

## **ETHICAL ISSUES IN OPIOID TREATMENT AGREEMENTS FOR PAIN CONTROL**

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### **Abstract**

Chronic pain is complicated by substantial psychological and functional impairment that can have a profound effect on quality of life. More than 75 million Americans suffer from chronic pain, and the number of these patients followed in primary care practices is rising (Adams et al., 2001; Gureje, 1998).

Opioid medications are known to be effective in relieving chronic pain and can improve mood and functional status as well (Turk, 2002). There is no question that competing public health concerns, i.e. the under-treatment of pain and the abuse of prescription drugs, present a major policy dilemma in the United States of America. The “War on Pain” stands at odds with the “War on Drugs” in America. On the one hand, the Institute of Medicine has called effective pain management a “moral imperative” and a “professional responsibility” while on the other hand the media and political environment highlights the dangers of addiction and diversion of opioid drugs to third parties (Institute of Medicine, 2011b). The balance struck between these two goals is often a policy of requiring opioid treatment agreements as standard practice (Fishman, 2010). Providers are cautious about prescribing opioids owing to concern about their addictive properties and side-effects, and concern about regulatory sanctions. As care of patients with chronic pain in the primary care setting increases, many physicians have come to rely on opioid treatment agreements (OTAs) to demonstrate their own professional compliance, causing numerous ethical quandaries (Texas Medical Board, July 2012).<sup>1</sup> This paper will explore ways to approach patients

<sup>1</sup> In Texas the Medical Board has adopted guidelines noting that “Treatment of chronic pain requires a reasonably detailed and documented plan to assure that the treatment is monitored. An explanation of the physician’s rationale is especially required for cases in which treatment with scheduled drugs is difficult to relate to the patients’ objective physical, radiographic, or laboratory findings.” TMB Bulletin, July 2012: See Chapter 170 of the Texas Medical Board rules

[http://www.tmb.state.tx.us/rules/docs/Board\\_Rules\\_Effective\\_05\\_16\\_2012.pdf](http://www.tmb.state.tx.us/rules/docs/Board_Rules_Effective_05_16_2012.pdf)

in need of pain control with a more nuanced approach than is now common.

### **I. Opioid Crisis 3.0**

Over 2 million Americans have a substance use disorder involving prescription pain relievers and over 590,000 are addicted to heroin (Center for Behavioral Health Statistics and Quality, 2016). Drug overdose has now become the leading cause of accidental death in the U.S. In 2015 alone, over 55,000 Americans died due to lethal overdose. The leading cause of the rise in drug overdose is opioid addiction. In 2015, over 20,000 Americans died from prescription opioid overdose and over 12,000 Americans died due to heroin overdose (Center for Disease Control, 2016). In 2012, over 250 million opioid prescriptions were written. To put that into perspective, that is enough to allow each adult living in the U.S. to have their own bottle of opioids (Center for Disease Control, 2014). The rise in the use of heroin is directly related to the misuse of prescription opiates, with 4 out of 5 heroin users admitting that they first started out abusing prescription pain relievers (Jones, 2013).

It may be tempting for some to perceive individuals suffering from addiction as morally weak; however, substance abuse disorder must be seen as a bio-psycho-socio-spiritual problem. Individuals have been demonstrated to be genetically predisposed to substance use disorders (Erwin, 2015). Drug addiction has been shown to reflect abnormal functioning of the neural circuitry that causes increased craving of substances and reduced impulse control (Eagleman, Corroero, & Singh, 2010). Drug abuse leads to changes in the structure of the epigenome and eventually the brain. Literature suggests that social and economic inequalities lead to poor health outcomes (Cushing, Morello-Frosch, Wander, & Pastor, 2015). Disease progression has shown susceptibility to early influences in the environment, with epigenetic changes directing the early development of the individual (Jirtle & Skinner, 2007).

Effectively treating chronic pain and curtailing opiate dependence poses a great dilemma among physicians. As mentioned previously, among the methods which attempt to manage this dilemma are OTAs. OTAs are used often due to the belief that they may lead to a better adherence to opiate treatment regimens with less chance of abuse. However, minimal research exists to support this belief (Helft, Williams, & Bandy, 2014). Nor is there any evidence to suggest that OTAs increase treatment efficacy (Fishman, 2010). On the contrary,

OTAs pose a threat to the physician-patient relationship. Insistence on a contractual agreement may cause diminished patient motivation to comply with treatment plans (Goldberg & Rich, 2014). Furthermore, increased prosecution of physician mis-prescribing has caused physicians to look at patients suffering from pain with suspicion. Perhaps most damaging of all is that this attitude of avoidance is preventing physicians from accurately diagnosing and treating patients with chronic pain and substance use disorder (Dineen & Dubois, 2015).

Nearly 100 million Americans suffer from chronic pain (Institute of Medicine, 2011a). The causes of these painful conditions include: spinal trauma, spinal disc disease and low back pain, fibromyalgia, arthritis, various types of neuropathies, migraine headaches, surgical complications, cancer, etc. (Adams et al., 2001). Despite the large numbers of patients suffering from chronic pain, under treatment continues to be a problem. In one study conducted in the U.S., about 34% of advanced cancer patients continued to report pain a month after their visit to the physician (Weingart, Cleary, & Stuver, 2012). In another U.S. study, 51% of chronic non-cancer pain sufferers reported that they had little to no control over their pain (American Academy of Pain Medicine, 2006). One reason for undertreated pain may be due to physician attitudes towards patients suffering from chronic pain. Patients suffering from pain have reported that their physicians tended to avoid them, or minimized their pain (Upshur, Bacigalupe, & Luckmann, 2010). This culture of avoidance will undoubtedly damage the therapeutic alliance. In order to make long-lasting behavioral changes in patients and to effectively treat pain, a good physician-patient relationship is needed (Farin, Gramm, & Schmidt, 2013). It has been demonstrated that a strong therapeutic alliance is a predictor of successful treatment in patients with a history of substance use disorder (Meier, Barrowclough, & Donmall, 2005).

It is clear that there needs to be a balance to counter the current dilemma. However, a balanced approach will require a comprehensive assessment and an individualized approach (St. Marie & Arnstein, 2016). Although it seems easier to implement utilizing OTAs as standard policy for all patients receiving opiates, there is tremendous collateral damage to the physician-patient relationship.

The increasing attractiveness of OTAs is likely a response to increased federal regulations to counter the current opioid epidemic (American Academy of Pain Medicine, 2013; Federation of State Medical Boards

2013). The thought process behind OTAs may be to provide a way to “mitigate professional and legal liability” for physicians in the wake of increased prosecution (Arnold, Han, & Seltzer, 2006).

Given the growing research in the field of epigenetics, and certain individuals’ genetic predisposition to drug abuse, we must ask if the addict is truly at fault. Since environmental factors are contributing to epigenetic changes, particularly those coming from a background of social and economic inequality, how much control does an individual possess over genetic predisposition to substance abuse?

## **II. History**

In the past century, the U.S. has seen multiple cycles of opioid use and consequent regulations (Frakt, 2014; Haffajee, 2016). And to this day, the pendulum continues to swing.

Beginning in the late 1800’s, when opioids were completely unregulated, physicians were known to prescribe opioids for all types of pain (Kolodny, 2015). Consequently, opioid dependence became a common problem. The response to rising opioid addiction was the 1906 Pure Drug and Food Act and the 1914 Harrison Anti-Narcotics Act. These regulations required physicians to physically write prescriptions for opiates, which were taxed, and also made it compulsory for physicians to keep records of the drugs they prescribed (Hohenstein, 2002; Weber, 2010).

Following this first cycle, in the 1950’s, the U.S. saw a resurgence of opioid use and lethal overdoses. The response to this second cycle was Nixon’s War on Drugs in the 1960’s. This response made it difficult for providers to prescribe pain relievers for fear of diversion and prosecution (Drug Enforcement Administration, 2010). However, by 1969 a counter-crisis had occurred. Undertreated pain was recognized as a human right to avoid unnecessary suffering (Institute of Medicine, 2011a). The resulting increase in opioid prescriptions and concurrent benzodiazepines has caused economic concerns (Robinson, 2015).

In Texas the Intractable Pain Treatment Act (IPTA) was passed in 1989 (Hill, 1992; Thorpe, 1990). This Act attempted to protect physicians from the Texas Medical Board discipline in the case of physicians prescribing for intractable pain. In 1996 the IPTA was amended to allow physicians to prescribe pain medications to patients in pain despite having a history of substance abuse (Leichter, 2013). Proper documentation was required for these patients in particular. This

amendment tried addressing the growing concerns about undertreated pain due to physician reluctance, particularly cancer pain. This Act was in line with the War on Cancer and recognizing that Cancer Centers were engines of economic growth in Texas.

This brings us to contemporary times. The third cycle started around 2010, where the U.S. saw another resurgence of opioid use and lethal overdoses. The U.S. is now responding to the fear that those suffering from opioid addiction are dangerous (Appelbaum, 2013). In Texas, the IPTA was reinterpreted to allow prosecution of physicians who fail to make responsible efforts to avoid diversion to third parties. Similarly, other states have enacted laws that aim to prevent prescription drug abuse (National Conference of State Legislatures, 2016). Furthermore, the Federal DEA publicizes cases against doctors who violate federal law (Drug Enforcement Administration, 2016).

### **III. Historic Policy Shifts**

The continuous cycles of policy shifts have created uncertainty for physicians and confusion for patients. The culture of avoidance may be a reflection of the uncertainty for physicians. The huge policy swings are driven by fear. Some of the fear may be justified. However, the fear needs to be balanced by rational thinking (Appelbaum, 2013). Fear and unpredictability have historically led to restrictions on liberty and the moral basis for informed consent. When patients are deemed a danger to themselves or to others, society is justified to restrict goods that would otherwise be seen as inappropriate. This is true of civil liberties, and explains why the Nixonian “War on drugs” worked to limit access, and why current stories of opioid addiction among middle class patients are widespread in the media (Frontline, 2018; NovusDetox, 2018; Times, 2016). Haffajee has suggested that ethical considerations of proportionality, minimal infringement, fairness, and public accountability are minimal requirements of any policy on OTA contracts. Reactions to fear will do little to promote reasoned discourse on this topic and should be replaced with a more balanced approach (Frakt, 2014; Haffajee, 2016).

Our current response to the opioid crisis requires physicians to predict patient behavior. This is not only difficult to do, it asks the physician to assume responsibility for behavior of the patient, rather than her own prescribing behavior (Dineen & Dubois, 2015). The conflict of interests between predicting patient behavior and protecting one’s own ability to practice medicine may result in physicians avoiding prescribing, or denying behavioral markers

indicating cause for concern (Upshur et al., 2010). The use of OTAs becomes a path to plausible deniability (Helft et al., 2014).

The use of OTAs interferes with the physician-patient relationship by substituting a contract for a conversation. And the damage to the therapeutic alliance undermines the long-term goal of the patient's health. Patients who do not understand the terms of the OTA may be coerced into signing a document in order to obtain needed pain control. Yet because predicting which patients are deceiving the physician regarding their intent, it may be the physician who is coerced into prescribing.

Looking at the history of opioid use in the U.S., it is apparent that the old way of looking at this problem has not worked in the area of opioid addiction. It is time to ask new questions.

## IV New Questions

The goals of the new questions should not change. We must find a way to adequately control the pain of patients who need it, while minimizing addiction to prescription medications and diversion to the black market for drugs. We propose attention should be directed towards the ethical issues raised by the use of treatment agreements in the prescribing of opioids to patients.

1. **Pressures on the Physician-Patient Relationship:** To reinforce the physician-patient relationship, reduce coercion, and bolster informed consent we need to ask: What would a personalized approach to opioid prescribing look like?

Goldberg, et al. have suggested that informed consent to the OTA should be required to include that the physician explain to the patient what is expected of her in order to safely engage in a trial of opioid analgesia (Goldberg & Rich, 2014). We will explore additional answers to this question in the next section.

2. **Coercion and Informed Consent:** Does the patient asked to sign an opioid treatment agreement adequately understand what the agreement means, or are they signing it in order to get the drugs?

There may be unlikely benefits and probable harms to a balancing approach that relies on opioid treatment agreements to ensure compliance with the prescribed pain medications. Patients are not aware of who will benefit from the OTA, with many believing the OTA is for the benefit of the physician. This indicates the need for

much more substantial education of patients prior to obtaining informed consent for the use of these instruments.

3. **Conflict of Interest:** To reduce the conflict of interests we should ask: Is the physician working below the standard of care in prescribing opioids?
  - a. Physicians face conflicts of interest and commitment in prescribing adequate pain control to patients.
  - b. Physicians have an obligation to place the interests of their patients first, including the balance of needed pain control and the potential for addiction.
  - c. However, the current legal environment encourages physicians to justify clinical decisions that are premised on predicting patient behavior.

The balance of the two pressures will predictably tend to push physicians to either under-prescribe pain medications, or require the use of an opioid treatment agreement in which the patient gives assurance they will not overuse or divert the medication. Current laws place the burden of lie detection on physicians who are labeled as “mis-prescribing” if they are duped into believing their patients (Dineen & Dubois, 2015). A more flexible standard of care analysis would require physicians to examine their own behavior, rather than the behavior of patients. This flexibility would put patients at the center of the balancing equation, rather than placing physicians in a conflicted position. However it could heighten the need for a particularized inquiry by regulatory agencies into the total facts of a case.

## V. Possible Answers

Our research is one small piece of the larger puzzle, but it gives clues to the direction we need to move. We surveyed 55 patients who were prescribed opiates and/or diagnosed with opiate dependence in the outpatient psychiatry clinic at Texas Tech University Health Sciences Center in Lubbock, Texas (Erwin, Sharma, Baronio, Abdali, & Manning, 2016). We administered an anonymous 21-item survey asking patients about their previous experiences with OTAs, history of detoxification, overdose, rehabilitation programs, likeliness to divert medications, thoughts about communicating such information with federal agencies, etc. Our survey population included majority women 69.09% (n=38/55) with a mean age of 46.7 years and men

30.91% (n=17/55) with a mean age of 41.94 years. The majority identified ethnically Caucasian (75%), African-American (3%), Hispanic (18%) and multiracial or other (3%). The average length of time our patient population had been using opiate medication was 7.21 years. The data compared patient characteristics and reported behaviors.

<b>Demographics of Participants and Providers in this Survey</b>		
<b>Gender</b>	Male	31%
	Female	69%
<b>Ethnicity</b>	Caucasian	75%
	Hispanic	18%
	African American	3%
	Multiracial	2%
	Other	2%
<b>Prescribing Physician</b>	Primary Care Physician	59%
	Psychiatrist	4%
	Other	37%

*Table 1*

- 1. Pressures on the Physician-Patient Relationship:** To reinforce the physician-patient relationship, reduce coercion, and bolster informed consent we need to ask: What would a personalized approach to opioid prescribing look like?

We found that those patients with a history of overdose/detoxification/rehabilitation (O/D/R) are 21 times as likely to divert medications to others as compared with those who have no history of O/D/R:

<b>Who Diverts Opioids to Third Persons By History of Overdose/Detox/Rehab (O/D/R)</b>			
	<b>All</b>	<b>History of O/D/R</b>	<b>No Prior History</b>
<b>Yes</b>	12%	83%	7%
<b>No</b>	88%	11%	89%



Chi-Square = 17.9434			
p-value = 0.001			
Who Diverts Opioids to Third Persons By Gender			
	All	Male	Female
Yes	12%	67%	33%
No	88%	23%	77%
Chi-Square = 4.9076			
p-value = 0.047			

Table 2

2. **Coercion and Informed Consent:** Does the patient asked to sign an opioid treatment agreement adequately understand what the agreement means, or are they signing it in order to get the drugs?

Who Does the Opiate Treatment Agreement Information go to?	
Health Care Providers	22%
Federal/State Reporting Agencies	4%
Insurance	2%
Employer	2%
Don't Know	70%
All of the Above	0%

Table 3

Key findings from our study include:

- Patients are not aware of who will benefit from the OTA, with many believing the OTA is for the benefit of the physician.
- The least likely person to divert drugs to others is a woman with no history of O/D/R.
- Those with a history of O/D/R are much more likely to share or divert medications to others.
- Furthermore, exploring patient comments gave us some further insight into the patients' perspectives on OTAs. Some patient comments included:

- “Lack of some privacy”
  - “If you have surgery and need something stronger you can’t get it”
  - “Prevents Emergency Room Doctors from Prescribing in Emergency”
  - “Just makes me feel the Dr. thinks you are an addict”
3. **Conflict of Interest:** To reduce the conflict of interests we should ask: Is the physician working below the standard of care in prescribing opioids?

Our study also illustrated ways that laws in many states provide unhelpful incentives to avoid the difficult issues of between-patient differences in propensity to become addicted. In Texas the Medical Board has adopted guidelines noting that state: “Treatment of chronic pain requires a reasonably detailed and documented plan to assure that the treatment is monitored.” Individual patients require personalized consideration and monitoring, yet OTAs have become an easy way to comply with the law. The use of OTAs seems to be used to provide coverage from the possibility of investigation by the Medical Board more than as an aid to patients.

To address this issue, the legal environment should recognize the conflicted position of physicians and rather than ask for documentation, ask for appropriate patient care.

## VI. Conclusion

Rather than continue on the pendulum of restrictive and then permissive policies that do not work, we need to engage the evidence and best thinking around the topic of new ways to provide the pain relief that patients need while engaging those most likely to abuse opioids in alternative treatments including referral to therapy for drug abuse.

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