

Novel Opioid Safety Clinic Initiative to Deliver Guideline-Concordant Chronic Opioid Therapy in Primary Care

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Abstract

Objective: To develop and evaluate a novel Opioid Safety Clinic (OSC) initiative to enhance adherence to guidelines on the assessment and monitoring of patients prescribed chronic opioid therapy (COT).

Patients and Methods: The OSC was developed at an urban Federally Qualified Health Center to provide guideline-concordant care for COT, standardize workflows, and efficiently use clinic staff. We evaluated the OSC using a matched cohort study. Five hundred thirty-nine patients participated in the clinic between July 1, 2014, and March 31, 2016. Of these, 472 clinic participants were matched to 472 nonparticipants by sex and age on the date of the OSC visit. The OSC was evaluated by its completion rates of standardized pain assessments, urine toxicology, and naloxone dispensings. We conducted logistic regression comparing OSC participants to OSC nonparticipants.

Results: A total of 539 patients attended an OSC visit, representing approximately 53% of patients in the chronic opioid registry. The OSC participants were more likely than nonparticipants to have completed a pain assessment (adjusted odds ratio [aOR], 169.8; 95% CI, 98.3-293.5), completed a urine toxicology (aOR, 46.1; 95% CI, 30.4-69.9), or had naloxone dispensed (aOR, 2.8; 95% CI, 1.9-4.3) over 12 months of follow-up.

Conclusion: The OSC model improved adherence to guideline-concordant COT in primary care. Future research is needed to assess the impact of these interventions on pain, quality of life, and adverse events from opioid analgesics.

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The United States has experienced unprecedented increases in chronic opioid therapy (COT) prescribing for chronic noncancer pain. As a result, the number of reported overdose deaths involving pharmaceutical opioids increased between 2000 and 2016.^{1,2} Pharmaco-education and risk mitigation strategies are needed to reduce overdose risks associated with COT.

A number of guidelines have been issued for the management of COT for chronic pain, including the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain.³⁻⁸ Despite a paucity of evidence regarding the effectiveness of risk mitigation strategies,^{9,10} health systems have sought to implement risk mitigation approaches based on expert

opinion and systematic reviews of the evidence to improve the safety of COT.³ Such guidelines commonly include (1) risk assessment using standardized, self-reported instruments, (2) opioid use agreements, (3) urine drug toxicology screens, (4) prescription drug monitoring program, and (5) naloxone prescribing.¹¹

Given time constraints and competing demands in primary care, little is known about how to efficiently operationalize risk mitigation strategies. Existing research suggests limited provider adherence with many recommended strategies, such as urine toxicology testing.¹²⁻¹⁴ Barriers to naloxone prescribing include time constraints and providers' desire for clear patient selection criteria.¹⁵ In addition to low adherence, risk mitigation strategies



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may be variably implemented on the basis of patient characteristics, such as race/ethnicity.¹⁶⁻¹⁸ Variable or biased application of risk mitigation based on patients' demographic characteristics is problematic given that patients with pain and receiving COT may already experience stigma.¹⁹ Federally Qualified Health Centers (FQHCs) serve populations that are disproportionately publicly insured and underinsured, belong to racial/ethnic minority, and have lower health literacy.²⁰ Systematic application of guidelines in such settings could reduce variability and bias and improve adherence with guideline-concordant care.

To address the need to systematically operationalize opioid risk mitigation guidelines, we developed, implemented, and evaluated an Opioid Safety Clinic (OSC) model at an FQHC. Our objective was to evaluate the feasibility, reach, adherence with local health system risk mitigation guidelines, and receipt of naloxone.

PATIENTS AND METHODS

The study was approved by the Institutional Review Board with a waiver of Health Insurance Portability and Accountability Act and consent.

Setting

The initiative was developed in an FQHC within an integrated safety net health delivery system.²¹ The FQHC's Adult Clinic is comprised of a team of physicians, advanced practice providers, nurses, medical assistants, social workers, behavioral health consultants, and pharmacists. In 2015, the Adult Clinic saw 7994 unique patients for a total of 21,459 visits. The health system developed and implemented a chronic opioid registry on November 1, 2013, and maintained it until April 2016, when it was discontinued because of a change in the electronic health record vendor.

Context

In 2013, before the publication of the CDC guidelines,³ the health system established local opioid prescribing guidelines, including recommendations that providers conduct risk assessments using structured written questionnaires (COT initiation checklist, and COT

assessment tool based on the Screener and Opioid Assessment for Patients with Pain [SOAPP]²²), review and ask patients to sign a Patient Consent/Agreement about Narcotic (Opioid) Pain Medications (pain medication patient agreement) at least once, check the state's prescription drug monitoring program (PDMP) at least every 3 months, check urine drug toxicology screens at least yearly, and consider prescribing naloxone to patients taking more than 200 morphine milligram equivalent (MME) per day. In 2013 and 2015, the state passed legislation that provided legal immunity for naloxone prescribers, dispensers, and bystanders.²³

Rationale

To operationalize an efficient response to the local health system guidelines, the OSC was developed at one of the health system's FQHCs. The clinic aimed to provide guideline-concordant care and pharmacoeconomic education, standardize workflows, use clinic staff at the highest level of their scope of practice, and ensure unbiased treatment of patients (Table 1).

The target population was patients receiving COT, as reflected in the chronic opioid registry. The clinic was not designed to adjust the dose of opioids or other sedating medications, such as benzodiazepines; although these are important, the clinic

TABLE 1. Aims of the Opioid Safety Clinic Initiative

1. Provide education to patients receiving chronic opioid therapy on the risks of opioid-induced oversedation and overdose
2. Provide opioid safety training, including safe home medication storage
3. Ensure completion of structured patient assessment for pain-related function and risk
4. Ensure completion of pain medication patient agreements
5. Monitor the electronic Prescription Drug Monitoring Program for additional prescribed sedating medications or unexpected medication prescription patterns
6. Collect urine or serum toxicology screens
7. Offer a prescription for an intranasal naloxone kit, and provide training for how to respond to an overdose and use naloxone

emphasized other safety strategies that could be standardized and implemented without the presence of a primary care provider at the visit.

Intervention

The OSC was developed by a multidisciplinary team that provided care to a broad range of patients in the clinic; the team included physician and nursing team leaders, 3 other primary care physicians, 1 other registered nurse, a medical assistant, and an administrative clerk. The team met monthly for approximately 6 months to develop the goals, workflow, staff responsibilities, outreach, and written educational materials for the clinic.

The educational material included adapted existing material available in the public sphere on what opioids are and how to recognize and respond to an overdose. New content was also developed to educate patients on how to keep medications safe from children and other household members in lock boxes or locked cabinets and the risks of sharing opioids with other people. This content was based on previous qualitative research that suggested that some patients prescribed long-term opioid therapy do not recall receiving such education.²⁴ Content also included the risks associated with coingesting opioids with alcohol, other drugs, and concurrent sedating medications, such as benzodiazepines. Educational materials were designed for a less than eighth-grade literacy level. After several iterations, educational materials were approved by the institutional educational committee and translated into Spanish.

Patients were identified from the opioid registry and contacted using a letter attached to their monthly opioid prescriptions. This approach was selected because some patients did not have working phone numbers or addresses. The introductory letter named the patient's primary care provider, introduced the reason for the appointment, and stated that a serum or urine specimen would be collected for toxicology screening. The letter indicated that dose adjustments would not be made at the visit, allowing patients and providers to focus on safe medication practices. Each patient had to schedule their own OSC visit. If the patient did not schedule the visit, the primary care provider was to be notified.

The clinic was staffed by a medical assistant, a registered nurse, and a physician, nurse practitioner, or physician's assistant (provider); these providers also provided care to non-OSC patients. The medical assistant's role was to give patients the COT initiation checklist, the COT assessment tool, and the pain medication patient agreement. The medical assistant was tasked with helping patients with limited literacy complete the questionnaires. The nurse's role was to review all educational materials and demonstrate the use of the intranasal naloxone kit. The provider's role was to check the PDMP, update the medication list with any other controlled substances from outside providers, review the pain medication patient agreement with the patient, clarify the pain diagnosis and document it, prescribe naloxone, and order toxicology and opiate quantitative confirmatory tests. A serum test was to be ordered if the patient indicated that they could not urinate because of a medical problem (eg, end-stage renal disease). Urine testing did not include cannabis, given its legal status in the state. Patients were directed to complete urine tests (unobserved) in the clinic on the same day, with specimens transported by clinic staff to the clinic-based laboratory. The medical assistant or nurse was asked to do a qualitative check on the temperature of the urine, and the laboratory staff was expected to generate a urine specific gravity on all specimens. Providers were supposed to be notified if the urine was cold or dilute.

At the conclusion of the visit, patients could pick up naloxone prescriptions at the on-site pharmacy, at 1 of the 8 health system pharmacies of their choice, or at an external pharmacy. The pharmacy staff packaged naloxone kits with a 1 mg/mL naloxone vial, a syringe, and a mucosal atomization device in a labeled prescription bottle and enclosed the educational handout. Naloxone kits were covered by Colorado Medicaid. Although local guidelines suggested providing naloxone to patients receiving high doses (>200 MME), the OSC offered naloxone to all patients who attended the OSC visit to standardize clinic procedures, reduce the stigma of naloxone receipt, and address additional overdose risk factors other than dose.

After the visit, the medical provider completed a visit note documenting any

concerns raised by the patient or findings on PDMP. The OSC providers were instructed to address additional urgent concerns as needed, but refer any requests for opioid refills or opioid dose adjustment requests back to the primary care provider. After the results of urine toxicology testing were available, the OSC visit provider communicated any positive results to the patient's primary care provider, who could act on them on the basis of their ongoing clinical relationship with the patient and clinical judgment. Primary care providers could then contact patients to discuss any concerns or unexpected findings, modify the dose of opioid therapy or other concurrent sedating medications, and/or provide substance use disorder treatment referrals. Because there was medical necessity to implement risk mitigation strategies, OSC visits were billed as regular encounters in the Denver Health system.

Evaluation Design and Population

Among OSC participants, a pre/post analysis was conducted comparing the outcomes before and after the OSC visit. Then, we conducted a matched cohort study to evaluate the OSC. As described previously, potential OSC participants were identified from the opioid therapy registry (n=1008). Patients who did not attend the OSC represented potential unexposed controls (nonparticipants). Each OSC participant was individually matched (1:1) to a patient who did not participate in the OSC by sex and age (± 5 years) on the date of OSC visit (index date).

Outcomes

The program was evaluated using a protocol developed by the research team as part of a National Institutes of Health–funded study designed to develop interventions to enhance naloxone prescribing in primary care. The evaluation targeted the following outcomes across groups: (1) feasibility (was the clinic model implemented and sustained?); (2) reach (number and demographic characteristics of patients receiving COT who attended OSC); (3) adherence with local guidelines (number of patients who completed the pain assessment tool and urine toxicology); and (4) naloxone dispensings. Electronic document codes were used to identify completed

agreements and questionnaires scanned into the medical record. Laboratory records were used to identify completed urine toxicology screens. Pharmacy records identified naloxone dispensings (excluding combined buprenorphine/naloxone products) from the health system's outpatient pharmacies for 12 months before and after the index date visit. Given the time frame of the evaluation, some patients may have forms completed more than 12 months before the index date; these could not be identified given changes in the electronic health record system over time.

Covariates

Demographic characteristics and diagnostic codes (eg, substance use disorder diagnoses in the previous 12 months) of OSC participants and nonparticipants were obtained from the health system's electronic health record databases. For opioid analgesic medications prescribed by the health system, opioid dispensings were identified on the basis of national drug classification codes from pharmacy records. These excluded buprenorphine-containing products and methadone treatment for opioid use disorder. All dispensed opioid medications were converted to MME.²⁵

Analysis

Three outcomes were assessed: completion of the COT assessment tool, completion of urine toxicology screening, and being dispensed a naloxone prescription within 12 months of the index date. First, a pre/post analysis was conducted comparing the outcomes before and after the OSC visit among all clinic participants using the McNemar test. Second, logistic regression analyses were conducted comparing OSC participants to nonparticipants on the 3 outcomes in the matched cohort. All logistic analyses were adjusted for sex, age, race/ethnicity, insurance payer, history of substance use disorder diagnosis, and whether there was an opioid prescription for greater than 200 MME filled on any day in the 12 months before the index date.

RESULTS

Feasibility and Reach

The OSC was implemented July 1, 2014. Given the acceptability of the model to

primary care providers, clinic staff, and patients, the clinic administration opted to sustain the model and it is still in use as of August 2018. A total of 539 patients attended an OSC visit between July 1, 2014, and March 31, 2016. This represented approximately 53% of patients (539 of 1008) in the opioid therapy registry and an estimated 6% of the clinic's patient population.

The OSC participants had a median age of 55 years (25th percentile, 48 years; 75th percentile, 61 years; [Table 2](#)). Half (53%; n=286) were women, 54% (n=293) were black, 25% (n=135) were Hispanic, and 20% (n=107) were white. Most had Medicaid (55%; n=295) or Medicare (41%; n=223).

Adherence With Institutional Guidelines and Naloxone Dispensings

In the 12 months before the index OSC visit, few OSC participants had evidence of completed opioid therapy initiation checklists (5.0%; n=27), pain medication patient agreements (11.5%; n=62), pain assessments (11.0%; n=59), or urine toxicology (41.4%; n=223). Naloxone dispensings were also rare (1.3%; n=7) in the 12 months before the OSC visit.

The following increased significantly ($P<.001$) in the 12 months after the index OSC visit: patients with evidence of completed opioid therapy initiation checklists (87.4%; n=471), pain medication patient agreements (93.3%; n=503), pain assessments (86.3%; n=465), urine toxicology tests (91.1%; n=491), and naloxone dispensings (47.7%; n=257). By March 31, 2016, 17 patients refilled the naloxone prescription at least once. Among these patients, a medical record review demonstrated that 1 overdose occurred after the OSC visit and was successfully reversed with naloxone.

Four hundred seventy-two OSC participants could be matched to 472 nonparticipants on sex and age. [Table 3](#) presents the baseline characteristics of OSC-matched participants and nonparticipants. The OSC participants differed from matched nonparticipants by race/ethnicity ($P<.001$), insurance type ($P=.006$), and substance use disorder diagnoses ($P=.001$). [Table 4](#) shows that the proportion who completed the assessments, underwent urine toxicology, and received naloxone 12

TABLE 2. Baseline Characteristics of the OSC Participants (n=539), July 1, 2014, to March 31, 2016^a

Characteristic	No. (%) or median (IQR)
Age (y), median (25th percentile-75th percentile)	55 (48-61)
Sex: female	286 (53)
Race/ethnicity	
Black/African American	293 (54)
Hispanic/Latino	135 (25)
White/Caucasian	107 (20)
American Indian/Alaska Native	4 (1)
Language	
English	532 (99)
Spanish	6 (1)
Insurance	
Medicaid	295 (55)
Medicare	223 (41)
Commercial	11 (2)
Indigent care plan	10 (2)
At least 1 date with opioid prescriptions totally MME >200 in 12 mo before the OSC date	28 (5.2)
Chronic opioid therapy assessment tool completed in 12 mo before the OSC date	59 (11.0)
Pain medication patient agreement in 12 mo before the OSC date ^b	62 (11.5)
Opioid initiation checklist in 12 mo before the OSC date	27 (5.0)
Urine toxicology screen in 12 mo before the OSC date	223 (41.4)
Naloxone prescription in 12 mo before the OSC date	7 (1.3)

^aIQR = interquartile range; MME = milligram morphine equivalent; OSC = Opioid Safety Clinic.
^bMay have been completed before the evaluation time period.

months after the index date was considerably higher in OSC participants than in nonparticipants.

In multivariable models ([Table 5](#)), OSC participants were more likely to complete a pain assessment (adjusted odds ratio [aOR], 169.8; 95% CI, 98.3-293.51) and urine toxicology (aOR, 46.1; 95% CI, 30.4-69.9) than nonparticipants. The OSC participants were also more likely than nonparticipants to have naloxone dispensed (aOR, 2.8; 95% CI, 1.9-4.3).

DISCUSSION

We successfully developed, implemented, and sustained a novel OSC model for primary care. This model was implemented using existing clinic resources to deliver several guideline-concordant risk mitigation strategies to patients receiving COT. Adding these

TABLE 3. OSC Participants Matched to Nonparticipants by Sex and Age at the Index Date (OSC Visit Date for OSC Participants)^a

Characteristic	OSC participants (n=472)	Nonparticipants (n=472)	P value
Female, No. (%) ^b	251 (53.2)	251 (53.2)	>.99
Age (y), mean ± SD ^b	55.9±10.4	56.0±10.5	0.86
Race/ethnicity, No. (%)			<.001
Black/African American	261 (55.3)	197 (41.7)	
Hispanic/Latino	101 (21.4)	132 (28.0)	
White/Caucasian	101 (21.4)	130 (27.5)	
Other	9 (1.9)	13 (2.8)	
Payer, No. (%)			<.01
Medicaid	160 (33.9)	185 (39.2)	
Medicare	194 (41.1)	151 (32.0)	
Uninsured	100 (21.2)	121 (25.6)	
Private	5 (1.1)	10 (2.1)	
Unknown	13 (2.8)	5 (1.1)	
Substance use disorder, No. (%)	89 (18.9)	131 (27.8)	<.01

^aOSC = Opioid Safety Clinic.^bMatched variables.

components to already busy primary care appointments raised concerns that they would not be completed in a consistent manner and that the safety education would not be performed. Our evaluation suggests that patients exposed to the clinic were considerably more likely than nonparticipants to complete standardized pain assessments, have a urine toxicology screen, and pick up naloxone. Given that OSC providers also cared for non-OSC patients, it is unlikely that our results were affected by provider bias.

Several features of the OSC visit model contributed to its success. The OSC visits were distinct visits from routine follow-up

visits with the patient's assigned primary care provider. Thus, the OSC health care team had the time to focus on opioid pharmacoeducation, safety training, and the other components of the OSC without competing with other health care needs. This also obviated having to engage in potentially difficult and contentious negotiations about opioid medication refills or dose changes, thus reducing barriers to patients absorbing safety messaging and enhancing the efficiency of the clinic. However, it is important to note that this may have also led to missed opportunities to optimize pain regimens and address potentially risky opioid dosages and medication interactions. Finally, the chronic opioid registry and a relatively large clinic may have facilitated operationalization of the OSC model.

In our evaluation, a naloxone prescription was accepted and dispensed at a health system pharmacy by nearly half (47.7%) of the OSC participants. Other patients may have filled their medications outside of the health system; these prescriptions could not be captured in available data. Given that a previous qualitative study identified numerous patient barriers to naloxone acceptance—including low perceived risk of overdose, fears of reprisal, and cost²⁶—the high proportion of naloxone fills was encouraging. In a San Francisco safety net health system, 38.2% of eligible patients were prescribed naloxone when clinic champions disseminated naloxone information to providers; the number of dispensings was not reported.²⁷

There were limitations to our study. We evaluated the OSC with an observational rather

TABLE 4. Assessments Completed by OSC Participants Compared With Nonparticipants Over the 12 Months After the Index (OSC Visit) Date^a

Outcome	OSC participants (n=472), No. (%)	Nonparticipants (n=472), No. (%)	P value
At least 1 prescription date with MME >200	28 (5.9)	23 (4.9)	.47
COT assessment	413 (87.5)	20 (4.2)	<.001
Pain medication patient agreement ^b	444 (94.0)	9 (1.9)	<.001
Opioid initiation checklist	417 (88.4)	6 (1.3)	<.001
Urine toxicology	428 (90.7)	93 (19.7)	<.001
Naloxone dispensed	225 (47.7)	42 (8.9)	<.001

^aCOT = chronic opioid therapy; MME = milligram morphine equivalent; OSC = Opioid Safety Clinic.^bAgreements may have been completed before the evaluation period; these are not reflected in the numbers provided.

TABLE 5. Association Between OSC Visit Participation and Outcomes in 12 Months After the OSC Visit (Index Date (n=944))

Characteristic	Adjusted odds ratios (95% CI)		
	Pain assessment completed	Urine toxicology completed	Naloxone dispensed
Outcome	169.8 (98.3-293.5)	46.1 (30.4-69.9)	2.8 (1.9-4.3)
Sex			
Female	1.0	1.0	1.0
Male	0.9 (0.6-1.5)	1.4 (0.9-2.0)	0.7 (0.5-1.1)
Age	1.0 (1.0-1.0)	1.0 (1.0-1.0)	1.0 (1.0-1.0)
Race/ethnicity			
Black/African American	1.0	1.0	1.0
Hispanic/Latino	0.8 (0.4-1.4)	0.7 (0.5-1.2)	0.8 (0.5-1.3)
White/Caucasian	1.1 (0.6-1.9)	0.7 (0.4-1.1)	0.9 (0.6-1.6)
Other	1.5 (0.3-8.6)	1.1 (0.3-4.0)	2.0 (0.7-5.8)
Insurance coverage			
Medicare	1.0	1.0	1.0
Medicaid	0.9 (0.5-1.7)	0.7 (0.5-1.2)	1.0 (0.7-1.6)
Private	3.2 (0.5-20.3)	1.1 (0.3-4.7)	0.5 (0.1-3.7)
Uninsured	1.2 (0.6-2.3)	0.6 (0.4-1.0)	0.9 (0.5-1.5)
Other/unknown	0.7 (0.2-3.0)	0.3 (0.1-1.1)	0.3 (0.0-2.4)
At least 1 prescription date with MME >200	0.6 (0.2-1.5)	1.4 (0.7-3.0)	1.8 (0.9-3.7)
Substance use disorder diagnosis at baseline	1.3 (0.7-2.4)	1.4 (0.9-2.4)	1.5 (0.9-2.4)

MME = milligram morphine equivalent; OSC = Opioid Safety Clinic.

than randomized study design. Several nonparticipants may have been invited to participate in the OSC but neglected to schedule or attend an appointment. Although we used a rigorous matched cohort study analysis controlling for various covariates, it is possible that our evaluation was subject to a selection bias. Patients who attended the clinic may have been inherently more likely to be adherent with the clinic initiatives than the matched unexposed patients, which may have led to an overestimate of the clinic's impact on guideline adherence. More intensive interventions may be needed to reach patients at highest overdose risk. In addition, the distribution of race/ethnicity was statistically different between the OSC participants and nonparticipants. However, given that our detected effect sizes were very large and that race/ethnicity was adjusted for in the multivariable regression models, it is unlikely that our positive results can be solely attributed to a selection bias. Although accessing the PDMP was a goal of the intervention, we did not have authorization to access PDMP data for the evaluation. Finally, although our quantitative results indicate

success, we did not evaluate other relevant outcomes, including patient pain control, quality of life, patient and provider satisfaction, cost to implement the clinic, opioid risk behavior, hospitalizations, and overdose.

CONCLUSION

The OSC model is a promising clinical initiative that could be disseminated into other practice settings to deliver opioid risk mitigation and overdose prevention strategies. Because the OSC was developed and implemented in a single health care system before the release of the CDC guidelines,³ OSC's goals reflected local consensus about appropriate clinical practices at the time of its implementation. Although OSC's goals align with CDC guidelines, risk mitigation approaches have a limited evidence base,^{3,10} and OSC practices will require modifications as the evidence base evolves. Future research is needed to understand the challenges to disseminating this model in other settings and to evaluate the intended and unintended effects of systematic implementation of risk mitigation approaches.

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Abbreviations and Acronyms: aOR = adjusted odds ratio; CDC = Centers for Disease Control and Prevention; COT = chronic opioid therapy; FQHC = Federally Qualified Health Center; MME = milligram morphine equivalents; OSC = Opioid Safety Clinic; PDMP = Prescription Drug Monitoring Program

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