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ORIGINAL ARTICLE

A Model for Improving Adherence to Prescribing Guidelines for Chronic Opioid Therapy in Rural Primary Care

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Abstract

Objective: To describe the steps taken and results obtained by a rural primary care practice to effectively implement opioid prescribing guidelines.

Patients and Methods: Between December 1, 2014, and May 30, 2017, a quality improvement project was undertaken. Elements included prescribing registries, a nurse coordinator, and an Opioid Use Review Panel. Clinic workflow was redesigned to more consistently incorporate these and other guideline recommendations into practice. The effect on opioid prescribing was measured as well as patient outcomes.

Results: There were 462 patients meeting inclusion criteria before implementation. At the conclusion, 16 patients (3%) had died, 9 patients (2%) were no longer seeing clinicians participating in the project, and 2 patients (0.4%) had transitioned to hospice or long-term care facilities. Of the remaining 435 patients, 96 (22.1%; 95% CI, 18.4-26.2) had decreased prescribing below the threshold for inclusion or were no longer receiving opioid prescriptions. Originally, 64 patients (13.9%; 95% CI, 11.0-17.3) were using average daily doses equal to or greater than 90 morphine milligram equivalents. After implementation, 54 of 435 patients (12.4%; 95% CI, 9.6-15.8) were still using equal to or greater than 90 morphine milligram equivalents per day after accounting for death or loss to follow-up.

Conclusion: A change in clinic process to implement guidelines for prescribing of chronic opioid therapy was completed. It was associated with a decrease in the number of patients using chronic opioid therapy, primarily at lower doses. This was accomplished in a rural practice with very limited resources in pain medicine, psychiatry, and addiction medicine.

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A number of studies have shown both an increase in prescriptions filled for opioids and the use of chronic opioid therapy (COT) for chronic noncancer pain (CNCP) over the past 20 years in the United States.[1,2] It is estimated that an average of 46 people die every day from an overdose of prescription painkillers.[3] The death rate from heroin overdose also continues to rise, with most users indicating that their initial drug was a prescription opioid.[4] Although many specialties prescribe opioid analgesics for various medical reasons, primary care providers (PCPs) prescribe nearly half of all dispensed opioid prescriptions.[5] Other factors are associated with variation in opioid prescribing rates including geographic location; rural areas have been shown to have higher rates of opioid prescribing compared with those in nonrural urban and suburban areas.[6,7]

As a result of increased morbidity and mortality associated with its use, guidelines for the prescribing of COT for CNCP have recently been issued and/or updated by the Centers for Disease Control and Prevention and other national organizations.[8,9] Many state organizations and licensing authorities have also developed their own guidelines for providers under their jurisdiction.[10] In the state of Wisconsin for example, the Medical Examining Board, the Wisconsin Medical Society, and the state legislature have all recently

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released separate guidelines, principles, or legislative mandates.[11-13]

Some studies have shown that there is a low rate of adherence to provider guidelines and risk reduction strategies for patients using COT, even for patients at high risk.[14] Numerous barriers to adherence to prescribing guidelines have been identified including inadequate time and lack of standardized tools. Some clinicians look at urine drug screenings as law enforcement tools rather than medical tests and will not use them.[15] Resources typically available in urban centers such as pain medicine, behavioral health, and addiction medicine specialists are more difficult to access in rural areas.

Many techniques and policies have been studied and developed with variable effectiveness in increasing adherence to treatment guidelines or improving safety outcomes.[16,17] However, there is a paucity of evidence about how these initiatives may best be disseminated and implemented in small rural practices compared with larger practices in urban settings. Parchman et al[18] recently surveyed 30 primary care practices to identify common attributes of clinic changes to improve COT prescribing. Within these practices, 6 "building blocks" were identified, with the typical clinic using only 2 or 3 of these. These building blocks were (1) leadership support; (2) standardization of policies/patient agreements/workflows; (3) patient registries; (4) planned, patient-centered visits; (5) identifying resources for complex patients; and (6) measurement of progress toward achieving clinic objectives. Ten of the 30 practices reviewed were using none of these building blocks.

This article describes a quality improvement project, the aims of which were to implement process changes to improve adherence to COT prescribing and monitoring guidelines within a primary care health system serving 3 small rural communities. The primary outcome was the implementation of these guidelines. Secondary outcomes were decreased prescribing of COT for CNCP.

PATIENTS AND METHODS

Framework

In 2013, the practice leadership of Mayo Clinic Health System — Northwest Wisconsin adopted a strategic goal of improving the care of patients with persistent noncancer pain using COT. Led by one of the coauthors (J.R.D.), a "discovery collaborative team" that included stakeholders from primary care, nursing, physical medicine, behavioral health, pharmacy, pain medicine, and palliative medicine was formed. The team developed a survey and distributed it to all 193 physicians, nurse practitioners, and physician assistants in family medicine, general internal medicine, urgent care, and pediatrics. It was distributed electronically through a commercial survey program, with 113 clinicians (59%) responding. The vast majority of respondents supported the development of uniform guidelines for the use of COT. Two focus groups were held with stakeholders to identify specific areas for improvement. Expert guidelines that were available at the time were reviewed and many of their recommendations considered.[19,20]

Ultimately a report was issued that called for process change centered around 5 primary recommendations: (1) chronic pain requiring COT should be treated as a chronic disease coordinated by a primary care provider, (2) a standard approach and workflow should be used, (3) increased support should be provided in a number of areas including nursing and administration, (4) improved access to behavioral health, physical medicine, and pain medicine consultants should be available, and (5) an Opioid Use Review Panel should be established to provide case review and guidance for complex or challenging cases. Based on these recommendations, a pilot was implemented. It initially included the patients of 5 PCPs (phase 1) who composed a Mayo Model of Community Care group within the practice. This group shared care coordination support and clinic facilities and provided cross-coverage of each physician's patient panel. Phase 2 included the patients of all 18 additional PCPs who had patients meeting inclusion criteria. The study was approved as a quality improvement project by the Mayo Clinic Institutional Review Board (Table 1).

Setting

Mayo Clinic Health System — Red Cedar in Menomonie (MCHS-RC) is part of Mayo Clinic Health System - Northwest Wisconsin and was selected as the site for pilot implementation. It is centered in Menomonie, WI Wisconsin, a rural

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TABLE 1. Recommendations of the MCHS NW WI Discovery Collaborative Team

1. Chronic pain requiring COT should be treated as a chronic disease coordinated by a primary care provider
2. A standard approach and workflow should be used
3. Increased support should be provided in a number of areas including nursing and administration
4. Improved access to behavioral health, physical medicine, and pain medicine consultants should be available
5. An Opiod Use Review Panel should be established to provide case review and guidance for complex or challenging cases

COT = chronic opioid therapy; MCHS NW WI = Mayo Clinic Health System - Northwest Wisconsin.

community with a population of approximately 16,000 people. It also has small practices in Elmwood, Wisconsin (population 810), and Glenwood City, Wisconsin (population 1231). There are approximately 31 clinicians practicing in the areas of family medicine and general internal medicine, including physicians, nurse practitioners, and physician assistants. There are limited pain medicine services provided by a visiting pain medicine specialist in Menomonie who does not manage patients using COT. There are no addiction medicine specialists in any of the 3 communities and limited psychiatry services in Menomonie only.

Participants and Recruitment

In phase 1 (December 1, 2014, to May 30, 2015), the potential patient pool came from the panels of 5 PCPs who were part of the Mayo Model of Community Care group at MCHS-RC described earlier (T.J.W., K.K.S., M.D.S., S.L.R., and M.R.P.). To meet inclusion criteria, patients had to use an average of at least 5 morphine milligram equivalents per day (MME/D) of a schedule II or III opioid analgesic over the previous 6 months with at least one prescription within the past 3 months. They were identified by a review of 6 months of clinic scheduling records followed by chart review including prescribing data. Excluded were patients with an active cancer diagnosis, enrolled in hospice care, residing in a skilled nursing facility, or at the discretion of their PCP. There were a total of 107 patients identified for inclusion in phase 1.

Between June 1, 2015, and November 30, 2015, the patient registry developed in phase 1 was used to identify 462 patients at MCHS-RC who met inclusion criteria and were not excluded for any of the conditions listed earlier. Among those excluded were 60 patients excluded at the discretion of their PCP for various reasons. The most common reasons for exclusion by PCPs were patients using low-dose COT receiving palliative care, those at extreme old age, and those who were already using low doses and tapering toward discontinuation. The potential patient pool included the panels of all 31 clinicians practicing in the departments of family medicine and general internal medicine. Of these 31 clinicians, there were 23 PCPs who had patients meeting criteria for inclusion.

Implemented Process and Guidelines

The phase 1 pilot served as a feedback experience, with many of the requirements identified and incorporated into phase 2. For example, in phase 2 a registered nurse (E.R.M.) was identified to act as a coordinator and educator. Numerous educational sessions were provided to PCPs and nursing staff. Educational sessions were also provided for consultants and staff in physical medicine, behavioral health, obstetrics, emergency medicine, and other departments.

The Opioid Use Review Panel was formed and began offering consultation to physicians upon request. It was composed of representatives of primary care, pharmacy, behavioral health, and physical medicine and offered advice on difficult management cases. This was done through chart review and written recommendations provided to the PCP. Services available in the areas of physical/occupational therapy, behavioral health, community education, and complementary and alternative medicine were identified and information offered to all providers and patients.

A prescribing registry of patients using COT was developed and used. This was done using the medication prescribing data extracted from the practice's electronic health record (EHR). The EHR was also used to gather a number of measures related to COT guideline adherence. First, the EHR and registry were used to identify patients who were being prescribed opioids chronically. Before this, providers had no way to identify patients

using COT other than review of their individual medical record. Next, the registry allowed providers to identify those patients who were being prescribed opioids at doses above those recommended for safer prescribing of opioids on the basis of MME/D calculation for all opioids prescribed. Finally, the registry allowed providers to identify those patients who had not completed appropriate safety measures. These data were compiled by the coordinator and made available to clinicians periodically. This allowed them to focus their efforts on patients who were not in compliance with recommended guidelines and presumably at higher risk.

As part of this project, a number of standard safety tools were identified and/or designed including a specific recommended urine drug test (UDT). Clinician education regarding availability and consistent use of the UDT was also part of the process. Frequent utilization of the Wisconsin Prescription Drug Monitoring Program database was encouraged. An opioid therapy agreement between the PCP and patient was developed and its consistent use was encouraged. Instead of stressing the consequences associated with problematic drug-related behavior, it emphasized the significant health risks associated with COT. A standard workflow was developed and used including the measures noted previously. Letters introducing and explaining the process were forwarded by US mail to all patients who had been identified through the registry and arrangements were made for an extended visit with their PCP specifically to discuss their use of COT and the new process. The regular use of UDTs and an opioid therapy agreement was encouraged during these extended visits, as well as completion of a risk assessment tool Opioid Risk Tool, Current Opioid Misuse Measure or Screener and Opioid Assessment for Patients with Pain-Revised. Also encouraged was depression screening (Patient Health Questionnaire-9), and screening for generalized anxiety disorder (Generalized Anxiety Disorder Questionnaire). The Pain/Enjoyment/General Activity Scale (PEG) was used to assess those specific measures. Periodic follow-up at least every 3 months was also recommended (Table 2).

TABLE 2. Chronic Opioid Assessment Tools

- Risk Assessment Tool (ORT, SOAPP-R or COMM)
- Pain/Enjoyment/General Activity (PEG) scale
- Patient Health Questionnaire-9 (PHQ-9)
- Generalized Anxiety Disorder 7-item (GAD7) scale
- Pain Clinic Survey, Urine (Mayo Clinic Laboratories)
- Wisconsin Prescription Drug Monitoring Program

COMM = Current Opioid Misuse Measure; ORT = Opioid Risk Tool; SOAPP-R = Screener and Opioid Assessment for Patients with Pain-Revised.

Outcomes

Using the prescribing registry, the average daily dose of COT prescribed for all patients was measured during the 6-month preimplementation period before phase 2 (June 1, 2015, to November 30, 2015) and again during the 6-month period at the conclusion of implementation (November 1, 2016, to April 30, 2017). We also measured the number of patients using high-dose COT (≥90 MME/D) as well as intermediate (≥50 and <90 MME/D) and low doses (<50 MME/D) during each of the 2 periods.

Statistical Analyses

Before the start of the quality improvement initiative, the literature was reviewed to determine whether there was a commonly accepted threshold to define chronic opioid use. At the time, there did not appear to be a consensus threshold or data relevant to our population of interest. Based on knowledge of the patient population and the clinical judgment of the initial panel of physicians, 5 MME/D was selected as a minimum threshold for use. Over the course of the project, a secondary analysis of a 90 MME/D threshold was included to reflect Centers for Disease Control and Prevention guidelines published in 2016.

Descriptive statistics are provided as counts and percentages. Because outcome measures were recorded only in aggregate, the proportion of patients confirmed to decrease usage below the 5 MME/D threshold and the proportion of patients using greater than or equal to 90 MME/D in each phase are also reported. Confidence intervals for binomial proportions were estimated using the Wilson/Score method. Patients who died or were lost to follow-up during phase 2 were excluded from the analysis of post−phase 2 proportions.

RESULTS

Of the 462 patients who were initially included during phase 2 of the study, 27

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patients were not participating at the conclusion. Within this group, 16 patients (3%) were deceased, 9 patients (1.9%) were no longer under the care of PCPs participating in the project or otherwise lost to follow-up, and 2 patients (0.4%) had transitioned to hospice or a skilled nursing care facility. Of the remaining 435 patients, 96 patients (22.1%; 95% CI, 18.4-26.2) had either discontinued COT or were using average daily doses below 5 MME/D and 339 patients (77.9%; 95% CI, 74.0-81.6) were still using at levels greater than or equal to 5 MME/D. Before phase 2, 13.9% (95% CI, 11.0-17.3; N=64 of 462) of patients were using doses greater than or equal to 90 MME/D. After phase 2, 12.4% (95% CI, 9.6-15.8; N=54 of 435) were using greater than or equal to 90 MME/D after accounting for death and loss to follow-up.

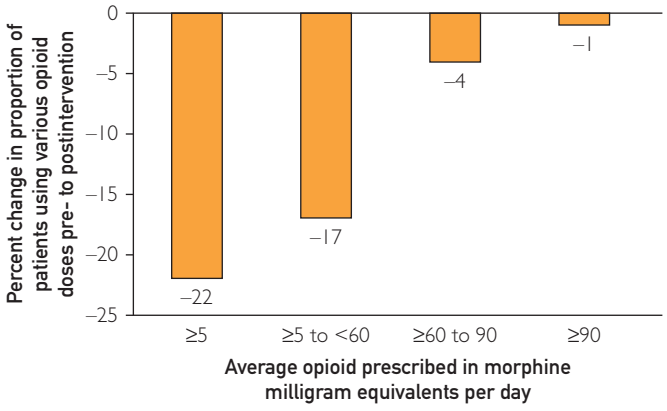

FIGURE. Percent change in proportion of patients using various opioid doses preintervention and postintervention.

DISCUSSION

The primary goal of this work was to describe the experience of guideline implementation for the use of COT within a rural primary care practice. This implementation was associated with a decrease in the number of patients using COT. Both as absolute percent change and as a proportion of original group size, patients using lower doses of COT showed greater declines than did the highest dose group (see Figure).

Many provider groups are considering changes in their practices to address the opioid epidemic and the considerable risk associated with COT. In spite of the release of numerous COT guidelines, limited published data exist on how to most effectively implement these prescribing guidelines. Implementing guidelines related to opioid use is particularly challenging in small rural primary care practices due to the relative lack of consultative services. Like many clinicians in small rural communities, physicians in this project had limited resources available as they tried to adjust to a changing landscape in chronic opioid management. Before this project, they expressed their desire for a standard process with increased support. Many providers expressed a desire for the availability of an "expert review" of patient cases when they needed input in numerous specialties but had difficulty obtaining formal consultations. This project addressed that need in a way that other groups could use.

We anecdotally identified several factors that they believe were associated with the overall decrease in patients using COT. First was increased communication between providers and patients relating to safety concerns as well as the limited proof of effectiveness of COT for CNCP. There were a number of patients who requested tapering of COT. Some patients stated that they had not been aware of potential adverse effects until discussions focused on COT were held with their PCPs or they became aware of the high risk through the publicity surrounding the opioid epidemic. Some simply decided that it was not worth the inconvenience of completing UDTs and the more frequent clinic visits required. It is possible, however, that some of these patients may have subsequently obtained prescription or illicit opioids outside of our clinics.

The change in the opioid therapy agreement used from a document focused on the consequences of problematic drug-related behaviors to one focused on the considerable risk associated with COT was felt to be a positive one. The use of the term *contract* was avoided.

Another important factor was a healthy patient-provider relationship. Through the comments of patients, we were reminded of the importance of assuring patients that tolerance and dependence on opioids was not the

same as addiction. It was also important for patients to be reassured that their PCP would not routinely stop prescribing COT abruptly but would instead usually work with them to taper to safer doses over a number of months if it could be done safely. The availability of a nurse coordinator to act as a focal point for questions, problems, and education was also a critical component of this process.

There are several important limitations to the quantitative analysis of this work as well as opportunities for similar programs in the future. The first is that estimates for patients' decrease in use, in the absence of or before such a program's implementation, have not been well studied, so it is difficult to fully quantify the effects of this project. Another is that data outcomes are currently available only in aggregate. This limits the type of analyses that can be performed (eg, unable to determine for most patients whether they had different starting vs ending use categories, unknown follow-up time per patient, and only presence or absence during the second phase) and the conclusions that can be drawn. For example, although the number of patients using greater than 90 MME/D decreased, it is unknown whether they are not present in the greater than 90 MME/D group due to decreased usage, death, or loss to follow-up.

At the start of this project, tramadol and tapentadol were not classified as controlled medications and were not included in our project. There are increasing concerns about the risks associated with both these medications.[21]

The survey used initially to determine the attitudes of clinicians regarding the need for this type of model was not validated and may have incorrectly identified clinicians' desire and willingness to adhere to a model such as this. Another limitation was that this model was developed in a single small rural health system and, therefore, may not be generalizable. Finally, further studies are also needed to determine patient and provider satisfaction as it relates to the process implementation.

The limitations also represent a learning opportunity for the quality initiative, which helped improve phase 2 and may assist other physicians and researchers in future projects. One example of this is the utility of the prescribing registry of patients, which could be used to identify patients and track individual outcomes. Changes to the prescribing registry could help improve understanding of baseline rates, change over time with program implementation, and allow the ability to adjust for factors such as death or loss to follow-up and improve subsequent analyses.

We believe that the process developed to improve adherence to accepted guidelines associated with COT provides a useful framework for other practices as they implement their own process changes. It is also very similar to guidance recently published by the Agency for Healthcare Research and Quality in July 2018 when it released "A Team-Based Approach to Improving Opioid Management in Primary Care." The Agency for Healthcare Research and Quality recommends a process very similar to that described in this work.[22]

This work was associated with an improvement in adherence to COT guidelines by PCPs within small rural practices with limited pain medicine, psychiatry, and addiction medicine support. It also provided some estimate of the small number of patients in a primary care practice who will end the relationship with their PCP when guidelines are implemented. Finally, it found that the process changes and improved communication regarding opioid prescribing guidelines were associated with a decrease in the number of patients using COT for CNCP.

CONCLUSION

Clinicians are increasingly being asked to adhere to new guidelines for the use of COT. We found that these process changes were associated with an improvement in adherence to these guidelines and fewer patients using COT. We were able to do this in a small rural practice with limited availability of consultative services.

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Abbreviations and Acronyms: **CNCP** = chronic noncancer pain; **COT** = chronic opioid therapy; **EHR** = electronic health record; **MCHS-RC** = Mayo Clinic Health System-Red Cedar in Menomonie; **MME/D** = morphine milligram equivalents/day; **PCP** = primary care provider; **UDT** = urine drug test

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