A New Quality Improvement Toolkit to Improve Opioid Prescribing in Primary Care

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**Introduction:** The role of opioids in managing chronic pain has evolved in light of the opioid misuse epidemic and new evidence regarding risks and benefits of long-term opioid therapy. With mounting national guidelines and local regulations, providers need interventions to standardize and improve safe, responsible prescribing. This article summarizes the evolution of an opioid management toolkit using a quality improvement (QI) approach to improve prescribing.

**Methods:** The authors developed a list of opioid-prescribing best practices and offered in-office, team-based QI projects to ambulatory clinics, updated and tested over 3 trials in the form of a toolkit. Outcome measures included pre- and postproject surveys on provider and staff satisfaction, toolkit completion, and process measures. The toolkit supports workflow planning, redesign, and implementation.

**Results:** Ten clinics participated in trial 1, completing the QI project on average in 3 months, with a mean of 9.1 hours of team time. Provider satisfaction with prescribing increased from 42% to 96% and staff satisfaction from 54% to 81%. The most common strategies in trials 1 and 2 focused on regulatory compliance (35% to 36%), whereas in Trial 3 there was a strong move toward peer support (81%).

**Discussion:** Clinics responded to implementation of opioid-related best practices using QI with improved provider and staff satisfaction. Once the goals of regulatory compliance and workflow improvements were met, clinics focused on strategies supporting providers in the lead role of managing chronic pain, building on strategies that provide peer support. Using QI methods, primary care clinics can improve opioid-prescribing best practices for patients. (J Am Board Fam Med 2020;33:17–26.)

**Keywords:** Addictive Behavior, Chronic Pain, Drug Overdose, Leadership, Opioid-Related Disorders, Opioids, Organizational Innovation, Outcome Measures, Primary Health Care, Process Measures, Quality Improvement, Registries, Risk Assessment, Surveys and Questionnaires, Workflow

Opioid misuse is an important public health challenge in the United States. Despite a decrease in opioid prescribing from its peak in 2010, per capita opioid use remains high and varies by location and region without a clinical basis.\(^1\) Drug overdose deaths increased 200% between 2000 and 2014, and opioids contributed to 33,091 deaths in 2015.\(^2\)^\(^3\)

Although a higher proportion of deaths in recent years is attributable to fentanyl mixed with heroin, diverted prescription opioids remain an important contributor to the opioid epidemic.\(^2\)^\(^4\)

Although there has been considerable attention paid to opioid prescribing in acute settings, such as the emergency department,\(^5\) dental offices,\(^6\) and in postoperative settings,\(^7\)^\(^8\) opioids prescribed in primary care are less frequently reported and yet generate the majority of prescribing volume, usually for chronic conditions.\(^9\) In 2016, the Centers for...
Disease Control and Prevention (CDC) published guidelines for the prescription of opioids for chronic pain, which emphasized the principles of avoiding opioids where possible, minimizing the dose, carefully balancing risks and benefits, and monitoring closely for potential side effects or misuse.10

Increasingly, states are establishing regulations that mandate the use of state-level prescription drug monitoring programs (PDMPs), specify quantity and duration limits of opioid prescriptions, or improve access to naloxone.11 The effects of these interventions on outcomes are not yet clear,12 although Washington state, which has implemented a wide range of policies and programs over the last decade, has demonstrated an important decrease in opioid-related deaths and hospitalizations.13

For busy primary care clinics, navigating the complexities of the CDC guidelines, state and local regulations, insurer requirements, and other specific policies enacted at the health care organizational level can be daunting. Beginning in 2012, our research team has been collaborating with the Vermont Department of Health to develop a pragmatic approach to opioid prescribing in ambulatory care clinics. Our initial goal was to apply a process improvement approach to improving opioid prescribing in ambulatory care clinics. The success of our first trial led to a new goal of standardizing our process improvement approach such that a trained quality improvement (QI) facilitator, sometimes available to clinics, could assist providers to improve prescribing. This second trial developed and tested the use of the Opioid Prescription Management Toolkit for Chronic Pain (first and second eds). The success of the toolkit led to a third trial: coaching clinic members not trained in QI to facilitate prescribing improvement with a clinic workbook for changing practice.

The purpose of this report is to share our experience with the evolution of improving opioid-prescribing practices in a wide variety of rural and small urban ambulatory care clinics.

Methods
The study design used in this project was an iterative toolkit-based QI approach with 3 cohorts of clinics over a 7-year period. We designed the toolkits for primary and specialty ambulatory care clinics in our region and described strategies to improve opioid prescribing based on best available evidence and accrued expertise. The third of these trials is still underway.

Trial 1
In 2012, as the potential for negative health outcomes of opioid prescribing became more apparent, the complexity of providing opioid therapy grew as well. Primary care providers found it challenging to care for patients with ongoing opioid prescriptions14 and some began avoiding pain management care altogether.15 Based on the clinical experience of the authors and discussion with colleagues, we predicted that clinicians and office staff would find a structured process improvement approach, laying out a team-based problem-solving method in steps, would be a helpful method of influencing opioid prescribing by providing best prescribing practices and increasing provider satisfaction with opioid prescribing. We assembled a list of best practices available at that time and offered an in-office, team-based project based on Lean process improvement, an easy-to-use structured QI approach. Lean is a systematic method of redesigning workflows to improve both care and provider satisfaction.16–18 Each project was facilitated by one of the authors (CvE) to Vermont providers through the Office of Primary Care and Area Health Education Centers Program at the University of Vermont Larner College of Medicine. In accordance with the policy of the University of Vermont Committees on Human Research, this effort was determined to be a QI project and, therefore, exempt from review.

From 2012 to 2013, 9 Vermont primary care clinics and 1 orthopedic office specializing in back pain were recruited by convenience sample. Clinics were given an overview of the project goal and asked to commit 1 provider, 1 nurse, and 1 front desk staff to regular meetings for approximately 8 hours over 4 months. Recruitment closed after 10 clinics volunteered to participate. These meetings were facilitated by a Lean expert to select from a menu of strategies taken from opioid-prescribing best practices. Team members selected strategies based on analysis of their patients’ needs and clinic’s current workflow. Each clinic determined its own schedule of team meetings and duration of the project. In addition, we offered each clinic the opportunity to attend an individualized medical education conference to review the epidemiology,
medication prescribing issues, and strategies for opioid prescribing. When requested, we also provided consultative visits and phone calls with local experts in the management of chronic pain. Participating clinics received a stipend of $1000 at the completion of their projects, determined to be 3 months after their last team meeting with their facilitator.

Our primary outcome measure was change in provider satisfaction with the clinic’s management of opioid prescribing, measured by pre- and postproject surveys. We conducted a paired response analysis using Wilcoxon sign-rank to test changes in preproject results to postproject results for significance. Providers and staff also completed postproject surveys on the degree of completion of their chosen prescribing strategies to implement. We used STATA 15 (Stata Corporation, College Station, TX) for data management and analysis. In addition, the facilitator collected team process measures (number of team meetings, number of hours in meetings, number of strategies selected by type, and completion of project) and field notes on contextual factors.

**Trial 2**

Based on the outcomes of this initial trial, we developed the toolkit (first ed) as a manual for QI facilitators—in our experience many clinics have access to QI facilitation through a parent organization (eg, hospital, Federally Qualified Health Center [FQHC]) or through other avenues (eg, state-sponsored QI initiatives, Department of Health). The toolkit included 3 stages: (1) preparing the team and baseline measures, (2) designing workflows using Lean with selected opioid-prescribing strategies (see Table 1), and (3) implementing the resulting plan with appropriate follow-up measures. An extensive appendix included applicable state laws, QI assessment tools, and sample patient assessment and care protocols. Trial 2 recruited 7 clinics new to the study, 4 primary care and 3 specialty (dentist, orthopedic rehabilitation, and rheumatology) from 2014–2016, 2 of which were affiliates of the study institution. Recruitment closed in 2015. Teams underwent the same recruitment, introductions, support, and stipends as in trial 1. Clinics were allowed to customize their pre- and postproject surveys and could choose not to use them.

### Table 1. Final Strategy Description List of 28 Strategies Organized by Category, Trial 3 (2018 to 2019)

| Category | Strategies |
|----------|------------|
| Maintain Regulatory Compliance | 1. Consider nonopioid alternatives, where possible  
2. Provide patient education on benefits and risks, initiate treatment agreement, and obtain informed consent*  
3. Conduct ongoing risk assessment, such as the Current Opioid Misuse Measure (COMM), and update plan regularly*  
4. Assess patient function  
5. Assess patient pain  
6. Check Prescription Drug Monitoring Program*  
7. Screen urine at least annually for presence/absence of substances (may screen randomly, depending on risk)*  
8. Use best practices in prescribing: prescribe immediate release opioids, monitor closely any doses of greater than 50 or 90 MME/day, or concurrent dosing of benzodiazepines, and provide naloxone  
9. Track dosage in MMEs, not only quantity prescribed  
10. Short interval follow up after initiating new opioid treatment to review effect  
11. Ongoing visits at least every 3 months* |
| Improve Workflow/Streamline Care | 12. Prescribe in multiples of 7 days in duration of dosage (eg, for 28 day, 56 days, up to 84 days) to support consistent provider/patient relationships*  
13. Prewrite prescriptions for up to 84 days when management is stable*  
14. Use a flowsheet to document repeating strategies for opioid management*  
15. Roster: Include patient in registry for population management reports* |
| Provide Peer-to-Peer Support | 16. Use a team-based care approach to opioid treatment*  
17. Use strategies from the toolkit consistently, so that all patients receive care consistently across the clinic*  
18. Convene clinic members in a “Pain Management Council” regularly to review and discuss complex patient needs*  
19. Share skills that are widely useful; eg, how to have “trigger” conversations  
20. Build community support with other partners/agencies |
| Monitor and Respond to Patients who may be at Risk | 21. Conduct an initial Risk Assessment*  
22. Assess side effects (bowel habit, nausea, vomiting...)  
23. Recognize special issues presented by patients for therapeutic conversations  
24. Prescribe bubble packs if risk level increasing, depending on availability†  
25. Conduct pill counts or random pill counts*  
26. Create a tapering schedule with visits based on individual need  
27. Identify resources that may be helpful and update periodically  
28. Build a patient resource list or offer a library with books, CDs, etc. |

*Appeared in 1st edition of the toolkit.  †Appeared in 2nd edition of the toolkit.

MME, morphine milligram equivalents.
Our primary measure of success for trial 2 was the percent of clinics that completed the toolkit’s activities. Second, we evaluated process measures collected by facilitators reflecting the uptake of the toolkit for each team: number of meetings, number of team hours, duration in months, and number of strategies selected by category (regulatory compliance; streamlining workflow; providing peer support; and responding to patients at risk). Facilitators also collected field notes on contextual factors.

During trial 2, we revised the toolkit (second ed) based on the new 2016 CDC guidelines, feedback from trained facilitators who utilized the toolkit with clinics in our region, and the passage of opioid-prescribing laws in Vermont.

Trial 3
During our recruitment process, we consistently heard that clinics had a high interest in improving prescribing practices but were unable to engage formally trained QI facilitators to support them. Learning from other Lean-based toolkits we had developed, we redesigned the toolkit from 2018 to 2019 by using a workbook format (third ed). This format uses team-based problem-solving rubrics and checklists for use by clinic staff not formally trained in facilitation, thus expanding the audience for the toolkit, and added new strategies on dosing and alternative therapies (see Table 1). We recruited 3 health care organizations representing 10 Vermont primary care clinics, 1 of which was a study affiliate (3 sites). Teams underwent the same recruitment, introductions, support, and stipends as in trials 1 and 2, with the addition of coaching support for internal facilitators. Teams were free to choose their own strategies and QI data. In this study, we report only on the improvement strategies trial 3 clinics chose, as their projects were not finished at the time of publication. For an overview of each trial’s goals, toolkit versions, requirements, outcome measures, and results, see Figure 1.

Results
Trial 1
The 10 ambulatory clinics that participated in 2012 included a combination of family medicine, primary care internal medicine, and surgical specialties. Half were owned by health systems and the remaining were independent clinics or members of FQHCs. The primary driver that motivated clinic participation was an engaged champion (60%); other drivers included a corporate decision to improve opioid prescribing or an investigation by the
state’s medical practice board regarding high prescribing (Table 2). All clinics completed the structured QI project through team meetings with providers, clinical staff, and front desk staff in an average of 3 months (range, 1 to 7). The teams met an average of 6 times (range, 3 to 10), spending a mean of 9.1 hours of team time (range, 5 to 12) to study workflow and design changes that incorporated a selection of best practice strategies. Teams implemented a range of 3 to 13 of 15 best practice strategies presented to them and half implemented 8 or 9 strategies. The most frequently chosen strategies (36%) were those responding to an emerging policy statement about best opioid-prescribing practices from the state Medical Practice Board, finalized in 2014,20 with the remaining strategies focused on streamlining workflow (28%), providing peer support among members within the clinic (22%), and responding to patients at risk (10%) (Table 3).

Respondents to the pre- and postproject surveys included providers, clinical staff, front desk staff,
and other clinic members. We matched respondents from both time periods and maintained a net response rate of 81%. In the matched group, 36 were providers and 83 were nonproviders. Both providers and staff reported that opioid prescribing was improved across a variety of domains. For example, provider satisfaction with opioid-prescribing management increased from 42% to 96% after the intervention, providers’ confidence in prescribing opioids improved from 69% to 88%, and staff satisfaction increased from 54% to 81%. Provider confidence in many other components of CDC guideline-based prescribing improved as well (Table 4). After 3 months of implementation, clinic staff evaluated strategy completion, with 47% reporting selected strategies as “All done,” 21% as “Partly done,” and 25% as “Started.” Furthermore, 76% of respondents felt that their QI project was effective in improving opioid management.

**Trial 2**

The first edition of the toolkit incorporated all 15 strategies presented to and used by the clinics in trial 1. Of the 7 clinics participating from 2014 to 2016, almost half were family medicine followed by primary care internal medicine and specialty care. As before, they were predominately owned by health systems with the remaining an independent clinic and a member of an FQHC. The primary driver of clinic change was again an engaged champion (71%) as well as a corporate decision to improve (Table 2). All clinics completed the structured QI project through team meetings with providers, clinical staff, and front desk staff in an average of 7.7 months (range, 4 to 15), more than twice the average of trial 1 clinics working with an expert facilitator (3.0 months). The teams met an average of 7.3 times (range, 2 to 11), spending a mean of 8.7 hours of team time (range, 2 to 13) to select and redesign workflows, similar to trial 1 results of 6.0 meetings and 9.1 hours, respectively.

Teams implemented an average of 8.6 best practice strategies (range, 1 to 13), similar to the trial 1 average of 8.9, with 5 of the 7 clinics implementing 9 or more strategies. As before, the most commonly chosen category of strategies (35%) responded to the now published state Medical Practice Board guidelines, with the remaining strategies focused on streamlining workflow (32%), providing peer support (20%), and responding to patients at risk (13%) (Table 3). Pre- and postproject surveys were modified and used at the discretion of the clinics; their QI outcomes are not available, although 1 clinic did publish its work.21 Our field notes indicated that these projects were also highly rated by clinic members and satisfaction with the process and outcomes were high. As trial 2 progressed, we updated the toolkit to reflect updates to the CDC guidelines, state law, and feedback from clinics and facilitators (second ed).

**Trial 3**

Toolkit 2019 (third ed) expanded to 28 strategies (from 16) but reduced the length of the instructions, offering a workbook format more usable by office personnel. These strategies, organized into workflow sections from “Before Prescribing” to “Manage the Population,” highlight CDC guidelines as well as commonly used strategies to manage pain and provide opioid therapy when chosen as

### Table 4. Pre- and Postproject Change in Provider and Staff Assessment of Opioid Prescribing for Trial 1 (2012 to 2013)

| Team Outcome Measures* | Pre project (%) | Post project (%) | P value |
|------------------------|-----------------|------------------|---------|
| Providers satisfied with opioid management | 42 | 96 | <.01 |
| Staff satisfied with opioid management | 54 | 81 | .01 |
| Clinic has clear policies on opioid prescription | 58 | 80 | <.01 |
| Clinic has a roster of opioid patients | 71 | 88 | .02 |
| Providers increased use of agreements | 38 | 58 | .03 |
| Providers more confident in using agreements | 62 | 85 | .02 |
| Providers more confident in drug testing | 54 | 69 | .04 |
| Providers more confident in prescription database | 69 | 88 | .01 |
| Providers more confident in prescribing Opioids | 46 | 77 | .01 |

*Based on responses of “4-Agree” or “5-Strongly Agree” on a 5-point Likert scale.
part of treatment. This toolkit is undergoing testing with new clinics; a complete list of all strategies is found in Table 1. Access to this and previous toolkit editions are available at http://www.med.uvm.edu/ahec/workforceresearchdevelopment/toolkits-and-workbooks.

In 2019, 10 primary care clinics came forward to participate in this project and have maintained their engagement. Over half are FQHC clinics, 3 are owned by a health system, and 1 is an independent group clinic. The primary driver motivating change is, once again, a champion in the clinic (60%), and other drivers include a corporate decision to improve and a medical practice board investigation. The owners of these clinics separately selected the same 3 strategies: a team approach, the use of consistent strategies across all providers in the clinic, and the initiation of a “pain management council” to formalize peer-to-peer support in managing patients at risk (Table 3). One clinic also added 7 strategies for process improvement and regulatory compliance. When we explored the shared emphasis on peer support as an initial set of strategies, we received comments such as “It is my job to manage substance use disorder” and “We will find a way to care for every chronic pain patient.” These comments come at a time when the number of available specialists in chronic pain or opioid use disorder has declined across the state and the need for supportive strategies has increased.

**Combined Results**

We aggregated the strategies chosen across all 27 clinics and identified the top 12, stratified by trial (Figure 2). We found 3 peer-to-peer strategies (team approach, consistent strategies, and pain management council) among the top 12, with greater representation in the third trial. Other frequently selected strategies include screening urine (on a scheduled basis or randomly), patient education followed by an agreement and consent, checking the PDMP regularly, ongoing risk assessments, dedicated chronic pain visits, and rosters/registries to support chronic pain care. These and other commonly selected strategies directly affect clinic workflow and are supported by the toolkit.

**Discussion**

During 7 years of developing an opioid management toolkit, we found that ambulatory clinics can be successful in adopting best practices in prescribing for patients with chronic pain, given an acceptable level of time and effort by the clinics. Lean is an approach for making changes that are feasible, efficient, and replicable. This toolkit assists clinics in improving opioid management.

Societal expectations include opioid management as part of primary care. An effective infrastructure, complete with workflows and support strategies to deliver high quality care, is key. Parchman et al. recently described 6 building blocks to successfully manage long-term opioids in primary care. These include leadership, clinic policies, registries, previsit planning for patients with chronic pain, resources for complex patients, and measuring patient outcomes. We also found these elements helpful to primary care clinics. In particular, clinics found the use of rosters/registries to track and manage patients helpful, ensuring that patients received care consistently. In addition, it is clear from our results that a clinic champion is a critical component to redesigning opioid management.

As the primary care community moves toward managing chronic pain as they do other chronic health conditions, the methods of QI can assist clinics to support patients and reduce the chaos that may accompany complex and socially difficult care management. This will involve implementing best practice strategies in addition to clinic redesign. The toolkit represents a spectrum of best practices, allowing clinics to select those that best meet their local requirements, community needs, and providers’ goals for providing high-quality care.

Toolkits to improve health care are ubiquitous but vary in development and content. When Hsu et al. reported on the development of a toolkit to spread Patient-Centered Medical Home redesign, they observed that the spread of innovation in health care is difficult, leading them to select a model of change that could be customized to the clinics while centered on patient-centered standardized work. They chose Lean as their method and formed their toolkit accordingly, which is also the method reported here. A review of 5 recently published toolkits on opioid use exemplifies that toolkits often explain what a process should look like but do not necessarily explain how to re-engineer that process, especially with the patient as the central focus and the front-line team as the enabled change agents. This toolkit provides specific guidance and can be used in support of key
outcomes described in other opioid management resources.

After studying the use of this toolkit over 7 years, we have seen a shift from strategies that maintain compliance with regulatory expectations to those that offer robust provider peer support. This may be because clinics in Vermont have had to conform rapidly to strict rules. Clinics in other settings, who may be developing clinical processes to support chronic pain management, may want to begin with strategies related to local requirements. As their workflow matures, they may find that reinforcing best practices moves them toward strategies related to peer consultation and support.

We think the strategies that these clinics implemented could be generalizable to other clinics. One strategy, an in-clinic chronic pain management council, provides prescriber peer support for complex patients, assists in the transition of “legacy” patients to new providers, and supports consistency by using a standardized treatment approach. A similar opioid use review panel was recently described as part of a QI project in Wisconsin. These support mechanisms could include providers from a clinic or groups of clinics, pharmacists, behavioral health clinicians, chronic pain specialists, or others from the local community. In addition, in areas where clinics are more remote, using tele-health modalities such as Project ECHO may help establish peer-to-peer support.

Previsit planning for patients on long-term opioids was another frequently chosen strategy. This strategy has been recommended in the literature and is shown to decrease opioid morphine milligram-equivalents in a small study involving pharmacists. In addition, a chronic pain management visit goes beyond previsit planning and was selected by clinics using the toolkit. This approach offers a convenient way to focus on chronic pain and opioid-related management, including time for ongoing risk assessment for pain or function, PDMP checks, urine screens, set up and use of agreements, and coordinating engagement of other community resources, such as behavioral health.

There are several limitations to our toolkit. The toolkit has not been tested in a randomized trial. It is possible that the many opioid-related interventions implemented in our area were responsible for some of the improvements seen by clinics. However, given the supporting prepost data for strategies selected and implemented in trial 1, the results are unlikely to be due to chance or cointerventions. We did not collect systemic or patient-level outcome data in this report. Our focus was improving workflow and use of best practice prescribing strategies. Our toolkit has only been tested in clinics in Vermont, which may not reflect the patients or clinics in other regions. However, it is likely the toolkit could be generalized to other clinics with similar characteristics, including rural and suburban areas. Since the toolkit has undergone 3 revisions in 7 years, a relatively small number of clinics used any individual version. Barriers to implementing changes in workflow were unavoidable. Each clinic needed to implement its changes in a way that fit local systems, processes, and culture. Therefore, although the toolkit can guide implementa-

Figure 2. Top 12 strategies selected by 27 ambulatory care clinics by trial period. Abbreviations: PDMP, prescription drug monitoring programs; Pt, Patient.
tion, clinic leadership must adapt the process to work within their communities.

The toolkit continues to support QI projects on opioid management after 7 years of field testing, modification, and additions of new practical resources. A Lean methodology for clinic redesign can standardize processes and ensure opioid best practices are provided to all patients with chronic pain.

Authors’ Note

The Standards for QUality Improvement Reporting Excellence (SQUIRE) were used as guidelines for preparing this Manuscript.33

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