

Transforming Prescription Opioid Practices in Primary Care With Change Theory

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ABSTRACT: The opioid epidemic continues to be an ongoing public health crisis. Many primary health care providers aptly serve as the gatekeeper to opioid prescriptions. The opioid epidemic has challenged the primary care profession whilst many of these providers have opted out of opioid prescribing altogether. This unintended consequence affirms erosion to primary care that is vital to the ecosystem of opioid management. The purpose of this study was to understand strategies to deliver opioids safely and effectively. Results indicate primary care providers are uniquely positioned to make a positive opioid impact through focused change initiatives. Five common themes arose from the inductive analysis: (1) provide leadership support; (2) define standard of work; (3) conduct pre-visit reviews; (4) conduct post-visit reviews; and (5) measure progress. Then, each common theme was deductively analyzed through a view of Kotter's change theory to support an effective proxy for implementing and sustaining chronic opioid therapy in a primary care context. These findings have potential to provide actionable implications for health care management professionals and primary care organizations such as hospitals and group practices.

KEYWORDS: Opioid epidemic, chronic opioid therapy, primary care, change theory

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Background

Substance abuse disorder remains a primary public health crisis.¹ Over 10 million Americans take prescription opioids for pain relief. Many primary health care providers serve as the gatekeeper to this pain. In recent years, the opioid epidemic has challenged the primary care profession whilst many of these providers have opted out of opioid prescribing altogether.² There is evidence this exodus has had inadvertent consequence for patients with chronic non-cancer pain. Many of these patients have turned to illicit substances and have limited oversight of their concomitant health comorbidities.^{3,4} This self-conversion can have spillover effects for the community in the way of people's ability to work and be financially healthy, life expectancy, educational attainment, safety and crime, and overall quality of life. This unintended cycle affirms primary care providers are vital to the ecosystem of opioids and community health. There remains a gap in understanding processes by which primary care providers can deliver opioids safely and effectively.⁵

On November 26, 2017 the Acting Secretary of Health and Human Services declared that a nationwide public health emergency existed as a consequence of the United States (U.S.) opioid crisis. In 2020 over 93 000 overdose deaths were reported in the U.S., a 29% increase from 2019.⁶ The ongoing epidemic of prescription opioid misuse, addiction, and overdose remains a public health crisis despite the issuance of the Center for Disease Control and Prevention (CDC) guideline aimed at helping primary care providers prescribe opioids for non-cancer pain.¹ The guideline is most noted for the recommendation that primary care providers should consider a daily cutoff rate of 90 morphine milligram equivalents (MME) for patients

experiencing chronic non-cancer pain. There is reliable evidence the introduction of opioid guidelines for primary care have had positive effect on overprescribing.^{7,8} Other evidence suggests the implementation of opioid prescribing laws is not associated with decline in prescription opioids.⁹ More importantly, there is credible proof the guideline left many chronic pain patients stranded with inadequate analgesic coverage.^{10,11} Many patients experiencing chronic non-cancer pain continue to have difficulty engaging a primary care practitioner for opioid management.²

Although the impact of the guidelines on opioid prescribing practices have been studied extensively in many contexts, including the primary care and community health settings,^{2,12–15} they have not paid much attention to case studies of successful longitudinal transformations of opioid prescription practices in primary care. Greater education about opioid management in primary care remains an emergent alarm.¹⁶ The question remains, how can primary care settings successfully transform and sustain their opioid prescription practices while maintaining integrity and cohesiveness of patient care? The purpose of this qualitative single case study was to identify and describe the challenges that must be addressed by primary care to reduce and sustain responsible opioid prescription practices. To do this, we examined the experiences of medical providers and support staff of a primary healthcare clinic that successfully transformed their opioid prescriptive practices over a 5-year period by using Kotter's¹⁷ change theory as the framework of their transition. Kotter's change theory is a top-down approach to change that engenders sequential steps to effectively prepare and build acceptability of change in organizational personnel. Kotter described 8 steps to an effective change process: (1)



establishing a sense of urgency; (2) create a guiding coalition; (3) develop a vision and strategy; (4) communicate the change vision; (5) empower broad-based action; (6) generate short-term wins; (7) consolidate gains and produce more change; and (8) anchor new approaches in the organizational culture. The following research questions (RQ) guided our study:

(RQ1) How was change theory used as a basis for transitioning opioid prescription practices in primary care?

(RQ2) What challenges were identified when reducing opioid prescriptions in primary care?

(RQ3) How can reduction of opioid prescription practices be sustained in primary care?

Methods

A case study was adopted to obtain rich and naturalistic data from the participants.¹⁸ Yin¹⁹ emphasized case study research is most relevant when it investigates a phenomenon within its real-life context. Data collection included qualitative data from participant experiences, quantitative data from 2 opioid risk questionnaires, and participants' daily MME values. The qualitative data investigated the phenomenon of sustained reduction in daily MME in a primary care context using inductive analysis of participant interviews.¹⁹ The quantitative analysis included participant intake scores on the Opioid Risk Tool (ORT) and Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) questionnaires along with daily MME values for each year under study.

Participants

Participants were recruited from a local primary care clinic in Northeast Texas. Seven participants were included in the study through purposeful sampling.²⁰ Audio recorded participant interviews ranged from 42 to 66 minutes. The participants consisted of multidisciplinary providers and ancillary staff members who were instrumental to the change initiative in this case study (Table 1). The majority (57.2%) of participants were female and/or White. The average participant health care experience was 18.6 years.

Data collection

Data were collected through semi-structured interviews (audio recordings and field notes)²¹ made up of questions that aligned with the purpose of the study.²⁰ Participants read a letter of consent to be interviewed. Interviews were guided by an interview protocol using an interview guide that included primary questions that were open-ended and follow-up questions.²⁰ The interview questions were constructed to discover aspects of the participants' experience that may add value to the study.²² Primary questions included background information, primary

Table 1. Participant interview demographics (n=7).

CHARACTERISTIC	MEAN	RANGE
Age, y	38.4	23-68
Years of experience	18.6	4-39
Gender distribution (n) (%)		
Male	3	42.8
Female	4	57.2
Ethnicity (n) (%)		
White	4	57.2
Black/African American	2	28.5
Hispanic	1	14.3
Degree (n) (%)		
Doctor of Osteopathic Medicine	1	14.3
Doctor of Chiropractic Medicine	1	14.3
Nurse Practitioner	1	14.3
Licensed Professional Counselor	1	14.3
Licensed Vocational Nurse	2	28.5
Medical Assistant	1	14.3

care experiences, and questions about the change initiative to reduce and sustain daily MME. Follow-up questions were used to obtain further details about the primary questions and how they related to Kotter's change theory. A deidentified code was used to preserve the anonymity of the participants. The interviews were transcribed by a professional transcriptionist and were reviewed for accuracy of the data for analysis.²² Patient specific ORT, SOAPP-R, and MME data was extracted from the clinics MicroMD[®] electronic medical records software for each year under study and assimilated in Microsoft Excel[®] for analysis.

Data analysis

The qualitative data analysis used an inductive coding approach identifying underlying ideas and concepts to result coding of common themes. Themes were considered when ideas and concepts emerged as recurrent in relation to the research questions.²³ As a form of member checking, the themes were shared with participants to provide opportunity for participant feedback and confirm that the participants' experiences resonated with the findings. Once common themes were identified, we deductively classified each theme for observed social processes that could be classified as rudiments of Kotter's change theory. Any intersubjectivity led to supplementary category classifications until agreement that the deductive coding remained faithful to the theory.

Table 2. Common themes for transforming opioid therapy with Kotter's change theory.

COMMON THEMES	DESCRIPTION	ACTION STEPS	KOTTER'S CHANGE THEORY
Provide leadership support	Leadership that can build organization-wide consensus for prioritize safe opioid prescribing.	Identify change agent (coalition team) to spearhead practice change initiatives.	Create a sense of urgency Build a core coalition
Define standard of work	Revise and implement opioid therapy policies and define standard of work for providers and staff to achieve safer opioid prescribing.	Convene team from each clinic department to create and communicate the change initiative. Update patient agreement and revise to ensure alignment with clinic and guideline policies.	Develop a vision and strategy Communicate the strategic vision Empower broad-based action
Conduct pre-visit reviews	Conduct pre-visit planning and screening for comorbidities and prescription aberrancies.	Review outside medical records. Review state prescription monitoring program patient data. Implement new patient exclusion criteria.	Generate short-term wins.
Conduct post-visit reviews	Conduct post-visit chart reviews for opioid outliers.	Monitor and adjust opioid therapy based upon function not pain scale. Conduct team reviews of outliers for consensus of care. Discharge outliers to improve staff efficiencies. Identify referral sources for behavior and mental health (eg, opioid abuse disorder).	Consolidate gains and produce more change.
Measure progress	Continuously monitor progress and improve with experience.	Identify key processes and outcome measures to monitor change implementation. Monitor prescription practices, provide and discussing data with medical providers and support staff at regular meetings (no less than monthly).	Anchor new approaches in the corporate culture.

Analysis of patient opioid risk tools (ORT, SOAPP-R) spanned a 5-year period and captured the initial psychometric properties of each participant's predisposition to opioid abuse. These measures were important to establish a baseline for predicting aberrant behaviors that may impact opioid compliance. Analysis of patient MME data spanned a 5-year period. Data for each year included any patient who was prescribed at least 1 narcotic prescription. Patients with daily MME less than 5 mg were excluded from the study. Following data extraction from MicroMD®, each year of interest for ORT, SOAPP-R, and MME was categorized in Microsoft Excel® for analysis.

Results

Five common themes arose from the inductive analysis: (1) provide leadership support; (2) define standard of work; (3) conduct pre-visit reviews; (4) conduct post-visit reviews; and (5) measure progress. Upon presentation of the common themes to the participants, all expressed support for the findings. The deductive analysis of each common theme was oriented and classified until agreement that the deductive coding remained faithful to Kotter's change theory (Table 2).

Analysis of the ORT revealed the mean participant intake score was 3.6. A score of 3 or lower indicates low risk, a score of 4 to 7 indicates moderate risk, and a score of 8 or higher indicates a high risk for opioid abuse. The mean participant intake score for the SOAPP-R was 9.2. A score >9 lower indicates low risk, a score of 10 to 21 indicates moderate risk, and a score

of 22 or higher indicates a high risk for opioid abuse. Importantly, the mean intake scores of each opioid risk tool remained fairly consistent each year under study (ORT range 3.3-4.0; SOAPP-R range 7.8-11.4).

Analysis of patient MME data spanned a 5-year period. The daily dosage per opioid therapy patient the year prior to the CDC guideline (April 2015-March 2016) was well above the ≥ 90 daily MME threshold ($\mu_1 = 102.5$ mg). The year following the CDC guideline showed a reduction in daily MME by 13% ($\mu_2 = 88.5$ mg) with year 3 ($\mu_3 = 74.0$ mg), 4 ($\mu_4 = 60.5$ mg), and 5 ($\mu_5 = 45.0$) showing greater annual reduction percentages respectively. Overall, the clinic was able to reduce daily MME by 56% in 5 years (Table 3) while maintaining total annual clinic patient visit volume.

Discussion

The opioid epidemic continues to challenge the primary care profession. There remains need to identify effective strategies to deliver opioids safely and effectively. This study presented evidence that change theory may be useful as a framework to reduce and sustain daily MME in a primary care context. A strategy that safely and effectively reduces opioid prescription practices is important to the health of primary care patients, primary care clinics, and communities. What follows is an explication of common themes through a view of Kotter's change theory during pre-launch, launch, and post launch phases to answer each research question (Table 4).

Table 3. Mean MME daily dose per opioid therapy patient per year.

MILLIGRAM MORPHINE EQUIVALENT (MME) PER OPIOID PATIENT			
DATE RANGE	MEAN (μ) (MG)	ANNUAL PERCENT (%) CHANGE	TOTAL PERCENT (%) CHANGE
April 2015-March 2016	102.5	0.00	0.00
April 2016-March 2017	88.5	13.65	13.65
April 2017-March 2018	74.0	16.38	27.80
April 2018-March 2019	60.5	18.24	40.98
April 2019-March 2020	45.0	25.62	56.02

Table 4. Common themes for transforming opioid therapy through launch phases.

COMMON THEMES	KOTTER'S CHANGE THEORY	
Provide leadership support	Create a sense of urgency	Pre-launch
	Build a core coalition	
Define standard of work	Develop a vision and strategy	Launch
	Communicate the change vision	
	Empower broad-based action	
Conduct pre-visit reviews	Generate short-term wins.	Post-launch
Conduct post-visit reviews	Consolidate gains and produce more change.	
Measure progress	Anchor new approaches in the corporate culture.	

Pre-launch

Pre-launch was considered efforts that included any preparation for or preliminary activity prior to the launch. Participants were consistent in their belief that pre-launch was the most important phase for successfully transitioning opioid prescription practices. Data included in the pre-launch phase provided insight to answer RQ1: how was change theory used as a basis for transitioning opioid prescription practices in primary care? Providing leadership support and defining standard of work were important common themes for underpinning the pre-launch phase. Providing leadership support was deductively considered a characteristic of Kotter's change theory through creating a sense of urgency and building a core coalition. Whereas defining standard of work was deductively considered a characteristic of Kotter's change theory through developing a vision and strategy, communicating the strategic vision and then empowering broad-based action.

Creating a sense of urgency

"We've become keenly aware of the opioid research and the regulatory oversight that comes with prescribing opioids. We knew proving opioids had a lot of associated risk and that there were better ways to manage chronic pain. . .and the CDC solidified that urgency for us."—Doctor

The CDC guideline created a sense of urgency in the delivery of opioids for chronic pain.⁶ The guideline provided recommendations for prescription practices outside of active cancer treatment, palliative care, or end-of-life care. Most importantly was concern that daily MME greater than 90 mg would not be considered standard of care. The guideline initiated need for implicit provider compliance. Participants expressed fear of balancing regulatory oversight with effective daily MME prescribing.²⁴ Titrating daily MME had potential for patient exodus or self-conversion to illicit substances that could impart deleterious effects on the patient, practice, and community. The urgency shifted to how to strategically undertake this task. Providing leadership support and defining standard of work were instrumental aspects to guide participants through urgency pressures. A team was needed to lead the change initiative.

Building a core coalition

"It was most certainly one of those 'everybody gets involved' changes, because we needed everyone in the clinic to understand what we were attempting to do."—Licensed Professional Counselor

A central team was developed to help lead creation and implementation of the change initiative. Participant's communicated that strong leadership was essential in driving change—by

prioritizing work and facilitating a consensus-building process for conversion. The central team included the clinic administrator, medical director, and licensed professional counselor. It was created to identify avenues that would be most effective for implementing the initiative. The central team considered different aspects of the change process, including unintended consequences and championed the initiative with a framework that included a core coalition. Coalition members were identified based upon their roles and responsibilities. The members represented a cross-section of clinic staff (the core coalition members represent the participants in this study; Table 1). This approach afforded opportunity to engage various clinic stakeholders in its creation and facilitated stakeholder buy-in throughout the organization.

Developing the strategic vision

“It didn’t take long for everyone to understand the strategy. We were going to develop this new change agenda, sort of a clinic roadmap if you will, and this agenda would dictate exactly how we managed opioids for the safety of our patients and the safety of our medical license.”—Medical Provider

A strategic vision involves developing the action plan of the organization. It was important for the coalition to have a shared understanding of the clinic’s strategic vision and approach to change. The strategic vision interconnected the need to change with the path to change. It incorporated objectives to address tools for providers to treat chronic pain with opioid therapy safely and compassionately. Internal policies would be standardized to ensure consistent prescribing practices that met common challenges in chronic pain management. The vision functioned to promote best practices through practice improvement programs, technical assistance (coaching), and literature review that facilitated efficacy and ensured compliance with Centers for Medicare & Medicaid Services fraud, waste, and abuse policies and with Drug Enforcement Administration rules. The vision served to illustrate high levels of strategic alignment relative to both the external and internal opioid prescription initiatives and provided frequent review policies to maintain compliance. The strategic vision represented the crafting and formulating of short-term and long-term initiatives directed at attaining organizational objectives. Next, it was important to get everyone on board.

Communicating the strategic vision

“Yeah, it was talked about all the time and everyone knew they had to get on board with managing these patients better. The patients needed it and we needed it as a staff. We were all working together with these patients and their concerns, and there were a lot of concerns. We really needed to understand how this was going to happen”—Nurse

Much of organizational change will not succeed without people adopting new ways of working.²⁵ One of the primary reasons employees resist change is their failure to understand

how change will occur. It is vital to any change management to reduce conflict and increase collaboration through communication. Organizations enacting change policies tend to focus on what has to be done and by when. Often, management does not follow through with the necessary communication employees need to achieve the desired results.²⁶ Communicating the strategic vision was important in order to assess employee readiness for change and to precisely recognize change barriers.²⁷ In developing the strategic vision the participants specified it was important to create reporting protocols and communication accountability. It was essential that the implementation plan clearly communicated responsibility, accountability, timeline expectations, and shared transparencies to understand desired outcomes of the change initiative.

Empower broad-based action

“. . . we had some disagreements on how to wean some of the patients down. There were different ideas and such. . . ultimately, we went to the literature and pulled down some references so that we could tie our titration methods back to other guidelines. At the end of the day, we needed something to fall back on that was central to the actions we needed.”—Medical

Removing barriers and reducing friction is essential to any successful broad based action within an organizational.²⁸ Participants identified 2 primary obstacles that were encountered during communication of the strategic vision. First, incongruous weaning methodologies were acknowledged between prescribers. The providers were from different generational medical backgrounds which culminated in dichotomous treatment opinions. Second, a sense of perturbation was offered by all providers when engaging patient needs during MME reduction. Concerns ranged from, “push back” or resistance by the patient, extended time to implement prescribing changes for each patient, detoxification comorbidities, and illicit substituting to manage chronic pain. Key to removing barriers was to address how concrete solutions would be introduced mitigating aforementioned provider concerns. Consolidating barriers that linked to operational clarity and consistency of norms for the launch phase was instrumental to sanctioning broad-based conformity and empowered action.

Launch. The launch considered labors that afforded operationalizing the change initiative. Although promoting change readiness in the pre-launch phase was vital, participants expressed the launch phase was the most challenging phase of the change process. Gilley et al²⁸ asserted that 30% to 60% of all change initiatives fail within organizations. Despite a clear understanding of the major initiatives, unintended consequences can plague organizational change strategy.²⁹ Here, data were used to categorize the launch phase and provide insight to answer RQ2: what challenges were identified when reducing opioid prescriptions in primary care? Conducting pre

and post-visit reviews and measuring progress were important common themes for underpinning the launch phase. Each common theme gave impetus to incorporate the Kotter's elements of short-term wins and consolidated gains. Important to the success of any change initiative is positive momentum.²⁸ Participants considered any incremental reduction in daily MME a condition of positive momentum.

Generating short-term wins

"We had some difficult patients at first, overall though; it was good to see some of these patients react to being able to function on less medication. I remember one patient was like 'I feel like my mind is clearer' because she was able to complete puzzles better. That little change was exciting for her and for us."—Licensed Professional Counselor

The change initiative was launched with an action plan coupled with training sessions on clarity of activities, responsibilities, and expected timeframes. Each section of the action plan (eg, new patient acceptance criteria, initiation of opioid therapy, policy for refills, short-acting opioids, polypharmacy) was conditioned by identifying the skill set and knowledge level of the clinic staff impacted by each section. Prerequisite knowledge and support materials were provided for rapid knowledge acquisition. Following each training session, open dialog was helpful to formalize processes and establish new cultural norms. Participants expressed resistance to the launch was more widespread than expected. We interpret this stage of resistance to be in line with Erwin's³⁰ findings that some healthcare employees are unprepared or simply decline to learn and develop new skills. To overcome any reluctance the staff was encouraged to expressly highlight moments of improvement (eg, operational efficacies and/or MME reductions) as short-term wins to be celebrated. Overtly recognizing positive change events helped to encourage conformity and adoption.

Consolidate gains and produce more change

"Once we got patients down to 90mg we were like, let's keep going. We were able to decrease some of the patients by 50–60%. I personally have seen more patient visits since we initiated the MME reduction because now alternative treatments are on the brain, not just more pills."—Chiropractor

Keeping the change effort viable is important. There must be concerted efforts to reinforce momentum of the change initiative. To do this, the coalition made it a point to consolidate the gains from previous short-term wins. Weekly meetings were used to demonstrate visual cues that provided a more tangible optic on their achievements. This view was instrumental in countering any continued resistance and kept the staff motivated to be engaged without sliding back to the old ways of doing things. Preventing recalcitrant behavior was central at this stage. The weekly meetings provided an open platform for

softening resistance points by including ways to "bake in" potential barriers and incorporate them into processes for more change. For example, early in the launch phase it was discovered the fear of patient resistance to MME reduction continued. This fear was addressed by abdication of a unimodal approach and incorporated multimodal treatment strategies to pain control. A licensed professional counselor was included to concurrently manage patients with psychosocial overlay concomitants. Detoxification comorbidities were supported with a "prescription pack" for treatment of opioid abstinence syndrome (ie, withdrawal) and was made available to the patient at the time of visit. The ability to consolidate gains, make adjustment, and incorporate new prospects for change gave opportunity for sustained acceleration of the change initiative.

Post launch. The post-launch was considered work that promoted lasting change to the prescriptive culture. Failure to implement lasting change frequently occurs unless there has been change in organizational culture.²⁸ Anchoring change to the culture with new norms and values that supported the change effort was important in this phase. In order to solidify change in the culture, the change effort needed to demonstrate positive organizational results. Data from the post-launch phase provided insight to RQ3: how was reduction of opioid prescription practices sustained in primary care? Similar to the launch phase, measuring progress was significant for the post-launch phase. It was important to measure progress to solidify Kotter's eighth step; anchor new approaches in the organizational culture.

Anchoring to the culture

"We continue to evolve our behaviors to promote stability in our opioid management practices. When something new comes up we meet on it and determine how it will be addressed and add that to our way of doing things. We also meet monthly to go over difficult patients and different procedures we need to modify. It keeps the team on their toes and has made us a much better clinic."—Nurse Practitioner

The post launch strategy was to shift the emphasis from maintenance to sustained improvement. Kotter stressed the point that sustained change must be anchored in order for change to take place successfully. The indoctrination of new norms of behavior and shared prescribing values were important to anchor to the culture. In this phase the core coalition provided continued leadership and reinforced new practices to anchor the transformation into the culture. Participants indicated sustainability occurred when the new culture began to exert itself on resistant staff members and new hires. Linking the new norms with core capabilities was instrumental in the opportunity to solidify the process away from people's tendency to revert to the old and comfortable ways of doing things. The new culture served as a reinforcing tool regarding the risks associated with continuing to prescribe opioids and reinforced signs of misuse,

abuse, or diversion that can result in (1) patient overdose and death, (2) negative community health byproducts like crime or motor vehicle accidents; and (3) implications for state and federal licensure. Built-in motivation to keep the patients, the organization, and the community safe and healthy was anchored into operations to help facilitate the opioid change initiative.

Conclusion

An ongoing challenge to the opioid crisis continues in large health care systems and rural clinics that treat and manage patients with opioids.^{31,32} Primary care providers are uniquely positioned to make positive impacts on the opioid crisis with planned change. Planned change in primary care is necessary, but change can be challenging to implement—especially in the context of chronic opioid therapy. The case study demonstrated a reduction in MME from 102.5 mg in 2015 to 45.0 mg in 2020 accounting for a 56% reduction over a 5-year period. The reduction in daily MME was concurrently successful in maintaining patient population and minimizing abuse, misuse, or diversion of opioids or illegal substances that may have potential deleterious effect on community health. Importantly, the psychometric properties of the 2 opioid risk tools (ORT, SOAPP-R) administered at intake for each participant revealed the category of potential aberrant behavior (low to moderate) was consistent over the 5 period under study. This analysis adds support to suggest the successful conversion was accomplished through planned change and adoption of change theory as a framework to a change initiative. An established process for continuous improvement was imperative for anchoring long-term cumulative gains over time. Ongoing monitoring and review of clinic policies to support management of opioid therapy has continued to provide sustainable benefits (Table 5). For example, as a byproduct of the change, clinic production was streamlined by eliminating outlier patients (eg, early refill requests, aberrant drug screens). Moreover, documentation efficiencies were gained due to treatment boundaries and parameters that severed to reduce costs of care.

The findings in this study demonstrate Kotter's theoretical framework an effective tool for implementing and sustaining transformational change in a primary care practices treating and managing patients with chronic opioid therapy. These finding have the potential to provide actionable implications for health care management professionals and primary care organizations such as hospitals and group practices.

Research limitations of the study

Rich data were obtained from the participant interviews that were conducted. However, data regarding the change initiative was absent any patient perspective—thus omitting a potentially valuable perspective on this research. Although the quantitative data was important to validate reduction in MME in participants with consistent opioid risk tendencies over the 5 year period, the data was devoid of urinary drug screen

Table 5. Ongoing monitoring to support chronic opioid therapy in primary care.

New patient acceptance criteria
Absolute contraindications
Severe respiratory instability
Acute psychiatric instability or uncontrolled suicide risk
True allergy to opioid agents (cannot be resolved by switching agents)
Serious adverse effects that cannot be treated
Illicit drug conviction
Relative contraindications
Medical condition in which COT may cause harm (eg, COPD)
Complicated pain (eg, headache not responsive to other pain treatment modalities)
Psychosocial behavioral overlay conditions
Prior to initiation of COT
Review of prior medical records
Establishment diagnosis that justifies COT
Review patients PAT for inconsistencies
Urinary drug screen
Screen and assess the patient's risk (SOAPP-R, ORT)
Signed pain management agreement
Only use 1 pharmacy
Only 1 provider
Established patient currently on COT
Signed pain management agreement
Random urinary drug screen
Review patients PAT for inconsistencies
No early refills
Police report for all lost prescriptions
30-D supply only
Monitor for co-prescribing of sedatives
Others
Naloxone prescribed to all patients >50 mg MEDD
Established protocol of referral to interventionist or mental health specialist (eg, aberrant behavior, >90 mg MEDD)
Primary goal of treatment should be clinically significant improvement in function

Abbreviations: COPD, chronic obstructive pulmonary disease; COT, chronic opioid therapy; MEDD, morphine equivalent daily dose; ORT, opioid risk tool; PAT, prescription access in Texas database; SOAPP-R, screener and opioid assessment for patients with pain-revised.

constancies/inconsistencies that may have provided further confirmation of change theory success in the primary care context. Furthermore, this case study only sought participants from the Northeast Texas region of the United States which limits generalizability. The sample size was small and further limits the potential to generalize the findings.

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Author Contributions

This study was conceived by RC as the principal investigators. RC and DS were responsible for study design, data collection, and participant interviews. RC and DS participated in data analysis, synthesis, and interpretation. RC wrote the initial draft. RC and JT wrote the final draft with input from the authors who each read and approved the final manuscript. The authors alone are responsible for the views expressed in this article. The corresponding author attests that all listed authors meet authorship criteria.

Availability of Data and Materials

The qualitative data used and analyzed during the current study are available from the corresponding author upon reasonable request.

Ethical Approval and Consent to Participate

Ethics approval was obtained from the Institutional Review Boards of the University of Texas at Tyler in Tyler, Texas (IRB #Sum2019-131). The principle investigator obtained written consent from participants and informed them that their participation would be voluntary and without professional or personal consequences or benefits of participation. Participants were given the option to read their transcribed interviews and respond to any noted aberrancies. No financial incentives were provided to the participants.

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