

ORIGINAL RESEARCH

Primary Care Clinic Re-Design for Prescription Opioid Management

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Background: The challenge of responding to prescription opioid overuse within the United States has fallen disproportionately on the primary care clinic setting. Here we describe a framework comprised of 6 Building Blocks to guide efforts within this setting to address the use of opioids for chronic pain.

Methods: Investigators conducted site visits to thirty primary care clinics across the United States selected for their use of team-based workforce innovations. Site visits included interviews with leadership, clinic tours, observations of clinic processes and team meetings, and interviews with staff and clinicians. Data were reviewed to identify common attributes of clinic system changes around chronic opioid therapy (COT) management. These concepts were reviewed to develop narrative descriptions of key components of changes made to improve COT use.

Results: Twenty of the thirty sites had addressed improvements in COT prescribing. Across these sites a common set of 6 Building Blocks were identified: 1) providing leadership support; 2) revising and aligning clinic policies, patient agreements (contracts) and workflows; 3) implementing a registry tracking system; 4) conducting planned, patient-centered visits; 5) identifying resources for complex patients; and 6) measuring progress toward achieving clinic objectives. Common components of clinic policies, patient agreements and data tracked in registries to assess progress are described.

Conclusions: In response to prescription opioid overuse and the resulting epidemic of overdose and addiction, primary care clinics are making improvements driven by a common set of best practices that address complex challenges of managing COT patients in primary care settings. (J Am Board Fam Med 2017;30:44–51.)

Keywords: Ambulatory Care Facilities; Analgesics, Opioid; Chronic Pain; Drug Overdose; Leadership; Opioid-Related Disorders; Prescriptions; Primary Health Care; Registries; Research Personnel; Workflow

The current epidemic of prescription opioid overdose and deaths may be the most significant iatrogenic epidemic in the recent history of medicine in the United States.^{1–3} Although the responsibility

for initiation of opioids for chronic pain may be attributed to primary care clinicians to some degree, the sheer numbers of patients taking a prescription opioid medication for long-term chronic pain has placed an enormous burden on primary care where the majority of opioid prescriptions are written.⁴ This burden may contribute to burnout and stress in primary care settings where both prescribers and clinic support staff struggle daily to balance risks and the potential for abuse and diversion with empathy for the suffering of chronic pain patients.⁵

As evidence accumulates to support more judicious use of COT, guidelines for prescribing opioids such as those recently released by the U.S. Center for Disease Control and Prevention have been released or updated.⁶ However, implementing

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these recommendations will require changes to clinic systems and workflows of health care teams across the entire clinic, not just changes by individual prescribers. Systematic changes to make opioid prescribing safer have been evaluated in large integrated health care delivery systems such as Veteran's Administration clinics and other large group practice settings.⁷⁻⁹ Less is known about systems approaches to improve address the overuse of COT across a diversity of primary care settings.

Here we describe a framework comprised of 6 Building Blocks to guide smaller clinics in practice redesign and improvement, derived from observations of thirty primary care clinics selected for their innovations in team-based care delivery. The intent is to provide general principles and best practices that can be adapted or applied across diverse primary care clinic settings.

Methods

Data Sources

In 2012 the Robert Wood Johnson Foundation funded Primary Care Teams: Learning from Exemplar Ambulatory Practices (LEAP).¹⁰ The goal of LEAP was to study team-based workforce innovations across diverse primary care clinics within the United States. A national advisory committee of experts and stakeholders in primary care provided nominations. Sites were screened in a telephone interview and reviewed by members of the LEAP study team who then made recommendations to the advisory committee who made the final selection of thirty clinics for site visits.

A team of 3-4 LEAP investigators conducted a 3-day site visit to each clinic. Site visits included group interviews with the leadership team, comprehensive tours of each clinic focused on understanding workflows and general clinic functioning, detailed observations of clinic processes and team meetings, interviews with individual staff and clinicians, and shadowing of patients during their visits. Supporting documents, tools, and resources such as clinic policies, workflows, patient-facing materials, and decision tools were also collected.

Data Coding and Analysis

Several LEAP investigators initially coded the site visit data (DC, CH) using broad codes to capture

key primary care team member roles and functions. One broad code for "medication management" included experiences with managing COT. One LEAP research team member (DC) then subcoded for opioid-related data within the broad medication management code by searching the LEAP dataset for key words such as "opioids," "pain," and "narcotics" to ensure that the opioid subcode would be applied to all relevant data. The opioid subcode contained 91 pages of data.

A small team of LEAP investigators (MLP, DC, CH) reviewed the coded data with the goal of identifying common components that informed clinic redesign efforts to improve COT management. These concepts were presented to the larger team (MVK, MS, LMB, EHW), who verified them and developed descriptions of each component. Themes and concepts were also compared and contrasted to a Group Health opioid improvement initiative to identify common elements and strategies.^{8,9} As descriptive phrases and definitions were developed, examples of activities used by the clinics to make the necessary changes were identified from the LEAP data sources.

Results

Twenty of the 30 LEAP clinics had made systematic improvements in COT management. (Table 1) Each site had different priorities in developing their policies and processes related to COT. These included avoiding the issue (eg, several refused to prescribe opioids for chronic pain); concerns about staff security (protecting staff from threats by drug seekers); enhancing safe management of opioids; and actively treating prescription opioid addiction. Concerns about drug seeking were a higher priority in many sites than opioid dose reduction and their COT-prescribing programs often reflected their priorities.

Across the LEAP site where COT was used for chronic noncancer pain, a common set of change principles were noted as playing an important role in addressing their priorities. Here we describe these elements as 6 Building Blocks that summarize our findings. (Table 2)

Building Block 1: Providing Leadership Support

"It was definitely another of those transformational efforts, because it required everyone in the organization to understand what we're doing and so even the folks at the

Table 1. Primary Care Clinic Characteristics and Examples of Opioid Improvement Efforts

State	Clinic Type	Location	Payer Mix	Example Opioid Improvement	Building Block(s)
PA	FQHC, nurse-led	Urban	4% Medicare 58% Medicaid 14% commercial 23% uninsured	Chronic pain group therapy	4,5
WV	FQHC, AHEC	Rural	17% Medicare 25% Medicaid 22% commercial 30% uninsured	Chronic pain group visits Pain registry Chronic opioid prescribing policy and pathway	1,2,3
SC	FQHC	Rural	32% Medicaid 12% Medicare 15% Other 40% uninsured	Standard care plans Patient agreements In house physical therapy Suboxone	2,3,4
OR	FQHC, residency	Urban	20% Medicare 50% Medicaid 0% commercial 30% uninsured	Chronic pain group visit In-house CAM therapy Revised policies Random urine drug tests Patient agreements Suboxone 28-day refills	2,3,4
NH	MMG	Rural	45% Medicare 2% Medicaid 50% commercial 3% uninsured	Patient agreements Opioid QI team Revised policies	2,5
WA	MMG	Rural, Suburban	20% Medicare 9% Medicaid 61.5% commercial 9.5% uninsured	Chronic pain re-design team Suboxone Pain registry Patient agreements Random urine drug screens Workflow for refills	2,4
MA	MMG	Suburban	23% Medicare 5% Medicaid 70% commercial 2% uninsured	Patient agreements Revised clinic policies Suboxone Chronic pain group visits Random urine drug screens	2,3,4
NM	FQHC	Frontier/ Rural	28% Medicaid 30% commercial 19% Medicare 17% Sliding Fee 6% self pay	Chronic pain group visits Behavioral health integration on teams Mental health “first aid” training for staff Suboxone	3,4
CO	FQHC	Rural	47% Sliding Scale 17% Medicaid 15% Medicare 18% commercial dental	Revised policies Routine PDMP check with refills Patient agreements No refills on Fridays	2
ME	MMG	Suburban	35% Medicare 4.4% Medicaid 45% commercial 5.4% uninsured	Registry with chronic pain manager Chronic pain group visits Revised policies	2,3,4

Continued

Table 1. Continued

State	Clinic Type	Location	Payer Mix	Example Opioid Improvement	Building Block(s)
CO	MMG	Urban, Suburban, Frontier/ Rural	20% Medicare 21% Medicaid 50% commercial 9% self-pay	Patient agreements Pre-visit preparation in daily huddle Random urine drug test Track PEG scores and PHQ-9 Suboxone	2,3,4
OH	FQHC	Urban	50% Medicaid 20% uninsured 20% commercial 10% Medicare	Random urine drug test State PDMP check with refills Clinic refill policies	2,3,4
PA	PVT	Suburban	90% commercial 8% Medicare 1% uninsured 1% Medicaid	Patient agreements Revised policies	2
ME	FQHC, residency	Suburban	26% Medicare 25% Medicaid 40% commercial 9% uninsured	Provider support and learning group Suboxone Revised policies	2,4
WA	MMG, residency	Suburban	10% Medicare 50% Medicaid 30% commercial 10% uninsured	Chronic pain registry with dedicated MA registry manager Revised policies Patient agreement Nurse intake for new patients on opioids Random urine drug test State PDMP check PEG scores Referral for high risk	1,2,3,4
WI	MMG	Rural	17.7% Medicare 5.5% Medicare 73.8% commercial 3% uninsured	Patient agreement Revised refill policies	2
MA	CHC (hospital network)	Urban	40% Public 40% uninsured 20% private	Physical therapy assistant Chronic pain group visits led by social worker	2,4
DC	FQHC	Urban	63% Medicaid 6% Medicare 20% DC Alliance 6% commercial 5% uninsured	Chronic pain group visits Massage therapy	4
NY	AHC, residency	Urban	10% Medicare 50% Medicaid 30% commercial 8% uninsured	Revised clinic policies Patient agreements Behavioral Health Social Worker	2,4
CA	FQHC	Rural	50% Medicaid 17% Medicare 3% commercial 28% uninsured	Chronic pain group visits Revised clinic policies Pre-visit planning in daily huddle Patient agreements	2,3,4

Abbreviations: AHC, Academic Health Center; AHEC, Area Health Education Center; CHC, community health center; FQHC, Federally Qualified Health Center; MMG, Multi-specialty Medical Group or part of large system; PVT, Private Practice; RHC, Rural Health Center; THC, Teaching Health Center.

Table 2. Six Building Blocks to Guide Management of Chronic Opioid Therapy

Building Block	Description	Examples of Action Steps
1. Provide Leadership Support	Leadership can build organization-wide consensus to prioritize safe, more selective, and more cautious opioid prescribing	Identify clinical champions to spearhead COT practice change initiatives. Provide protected time and space for providers and staff to discuss and agree upon short and long-term goals for COT practice change initiatives
2. Revise Policies, Patient Agreements and Workflows	Revise and implement clinic policies and define standard work for health care team members to achieve safer opioid prescribing and COT management in each clinical contact with COT patients.	Convene a team from each area of the clinic to revise existing policies or write new ones Review patient agreement and revise to ensure alignment with clinic policies. Discuss with all staff and clinicians and modify roles, responsibilities and workflows accordingly
3. Implement a Registry for Population Management	Implement pro-active population management before, during, and between clinic visits of all COT patients to ensure that care is safe and appropriate and provide measure to track COT improvement activities.	Enter all existing COT patients and their relevant enrollment data into a COT registry. Assign each COT patient to a single provider responsible for managing their opioid use and. Assign a team member in each clinic with responsibility and protected time for managing and updating the registry. Use the registry to track data for prescription management (e.g., COT dose, PEG scores to monitor function and pain, date of state prescription database checks)
4. Conduct Planned Patient-Centered Visits	Conduct pre-visit planning and support patient-centered, empathic communication for COT patient care.	Review COT registry reports prior to the visit to identify care gaps Monitor and adjust management based on function and quality of life rather than pain scores (the PEG scale) Offer organizational support for clinic staff and providers to preview charts and do team huddles about COT patients Support staff training, to encourage the use of empathic communication techniques that
5. Identify Resources for Complex Patients	Develop resources to ensure that patients who develop complex opioid dependence, are identified and provided with appropriate care	Identify addiction referral resources and other mental/behavioral health resources, and ensure they are readily available, setting-up referral protocols or agreements as necessary.
6. Measure Progress	Continuously monitor progress and improve with experience.	Identify key process and outcome measures to monitor practice change implementation. Monitor agreed upon COT patient care data, providing and discussing data with clinic staff and medical providers at monthly meetings.

COT, chronic opioid therapy.

front desk had to understand we were not all a sudden changing or getting tough, thinking that people were drug seeking or abusing.”—Office Manager, LEAP site Leadership played an essential role by both prioritizing the work and facilitating a consensus-building process to help providers and staff reach a shared understanding about standards of care for COT patients. Consensus building often started around defining who qualified as a COT patient and discussions about the growing evidence of harm for their patients. Many times this took the form of a story about a patient from their own clinic who experienced harm from COT use.

Building Block 2: Revising Clinic Policies, Patient Agreement, and Workflows

“We’ve become aware of the evidence and the research indicating that providing opiates has a lot of risk associated with it and there’s better ways of dealing with chronic pain than just providing prescriptions.... So we put a lot of time into defining what kind of system should we put in place to make sure we evaluate people appropriately, that we monitor use, and we have a system and act when we discover an issue or a problem with potential misuse.... So that took some years, I guess, doing that.”—Medical Director, LEAP site The work often began with revising 2 documents, clinic policies, and pa-

Table 3. Examples of Common Clinic Policies to Support Management of Chronic Opioid Therapy

New patients currently on COT
All new patients require a urine drug test and copies of prior medical records prior to an opioid prescription
Standard elements of a pain assessment on all new patients
Established Patients COT Management
No refills on Monday and Fridays
No early refills for lost or stolen prescriptions or or a police report for such a refill
Face-to-face visit intervals required for a refill based on level of risk
28-day supply only (to avoid running out on weekends)
Advanced notification period (e.g. 4 business days) for a refill request to be processed
Random urine drug screening frequency
Frequency of required PDMP check and who is responsible
Frequency and documentation of screening for depression and post traumatic stress disorder
Monitoring for co-prescribing of sedatives
Others:
No initiation of opioids to treat headaches, fibromyalgia or chronic low back pain
Standards for when a referral is required to a pain specialist or mental/behavioral health specialist (e.g., aberrant behaviors, high dose such as >100 morphine medication equivalent)

COT, chronic opioid therapy; PDMP, prescription drug monitoring program.

tient agreements (contracts). Fifteen of the twenty LEAP sites had clinic policies and/or patient agreements in place. In some clinics, the discussions about what to include in these 2 documents provided a scaffold for on-going hallway conversations among providers and staff that resulted in a shared understanding about their approach to COT management. Some clinics discovered a lack of alignment between language in the patient agreement and their clinic policies and worked to align the 2 documents.

“I explain to them the policies, that I might call them for a pill count or a urine drug screen just so they know who I am. But for the most part, I have pretty good rapport, I think, with them. Like, ‘I am not here to attack you; we’re here to help you. We want to make sure you are taking them safely.’ And it seems to go really well.” –RN Pain Registry Manager, LEAP Site
Common elements of clinic policies are found in Table 3. Clinic policies addressed common situations such as new patients who present with an opioid refill request, activities to monitor the safety of established patients, and policies around standards of care for COT refills. Clinic staff used the

policies to discuss workflow redesign efforts such as checking the state Prescription Drug Monitoring Program’s (PDMP) database so that policies were applied to daily patient care.

Patient agreements were sometimes used as tools to guide discussions with patients about the risks associated with COT, alternative treatments, and signs of aberrant behaviors such as repeated requests for early refills that would raise concerns. They were often renewed annually and some providers used them to have discussions about tapering COT with patients for whom the benefit of continued use of COT was questionable.

Building Block 3: Implementing a Registry for Population Management

“My registry... is kind of helpful because it has everything. It says what the patient has and if they are out of compliance, like they need a new pain agreement that expired 2 months ago.” –Pain Registry Manager, LEAP Site
A registry or some form of tracking system was commonly used to monitor COT patients between visits and manage refills requests. A few had a designated registry manager, usually a medical assistant or nurse, with protected time each week or month to update the registry and identify patients with care gaps. In several clinics reports from the registry were reviewed during previsit planning such as a morning huddle to prepare for a visit. Some sites routed COT refill requests through the registry manager to identify care gaps and address them in between visits. In addition, data from the registry was commonly used to track agreed-on measures for quality improvement in the area of COT management. Some of the items included in a typical registry are found in Table 4.

Table 4. Common Elements Seen in registries

Date of renewal of patient agreement (signed by patient)
Current morphine medication equivalent dose of opioid medications
Date of most recent PDMP check
Date and result most recent urine drug screen
PEG scores (trended at regular intervals)
Opioid risk tool score
Medication list reviewed for concurrent use of sedatives
PHQ screen for depression

PDMP, prescription drug monitoring program; PEG, pain, enjoyment, general activity; PHQ, patient health questionnaire.

Building Block 4: Conducting Planned Patient-Centered Visits

Clinics often used huddles or some type of chart review the day before to prepare for visits with chronic pain patients. They identified care gaps such as an out-of-date patient agreement or an overdue check of the state PDMP and used the visit as an opportunity to close those gaps. Staff and clinicians would occasionally rehearse how to have difficult conversations with patients about aberrant refill behaviors or abnormal urine drug tests.

“And it was also the process of learning how to say no in a kind way, because it is very difficult when somebody who is misusing—it is much easier when somebody who is not misusing, but when somebody is misusing and they know they are misusing, they get very confrontational. The staff over the past 7 years has learned how to not inflame that.” –Nurse Practitioner, LEAP Site

They often shared “scripts” with each other about language they used in talking with patients who “expect” their prescription pain medications and are reluctant to hear about alternative treatments.

One important patient-centered component that LEAP sites often mentioned was moving away from the traditional visual-analog pain scale to assess the effectiveness of current management strategies to a more robust patient-centered assessment of pain, function, and enjoyment of life. The Pain, Enjoyment, General activity (PEG) scale was becoming more widely used across sites.^{11–12} Several providers mentioned that tracking the PEG scale at every visit helped them avoid inappropriate COT dose escalation and sometimes led to conversations about tapering the dose.

Building Block 5: Identifying Resources for Complex Patients

“Both patients and providers were very concerned that they did not have access to traditional resources such as Physical Therapy to support patients with chronic pain so we created group clinics for chronic pain staff by a behavioral health consultant, a physical therapy assistant... and a health coach from our clinic.” –Behavioral Health Social Worker, LEAP Site

Clinics recognized that some patients required more support and treatment for addiction, opioid use disorder, or mental/behavioral health issues than was currently available within their clinic system. Some identified existing community resources and built stronger linkages with them. Others de-

veloped resources within their setting to deliver these services to the patient directly. A few clinics used shared appointment (group) visits with a standard curriculum to improve patient self efficacy around managing their chronic pain. In 1 LEAP site patients on high-dose opioids were required to attend these sessions to refill their opioid medication. Seven of the clinics had a buprenorphine prescriber who provided medication-assisted therapy.

Building Block 6: Measuring progress

“My [work with] chronic pain [patients] is my favorite part of my job because I love to feel like I can help them.”

–Medical Assistant Registry Manager, LEAP Site
Clinics often had improvement teams with a specific focus on COT use. They selected process measures such as proportion of patients with an up-to-date agreement in the chart, proportion of patients with a PDMP check twice in the past year. Important outcome measures that clinics found valuable to track included: average PEG scale scores^{11–12} (see Building Block 4), the proportion of patients on high-dose COT (eg, daily morphine-equivalent dose ≥ 90), and the monthly number of patients who transitioned from opioids for acute pain to those on COT. Clinics reported these measures and discussed them during monthly staff meetings and leadership team meetings.

Discussion

Through data gathered from site visits to primary care clinics that exemplified team-based models of care, we identified 6 common change strategies or ‘building blocks’ used by innovative primary care clinics to improve COT management. The themes that emerged consolidate and systemize best practice approaches to addressing the complex challenge of managing COT patients in primary care settings. These findings are not meant to be comprehensive or exclusive of other approaches or strategies that might be equally effective or necessary and clearly must be adapted to local context and resources.

Ongoing challenges faced by smaller primary care clinic settings included a lack of validated clinical performance measures for improving care provided to COT patients, difficulty identifying adequate community resources such as access to mental/behavioral health and addiction services, and concerns about a paucity of evidence-based

alternatives to COT for chronic pain. At least 1 LEAP site made the decision to no longer prescribe opioids for managing chronic pain because of these and other concerns. Providers in many of the LEAP sites that made systematic changes to support safer opioid prescribing reported that tackling these challenges restored a sense of joy and fulfillment in their daily work.

The recent release of new COT-prescribing guidelines combined with growing evidence of patient harm with use of COT for chronic noncancer pain will require changes in workflow and clinic-wide systems to adopt and implement the new standards.⁶ Changing systems of care is different from changing provider prescribing habits, but experience suggests that system change in primary care settings is a critical component to sustained change in provider behaviors.¹³ The practical steps and strategies represented in the 6 Building Blocks were used by innovative clinics to address the use of COT in their patient population and should be considered in designing improvement initiatives in other primary care settings. It is important to note, however, that these new guidelines and the associated workflow redesigns to implement them cause burdens of their own. Unless they can be demonstrated to significantly improve patient outcomes, while also decreasing provider and staff burnout, there may be resistance to implementation. In addition, primary care clinics alone cannot stem the tide of opioid overuse within local communities; it will require community-wide initiatives that include all prescribers.

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To see this article online, please go to: <http://jabfm.org/content/30/1/44.full>.

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