Title of Project
An Integrative and Sustainable Approach to Pain Management in Primary Care

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Abstract

Purpose: The goal of this study was to evaluate a novel model of chronic pain care that supports PCPs in delivering evidence-based pain care. The care model employed provider education (Phase 1) and standardized data and decision support (Phase 2) delivered through an electronic health record (EHR).

Scope: Chronic pain affects over 100 million Americans and the cost of care related to pain is estimated to be $635 billion annually. PCPs report time constraints and low levels of knowledge, confidence, and satisfaction in managing chronic pain.

Methods: Using a pragmatic, cluster randomized study design, the pain care model was implemented in two academic-affiliated family practice sites. Two similar sites served as a randomly assigned control group. Eligible provider participants included all physician and physician assistant PCPs practicing in the study practices. Eligible patient participants included all patients with chronic pain between the ages of 18 and 89 who were seen in a participating clinic by a participating provider. Differences in patient and provider satisfaction were compared between intervention and control groups within and across the education phase and the standardized data/decision support phase.

Results: Twenty-one PCPs were enrolled across the four participating clinics (11 control group, 10 treatment group). Data were collected from 720 patients over 1,203 clinical visits. There were no significant differences in patient visit satisfaction measures between intervention and control groups. There was no significant difference in overall provider satisfaction between intervention and control groups. Similarly, there were no significant treatment-control differences in the outcomes across the two intervention phases.

Key Words: chronic pain, opioids, patient-reported outcomes, electronic health records, decision support

Purpose

The goal of this study was to evaluate a novel model of chronic pain care that supports PCPs in delivering evidence-based pain care. The care model employed provider education, standardized data, and decision support. Provider education was be delivered through a web-based and in-person didactic education curriculum emphasizing the use of evidence-based approaches, including physical modalities and psychological approaches in addition to the traditional medical model of pain care. Standardized data employed a patient and practice staff oriented model for collecting standardized patient reported health outcome (PRO) data in the electronic health record (EHR). Decision support was delivered through the EHR by presenting PCPs with interpretation of the PROs delivered via the EHR. We designed the elements of the care model to address established needs for improved knowledge, improved access to patient data, and efficient treatment guidance for time-constrained PCPs.

Scope

Chronic pain affects over 100 million Americans and the cost of care related to pain is estimated to be $635 billion annually [1, 2]. Pain is one of the most common reasons patients visit a primary care provider (PCP). However, PCPs report time constraints and low levels of knowledge, confidence, and satisfaction in managing chronic pain [3, 4]. At the same time, the number of people seeking pain treatment is substantially greater than the supply of pain physician specialists. Therefore, PCPs critically need more knowledge and resources for treating chronic pain, so they can provide evidence-based care and refer only the most challenging cases to specialists.

Patients seeing PCPs can be seen more quickly and may be able to provide lower cost care than specialist physicians for non-complex needs. Moreover, there are approximately 25,000 patients with chronic pain for every pain specialist physician in the United States [1]. However, primary care physicians, like other medical specialties, receive little formal training in pain condition etiology, diagnosis, management in medical school [1, 5] and residency [6], which leads to an increased risk of delivering less informed pain care in those physicians who do not pursue advanced pain training.

This randomized experiment implemented a sequential two-phase intervention in family medicine clinics in the University of Florida health system (UF Health). Phase one involved giving multidisciplinary pain care education to providers in two intervention group clinics. Phase two involved giving PRO data and related decision support to intervention group providers, via their EHR, during visits involving patients with chronic pain. As study outcomes, intervention and control clinics were compared in terms of patient measures: satisfaction (first primary outcome), pain-related outcomes; provider measures: satisfaction (second primary outcome), treatments recommended/ordered, and patient service utilization/costs.

Methods

Trial Design

This study is consistent with Consolidated Standards of Reporting Trials (CONSORT) recommendations for randomized controlled trials and extensions for trials of pragmatic and cluster designs [7-9]. The design exemplifies the goals of a learning health system: to foster close collaboration between research and practice, so that high quality patient care processes can be designed, rigorously evaluated, and practically implemented. Using a pragmatic, cluster randomized design, the aforementioned care model for pain was implemented in four academic-affiliated family practices. The EHR served as a conduit for collecting and communicating key pain-related patient information and care recommendations. The approach allowed the care model to be rolled out in practice, with minimal direct involvement by the researchers on practice workflows and patient tasks. Due to the nature of the intervention, participants could not be blinded. This study was registered as a randomized controlled trial with ClinicalTrials.gov (Identifier: NCT02188667).

Participants

The practice sites from which the study recruited PCPs and patients were staffed by physicians and physician assistants. PCPs were made aware of the study through e-mail and in-person meetings, such as regular faculty meetings and individual appointments. These meetings were also used to identify concerns about the clinical workflow impact of the new care model and study procedures. Before randomization, intervention implementation, or data collection, a study team member met with prospective provider participants and obtained written informed consent to participate. Next, the four practices were matched as two pairs based on aggregate practice and patient demographics. One member of each clinic pair was then randomly assigned to intervention and control groups.

Patients, ages 18-89, seen in participating family medicine clinics were flagged for recruitment if their recent diagnosis and/or medication prescription history within our health system indicated a possible chronic pain condition, including musculoskeletal, headache, or neuropathic pain. First, the most recent 15 months of health record data was reviewed to identify patients who met one or more of the following criteria: (i) at least three pain-related diagnosis codes that were separated by 30 days or more; or (ii) at least two pain-related diagnosis codes and two or more pain-related medication prescriptions, each separated by 30 days or more; or (iii) at least two opioid medication prescriptions separated by 30 days or more. The specific diagnoses used in the identification were identified by the following ICD-9 CM codes: 721.3x, 722.81, 722.83, 722.91, 723.1x, 722.93, 723.0x, 723.4x, 723.8x, 724.02, 724.2x, 724.4x, 729.1x, 729.2x, 729.5x, 338.0x, 338.1x, 338.2x, 338.4x, 346.0x, 346.7x, 350.1x, 350.2x, 350.9x, 780.96, 784.0x, 053.12, 339.xx. For medications, we identified any prescriptions containing the following medications commonly used in pain treatment: opioids, tramadol, nortriptyline, amitriptyline, gabapentin, pregabalin, or duloxetine. In addition to the aforementioned identification process, PCPs participating in the study were able to nominate other patients for recruitment, such as new patients they were seeing for chronic pain. We flagged all identified patients in the EHR. This flag cued clinic staff to approach the patient when they visited a participating PCP. Upon their arrival for a visit,

patients received a study notice document. The study notice provided instructions on how patient participants may refuse to participate by signing an opt-out form or simply declining to complete the study's follow-up phone survey when called. Patients participated in the study at a maximum of three visits.

Intervention

Our intervention involved two phases that were sequentially rolled out in intervention group practices: PCP education, and standardized PRO data collection and integration into the EHR.

Education: Phase 1

A six-module education curriculum was implemented that emphasizes evidence-based, multimodal and comprehensive pain care, including physical modalities and psychological approaches in addition to the traditional medical model of pain care. The curriculum was based on published evidence-based guidelines and systematic reviews [10-12]. The education included training on structured and validated data collection instruments that PCPs can use to assess risks and benefits of different treatment modalities and to assess patient changes in pain and function. One module focused on PRO measurement and the value of structured data for monitoring patients with chronic pain. Also, one module described the clinical value of and how to use validated opioid screening tools to predict opioid-related risks of abuse and misuse [13].

The education curriculum combined web-based lectures and in-person didactic sessions led by pain medicine and family medicine physicians. Intervention group PCPs were invited to in-person lectures and given access to six web-based lectures. We did not require completion of the education for continued participation. We offered up to 6.0 hours of continuing medical education (CME) credits to participating PCPs. Once the study's data collection was complete, the lectures and CMEs were made available to control group participants.

Standardized PRO data and decision support: Phase 2

Upon arrival for an office visit, patients electronically completed a series of PRO assessments using a tablet computer and the Collaborative Health Outcome Information Registry (CHOIR) software. CHOIR is a web-based software package developed at Stanford University that administers PRO assessments [14, 15]. We developed CHOIR at the University of Florida (UF-CHOIR) to interface with the Epic EHR system, so that patients' PRO data could be viewed by clinicians in the EHR during patient visits [16]. For this study, UF-CHOIR assessed 13 PRO measures. Nine measures, including pain interference, pain behavior, fatigue, anger, depression, sleep disturbance, sleep-related impairment, anxiety and physical function, were from the NIH Patient Reported Outcomes Measurement Information System (PROMIS) [17, 18]. These PROMIS measures were administered computer-adaptively by CHOIR, which reduces response burden. Three measures were administered with static scales,

including pain intensity (average, now, worst, least) [19], the pain catastrophizing scale [20] and the opioid risk tool [13]. Finally, a clickable body map allowed patients to select the location(s) of their pain.

Results from the PRO assessments described above were available to PCPs in the EHR immediately following patient completion. Each PROMIS measure was recorded in the EHR's results module as a t-score and as a population percentile. Pain intensities (range 0-10), pain catastrophizing (range 0-52), and opioid risk tool (range 0-26) results were available in the EHR. In addition to being recorded in the EHR's results review section, PCPs could graph the results longitudinally and insert the results in their clinical notes. Finally, a body map image showing patients' pain location(s) was available in the EHR in portable document format (PDF) as part of a document that also contained the other PRO results.

Outcomes

The general approach for collecting patient data was to allow PRO and other clinical data to flow through normal clinical systems and processes into our academic health center's Integrated Data Repository (IDR). The IDR is a secure clinical data warehouse that supports institutional operations and research. For outcomes analysis, the research team then obtained a de-identified analytic dataset through an honest broker process associated with the IDR. The two primary outcomes were patient satisfaction and PCP satisfaction. Secondary outcomes, when available from the IDR, included pain-related outcomes (e.g., pain intensity and laboratory results), PCP treatment choices (e.g., tests ordered, medications prescribed, and referrals), care costs, and health services utilization. Data were collected at the level of the patient visit with the exception of PCP satisfaction. PCP satisfaction was assessed monthly.

Patient Satisfaction

Following a visit to their PCP, enrolled patients were approached to complete a brief phone survey, about their general and pain-specific satisfaction with their office visit. As the primary satisfaction questions, patients were asked to rate their general satisfaction with their visit on a scale of 0 (worst visit possible) to 10 (Best visit possible). Next, patients completed a screener question to determine if they actually discussed pain or discomfort with their PCP during the visit. Patients who passed this screening question were asked two additional questions on pain. We developed these two questions based on the two pain-related items found on the Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) survey [21]. The first item addresses patient perception that their provider did everything he/she could to help with pain. The second item addresses patient confidence that their pain will be well controlled in the future based on their visit experience.

PCP Satisfaction

Starting at baseline and then once per month for the duration of the study, all participating PCPs were asked to complete a web-based survey on their satisfaction

caring for patients with chronic pain. This survey included a 14-item questionnaire assessing general experiences and satisfaction with providing care to patients with chronic pain. The questionnaire was modified from a visit-specific physician satisfaction questionnaire [22] such that the item wordings referred to general satisfaction with visits by patients who have chronic pain. The 14 items include one item for global satisfaction. The remaining items address satisfaction with quality of the patient-provider relationship, appropriate use of time during visits, adequacy of data collection during visits, and patients' cooperation during visits. Each item contained a five-point agree/disagree response scale anchored by "strongly disagree" and "strongly agree." At each survey administration, PCPs were also asked if they had any concerns or comments to discuss with the study investigators (yes/no) and if they had any additional comments (open-ended response).

Sample Size

Our a priori sample size estimations were based on the patient satisfaction outcome. Because we have separate interest in each outcome, no bivariate error control was employed. Our sample size algorithm assumed 10 PCPs in each of treatment and control group, a uniformly distributed random number of patients per PCP between 20 and 40 (600 expected total per phase), and the parameters (power and type I errors) were simulated based on 20,000 replications using normally distributed outcomes. However, because we expect actual enrollment may be unbalanced (11 PCPs in control and 9 PCPs in intervention), efficiency is slightly reduced to 99%. Therefore, a 1% sample size inflation, 606 patients per phase, adjusts for this imbalance. Table 1, below, describes estimated power calculations. Delta is the mean difference between the intervention and control, 1.5 points on the 0-10 patient general satisfaction scale. And, anticipated planning between physician standard deviation and within patient standard deviation are provided. Power and Type I error rates are empirically estimated (Type I error sets Delta=0).

Table 1. Estimated Power Calculations

Delta	(σ Between)	(σ Within)	Single measure SD	Power (Type I error)
1.5	1.0	1.5	1.8	85% (5.2%)
1.5	1.0	2.0	2.2	83% (5.0%)
1.5	1.0	2.5	2.7	81% (5.2%)

Statistical Methods

Regarding provider satisfaction outcomes, linear mixed models were applied with scores recoded for positive polarity of responses (1-5). An autoregressive covariance structure was used. Independent variables were subject ID (random) and intervention group (fixed) for comparisons within phases, and subject ID (random) and Phase (fixed) for comparisons between phases. Time and time by intervention fixed effects were

added to study time trends and interaction; however, these results were not significant (details not reported).

For patient satisfaction outcomes, we first computed a personal mean for each physician within phases, and compared the two intervention groups by a weighted least squares analysis with weights proportional to the physician total sample size. The independent variable was intervention group (intervention vs. control)

For comparison of phases (interaction), we used the paired difference in physician mean between the phases, with weights N1N2/(N1_N2), using weighted least squares as above. The intercept represents the interaction and the slope represents the main effect of treatment. That is, we test the interaction null hypothesis: Are the differences between Phase 1 and Phase 2 the same for the intervention physicians as the control physicians?

Results

Twenty-one PCPs were enrolled across the four participating clinics (11 control group, 10 treatment group). Data were collected from 720 patients over 1,203 clinical visits.

PCP Satisfaction

PCPs were administered a 14 item satisfaction questionnaire monthly during participation in the study, with responses ranging from 1 (*strongly disagree*) to 5 (*strongly agree*), including:

Overall satisfaction

1.) “Visits by patients with chronic pain conditions are very satisfying for me”

Relation subscale

2.) “Patients who have chronic pain trust me a great deal”
3.) “Patients who have chronic pain are very personable”
4.) “I establish effective rapport with patients who have chronic pain conditions”
5.) “I am effective in influencing the behavior of patients who have chronic pain conditions”

Data subscale

6.) “For patients with chronic pain conditions, I get all the detail I need regarding patients’ history”
7.) “For patients with chronic pain conditions, I get all the detail I want on patients’ problems and symptoms”
8.) “For patients with chronic pain conditions I get enough detail regarding their psychosocial condition”

Time subscale

9.) “For patients with chronic pain conditions, I often think their visits are necessary”
10.) “Visits by patients with chronic pain are boring and unchallenging”

11.) “My time is well spent during visits by patients who have chronic pain conditions”

Demand subscale
12.) “Patients with chronic pain conditions demand a lot of personal attention”
13.) “I spend more time with patients with chronic pain conditions than I would like”
14.) “Patients with chronic pain conditions constantly complain”

Results are reported as the main score (i.e., the average across the 14 item scores) as well as the subscale scores (i.e., the average across the items for each subscale). For the data subscale score during phase 2, the estimated means for the intervention group and control group are 3.06 and 2.60, for a significant difference intervention-control of 0.46 (SE=0.19), p=0.03 two-sided. These and the remaining main score and subscale score results are displayed in Table 2 below. There were no significant differences observed between the intervention and control groups for the remaining scores. As previously described, a linear time effect and a time by intervention interaction were also tested. All 10 time slopes were not significant and all 10 interaction effects were non-significant (p>0.05).

Table 2. Differences between Intervention and Control in PCP Satisfaction with Providing Pain Care

	Phase 1 Intervention Mean	*Phase 1 Control Mean*	*Phase 1 Intervention-Control*	*Phase 2 Intervention Mean*	*Phase 2 Control Mean*	*Phase 2 Intervention-Control*
Overall Score	2.96	2.93	-0.03 (0.12) [0.77]	3.16	2.99	0.17 (0.11) [0.14]
Relation Score	3.23	3.22	0.01 (0.12) [0.96]	3.30	3.23	0.07 (0.11) [0.55]
Data Score	2.78	2.61	0.08 (0.17) [0.64]	3.06	2.60	0.46 (0.19) [0.03]
Time Score	3.42	3.52	-0.10 (0.18) [0.58]	3.57	3.34	0.23 (0.19) [0.24]
Demand Score	2.50	2.67	-0.17 (0.17) [0.34]	2.74	2.74	0.002 (0.20) [0.99]

Note: Entries are *Mean (SE) [P-Value, 2 sided]*

In regards to testing an interaction between intervention and phase, the two phases reported similar results for each phase. Further, similar treatment differences were seen in each phase.

Patient Satisfaction

Patients were administered a satisfaction questionnaire after each visit during participation in the study. The first question comprised: "*Using any number from 0 to 10, where 0 is the worst health care possible and 10 is the best health care possible, what number would you use to rate all your health care at you recent visit?*" The second question comprised: "*Your doctor did everything he/she could to help you with your pain or discomfort*" and responses ranged from 1 (*strongly disagree*) to 5 (*strongly agree*). The final question comprised: "*Based on your visit with your doctor or other health care provider, you are confident that in the future your pain or discomfort will be well controlled*" and responses ranged from 1 (*strongly disagree*) to 5 (*strongly agree*).

For the first question during phase 1, the estimated weighted means for the control group and intervention groups are 9.33 and 9.08 for a difference treatment-control of -0.25 (SE=0.19), p=0.20 two-sided. For the first question during phase 2, the estimated weighted means for the control group and intervention groups are 9.28 and 9.01 for a difference treatment-control of -0.27 (SE=0.20), p=0.20 two-sided. These, and the remaining questionnaire results, are displayed in Table 3 below.

Table 3. Within-Phase Differences between Intervention and Control in Patient Satisfaction with Visit

	Phase	*Control*	*Intervention*	*Difference*	*P-Value*
Overall visit rating	1	9.33 (0.16)	9.08 (0.10)	-0.25 (0.19)	0.20
Overall visit rating	2	9.28 (0.14)	9.01 (0.14)	-0.27 (0.20)	0.20
Your doctor did everything he/she could …	1	3.99 (0.18)	3.86 (0.12)	-0.13 (0.22)	0.58
Your doctor did everything he/she could …	2	3.93 (0.17)	3.84 (0.16)	-0.09 (0.23)	0.71
Confidence in future pain control	1	3.63 (0.19)	3.55 (0.12)	-0.08 (0.22)	0.73
Confidence in future pain control	2	3.48 (0.18)	3.53 (0.17)	0.05 (0.24)	0.83

Note: *Entries are Mean(SE)*

In regards to testing an interaction between treatment and phase, the two phases reported similar results for each phase. Further, similar treatment differences were seen in each phase.

Discussion

The goal of this study was to evaluate a novel model of chronic pain care that supports PCPs in delivering evidence-based pain care. The care model employed provider education, standardized data, and decision support delivered through an electronic

health record (EHR). Overall, we found no effect of any component of the care model on PCP or patient satisfaction with care. We are continuing to analyze secondary outcomes, including PCP referrals and other orders, to determine if the care model had any effect on these outcomes.

Chronic pain is the most commonly reported symptom resulting in a primary care medicine and primary care physicians receive little instruction on the management of pain during post-graduate training. Therefore, as the first component of our novel pain care intervention, we developed an educational program designed by and for family medicine clinicians about the etiology, diagnosis and management of common pain conditions. Our online adaptation of traditional in-person continuing medical education had exceptionally low utilization by clinicians despite the format and content being requested by the same clinicians and the incentive of without cost CME credits. Therefore, we provided in-person CME lectures in order to ensure receipt of "treatment" and test the effect of PCP education on care satisfaction. The in-person lectures were well-attended and clinicians expressed appreciation and interest in the topic. Thus, in some sense, the in-person approach was immediately successful. However, as described, the education did not result in general improvements in satisfaction with pain care (provider or patient). Moreover, delivering purely in-person education is not pragmatic and would is not sustainable in the long term and for many PCPs. Thus, further research is needed to identify usable and effective educational strategies for busy clinicians.

Primary care physicians have expressed dissatisfaction with the quantity of objective data regarding patients complaining of pain leading to insecurity in management. Therefore, we sought to reinforce and enhance the aforementioned education program with the development and implementation of a learning health system (CHOIR) in PCP's clinical practice. CHOIR provided an efficient and usable technology for collecting PROs and communicating PROs to PCPs at the point of care. The CHOIR system was successfully implemented within clinic workflows and integrated technologically with the UF Health EHR system, Epic. During this implementation and integration, we overcame several barriers to adoption and use, including time, workflow, and effort constraints. The three primary facilitators that helped overcome these barriers were (i) *process automation*, (ii) *usable system interfaces*, and (iii) ensuring that the PRO results were created and communicated for the *right patient at the right time.*

Despite implementation success, our study determined that collecting and communicating standardized PRO data provided to clinicians at the point of care affected neither PCP satisfaction nor patient satisfaction. There are numerous possible explanations for the lack of change. First, we experienced technological failures of the learning health system platform at the two clinical sites at various points during the study. While the root cause of these failures was never clearly identified, they may have related to internal network communication failures. Because of these failures, some patients were unable to report their PROs and thus their PCP did not have the opportunity to review their outcomes data at each visit. Essentially, this meant that the study treatment was inconsistently received by the provider and patient participants.

Second, we speculate, based on anecdotal feedback, that PCPs may have inconsistently reviewed the PRO data even when it was available in the EHR. Similar to the technological failures, this would have led to inconsistent receipt of treatment and thus dampened potential treatment effects.

The study had a number of strengths and weaknesses. The pragmatic nature of the study was both a strength and a weakness. On one hand, the pragmatic design likely increases the generalizability of our findings to similar high-volume primary care practices in which pain care is delivered to many patients in the every day. Also, while the intervention was designed in an academic institution, it could be implemented in other academic or non-academic affiliated practices, most of which now use EHR systems. On the other hand, pragmatic studies can create a lack of tight control over the precise selection of enrolled patients. Furthermore, as with most pragmatic trials, the consistency in which the intervention was applied was unclear. Another strength of the study was the fact that the intervention's features were consistent with the recently drafted National Pain Strategy that was developed by the National Institutes of Health (NIH) [23]. Still, another weakness of the study includes the fact that its generalizability could be limited because the intervention was implemented in a single health system's clinics in one U.S. city.

National leaders in pain care have emphatically called for progress in the use of standardized electronic data on pain assessment and treatment as well as health systems that maintain pain data registries of the biopsychosocial impact of chronic pain and effectiveness of interventions [1, 23]. At the individual level, PCPs and patients have been shown to be less satisfied with clinical encounters when they involve pain management. Thus, we sought to improve satisfaction with pain-related clinical visits through enhancements in clinicians' knowledge bases and their access to pain-relevant electronic outcomes data at the point of care. However, the intervention, as implemented, did not affect patient or PCP satisfaction. On the positive side, in the modern health care environment, PCPs are often concerned about any interventions that could negatively impact their clinical workflows given pressures for efficiency in caring for many patients. And, we found no evidence, via satisfaction surveys or complementary qualitative assessments, that integrating in-clinic PRO collecting and PRO integration in EHRs negatively impacted workflows. Therefore, our study demonstrated the feasibility of PRO-enabled pain care. Future studies and technological innovations are needed to most effective translate such care models to consistent improvements in patient and provider experiences as well as improvements in patient outcomes.

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List of Publications and Products Resulting from the Project

1. Harle, CA, Lipori G, Hurley RW. Collecting, Integrating, and Disseminating Patient-Reported Outcomes for Research in a Learning Healthcare System. *eGEMs (Generating Evidence & Methods to improve patient outcomes).* 2016 (In Press).

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