Pain Screening in Primary Care

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A Master's Paper submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Public Health in the Public Health Leadership Program

April 10, 2006

Advisor /

Second reader -

412/26 Date

Introduction

Pain screening has become an increasingly common practice in primary care, largely because pain screening has been adopted as a quality benchmark by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).¹ The principal goal of universal pain screening is to systematically identify patients in need of additional assessment and treatment for pain. Although this practice is now widespread and mandatory in many primary care settings, it has not been adequately evaluated.

This paper will describe 3 projects that were conducted to evaluate the effectiveness of pain screening in primary care: a literature review, a retrospective chart review, and a prospective observational study conducted in the University of North Carolina (UNC) Internal Medicine Clinic. We used criteria developed by the US Preventive Services Task Force (USPSTF) to guide our evaluations. These criteria for a good screening test are: 1) the test must be sufficiently accurate and capable of detecting a condition earlier than routine care and 2) the likelihood of favorable outcomes should be improved by screening and early treatment.² We conducted a literature review to determine whether studies were available to assess either of these criteria. We then conducted a retrospective chart review and a prospective observational study to evaluate the first of the two USPSTF criteria, the accuracy of pain screening as a way to identify patients in need of additional assessment and treatment.

Background

The phrase "pain: the 5th vital sign" was coined by the American Pain Society (APS) and has been promoted to increase the visibility of pain as a clinical problem. James Campbell, a past president of the APS, described the rationale for this campaign in 1995 as the following: "Vital signs are taken seriously. If pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly."³

In 2001, JCAHO launched pain assessment and management standards that require accredited hospitals and clinics to routinely assess all patients for pain in both inpatient and ambulatory care settings.¹ Inadequate pain assessment is cited by JCAHO as one of the key barriers to appropriate pain management.⁴ Evidence supports this assertion in the case of hospitalized patients, especially those who have recently undergone surgery.⁵ Evidence also suggests that routine pain assessment may improve pain recognition and management in specialized settings where disease-related chronic pain is common, such as oncology clinics.⁶ These findings from relatively specialized settings may not be generalizable to other clinical settings, such as primary care.

JCAHO accredits over 15,000 health care organizations, including 80% of U.S. hospitals, so these standards directly affect most health care providers in the nation.⁷ Although they do not specifically mandate that pain must be recorded as

a vital sign, many organizations have responded to the requirement for universal assessment by adopting the "fifth vital sign".⁸

In accordance with JCAHO requirements, UNC pain management policy requires screening for the presence and intensity of pain with an objective scale at the time of presentation for care in both hospital and clinic settings.⁹ The most commonly used scale in UNC adult care settings is the 11 point numeric rating scale (NRS) in which patients are asked to report the intensity of pain as a number, from 0 for "no pain" to 10 for "worst possible pain." In addition, UNC policy requires physicians to develop and document a pain intervention plan for any pain screening score of 4 or greater.

Pain in Primary Care

The mission of primary care is broad, and includes the delivery of preventive services, acute illness care, and chronic disease management. Pain symptoms are among the most common complaints in primary care clinics and represent the principal reason for presenting to clinic in up to 29% of primary care visits.^{10, 11} Approximately 20% of primary care patients suffer from persistent pain (pain that is present most of the time for at least 6 months).¹² On the other hand, many pain problems presenting in primary care are minor and transitory. In one general medicine clinic-based study of symptom outcomes, the percent of patients reporting improvement in their index pain symptom at 2 weeks ranged from 62% for back pain to 80% for abdominal pain.¹³

Pain and other symptoms in primary care are often associated with the presence of undiagnosed mood disorders. In fact, the majority of patients who are seen in primary care with depression report only physical symptoms.^{14, 15} Primary care physicians are less likely to recognize and treat depression in patients who present with pain or other physical symptoms than those who complain of psychological problems.¹⁴ Therefore, it is important to consider additional sources of distress that may be present in patients with positive pain screening scores.

Measuring Pain

Pain is an inherently subjective phenomenon. There are no laboratory, imaging, or exam findings that can replace patient report in the assessment of pain. In part this is because the intensity and impact of pain, especially chronic pain, are poorly correlated with objective pathology or observable behavior.

Current conceptual models of pain emphasize its multidimensional nature.^{16, 17} The individual experience of pain involves a complex interplay of factors, including sensory input, cognitive processes, emotional responses, and social and cultural context. Therefore, measuring pain is a challenging task.

Simple one-dimensional pain intensity rating scores are the mainstay of routine pain assessment in adults. The most commonly used measurements are numeric rating scales (NRS). A common alternative method is the visual analogue scale

(VAS), in which pain is rated on a visual representation of a scale from 0-10 or 0-100. One-dimensional pain scales have been validated as measures of pain intensity in chronic pain populations and in patients with acute postoperative pain.¹⁸⁻²¹ They appear to correlate well with other measures of pain intensity and are sensitive to change in patients with chronic pain and in those with acute postoperative or procedural pain.²¹ Studies of cancer patients with chronic pain suggest that the midpoint of pain intensity scales (e.g. 5 on a 0-10 scale) represents a threshold above which patients report more interference with daily function.^{22, 23}

An obvious limitation to the use of NRS scores as screening devices is that they provide a simplified one-dimensional measure of a complex phenomenon. Patients take many factors into account when choosing a score to represent their pain severity, including mood, disability, and non-pain symptoms. The meanings of intermediate points and endpoint anchors on pain intensity scales differ between individuals and groups.^{24, 25}

Project 1: Literature review

A literature review was conducted to answer the following questions, modeled on the USPSTF framework for evaluation of a screening test: whether routine pain screening in primary care 1) accurately identifies patients with unrelieved pain; 2) improves physician recognition of patients with unrelieved pain; and 3) improves pain outcomes. PubMed was searched from 1966 through March 30, 2006 using the following search terms: *pain measurement, pain screening, fifth vital sign, pain assessment, numeric rating scale, visual analogue scale.* In addition, citations from relevant publications were searched for additional articles. Because the literature was expected to be limited, all types of studies conducted in primary care settings were considered. Studies in chronic pain populations and inpatient settings were excluded.

No studies relevant to primary care were identified. However, one study conducted in an emergency department was found: a retrospective analysis of analgesic administration before and after institution of a universal pain screening protocol.²⁶ Participants in the study were 1000 consecutive patients presenting to the emergency department with renal colic, headache, soft tissue injury, or trauma to the eye or extremity during 2 days before and 2 days after pain screening was instituted. The authors found that the percentage of patients receiving analgesics increased from 25% before pain screening to 36% afterwards. The mean time to analgesic administration decreased by 39 minutes (95% CI: -7 to 84 minutes). Patient outcomes were not reported. This study suggests that, at least in an emergency department setting, pain screening may improve physician recognition of unrelieved pain, leading to increased analgesic prescribing.

Project 2: Retrospective chart review to describe the distribution of pain screening scores and the relationship between pain screening scores and physician documentation of pain assessment and management

We conducted a preliminary retrospective study to provide background information for our planned prospective study. This was an electronic medical record review of patients seen in the Internal Medicine Clinic at the University of North Carolina (UNC). Our objectives were to determine: 1) the distribution of pain screening scores in the clinic population, 2) the prevalence of physician documentation of pain assessment and management, and 3) whether physician documentation of pain assessment and management differed according to pain screening scores.

Setting and participants

The UNC Internal Medicine Clinic is an academic practice staffed by both attending and resident physicians. Nurses ask all patients presenting to clinic about the presence and severity of pain, measured on a NRS from 0 (no pain) to 10 (worst possible pain). Pain screening is done at the time of vital sign measurement and the pain score is hand-entered in the electronic vital sign record. Physicians dictate their notes, which are then transcribed into the electronic medical record.

The study protocol was approved by the UNC Institutional Review Board. Patients were eligible for inclusion if they were adults (≥ 18 years old) who completed an appointment with a physician in the clinic between January 1 and December 31, 2004. A random sample of 300 patient visits was selected using a random number generator. Patients were excluded if the index visit was their first

visit to the clinic or if no pain score was recorded for the visit. If a patient was selected twice, only the first visit was sampled. We abstracted the following data from the electronic record: patient demographic information, nurse-entered pain screening scores, and physician-documented elements of pain assessment and management.

We categorized pain screening scores for analysis using standard cutoffs for mild (1-4), moderate (5-6), and severe (7-10) pain.²³ Our physician documentation outcomes were dichotomous measures indicating presence or absence of documentation anywhere in the physician note of 1) the presence of pain and 2) a plan for diagnosis or management of pain. We used Pearson's chi-square and one-way analysis of variance for bivariate comparisons.

<u>Results</u>

Four hundred-twenty one randomly selected patient records were reviewed to find 300 patient charts meeting our inclusion criteria (Figure 2.1). The 300 patients included had a mean age of 59 years. The majority were female (60%) and white (59%). Sixty percent had a pain screening score of 0, 9% had a score of 1-4, 12% had a score of 5-6, and 19% had a score of 7 or greater (Table 2.1). Patient demographic characteristics did not differ across categories of pain screening score (Table 2.2).

A pain problem was documented in 53% of patient visits. A pain management plan was documented in 81% of visits in which a pain problem was documented. Physicians were more likely to document pain assessment and management when the pain screening score was positive (≥ 1). Physician documentation of a pain problem was present in 33% of visits when the pain score was 0 and in 84% of visits when the pain score was ≥ 1 (p<0.001). Similarly, documentation of a pain management plan was present in 22% of visits when the pain score was 0 and 74% of visits when the pain score was ≥ 1 (p<0.001).

Physician documentation of pain assessment and management was not associated with level of pain screening score when the score was positive (Table 2.3). For example, a physician-documented pain management plan was present in 68% of charts with a pain screening score of 1-4, 74% of charts with a pain score of 5-6, and 77% of charts with a pain score of 77% (p=0.679).

Figure 2.1: Excluded and eligible participants

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Table 2.1: Participant characteristics (n=300)

Mean age, years (SD)	59
Women, %	60
Race, %	
White	59
Black	38
Insurance, %	
None	20
Public	36
Private	44
Pain screening score, %	
0	60
1-4	9
5-6	12
7-10	19

	Pain screening score				
	0	1-4	5-6	7-10	
Characteristic	(n=181)	(n=28)	(n=35)	(n=56)	p-value
Mean age, years	60.6	59.3	55	55.9	0.06
Sex, %					
Female	66	8	13	14	0.26
Male	57	11	11	22	
Race, %					
White	59	11	10	20	0.59
Black	63	6	15	17	
Insurance, %					
None	68	7	12	13	0.19
Public	50	10	14	26	
Private	65	10	10	15	

Table 2.2: Patient characteristics by pain screening score

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 Table 2.3: Chart review: Physician documentation by pain screening score

 Documentation present, %

	Documentation present, 78			
Pain screening			Pain management	
score	Pain problem	Pain exam	plan	
0	33	8	22	
1-4	75	43	68	
5-6	86	46	74	
7-10	88	36	77	
p-value	< 0.001	< 0.001	< 0.001	

Project 3: Prospective study to determine the accuracy of pain screening in primary care

We conducted a prospective cohort study of pain screening in the UNC general internal medicine clinic. The primary study objective was to evaluate the sensitivity and specificity of pain screening with an 11 point NRS for the identification of patients with substantial functional impairment due to pain, and to determine the best pain screening score cutoff for identification of patients with substantial functional impairment to evaluate associations between pain scores and non-pain factor, such as depression, anxiety, somatic symptom severity; and 2) to determine predictors of improvement in pain severity and functional interference at 4 weeks.

For our primary objective, determining the accuracy of pain screening, we chose to use a measure of functional impairment as the "gold standard" for clinically important pain. From a clinical perspective, it is important to address pain that interferes with physical or psychological functioning. Minor pain that does not interfere with functioning may not require intervention.

Setting and participants

The UNC general medicine clinic is an academic primary care clinic staffed by both resident and attending physicians. In accordance with UNC policy, clinic nurses screen patients for pain at the time of presentation for care using a pain intensity NRS.

We invited adult patients who were in clinic for a return physician visit to participate. Patients who were new to the clinic or who were unable to complete the interview for reasons such as language barrier, dementia, or incapacitating medical or psychiatric illness were excluded. Physicians were given the opportunity to opt individual patients out of the study. Study protocols were approved by the UNC Institutional Review Board.

Procedures

Because previous studies in the clinic have documented a high prevalence of low literacy,²⁷ all data was collected by interview. Potential participants were approached by a research assistant for written informed consent after their vital signs and pain scores were measured and before they were seen by the physician. Patients were not alerted to the focus of the study, which was described in general terms as a study of symptoms in primary care. After consent was obtained, the research assistant elicited the chief complaint and any secondary concerns by asking, "What is the main reason for your visit today?" and "What other concerns would you like to talk to the doctor about today?"

Patients were then seen by their regular physicians as scheduled. They were asked to return to the study room in clinic for a face-to-face interview after their scheduled appointment was completed. Nursing notes, dictated physician notes, and medication and problem lists were abstracted from the electronic medical

record after the interview was completed. Phone follow-up was obtained approximately four weeks after the index visit.

<u>Measures</u>

We choose measures that have been used in a variety of settings with diverse patient populations, including primary care populations.

Brief Pain Inventory (BPI): The BPI was chosen as the primary measure of pain severity and pain-related functional impairment. It was originally developed for use in populations with cancer-related pain,^{22, 28} but has been validated for use in numerous other populations, including primary care and patients with non-cancer chronic pain.²⁹ The BPI Severity scale consists of four numeric rating scales with possible scores of 0 ("no pain") to 10 ("pain as bad as you can imagine"), which measure current pain severity and pain at its worst, least, and average severity over the preceding week. Our measure of functional impairment, the BPI Interference scale, measures interference due to pain in seven domains: general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. Possible scores range from 0 ("does not interfere") to 10 ("interferes completely").

Patient Health Questionnaire (PHQ): We used the PHQ, a brief instrument designed to detect mental disorders in primary care using DSM-IV based criteria, for our measures of depression, anxiety, and overall somatic symptom severity.³⁰

The PHQ-8 was used to measure major depression. This version of the PHQ depression module excludes the final item from the original measure, a question about thoughts of death or suicide.³¹ It has been shown to have equivalent accuracy to the original nine-item version.³² We used PHQ modules for anxiety syndrome (a sub-threshold diagnosis) and panic disorder (according to DSM-IV criteria). Somatic symptom severity was measured with the 15-item PHQ somatic symptom severity scale, which asks about how bothersome 15 common physical symptoms have been in the past four weeks.³³

Additional measures: We used visit satisfaction items from the Medical Outcomes Study,^{34, 35} pain management satisfaction items from the American Pain Society pain outcome questionnaire,³⁶ and questions about unmet expectations from previous studies.³⁷

Sampling plan

Our primary outcome was the sensitivity and specificity of the pain screening NRS for detection of substantial pain-related functional impairment. We used the BPI Interference scale as the measure of functional impairment, and the midpoint on the scale as our definition of substantial impairment. Since this cutoff choice was based on clinical reasoning rather than published data, we planned in advance to do sensitivity analysis using different BPI Interference scale cutoffs. We estimated that 20% of our sample would meet our definition of substantial functional interference. Using this assumption, we determined a sample size of

310 would be needed to provide an estimate of sensitivity and specificity with a 95% confidence interval of \pm 0.10. After 214 participants were enrolled, a check of the data revealed that 46% of participants met our criteria for substantial functional impairment. Since this prevalence was higher than expected, we decreased our target sample size to 275.

We planned to oversample patients with pain scores of one or greater. All eligible patients were invited to enroll until approximately 20% of the enrolled participants had a pain score of zero. Thereafter, only patients with scores greater than zero were invited to participate.

Data analysis

For our primary objective, we calculated sensitivity and specificity and fit receiver operator characteristic (ROC) curves to describe the accuracy of pain screening score cutoffs for detection of substantial functional impairment (BPI Interference score \geq 35) due to pain.

We plan to use logistic regression models to determine the relationship between pain screening scores and BPI Severity and Interference scores. Multivariable regression models will also be used to determine associations between pain scores and non-pain factors, including depression, anxiety, somatic symptom severity, and satisfaction. Multivariable predictive models will be used to assess predictors of improvement in NRS pain score and BPI Interference at 4 weeks. We plan to

do subgroup analyses of patients with chronic pain and patients with pain as a chief complaint.

<u>Results</u>

The study is in progress, so only primary results for the first 107 participants will be presented. Baseline characteristics of the first 107 participants are shown in Table 3.1. The mean age was 53 years and 64% of participants were women. 18% of participants reported a pain symptom as the chief complaint for their visit and another 16% reported a secondary pain concern. The mean pain screening score was 2. The distribution of pain screening scores was 60% 0, 13% 1-4, 12% 5-6, and 15% 7-10.

The sensitivity, specificity, and overall accuracy for detection of substantial painrelated functional impairment (defined as a BPI interference score of \geq 35) was determined for each of the possible pain score cutpoints (Table 3.2). A pain score of 1 was 68% sensitive, 71% specific, and 70% accurate. Overall accuracy was similar for each cutpoint, with a range of 70-76%.

The ROC curve for the pain screening score as a test for substantial functional impairment is shown in Figure 3.1. The area under the curve (AUC) is 0.73, which compares to 0.5 for a worthless test and 1.0 for a perfect test. Sensitivity analyses using different BPI Interference cutoffs as the definition of substantial functional impairment produced similar results.

Table 3.1: Characteristics of participants (n=107)		
Mean age, years (SD)	53 (14)	
Women, %	64	
White, %	67	
Education beyond high school, %	53	
Insurance, %		
None	15	
Public	31	
Private	54	
Saw primary doctor, %	76	
Mean pain screening score (SD)	2 (3)	
PHQ-8 major depression, %	21	
PHQ-15 high somatic severity, %	16	
PHQ anxiety syndrome, %	31	
Chronic pain, %	55	
Pain chief complaint, %	18	
BPI-Interference >35, %	29	

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cutpoint	Sensitivity	Specificity	Accuracy
1	68	71	70
2	68	72	71
3	61	76	72
4	61	78	73
5	55	84	76
6	45	88	76
7	32	92	75
8	26	96	76
9	7	100	73

Table 3.2: Accuracy of pain screening score cutpoints

Pain screening

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Figure 3.1: Pain screening as a test for functional impairment (BPI 35+)

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Conclusions

The published evidence for effectiveness of pain screening tests is extremely limited. Despite their widespread use in all kinds of clinical settings, pain intensity measures have not been adequately evaluated as screening tests. A single study, conducted in an emergency department, found an improvement in analgesic administration after institution of universal pain screening. No published studies have evaluated the accuracy or effectiveness of pain screening tests in primary care.

In a general medicine clinic where universal pain screening was already in place, we found that physicians were more likely to document pain assessment and management when the pain screening score was positive, but that physician documentation was not associated with level of pain screening score when the score was positive. We did not compare physician documentation in an unscreened group, so we cannot determine whether the pain screening score influenced documentation.

The preliminary results from our prospective evaluation of pain screening in a general medicine clinic suggest that pain screening scores have only modest accuracy for detection of substantial functional impairment due to pain. Even the lowest pain screening score cutoff was only 68% sensitive.

Implications

The effectiveness of pain screening in primary care is unknown, but our findings suggest that it may not be as useful as previously hoped.

Efforts to make patients' pain more visible should take relevant literature on patient-physician communication in primary care into account. Problems with physician recognition of patient concerns in general have been repeatedly documented.³⁸⁻⁴⁴ For example, in a recent update of a classic study, investigators audiotaped patient-physician visits and found that physicians did not solicit the patient's agenda in 25% of visits, and allowed patients to finish their initial statement of concerns only 28% of the time. Patients were given a mean of 23 seconds to speak about their concerns before they were interrupted and redirected by their physician.⁴⁵ Various interventions to improve physicians' awareness of patient concerns have been tried in small studies, with mixed results.⁴⁶⁻⁴⁸ Improving physicians' focus on concerns and desires of patients has proved to be a challenging task. Considering the diverse competing priorities in primary care, it is unlikely that a simple one-size-fits-all intervention will dramatically improve care for a complex problem like pain.

It is yet to be seen whether dedicating nursing time to pain screening and physician time to following up on positive screens improves pain management, overall visit quality, or the patient-centeredness of primary care visits. Because a mandate to screen every patient for pain may crowd out other services, it is

critical that we determine whether or not pain screening is an effective activity in primary care. Until that time, efforts to improve the quality of pain care should be focused elsewhere.

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