Commentary

Opioid treatment agreements in chronic non-malignant pain: The solution or the problem?

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Abstract

Opioid treatment agreements (OTAs) are routinely used in the primary care setting for patients initiating chronic opioid therapy for non-malignant pain despite limited empirical evidence supporting their use. In this commentary, we contextualize current practices in Ontario with regard to OTAs. We highlight the lack of high-quality evidence showing that utilizing OTAs leads to beneficial outcomes for patients or prescribing physicians, and explore the ethical quagmire they create in clinical practice. Physicians utilizing OTAs need to be aware of the limitations of OTAs and sensitive to their potential impact on the physician-patient relationship. We advocate for a return to a collaborative, patient-centered approach with physicians encouraged to involve patients in a shared decision-making process to set mutually agreeable goals for treatment with opioids, to obtain informed consent from patients, and to better tailor these agreements to reflect the interests of all parties involved. Further research and debate are required to improve the effectiveness and ethical justification for using OTAs in clinical practice.

Keywords: opioids, ethics, primary care, opioid treatment agreement, contract.

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Introduction

Opioid treatment agreements (OTAs) are a ubiquitous part of managing chronic opioid use in the primary care setting. First introduced in a 1994 abstract by Kirkpatrick *et al*. and formalized in 1995 by Burchman and Pagel (1,2), the original opioid "protocol-contract" (Figure 1) for non-malignant chronic pain has faded from the literature, and current clinical practice has diverged from its roots.

Original formulations of OTAs began with a statement of the lack of evidence of opioids for the treatment of chronic non-malignant pain. Patients were clearly warned about the risks of constipation, sedation, cognitive impairment, respiratory arrest, physical and psychological dependence, tolerance, and neonatal abstinence syndrome (2). Further iterations focused on patient expectations: analgesia as an approach to maintaining function and not to completely eliminate pain; opioids as bridging measures while developing pain management behaviours; and frequently scheduled re-evaluations of opioid requirements and response (1).

In contrast, modern OTAs delineate strict limits on behaviours, doses, refills, and firmly defend the right of the physician to terminate the prescription or relationship (3). Although today's iterations seem more proscriptive and less informative, OTAs used in major United States academic pain centres even in the late 1990s had consistent themes of disallowed behaviour and termination procedures (4).

In this article, we aim to provide commentary on OTAs in the current local context given the shift in the opioid-related landscape over the past few decades. We narratively summarize pertinent evidence supporting utilization of OTAs in practice, potential ethical concerns associated with their use, and advocate for a transition away from OTAs to a more collaborative, patient-centered approach towards chronic pain.

I understand that I am receiving opioid medication from Dr _____ to treat my pain condition. I agree to the following conditions under which this medication is prescribed:

1. I will not seek opioid medication from another physician. Only Dr _____ will prescribe opioids for me.
2. I will not take opioid medication in larger amounts or more frequently than is prescribed by Dr _____.
3. I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else.
4. I will not use over-the-counter opioid medications.
5. I will only fill my prescriptions at one pharmacy, which is: _____
6. I understand that if my prescription runs out early for any reason, I will have to wait until the next prescription is due.

I understand that if I break these conditions, Dr _____ may choose to cease writing opiate prescriptions for me, and this will be noted in my medical record.

Figure 1. Example opioid treatment agreement, adapted from Kahan 2006 (3).

Current utilization of opioid treatment agreements in Canadian practice

There are no specific Canadian federal or provincial legislative requirements for clinicians to use OTAs when prescribing opioids. However, national regulatory and medico-legal bodies have made recommendations in this context (5). The official stance of the College of Physicians and Surgeons of Ontario (CPSO) is that OTAs may be considered, but not required when prescribing opioids (5). The Canadian Medical Protective Association has recommended the use of OTAs based on now-outdated guidelines (6). These recommendations have made their way into provincial standards and metrics for primary care as well: Ontario's Family Health Teams (FHTs) may require OTAs for every patient on chronic opioid therapy regardless of individual risk for misuse or diversion, and Health Quality Ontario's Primary Care Reports delivered biannually to FHTs specifically suggest OTA uptake (7).

Rationalizing opioid treatment agreement use

If not strict legal or professional requirements, what drives this practice? The indoctrination of OTAs as standard management of patients on chronic opioids in the primary care setting may originate from physician unease with opioids.

In their paper, Arnold and colleagues theorize that physicians cling to OTAs due to "opiophobia" originating from hyper-awareness of the negative effects of opioids on individuals and society—thereby ensuring legal and moral defensibility of their prescribing practices—as well as a need to control the perceived inherent uncertainties associated with patients on chronic opioid therapy (8). Concordantly, medical residents demonstrate increased use of OTAs compared to more experienced clinicians, suggesting that they may be more malleable to expectations of "good clinical practice" given their relative inexperience (9). Furthermore, the use of OTAs increases residents' comfort and sense of reward with managing chronic opioids, which tend to be low at baseline (10,11). Symbolic control codified as OTAs may justify overly rigid limits, unilaterally modifying treatment plans, or limited individualization of treatment plans.

Evidence for opioid treatment agreements is limited

A 2010 systematic review showed a 7–23% absolute risk reduction in opioid misuse with OTAs in four cohort studies (12). However, the overall evidence was of poor quality and high heterogeneity, limited by considerable variation in the definition of opioid misuse in the identified studies (12). Additionally, most studies included were conducted in specialty pain clinics or primary care practices with complex management strategies not representative of the outpatient settings where most patients are prescribed long-term opioids for chronic non-malignant pain (12). Most recently, the 2017 Canadian Guidelines for Opioids for Chronic Non-Cancer Pain did not recommend OTAs based on a meta-analysis of four studies, which concluded that formal structured treatment agreements did not lead to a significant difference in opioid misuse rates in patients with chronic non-cancer pain and resulted in a small trend towards harm (13).

Most analyses and guidelines discuss the effects of agreements on opioid misuse or diversion: these are real and pressing public health and safety concerns that happen to directly

challenge the ego of physician authority. Yet, beyond misuse, there was an astonishing lack of evidence in the literature for whether OTAs decrease inappropriate opioid prescribing; decrease the duration of such therapy; increase patient satisfaction, pain control, or functional status; or reduce the adverse effects of chronic opioid therapy. One nonrandomized study conducted in Arizona showed that OTAs are negatively associated with opioid discontinuation and have no impact on decreasing opioid dosage (14). These individualized patient-centered outcomes should be more important in our clinical practice than determining misuse or diversion and should be more thoroughly explored.

OTAs damage the physician-patient relationship and are ethically questionable

OTAs significantly conflict with our basic duty: *primum non nocere* or first, do no harm. When OTAs are used to alleviate physician discomfort, the measured balance between benefits and harms to individual patients is disrupted with paternalistic considerations that constrain the freedoms and rights of patients (8).

The potential for harm resulting from "best practice" opioid management cannot be ignored. Physicians who tend to use urine drug tests (UDTs), OTAs, and other "opioid best practice" tools tend to be more likely to discontinue opioids for patients with aberrant opioid-related behaviours; paradoxically, they are more likely to confidently prescribe opioids in the first place (15). These same practices may exacerbate bias and discrimination in pain management. For example, Black primary care patients are less likely to have their pain documented or to be seen by a pain specialist, but more likely to have higher numbers of UDTs and to be referred for substance abuse assessments (16). OTAs provide prior justification for this nonrandom screening. Results of these UDTs are inconsistently interpreted: when positive for heroin or cocaine, opioid renewal rates are significantly lower than if nonprescribed marijuana, opioids, or benzodiazepines are found (17). Yet, logically, concomitant use of so-called illicit drugs does not necessarily negate valid indications for opioids.

Requiring patients to sign OTAs can be construed as coercive, particularly when presented as a mandatory condition to treatment. Coercion prevents informed consent in all circumstances (18). Patients, especially those with chronic pain, are by design placed into a situation where they have no choice but to sign an agreement that is physician-centric in order to obtain controlled medications, or risk being under-treated (19,20). One ethically concerning study forced patients already on chronic opioids into choosing to comply with OTAs and UDT, wean opioids, or leave the practice (21). No consideration in the analysis was given to factors in their decisions. Unsurprisingly, patients who sign OTAs worry more about having their opioids discontinued and feel less trusted by their doctor (22).

As with other aspects of healthcare, the true meaning of OTAs remains inaccessible to the layperson. Only half of patients with OTAs are aware of them (23). The language used is typically eight grade levels above the recommended reading level for healthcare documents (24). It is reasonable to question whether patients can justifiably be threatened with penalties, when a significant portion of them cannot understand or acknowledge the very nature of their agreement, limiting true informed consent. Given that adequate pain control is a fundamental human right as well as a core obligation of physicians, we should be more vigilant about reducing these barriers to better treatment of chronic pain (25).

Moving past treatment agreements

OTAs were initially devised with positive intentions in the wake of increasing recognition of the harms of opioids, leading to uptake and inclusion of recommendations by regulatory and medico-legal bodies such as the CPSO to prevent opioid misuse and diversion. However, we need to openly acknowledge the limited high-quality evidence to date supporting their effectiveness and impact on patient-centered health outcomes (12,26,27). Recommendations for their use should be based on proven benefits and harms in practice.

It is therefore difficult to draw meaningful conclusions on the effectiveness of OTAs or necessarily advocate for their exclusion from clinical practice. Physicians should utilize caution and reflect on their personal rationale for utilizing OTAs and the specific contents therein. In lieu of continuing to promote the use of OTAs via medical dogma and organizational standards, this defensive contractual approach to patient care should be modified into a less rigid, more individualized patient-centered approach. This will be an enormous challenge given their integration into many facets of medicine. Yet, their lack of certain benefits counterbalancing significant potential ethical issues calls for change at all levels.

We encourage physicians to engage patients in a shared decision-making process where both parties can negotiate, settle on mutually agreeable goals for treatment, and carefully document informed consent for that plan (28). In a return to original intentions, more emphasis should be placed on communicating the potential benefits and harms of opioids, and frequent re-evaluation of response and requirement for chronic opioid therapy should be strongly considered. Foreseeable challenges are that shared decision-making models of chronic opioid therapy and monitoring likely require more time, attention, and careful consideration in day-to-day practice. Many physicians may require additional support and education from their institutions, regulatory bodies, and government health authorities to effectively navigate such conversations with patients.

At the minimum, health-care practitioners should be aware of the scope and limitations of the available evidence supporting OTAs in current clinical use. As a whole, we should advocate for more research and clinical integration of patient-centered outcomes and collaborative opioid treatment in primary care.

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