Order From Chaos: An Initiative to Improve Opioid Prescribing in Rheumatology Using Lean A3

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Objective. Use an established quality improvement method, Lean A3, to improve the process of opioid prescribing in an academic rheumatology ambulatory clinic.

Methods. This retrospective pre-postintervention analysis of rheumatology records included patients prescribed opioids at least once during the study period. Lean A3 was used to develop a Controlled Substance Visit Protocol to standardize eight recommended elements of the opioid prescribing workflow. Analyses included changes in the recommended workflow elements and changes in opioid prescribing volume.

Results. Improvements were observed in seven of the eight recommended elements. Patient education, including treatment agreements and consent forms (39% completion for both preimplementation) increased to 78% and 80%, respectively (P < 0.001 for both). Risk assessment, as measured by the Current Opioid Misuse Measure, increased from 0.5% to 76% (P < 0.001). Best practices in prescribing, including prescribing in multiples of seven to avoid weekend refill requests, increased from 1% to 79% (P < 0.001). Monitoring parameters, including standardized functional assessment (0% vs. 86%), prescription drug monitoring program queries (49% vs. 84%), and urine testing (1% vs. 32%) all increased (P < 0.001). Visits scheduled at least quarterly for patients on chronic opioids did not change (P = 0.18). Overall, the number of patients prescribed opioids (185 vs. 160; P < 0.001) and annual prescription opioid morphine milligram equivalents (MMEs) (1,933,585 MME vs. 1,386,368 MME; P < 0.001) decreased.

Conclusion. The Lean A3 method is a successful quality improvement tool for improving and sustaining opioid prescribing within a single academic rheumatology clinic. This method has potential applicability to similar clinics interested in improving opioid prescribing.

INTRODUCTION

Opioids are a major cause of mortality in the United States, with over 42,000 drug overdose deaths in 2016 (1), making efforts to improve prescribing a nationwide focus (2). In 2016, the Centers for Disease Control and Prevention (CDC) issued guidelines regarding safe and effective opioid prescribing (3,4). Increasingly, states are mandating use of prescription drug monitoring programs (PDMPs), setting quantity and duration limits for opioids and making naloxone more available (2,4,5).

There are limited data regarding opioid prescribing in rheumatology clinics. Retrospective cohort data from 2005-2014 found that more than 30% of patients with rheumatoid arthritis (RA) received an opioid prescription (a higher prevalence of opioid use than that found in patients with chronic pain from fibromyalgia and depression), and increased opioid use over time (6). When opioids are being considered as part of any treatment plan, careful assessment of risks and benefits, patient education and consent, and appropriate monitoring are recommended (3,4).

Lean Quality Improvement (QI) (7) uses a structured approach to analyze workflow and is known to produce sustained, effective change in health care organizations (8). A standard Lean method called Lean A3 provides a rapid problem-solving, team-based approach to improve patient care. Lean A3 is based on a template of steps to guide a team of providers and staff through a workflow analysis that leads to problem identification, root cause analysis, and agreement on redesigned clinic workflows (7). The team is responsible for an implementation plan with measures and

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IMPROVING OPIOID PRESCRIBING IN RHEUMATOLOGY

strategies for adapting to organizational challenges. Lean A3 has been demonstrated to be an efficient QI approach in a variety of ambulatory care clinics (9).

The Division of Rheumatology and Clinical Immunology at the University of Vermont Medical Center, an academic rheumatology practice, recognized in 2015 that the office process for prescribing and refilling opioids for outpatients was inefficient, variable, and not current with the latest guidelines and Vermont Board of Medical Practice recommendations. Our purpose was to demonstrate that an established QI method can successfully improve the process of opioid prescribing in an ambulatory rheumatology clinic. The goal of this study was to increase the consistency of opioid prescribing with recommended elements. Secondary goals were improving satisfaction among providers and staff.

PATIENTS AND METHODS

Context. This case study took place in an academic outpatient rheumatology clinic in northern Vermont with 7 physicians, 2 fellowship trainees, 1 nurse practitioner, and 11 000 annual patient visits. The clinic providers were salaried employees, with no financial incentives directly related to this project. The clinic used an Epic (Epic Systems Corporation) electronic health record (EHR).

At the start of the project, the clinic used a reactive process for prescribing opioids in response to patient-reported pain. Patients on opioids needing added or renewed pain management therapy would typically call the clinic and leave a message that would move through a triage, review, and response process based on the availability of clinical staff and providers. The protocol for opioid prescribing was an inefficient and complex process, with providers using a variety of approaches and documentation strategies.

Clinic leaders responded to an invitation to participate in a project on opioid prescription management funded by the Vermont Department of Health. At that time (2015-2016), the State of Vermont legislation was considering specific expectations of providers prescribing opioids, foreshadowing current recommendations. The team created an ideal workflow and protocol built on published standards of care and recommendations related to opioid prescribing (3,4,10), including checking the state’s PDMP. To measure and improve service to patients as well as to prepare for regulatory changes, the project included all patients prescribed opioid treatment therapy by the clinic. The four-member QI team included a provider, nurse, pharmacist, and QI facilitator, the last three of whom are the authors (ME, AGK, and CvE, respectively, with support from the Division Chief, author BL). The grant-funded project supported the QI facilitator and the clinic’s specialty pharmacy. The pharmacist’s role primarily supported prescribing of biologics; however, the pharmacist was also available to support ongoing QI initiatives of the clinic.

Patients. All clinic patients prescribed opioids by rheumatology providers at least once during the study period (June 1, 2014, to May 31, 2017) were included. Patients receiving opioid therapy from other prescribers, such as primary care, were not included. We defined the population of patients prescribed chronic opioids as patients receiving opioids for 90 days or longer.

Intervention. Using Lean A3, the QI team developed a standardized protocol for prescribing opioids. The team began by studying the current workflow, beginning with a patient request for an opioid prescription refill. The team mapped the process from the first call through a review of the patient record, response by provider, and distribution of the paper prescription (electronic prescribing of controlled substances was not yet available). Causes of less-than-ideal care included delays in excess of four days to respond to patients’ requests, out of date protocols, lack of available providers, and high volumes of patients.

After identifying that care outcomes were not optimal, the team created an ideal workflow and protocol built on published standards of care and recommendations related to opioid prescribing (4). The protocol was designed to standardize eight recommended elements of opioid prescribing (Table 1). These elements were categorized into the domains of patient education (treatment agreements and consent forms), risk assessment (use of the Current Opioid Misuse Measure (COMM)), prescribing strategies (prescribing in quantities divisible by seven to avoid week-

| Table 1. Eight recommended elements of opioid prescribing (3,4,10) |
|-----------------------------|---------------------------------|
| Domain                     | Recommended Elements             |
| Patient education           | • Completion of a pain management treatment agreement with the patient that describes the terms for receiving opioid therapy  |
| Risk assessment             | • Completion of patient consent for treatment with opioid therapy  |
| Prescribing strategies      | • Prescription durations written in 7-day increments to avoid the need for refills on weekends or by cross-covering providers  |
| Monitoring                  | • Completion of one or more functional assessments, including the Routine Assessment of Patient Index Data 3 (RAPID3)  |
|                             | • Review of a patient’s controlled substance prescriptions using Vermont’s prescription drug monitoring program (PDMP)  |
|                             | • Review of urine drug screen results  |
end refill dates, follow up visit intervals of 90 days or less), and monitoring strategies (queries of the PDMP, assessment of patient function using the Routine Assessment of Patient Index Data 3 instrument, urine drug testing). The team predicted that embedding a 30-minute “Controlled Substance” nurse previsit for regularly scheduled patient appointments would provide time to support the eight recommended elements associated with opioid prescribing. This Controlled Substance Visit Protocol was designed to eliminate the need for numerous refill requests and was supported by documentation templates to include all required elements. There was no separate fee for this previsit.

Table 2. Electronic health record smart phrases supporting the project

| Controlled Substance Previsit Chart Review | CSPREVISIT |
|------------------------------------------|------------|
| Date of previsit chart review: (insert date) | Chronic controlled substance prescribed: (insert medication) |
| Controlled substance prescriber: (insert name) | Pharmacy: (insert pharmacy) |
| Documentation Patient has a treatment agreement in the chart: (yes/no) | Patient has an informed consent document in the chart: (yes/no) |
| Chronic pain syndrome is listed as a permanent problem: (yes/no) | Vermont Prescription Monitoring System (VPMS is Vermont’s Prescription Drug Monitoring Program) |
| The Vermont Prescription Monitoring System query has been completed: | Date: (insert date) |
| Prescriber(s): (insert name/s) | Pharmacies used: (insert pharmacy/ies) |
| Other findings: (insert text) | Note: This smart phrase was used as part of previsit planning. Any “no” responses or documentation in “Other findings” was reviewed by the nurse and/or provider for appropriate follow-up. |

| Controlled Substance Nurse Visit | CSNURSE |
|---------------------------------|---------|
| The controlled substance previsit chart note was reviewed and identified action items were addressed. | The RAPID3 and COMM assessments were provided to the patient for completion. |
| The prescription(s) has/have been written in multiples of 7 (eg, 7, 14, 21, 28 days) and were pended for the prescriber. | The RAPID3 score was documented in the prescriber encounter. |
| The 5As assessment was initiated and documented in the prescriber encounter. | The CSVISIT smart phrase was initiated in the prescriber encounter. |
| The COMM score was documented in the prescriber encounter. | A future controlled substance nursing visit was requested as part of the After Visit Summary, if appropriate. |
| Note: This smart phrase was used by the nurse as a checklist and as documentation for the activities conducted during the controlled substance nurse visit. |

| Controlled Substance Annual Evaluation | CSVISIT |
|---------------------------------------|---------|
| Patient is a nonpalliative long-term patient whose controlled substance use exceeds 90 days or is expected to exceed 90 days. | Patient has a treatment agreement in the chart. |
| Patient has an informed consent document in the chart. | Chronic pain syndrome is listed as a permanent problem. |
| Queries and Assessments | The VPMS Query has been completed. |
| The COMM has been completed. | The RAPID3 as a functional assessment has been completed. |
| The 5As of assessment (analgesia, activities of daily living, adverse effects, affect, and aberrant drug-related behaviors) have been completed. | Prescriptions. |
| The prescription(s) has/have been written in multiples of 7 (e.g. 7, 14, 21, 28 days). | The prescription(s) include the maximum daily dose or a “not to exceed” equivalent. |
| Other Therapies. | Nonopioid alternatives up to a maximum recommended by the U.S. Federal and Drug Administration, including nonpharmacological treatments, have been considered. |
| The patient has been asked if he or she is currently, or has recently been, dispensed methadone from an opioid treatment program or prescribed and taken any other controlled substance. The patient is required by law to disclose this information (18 V.S.A.§4223): (yes/no) | The COMM score suggests it is acceptable for this patient to continue therapy: (yes/no) |
| The patient is on a bowel regimen, if appropriate, and is not experiencing adverse effects that change the risk versus benefit profile for this patient: (yes/no) | The overall benefits of continued therapy outweigh the risks for this patient: (yes/no) |
| Note: This smart phrase was used by the provider as a checklist and as documentation for the activities conducted during the controlled substance provider visit. |

Abbreviation: RAPID3, Routine Assessment of Patient Index Data 3; COMM, Current Opioid Misuse Measure.
The team designed templates, or smart phrases, in the EHR to guide clinical staff through the new workflow and to support documentation of the eight elements (Table 2). The smart phrases were created and used by the nurse and clinical pharmacist to support the workflow. Because the team did not have access to information technology support beyond weekly report runs, the smart phrases were free text in the EHR and not searchable for ongoing data tracking. This new workflow required no increase in staff. Instead, the clinic rebalanced workloads to allow two clinical staff, the nurse and clinical pharmacist, to support the protocol consistently.

In order to accomplish these changes without new resources, this protocol was implemented one provider at a time, gradually including all active patients treated with opioids. Additional providers were not added until the QI team felt the clinic workflow was stable. All clinic providers agreed to participate. The time needed for the provider to review the opioid visit materials was one to two minutes. Clinical staff notified patients of the change in the care delivery process by telephone prior to their regular appointments and in time to schedule the controlled substance visit with the nurse. Protocol implementation started on September 1, 2015, with the patients of one provider and continued by gradually adding providers and their patients to the workflow over 9 months, to May 31, 2016.

**Analytic approach.** Data elements extracted from the EHR included problem list diagnoses, medication orders (including dates and prescription specifics), dates associated with the monitoring strategies, and dates of office visits. We summarized prescribed opioid volume using the opioid conversion calculator provided by the CDC (11). Proportion of opioids prescribed in multiples of seven was determined based on the quantity of pills prescribed in each prescription. We surveyed providers and staff regarding their use of the standardized prescribing elements, their confidence in using recommended elements of prescribing, their satisfaction with their current opioid prescribing methods, their completion of strategy implementation for more patient-centered care, and their assessment of the overall effectiveness of the project. This survey was adopted from a previously used instrument developed by one of the authors (12) (see Supplement).

The main outcomes of interest were pre-post changes in the eight recommended elements. The pre–Lean A3 period was June 1, 2014, to May 31, 2015, and the post–Lean A3 period was June 1, 2016, to May 31, 2017. Demographic characteristics, diagnoses, and the proportion of the population with recommended prescribing strategies were summarized at baseline using descriptive statistics. To compare the changes between the preintervention and postintervention periods, we used Chi squared and Fisher’s exact tests for categorical variables and Student’s t test for comparison of prescribing volume in morphine milligram equivalents (MMEs). All analyses were two-tailed with a value $P < 0.05$ required for statistical significance. The provider and staff survey results were analyzed using descriptive statistics. Analyses were completed using Stata 15 (StataCorp).

**Ethical considerations.** All providers and staff clinic members received verbal information about this research study. Those who worked on the study within the clinic were free to accept or decline this opportunity without penalty. The University of Vermont Committees on Human Subjects, our local Institutional Review Board, approved the project.

**RESULTS**

The QI team used the Lean A3 method over a 15-month period, meeting six times for a total of 11 hours. The clinic cared for 9,599 unique patients during the study period. The sociodemographic characteristics are shown in Table 3. Commonly managed

| Characteristic | Patients Not Prescribed Opioids $^a$ N = 9333 | Range, %, or SD | Patients Prescribed Opioids $^b$ N = 212 | Range, %, or SD |
|---------------|---------------------------------------------|----------------|------------------------------------------|----------------|
| Age, median years (range) | 57 | (18-98) | 60 | (22-92) |
| Female sex | 6636 | 71.1% | 152 | 71.7% |
| Insurance | | | | |
| Commercial | 5105 | 54.7% | 85 | 40.1% |
| Medicare | 2761 | 29.6% | 94 | 44.3% |
| Medicaid | 1085 | 11.6% | 23 | 10.9% |
| Other or missing | 382 | 4.1% | 10 | 4.7% |
| Smoker, current | 1127/8521 | 13.2% | 48/189 | 25.4% |
| Rheumatology-related diagnoses $^c$ | | | | |
| Osteoarthritis | 4928 | 52.8% | 152 | 71.7% |
| Fibromyalgia | 2306 | 24.7% | 90 | 42.5% |
| Rheumatoid arthritis | 1262 | 13.5% | 67 | 31.6% |
| Psoriatic arthritis | 695 | 7.5% | 18 | 8.5% |
| RAPID3, median (SD) | 15.8 | (5.8) | 14.3 | (6.1) |

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$^a$Denominators may vary slightly based on missing data as indicated. $^b$Includes all patients prescribed opioids at least once, of whom 185 were prescribed preimplementation and 160 postimplementation. $^c$Patients may have more than one diagnosis.
rheumatology-related diagnoses included osteoarthritis (53.2%), fibromyalgia (25.1%), rheumatoid arthritis (14.1%), and psoriatic arthritis (7.5%). One hundred and eighty-five patients (1.9%) were prescribed opioids at baseline.

There were significant differences in the use of recommended opioid prescribing elements between baseline and postimplementation (Table 4). Patient education increased from pre- to postimplementation, with signed patient consent to opioid treatment increasing from 39% to 80%, and treatment agreements increasing from 39% completion to 78% ($P < 0.001$ for both). Formal risk assessment with the COMM increased from 0.5% to 76% ($P < 0.001$). Best practices in prescribing, including prescribing in multiples of seven to avoid weekend refill requests, increased from 1% to 79% ($P < 0.001$); however, scheduling visits at least every 90 days for patients on chronic opioids did not change (48% to 45%, $P = 0.18$). Monitoring parameters, including Routine Assessment of Patient Index Data 3 (RAPID3; 0% vs. 86%), PDMP queries (49% vs. 84%), and urine testing (1% vs. 32%) all increased significantly from baseline ($P < 0.001$). Overall, the number of patients prescribed opioids (185 vs. 160; $P < 0.001$) and the annual volume of opioids prescribed (1,933,585 MME vs. 1,386,368 MME; $P < 0.001$) decreased.

A preproject survey drew responses from 12 out of 24 (50%) providers and staff; the postproject survey received responses from 10 out of 23 (43%). Although respondents appeared to have more positive views of clinic policies and opioid management and reported increased job effectiveness following implementation, no changes were statistically significant.

At the end of the study, the Controlled Substance Visit Protocol became a practice standard for all patients receiving opioids.

**DISCUSSION**

In this report, we describe the successful use of a QI method, Lean A3, to improve opioid prescribing in our academic rheumatology clinic. Although Lean A3 has been successfully used in other ambulatory care clinics (9), we believe this is the first report describing successful use of Lean A3 to improve chronic opioid prescribing in an ambulatory rheumatology clinic. We were able to improve our adherence to guidelines for seven of eight recommended prescribing elements and recommendations regarding opioid prescribing and our care process. In some cases, we were able to reduce opioid doses. We maintained the new process and its outcomes over a sustained period.

Other ambulatory clinics have used QI methods to improve the opioid prescribing process. A report on opioid prescribing at an academic family medicine practice described a QI project that documented a need for improved care and assessment of patients on opioids but did not report on implementation of their process (13). Cahana and colleagues (14) reported a model of pain management that would address opioid prescribing and comply with state legislation that effectively reduced opioid-related abuse and death. This was based upon a previously published model of biopsychosocial medicine (15). However, they did not describe an implementation process by which to operationalize the model nor did their model include follow-up information on whether it was successful. Fawcett et al (16) used opiate prescribing as an example of a quality framework and implementation template but did not assess success or the outcome of their intervention.

What worked well for our process was engagement and involvement of all stakeholders along with clearly defined outcomes of interest and goals for improvement. The stepwise approach of starting with one provider and then involving remaining providers allowed for continued process reassessment and refinement before a broader implementation. The ability to utilize templates and sections within the EHR promoted efficiency and fostered use of the new process.

There were a number of barriers to implementation and maintenance of our process. These included initial resistance from pro-

| Prescribing Strategy | % Completed Pre-Lean A3 N = 185 | % Completed Post-Lean A3 N = 160 | $P$ value$^a$ |
|----------------------|-------------------------------|-------------------------------|-----------|
| Patient education    | 39%                           | 78%                           | <0.001    |
| Consent form         | 39%                           | 80%                           | <0.001    |
| Risk assessment      | 0.5%                          | 76%                           | <0.001    |
| Current Opioid Misuse Measure (COMM) | 49%                           | 84%                           | <0.001    |
| Monitoring           | 4%                            | 16%                           | <0.001    |
| Number of opioid patients | 185                           | 160                           | <0.001    |
| MME, millions        | 1,933,585                     | 1,386,368                     | <0.001    |

Abbreviation: MME, morphine milligram equivalent; PDMP, prescription drug monitoring program; $^a$Chi squared or Fischer’s exact test for categorical variables; test for continuous variables.
viders about the necessity and benefit of a nurse visit linked to a provider visit as well as concerns about whether this would interfere with the provider visit. There were barriers regarding inefficiencies and limitations related to PDMP checks that resulted in inconsistent monitoring, difficulty identifying eligible patients on chronic opioids from other sites or if prescriptions had expired, and lack of time in the clinic to adequately prepare for or conduct the controlled substance visit. All of these barriers were addressed over the 9-month implementation period. We were unable to resolve the barriers related to the prescribing strategy of seeing patients at least every 84 days. Availability of provider appointments continues to be too limited to meet this recommendation.

Limitations. There are several limitations to our study. First, it involved a small specialty practice with a limited number of stakeholders within one institution, so the results may not be applicable to practices that differ greatly in size or cover a larger geographical region. Second, although there was a trend of improved provider and staff satisfaction, the small numbers of providers and staff were insufficient to achieve statistical significance. Third, nearly all our patients had insurance coverage that minimized financial barriers to interventions such as urine drug screening that may not be feasible in other practice settings.

In conclusion, the Lean A3 method was successfully used to improve the process of opioid prescribing within an ambulatory rheumatology clinic, resulting in sustained adherence to recommended prescribing strategies. This method has potential applicability to other practices interested in improving opioid prescribing.

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AUTHOR CONTRIBUTIONS

All authors participated in drafting the article and revising it critically for important intellectual content, and gave final approval of the version of the article to be published.

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