What do you do, when a patient violates a pain agreement?

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"It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has." William Osler

When prescribing long term opioid medication for non-cancer pain, whether for a new patient or existing patient, there needs to be an understanding that long term use of opioids cause physiologic dependence. A pain agreement, prior to starting chronic opioids is expected and facilitates an honest discussion of risk, benefit and mutual expectations.

Pain agreements are meant to establish boundaries, yet are made in the context of a therapeutic relationship between the patient and the physician. If an agreement has value, it must be enforceable, yet any infraction needs to be interpreted in context and a decision made based on sound judgment and not emotion.

The pain agreement, like the prescription monitoring program (PMP), is meant to enhance the physician-patient relationship and function as a clinical tool. Much like a stethoscope, the pain agreement and the PMP allow the prescriber to have more information to make the best clinical decision for the individual patient.

Evaluating Pain

As a prescriber, do you consistently evaluate pain in the context of function, activities of daily living and verifiable goals? Or, are you stuck looking at a number between 0 and 10 which is nebulous and unverifiable? Evaluating pain clearly and consistently helps establish a clear baseline and allows for objective future visits. Pain is subjective, yet the impact on any patient's activities of daily living and function is not subjective.

Transitions

Patients are individuals; their symptoms and signs, which might not be unique to physician's ears, are unique to the patient. Each patient should have treatment tailored to them using the intellect, judgment and compassion. Ideally, after a physician has performed a comprehensive evaluation, constructed a thorough assessment, they will embark on a jointly agreed plan for each patient.

Care is best delivered in a continuous manner; patients with chronic disease benefit from continuity of care and a thoughtful approach to the long term management of their chronic disease.[1] At times, any patient might need care in a different venue, when care changes venues or providers; "transition of care[2]" needs to occur.

A successful transition of care involves active participation from the patient, direct communication with the accepting provider and a written summary with up to date information and a clear understanding of treatment goals for both. Coordination of care when a patient changes treatment venues avoids errors and patient suffering[3]. Moving throughout the health care marketplace can be challenging for patients and present obstacles more difficult to overcome when trying to acquire care for chronic pain, addiction or dependence. One resource to help facilitate a referral for treatment for addiction is located here (health.ri.gov) - see orange box.

Patients with chronic pain, as with other chronic diseases require continuity of care and an understanding of the whole patient. An important difference regarding patients with chronic pain who are treated with chronic opioids is the physiologic dependence that occurs (not necessarily addiction) in the vast majority of patients. Assuring an opportunity for a successful transition of care is a duty[4] we owe our patients and part of our professional responsibility. The provider patient relationship is vital to this transition, so remain available, supportive and collaborative.

An important caveat regarding patients taking opioids for long periods of time is that interruption of medication leads to withdrawal. Withdrawal is unpleasant and can cause patients to seek alternative sources to satisfy their dependence. Prescribed use of opioids can cause patients in recovery from substance abuse disorders to reinitiate cravings or to relapse. Prescribers have a duty and requirement[5] to be thoughtful in how they transition patients who are on long term opioids to optimize their chances of a positive outcome. For patients on long term opioids, a practitioner to practitioner communication is required.

Pain Agreements

Pain agreements[6] are a helpful tool in setting expectations for chronic pain treatment of non-cancer pain with opioids. These agreements have both educational and boundary setting value and can help illuminate the risk/benefits of the proposed therapy in a neutral manner. Chronic opioids, such as other therapies have risks; it is important the prescriber and patient clearly understand treatment goals, risks and benefits before chronic opioids have been started.

What do you do, when the agreement is broken? Unexpected events occur, emergencies happen, what are the boundaries and how are they enforced and by whom? An agreement that will never be enforced is of no value and is not consistent with responsible prescribing of opioids. An agreement that results in dismissal over the slightest infraction could be somewhat harsh, expose the patient to severe pain, and send the wrong message to the patient.

Balance, clinical judgment and individualization are common to the patient physician relationship and help us make wise and individualized decisions. Events that cause concern regarding a pain agreement need to be interpreted in the context of the whole patient.

Here is a possible approach regarding what to do when there is an infraction with a pain agreement. Keep in mind each patient is unique and as in the cases of other serious diseases, your clinical judgment is critical and your decision making process should be documented in the medical record.

As you look at any algorithm, some violations are more serious than others and warrant an interpreted response. Keep your emotions in check. A violation of a pain agreement should never be taken as a personal attack.. Keep your thoughts professional, objective and neutral and treat the matter as you would any clinical situation by taking a history and examining the facts. Violating a pain agreement could be an oversight, misunderstanding, a symptom of addiction or something else.

Here are some questions in mind:

- Are functional goals being met?
- Is patient making progress?
- Did I screen before treatment for addiction?
- What are the bio-psychosocial issues that need to be considered?

The scenarios below illustrates common violations or events , and some ideas about what to do, to learn more and help find reasonable next steps.

Scenario #1 Lost RX:

Patient loses a prescription for a controlled substance, such as hydrocodone with acetaminophen.

Losing a prescription is problematic in as much as it might resurface again or could be diverted. Check the PMP, see if it was filled, if the prescription was filled, you need to have a different conversation with your patient about how this occurred. Are prescriptions being treated like *cash*, appropriately stored and safeguarded, is the patient being responsible?

You are under no obligation to replace a prescription that is lost, yet may do so if you are convinced there has a been a good faith effort to find the prescription, it has not been filled and no prior report of a lost prescription.

Scenario #2 Multiple Pharmacies and Multiple Prescribers

Most patients do not use multiple pharmacies, most patients' value continuity of care not just with their prescriber, yet also with the pharmacy. Pain agreements limit patients to one pharmacy for good reason; to avoid accidental interactions from other medications from other prescribers as well as over utilization.

If a patient is going to multiple pharmacies, ask why? Absent a legitimate reason remind them to follow the agreement and use 1 pharmacy. Patients who purposely go to multiple pharmacies or multiple prescribers might be drug seeking and this needs to be considered. If a patient has a legitimate reason to see a different prescriber, the patient should contact you first or as soon as practical (if emergency) and make sure you are aware. This is important not only avoid diversion, yet to avoid different prescribers unwittingly over dosing the patient.

Scenario #3 Calling for early refills/ increasing the dose on their own

Patients who call your office often for early refills, or are taking larger doses than prescribed present a challenge. The first question is why are they doing this? Is the patient undertreated, is this the right medication at all, should you consider a longer acting medication, or an additional non-opioid medication. The clinical decision is yours to make, yet you need to assess the patient and see if the issue is under treatment of pain. Under treatment of pain can lead to pseudo-addiction[7] and this should be considered as part of you differential diagnosis.

Some patients who come for early refills or increase their dose, or simply run out early are either over utilizing, the medication or even worse diverting. Over utilizing with medications such as opioids which have a narrow therapeutic index, presents a patient safety risk, specifically regarding accidental overdose.

Prescribers should check the PMP prior to prescribing a controlled substance, so it is clear when medications are filled and when they should need to be renewed. It is imperative that prescribers issue controlled substance prescriptions responsibly. Using the PMP can help alert the prescriber to concerning patterns such as over utilizing. Opioids and other controlled substances have a substantial "street value" and make a tempting product for illegal sale and misuse.

Prescribers must be on their guard for diversion, yet also recognize that some patients who are diverting are also addicted and in need of treatment for addiction.

Addiction:

Addiction is a chronic disease and needs to be treated as such. Patients who are addicted may exhibit aberrant behavior such as poly-substance use and/or selling medications, while this can not be tolerated; efforts need to be made on the part of the prescriber to ensure the patient received appropriate treatment.

Telling a patient they need help and have become addicted; and having the patient willing to be treated for addiction are different things. It is important to assess a patient's willingness to seek help for addiction. Patients who are willing to get help for addiction and willing to set up an appointment are more likely to succeed. There are many resources[8] to help find addiction treatment for your patient.

Prescribing to a patient who has admitted to selling or diverting is generally very unwise. Patients who are addicted will do anything to get an opioid, getting the patient to treatment as soon as possible. If you have a patient who has an appointment and you have coordinated with the receiving addiction provider, it usually makes sense to prescribing a limited amount of medication to avoid withdrawal makes sense.

Patients who test positive for illicit substances on urine drug screen require thoughtful deliberation by the prescriber. Patients who are using prescription opioids and illicit substances are at higher risk of accidental overdose. Strong consideration of referral for treatment for substance abuse or addiction is warranted. Ideally, the patient is willing to go and a smooth transition of care can be arranged.

Scenario #4 Shared medication with a family member/friend

For a variety of reasons, patients may share opioids with a family member or friend. Sharing with a friend or family member is the most common form of drug diversion.[9]

Although this type of sharing of medication is common, it can not be tolerated and is a violation of federal and state law. The intent of sharing with friends and family is not nefarious, yet often naïveté or misplaced compassion.

Patients who routinely share medication may have negative drug screens or may run out of medication early repeatedly. The prescriber needs to carefully consider whether or not to continue prescribing to someone who shares medication. You would be well within your rights to cease prescribing to a patient who participated with this type of diversion. Alternatively, some prescribers, will assess the situation for what it is and may agree to prescribe smaller amounts with more frequent follow up as indicated.

Tapering

Periodically, you will need to taper a patient from opioids. Tapering should be done after consultation with the patient. There is no "one way" to taper a patient, yet generally, the longer the patient has been on opioids, the longer it will take for a successful taper.

Some reason you might consider a taper include[10]:

Severe unmanageable adverse effects
Serious non-adherence to the treatment plan
Evidence of illegal or unsafe behaviors
Misuse suggestive of addiction to prescribed medication
Lack of effectiveness
Patient requests to discontinue therapy
Decreased level of pain in stable patients
Goals of treatment are not met

Some approaches to tapers for methadone, long acting opioids and short acting opioids are addressed in these references.[11], [12] The goal is to wean the patient in a reasonable period of time and keep the patient safe. Patients who are not taking opioids daily or on small doses generally do not need to be weaned.

There are times, when a taper is not needed, one example is when the patient is not taking the medication, rather is diverting the medication. This may not always be apparent in the prescriber-patient relationship, yet once this is known, continuing to prescribe even from a taper might seem out of the norm.

Summary:

These are a few scenarios that describe some common events that can occur for patients on chronic using pain medication. The overarching concept is to treat each patient as an individual and to document your prescribing rationale in the medical record. If you decide you can not continue to prescribe to your patient for what ever reason, take steps to ensure a warm transition of care from you to the receiving provider.

Having informed consent and a pain agreement in place before initiating chronic opioid therapy helps set expectations in the beginning and is the best way to provide safe effective care for your patients.

It is impossible to detail every situation; one needs to rely on clinical judgment and your own acumen. Prescribers should check the PMP before prescribing any controlled substance on every patient. Patients who are drug seeking, do not always show red flags, some are so professional about this, they are impossible to detect. Checking the PMP and documenting that review in the medical record is imperative and can help protect your conscious and career.

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[1] WHO: General Principles of Good Chronic Care, 2004, http://www.who.int/hiv/pub/imai/generalprinciples082004.pdf accessed 7.29.2014

[2] HEALTHIT.gov http://www.healthit.gov/providers-professionals/achieve-meaningful-use/menu-measures/transition-of-care accessed 7.29.2014

[3] AHRQ Toolkit by Patient Safety area: http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/pips/issues.html

[4] Baier, Keough, McDonald, Transitions of Care Professional expectations, Rhode Island Medical Journal, Nov 2013, 26-32,

[5] RULES AND REGULATIONS FOR PAIN MANAGEMENT, OPIOID USE AND THE REGISTRATION OF DISTRIBUTORS OF CONTROLLED SUBSTANCES IN RHODE ISLAND [R21-28-CSD] http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/8003.pdf

[6] Pain Agreement sample: http://www.health.ri.gov/healthcare/medicine/about/safeopioidprescribing/ accessed 7.29.2014

[7] PseudoAddcition http://www.whocancerpain.wisc.edu/?q=node/245 accessed 7.29.2014

[8] Addiction Treatment: http://www.health.ri.gov/healthrisks/addiction/for/providers/

[9] *Reg Anesth Pain Med* Fall 2011; http://www.asra.com/display_fall_2011.php?id=62 accessed 7.31.2014

[10] Tapering and Discontinuing Opioids, May 2013, http://www.healthquality.va.gov/guidelines/Pain/cot/OpioidTaperingFactSheet23May2013v1.pdf

[11] When and How to Taper, 2012, http://www.cpso.on.ca/uploadedFiles/members/resources/Opioid-Tapering-Protocols_Dial-I_2012.pdf

[12] Tapering and Discontining Opioids, May, 2013, http://www.healthquality.va.gov/guidelines/Pain/cot/OpioidTaperingFactSheet23May2013v1.pdf page 2