the PDMP report, allowing prescribers and dispensers to detect individuals who may be "doctor shopping" to acquire drugs for the purpose of abuse or diversion. In addition to prescribers and dispensers, many states allow regulatory and law enforcement agencies involved in drug-related investigations to access PDMP databases, enabling efficient collection of data that may be useful to identify individuals involved in diversion or misuse of controlled prescription drugs.

The few evaluations of state PDMPs that have been conducted thus far have found that the programs are somewhat successful at reducing diversion (7,8), though a criticism of PDMPs is that they have a negative impact on patient access to needed medical treatment. This has been dubbed "the Chilling Effect" of PDMPs, and it refers to the reluctance to prescribe or dispense controlled substances for fear of legal retribution (2,9). A chilling effect could limit access to controlled substances for appropriate medical care. To date, formal research on the chilling effect is rare. Surveys indicate that some prescribers underutilize controlled substances due to fear of legal repercussions (2,10); empirical research confirms potentially inappropriate underutilization of controlled substances in select diseases and conditions (11).

In 1999, Kentucky implemented the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program. This PDMP allows prescribers, pharmacists, and law enforcement officials to request reports that provide detailed information about the history of controlled substances dispensed to an individual. In 2005, an electronic version of KASPER was implemented that allows prescribers and pharmacists to receive reports in real time. Dispensers of controlled substances are required to submit dispensing records to KASPER within 7 days of dispensing.

Surveys of prescribers, pharmacists, and law enforcement officials that use KASPER suggest that it is effective at curbing controlled substance abuse and diversion (12), yet objective data to confirm these subjective findings is somewhat lacking. Recently, an independent evaluation of the KASPER program was conducted to assess its impact and effectiveness on curbing controlled substance abuse and to determine if it was causing a chilling effect (12). The review examined evidence from interviews with key stakeholders, a survey of KASPER system users, analysis of KASPER usage, and review of relevant data sets, including Automation of Reports and Consolidated Orders System, Treatment Episode Data Set, and Kentucky Medicaid. The authors conclude that KASPER has been an effective tool to reduce controlled substance abuse and does not appear to impart a chilling effect. The authors note, however, that additional research is needed to understand whether a chilling effect is occurring.

Surprisingly, no published research has evaluated the chilling effect from the patient's perspective. This is curious, as ultimately it is the individual consumer/patient who will bear the consequences of such an effect via inadequate treatment. As an initial assessment of patient experiences, this project surveyed Kentucky Medicaid beneficiaries to obtain information about their experience with the KASPER program. Our hypotheses were:

1) The majority of Kentucky Medicaid recipients with chronic pain conditions have discussed their KASPER report with a health care provider.
2) Medicaid recipients do not encounter difficulty accessing health care providers willing to issue controlled substance prescriptions.
3) Medicaid recipients do not encounter difficulty accessing pharmacists willing to dispense controlled substance prescriptions.
4) Medicaid recipients with chronic pain conditions are more likely to encounter difficulty accessing con-

trolled substance prescriptions than those who do not have chronic pain.

Methods

Survey methodology was used to elicit consumer/patient opinions about controlled substance access and the KASPER PDMP. A random sample of Kentucky Medicaid beneficiaries over age 18 was contacted by mail to complete a modified version of the Consumer Assessment of Health Plans Survey (CAHPS) (13). The CAHPS instrument queries participants about health status, service utilization, and demographic characteristics, and asks them to rate their providers and health plans (14). Twenty-two questions were added to address Kentucky-specific health issues; 3 of these questions asked about experience with the KASPER program. A reminder postcard and second survey were sent to those who did not respond 2 weeks after the first mailing. They were not contacted again after the reminder postcard and second survey mailing. Responses were coded and 25% of the surveys were re-coded to test intercoder reliability. As part of the sampling process, medical claims data were used to create chronic condition flags for all patients in the sample. The flags were based on all medical claims data for the 6 months preceding the survey collection period. For this study, we utlized the flags for chronic non-cancer pain conditions (rheumatoid arthritis, osteoarthritis, spondylosis, and other back pain) and any cancer-related diagnosis. Statistical analyses were conducted in STATA v11.0 (StataCorp LP, College Station, TX). The University of Kentucky Institutional Review Board approved the survey protocol.

The main outcome of interest was whether the respondent had ever encountered difficulty obtaining a controlled substance prescription when presenting to a health care provider for care or when presenting a prescription to a pharmacy for dispensing. Descriptive statistics were used to characterize responses using frequencies, means, and medians. The influence of sex, race, education, location of residence (urban or rural) and a diagnosis of chronic non-cancer pain were evaluated with bivariate analyses. Multivariate logistic regression was performed to determine the independent effects of key predictors of interest, including whether individuals with conditions indicative of potential legitimate controlled substance need (i.e., chronic pain, including cancer-related and non-cancer related) differ from individuals who do not have such conditions, and whether those residing in urban counties differ from those in rural counties.

Results

Descriptive and Bivariate

A total of 4,439 surveys were mailed and 1,279 surveys were returned for a response rate of 28.81%). Of the 1,279 returned surveys, 707 respondents answered questions pertaining to KASPER. The characteristics of the respondents are shown in Table 1.

For the 707 respondents who answered questions about KASPER, 74 (10.47%) reported that their health care provider had discussed their KASPER report with them. Fewer respondents reported that KASPER prevented them from obtaining (6.74%) or filling (7.04%) a prescription. Responses to the KASPER-related survey questions are shown in Fig. 1.

Table 1. *Demographic profile of respondents answering KASPER questions.**

Age	**Number (%)**
18 to 24 years old	48 (7.01)
25 to 34 years old	107 (15.62)
35 to 44 years old	124 (18.10)
45 to 54 years old	143 (20.88)
55 to 64 years old	149 (21.75)
65 years and older	114 (16.64)
Sex	
Male	188 (27.13)
Female	505 (72.87)
Education	
Less than High School	304 (44.38)
High School Graduate or Beyond	381 (55.62)
Race	
White	605 (85.57)
Other Races	102 (14.43)
Hispanic Ethnicity	11 (1.74)
Geographic Distribution	
Rural	493 (69.73)
Urban	214 (30.27)
Chronic Pain Diagnosis	
Rheumatoid Arthritis and Related Disease	10 (1.42)
Osteoarthritis	67 (9.50)
Spondylosis and Other Back Pain	199 (28.23)
Any Cancer Diagnosis	50 (7.09)

*Note: some categories do not total to 707 respondents due to questions that were left unanswered.

Respondents that had been diagnosed with chronic non-cancer pain conditions (rheumatoid arthritis, osteoarthritis, spondylosis and other back pain) were less likely to have a health care provider discuss a KASPER report with them (4.78%) than those who had not been diagnosed with chronic non-cancer pain conditions (5.92%), and bivariate analysis indicates that this difference was statistically significant (P = 0.019). Respondents diagnosed with a chronic non-cancer pain condition were also more likely to indicate that a KASPER report prevented them from obtaining a controlled substance prescription than those who did not report a chronic non-cancer pain condition (3.46% versus 3.03%, *P* = 0.035). Those with a chronic non-cancer pain condition were also more likely to indicate that a KASPER report prevented them from filling a controlled substance prescription at a pharmacy than those who were not diagnosed with a chronic non-cancer pain condition (2.74% versus 4.32%), though this difference was not statistically significant (*P* = 0.324).

Table 2 presents the results of a logistic regression predicting patient reports of a KASPER report discussion with a physician. After controlling for age, education, race, sex, and location of residence, the results

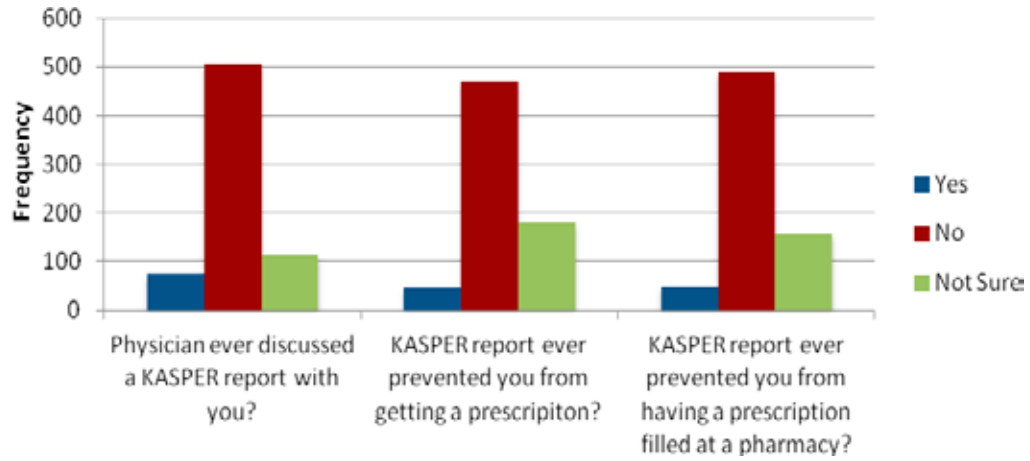

Fig. 1. *Survey question responses.*

Table 2. *Physician discussion of KASPER Report (logistic regression).*

	Odds Ratio	(95% CI*)	P Value
Chronic Pain Diagnosis (Non-cancer)**	1.815	(1.028 to 3.202)	0.040
Cancer Diagnosis	0.486	(0.141 to 1.675)	0.253
Age 18 to 24	1.151	(0.326 to 4.065)	0.827
Age 25 to 34	0.760	(0.244 to 2.373)	0.637
Age 35 to 44	1.484	(0.562 to 3.921)	0.426
Age 45 to 54	1.390	(0.547 to 3.353)	0.489
Age 55 to 64	1.143	(0.432 to 3.029)	0.788
High School Graduate	0.922	(0.519 to 1.639)	0.783
Race (White)	0.811	(0.341 to 1.928)	0.635
Hispanic**	6.437	(1.630 to 25.420)	0.008
Rural	1.156	(0.610 to 2.190)	0.656
Female	0.695	(0.387 to 1.249)	0.224

*CI = Confidence Interval
**Notes statistical significance at α=0.05

indicate that Hispanic respondents are more likely to have a physician discuss their KASPER report with them (Table 2). Respondents diagnosed with chronic non-cancer pain conditions are also more likely to have a physician discuss their KASPER report with them than respondents without chronic non-cancer pain; this difference is statistically significant.

Table 3 presents results testing the impact of KASPER on patients receiving a prescription from a prescriber. Respondents diagnosed with chronic non-cancer pain conditions are significantly more likely to report difficulty obtaining prescriptions due to KASPER reports, while rural residents are less likely to report problems obtaining a prescription than respondents with urban residences (Table 3).

Table 4 presents results testing the impact of KASPER on patients reporting difficulty getting controlled substance prescriptions filled at a pharmacy. As seen in the previous analysis (Table 3), respondents in rural areas are considerably less likely to report that KASPER prevented them from getting a prescription filled at a pharmacy (Table 4). The ability of respondents with chronic non-cancer pain conditions to get a controlled substance prescription filled at the pharmacy is not statistically

Table 3. *KASPER Report prevented prescription from a provider (logistic regression).*

	Odds Ratio	(95% CI*)	P Value
Chronic Pain Diagnosis (Non-cancer)**	2.566	(1.246 to 5.283)	0.011
Cancer Diagnosis	0.989	(0.276 to 3.541)	0.987
Age 18 to 24	0.769	(0.139 to 4.247)	0.764
Age 25 to 34	0.850	(0.246 to 2.936)	0.797
Age 35 to 44	0.718	(0.207 to 2.491)	0.601
Age 45 to 54	0.621	(0.183 to 2.104)	0.444
Age 55 to 64	1.228	(0.398 to 3.786)	0.721
High School Graduate	0.856	(0.409 to 1.789)	0.679
Race (White)	2.117	(0.591 to 7.581)	0.249
Hispanic	1.534	(0.176 to 13.390)	0.698
Rural**	0.423	(0.205 to 0.872)	0.020
Female	2.425	(0.901 to 6.525)	0.079

*CI = Confidence Interval
**Notes statistical significance at α=0.05

Table 4. *KASPER Report prevented prescription filled at a pharmacy (logistic regression).*

	Odds Ratio	(95% CI*)	P Value
Chronic Pain Diagnosis (Non-cancer)	1.352	(0.668 to 2.737)	0.401
Cancer Diagnosis	1.231	(0.401 to 3.773)	0.717
Age 18 to 24	0.884	(0.139 to 5.627)	0.896
Age 25 to 34	1.801	(0.466 to 6.952)	0.393
Age 35 to 44	1.675	(0.434 to 6.469)	0.454
Age 45 to 54	1.221	(0.313 to 4.765)	0.774
Age 55 to 64	2.954	(0.859 to 10.164)	0.086
High School Graduate	0.988	(0.480 to 2.032)	0.973
Race (White)	1.472	(0.517 to 4.189)	0.469
Hispanic**	8.121	(1.767 to 37.313)	0.007
Rural**	0.416	(0.206 to 0.841)	0.015
Female	1.772	(0.743 to 4.224)	0.197

*CI = Confidence Interval
**Notes statistical significance at α=0.05

different from those without this diagnosis. Therefore, only the rural/urban measure and Hispanic ethnicity are significant predictors of encountering difficulty getting a prescription filled at a pharmacy.

Discussion

In this survey of a random sample of Kentucky Medicaid beneficiaries, nearly 90% of respondents report they are unaffected by the KASPER program. Of the small group affected, Hispanic respondents are more likely to report discussing KASPER with a health care provider. Respondents with non-cancer chronic pain conditions are also more apt to report discussing KASPER with a health care provider as well as difficulty obtaining controlled substance prescriptions due to KASPER when confounding factors are controlled for in multivariate analyses. Respondents living in rural counties report less difficulty obtaining and filling controlled substance prescriptions due to KASPER. This result is not surprising, given that data reported by the KASPER program consistently shows higher usage of controlled substances (per 1,000 patients) in Kentucky's rural counties compared with urban counties (16).

In the war on prescription drug abuse, PDMPs have been proposed as an important tool for the prevention of controlled substance abuse and diversion. However, a balance between reduced diversion/abuse and access to legitimate medical therapy must be attained. Balance is not achieved if individuals with chronic pain (or other conditions necessitating controlled substance therapy) face diminished access to appropriate medical therapy. To optimize care for all patients, states should structure PDMPs so that they have the largest effect on decreasing prescription drug diversion and abuse without compromising access to medically necessary therapies.

The results of this pilot study indicate that a relatively small proportion of Medicaid beneficiaries currently report access issues. Unfortunately, the data available do not allow us to investigate the therapeutic appropriateness of controlled substances in those cases where access difficulties were encountered. In some cases, it is possible that access was appropriately denied (i.e., some respondents reporting access issues may not have diseases/conditions that warrant controlled substance therapy). Further research on the consumer/patient perspective of PDMPs is necessary so that both appropriate and inappropriate access barriers can be identified.

There are other limitations to this study as well. The low response rate, though consistent with previous survey response rates of the Kentucky Medicaid population, may not have provided a thorough and diverse reflection of patient experiences. Low response rates to mailed surveys are typical of Medicaid patients and low-income patients in general, due in part to low literacy and high mobility (15). Future survey research with this population should incorporate techniques to encourage responding, such as providing a monetary incentive, oversampling of Hispanic beneficiaries, and continued follow-up with those who do not respond. It is also unlikely that Medicaid recipients represent the perspective of the overall population in Kentucky on the effect of KASPER on controlled substance medication access. Given that the chilling effect is a key concern for policy makers and health care providers, it is crucial to evaluate the potential for the unintended outcome of diminished access to legitimate controlled substance therapy. Inadequate access to pain medications has been a primary concern voiced from pain specialists and several patient advocacy groups (2,17). While previous research indicates prescribers, dispensers, and law enforcement officials believe the KASPER program is providing a valuable tool to decrease doctor shopping and prescription drug misuse (12), the consumer/patient's perspective on controlled substance access is clearly needed to authenticate the claim that the benefits of KASPER are not coming at the cost of diminished access to medically appropriate therapy.

Conclusion

The purpose of this project was to assess the effect of the Kentucky PDMP on access to controlled substances. Information obtained from this state-specific evaluation suggests that a relatively small proportion of Medicaid beneficiaries report access problems, and that these problems are significantly more apt to occur with recipients who report chronic non-cancer pain conditions and recipients who live in urban counties. Further investigation of consumer-patient opinions about, and experience with, PDMPs is warranted as the patient perspective is key to ensuring that current PDMP policy, aimed at decreasing the abuse and diversion of controlled substances, is not compromising access to medically necessary therapy.

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