# Using the Electronic Medical Record to Ensure Compliance with Opioid Prescription Laws in Texas

by

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DISSERTATION

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ABSTRACT

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***Background:*** The American population currently finds itself in the midst of a prescription drug overdose epidemic. This crisis has been fueled by an overreliance on opioid medications for the treatment of chronic pain. The state of Texas medical board (TMB) enacted a law change that restricts and regulates the prescribing and dispensing of controlled substances with respect to patients experiencing chronic pain.

***Local Problem:*** At the onset of this project, the University of Texas Southwestern (UTSW) system had no comprehensive measures in place to ensure compliance with these rules, and the current state of compliance was unknown.

***Methods:*** Three clinics were chosen for observation to help understand the process of opioid prescribing for chronic pain treatment and the steps necessary to comply with the new law. Multiple Plan, Do, Study, Act (PDSA) cycles were applied to the process of baseline data measurement culminating in a final estimate of $3.1\% \pm 0.4\%$ of applicable patient records written by UTSW providers in compliance with the law.

***Interventions:*** Tools in the electronic medical record system (EMR) for tracking the use of scheduled medications in the treatment of chronic pain as well as for ensuring compliance with the new law have been developed and are in the process of implementation at the clinics with the largest populations of opioid-prescribed chronic pain patients.

**Results**: A chronic opioid registry was created, containing about 200 patients. Data retrieval is in process to determine the current rate of compliance.

**Conclusion**: This project has successfully created a registry of the patients at UTSW on chronic opioid therapy and built an EMR structure that will ensure that these patients are cared for in a fashion compliant with TMB laws.

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# CHAPTER 1

## Introduction

### *Problem Description:*

Prescription opioid abuse and overdose represents a major healthcare problem. The American prescription and consumption of opioids dwarfs that of other countries, with America prescribing approximately 60% more per capita than the next leading country.[1] Overdose deaths caused by opioids in the year 2014 numbered over 28,000, of which more than half were due to prescription drugs rather than the illicit use of opioids, and the past two decades Centers for Disease Control (CDC) data has shown an exponential increase in overdose deaths from opioids, correlating closely with increasing prescription rates.[2] After an extended period of growth, this overdose epidemic has captured public attention resulting in extensive media coverage and a prominent place in discussions of public health. This attention has resulted in a variety of governmental actions taking place on local, state, and federal levels as officials hope to curtail its deadly effects; however, the consequences for physicians remain to be seen as many new and untested legislative proposals begin to take effect.

Of the many opioid related regulations that have recently been enacted, the one that this project has focused on is a change in rules regarding the treatment of chronic pain by the TMB. On August 5th, 2015 the TMB changed the language in rule 170.3, replacing the word "should" with "must" in multiple locations, with the effect of transforming what was previously a series of recommendations into a mandated set of standard practices.[3] The content focuses on appropriately documenting multiple aspects of pain management,

including mandating the use of the Texas Physician Drug Monitoring Program (PDMP), a written pain management agreement signed by the patient, and toxicology drug screening for patients receiving scheduled drugs for the treatment of pain. The effect of these mandated regulations on opioid use and abuse is still to be determined. The more immediate concern, however, is ensuring our familiarity and compliance with the relatively new mandates. More recently, the Texas House of Representatives passed House Bill (HB) 2561, which included an amendment requiring all physicians to check the PDMP every time they prescribe any of four drug classes including opioids, a law which wil officially come into effect on September 1st, 2019.[4]

At the outset of this project, UT Southwestern had no system or infrastructure in place to ensure compliance with these rules, and the actual rate of adherence was unknown. The use of opiate medications for the treatment of pain is present throughout many different aspects of the healthcare system, and frequency ranges from rare to common based on the clinic and the setting of patient care. Prior to this project, no official distinction existed in the system to differentiate chronic opioid users from those who were prescribed opioids for acute pain or a short course. Changes in practice regarding the new rules have been implemented in some locations, but exist sporadically with varying rates of adherence. This lack of compliance represents both a legal hazard, with consequences as severe as loss of licensure, and a patient safety concern, as the best practices are necessary to protect patients from the risks of prescription drug abuse and overdose.

***Available Knowledge:***

*History*[56]*:*

Opiates have been present throughout most of the history of human civilization and were first derived as opium, a resin extracted from the sap of the poppy plant, in ancient Mesopotamia. Opium subsequently spread throughout Greek, Roman, and Arabic cultures, and was recognized for the analgesic and euphoric effects it produced. Over many centuries its spread continued into Europe and East Asia as it was prescribed for a variety of medicinal purposes and also became a drug of recreational use in so-called "opium dens" where the resin was smoked for its intoxicating effects. Its use consequentially generated two wars in the nineteenth century between China and the British empire as China sought to restrict the profitable importation of opium into the country by the British East India Company.

Isolation of a single opiate compound was first achieved by German chemist Friedrich Wilhelm Adam Sertürner in 1806 when he extracted morphine from opium, the first of many opiate derivatives and synthetic opioids that would subsequently be developed. Diacetylmorphine, a more potent opiate more commonly known as heroin, was developed and distributed by Bayer pharmaceutical company starting in 1898 as a cough supressant. Its addictive potential, however, became alarmingly clear to medical professionals over the next few decades, resulting in a restriction requiring physician and pharmacist oversight of any opiate prescriptions along with a total ban on heroin in the United States by 1924. Synthetic opioids including oxycodone, methadone, and fentanyl were all developed in the mid-twentieth century in a search for opiate alternatives that would retain analgesic effects while avoiding the addictive qualities and potential for abuse seen in morphine and heroin. Opioid abuse emerged as a significant problem in the US during the 1960s and 70's as

soldiers in Vietnam found the drug easily obtainable abroad and brought their addictions home while counterculture movements simultaneously were embracing recreational drug use and facilitating its spread.

Physicians in this period were well aware of the dangers of opioids during this period, and attitudes did not begin to change until the 1990s, when evidence was collected that showed an under-treatment of pain in America's hospitals and emergency rooms. In response, the American Pain Society aggressively campaigned for the concept of pain as a "fifth vital sign," and pushed for the goal of achieving complete pain relief for all patients with the liberal use of opioid medications. This movement was supported by The Joint Commission in 2001, as it incorporated the "fifth vital sign" concept into its Pain Management Standards. Opioid prescription and use in America grew at a rapid rate in the early 2000's, followed by the opioid overdose epidemic detailed above.

*Pharmacology*[7]*:*

Opioid medications target and bind to the mu-opioid receptor which exists both in the central nervous system and throughout peripheral tissues. Mu-opioid receptor activation causes a wide variety of effects including analgesia, sedation, euphoria, respiratory depression, anorexia, and urinary retention. These receptors are activated by many endogenous compounds including enkephalins, endorphins, dynorphins, and nociceptins. Opioid medications are classified into four broad categories; phenanthranes include most common opioids such as morphine and hydrocodone, benzomorphans consist only of pentazocine which acts as an agonist/antagonist, phenylpiperidines include compounds with a

high affinity for the mu receptor such as fentanyl, and diphenylheptanes include propoxyphene and methadone. Tramadol, however, is classified on its own as an atypical opioid as it also has GABA, catecholamine, and serotonergic activities.

*Medical Practice:*

There are many published guidelines currently in existence that recommend how to safely prescribe opioids and treat chronic pain, and a few papers have attempted to summarize these to establish consensus on the best practices. The new TMB rules are largely congruent with these findings, as the CDC outlines twelve rules, which include established goals at the beginning of therapy, a discussion of risks and benefits, periodic re-evaluation every three months, monitoring with the use of the state prescription drug monitoring program data, and urine drug screening, all of which are covered in TMB new rules.[8] Another such synthesis in the journal *Annals of Internal Medicine* supports the notion that drug screening should be included as a part of opioid therapy.[9]

Despite the extensive use of opioids in chronic pain, evidence supporting its efficacy is lacking. A comprehensive review of randomized controlled trials (RCT) focused on opioid alternatives for chronic pain in the journal *Anesthesia and Analgesia* shows that effective treatment of chronic pain is highly dependent on the etiologic condition, and ultimately concludes that high quality evidence in the form of RCT's is lacking in comparison to other fields of medicine.[10] The most high profile RCT published recently in the area of opioid treatment for chronic pain was the SPACE randomized clinical trial, which showed no significant difference in pain severity and pain-related function between opioid therapy and

therapy with acetaminophen or NSAIDs for chronic back pain, hip pain, and knee osteoarthritis.[11] Given the current lack of strong evidence for chronic pain therapies, most providers will have to proceed on a trial and error basis, and opioids will likely continue to be one of the therapies included, especially considering the large number of patients already maintained on opioid therapy. A prudent course of action for these providers would be to vigilantly monitor for the risks involved with opioid therapy including tolerance, addiction, and opioid-induced hyperalgesia.

*Quality Improvement Initiatives:*

To the best of the authors knowledge, no other reports have been published on quality improvement projects explicitly designed to improve to the safety of chronic opioid prescription, however there are multiple existing projects which approach institutional policies on opioid prescription in general and in the inpatient setting. An abstract by Ackerman et al describes changing order sets in the hospital EMR to decrease the use of parenteral opioids, and another abstract by Kumar describes using a modified Delphi method to select care bundles of best practices which successfully reduced opioid related harm.[1213] Another project describes using provider and patient education along with EMR tools to successfully lower average opioid doses prescribed across all patient encounters.[14] In sum these initiatives suggest that practices around opioid prescription can be successfully change with provider targeted interventions and EMR changes.

***Rationale:*** This project aims to have achievable results by aligning its goals with those mandated by current law, thus creating an institutional imperative, as well as by keeping a focused scope that begins with a small number of clinics before expanding to the system as a whole. Noncompliance with state guidelines could result in consequences as severe as loss of licensure, so there is a powerful motivation for addressing the problem in a timely manner.

***Specific Aims:*** To improve the treatment of patients with chronic pain in accordance with the new TMB guidelines by first measuring compliance with the TMB laws and then achieving complete compliance at UT Southwestern and its associated clinics by the end of 2019.

## CHAPTER 2
## Methods

***Context:***

*Health System:*

UTSW is a large academic medical center that operates two inpatient hospital facilities, Zale Lipshy (ZL) and Clements University Hospital (CUH) and a large number of outpatient clinics throughout the Dallas-Fort Worth (DFW) metropolitan area. It serves a combination of mostly privately insured patients along with Medicare and Medicaid patients and is a tertiary referral center for complicated medical cases.

*Processes:*

The first step in addressing the problem was to gain a complete understanding of the requirements of the law. A detailed reading of the law's text yielded the following eight elements as items that are all required to be completed and documented in the EMR.

1. History and physical exam
2. Use of the state prescription drug monitoring program
3. Baseline drug screening
4. Discussion of risks and benefits
5. Treatment plan that outlines goals of care
6. Written pain management agreement
7. List of patient medications
8. Periodic Review

Gathering information on the process of chronic pain treatment started with visits to three

different clinics in order to observe real interactions of physicians with patients and create a process map of how patients with chronic pain are seen by each of the providers. The process maps were created with a focus on when and by whom the elements critical to compliance were performed, and the differences between each clinic. The four process maps created are shown below, one for each of the three clinics, and one that demonstrates the treatment options used for chronic pain. The processes were generally similar, but there were some key differences around how each clinic handled the new rule changes. Regarding the state prescription database, the palliative care clinic had a systematic approach which delegated the task of printing out the report to the nurse and attaching it to the patient chart before the visit, while at the other two clinics doctors simply checked it whenever they remembered, either before, after, or during the visit. The palliative care clinic did not, however, have any system in place for pain contracts or drug screening, both of which were already in use at the other two clinics. The multispecialty clinic perhaps stands out at the most different of the three, as opioids are used far less commonly in its practice, so the physicians felt the new regulations were less relevant to their day-to-day work. The multispecialty clinic map is colored to indicate where elements of the law may or may not be followed.

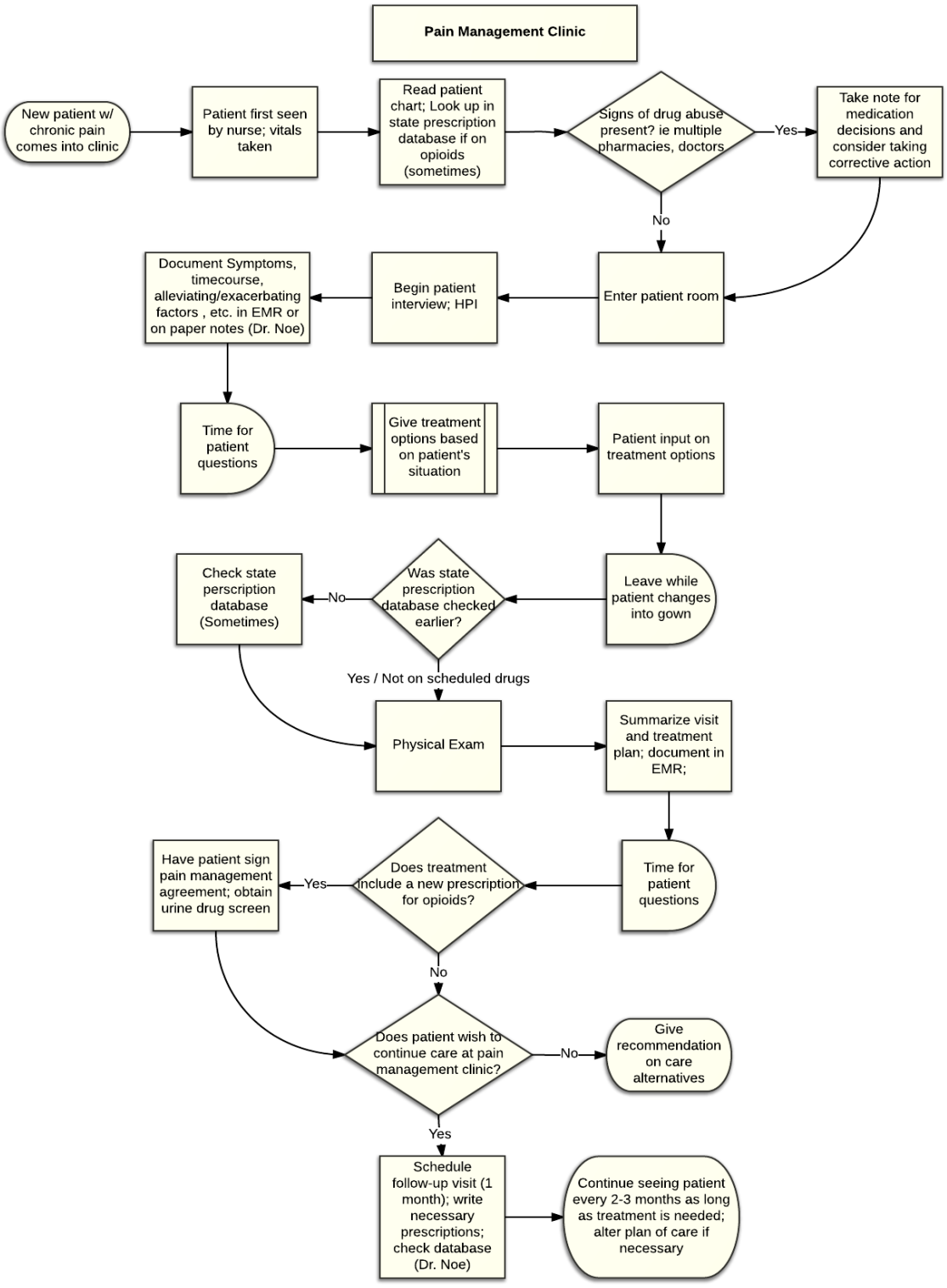



Figure 1: Pain Management Clinic Flowchart

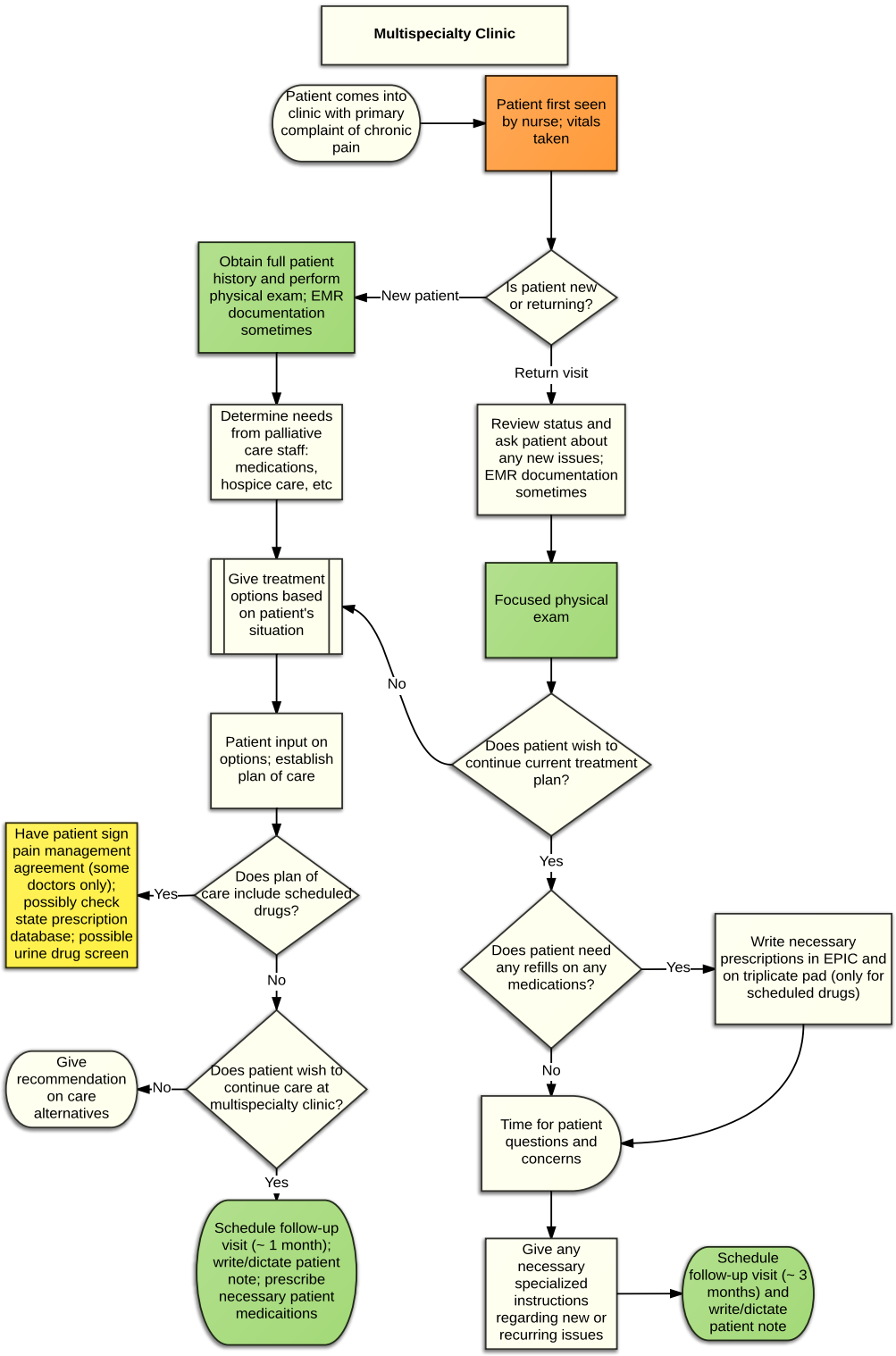



Figure 2: Multispecialty Clinic Flowchart

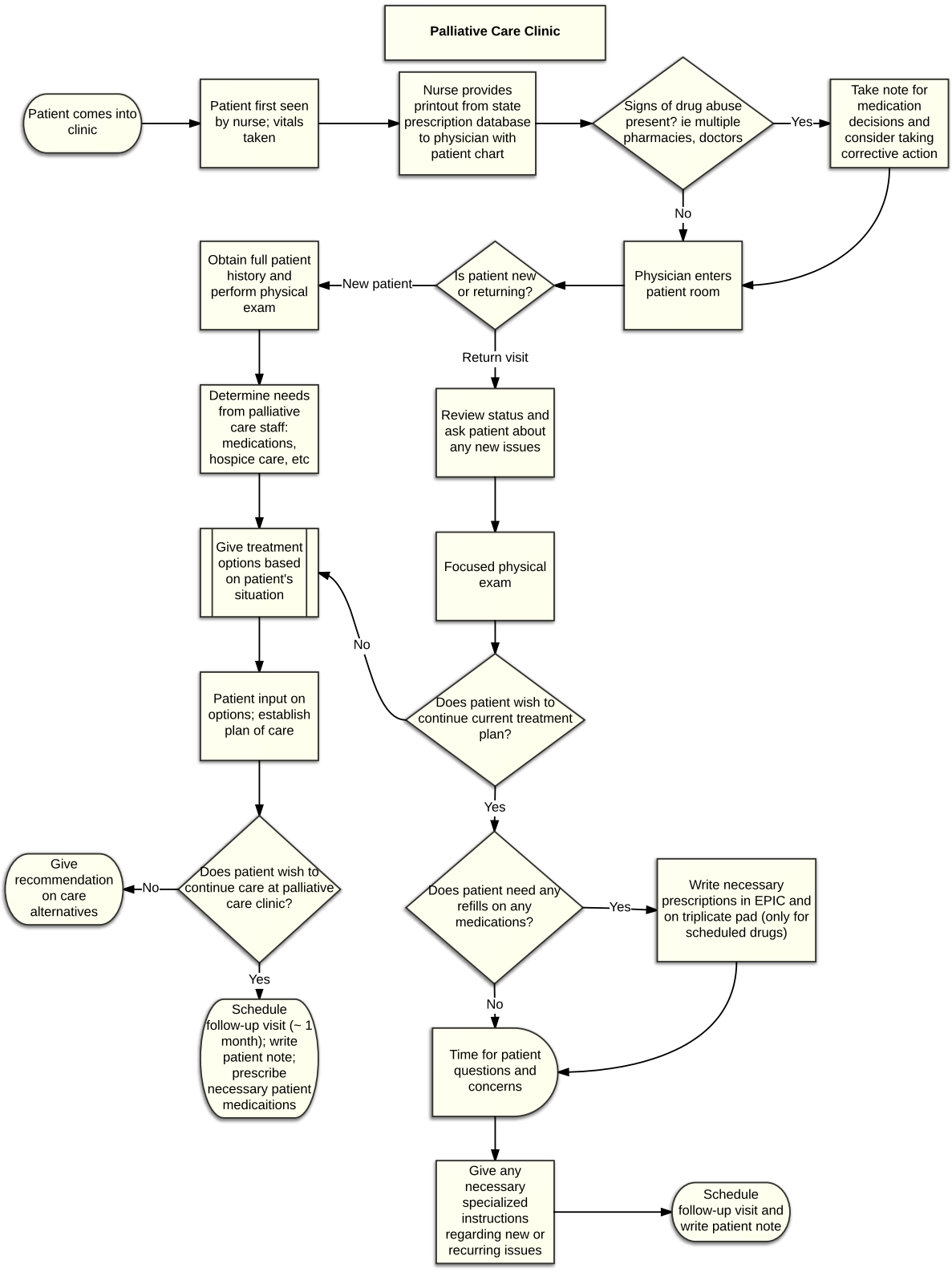



Figure 3: Palliative Care Clinic Flowchart

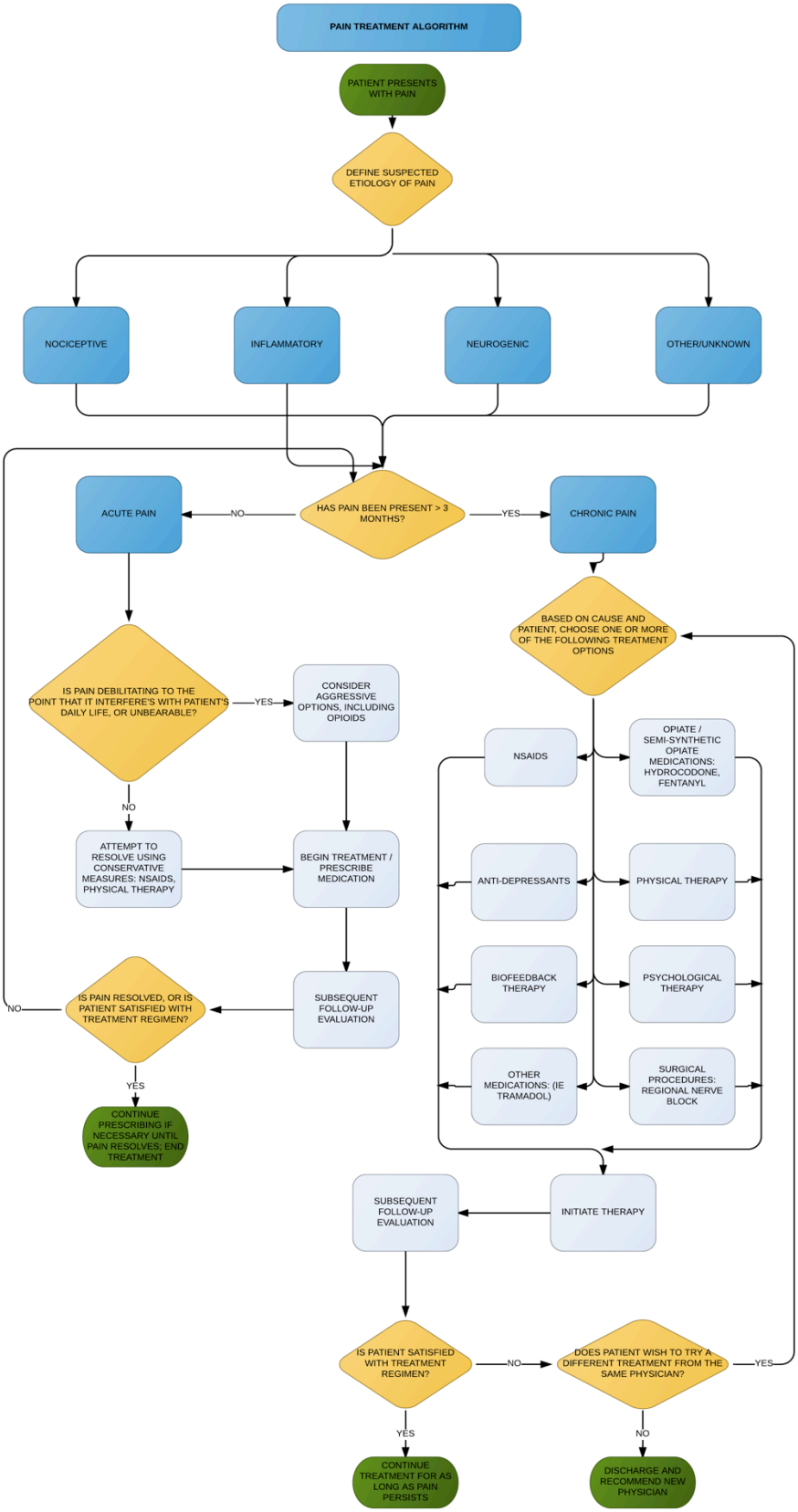
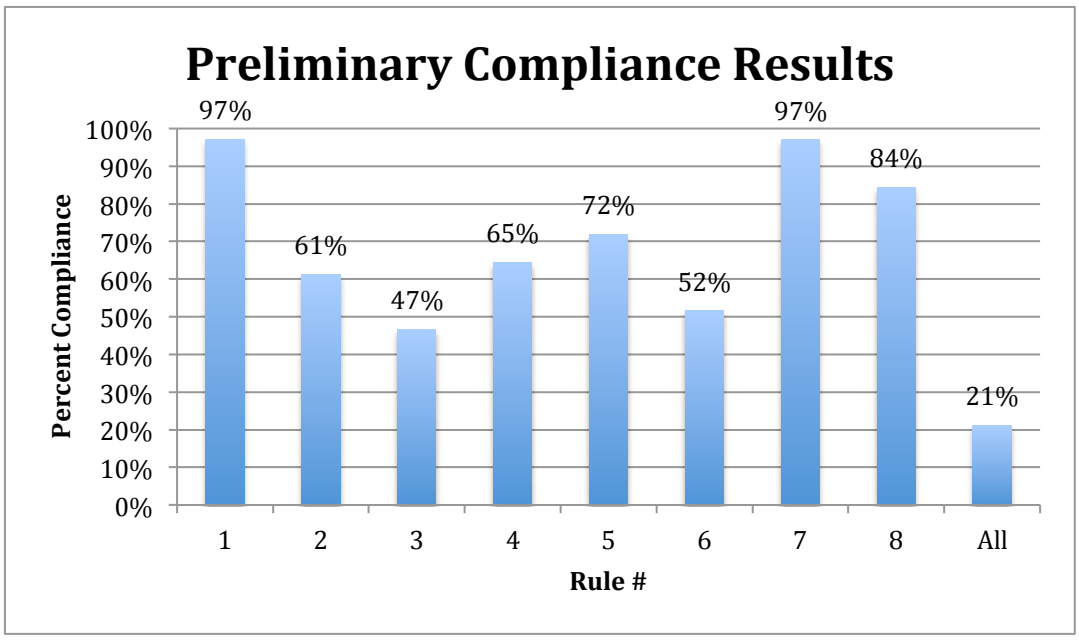



Figure 4: Pain Treatment Algorithm

*Baseline Data:*

Data analysis to estimate compliance was performed using a Plan, Do, Study, Act (PDSA) methodology. The first run, performed in June – August 2016 used a previously compiled dataset of 534 patients that were identified as using scheduled drugs and having been seen in the pain management clinic. An initial convenience sample through 100 of the patients identified 33 patients that had their medications prescribed within the UTSW system. Each patient's chart was manually reviewed and assessed for The following graph represents the data obtained from the preliminary run, in which only 21% of patient records were found to be in complete compliance, broken down by the results for each rule:

Figure 5: Preliminary compliance bar chart




Additionally this data was compiled into a Pareto Chart, which demonstrates that five of the rules represent a large majority of the instances of noncompliance and that three of the rules caused over sixty percent of the total.

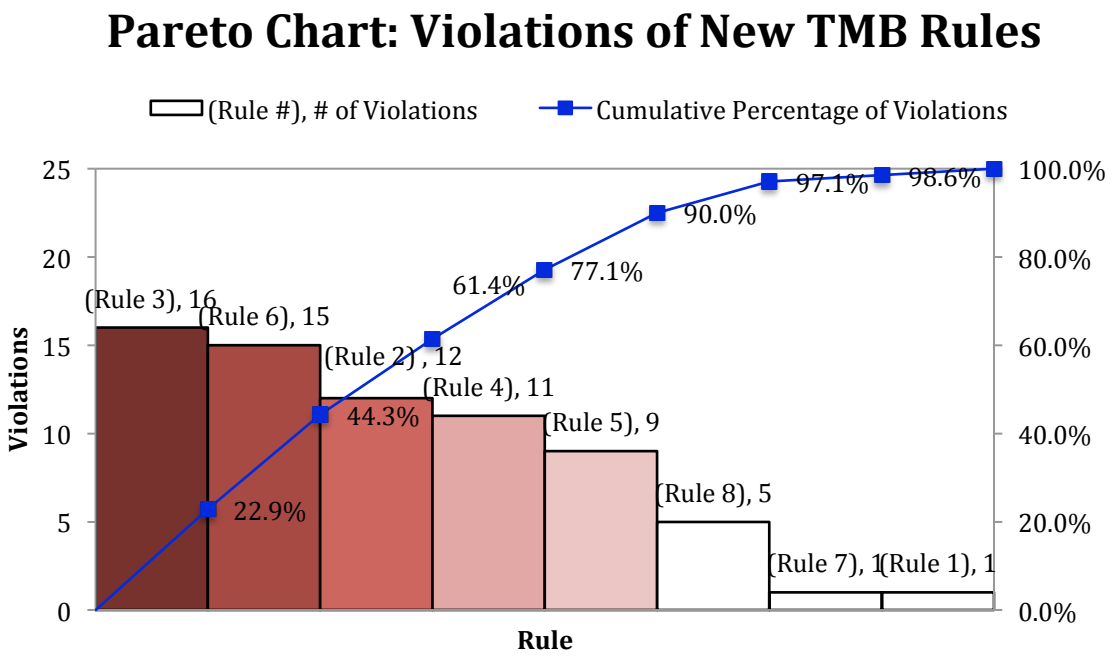



Figure 6: Compliance Pareto Chart

This initial data run was important for establishing the large opportunity for improvement present. It revealed that a large number of patients with records were out of compliance. It also provided the authors with a better understanding of how these elements are documented in the EMR through a detailed examination of physicians' notes. It was, however, ultimately determined to be insufficient to establish an accurate baseline for UTSW as a whole due to the small sample size, and more importantly due to the non-random selection of the patients. Evaluating all UTSW patients using this method would be extraordinarily time-consuming, and would not have reproducible results, as it relies on the subjective evaluation of someone reading a patient chart.

The subsequent data run performed in April 2017 attempted to fix the shortcomings of the previous one by creating a database of all patients on opioid therapy for chronic pain. The rules for this set included all patients who received three opioid prescriptions within any

ninety day period in 2016, pulling a total of 10,846 patients. After patients with a cancer diagnosis were excluded, as their treatment is not included in the law, 8,487 patients were left fitting this definition. Based on results from this initial data run, the focus of the analysis was tightened to the three rules with the lowest compliance rates, namely the requirements for baseline drug screening, for a signed pain mangement agreement, and for use of the state prescription database. In order to analyze patient records more quickly and efficiently, the method of text analysis was used to find specific phrases associated with compliance with the law. All physician written notes for these patients were searched and occurrences of the following phrases were tallied:

Drug screening associated phrases:

- "Urine drug screen"
- "Urine drug toxicology”

Prescription monitoring associated phrases:

- "prescription monitoring program"
- "prescription database"
- "prescription access database”

Pain contract associated phrases:

- "Pain contract"
- "Opioid contract"
- "Pain management agreement"
- "Medication management agreement”

These phrases were selected based on previous readings of patient charts as well as the note template used by a pain management physician. Additionally, data was pulled for any drug screens performed on these patients, as these orders are logged separately in the EMR. Results of this data search are detailed in the table below:

Table 1: Baseline Compliance

| Category | Number | Percentage of total (N=8,487) |
|---|---|---|
| Patients with drug screen | 877 | 10.3% |
| Patients with drug screening associated phrases | 72 | 0.85% |
| Patients with prescription monitoring associated phrases | 28 | 0.33% |
| Patients with pain contract associated phrases | 21 | 0.25% |
| Patients with any phrases | 88 | 1.03% |

Because the results were much lower than expected, individual patient charts were again examined to determine the relationship between the data and what was actually present in the EMR. This analysis revealed that many patients included in the set did not fit the definition of chronic opioid therapy due to some of the practices used to document medications in the EMR. This included discontinued medications still listed as open and individual administrations of opioids in the hospital being logged separately. To get an estimate of the portion of the total representing true chronic pain patients, a randomized sample of 100 patients was selected and evaluated as either appropriate for inclusion or not,

so that the results could be extrapolated to the entire dataset. 34 of the patients examined were determined to fit the criteria, amending the previous results to the following:

Table 2: Modified Baseline Compliance

| Category | Number | Percentage of total (N=2,886 ± 399) |
|---|---|---|
| Patients with drug screen | 877 | 26.7% - 35.7% |
| Patients with drug screening associated phrases | 72 | 2.2% - 2.9% |
| Patients with prescription monitoring associated phrases | 28 | 0.85% - 1.1% |
| Patients with pain contract associated phrases | 21 | 0.64% - 0.84% |
| Patients with any phrases | 88 | 2.7% - 3.5% |

It became clear from this data that provable compliance at UTSW with the law is a significant problem. However, it was difficut to interpret precisely what these numbers imply. While the rates appear very low, it is possible that some providers may have been complying with the requirements of the law without documenting this textually in their patient encounter notes.

To further address this issue, the Opioid Prescription Policy and Workflow group was formed, which included UTSW leadership from relevant departments, content experts from the area of pain management, and information technology workers able to implement changes in the EMR. This group developed a chronic opioids registry tool track all patients at UTSW that qualify as on chronic opioid therapy at a given time by fulfilling the criteria of having

been prescribed an opioid medication in at least three consecutive months. One significant change made for this registry in comparison to the data used for the baseline compliance estimate was that tramadol, an atypical opioid described in the introduction, was excluded given its low potential for abuse. These changes significantly shrunk the number of qualifying patients from around 3,000 to around 200.

Patients from the registry were sorted by prescribing provider and clinic so that the top prescribers could be identified and so that the intervention could be targeted to the locations where it would be most active. Results are displayed below in a Pareto Chart.

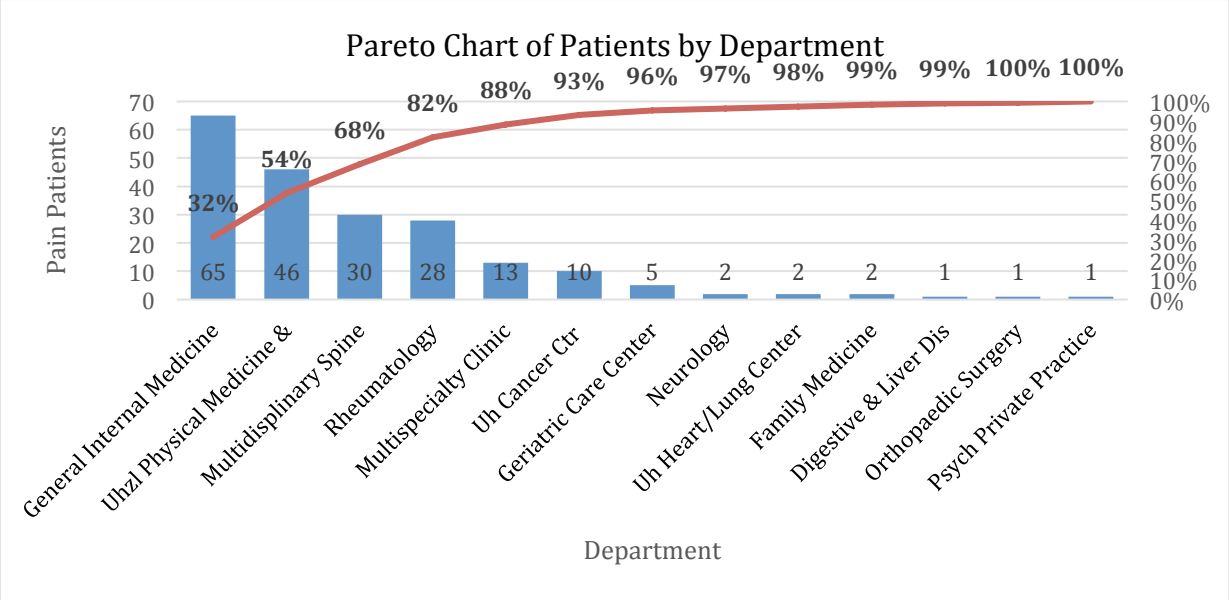



Figure 6: Chronic Opioid Patients Per Clinic Pareto Chart (Courtesy of Aemen Zamir)

These data established five clinics as candidates for targeted intervention based on their volume of patients on chronic opoids, namely the General Internal Medicine Clinic (GIM), the Zale Physical Medicine and Rehabilitation Clinic (PM&R), the Multidisciplinary Spine Clinic, the Rheumatology Clinic, and the Multispecialty Clinic.

***Interventions:***

A suite of changes for the EMR has been developed that will track all patients on the chronic opioid registry to determine whether requirements of the law are met, and will issue reminders if they are not. This includes a standardized pain contract to be used by all UTSW providers that can be accessed in the EMR and stored in an identifiable location, along with alerts that will tell providers if a qualifying patient either needs a contract and does not have one, or has a contract with another provider. Additionally, alerts will trigger for any patient that is due for urine drug screening. A link to the PDMP database has been added to the EMR, and a system was designed that would allow providers to record their use of the database and track if the link had been clicked. Its implementation, however, has been delayed due to the Texas House Bill referenced in the problem description. Since the requirement for PDMP usage has expanded beyond just chronic opioid patients, the group decided that helping to ensure compliance with this new law will require a separate project.

These tools have been piloted by a small number of providers order to ensure their functionality. Small technical tweaks have been made based on user feedback, however no major structural changes occurred. Meetings have been arranged with leadership at all of the top prescribing clinics mentioned previously with a staggered rollout for activation of the EMR tools occurring at each clinic individually throughout February and March of 2019. This will allow for the opportunity to progressively improve the interface based on provider feedback before it is released to the system as a whole. In addition to on-site training and education, online training modules have been developed that teach providers about the new tools, and they will be freely available for providers to complete at their convenience.

***Ethical Considerations:*** The main ethical considerations at play in this project regard the privacy of sensitive information, which is handled with the practices recommended by UT Southwestern. Patient information was stored on an encrypted flash drive that required a passcode to access.

## CHAPTER 3
## Results

Data retrieval is still pending, and will be presented in the form of a monthly timeline for compliance in each of the specified clinics, as well as the system as a whole.

## CHAPTER 4
## Discussion

***Summary:***

This project at UTSW is using EMR changes to track and enforce compliance with state laws regarding the treatment of chronic pain with opioid medications. Specifically, providers will be monitored in their use of standardized pain contracts, baseline urine drug screening, and the PDMP, and provided with resources to help them do so.

***Interpretation:***

Given the disruptive nature of the proposed changes, implementation of the intervention has been cautious and slow to ensure success and the buy-in of individual providers. Ideally, EMR tools allow for a more efficient provider workflow while also enhancing patient safety, but a poorly implemented fix may have the opposite effect, hence the staggered rollout that allows for provider feedback. If successful, this project will join a growing number of examples of the use of EMR tools to enhance opioid safety. The project represents a health system's response to regulatory changes enacted by both the state medical board and legislative body and shows that such a response requires sufficient time and careful planning to be executed successfully.

***Limitations:***

This project takes places at a large academic institution with multiple clinical sites, a commercial EMR, and a large patient base, and thus its lessons will translate best to other similar practice environments. Different strategies for law compliance would most likely be

necessary at a smaller medical practice, especially one that does not have an EMR or one with a low volume of patients on chronic opioid therapy. Compliance results changed over throughout the project due to an evolving definition of which patients qualified as on chronic opioid therapy; a coherent and consistent definition could be seen as one of the important results of the project. The project has also had to adapt to a changing legal environment, as new laws passed during the project changed the scope and legal requirements.

***Conclusions:***

This project has successfully created a registry of the patients at UTSW on chronic opioid therapy and built an EMR structure that will ensure that these patients are cared for in a fashion compliant with TMB laws. Once implemented, the required practices will be structured into provider workflows and tracked through the EMR. The lessons learned will help to adapt to further changes in the legal environment, and to better care for patients on chronic opioid therapy. The next most important steps will be to roll out the intervention to individual clinics and to the entire UTSW system.

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