Evaluation of Interprofessional Quality Improvement Interventions Led by an Ambulatory Care Pharmacist on Adherence to a Controlled Substance Agreement Policy

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Abstract

Background: *A controlled substance agreement (CSA) is a risk mitigation strategy for patients managed on controlled substance medications such as opioids and benzodiazepines. Limited literature exists to describe the role of the clinic pharmacy team to promote adherence to CSA monitoring parameters.* ***Objective:*** *The objective of this study is to evaluate the impact of interprofessional educational and clinical interventions led by an ambulatory care pharmacist on adherence to monitoring parameters within a CSA policy.* ***Methods:*** *This retrospective observational study included patients on long-term controlled substances who had a clinic visit every 3 months during the study period. The primary outcomes were the proportion of patients with a signed CSA in the electronic medical record (EMR), urine drug screen (UDS) completion, and documentation of review of the statewide prescription drug monitoring program (PDMP) in the EMR 8 months prior to as compared to 8 months after implementation of pharmacist interventions.* ***Results:*** *Among 79 patients (mean age 55.7 years, 65.8% female, 54.4% African American), 8.9% pre- vs 88.6% post-interventions had a signed CSA (p<0.001), 35.4% pre- vs 65.8% post-interventions had a UDS completed (p<0.001), and 32.9% pre- vs 57% post-interventions had documentation of PDMP review (p=0.002).* ***Conclusion:*** *Adherence to monitoring parameters within a CSA policy significantly improved after educational and clinical interventions led by an ambulatory care pharmacist.*

Keywords: interprofessional, ambulatory care, pharmacist, controlled substance, opioid

Introduction

Overuse of controlled substances has created a public health crisis that requires enhanced efforts to prevent misuse, harm, and death. Although many guidelines recommend measures such as controlled substance agreements (CSAs), urine drug screen (UDS) monitoring, and review of prescription drug monitoring programs (PDMP) to attenuate risks, there is substantial variability across recommendations which may lead to underutilization in practice.[1-4] A CSA outlines provider-patient responsibilities regarding controlled substances, such as opioids and benzodiazepines. Traditional CSAs highlight patient education regarding risks versus benefits of therapy, goals of therapy, stipulations for refills, and monitoring parameters such as frequency of UDS and review of PDMP.[2] CSAs have been described as a risk mitigation strategy in the management of controlled substances and are recommended by clinical practice guidelines.[1] However, there is mixed evidence on their effectiveness and therefore best practices to promote use of and adherence to CSAs are not clearly defined.[2,5,6]

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Despite existing literature describing the efforts of pharmacists in the area of chronic pain management, limited studies exist that evaluate pharmacist impact on adherence to CSA policies or that describe processes to improve adherence to their use.[7-11] Pharmacist-led initiatives have included education on adhering to best-practice standards and guidelines, appropriate opioid tapering and discontinuation, utilization of PDMPs, reviewing UDS adherence, counseling and educating patients on opioid safety, storage, disposal, as well as providing resources for opioid misuse and addiction treatment.[7-11] Hellier et al evaluated the addition of a pharmacist in an academic primary care setting, where the pharmacist assisted medical residents in monitoring patients receiving opioid medications.[9] In this study, the pharmacist-assisted creation of CSAs, annual drug screenings, and review of the PDMP increased significantly compared to the control group.[9] Boren et al evaluated the impact of a clinical pharmacist in a multidisciplinary team on the reduction of opioid use, UDS completion, and review of CSAs.[10] In this study, the patients referred to the pharmacist had significant reductions in opioid morphine milligram equivalents and increase in completion of UDS and CSA reviews compared to patients who were not referred to the pharmacist.[10] Lagisetty et al implemented a pharmacist-physician collaborative model for patients with chronic pain.[11] The collaborative model including in-person patient visits with the pharmacist resulted in more pharmacist-led interventions including non-opioid pain management, switching to buprenorphine for pain, or opioid

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tapering.[11] However, these previous studies have not evaluated the impact of a pharmacist on multiple monitoring parameters including CSA, UDS, and PDMP adherence via educational and clinical efforts in an academic clinic with identification of high-risk patients (including patients with concomitant controlled substances, increased risk of opioid-related harm or death, morphine milligram equivalents ≥50 mg/day, etc.) and shared medical appointments which highlights the novelty of our study.

The objective of this study is to evaluate the impact of educational and clinical interventions led by an ambulatory care pharmacist on adherence to monitoring parameters within a CSA policy, including CSA signed in the electronic medical record (EMR), UDS completion, and PDMP review documented in the EMR.

Methods

This is a retrospective observational chart review study evaluating the change in adherence to CSA monitoring parameters 8 months prior to and 8 months after ambulatory care pharmacist interventions which began on January 1, 2018. Data collection occurred from May 2017 through September 2018 (8 months pre-interventions through 8 months post-interventions). Patients served as their own control.

This study was conducted in an internal medicine clinic which serves as an academic training site for medical residents, pharmacy residents, and pharmacy students. The practice site is a large primary care clinic comprised of 33 medical residents, 6 attending physicians, 1 embedded ambulatory care clinical pharmacist, rotating pharmacy residents and students, and 4 medical assistants. A CSA policy exists at the health-system for all ambulatory sites. The CSA policy applies to all patients over the age of 18 years old receiving long-term controlled substances, defined as use for 3 or more continuous months or recurrent use for 6 or more months. The CSA highlights risks versus benefits of therapy, goals of treatment (including goals for functional improvement and pain reduction), the treatment plan, refill policies, frequency of follow-up visits, and monitoring parameters such as frequency of UDS and review of the state-wide PDMP. The policy stipulates that eligible patients must have a CSA signed in the EMR once annually, UDS obtained at least once annually or more often per clinical discretion, and PDMP review on each refill of the controlled substance. The CSA exists within the EMR to be printed, signed by the patient and provider, then scanned back into the EMR.
In January 2018, quality improvement interventions led by an ambulatory care clinical pharmacist were implemented to improve adherence to the clinic CSA policy (Table 1). For the educational intervention, the pharmacist delivered weekly educational sessions over the course of 5 weeks to small groups of 5 to 6 medical residents and 1 to 2 attending providers; each session was approximately 2.5 hours. The clinical pharmacist educated medical residents, providers, and staff on the parameters within CSAs to ensure that they were adhered to. Each session included review of the following parameters: CSAs, UDS frequency and interpretation, PDMP review, patient-specific communication strategies regarding the risks and benefits of therapy, setting shared functional improvement goals, and risk mitigation opportunities such as when initiating a discussion regarding tapering is warranted, alternative therapies, and naloxone co-prescribing. During each educational session, case-based examples were used to describe how to discuss the CSA policy and implement the monitoring parameters therein. For the clinical intervention, the clinic pharmacy team (comprised of the pharmacist, student pharmacists, and pharmacy residents) identified patients via daily manual clinic schedule screening and reports obtained from the EMR identifying patients on long-term controlled substances. Patients were identified for discussion with the medical team if they were prescribed a long-term controlled substance, with extra emphasis on patients who were considered higher risk for overdose-related harm or death, such as patients who were on concomitant controlled substances or who had comorbidities that increased risk of harm. In identifying such patients, the clinical pharmacy team engaged in discussions with medical residents and attending physicians to provide recommendations for optimization of therapy, suggest risk mitigation strategies, and reinforce adherence to the CSA policy and its components. The pharmacist often joined shared clinic visits (selected per pharmacist and medical team discretion based on complexity of the case) with the medical team to discuss risk mitigation opportunities with the patient. These interventions also allowed for the clinic pharmacist to identify additional issues requiring intervention, such as the need for naloxone co-prescribing, weaning of high-risk concomitant regimens when warranted, and education on appropriate interpretation of UDS results. The pharmacist trained rotating student pharmacists and pharmacy residents to conduct the aforementioned activities described.

Inclusion criteria consisted of patients who met CSA policy criteria – patients over the age of 18 years on long-term controlled substances as previously defined (use for 3 or more continuous months or recurrent use for 6 or more months). Patients were included only if they were on a long-term controlled substance in the pre- and post- implementation period and had a clinic visit every 3 months throughout both time periods given that these are criteria within the CSA policy. As per CSA policy exclusion criteria, patients were excluded if their controlled substance(s) was/were prescribed by an outside prescriber, if they were diagnosed with cancer, patients in hospice, and patients receiving palliative care. This study was reviewed by the Institutional Review Board and deemed to be exempt.

Data collection parameters from the EMR included the following: gender, patient-identified race, age, smoking status,

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recreational drug use, co-existing mental health conditions (depression, anxiety, and/or bipolar disorder captured from the EMR problem list), diagnosis for controlled substance use (determined by reviewing the diagnosis linked to the controlled substance prescription and verified on the EMR problem list), overdose risk score (ORS), type of controlled substance medication prescribed (at least one opioid medication, benzodiazepine, or both), and morphine milligram equivalent (captured from the EMR reported auto-calculation). Overdose risk was captured using the opioid risk score (ORS) that is reported by the statewide PDMP (Michigan PMP Aware®), known as the NARxCHECK Narcotic Score, which has been described as an effective measurement tool to predict unintentional overdose death derived from a case-control study of overdose deaths in 2014.[12] Further, it has been shown that this tool is highly accurate, readily accessible, and validated. The ORS is a composite of risk factors that takes into account drug equivalents, number of pharmacies, number of overlapping prescription days, number of providers, and potentiating drugs. The ORS ranges from 000-999, representing the risk of unintentional overdose death with increasing odds ratios as the scoring thresholds increase. [12,13,14] Data was collected manually from the EMR using a standardized data collection form. Data collection and entry was conducted by one of the authors, with quality assurance data entry verification of a sample of approximately 10% of patients by another author to ensure validity of data. Discrepancies were discussed among both authors for resolution and standardization of collection was ensured across all other patients.

The primary outcomes were the proportion of patients with the following parameters completed at least once during each time period (8 months pre- as compared to 8 months post-implementation of the pharmacist-led educational and clinical interventions): (a) signed CSA in the EMR, (b) completed UDS, and (c) PDMP review documented in the EMR.

Statistical Analysis

The proportion of patients who completed each measure (CSA signed, UDS completed, and PDMP review documentation) was calculated for both time periods. The difference in the proportion of patients meeting each measure in the pre- as compared to the post-intervention time period was analyzed using chi-squared tests. P-value < 0.017 was considered statistically significant. The significance level was adjusted to account for multiple comparisons. Given that three measures (CSA signed, UDS completed, and PDMP review documentation) were compared, the correction for significance level was 0.05/3 which is approximately 0.017. A post-hoc power calculation was conducted based on the smallest difference in proportion (i.e. PDMP), which shows that the sample size of 79 has 75% power to detect the difference at a significance level of 0.017. All statistical analyses were performed with SAS v9.4 (SAS Institute, Inc., Cary, NC).

Results

Baseline Demographics and Characteristics

A total of 79 out of 123 patients considered were enrolled in this study. A total of 44 patients were excluded as 42 patients did not have a visit every 3 months over the study period and 2 patients did not have long-term controlled substance use. All enrolled patients were evaluated for 8 months pre- and 8 months post-implementation of the interventions. Baseline demographics and characteristics are shown in Table 2. Most patients were female (65.8%), African American (54.4%), with a mean age of 55.7 years (range 31 to 81 years). Over half of the sample had a diagnosis of depression (59.5%) or anxiety (75.9%). In terms of controlled substance medications, 45.6% of patients were on an opioid only, 49.4% of patients were on a combination of an opioid and benzodiazepine, and 5.1% were on a benzodiazepine only. The mean ORS was 369.6 and the mean morphine milligram equivalent (MME) was 51.4 among all patients. The MME was 60.3 among patients on concomitant opioid and benzodiazepine medications.

Primary Outcome Results

As depicted in Table 3, pre-interventions, 8.9% of patients as compared to 88.6% post-interventions had a signed CSA in the EMR (difference 79.8, p<0.001). Pre-interventions, 35.4% of patients as compared to 65.8% post-interventions had a UDS completed (difference 30.4, p<0.001). Pre-interventions, 32.9% of patients as compared to 57% post-interventions had documentation of PDMP review in the EMR (difference 24.1, p=0.002).

Discussion

Our study highlights the importance of interprofessional collaboration with an ambulatory pharmacist to optimize utilization of risk mitigation strategies for patients on controlled substances. Our study has shown the positive effects of ambulatory care pharmacist interventions as demonstrated by an increase in CSA signed in the EMR, UDS completion, and PDMP review among patients receiving controlled substances. After pharmacist interventions, providers were more likely to provide safe controlled substance use. This improvement was appreciated after the educational and clinical interventions of an ambulatory pharmacist to increase attention to parameters important to safe controlled substance use as described in Table 1. The literature suggests that implementation of and adherence to risk mitigation strategies such as CSAs, UDS, and PDMP review is subpar, with compliance of less than 50% of eligible patients across primary care practices.[1,15-17] Prior to the implementation of our interventions, CSA, UDS, and PDMP measures were less than 50%. However, after pharmacist intervention, these measures significantly improved. Compared to other studies that evaluated adherence to CSA policies in small practices, our study evaluated these measures in a large academic practice with multiple providers where adherence is generally perceived to be more challenging than in a smaller practice with fewer providers.[18]

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The benefits of a pharmacist in this initiative are important to highlight. The value of a pharmacist in our model was the structured educational and clinical interventions provided; without this, CSA adherence may be considered a "checklist item". This is especially important in an academic internal medicine clinic that serves as a training site for medical and pharmacy trainees. The pharmacist's interventions ensure that adherence to these measures is a risk mitigation strategy where the risks versus benefits of therapy were discussed with patients, naloxone co-prescribing was recommended, alternative treatment plans were considered, tapering of controlled substance therapy were considered and planned when appropriate, UDS results were appropriately interpreted, and pharmacologic drug information was provided when necessary.

In our sample of patients, there was a theoretical high risk for overdose and death, as denoted by the mean ORS, the high MME >50, mental health comorbidities, and the use of concomitant controlled substances.[4] Approximately 49% of patients were on a combination of at least one opioid and a benzodiazepine with a mean MME of 60.3, a combination that is known to increase risk of overdose and death, particularly among patients with underlying mental health conditions.[4] Notably, over half of the patients in this study had underlying depression or anxiety. The mean ORS in our study (approximately 370) suggests an odds ratio of 10 for unintentional death.[12] In another study, a score greater than 200 indicated a tenfold increased risk of opioid overdose.[19] This provides some insight into the high-risk nature of our patients. Higher ORS may warrant additional interventions, demonstrating the value of the enhanced monitoring prompted by the pharmacist's interventions in our study.[12,20]

This study did have some limitations. The improvements appreciated across the different parameters may have partly been related to the heightened attention to the opioid epidemic nationally and specifically within our clinic. Additionally, our sample size was small and patients served as their own control. Due to the retrospective nature of this study and manual chart review, some information may be missing. For example, adherence to the PDMP review measure was based on documentation in the EMR. Given that the post-intervention period occurred for 8 months, some patients or prescribers may have been acted on with pharmacist intervention more than once. Also, we did not collect data on the number of individual patient shared visits or prescriber consultations outside of the 5 week educational sessions. We did not evaluate outcomes pertaining to opioid overdose or death, which are the ultimate endpoints for risk mitigation strategies in the context of the opioid epidemic. Rather, this study demonstrated the impact of pharmacist interventions on adherence to controlled substance safety parameters in a singular clinic. It is important to note that some systematic reviews note that effectiveness of CSAs may be weak in reducing opioid misuse.[5,6] While there is mixed evidence on the benefits of CSAs, some literature describes benefits such as facilitating open conversations regarding patient adherence, clarity regarding the benefits and risks of opioid therapy, as well as improved patient safety.[2,5,6]

This study was a call to action for the ambulatory care pharmacist and clinic team. This study identified the opportunity to reduce prescriptions for concomitant opioid and benzodiazepines and increase naloxone co-prescription. While not described in this manuscript, these opportunities became the new priorities of the clinic team and ambulatory pharmacist after study completion. The pharmacist used this information to implement initiatives focused on reducing inappropriate use of concomitant opioid and benzodiazepines by providing formal education sessions on appropriate alternative treatments and safe weaning approaches when warranted. This information was also used to prompt increased emphasis on naloxone co-prescribing in the clinic, the efforts of which prompted a provider survey and quality improvement initiative although the results are not described in this manuscript. While our study demonstrated an overall increase in UDS completion, it should be noted that UDS completion should be accompanied by appropriate review, interpretation, non-punitive action, and documentation. While not described in this study, after the study was completed, there was increased emphasis on appropriate interpretation of the UDS results based on the type of UDS (immunoassay or gas chromatography) and ensuring that the UDS is used as a therapeutic rather than punitive tool. This study should also prompt other clinics to review their safety practices and opportunities for intervention. Additionally, this study presents an opportunity for trainees such as student pharmacists and pharmacy residents to engage in such interventions, while allowing the clinic pharmacist to devote time to work with clinic providers on optimizing medication regimens, tapering controlled substances, and addressing complex patient cases. One future direction includes evaluation of a measure specific to provider behavior to strengthen the impact of the educational intervention. Lastly, pharmacists seeking to implement similar interventions must navigate how to sustain educational and clinical efforts particularly as monitoring parameters require annual adherence and turnover of trainees exists in teaching clinics.

Conclusion

In our current national landscape of opioid overuse, misuse, and death, it is important for primary care practices to identify opportunities to mitigate risks for patients on controlled substances. Interprofessional collaboration with a clinical pharmacist is an opportunity to improve meaningful use of risk mitigation strategies such as CSAs, UDS monitoring, and PDMP review. Overall, this study demonstrated the benefit of an interprofessional quality improvement initiative led by an ambulatory care pharmacist to improve adherence to a CSA

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policy and risk mitigation strategies. Ambulatory care pharmacists across other clinics may evaluate their adherence to risk mitigation strategies and determine how to best implement interventions as described in this study to improve their controlled substance safety. Future studies are needed to determine the impact of such efforts on reduction in overdose, harm, and death for patients on long-term controlled substances.

Conflicts of Interest: We declare no conflicts of interest or financial interests that the authors or members of their immediate families have in any product or service discussed in the manuscript, including grants (pending or received), employment, gifts, stock holdings or options, honoraria, consultancies, expert testimony, patents, and royalties.

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The opinions expressed in this paper are those of the author(s).

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Table 1. Ambulatory Care Pharmacist Quality Improvement Interventions
Educational Intervention: Small Group Weekly Educational Sessions Led by the Ambulatory Care Pharmacist
• Each 2.5 hour weekly session consisted of a cohort of 5 to 6 medical residents (total of 33 medical residents educated over the course of 5 weeks) • Medical residents prepared for session in advance by reviewing a module covering pain- and opioid-related topics • Case-based examples were discussed during the session which incorporated key risk mitigation strategies for patients on long-term opioids and controlled substances, including: ○ Co-prescribing naloxone ○ Appropriate weaning strategies for opioids, benzodiazepines, and other controlled substances when warranted, particularly for patients on high-risk combinations ○ Non-pharmacologic and alternative therapies ○ Screening for opioid use disorder ○ Discussion of interpreting, responding to, and communicating goal of UDS • Components of CSA were reviewed, with discussion of strategies for communicating the following components with patients: ○ Importance of at least annual urine drug screening as a therapeutic, non-punitive tool ○ Benefits of reviewing PDMP at every visit and importance of documenting its completion ○ Discussion of risks versus benefits of opioid therapy, functional goals, and shared-decision making
Clinical Intervention: Clinic Interventions between Clinic Pharmacy Team, Medical Residents, and Clinic Physicians
• Pharmacy team identification of patients on long-term controlled substances for individual recommendations on optimization of therapy, risk mitigation strategies, and reinforcement of CSA policy adherence ○ Individualized recommendations for naloxone co-prescribing, weaning recommendations (particularly for patients on concomitant long-term opioid and benzodiazepines), and optimization of regimen • Shared clinic visits with medical resident or physician for patient discussion per pharmacist and medical team discretion based on complexity of the patient case

Table 1. Summary of ambulatory care pharmacist team interventions including educational sessions and clinic interventions

Table 2. Baseline Patient and Controlled Substance Medication Characteristics	
n	79
Age, yrs (Mean ± SD, range)	55.7 ± 11.1, 31-81
Gender (n, %)	
Female	52 (65.8)
Male	27 (34.2)
Patient-Identified Race (n, %)	
African American	43 (54.4)
Caucasian	31 (39.2)
Other	5 (6.3)
Smoking (n, %)	
No	25 (31.6)
Yes	31 (39.2)
Former	23 (29.1)
Recreational Drug Use (n, %)	
Cocaine	0 (0.0)
Marijuana	9 (11.4)
None	68 (86.1)
Not documented	2 (2.5)
Mental Health Conditions (n, %)	
Depression	47 (59.5)
Anxiety	60 (75.9)
Bipolar Disorder	10 (12.7)
Controlled Substance Medications Prescribed (n, %)	
Opioid only	36 (45.6)
Opioid + Benzodiazepine	39 (49.4)
Benzodiazepine only	4 (5.0)
Diagnosis for Controlled Substance Medication (n, %)	
Chronic pain	38 (48.1)
Anxiety	4 (5.1)
Chronic pain and Anxiety	33 (41.8)
Other	4 (5.0)
Overdose Risk Score (Mean ± SD, range)	369.6 ± 179.4, 70-840
Morphine Milligram Equivalent (Mean ± SD)	
Among all patients	51.4 ± 64.1
Among patients on opioid only	47.1 ± 48.8
Among patients on opioid + benzodiazepine	60.3 ± 76.8

Table 2. Baseline characteristics including demographics and controlled substance medication details

Table 3: Adherence to CSA Policy Parameters				
	Pre-Interventions	**Post-Interventions**	**Difference**	**p-value**
CSA (n, %)	7 (8.9)	70 (88.6)	79.8	<0.001
UDS (n, %)	28 (35.4)	52 (65.8)	30.4	<0.001
PDMP (n, %)	26 (32.9)	45 (57.0)	24.1	0.002

Table 3. Proportion of patients with CSA signed, UDS completion, and PDMP review documented pre- vs post-interventions, with difference between time periods (p-value < 0.017 considered statistically significant)