

A Tale of Two Systems:
Standardizing Primary Care Pain Management
during the Joining of Two Physician Practice Groups

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Abstract

The physicians group of JPS Health Network and UNT Health Science Center in Tarrant County, Texas are merging under an agreed joint governance plan. The joining will bring together providers from an academic medical center and the county hospital system under a non-profit umbrella to more efficiently and effectively serve patients and educate future generations of providers. Currently, there is no standardized way chronic pain is managed across clinics from the two systems, and at the primary care level, the lack of a coordinated approach creates a serious gap for patients, especially the large number of indigent or Medicaid/Medicare patients seen by both systems. The overall goal of this project is to standardize and improve upon the way chronic pain is managed in primary care as two health systems, with different ways of treating chronic pain, merge into a single entity. Low back pain, as a significant contributor of chronic pain, will be studied. Primary and secondary measures, including an innovative use of biometric data captured by personal fitness trackers, will demonstrate the effectiveness of a common care pathway, facilitating its adoption and adaptation by other systems. This project is sustainable and scalable, with the necessary commitment from each participating organization to facilitate success.

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Overall Goal and Objectives

Goal:

The overall goal of this project is to explore ways to standardize and improve upon the way chronic pain is managed in primary care as two health systems, with different ways of treating low back pain, merge into a single entity. The secondary goal is to identify characteristics of chronic pain patients that make them less likely to succeed with standard interventions and seek inappropriate or increased pain medication outside of the integrated system of care.

Overall Objectives:

1. Standardize low back pain management to study its impact on improved quality of care in primary care settings across two clinical systems that are merging into a single system
2. Reduce the cost of chronic low back pain management to the system and patients
3. Equip primary care providers with the resources necessary to adequately manage chronic low back pain in the new system clinics according to evidence-based guidelines
4. Identify characteristics of chronic pain patients that make them less likely to succeed with standard interventions

Technical Approach

It was the best of times, it was the worst of times, it was an era of epic change in healthcare, it was an era where old discussions were revisited – in short, the period was to see cooperation never before experienced and that some of the nosiest authorities insisted would never occur.

Last summer, the physicians' groups of JPS Health Network and UNT Health Science Center agreed to a joint governance plan. An essential merger, the joining will bring together providers from an academic medical center with a strong family medicine focus and the publicly-funded county health network with a large family medicine residency. Under a non-profit umbrella, it will more efficiently and effectively serve patients and educate future generations of providers. As these two **very** different systems forge a single entity, a rare opportunity exists to improve the quality of care related to chronic pain management so evidence-based and guideline-based care is applied consistently across the primary care clinics of the new system. The new system is called Acclaim.

Opportunities Abound

This project leverages the merger of the two systems to prioritize chronic pain within the newly-formed system. After full implementation, all Acclaim primary care clinics will use the same mechanism to diagnose, manage and treat low back pain. Following this study, the opportunity exists for data systems across the new organization to facilitate care pathways for most chronic pain to be managed in the primary care setting, only referring to specialists when necessary. This opportunity only exists because of the approved joint governance agreement,

and with commitment from both systems and the head of the newly formed system, the merger will insure the goals of the project are satisfied.

This project has the commitment from UNTHSC and JPS, in addition to that of Acclaim to meet the proposed goals. Everything is in place to succeed. A commitment to continuous assessment and improvement will be fulfilled through use of the **PLAN-DO-STUDY-ACT** (PDSA) process throughout the project.

This project directly relates to UNTHSC's Core Values of collaboration, integrity and respect, ensuring patients receive the best care, regardless of socioeconomic status regardless of where care is received.

Assessment of Need

As stated above, each system currently handles chronic pain management in very different ways.

JPS Health Network (JPS)

JPS Health Network (the District) is the publicly-funded county health network. The system consists of approximately 95 physicians and 45 midlevel providers. The service area is all of Tarrant County (897 square miles, 1.94 million residents). Providers work almost exclusively in JPS Health Network facilities (the region's public/safety net hospital system) treating JPS patients. Approximately 26.6% of JPS Physician Group patients are Medicaid and 51.5% are indigent/uninsured.

In the past eight months, the care of chronic pain at the county hospital system has undergone a tremendous transformation. The absence of clear diagnostic and therapeutic algorithms combined with use of a primarily pharmacological approach with a significant predisposition to the use of high dose opiates led to multiple issues including the placement of pharmacy department in the Drug Enforcement Administration's (DEA) watch list. The inadequate access to specialty care led to a more than one-year long waiting list for pain evaluation. Additionally, the approach of placing multiple screeners who focused on opiates resulted in PCPs finding it very difficult to refer patients. This led to escalation of opiate doses under pressure from the patients in an overall system that tends to seek patient satisfaction and is averse to patient complaints.

Some of the cautions in analgesic opioid prescription are mental illness and addictive disorders. This system is a safety net hospital that serves patients from lower socioeconomic status, with higher prevalence of mental illness and substance use disorders than found in other populations¹. In the absence of a multidisciplinary approach, these patients tend to be prescribed opioids, especially at high doses²⁻¹⁰. This appears to have happened within the JPS and UNTHSC systems.

About eight months ago, the system hired a new pain management specialist who turned how chronic pain is managed on its ear. This physician’s leadership resulted in the chronic pain clinic implementing guidelines, interviewing and properly assessing patients, reviewing prescriptions and dosing, and providing avenues for better pain management for patients. Lower levels of narcotic utilization have also been realized. In fact pharmacy spending on narcotics has dropped almost 50% at JPS, while spending on all other drug classes has increased by approximately 80%. This corresponds with an overall reduction in other patient red flags, including lost prescriptions and inconsistencies in urine drug tests. Chronic pain is largely managed by the specialty clinic with less complex cases addressed at the primary care level with no specific guideline endorsed by the system.

Between 6/1/2014 and 5/31/2015, JPS saw 12,936 patients with chronic back pain across all of its clinics.

JPS Health Network’s patient satisfaction scores related to pain control are at 67%, significantly lower than the Texas average of 73%. Only 62% of patients felt staff always explained about medications. It should be noted that these scores were aggregated prior to the redesign of the chronic pain clinic.

UNT Health Science Center (UNTHSC)

UNTHSC does not have a coordinated approach for the management of patients with chronic pain conditions, except for those UNT Health patients seen in JPS clinics who likely have access to the programs described above. The UNT Health practice generally relies on a traditional, specialty-based care delivery model with patients receiving care in a primary care (largely family medicine) office or by surgical specialists such as orthopedic spine surgeons. Patients requiring sophisticated approaches are likely referred out to community pain medicine specialists (assuming they are financially able and can find a clinician). UNTHSC does not currently offer a multidisciplinary, multimodal approach for patients with chronic pain.

UNT Health Science Center Physician group in Fort Worth, TX has more than 260 physician and non-physician providers in nearly 50 clinical practice sites across Tarrant County as well as most area hospitals, and will have over a half million patient encounters this year.

According to UNTHSC’s electronic health record and billing data, in the past 24 months, UNTHSC providers have provided chronic pain care to 29,342 patients during 57,543 encounters.

	Unique Patients	Total Encounters	Total Charges
6/1/13 – 5/31/15	29,342	57,543	\$8.57 million

Patient satisfaction scores related to pain management in primary care at UNTHSC currently do not exist. These will be collected at the beginning of the project with a custom-designed survey.

At the primary care level in both systems, patients with chronic pain receive suboptimal management. Care is not consistent across clinics and providers. JPS' chronic pain clinic currently provides a bridge for some of its patients, but even at the current levels, it is exceeding its capacity. While the initial results of the pain clinic's restructuring are positive, it is unsustainable as a long-term solution for the day-to-day management of all JPS patients with chronic pain. Adding UNTHSC's almost 30,000 chronic pain patients creates an urgency to develop a long-term, sustainable strategy for primary care. As the two systems converge into Acclaim, a consistent and sustainable primary care management strategy for chronic pain is needed.

Target Audience

The audience for this project are the primary care providers and staff of the primary care clinics where Acclaim-affiliated physicians practice.

Project Design and Methods

This project is designed to improve the patient experience by providing patient-centric care, improve patient quality of life, promote health professional education and reduce the overall costs of chronic pain care within the new system. The establishment of Acclaim is currently underway and it is expected to be fully operational by early 2016. However, both organizations have agreed to begin this project before the joint governance is finalized to satisfy the project timeline.

This project will be structured as an IRB-approved study. It is a prospective controlled study comparing outcomes of patients with chronic pain. For the purposes of the study, we will focus on low back pain with or without radicular pain or other neurological symptoms.

Hypothesis: The use of a structured protocol to manage a pain condition leads to better patient outcomes, patient engagement and reduced healthcare utilization.

Low back pain was selected for this study as it is a common cause of chronic pain and is associated with significant morbidity and healthcare utilization¹¹. The long-term hypothesis is that application of evidence based protocols in a variety of chronic pain conditions (and perhaps other conditions) will lead to improved outcomes. To the best of our knowledge, this is the first study that examines the impact of a pain treatment algorithm and uses active biometric data obtained from fitness trackers to monitor outcomes in a pain condition.

Subjects: Patients presenting with low back pain at any of four primary health or family health centers (PHC). The patients in two of the PHCs are managed with a protocol of generally accepted treatment guidelines or protocols that are integrated into the EMR. Patients in the control group are managed without change to existing clinical protocols or procedures and without a set of clearly defined treatment guidelines. In the control, primary care providers and patients decide on the care based on the providers' usual practice. We anticipate between 150-200 patients in each group.

Inclusion criteria:

1. Adults >18 YO
2. Male and female
3. Low back pain

Exclusion criteria:

1. <18 YO
2. Inability to consent
3. Fracture
4. Recent (< 1 month trauma) induced back pain
5. Malignancy related back pain
6. Current illicit substance use including marijuana
7. Major mental illness like schizophrenia, uncontrolled severe depression and bipolar affective disorder
8. Cognitive disability that impacts the patients' ability to give independent consent
9. Unwilling to participate in the treatment protocol if they present to the location where this is being implemented. In that case, the provider will refer the patient to another non-participating location or to a specialist. (Sports medicine, orthopedics or pain management)
10. Red flags of back pain (cauda equina syndrome, significant weight loss, night sweats, other indicators of malignancy, significant myelopathic symptoms characterized by new onset extremity weakness)
11. Spinal infection

Clinic Site Locations: One UNTHSC and one JPS primary care clinic will be in each of the two groups of the study. The primary care clinics that have the highest documented cases of chronic low back pain will be selected for the study. Following the initial clinical study and analysis, the pathway will be integrated within the clinical operations of every primary care clinic in the system.

Management Algorithm/Protocol: The Chronic Pain Committee will be formed with a task of establishing a management algorithm/protocol for the treatment of low back pain. The care pathway will take into consideration the six domains of chronic pain management: pharmacologic, physical medicine, behavioral medicine, neuromodulation, interventional, and surgical approaches. The pathway will be programmed into the study clinics' electronic health record and providers and staff at both study clinics will receive training using the new algorithm and on chronic pain management, in general. The PDSA process will be used to refine the algorithm, as necessary. The general chronic pain educational modules will be adapted as web-

based enduring materials and hosted on UNTHSC's online learning management system for a wider audience of providers.

Sustainability

Sustainability of a project is often difficult to assess. Sarriott, *et al.*, suggest six stages to plan for sustainable development¹²:

1. Define the system to be assessed, its vision and its goals
2. Identify the relevant elements/general objectives for the local system
3. Choose indicators and performance criteria (or indicator status definitions) measuring progress on the determined elements
4. Measure and map the status on the indicators combining the appropriate evaluation tools
5. Combine the indicators and build indices as needed
6. Review results and propose programmatic intervention (including specific project objectives) or policies.

This project has incorporated these stages in its design and implementation. Once tested and deployed in all clinics staffed by Acclaim physicians, the care pathway will be a standard of care for management of low back pain. Furthermore, using data collected and lessons learned from this study, algorithms based on a multidisciplinary evaluation and management principles can be created and implemented in other disease states like chronic abdominal pain, pelvic pain, neck pain, headache disorders and others with a similar effect. The implications are far reaching for improving the care of chronic pain at the primary care level.

There are components of this project that support sustainability, as defined by the Community Benefit Sustainability Framework¹³:

1. This project has an organizational home
2. Once the funding period expires, Acclaim will continue to use what was developed during the program period, dedicating resources to ensure the care pathway is universally applied to its primary care clinics
3. Additionally, the design of this project ensures that the final pathway will be scaled-up to achieve impact

Designing it as an IRB-approved study permits the data to be published and disseminated widely in peer-reviewed journals and professional meeting presentations and posters.

Research Commitment

UNTHSC commits to:

- Obtaining institutional review board (IRB)/independent ethics committee (IEC) approval for studies involving human subjects or human tissue and obtaining a subsequent renewal of this approval as required by local regulations (e.g., yearly, biannually, etc.). In

addition, obtaining any IRB/IEC approval for amendments to protocol as they pertain to the research

- Obtaining all required personal data privacy or informed consent documentation (as appropriate)
- Obtaining all required regulatory approval(s) per local regulations
- Assuming all reporting obligations to local regulatory authorities
- A statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation, Good Clinical Practice, or Good Pharmacoeconomics Practice guidelines and all applicable local legal and regulatory Requirements

Innovation

This project incorporates multiple innovative elements to achieve its goals and outcomes measures. Primarily, the joint governance of two physicians groups into a single entity provides the opportunity to innovate with care pathways, standards and protocols, as proposed in this project. Linking the project to patient safety and interprofessional practice and the new patient safety institute (please see Work Plan section) is also innovative. Additionally, we are proposing using common, off-the-shelf personal fitness monitors to collect patient biometric data and use said data as secondary measures of the effectiveness of the pain interventions. We are currently in discussions with Microsoft regarding the availability of its recent Microsoft Band monitor, which will capture the biometric data listed in the secondary outcomes below via a research API. However, other trackers may be used. Budgetary limitations permit only a subset of patients at the study clinics and control clinics are provided activity trackers. These and other data will help determine characteristics of patients who may require additional interventions for effective pain management.

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Evaluation Design

This project will make use of both formative and summative assessments. Multiple sets of data will be used to assess the effectiveness of this initiative at meeting the goals and objectives. Outcomes will be framed and reported using the seven-level scale recommended by Moore, Green and Gallis. (JCEHP 2009). This scale divides outcomes into lower level outcomes (1-Participation, 2-Satisfaction and 3-Knowledge, 4-competence) and higher level outcomes (5-performance, 6-patient health, and 7-community health). Outcomes reporting for this project will focus on levels 5-7:

Outcomes Level	What will be assessed	Type & Sources of Data
5. Performance	Assessment of provider and staff performance in appropriately applying the care pathway	Objective: EMR Data (Registry-specific)
6. Patient Health	Satisfaction Quality Measures Quality of Life Overall Health Status	Objective: Patient Satisfaction Surveys Biometric Data EMR Data
7. Community/ Population Health	Care for chronic pain provided consistently across the new system	Objective: EMR Data (Panel-specific) Implementation of care pathway system-wide

The primary outcomes measures that will be determined are listed below:

<i>Primary Outcomes Measures</i>		
Measure	Anticipated Improvement	Sources of Data
Pain	2 Point improvement in patients in study clinics vs. patients in control clinics	Measured by 0-10 Numeric Rating Scale (NRS), Tracked on EMR
Disability	20% improvement in patients in study clinics vs. patients in control clinics	Measured by Pain Disability Index (PDI), Tracked on EMR
Satisfaction	10% improvement of patient satisfaction in patients in study clinics vs. patients in control clinics	Measured by patient satisfaction questionnaire developed for this study

In addition to the primary measures, secondary outcomes measures will also be analyzed.

Secondary Outcomes Measures		
Measure	Anticipated Improvement	Sources of Data
Quality of Life		
Employment status	Employment status of patients in study clinics will be improved over those in control clinics	Demographic data on EMR
Change in Sleep	Patients in study clinics will achieve more restful sleep than patients in control clinics	Biometric data collected by personal fitness tracker
Change in baseline heart rate	Patients in study clinics will achieve more consistent target heart rate than patients in control clinics	Biometric data collected by personal fitness tracker
Change in daily physical activity level	Patients in study clinics will achieve increased physical activity level over patients in control clinics	Biometric data collected by personal fitness tracker
Change in calories burned per day	Patients in study clinics will burn more daily calories than patients in control clinics	Biometric data collected by personal fitness tracker
Change in Blood Pressure	Patients in study clinics will achieve improved blood pressure over patients at control clinics	EMR Data
Healthcare Utilization		
Office Visits	Number of back pain related, non-back pain related and other office visits for patients in study clinics will decrease over patients in control clinics	EMR Data
Telephone Calls	Number of back pain related, non-back pain related and other telephone calls from patients to clinics will decrease in study clinics vs. patients in control clinics	Call Records/EMR Data
Imaging Studies	More appropriate imaging will be conducted by study clinics than control clinics, specifically: <ul style="list-style-type: none"> - Time from the first episode presentation to the ordering of imaging in both groups. - Spine: Lumbar imaging (X-ray, CT, MR), non-lumbar spine imaging (X-ray, CT, MR), all other body part imaging. 	EMR Data
Urgent Care/ED Visits	Patients receiving care in the study clinics will visit urgent care/emergency departments fewer than patients in the	EMR Data

	control clinics for back pain related, non-back pain related and other	
Hospitalizations	Hospitalizations related to Back Pain, non-back pain related and other will be reduced in patients receiving care in study clinics vs. control clinics.	EMR Data
Use of Prescription Analgesics	The use of opioid and non-opioid analgesics in patients receiving care at study clinics will be reduced and more appropriate vs. patients in control clinics.	EMR & Pharmacy Data
Cost of Care	The cost of care are for chronic pain patients in the study clinics will be, on average, less than that in the control clinics.	EMR and Billing Data

Opioid analgesics: All formulations of the following basic molecules
Morphine, Hydrocodone, Oxycodone, Fentanyl, Hydromorphone, Oxymorphone, Tylenol with codeine, Tramadol (those in bold being schedule-II will be tracked separately).
Non-opioids
Antidepressant class: amitriptyline, nortriptyline, imipramine, maprotiline, desipramine, trazodone, duloxetine, venlafaxine, desvenlafaxine Antiepileptic class: gabapentin, pregabalin, carbamazepine, levetiracetam, valproic acid, sodium valproate Non-steroidal anti-inflammatory: ibuprofen, naproxen, indomethacin, celecoxib, meloxicam, ketoprofen.

The formative assessment and PDSA models will also be reported as outcome measures to assist other systems who wish to implement similar transformations.

Dissemination Plans

The results from this project will be summarized in at least one manuscript and presented to at least one peer reviewed medical journal for publication, as well as submitted to medical and CPD conferences for dissemination. We believe this project will serve as a model for integrated care and its learnings will be disseminated throughout Acclaim in other clinical areas for adaptation and adoption in other systems.

Work Plan

This project is scheduled to begin on October 1, 2015 and end in April 2017, 18 months in duration. The design will ensure the systems and participants are actively engaged in the development of the primary care chronic pain management plan under the Acclaim system. Since the appropriate management of chronic pain is a patient safety

issue, resources developed for the institute will be leveraged to complement this project. Such resources could include administrative assistance, technical assistance, best practice dissemination and others. **This appropriation is a recent development that occurred between the time the LOI was submitted and the submission of the full proposal.** We believe this strengthens the project and raises the awareness and profile of the efforts to improve the way chronic pain is managed in primary care.

Upon notification of the award, the chronic pain committee will be formally established, consisting of the Co-PIs, EHR and data experts, Acclaim Primary Care Physicians, leadership from UNTHSC, JPS and Acclaim, QI personnel and the project managers from UNTHSC. We will also seek to involve patients in the committee, although it is currently unknown if they will be current or former chronic pain patients. Any patient-centric process requires patient input. During the first month, the Institutional Review Board (IRB) application will be prepared and submitted to UNTHSC and JPS.

The chronic pain committee will convene at least monthly to discuss the project, review data collected for the project relevant to its goal and evaluation design, and recommend modifications to the plan as necessary. One of the priorities of the committee is to conduct formative assessments during the project using the **PLAN-DO-STUDY-ACT (PDSA)** model. This formative assessment will serve as the continuous quality improvement activity for this project, ensuring goals and milestones are achieved and the project stays on task, while providing the opportunity modify the overall plan in small ways as necessary.

The chronic pain committee is vital to the success of this project since it is where the plan will be developed, assessed, analyzed and adjusted. In addition, the committee will use its insight into the data, processes and feedback from providers to recommend topics for which educational interventions are identified or developed for the project. Should educational modules be developed that are applicable to a broader audience, they will be made available via UNTHSC's online Learning Management System.

Project staff will participate in required project meetings and calls, as outlined in the RFP document.

Schedule of Deliverables

Below is the planned schedule of deliverables.

Month	Deliverables		
Oct 2015	Chronic Pain Committee formed IRB application submitted Patient Satisfaction Survey Developed for Project Project Launch Meeting	Baseline Data Collected for June-December 2015	
Nov 2015	Chronic Pain Committee meeting IRB application approved by both entities Care Pathway Design Begins PDSA Review Collaborative Check-In		
Dec 2015	Chronic Pain Committee meeting Collaborative Check-In PDSA Review Training at Treatment sites on New Care Pathway (No training at Controls)		
Jan 2016	Chronic Pain Committee meeting Collaborative Check-In Roll out new chronic pain pathway at Treatment sites	Test of Care Pathway vs No Modified Interventions	12 month test of care pathway vs. control clinics
Feb 2016	Data Refresh And Review Biometric Data Assessment PDSA Review Chronic Pain Committee meeting Launch of appropriate chronic pain management education to non-study audience (est. 2-3 online modules) Collaborative Check-In		
Mar 2016	Data Refresh And Review Biometric Data Assessment PDSA Review Chronic Pain Committee meeting Collaborative Check-In		
Apr 2016	Data Refresh And Review Biometric Data Assessment PDSA Review Chronic Pain Committee meeting Collaborative Check-In		
May 2016	Data Refresh And Review Biometric Data Assessment PDSA Review Chronic Pain Committee meeting Collaborative Check-In		

Jun 2016	Data Refresh And Review Biometric Data Assessment PDSA Review Chronic Pain Committee meeting Collaborative Check-In			
Jul 2016	Data Refresh And Review Chronic Pain Committee meeting PDSA Review Review data from six month test Collaborative Check-In			
Aug 2016	Data Refresh And Review Chronic Pain Committee meeting PDSA Review Revise pathway as necessary Collaborative Check-In			
Sep 2016	Implement care pathway system-wide (Acclaim) Chronic Pain Committee meeting PDSA Review Collaborative Check-In			
Oct 2016	Data Refresh And Review Chronic Pain Committee meeting PDSA Review Collaborative Check-In			
Nov 2016	Data Refresh And Review Chronic Pain Committee meeting PDSA Review Collaborative Check-In			
Dec 2016	Data Refresh And Review Chronic Pain Committee meeting PDSA Review Collaborative Check-In	Outcomes Analysis		
Jan 2017	Data Refresh And Review Chronic Pain Committee meeting PDSA Review Begin drafting publication Collaborative Check-In		Roll out to all clinics	Continuous Assessment
Feb 2017	Data Refresh And Review Chronic Pain Committee meeting Collaborative Check-In			
Mar 2017	Data Refresh And Review Chronic Pain Committee meeting Collaborative Check-In			
Apr 2017	Convocation & Reconciliation			