Chapter 9
The Opioid Requiring Patient: Office Level Management

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Introduction

A systems level approach to management of the patient on chronic opioid therapy (COT) at the office or clinic level is essentially a standardized approach to this special patient population. At the heart of this is the opioid treatment agreement which spells out the expectations of treatment for both the primary care provider and the patient. As managing chronic pain may be time consuming, it may not only make the physician's life easier [1], but also is recommended by the CDC [2] and may be required by law depending on the state. The opioid treatment agreement comprises of many components. It essentially states treatment goals, risks, qualifications for obtaining prescription opioids, and explains the monitoring process.

Currently, there is no evidence that treatment agreements reduce overdose and death. In addition, there are varying physician views [1] on the usage of "pain contracts" or "pain agreements" from punitive and self-serving, to much needed

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and an improvement to chronic pain management workflow. Usage of the word "agreement" may make this treatment document more collaborative instead of punitive [2]. Explanations introducing the opioid treatment agreement can discuss the reasons that this agreement exists. Scripts can include the opioid epidemic, risks of opioid therapy, and that it is a universal policy for all patients on COT, much akin to using gloves and other forms of universal precautions (Table 9.1). Of course, the individual provider can use any combination he or she wishes or invent their own standardized script when introducing the need for the opioid treatment agreement.

Treatment agreements, and the office polices they contain, may improve provider satisfaction and confidence with opioid treatment management [3, 4]. Example office policies regarding COT [2, 5] that may be of benefit are listed in Table 9.2.

All office policies do not need to be included in the treatment agreement as they may not be pertinent to the actual

Table 9.1 Example scripts to use when introducing an opioid treatment agreement

Reason	Example script
Universal precautions	The opioid treatment agreement is for everyone on long-term opioid therapy, not just you. It is currently our office policy (or state law/ or recommended by the CDC).
Opioid epidemic	Currently, there is a prescription opioid abuse epidemic. Although I do not suspect you will misuse opioids, it is very common. For everyone's safety, I will need to err on the side of caution and monitor your treatment according to this treatment agreement.
Opioid risk	Currently, long-term opioid therapy has many risks and little known benefit. Consequently, this treatment agreement helps us to know if it is working well. It contains a lot of information on how we will monitor opioid therapy.

Table 9.2 Example office policies for the management of patients on chronic opioid therapy

Policy type	Examples
Refill	Timing of refills Scripts are written for a 28 day supply to prevent needing a refill on weekends when scripts are written for 30 days, etc. Scripts are written only from Tuesday to Thursday, and for a 28 days supply to minimize needing a refill on a holiday Refill requests without a visit must be given 4 business days notification No refill requests will be allowed after business hours, weekends, or holidays Who can refill Refills will not be made by another physician if the PCP is available. Conditions for refill There will be no refill of lost or stolen prescriptions (unless there is a police report filed) No walk-in refills, no early refills/or if patient "runs out" Must go to specialist referrals, must obtain recommended laboratories, must attend appointments for care of other chronic conditions. Patient must attend group visit (centered around opioid risk education, naloxone, etc.)
New patients on COT	New patients must have a urine toxicology at first appointment and bring their records or office must receive all records prior to scheduling of first appointment. When instituting a new pain agreement, patients are allowed a 30 minute appointment

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Table 9.2 (continued)

Policy type	Examples
Follow up visits	Minimum intervals between office visits Must be made with PCP (if available) PCP cannot be changed for at least 6 months Requests to change PCP must be done with clinic manager (or other designated 3rd party as provider may feel it is unfair if chronic pain patients are unequally distributed)
Workflow	Designate and train person responsible for checking PDMP Designate and train person responsible for obtaining urine toxicology (or other requirement for monitoring the safety of opioid therapy) (medical assistant) and frequency (every visit?) Discuss with medical assistant/office staff ("huddle") to anticipate needs of clinic schedule and patient on COT
Pain management standards	Standards for when a referral to pain specialist or behavioral health specialist is required No initiation of opioids to treat headaches, fibromyalgia, or chronic low back pain Standardized consequences for various violations of the treatment agreement. Example: known diversion and violence towards staff leads to immediate discontinuation of opioid prescriptions. Increasing dosage without discussion with provider or using a different pharmacy is a minor violation. Violations are often categorized into "Major" and "Minor." Offices may have polices that stipulate how many major and minor violations incurred will lead to termination/weaning of opioid therapy.

chronic opioid treatment agreement whose chief purpose is to inform the patient standard requirements for refills, opioid risks, and measures to improve opioid safety. A separate chronic pain (or more specifically chronic opioid treatment) policy can address what is included in the treatment agreement along with other specifics concerning new patients on COT, frequency of checking PDMP databases and urine toxicology, standards for referrals, criteria for initiating a chronic opioid treatment agreement, definitions of and consequences for major and minor violations, etc. Of course, a clinic can simply adopt components of previously published guidelines as part of its chronic pain policy. One readily available example of a complete policy on chronic noncancer pain can be found at the University of Michigan Health System [6]. Essentially, the office policies on chronic opioid therapy will define chronic opioid therapy and dictate how a patient on chronic opioid therapy will be managed. The process of developing thorough guidelines for an entire healthcare system is beyond the scope of this book (which focuses more on the practice-based aspects of opioid management).

Lastly, there are various components crucial to constructing an opioid treatment agreement (Table 9.3). These were gleaned from readily available sample opioid treatment agreements listed in the CDC toolkit part C [2]. Main points are to discuss risks and unproven benefits of opioids, monitoring for safety, and refill requirements. Incorporating patient specific diagnosis, goals, and treatment plan will not only personalize the agreement, but help quantify treatment effectiveness (in terms of the patient's functional and pain related goals). Remember to give the patient a copy of the opioid treatment agreement. Renew annually [2] or according to current recommendations.

Table 9.3 Main components of a chronic opioid treatment agreement

Components	Example statements
Specific diagnosis and treatment plan	I, (patient's name), am being treated for (patient's pain diagnosis), with (list following medications and nonpharmacological therapies.) Treatment of chronic pain should include other classes of pain medications, behavioral health treatment, physical therapy, exercise, and specialists. Opioid therapy may be changed depending on progress or adverse effects. If there is no documented improvement, therapy may be tapered or discontinued. My goals for opioid therapy include: One of the goals of opioid therapy is to improve function and return to work I understand that pain cannot be totally eliminated but only partially relieved in order to improve my function Specifics regarding when opioids will be weaned or discontinued. Opioid withdrawal may occur, but is not life-threatening. I will not change dosage of medications without discussion with my doctor first

Table 9.3 (continued)

Components	Example statements
Risks and unproven benefits of opioid therapy	Long term opioid therapy is currently not proven for chronic non- cancer pain to provide long lasting relief or improvement in function There are substantial risks to opioid therapy including risks of addiction, overdose, death or permanent disability. Side effects may include nausea, itchiness, constipation, drowsiness, and sexual side effects. I agree not to drive or operate machinery when drowsy. Alternative therapy includes… Concurrent use of benzodiazepines (provide a list), illegal drugs, unauthorized prescription drug use, marijuana, or alcohol can lead to death, or disability. There is no minimum amount of opioids that is considered absolutely safe I understand that there is a risk of addiction with opioid therapy and I will comply with the treatment plan or referral to an addiction specialist for this condition.

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Table 9.3 (continued)

Components	Example statements
Refill requirements	Refill at one pharmacy (patient's selected pharmacy) changes will be made only... Refill intervals, office visit must be made with Dr. (PCP) every (specify interval). I agree to obtain opioid therapy only from Dr. (PCP) Refill requests must be made 4 business days in advance No after hours, weekend, or holiday requests Lost/stolen prescriptions require a police report in order to consider re-prescribing. Refills require: compliance with treatment plan including referrals to specialists, laboratories, radiology, etc. I agree to attend appointments… No early refills. In the event I took more than prescribed or lost some pills, I understand that I will have to wait until when the next prescription is due. Separate visits required for chronic opioid therapy No walk-in refills will be made. If I am late to my appointment it may be rescheduled. Must attend one group visit/ educational seminar

Table 9.3 (continued)

Components	Example statements
Safety protocols and monitoring	There will be random urine collections at any time for your safety There may be random pill counts to ensure your safety, please bring medication bottles when asked. Keep opioids locked Naloxone prescription and instruction I will not take someone else's medications Safe disposal of opioids (Locations, or phone numbers) We need a valid phone number to contact you. In case you cannot be reached when we call, you must return our call in 24 hours.

Below are links to example opioid treatment agreements (Table 9.4). Some are written in layman's terms and may be more appropriate for those with lower health literacy. The FDA uses more of a discussion format instead of a "contract" format written with input from plain language experts [7]. In general, when initiating an opioid treatment agreement, I will discuss each point with the patient in order to ensure comprehension and foster a collaborative relationship.

Table 9.4 Example opioid treatment agreements available on the world wide web

Institution	Website
CDC	https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf
Veterans Affairs and Department of Defense	https://www.nhms.org/sites/default/files/Pdfs/OpioidTxAgreement-VA2010.pdf
Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer	http://nationalpaincentre.mcmaster.ca/documents/opioid_guideline_part_b_v5_6.pdf Appendix B-5
Utah State	http://health.utah.gov/prescription/pdf/guidelines/treatment_plan.pdf
University of Michigan Health System	http://www.med.umich.edu/1info/FHP/practiceguides/pain/pain.pdf Appendix C
Oregon State	http://www.oregonpainguidance.org/app/content/uploads/2016/05/Patient-Treatment-Agreements.pdf
New Jersey State	https://www.njconsumeraffairs.gov/prescribing-for-pain/Documents/Pain-Treatment-with-Opioid-Medications-Patient-Agreement.pdf
FDA	https://www.fda.gov/media/114694/download

Conclusions

Opioid treatment agreements and chronic pain policies currently have scant evidence (if any) concerning effectiveness in prevention of adverse events such as addiction, overdose, and death. However, it may make the management of deviant behavior (violations of the agreement), or adverse events (addiction, side effects, or overdose) a little more straightforward (and less stressful) when a protocol is already in place and the patient is aware of the protocol. Adopt and adapt various policies and work flows to make management of these complex patients a little easier.

References

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