A Novel Scope-of-Practice Based Paradigm for Empowering Family Physicians to Manage Chronic Nonmalignant Pain

F. Stuart Leeds1 and Josephine F. Wilson2*
1Department of Family Medicine, Wright State University, USA
2Department of Community Health, Wright State University, USA

INTRODUCTION

Chronic nonmalignant pain (CNMP) is one of the most common reasons for office visits to family physicians [1-4]. According to recent studies, nearly 100 million American adults have persistent or chronic pain symptoms [5,6]. Treating CNMP is extremely difficult because the reported pain is often not proportional to objective disease severity, and pain reduction alone is not an adequate treatment goal. Patients diagnosed with chronic pain and treated by a family physician are rarely satisfied with their treatment, and 64% report inadequate pain relief and/or continued loss of function two years after initiation of treatment [7,6]. Given their lack of success in treating patients with CNMP, only 15% of family physicians report that they enjoy treating these patients [8].

Currently, specialty pain care is inadequate to meet the demand for treatment. There are too few pain specialists in most geographic areas to handle the large numbers of patients with CNMP [9-11]. Most pain specialists prefer to provide consultation services, making initial treatment recommendations before sending the patient back to their family physician for ongoing medication management [12]. With little or no guidance, the family doctor must try to meet the needs of patients who return repeatedly with little or no improvement to their CNMP symptoms.

In addition to the paucity of available consultation services by pain specialists, the lack of appropriate training of family physicians in CNMP management also contributes to the under-treatment of patients in the primary care setting [2,4]. Although primary care physicians reported a high level of comfort prescribing opioids for palliative or hospice care, they were not...
comfortable prescribing opioids to manage CNMP [13]. Studies of CNMP treatment by family and other primary care physicians reveal that primary care physicians feel that they have inadequate training, limited confidence in their ability to provide effective treatment for CNMP, and low satisfaction with treating chronic pain patients [4,8,13-16]. Although long acting opioids may be appropriate for patients with moderate to moderately severe CNMP, many family physicians are reluctant to prescribe these medications due to concerns about diversion, dependence, and abuse, the subjectivity of pain, insufficient knowledge regarding conversion between opioids, limited access to interdisciplinary care, concerns about patient self management, and perceived regulatory scrutiny [4,13,17-22]. Surveyed family physicians generally were not aware that most patients who present with CNMP to their family physician are low risk and can be managed routinely in a primary care setting [23]. Opioid therapy for CNMP has been demonstrated to provide sustained analgesia and improved sleep, mood, compliance, and quality of life [24,25]. Thus, many patients with CNMP are not receiving adequate or appropriate treatment for their pain.

Scope of Practice

Another way of framing the problem of the lack of willingness of family physicians to treat CNMP is to note that the scope of practice for this clinical scenario is poorly defined. What constitutes a candidate for primary care-based chronic pain management? What is a reasonable scope of practice for a family physician treating chronic pain, and what constitutes a reasonable threshold for referral? In this sense, CNMP does not differ from other problems in primary care practice – viz., for a given clinical presentation, there is a scope of practice within which a family physician can safely, effectively, and ethically operate, and outside of which a referral to specialty care is indicated.

Scope of practice can be conceptualized as a series of concentric circles (Figure 1), with the outer circles defined by the standards of care of the specialty and various practice environments, and the innermost circle reflecting the training, experience, and disposition of the individual practitioner. Thus, the establishment of a scope of practice for a given care category is a twofold process – first setting the limits of the outer circle (establishing criteria for what is reasonably in the purview of the primary care physician), and then insuring that training and support of practitioners expands the inner circle to its fullest potential.

In a scope-of-practice model, it becomes clear that the reluctance of family physicians to utilize rational, opioid-centered regimens for CNMP stems not only from inadequate training and experience, but more fundamentally from a failure to establish appropriate inclusion criteria and thresholds for referral. Simply put, there is no well defined scope of practice for CNMP in family medicine.

Scope of practice-Oriented Pain Engagement (SCOPE)

SCOPE is a structured CNMP protocol (developed by the first author at the University of Cincinnati/Wilmington Family Medicine Residency Program) that is designed to guide clinicians in patient selection, initial treatment plan, and interval management. It is built around a concise articulation of the scope of practice for CNMP in family medicine. With respect to patient selection, the cornerstone of the protocol, SCOPE uses three criteria to determine a patient’s candidacy for primary care based pain management:

- The patient must be reliable and reasonable.
- The patient’s anticipated regimen and overall clinical complexity must be straightforward.
- All practical non-opioid alternatives must be exhausted.

The first two criteria are aimed at manageability at the primary care level, with respect to the practical considerations of a family physician’s time and extent of training. “Reliable and reasonable” refers to patient compliance, and the absence of “red flag” behaviors concerning the use of controlled substances. The final criterion is consonant with a general and broadly accepted principle of pain management across specialties [26]. The SCOPE Protocol itself is a checklist driven instrument consisting of three one page sections, comprising: (I) Initial Patient Evaluation, (II) Initial Treatment Plan, and (III) Interval Management. Section I is designed to answer the key question of whether a patient meets the scope-of-practice criteria, and it works by reinforcing the foundations of sound medical practice: obtaining a thorough and context sensitive history, performing a focused exam, characterizing the prior treatment history, and identifying risk factors for abuse and diversion (i.e., red flags). To enhance ease of use, particularly for those inexperienced with the protocol, Section I can be summarized as an acronym – DESCRIBE:

- Duration - must be chronic
- Etiology - one or more diagnoses to explain pain symptoms
- Story - narrative from onset to present
- Consultation - has had evaluation by specialist consultant (specific to diagnosis)
- Red Flags
- Irreversible - reversible causes of chronic pain addressed
- Exhausted non-opioid alternatives
Section II (Initial Treatment Plan) is structured around evidence based principles of pain management that are easily grasped and implemented by the primary care physician. These principles include use of compliance tools, patient education, appropriate use of long acting vs. short acting opioids, maximized use of adjunct therapies, and treatment of concomitant mood disorders, enhancing patient enfranchisement and self care, and prospective management of adverse reactions to therapy. Section III, for interval management of patients established in SCOPE extends the principles behind the initial treatment plan, with special attention to the need for a consistent visit schedule, vigorous compliance measures, monitoring for efficacy and adverse reactions, and assessment of the patient’s functional status (the improvement of which is a primary goal under SCOPE).

We have hypothesized that a CNMP protocol built around a scope-of-practice framework can be readily and rapidly taught to family physicians and will result in a number of measurable improvements in the provider’s experience of working with CNMP patients, thus reducing many of the critical barriers to treatment and markedly enhancing access to care for patients with chronic pain. In this study, we provided family medicine residents with two half day patient care sessions in a specialized clinic in which the residents were taught to use the SCOPE protocol for initial and subsequent evaluation and treatment of patients with CNMP. Their attitudes, beliefs, and self perceptions with respect to treatment of chronic pain patients were assessed before and after the Protocol Clinic experience, and the results of this pilot study are presented in this report.

METHOD

Participants

Twelve medical residents (three female and nine male) in the University of Cincinnati/Wilmington Family Medicine Residency Program participated in this study. Data collection from these residents was approved by the Institutional Review Board (IRB).

Procedure

This study was conducted over a period of three years, with an average of four residents participating each year. The residents attended two half day patient care sessions in a specialized “Protocol Clinic,” during which the residents were taught to use the SCOPE protocol for initial and subsequent evaluation and treatment of CNMP patients. Training consisted of a brief (approximately 30-minute) introduction to the conceptual elements and principles underlying the SCOPE protocol, followed by brief (5-10 minute) teaching sessions before and after each patient encounter. Patient census for these sessions was typically 4-8, with significant variability (as is typical for residency practices). All patients in Protocol Clinic had been referred by other providers within the same practice, for the express purpose of insuring that all CNMP patients were receiving best practices care, in compliance with the aims and principles of the SCOPE protocol.

To assess the effectiveness of the SCOPE training, the residents’ attitudes, beliefs, and self perceptions with respect to treatment of chronic pain patients were assessed before and after the Protocol Clinic experience. The residents completed a brief survey consisting of 18 questions before the first half day Protocol Clinic sessions and the same survey after the second half day. The survey questions were of four distinct types, for the purpose of assessing the resident’s Subjective Experience, Perceived Competence, Provider Beliefs, and Provider Behaviors (Table 1). Subjective Experience refers to level of comfort in managing patients with CNMP, level of stress when dealing with CNMP patients, and emotional response when patients exhibit aberrant behaviors. Perceived Competence reflects provider knowledge and confidence regarding appropriate patient selection, medication/intervention selection, use of adjunct (non-opiod) therapies, and detection of patient abuse or diversion of prescribed opioids. Provider Beliefs is a measure of physicians’ beliefs regarding their ability to directly care for CNMP patients, the role of primary care physicians in the management of patients on long term opioids, the legal risk associated with managing CNMP patients, and the trustworthiness of CNMP patients. Provider Behaviors refers to use of compliance testing, emphasis on long acting opioids for managing CNMP, and the judicious and limited use of breakthrough medications. For each item on the survey, the residents indicated their responses on a Likert scale from “disagree strongly” (scored 1) to “agree strongly” (scored 5). Six of the 18 questions were worded to reflect reduced feelings of competency or willingness to work with patients with CNMP and were reverse scored.

Paired samples t tests were conducted to compare the residents’ responses on each survey item before and after the Protocol Clinic experience. The total score for the entire survey for each resident was calculated by summing the scores for each individual item, taking into account the reverse scoring for six of the items. A paired sample t-test was also conducted for the total score data. In addition, scores were calculated for each Question Type, by adding the scores for items associated with each Question Type. The Question Type associated with each survey item is identified in (Table 1). A paired sample t-test was calculated for composite scores for each Question Type (Subjective Experience, Perceived Competence, Provider Beliefs, and Provider Behaviors).

RESULTS

In terms of the residents’ readiness to manage CNMP, data from the participants before SCOPE training indicate relatively low scores on measures of Subjective Experience (M = 8.2 out of 15, or 54.7%), Perceived Competence (M = 17.1 out of 25, or 68.4%), Provider Beliefs (M = 23.9 out of 35, or 68.3%), and Provider Behaviors (M = 10.7 out of 15, or 71.3%). Following SCOPE training, residents’ scores improved for all four indicators, with scores for Subjective Experience and Perceived Competency improving significantly (Table 2). The residents’ overall performance on the survey improved significantly as well, with a mean total score of 59.8 (66.4% of total possible points) before SCOPE and a mean total score of 68.8 (76.4%) after SCOPE training. t(11) = -3.45, p = .005. Significant improvements were observed for 7 of the 18 questions (Table 1).

Sixteen of the 18 questions trended in the hypothesized direction. Only questions #11 and #16 did not:

#11: I think restoration of functional capacity is an important
Table 1: Survey Responses of Family Medicine Residents before and After SCOPE Training.

<table>
<thead>
<tr>
<th>Survey Questions</th>
<th>Question Type</th>
<th>Mean Score Before SCOPE</th>
<th>Mean Score After SCOPE</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel comfortable managing patients with chronic non-malignant pain.</td>
<td>Subjective Experience</td>
<td>2.9</td>
<td>4.1</td>
<td>-5.63</td>
<td>.000</td>
</tr>
<tr>
<td>I am competent in determining to whom I can safely give opioids.</td>
<td>Perceived Competence</td>
<td>3.6</td>
<td>4.2</td>
<td>-2.34</td>
<td>.039</td>
</tr>
<tr>
<td>I feel I am really helping chronic pain patients by treating them myself.</td>
<td>Provider Beliefs</td>
<td>3.1</td>
<td>3.8</td>
<td>-1.88</td>
<td>n.s.</td>
</tr>
<tr>
<td>I have the tools to determine whether a patient is abusing or diverting controlled medications.</td>
<td>Perceived Competence</td>
<td>3.6</td>
<td>4.1</td>
<td>-1.92</td>
<td>n.s.</td>
</tr>
<tr>
<td>I will treat chronic pain patients in my future practice settings.</td>
<td>Provider Beliefs</td>
<td>2.9</td>
<td>3.3</td>
<td>-1.09</td>
<td>n.s.</td>
</tr>
<tr>
<td>I know what medications and interventions to use before considering long-term opioid therapy.</td>
<td>Perceived Competence</td>
<td>3.8</td>
<td>4.3</td>
<td>-3.92</td>
<td>.002</td>
</tr>
<tr>
<td>I know how to use adjunct therapies, along with opioids, to maximize pain relief.</td>
<td>Perceived Competence</td>
<td>3.5</td>
<td>4.2</td>
<td>-2.69</td>
<td>.021</td>
</tr>
<tr>
<td>I consistently use compliance testing (u-tox, pill counts, OARRS, CSA).</td>
<td>Provider Behaviors</td>
<td>3.5</td>
<td>4.4</td>
<td>-3.53</td>
<td>.005</td>
</tr>
<tr>
<td>I know how to dose and adjust long-acting opioids.</td>
<td>Provider Competence</td>
<td>2.7</td>
<td>4.3</td>
<td>-5.86</td>
<td>.000</td>
</tr>
<tr>
<td>I believe chronic pain management is within the scope of primary care.</td>
<td>Provider Beliefs</td>
<td>3.6</td>
<td>4.0</td>
<td>-1.33</td>
<td>n.s.</td>
</tr>
<tr>
<td>I think restoration of functional capacity is an important goal of long-term pain management.</td>
<td>Provider Beliefs</td>
<td>4.7</td>
<td>4.7</td>
<td>&lt;.000</td>
<td>n.s.</td>
</tr>
<tr>
<td>I feel that all patients on long-term opioids should managed by pain clinic.*</td>
<td>Provider Beliefs</td>
<td>3.2</td>
<td>2.7</td>
<td>1.59</td>
<td>n.s.</td>
</tr>
<tr>
<td>I feel more than usual stress in dealing with chronic pain patients.*</td>
<td>Subjective Experience</td>
<td>2.2</td>
<td>2.7</td>
<td>-1.16</td>
<td>n.s.</td>
</tr>
<tr>
<td>I feel that managing chronic pain patients puts me at legal risk.*</td>
<td>Provider Beliefs</td>
<td>2.7</td>
<td>3.0</td>
<td>-1.08</td>
<td>n.s.</td>
</tr>
<tr>
<td>I use short-acting medications as primary medications for managing chronic pain.*</td>
<td>Provider Behaviors</td>
<td>3.4</td>
<td>3.8</td>
<td>-1.16</td>
<td>n.s.</td>
</tr>
<tr>
<td>I prescribe breakthrough medications to be taken on a daily, scheduled (non-PRN) basis.</td>
<td>Provider Behaviors</td>
<td>3.8</td>
<td>3.4</td>
<td>0.84</td>
<td>n.s.</td>
</tr>
<tr>
<td>I become angry or upset when patients violate their CSAs (pain contracts).*</td>
<td>Subjective Experience</td>
<td>3.0</td>
<td>3.8</td>
<td>-2.69</td>
<td>.021</td>
</tr>
<tr>
<td>Patients with chronic pain are untrustworthy.*</td>
<td>Provider Beliefs</td>
<td>3.8</td>
<td>4.0</td>
<td>-1.39</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

* Reverse-scored

Table 2: Composite and Total Scores of Family Medicine Residents Before and After SCOPE Training.

<table>
<thead>
<tr>
<th>Score Type</th>
<th>Mean Score Before SCOPE</th>
<th>Mean Score After SCOPE</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Score</td>
<td>59.8</td>
<td>68.8</td>
<td>-3.45</td>
<td>.005</td>
</tr>
<tr>
<td>Composite Score for Subjective Experience</td>
<td>8.2</td>
<td>10.5</td>
<td>-4.10</td>
<td>.002</td>
</tr>
<tr>
<td>Composite Score for Perceived Competence</td>
<td>17.1</td>
<td>21.2</td>
<td>-4.70</td>
<td>.001</td>
</tr>
<tr>
<td>Composite Score for Provider Beliefs</td>
<td>23.9</td>
<td>25.4</td>
<td>-1.18</td>
<td>n.s.</td>
</tr>
<tr>
<td>Composite Score for Provider Behaviors</td>
<td>10.7</td>
<td>11.7</td>
<td>-1.51</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

DISCUSSION

The SCOPE Protocol was designed to give primary care providers a structured, rational tool for managing CNMP patients in the primary care setting. Its underlying philosophy is that, by clearly defining a reasonable scope of practice for such patients,
physicians will be empowered to deliver that care – with the same sense of confidence and competence that accompanies the care they deliver in other clinical scenarios. In this study, we set out to determine if SCOPE could be readily and rapidly taught to resident physicians in a manner that instilled these qualities, thereby potentially reducing the barriers to providing care for CNMP, and promoting access to this very important care resource in a primary care setting.

This pilot study demonstrated that residents in Family Medicine consistently showed improvement in scores reflecting Subjective Experience, Perceived Competence, Provider Behaviors, and Provider Beliefs with respect to CNMP, as a result of SCOPE training. Their scores prior to SCOPE training reflected a level of relative discomfort and distaste for treating CNMP, consistent with reports in the literature [4,13]. Statistical analyses demonstrated a marked improvement in all four measures (Subjective Experience, Perceived Competence, Provider Behaviors, and Provider Beliefs) as well as in the overall composite scores for the entire questionnaire (Table 2). This is strong initial support for our core hypothesis and suggests that SCOPE is a tool that can be readily learned and applied in clinical settings, yielding significant dividends with respect to physicians’ capabilities and comfort level in managing patients with chronic pain.

In simpler terms, it appears that residents using SCOPE had better overall clinical experiences with CNMP patients, compared with their previous, unstructured “usual care” approaches.

One limitation of this pilot study is the absence of a control group to confirm that the improvements in the resident’s experience is truly due to using SCOPE as practice tool with CNMP patients and not due to the learning and experience accumulating from regular clinic practice with chronic pain patients and prescribing opioid. For the participants in this study, the effect was noted, on average, in a period of two to three weeks, which is too little time for standard training to be a confounder. Further, the baseline questionnaire scores reported were for residents in all three years of training. If there were a standard training effect, we would see baseline differences between first and third year residents, which were not evident.

It is the authors’ assertion that SCOPE exerts its measurable effects via several mechanisms, including: objective, non-prejudicial patient selection criteria; clearly articulated boundaries for scope of practice and referral; and principle driven, evidence based interventions. How and why SCOPE is effective, of course, was not directly addressed in this trial, and further study will be needed to elucidate mechanisms and refine the parameters by which SCOPE operates. That said, it seems likely that the effect of SCOPE training is mediated, in large part, by reframing patient inclusion criteria as a scope-of-practice question – and then proposing a means for training physicians to define and develop this scope of practice. Absent this, physicians will tend to simply avoid patient scenarios for which they feel inadequately trained [27]. This must be considered unacceptable, given that chronic pain management is squarely in the purview of the family physician’s scope of practice [28], and also taking into account that the specialty level pain management resources are frequently unable to meet the demand for these services [9-11]. The take home message here is that primary care physicians can and should manage a carefully selected subset of patients with CNMP and that they can be successful doing so by following a structured, rational approach [24,31]. It is our belief, supported by our reported findings, that such an approach should be fully integrated into a primary care scope-of-practice paradigm.

The SCOPE Protocol and supporting documents and clinical tools are freely available from the authors upon request.

REFERENCES

17. Bendtsen P, Hensing G, Ebeling C, Schedin A. What are the qualities of


