A Partnered Approach to Opioid Management, Guideline Concordant Care and the Stepped Care Model of Pain Management

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BACKGROUND: Pain is the most common presenting problem in primary care. Opioid therapy (OT) for chronic pain has increased dramatically over the past decade, as have related negative outcomes. Despite the development and dissemination of policy and clinical practice guidelines for pain management and OT, adoption has been variable. The Veterans Health Administration (VHA) has established a Stepped Care Model of Pain Management (SCM-PM) as an evidence-based framework and single standard of pain care to promote guideline-concordant care, but to date its adoption and related outcomes have not been systematically examined.

OBJECTIVE: Our aim was to examine changes in care for Veterans receiving long-term OT for management of chronic pain over a four-year study period.

DESIGN: As part of a comprehensive implementation evaluation of performance improvements, the current evaluation reports performance improvement outcomes related to pain management and OT over a four-year period.

SUBJECTS: We studied Veterans receiving long-term (90+ consecutive days) OT through primary care.

INTERVENTIONS: We engaged an interdisciplinary clinical-research team to develop and implement a multifaceted performance improvement approach that included interactive educational strategies and other organizational initiatives.

MAIN MEASURES: We measured the proportion of patients receiving long-term OT; use of opioid risk mitigation strategies; referrals to pain-related specialty services; and use of non-opioid analgesics.

KEY RESULTS: The proportion of patients receiving high-dose opioids decreased over four years (27.7 % to 24.7 %). The use of opioid risk mitigation strategies increased significantly. Referrals to physical therapy and chiropractic care and prescriptions for topical analgesics increased significantly, while referrals to the pain medicine specialty clinic decreased.

CONCLUSIONS: We demonstrate improvements in the management of veterans receiving OT that are consistent with the SCM-PM and published practice guidelines. We highlight how partnerships among funders, researchers, clinicians, and administrators contributed to the project's design and implementation, and to the dissemination strategy and future directions for improving opioid management and pain care.

KEY WORDS: pain; primary care; veterans.

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INTRODUCTION

Chronic non-cancer pain is one of the most common presenting problems in primary care.¹⁻⁴ Within the United States, the number of individuals with chronic pain and the associated cost burden exceeds those of cancer, diabetes, and heart disease combined.^{5,6} Prevalence of pain among Veterans is high, with estimates ranging from 50 to 75 %.^{1,3,7} Within and outside of the Veterans Health Administration (VHA), rates of opioid prescribing for chronic pain management, as well as negative outcomes related to opioid use, including abuse and unintentional deaths, have increased significantly over time.⁸⁻¹⁰ Veterans with chronic pain seen in VHA primary care clinics have a high lifetime prevalence of mental health and substance use disorders, and a significant minority have a documented history of behaviors suggesting potential opioid abuse, including reports of lost or stolen opioids, repeated requests for early refills, or multiple providers prescribing opioids.^{2,11,12} While guidelines for managing chronic pain and mitigating risks of long-term opioid therapy (OT) have been developed and published,¹³⁻¹⁵ uptake has been variable, despite evidence demonstrating that guideline-concordant care is associated with reduced healthcare costs and improved outcomes.¹⁶⁻¹⁸

The Veterans Health Administration (VHA) has identified pain management as a high priority, with opioid safety as one of the primary foci of quality improvement efforts.¹⁹ Broadly speaking, the VHA's approach has been two-pronged: increasing safe opioid prescribing practices and bolstering non-opioid, multi-modal pain care. The latter aspect is guided by the evidence-based Stepped Care Model of Pain Management (SCM-PM), where management of most common pain conditions occurs in the primary care setting with stepped support from pain specialty care services as needed.²⁰

While addressing opioid safety issues and adoption of the SCM-PM has widespread support throughout the VHA, to date, uptake within the healthcare system has not been rigorously studied. In light of this gap, a public–private partnership involving the VHA Pain Management Program office, local facility clinical and administrative leaders, and two private foundations, the Donaghue Medical Research Foundation and the Mayday Fund, was established. This partnership supported a four-year study of opioid prescribing and the SCM-PM at VA Connecticut Healthcare System (VACHS). The vision of the project, referred to as “Project Step,” was to engage VACHS as a “learning organization,” to examine and facilitate local efforts to implement opioid safety practices, and the SCM-PM as an aid in national VHA implementation efforts.²¹

METHODS

Study Design

The primary objectives of Project Step were to develop and engage action-oriented interdisciplinary teams to foster collaborative, partnered initiatives to advance guideline-concordant care for patients with chronic pain, including those receiving OT, and to promote organizational improvements in pain care consistent with the SCM-PM. We employed mixed qualitative and quantitative methods to evaluate these quality improvement efforts on key processes and outcomes, and to inform the sustainable quality improvement approach.²² While results of the qualitative evaluations have been reported elsewhere,^{23–25} in this report, we focus on implementation efforts related to opioid safety, given the importance and timeliness of the topic with respect to public health and because this objective was prioritized by our VHA partners. Here we report solely on quantitative outcomes of primary care provider behavior based on the VHA electronic health record (EHR).

The study was approved by the VACHS Institutional Review Board and the Yale Human Investigation Committee.

Development of a Multifaceted Approach to Promote Organizational Improvements

Qualitative evaluations of narratives from primary care providers (PCPs), primary care nurses, and specialists regarding their experiences in caring for patients with pain, reported elsewhere, served as the impetus for initial discussions among Project Step team members and partners about organizational and educational initiatives.^{23–25} Consistent with published recommendations^{21,26}, a multifaceted, partnered approach to promote organizational improvements was identified and enacted. Although a comprehensive discussion of the

initiatives undertaken is beyond the scope of this paper, we summarize initiatives that are most relevant to improving care among patients receiving long-term OT for chronic pain.²⁷

Engagement of a Clinical-research Team

Particularly important to the foundation funding partners was a project that not only addressed an important clinical issue, but that also explored the role of “team building” in promoting organizational change. Project Step involved development of an interdisciplinary clinical-research team at VACHS that collaborated to plan, implement, and analyze the process of adoption of the SCM-PM. This team consisted of the Project Step coordinator—a doctoral-level psychologist—and research staff, facility “pain champions” from primary care and specialty pain care settings, and representatives from the hospital quality management and hospital education services. The team met biweekly for the first three years of the project, and monthly during the final year. The agenda for each meeting included a review of progress on prior and ongoing interventions, including a consideration of relevant qualitative and quantitative data as described below; planning new interventions; brainstorming additional ideas for interventions; and reviewing inter-meeting assignments and the agenda for the next meeting. In this way, there was an explicit attempt to use data derived from Project Step to both inform the discussion about interventions and to monitor progress and outcomes.

As the qualitative data highlighted, the educational needs of PCPs and staff were prioritized. A number of interactive education and training sessions were provided on topics such as pain assessment and diagnosis, the biopsychosocial model and its application to treatment and assessment of chronic pain²⁸, non-opioid pharmacological management of pain, and non-pharmacological approaches to pain management. Particular emphasis was placed on education regarding safe opioid prescribing—including information on dosing, guidelines, and risk mitigation strategies (i.e., use of opioid pain care agreements and frequent urine drug testing)—as well as effective communication with patients about opioids and pain care. In response to PCP reports of difficulty with determining when and to which specialty service to refer patients for additional pain management options, education was provided on pain specialty services available at VACHS and steps for referral to each service. Learning objectives, session content and structure, and evaluation methods were developed by the team, and several team members served as faculty.

In order to foster a supportive environment for providers, as well as to develop unified approaches to managing complex issues in chronic pain, both formal and informal peer support services were implemented. A primary care “Pain Champion” organized a small interdisciplinary group of primary care colleagues who served as a “Peer Support Team” and offered monthly case-based discussion sessions open to all primary care staff.

A package of progress note templates, termed the “Primary Care Pain Toolkit,” was developed and made available in the EHR. This package included note templates for assessing pain, safety and effectiveness of opioids prior to opioid renewal, and risk for aberrant opioid-related behaviors.²⁹ In addition, a template of the opioid pain care agreement, a tool for promoting information exchange and shared decision making between providers and patients about roles and responsibilities related to opioid therapy, was developed to aid in documentation. The routine use of opioid pain care agreements for all patients receiving OT was emphasized as a widely accepted standard of practice.

Engagement of Partners

Sustained engagement of partners was viewed as a particularly important goal of the project. The Project Step Principal Investigator (RDK), who was also the VHA National Program Director for Pain Management, met monthly via teleconference and yearly in person with a multidisciplinary VHA National Pain Management Strategy Coordinating Committee to discuss the project, its findings, and related policy implications. Input from this senior leadership team was particularly important in helping the local clinical research team stay abreast of a large and continually evolving list of policy and practice initiatives that were especially relevant to Project Step.

In addition, the Project Step team met yearly, in person, with senior representatives from both private foundations to review progress, plan next steps, and generate new ideas for implementation and dissemination initiatives. Two examples can be cited as evidence of the strength of the partnership and the role of partners in influencing performance improvement interventions. From the outset, foundation partners were particularly enthusiastic about our inclusion of qualitative data from providers and nurses to inform the selection and design of our interventions. Upon reviewing the earliest narrative data, these partners encouraged the development of a “Peer Support Team” to address providers’ and nurses’ reports of being frankly threatened by patients related to opioid prescribing. Similarly, discussion of both qualitative and quantitative data suggesting inefficiencies in processes of referring patients for specialty pain management services led to the development of a primary-care-based Integrated Pain Clinic to promote patient-centered plans of care, efficiencies in use of specialists, and care coordination. These sustained relationships assured a process of continued influence of the partners on the operational plan of Project Step, and supported a strong and continually evolving dissemination plan.

Participants

The sample consisted of all veterans who were prescribed at least 90 consecutive days of opioids by a VA PCP within a

given year and who attended at least one primary care visit at VACHS during the study years (July 2008 to June 2012, N=2,261 of 178,144). Receipt of opioids was based on one or more prescriptions in the EHR for VHA class CN101 drugs, which includes: codeine, fentanyl, hydrocodone, methadone, morphine, oxycodone, oxymorphone, and hydromorphone. We excluded buprenorphine. There were no patient exclusion criteria.

Clinical Outcome Evaluation

We evaluated whether level of opioids prescribed differed by year based on mutually exclusive categories of average daily morphine equivalent dose (MED) (< 20 MED, 20–119 MED, or ≥120 MED). These categories were used because high dose opioid prescribing has been associated with increased adverse events, including overdose deaths,^{30–35} and the criteria have been used in clinical guidelines.^{14,15} EHR information was also extracted to assess for documentation of an opioid pain care agreement and annual urine toxicology testing.

Pain intensity, assessed during primary care visits using the 0 (no pain) to 10 (worst pain imaginable) pain numerical rating scale and entered as a vital sign, was also extracted from the EHR. We used the highest pain intensity rating entered during each year for each patient in the sample. Information was also extracted to determine whether patients in the sample had an opioid pain care agreement documented in the EHR and whether urine drug testing had been completed within a one-year time frame.

We extracted information from the EHR on referrals from primary care providers ($n=60$) to specialty services that were deemed to be particularly relevant to different aspects of pain care—specifically, physical therapy, pain medicine, chiropractic medicine, and mental health.

Prescriptions for other pain-related medications were also extracted, including topical analgesics, non-steroidal anti-inflammatory drugs, anticonvulsants, and antidepressants (specifically, selective serotonin and norepinephrine reuptake inhibitors and tricyclic antidepressants).

Statistical Analyses

We used generalized linear models with unstructured covariance matrices to estimate the association of patient demographic and clinical characteristics with receipt of evaluation metrics by year, and to account for the potential repeated measures on patients in each of the years of observation. Generalized estimating equations (GEE) with logit link were used for dichotomous outcomes. For instances in which the model failed to converge, we used an autoregressive (AR1) covariance matrix. Post-hoc follow-up tests used Bonferroni

adjustment. All analyses were conducted in SAS 9.2 (SAS Institute Inc., Cary, NC).

RESULTS

The majority of the sample was male (95.4 %) and the proportion of males did not differ by year ($p=0.72$). The mean age was 61.9 ($SD=23.4$) and increased over the four study years from 60.1 in year 2008–09 to 63.1 in year 2011–12 ($p<0.0001$).

The overall proportion of patients receiving long term OT in primary care remained consistent over time (1.3 %, $p=0.20$). However, among patients receiving OT, the proportion of patients receiving the different dose levels varied over time ($p=0.02$; see Fig. 1). Follow-up comparisons from year 1 to year 4 ($p=0.0079$) indicated that the proportion of patients increased for lower doses (< 20 MED), and decreased for higher doses (≥ 20 MED).

Table 1 presents study outcomes over each of the four Project Step years. The mean highest reported pain intensity rating was 6.52 and did not differ by year. Rates of opioid pain care agreements and yearly urine drug testing significantly increased over the four study years. Provider referrals to chiropractic care and physical therapy significantly increased over time. Referrals to the pain medicine service significantly decreased over time. There were no significant changes in mental health referrals. Prescriptions for non-opioid pain medications tended to increase over time, although only prescribing of topical analgesics increased significantly.

DISCUSSION

This project addresses two widely recognized public health challenges, namely the need to improve care of persons with chronic pain and the opioid abuse crisis. This is the first study to investigate the SCM-PM over time in an integrated healthcare system, as opposed to a tightly controlled clinical

trial. The VHA's SCM-PM has been identified as an innovative model for efforts to transform pain care in the US, and represents a systematic, evidence-based approach to providing appropriate pain care in a timely, cost-effective manner consistent with the level of need. This project was driven by a desire among our partners not only to evaluate the SCM-PM, but also to improve opioid safety, given the significance of this area of study and improvement both within and outside of VHA. Although the design precludes a purely causal explanation, the findings are consistent with the idea that the organizational improvement efforts were effective. Evidence of improvements in the management of veterans receiving long term OT that are consistent with the SCM-PM and published practice guidelines are particularly promising and encourage transportability.

There were notable differences in degree of change among the metrics, suggesting that diffusion and uptake can vary a great deal, depending on both the metric as well as the method of diffusion or implementation. The most dramatic changes made were in the area of opioid risk mitigation, namely use of opioid pain care agreements and routine urine toxicology testing. These changes may have increased more dramatically because of specific guidance from the Pain Management program leadership and the prioritization of this issue among PCPs and nurses, as documented in the Project Step qualitative data. Further, decision and documentation support was easily available to providers through the use of note templates in the EHR, which also likely increased uptake of use. Smaller changes were observed for utilization of multimodal pain care, perhaps because recommendations regarding multimodal pain are much broader in nature. While use of opioid pain care agreements and urine toxicology have emerged as universal standards for all patients receiving long-term OT, expectations for multimodal pain care can be met via multiple pathways. An additional challenge relates to limitations of the EHR in reliably capturing a growing array of complementary health approaches to chronic pain management, including cognitive-behavioral therapy, yoga, and acupuncture, among others. It is possible that if a more

Figure 1. Percent of patients receiving low, moderate or high average daily morphine equivalent dose (MED) by Project Step year.

Table 1. Pain, Opioid Safety, Pain Support Services and Alternative Prescription Outcomes by Project Step Year*

	Project Step Year				p value
	2008–09	2009–10	2010–11	2011–12	
Maximum Pain Severity Rating, mean (SD)	6.50 (2.78)	6.54 (2.79)	6.39 (2.87)	6.65 (2.77)	0.38
Opioid Safety					
Opioid Agreement, % (n)	27.9% ^a (154)	71.5% ^b (426)	76.5% ^c (442)	81.1% ^c (434)	<0.0001
Urine Toxicology Test, % (n)	52.5% ^a (290)	82.4% ^b (491)	78.9% ^b (456)	79.6% ^b (426)	<0.0001
Pain Support Services					
Mental Health Referral, % (n)	9.4 % (52)	8.6 % (51)	8.1 % (47)	8.2 % (44)	0.77
Physical Therapy Referral, % (n)	21.9% ^a (121)	24.5 % (146)	26.1 % (151)	29.7% ^b (159)	0.02
Pain Management Referral,% (n)	13.6 % (75)	16.5% ^a (97)	11.7% ^b (66)	11.5% ^b (61)	0.04
Chiropractic Referral,% (n)	1.8% ^a (10)	2.5 % (15)	2.1% ^a (12)	5.2% ^b (28)	0.02
Alternative Prescriptions					
Topical Analgesic, % (n)	3.3% ^a (17)	4.9 % (29)	6.9% ^b (41)	5.4 % (29)	0.02
NSAID ,% (n)	20.5 % (113)	23.3 % (139)	24.4 % (141)	21.9 % (117)	0.10
Antidepressant/neuro, % (n)	17.0 % (94)	17.8 % (106)	18.0 % (104)	20.9 % (112)	0.45
Anticonvulsant, % (n)	27.4 % (151)	29.4 % (175)	28.0 % (162)	31.4 % (168)	0.13

*Patients could be included in multiple cohort years

^{a, b, c} Groups with different letter superscripts are significantly different from each other

comprehensive composite measure of engagement in multimodal pain care was developed and assessed, observed changes would be greater and consistent with a larger clinical and public health impact.

It is important to note limitations of the current findings. First, the study was conducted only in VACHS. Despite the diversity of VACHS, there are many unevaluated factors that may affect implementation and adaptability to other settings.³⁶ Second, the study used only VHA EHR data. Third, information collected about providers is limited. Demographic information about providers was not collected, and likely changed over the course of the four years, given staff turnover. Information on “dose” is also limited, given that, while generally well-attended, provider education meetings were not mandatory and data on the number of providers attending each session were not collected. Data on the use of additional resources developed by the Project Step team, such as progress note templates and clinical decision support tools, are also not available. Further, our analytic approach did not permit examination of individual provider behavior, so it is possible that observed changes are largely attributable to a subgroup of providers rather than more broadly distributed. Finally, we assessed changes related only to the behavior of providers. However, patient engagement in these services is also necessary in order to achieve benefit. Future studies could examine factors that predict patient engagement in services and effective utilization of non-opioid pharmacological pain treatments, as well as the role of providers in facilitating patient engagement and treatment adherence.

Project Step is currently in its fifth year due to a no cost extension of the project. Sustainment of continuous performance improvement efforts related to pain management is ensured by the elevated status of similar initiatives nationally and regionally in VHA to promote successful implementation of the SCM-PM. Several members of the Project Step team now

serve in key leadership roles at VACHS, including a restructured facility pain committee that is chaired by and includes additional members of the Project Step team who continue to promote adoption of the project’s core principles, metrics, and processes. New funding from VHA and from the National Institutes of Health also promise to support a positive legacy and continued advancement of Project Step’s aims and objectives.

CONCLUSION

Findings provide evidence of significant improvements in guideline-concordant pain care for veterans receiving long-term OT in a VHA primary care setting. A significant decrease in referrals to pain medicine specialists was observed, suggesting enhanced competencies of primary care providers and decreased reliance on pain medicine specialists to address issues related to problematic OT, consistent with the goals of the SCM-PM. Importantly, in addition to declines in the proportion of veterans receiving high dose OT, we observed substantial increases in OT risk mitigation strategies and referral to several pain specialty care services. Given the focus on opioid safety in recent years, our findings seem promising from a public health perspective. Our experience encourages engagement of interdisciplinary teams, including key stakeholder groups and partnerships to promote organizational improvements to promote increased use of risk mitigation strategies and integrated, multimodal care for patients receiving OT for chronic pain.

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